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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

MEETING

+ + + + +

Tuesday, June 12, 2007

+ + + + +

The meeting came to order at 8:00 a.m. in room
T2B3 of Two White Flint North, Rockville, Maryland,
Leon S. Malmud, MD, Chair, Presiding.

MEMBERS PRESENT:

Leon S. Malmud, MD - Chairman

William Van Decker, MD

Douglas F. Eggli, MD

Ralph P. Lieto

Subir Nag, MD

Sally W. Schwarz

Orhan H. Suleiman, PhD

Jeffrey Williamson, PhD

James Welsh, MD

Darrell Fisher, PhD

Debbie Gilley

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- 1 NRC STAFF PRESENT:
- 2 Scott Moore
- 3 Sandra Wastler, Designated Federal Officer
- 4 Andrew Mauer
- 5 Duane White
- 6 Angela McIntosh
- 7 Cindy Flannery. Alternate Federal Officer
- 8 Ashley Tull
- 9 Theron Brown
- 10 Lydia Chang
- 11 Donna-Beth Howe
- 12 Patricia Rathbun
- 13 Ron Zelac
- 14 Ed Lohr
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1 ALSO PRESENT:
2 Lynne Fairbent
3 Richard Morin
4 Phil Alderson
5 Terence Beven
6 Melissa Martin
7 Herb Mower
8 Kent Lambert
9 Henry Royal
10 Ram Bhat (phone)
11 Ian Hamilton (phone)
12 Darlene Metter (phone)
13 Richard Ratliff (phone)
14 Bruce Haffty
15 Gerald White
16 Paul Schmidt (phone)
17 Mike Stevens (phone)
18 Dean Broga
19 Margaret Roybal (phone)
20 Daniela Bowman (phone)
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A-G-E-N-D-A

OPENING

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Mr. Moore 7

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Adjourn

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

8:09 a.m.

MS. WASTLER: Welcome everyone.

As the Designated Federal Officer for this meeting, I'm pleased to welcome you to Rockville for the public meeting of the Advisory Committee on the Medical Use of Isotopes.

My name is Sandra Wastler. I'm the Chief of the Medical and Events Assessment Branch. And I've been designed as the Federal Officer for this Advisory Committee in accordance with 10 CFR Part 7.11

Present today as an alternate Designated Federal Officer is Cindy Flannery, Team Leader for Medical Radiation Safety.

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

The meeting was announced in a May 8, 2007 edition of the *Federal Register*.

The function of the Committee is to advise the Staff on issues and questions that arise on the medical uses of byproduct material. The Committee provides counsel to the Staff, but does not determine or direct the actual decisions of the Staff or the

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1 Commission. The NRC solicits the views of the
2 Committee and values their opinions greatly.

3 I request that whenever possible we try to
4 reach a consensus on various issues that we will
5 discuss today, but I also recognize that there will be
6 minority and dissenting opinions. If you have such an
7 opinion, please them to be read into the record.

8 As part of the preparation for this
9 meeting I've reviewed the agenda for the members and
10 employment interests based on their very general
11 nature of the discussion that we're going to have
12 today. I have not identified any items that would pose
13 a conflict, therefore I see no need for an individual
14 member of the Committee to recuse themselves from the
15 Committee's decision making activities. However if
16 during the course of our business you determine that
17 you have a conflict, please state it for the record
18 and recuse yourself from the particular aspects of the
19 discussion.

20 At this point I would like to introduce
21 the individuals seated at the table today. Dr. Leon
22 Malmud, Chairman; Dr. Jeffrey Williamson, therapy
23 physicist; Ms. Sally Schwarz, nuclear pharmacist; Mr.
24 Ralph Lieto, nuclear medicine physicist; Dr. Subir
25 Nag, radiation oncologist. Dr. Van Decker is supposed

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1 to be joining us. He's apparently not here right here.
2 He's the nuclear cardiologist. Dr. Douglas Eggli,
3 nuclear medicine physician; Dr. Orhan Suleiman, FDA
4 representative; Dr. James Welsh, radiation oncologist;
5 Dr. Darrell Fisher, patient advocate; and Ms. Debbie
6 Gilley, State Government Representative.

7 I would like to welcome Dr. James Welsh to
8 the ACMUI. Dr. Welsh is a radiation oncologist at the
9 University of Wisconsin Cancer Center Riverview. He
10 has completed the NRC security clearance process and
11 is joining us a full member for this meeting.

12 I would also like to recognize the newest
13 member of ACMUI, Dr. Darrell Fisher. Dr. Fisher is a
14 medical physicist at Pacific Northwest National
15 Laboratory, and he is serving at the patient's right
16 advocate on ACMUI. Dr. Fisher has completed the NRC
17 security clearance process and is also joining us as
18 a full time member.

19 Dr. Vetter, the RSO representative, was
20 unable to be here today. He had a conflict with the
21 schedule.

22 And I would also like to mention that Ms.
23 Debbie Gilley from the State of Florida is
24 representing the agreement state since the state
25 government position is currently vacant.

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1 I'd like to thank Ms. Gilley for acting in
2 this capacity.

3 And lastly, I wanted to note that Dr.
4 Thomadsen will be joining us tomorrow. He has been
5 selected as the therapy medical physicist to replace
6 Dr. Williamson later this year. Dr. Thomadsen is a
7 medical physicist at the University of Wisconsin,
8 Madison. And his full ACMUI membership is pending
9 completion of the security clearance.

10 Dr. Malmud, ACMUI Chairman, will conduct
11 today's meeting. Following a discussion of each
12 agenda item the Chair and his option may entertain
13 comments or questions from members of the public who
14 are participating with us today.

15 And I'd also like to mention that we are
16 also having an open discussion this afternoon where we
17 will have a facilitator. And that facilitator will be
18 Dr. Patricia Rathburn.

19 Thank you.

20 Dr. Malmud?

21 CHAIRMAN MALMUD: Thank you, Ms. Wastler.

22 We'll move right ahead with the agenda, if
23 we may. And I'd like to introduce first Scott Moore,
24 who is filling in for Ms. Schlueter, who is unable to
25 be here today.

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1 MR. MOORE: Thank you, Dr. Malmud.

2 I'll just have a few remarks.

3 I'm Scott Moore. I'm the Deputy Director
4 of the Division of Material Safety and State
5 Agreements. As Dr. Malmud mentioned, I'm filling in
6 for Janet Schlueter, the Division Director, who is
7 recovering from a medical test that she had at the end
8 of last week.

9 We have a full agenda this week. You're
10 discussing today the NARM rule implementation and
11 guidance regarding the NARM rule units specialty
12 boards. And finally, you're going to have a
13 facilitated discussion this afternoon on training and
14 experience.

15 Tomorrow you have a similarly packed day
16 with a number of topics presented by both NRC staff
17 and members of the Board.

18 I would like to bring your attention to a
19 medical list server that NRC Staff has prepared to
20 keep the Advisory Committee licensees and other
21 interested stakeholders informed about NRC's
22 publications. It's on NRC website that's operated by
23 ORNL. Ashley Tull, our coordinator for the ACMUI will
24 provide you with that ORNL website, and we'll get it
25 posted for you by the end of your time period here.

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1 But we want you to know that the ORNL website is one
2 that the agreement states use frequently. Debbie
3 Gilley knows it fairly well. And we get literally
4 hundreds of thousands of hits in a given year. So
5 it's one that will make the information that's
6 available to the medical community more available to
7 everybody. And so we will provide that website
8 information to you today or tomorrow.

9 I'd like to introduce a new ACMUI
10 coordinator to the Committee, Ashley Tull. Ashley is
11 sitting back there. And she's serving as the
12 coordinator for this meeting.

13 And finally, I'd like to note that this is
14 Dr. Williamson's last meeting. He served as a member
15 of the Board since 2000. And the Staff has prepared
16 a certificate of appreciation for him.

17 Thank you very much, Dr. Williamson.

18 (Applause).

19 MR. MOORE: That concludes my remarks.

20 Dr. Malmud.

21 CHAIRMAN MALMUD: Thank you very much.

22 We will then move on to the next item on
23 the agenda, if we may. May we move ahead of our
24 agenda? Are we allowed to do that.

25 MS. WASTLER: That's fine. Oh, yes,

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1 please.

2 CHAIRMAN MALMUD: Thank you very much.

3 The next item will be presented by --

4 MR. BROWN: Regions, the PowerPoint is
5 down on our system. So what I'm going to do is try to
6 project from the camera to the screen so you all can
7 follow the slides as you can. So you got to bear with
8 today, okay?

9 MS. WASTLER: Thank you. Technical
10 difficulties we had to let the regions know about.

11 CHAIRMAN MALMUD: Thank you.

12 So the next item on the agenda is the NARM
13 rule discussion by Lydia Chang. Ms. Chang?

14 MS. CHANG: My name is Lydia Chang. Last
15 time I briefed the Committee was back in October 24th
16 of last year. And back then we were still in the
17 middle of evaluating all the comments. So today I'm
18 just going to provide you an update since last time I
19 briefed you.

20 Again, just summarize a couple of items.
21 Back in July 28, 2006 we did publish a proposed rule
22 in the *Federal Register*. I've provided a citation
23 here.

24 On August 22nd we had a public meeting in
25 Las Vegas to solicit comments. Quite a few societies

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1 did show up to give us written comments as well as
2 verbal comments.

3 The public comment ended back in September
4 11.

5 Most recently on April the 3rd we have
6 issued a Commission paper to the Commission for the
7 draft final rule. And it's issued as a SECY-07-0062.
8 Last month on May the 14th the Commission has approved
9 the draft final rule and has issued an SRM.

10 You probably saw this slide from last time
11 when I updated you. We received a total of 39 comment
12 letters. Fourteen comment letters were from the
13 states, 14 from other federal agencies. And the
14 remaining comments were from citizen groups,
15 professional organizations, universities, medical
16 communities and industry.

17 Today I just want to highlight a few items
18 that we have changed since the proposed rule that was
19 published.

20 One is the definition of discrete source.
21 We did indeed add the nitrogen and oxygen to Part 20,
22 Appendix B table per ACMUI comments and a whole bunch
23 of other medical communities' comments.

24 We did revise a little bit of the
25 regulatory approach for items containing radium-226

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1 We did try to clarify the production of
2 PET produced radioactive materials and also the
3 noncommercial distribution of PET radionuclides and
4 PET drugs.

5 And I also wanted to highlight some of the
6 implementation items that you might want to be aware
7 of.

8 The definition of discrete source I have
9 listed here three definitions. The very first one is
10 the one that we included in the proposed rule. It
11 stated that a discrete source is a source with
12 physical boundaries which is separate and distinct
13 from the radiation present in nature and in which the
14 radionuclide concentration has been increased by human
15 processes with intent that the radionuclide
16 concentrated radioactive material will be used for its
17 radiological property.

18 We received a huge number of comments
19 associated with this definition. A lot of the people
20 indicated that the definition was way too complicated
21 and so convoluted. A lot of comments was also focused
22 on the need to include physical boundary. I think
23 including the word "physical boundary" created a lot
24 more confusion and ambiguity. People also made
25 comments on why should it be limited to just for its

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1 radiological property.

2 So after we considered all the comments
3 that we received, the Staff did come up with a much
4 more simplified and still captured the essence of what
5 we want to include in the source and not changing the
6 intent, specifically not to regulate the TNORMs, the
7 technically enhanced radioactive materials such as fly
8 ash from coal burning power plant or fertilizer or
9 such. So we did not change the intent, per se, but we
10 did try to simplify the definition by changing some of
11 the words.

12 So within the SECY paper the draft final
13 rule we revised it the discrete source to be a
14 radionuclide that is distinct from sources of
15 radiation present in nature and that has been
16 processed so that its concentration within the
17 material has been purposely increased for use for
18 commercial, medical and research activity.

19 This revised definition is definitely
20 consistent with Energy Policy Act. We also throw in
21 the words for use for commercial, medical and research
22 activity, which is in the exact words that is in the
23 Energy Policy Act, which also narrow the NRC
24 restriction on what we're supposed to be regulating in
25 with the source.

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1 We also removed a word human process
2 because once it's increased, it's by definition --
3 it's by humans so it's no need to emphasizing the
4 human factor. It's going to be purposely
5 concentrated, then it is regulated.

6 We also have removed for radiological
7 property because as long as it's concentrated, whether
8 it's going to be used for its chemical or
9 radiological, we will be regulating. This approach is
10 similar to depleted uranium. We don't care what
11 depleted uranium is used for, it's uranium, radiologic
12 property or for its physical property, you know, for
13 its density as a shielding. So this is real consistent
14 with NRC's past regulatory process.

15 However, once we submitted the Commission
16 paper to the Commission, the Commission did come back
17 and wants to further simplify the definition. And,
18 you know, after discussion with the technical
19 assistants within the Commission and also the
20 technical staff within the working group, we have
21 further revised the definition by deleting the word
22 "distinct from sources of radiation present in
23 nature."

24 By having this phrase it actually creates
25 a little bit more confusion because people thought --

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1 the radium-226 it's actually from the nature, but then
2 once it's processed, it's actually already removed
3 from the nature.

4 Another thing that the technical study
5 included as far as originally was for the purpose of
6 decommissioning consideration in the future. And for
7 the evaluation we thought this is not needed because
8 once a discrete source is defined as a byproduct
9 material, it will always be a byproduct material. If
10 you spilled it or it leaked into the environment, then
11 the decommissioning criteria would kick in. It really
12 doesn't matter whether it's still distinct from the
13 nature or not. The decommissioning criteria such as
14 DC-GL, another criteria that uses distinct from
15 background, that will kick in. So this is sort of like
16 a phrase that's really not necessary. So we further
17 simplified the definition to be a radionuclide that
18 has been processed so that its concentration within
19 the material has been purposely increased for use for
20 commercial, medical and research activity.

21 And we also have discussed this new
22 revised definition with all the agreement states. And
23 they all concur that this is much simplified and easy
24 to understand definition.

25 Again, as I indicated before, we did

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1 include nitrogen and oxygen-15 in Part 20 Appendix B
2 table, table 1 and table 2. Table 1 is for
3 occupational value and the column three it's for
4 derived air concentration for inhalation and listed
5 here are the values for both nitrogen and oxygen.

6 We also included table 2 column one F1
7 concentration for air. And, again, the volumes are
8 listed here.

9 Items containing radium-226, it's probably
10 not an interest item for ACMUI, but for the
11 completeness I have included here. Within the proposed
12 rule we actually exemption for timepieces and also
13 limited number of repairs within timepieces. And we
14 have since modified that within the rule. Only include
15 intact timepieces containing 1 microcurie or less of
16 radium-226.

17 We also have further refined the general
18 license approach. The general license approach would
19 allow individuals to acquire, receive, possess, use
20 and transfer the list of items here including
21 antiquities. There are no limits on the number of
22 antiquities or the type of antiquities. An individual
23 can have them under the general license approach.

24 For intact timepieces containing greater
25 than one microcurie of radium-226, that's not exempt,

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1 it's also being included in here along with NARM
2 intact timepieces and hands and dials. There is no
3 limit under this item, so individuals can have as many
4 as they like under the general license approach.

5 We're also including luminous items stored
6 in air, marine and land vehicle. This is a
7 modification from the proposed rule. In the proposed
8 rule we only allow luminous items stored in air under
9 the general license. But based on the comment letters
10 we have included marine and land vehicles since a lot
11 of museums and defense organizations do have those
12 items installed in airplanes and ships and jeeps.

13 We also modified it, the fourth item to
14 allow less than 100 items of other luminous products
15 used or stored at the same location at any one time.
16 This would allow, you know, individual collectors to
17 have a number of items in hand and still -- and not
18 present a significant risk to those individual
19 collections.

20 And the last item, we did not make any
21 changes under the general license.

22 The general license approach is really
23 sort of like a risk-informed approach and try not to
24 be too burdensome to the public. Under general
25 license an individual does not need to come to NRC to

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1 get a license. They do not need to pay a license fee.
2 There's only limited requirements that they have to
3 meet such as, you know, if an item leaked, they need
4 to notify us. They are not supposed to dispose of the
5 items unless it's disposed at a permitted facility.
6 And that they also need to respond to NRC's
7 informational requests if NRC does make such a
8 request. From what I understand, we haven't made that
9 kind of request for the past 10 years. So it's really
10 minimal burden and try to provide as much flexibility
11 to the individual collectors as possible and still
12 ensure that the item does not pose a significant
13 hazard to the public.

14 And, of course, anything that's not
15 covered under exemption or under the general license
16 will require a specific license.

17 The radionuclide production for Part 30.
18 In the proposed rule even though in presentations we
19 have indicated that it is regulated under Part 30, but
20 a lot of the commenters were still confused on how
21 does that work. In a sense a lot of the medical use
22 licensees also have cyclotrons that produce
23 radionuclides. So in here we tried to further clarify
24 that radionuclide production facilities are indeed
25 regulated under Part 30. And within that we have also

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1 added the noncommercial distribution within 30.32 and
2 30.34 to make sure that everybody's clear what's
3 allowed to do under Part 30.

4 Specifically section 30.32, it's allows
5 noncommercial transfer, and then section 30.34 it's
6 the labeling and measurement requirement, which is all
7 very similar to 30.32 -- 32.72.

8 Of course, we did not make any changes to
9 Part 32 the commercial distribution for byproduct
10 material. If you a PET cyclotron that you are
11 manufacturing radionuclide -- PET radionuclides or PET
12 drugs under the commercial distribution, you can still
13 do that under Part 32.

14 And under Part 35 for medical use
15 licensees, we specifically allow the medical use
16 licensees to receive radioactive drugs from commercial
17 distributors, which it's already in Part 35, but we
18 also added the noncommercial transfer from a PET
19 radionuclide production facility within a consortium.

20 The definition of consortium is also new
21 to the final rule. Within the proposed rule we did not
22 have a definition for consortium. Several commenters
23 indicated it's necessary to include a definition, so
24 we did include that in the final rule. And it is
25 defined as an association of medical use licensees in

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1 a PET radionuclide production facility in the same
2 geographical area that generally own or share in the
3 operation and maintenance costs of the PET
4 radionuclide production facility but produces PET
5 radionuclides used in producing radioactive drugs
6 within the consortium from noncommercial distributions
7 among its associated members for medical use. The PET
8 radionuclide production facility within the consortium
9 must be located at an educational institution or a
10 federal facility or a medical facility.

11 And I guess once during the agreement
12 state review and also ACMUI revealed the draft final
13 rule, comments did raise regarding the geographical
14 area. They thought that that was a little bit
15 limiting. However, based on the technical Staff's
16 evaluation that PET radionuclides are fairly short
17 lived, so most likely for consortium to use the
18 radioactive drugs within their consortium, they
19 normally are located in a very close proximity. And
20 the interpretation of same geographical area could
21 also be somewhat flexibility. For instance,
22 Washington metropolitan area, it's considered
23 geographical area. So you could go as far as Baltimore
24 to NIH. I mean, that would still be considered
25 geographical area. But if somebody from -- I don't

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1 know, Florida, its operating something to try to ship
2 to D.C., that would be a little far. And from what we
3 understand, those are quite often operated under a
4 commercial production type of scale that they know the
5 operations and they have airplanes, you know, on the
6 standby to ship the material. So those are, in our
7 opinion, more on a commercial basis rather than on a
8 noncommercial basis. So we did in fact still have
9 those same geographical area within the definition.

10 Another comment that we received was from
11 agreements regarding the second sentence. They were
12 confused of whether -- you know, that the consortium
13 has to be located at an educational institution or
14 federal facilities or medical facilities. They
15 thought, you know, geographical area kind of covers
16 it, why doesn't it still have to be located in
17 different kind of facilities. And in our mind, the
18 purpose of the noncommercial distribution was purely
19 for the medical facilities and educational
20 institutions and federal facilities for them to
21 maximize their radioactive material usage. It's not
22 intended for commercial purposes at all. So we still
23 have that limitation to try to narrowly allow what
24 it's allowed under the noncommercial distribution.

25 Here I just want to kind of summarize the

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1 specific provisions for Part 35, some of which have
2 not changed since the proposed rule, but I kind of
3 just want to summarize it for you since ACMUI's most
4 interesting Part 35 medical use licensees.

5 The Part 35 does include effective date
6 under 35.10, the effective date is 60 days from the
7 day of the publication of the final rule. The
8 authorization to continue to use until the individual
9 have license. Under Section 35.11 it's for new
10 license application, those individuals will still have
11 up to one year from the effective date to submit a new
12 license application.

13 Section 35.14 it's for amendments. We
14 have made any changes to that, so the licensee still
15 has up to six months from the effective date to submit
16 a license amendment.

17 Section 35.13 its relocation. To relocate
18 a PET radioactive drug production area or delivery
19 line, we have not made any changes. 35.13 require
20 amendment for such relocation.

21 Grandfathering certain individuals.
22 Between the proposed rule and the final rule, we did
23 delete the revision to the definition of authorized
24 user and authorized medical physicist and authorized
25 nuclear pharmacist. And the reason we deleted it is

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1 because we believed that the grandfather clause
2 included within 31.13, .14 and .15 and .57 are
3 sufficient to provide a grandfathering clause. There's
4 no reason to change the definition to further
5 complicate things. And another reason is the
6 agreement states also was objecting to the change of
7 definition since definitions are compatibility
8 category Bs that would have forced agreement states to
9 have a definition that may not be consistent with
10 their existing program.

11 Again, section 35.13 permits individuals
12 who has worked to continue to work as the authorized
13 user or authorized nuclear pharmacist and authorized
14 medical physicist.

15 35.14 it's allowing use of notification to
16 inform NRC that these individuals are indeed work as
17 AU, AMPs and AMPs.

18 35.13 is a grandfathering clause
19 grandfathering those individuals who used only NARM
20 material from the training and experience
21 requirements.

22 And the last item is the generators. We
23 have added strontium and rubidium generators within
24 Part 35.

25 35.204 is for the contamination

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1 concentration limits for the generator which is .02
2 microcurie of strontium per millicurie of rubidium.

3 And 35.2204 is the record keeping of the
4 results from those analysis.

5 For PET radionuclides in drugs 35.63
6 basically would allow medical use licensees to
7 determine the activity level based on numerical
8 calculations using volumetric measurements and
9 measurements that they got from the manufacturer or
10 they got from the noncommercial distribution from PET
11 radioactive drug under Part 32.32(j).

12 And as far as NARM PET radionuclide and
13 NARM PET drugs there are no changes needed within Part
14 35.

15 Some of the implementation considerations
16 that you might need to be aware of is the waiver
17 termination. The waiver will be terminated once the
18 final rule becomes effective for the federal agencies
19 and Indian tribes. And we also have included several
20 states such as Delaware, Indiana, Wyoming, Montana,
21 District of Columbia, Puerto Rico, U.S. Virgin
22 Islands. So these states and territories their waiver
23 will be terminated on the effective date once we
24 publish a final rule.

25 As far as the agreement states, I'm sure

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1 Andrew will go into all the details on how the waiver
2 termination and how the transition plan will work. But
3 in short, the agreements states waiver will be
4 terminated once the final transition plan is
5 published. By then all the governors would already be
6 submitting -- will at least have submitted their
7 certification for the adequacy of their programs. So
8 it will be a seamless transition since they are
9 regulating the NARM material already under the waiver,
10 they will continue to be regulating the NARM material
11 under NRC authority once the final rule is published
12 and becomes effective.

13 As far as the non-agreement states, we are
14 using a phased approach probably two to three stages
15 to terminate the non-agreement states depending on
16 whether those non-agreement states have expressed
17 interest to become an agreement states and whether
18 they have extensive NARM program and whatever it would
19 take time for NRC to transition over.

20 And, of course, the waiver would expire I
21 guess in August 7, 2009. So that would be the bottom
22 line the we would terminate. There's no extension on
23 that.

24 License for NARM, as I have included
25 before, the license amendments individual have six

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1 months from the effective date or waiver of
2 termination to submit license amendment. New license
3 applications they have one year from the effective
4 date to submit that.

5 The start of the clock gets a little bit
6 tricky. Because even though the effective date might
7 become effective, but the waiver's still in effect. So
8 you really need to take a look at two components, you
9 know, whether the waiver has been terminated. So even
10 if the effective date has arrived, you might still be
11 operating under the waiver and you can continue to use
12 the material until the waiver termination date or the
13 waive expiration day.

14 We also have made a minor adjustment
15 between the proposal and the final rule on the waiver
16 expiration date. I guess in the proposed rule
17 individuals doesn't have that six month and one year
18 built in on top of the waiver expiration date. And we
19 did make that minor adjustment so that upon waiver
20 expiration day, the individual still has six months to
21 submit amendments and one year for a new license
22 application.

23 The next step, right now we're revising
24 the draft final rule per the Commissioner's direction,
25 such as revising the discrete source definition, make

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1 some minor corrections. We are also working on
2 clarifying military use of radium items within the
3 final rule to make sure it's clear on the exemptions
4 for military use.

5 And we will be forwarding the final rule
6 to the Office of Management and Budget for review and
7 approval. OMB has 60 days to review the final package,
8 so therefore you know you're probably not going to see
9 the final rule published until at least two or three
10 months from now. Probably sometime in September or
11 so.

12 That's what I have. Thank you, Chairman.

13 CHAIRMAN MALMUD: Thank you for a very
14 complete review.

15 Are there any comments or questions for
16 Ms. Chang? Sally

17 MEMBER SCHWARZ: Thank you, Lydia. That
18 was a nice presentation. I did have a couple of
19 questions. I was reading, you had sent out the copy of
20 Commission paper and some enclosures were on the
21 website.

22 MS. CHANG: Yes.

23 MEMBER SCHWARZ: So I had it on the
24 website and I was comparing what was there to what we
25 had received initially.

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1 And in your presentation, I think in Part
2 35.100 and .200 originally, I mean you're stating that
3 the facilities can still receive PET radionuclides
4 because they've taken that out of what's on the list.
5 They only have drugs listed, and I was real curious
6 about why they had taken out PET radionuclides.

7 MS. CHANG: Oh, okay. The reason -- the
8 PET radionuclides is a radionuclide you can always
9 transfer from a Part 30 license to anybody, as long as
10 it's not used for medical use on human beings. You
11 can transfer without any other specific authorization.
12 That was one of the reasons and would still include--

13 MEMBER SCHWARZ: Okay --

14 MS. CHANG: If you have the pharmacist
15 that would transfer -- I guess that can bless the
16 radionuclide to become a drug, then yes.

17 MEMBER SCHWARZ: Okay. I was just curious
18 why --

19 MS. CHANG: That was the reason.

20 MEMBER SCHWARZ: And then the other
21 question that I have is the transition plan. And I
22 know that you probably can't give me an answer, but
23 I'm going to ask the question anyway. I do realize
24 that we've defined the first group of states that will
25 have the waiver lifted. And I'm realizing that there

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1 probably will be two additional groups. And since
2 there are a limited number of nonagreement states, it
3 would certainly be tremendously beneficial when they
4 publish this rule that the other two groups would be
5 designated in writing so that the states would know
6 what the plan is. I mean, we're talking about a
7 limited time period here anyway, and that certain if
8 those states could have a true idea of when their
9 waiver would be lifted, you know when the rule is
10 published, that would be tremendous.

11 MS. CHANG: Right. I'm sure Andrew has all
12 the details once he does his presentation. I do know
13 that, you know, several states already expressed
14 interest to become agreement states. So those would
15 definitely be leaning towards the later part of the
16 waiver period to be terminated, such as Pennsylvania,
17 New Jersey and Virginia. I also know that Andrew has
18 been communicating with many of the states both
19 agreement and nonagreement states. So I'm sure that
20 he will be able to give you a lot more information on
21 that.

22 CHAIRMAN MALMUD: Are there other
23 questions? Dr. Suleiman?

24 MEMBER SULEIMAN: I just wanted
25 clarification for the PET consortiums. That they would

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1 be for noncommercial use. So if the facility wanted
2 to use it for commercial, they would have to have a
3 commercial license?

4 MS. CHANG: That's correct. If they want
5 to use commercial, they have to get 32.72 license.

6 Thank you.

7 CHAIRMAN MALMUD: Any other questions?

8 Mr. Lieto?

9 MEMBER LIETO: I have a question to follow
10 up to Dr. Suleiman's regarding the consortium
11 definition. And you were talking about in
12 geographical areas.

13 MS. CHANG: Yes.

14 MEMBER LIETO: There are some very large
15 medical facilities that are located in the northern
16 states that have facilities in southern states. And
17 what this would seem to be is overly restrictive in
18 that if they did have such a facility and wanted to
19 ship to their sites, they would be precluded from
20 doing this because of this definition?

21 MS. CHANG: Well, in our view the
22 geographical locations really are very flexible. And
23 it could be really during the licensing process. I
24 mean --

25 MEMBER LIETO: I guess the point is why

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1 not just delete it?

2 MS. CHANG: Well, because you don't --

3 MEMBER LIETO: You're saying it's for
4 noncommercial uses anyhow. So whether you go across
5 the street or you go across the country, what does it
6 matter if it's for noncommercial use and it's from one
7 of these three types of facilities that you've
8 indicated?

9 MS. CHANG: Yes. Because the only reason
10 we included noncommercial distribution for PET
11 radionuclides it's because of the short half life.
12 And it just does not make sense when you have to ship
13 from cross country. That would take, you know, a long,
14 long time. And then it also means that you're going
15 to be producing a huge volume of radionuclides just
16 for noncommercial --

17 MEMBER LIETO: But if the consortium wants
18 to have -- if they want to ship it to their site and
19 they want to have an increased amount of activity and
20 pay for the added shipping of the increased shielding,
21 why restrict them? It's for noncommercial use. To me
22 the person that's going to be compromised here is the
23 patient.

24 MEMBER NAG: This is Dr. Nag.

25 Let me support the last viewpoint. In the

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1 modern day and age this may no longer matter. I mean,
2 you can say one particular area means, you know, the
3 whole earth is one geographical location, which is a
4 different planet, but that's not what you're meaning.
5 No.

6 Nowadays, shipping from one place to the
7 other is not a problem. People even have their own --
8 so I would say remove would be a practical approach.

9 MS. CHANG: Well, for commercial
10 distribution we have no -- you know, you have people
11 ship things all the time. But the whole purpose of
12 noncommercial distribution is to allow a nonprofit
13 organization to not waste the radionuclide that they
14 produced --

15 MEMBER NAG: Right.

16 MS. CHANG: -- to enabling for third use
17 close by. If you had to manufacture such large
18 quantities, then you should be a commercial
19 distributor.

20 MEMBER NAG: For example, Mayo Clinic has
21 -- Rochester, Minnesota is the main place. They ship
22 it to other Mayo Clinics, they're all Mayo Clinics but
23 one is in Florida and one is in Arizona. And it's much
24 easier for them to ship it, you know, between each
25 other than to buy a separate from some other place.

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1 MS. CHANG: I don't know. I mean, you
2 know the technical Staff really sees it differently.
3 Because if you're going to produce so much and the
4 decay is what? Less than an hour, right?

5 MEMBER EGGLI: A 110 minutes.

6 MS. CHANG: What?

7 MEMBER EGGLI: A 110 minutes for FDG. A
8 half life. A 110 minutes for FDG.

9 MS. CHANG: Right. Basically in a day the
10 material, it's already gone. I mean the whole
11 purpose--

12 CHAIRMAN MALMUD: Some nuclides could be
13 longer, but I think we're talking about fluorine 18,
14 which has an approximate two hour half life.

15 MS. CHANG: Yes. More than 80 percent of
16 the time we're talking about fluorine 18 and sometimes
17 oxygen or nitrogen, which is even shorter half life.
18 I mean, the whole purpose is not for you to make a
19 huge amount of the material and pose health and safety
20 concerns to the medical facility and then be able to
21 ship, you know, by the time it gets there a fraction
22 of that material. The whole purpose of noncommercial
23 distribution is enough for you to not waste what you
24 already produced.

25 CHAIRMAN MALMUD: Well, or stated

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1 differently, what I hear Lydia saying is the reason
2 the Staff included a provision for noncommercial
3 distribution in the regulations was to allow for short
4 half life material to be used rather than waste it,
5 essentially.

6 MS. CHANG: Right. Right.

7 CHAIRMAN MALMUD: And the argument you're
8 making is for, if there are large activities, very
9 large activities, then that negates the argument --

10 MS. CHANG: Right.

11 CHAIRMAN MALMUD: -- that, you know, it
12 would have to be wasted.

13 MS. CHANG: Right.

14 CHAIRMAN MALMUD: Dr. Schwarz?

15 MEMBER SCHWARZ: In terms of if you are
16 not a consortium, I guess Mayo Clinic would be a
17 consortium, but there would be other institutions
18 shipping noncommercially not being consortiums. And
19 that is provided for in the regulations, right?

20 MS. CHANG: If it is radionuclide, yes.

21 Okay. Thank you.

22 CHAIRMAN MALMUD: Are there other
23 concerns? Ralph?

24 MEMBER LIETO: Just some clarifications.
25 So your grandfather provisions there's not going to be

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1 any wording change? You're saying that the wording in
2 13.12, .13, 14 and .57 are appropriate enough that we
3 don't need to make any changes to those specific
4 rules?

5 MS. CHANG: We did not make any changes to
6 the definition, but within the 35.13, .14, .57 we
7 actually made additional clarification to make sure
8 that they are indeed authorized users and authorized
9 nuclear pharmacists. So we actually add one sentence
10 to further clarify that.

11 MEMBER LIETO: All right. And then
12 regarding the dates. If a nonagreement state is
13 pursuing agreement states status, you're saying that
14 by August of '09 if they're not an agreement state by
15 then they're going to fall into some type of a
16 transition plan?

17 MR. MOORE: The transition plan questions
18 will be addressed by Andrew in the next presentation
19 and Duane.

20 MEMBER LIETO: Okay. So just hold off on
21 that one?

22 MR. MOORE: Yes.

23 MEMBER LIETO: All right. And the dates
24 regarding the waiver, you seemed to indicate that the
25 waiver has precedent over the effective date?

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1 MS. CHANG: Yes.

2 MEMBER LIETO: And that even when that
3 last date occurs, you still have six months for an
4 amendment, another year or less a license regardless
5 of when those dates are, is that correct?

6 MS. CHANG: Repeat that. Let me make sure
7 I understand.

8 MEMBER LIETO: If you have a waiver,
9 there's a waiver date which will have precedent over
10 an effective date?

11 MS. CHANG: Right. Right.

12 MEMBER LIETO: And then whichever one is
13 last, you still have another six months --

14 MS. CHANG: Six months to a year.

15 MEMBER LIETO: -- for an amendment or a
16 year before the license is up.

17 MS. CHANG: That's correct. That's
18 correct.

19 MEMBER LIETO: Okay.

20 MS. CHANG: So the final drop dead day is
21 August, 2009 if the waiver has not been terminated
22 earlier than that.

23 CHAIRMAN MALMUD: Thank you, Lydia.

24 If we may, we'll move on to the next item
25 on the agenda, which is the NARM transition plan. And

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1 that will be presented by Mr. Mauer and Mr. White.

2 MR. MAUER: Good morning. I'm Andrew
3 Mauer, and this is Duane White, and we're working
4 together to implement the transition plan that we
5 developed for NARM. And the purpose of our briefing
6 this morning is to give you update on our efforts to
7 publish the plan and to implement it.

8 And the transition plan, the formal name
9 is the Transition Plan To Facilitate an Orderly
10 Transition of Regulatory Authority for NARM. And
11 we'll go through each of the different components and
12 give you an update of where we are this morning.

13 I'm sure that Lydia's covered the first
14 bullet here under the overview. But one thing we
15 wanted to mention is this is actually a requirement of
16 the Energy Policy Act that the agency publish a
17 transition plan. And so that's what we're working to
18 do.

19 Lydia also mentioned the waiver. We
20 issued a waiver following the passage of the Energy
21 Policy Act on August 31, 2005. And that will allow
22 states and individuals to continue their activities
23 involving NARM until we terminate the waiver or it
24 expires. And as was mentioned, we plan to terminate
25 the waiver in phases starting with the effective date

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1 of the rule and ending on August 7, 2009.

2 And to clarify the question from before,
3 just to reiterate really, once the waiver is
4 terminated in the jurisdiction, that's when the
5 effective date is for that jurisdiction. So,
6 hopefully, that's clear.

7 As far as the transition plan, it was
8 developed to address each of the different transition
9 scenarios, and we'll walk through those.

10 Our plan is to publish the final
11 transition plan in between the time that the final
12 rule is published and when it becomes effective. So
13 once the rule is published, it will be effective 60
14 days later and the transition plan will be published
15 within that time window.

16 So given that the timing that Lydia
17 mentioned as far as the schedule, the earliest
18 possible effective date would be realistically three
19 to four months from now, given the OMB review process
20 that Lydia mentioned.

21 The transition plan addresses agreements
22 states. When we put these slides together we had 31
23 certifications from agreement state governors
24 documenting that their state has a program for
25 licensing the new materials and that they intend to

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1 continue to regulate those materials. Since then we've
2 received certifications from the remaining agreement
3 states, so we now have certificates from all of the
4 agreement states indicating they intend to continue to
5 implement their programs.

6 Our plan is for the NRC Chairman to sign
7 responses back to the governors approving the
8 certifications in conjunction with the effective date
9 of the regulations. And this is 60 days after their
10 published that effective date.

11 Overall, in this aspect of the transition
12 plan we expect transparency. And what we mean by that
13 is really transparency from an agreement state
14 licensee standpoint they shouldn't see anything
15 different.

16 For the nonagreement states, federal
17 agencies and tribes that constitutes another few
18 components of the transition plan. We kind of tried
19 to consolidate for our presentation here today because
20 these entities are similar as far as the transition
21 goes. And we've been closely coordinating with the
22 nonagreement states, licensees and industry groups
23 through various communication methods. And we'll talk
24 about those in a later slide. But one thing that
25 Lydia mentioned concerning the waiver is once it's

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1 terminated, that will be the effective date for folks
2 who are effected and all persons that possess the new
3 materials in NRC jurisdiction must be in compliance
4 with the regulations immediately. And they'll be
5 given a time period to apply for a license amendment
6 or a new license if they don't already have an NRC
7 license. And those time periods are six and 12 months
8 respectively.

9 And the next slide just lays out for the
10 nonagreement states which ones will have the waiver
11 terminated on the effective date of the regulations
12 and also just to reiterate federal government agencies
13 and federally recognized Indian tribes will also have
14 the waiver terminated coincidentally.

15 For the remainder of the nonagreement
16 states we plan to terminate the waiver in phases.
17 We're tentatively looking at summer to fall 2008 for
18 the second phase. And the final phase being in the
19 spring to summer 2009 with the latest possible date
20 being when the waiver expires.

21 And I understand the need to have as much
22 notice as possible. And I can assure you that once we
23 make a decision, we will inform everyone. We have not
24 made the decision yet. We're still waiting to see
25 whether any nonagreement states express interest in

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1 becoming agreement states. Currently we have
2 Pennsylvania we're working with, New Jersey and
3 Virginia. And if we have any other formal letters of
4 intent that we receive, we'd like to factor that in
5 and really when we communicate the information, we
6 want to only do it once, and we want to have it right.
7 But we would expect to have at least six months
8 notice. I personally think it will be more notice than
9 that. And I believe that once we do provide
10 notification on which states will fall into the second
11 phase, we may even be able to --well, you'll at least
12 be able to understand which states will likely fall
13 into the final phase if we're not prepared to actually
14 set a date for it by process of elimination.

15 And the last bullet here indicates that
16 states that become agreement states by August 2009
17 will have their waiver terminated coincident with the
18 effective date of their agreement. So they're not
19 going to fall into a particular phase necessarily.
20 For example, we're currently working with
21 Pennsylvania. And if they become an agreement state in
22 the near term, their waiver will be terminated
23 coincidentally with the effective date of their
24 agreement with us.

25 The transition plan also addresses what

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1 I'm calling some miscellaneous scenarios. The NRC
2 will assume regulatory authority for exempt
3 distribution of NARM. And that will occur upon waiver
4 termination. We're currently working with a limited
5 number of licensees effected there to effect that
6 transition.

7 And from the standpoint, we're also
8 working to assume regulatory authority for all sealed
9 source and device, evaluations and registration for
10 NARM and jurisdictions that do not have that
11 authority. In other words, for nonagreement states or
12 agreement states who did not assume that authority
13 within their agreement with the NRC. And that will
14 occur the same time, upon waiver termination.

15 And as you can see the common theme is
16 once your waiver is terminated, that's when the
17 transition will begin for you.

18 The last slide is called communications.
19 And this is really something that we've had to focus
20 on and tried to focus on extensively throughout this
21 process. And hopefully more so in the future. And
22 because we're really going to be communicating with in
23 a new area, and in some cases with folks who haven't
24 been regulated by the NRC. So we're trying to get our
25 message out with respect to -- for now we've been

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1 focusing on the schedule and what our estimates are
2 and when all the different pieces of the
3 implementation will fall together as far as the
4 guidance, which you'll hear from in the next
5 presentations, and the regulations and the transition
6 plan. How everything fits together. So in that
7 regard actually issue a regulatory issue summary in
8 March giving all licensees a status update, and we
9 also put some frequently asked questions at the end
10 there that we thought would be helpful. And you all
11 should have received a copy of that being an
12 addressee.

13 And we've tried to take the information,
14 the pertinent information from that RIS, summarize it
15 and communicate it through other avenues, through
16 other industry groups and other forums to try and get
17 that message out. So we're working beyond our
18 addressees for a material licensee standpoint and
19 we've asked our agreement state partners to
20 communicate, disseminate the information to their
21 licensees as appropriate.

22 And we're currently planning to do a
23 follow-up regulatory issue summary once the
24 regulations are published to let folks know this is
25 your effective date, at least for what we're calling

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1 the first phase with the effective date of the
2 regulations. So once the regulations are published,
3 we're actually planning to issue another regulatory
4 issue summary.

5 And I would just close by noting a website
6 that we've developed with all items NARM, hopefully,
7 for general use. It includes information on the
8 regulations, the guidance, the agreement state
9 governor certifications, letters that we've sent to
10 the states. You can find a copy of the draft
11 transition plan there. And maybe some other things.

12 That concludes the presentation. With
13 that, we would take any questions you have.

14 CHAIRMAN MALMUD: Thank you, Mr. Mauer.

15 Are there any questions or comments for
16 Mr. Mauer? Sally?

17 MEMBER SCHWARZ: I just wanted to restate
18 what I asked Lydia. And in terms of the last two
19 groups, is it your thinking that those states that are
20 becoming agreement states might have formed the later
21 group and that possibly the remaining nonagreement
22 states would be in the phase 2?

23 MR. MAUER: We would see -- if you look at
24 the remaining nonagreement states including those that
25 are intending to become agreement states, we would see

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1 some states in phase 2 and some states in phase 3.

2 I guess the answer to your question there
3 may be nonagreement states who do not become agreement
4 states that are in phase 3. Does that --

5 MEMBER SCHWARZ: Any idea what would move
6 them into phase 3?

7 MR. MAUER: Well, there's three factors
8 that we're looking at from a selection standpoint.
9 We're looking at intent, expressed intent to become an
10 agreement state. We're looking at what their current
11 regulatory program is for these materials. And we're
12 looking at the size of the program.

13 MEMBER SCHWARZ: And size would make them
14 go later or soon?

15 MR. MAUER: Let me just make sure. I
16 named two of the things for sure, and I just want to--
17 let's see. The scope of the current state's regulatory
18 program, the estimated number of total licensees
19 impacted and the states level of interest in becoming
20 agreement states as far as -- we're looking at all
21 three areas together and kind of looking at our
22 overall transition as an agency as far -- we're seeing
23 a lot of increased workload with the transition that
24 our regional offices in particular will be facing. So
25 we're trying to spread it out and divide it up, if you

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1 will. But in a manner that's risk-informed.

2 MEMBER SCHWARZ: All right. Thank you.

3 MR. MOORE: This is Scott Moore.

4 And learn from the transitions as the
5 happen. Since it's a three phased transition, we
6 should learn from the transition in phase 1 and make
7 phase 2 and phase 3 that much more efficient.

8 In phase 1 we have some states that have
9 less robust programs, you know, or very little
10 regulatory oversight programs in some of the states.
11 And other states that have, you know, full regulatory
12 programs or territories that have full regulatory
13 programs.

14 And so in phase 1 we're trying to pick up
15 the programs that don't have much. In phase 3 we're
16 trying to leave some of the programs that may become
17 agreement states so we don't, you know, move work that
18 we may not need to do. So the ones that are in
19 between are in phase 2.

20 Does that answer your question, Ms.
21 Schwarz?

22 MEMBER SCHWARZ: It helps.

23 MR. MOORE: Okay.

24 MEMBER SCHWARZ: Essentially, you know,
25 kind of waiting where programs would lie based on the

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1 amount of work that they have and the extent of the
2 program that they're dealing with?

3 MR. MOORE: Right. As we get into phase
4 1, I think we should have a much better handle on
5 which will be in phase 2. And then that will dictate
6 which are in phase 3.

7 MEMBER SCHWARZ: And you think that that
8 will be posted or essentially made known shortly after
9 the rule is published?

10 MR. MOORE: I don't know about after the
11 rule is published, but as we move into phase 1, I
12 think, yes.

13 MEMBER SCHWARZ: Within six months maybe
14 of publication do you anticipate?

15 MS. CHANG: Something like --

16 MR. MOORE: Yes. I think --

17 MEMBER SCHWARZ: Somewhere that
18 information can be made available. I understand it's
19 a difficult decision to make, but certainly for all
20 the licensees involved, it's very important. The
21 sooner that we know, the easier it is for us to begin
22 to prepare.

23 MR. MOORE: Absolutely. And then I'd like
24 to note, you know, as Lydia and I think Andrew noted,
25 once the state, the nonagreement state transitions

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1 over to NRC jurisdiction, the licensees within that
2 state if they have an NRC license and they come and
3 they have NARM accelerator-produced material and
4 discrete sources of radium-226, they still will have
5 six months to apply for an amendment if they already
6 have an NRC license or a year to apply for a new
7 license if they don't yet have an NRC license.

8 MEMBER SCHWARZ: Thank you.

9 CHAIRMAN MALMUD: Thank you.

10 We also have a question from a member of
11 the public.

12 MS. FAIROBENT: Yes. Lynne Fairobent with
13 the American Association of Physicists in Medicine.

14 Andrew, for the two states that have just
15 recently announced their intent to go agreement,
16 Virginia and New Jersey, given the time that it takes
17 for a state to go agreement realistically other than
18 Pennsylvania, do you anticipate they can make the
19 August date for 2007? Is there going to be an
20 expedited review process for transitioning Virginia
21 and New Jersey to agreement status?

22 MR. MAUER: Well, at this point those
23 states have expressed letters of intent to become
24 agreement states. And they've indicated to us they
25 expect to submit a draft request for an application.

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1 Obviously they're -- you know, we'll need to look at
2 that. We're not going to expedite anything as far as
3 compromising our processes or anything like that, but
4 we're going to continue our normal processes. But
5 we'll need to receive quality applications, obviously
6 given what you note as there's not the crunch time
7 frame up until August 2009. But at this point we
8 can't say one way or another how that's going to work.

9 We need too see where they are in process
10 at that time, and at that time we can make a decision
11 and look at how those states would transition, if you
12 will.

13 MS. FAIROBENT: And the August 9 date is
14 a hard date without congressional relief, correct?

15 MR. MAUER: That's the date --

16 MS. FAIROBENT: August, 2009?

17 MR. MAUER: August 7, 2009 is four years
18 after the Energy Policy Act was passed, which is the
19 longest that the waiver can be in effect for. So we
20 put that date as the latest the waiver can be in
21 effect.

22 MS. FAIROBENT: Okay. Thank you.

23 CHAIRMAN MALMUD: Any other questions?

24 Yes.

25 MEMBER GILLEY: Debbie Gilley.

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1 Andrew, you mentioned that the governors
2 would be notified in the agreement states 60 days
3 after the final rule, is that correct?

4 MR. MAUER: Correct.

5 MEMBER GILLEY: Will you also be notifying
6 the director members that those letters are on the way
7 to the governor?

8 MR. MAUER: We have a multi-stage
9 notification process with all sorts of notifications
10 planned out. Basically after the transition plan is
11 published, I mentioned the transition plan will be
12 published within the 60 day window. And then on the
13 effective date -- well, when the transition plan is
14 published, that's when the governors' certifications
15 become effective. And so once they're effective, we
16 can approve them once we have regulations that are
17 effective.

18 So to answer your question, there will be
19 several notifications, we'll issue a press release,
20 more than likely the state programs will be notified,
21 ACMUI will be notified. Everyone's going to be
22 notified.

23 MEMBER GILLEY: Thank you.

24 CHAIRMAN MALMUD: Thank you.

25 If we may, we'll move on.

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1 Thank you, Mr. Mauer.

2 We now move on to Mr. White -- oh, excuse
3 me. Mr. Lieto?

4 MEMBER LIETO: Yes. I had one question for
5 the gentleman for the nonagreement states, which
6 obviously are the minority of the states involved in
7 this process. But I think there's maybe some
8 confusion with, obviously, the transition plan is just
9 how the dates and when the rules become effective and
10 so forth. From the standpoint of license
11 applications, in the regulatory issue summary that you
12 issued there were just only a couple of questions that
13 addressed this. And as far as the individual licensee
14 is concerned in the nonagreement states, it's not
15 clear if they are under an NRC license right now using
16 both old byproduct and new byproduct -- in other
17 words, NARM plus the old byproduct definition, that
18 they're going to have to amend their license. If
19 they're not, you don't have radionuclide specific.
20 For example, you have a 100 and 200 licensee, they're
21 using thallium, gallium, indium, other NARM type
22 materials. That's not specified by radionuclide, but
23 it seems to indicate that they have to go and get a
24 new license amendment when the new rule comes into
25 place. And I don't think that's the intent, but that

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1 point needs to be clarified.

2 So I think in your next RIS, I think you
3 need to look at -- you know, kind of sit in the seat
4 of the licensee and say do I really need a license
5 amendment? Do I need -- because I don't think you
6 want to burden the regions with a licensing amendments
7 that are superfluous and just take up a lot of time,
8 especially in the time crunches that are going to be
9 going on here.

10 You know, very few medical licensees have
11 radium sources. I imagine there might be a few out
12 there. I could see those might need to be -- these
13 might need to be specified by a license amendment. But
14 I think it needs to be really specific do I need to
15 apply or don't I need to apply. The same thing for
16 Part 300. There's not really radionuclide specific,
17 okay So if they get some NARM -- NARM generated
18 radionuclide comes down the pike that's used for
19 therapeutic purposes, do they need to apply for a
20 license amendment? My way of thinking no. But, you
21 know, I think that needs to really be laid out clear
22 because most of the things in that RIS that came out
23 in March are aimed more at dates or more addressing
24 when things become effective and so forth. Not as
25 what needs to be specifically amended in your license

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1 in an agreement states -- excuse me. Nonagreement
2 state.

3 MR. MAUER: That's a very good point, and
4 something that we're definitely aware of and looking
5 at. We can definitely take a look at whether we can
6 include something in the next regulatory issue summary
7 in that regard. But your understanding is consistent
8 with the approach we're taking as far as if your
9 license is written in a manner that the authorities
10 that you'll need to operate under are already there
11 and you don't need any changes. You won't need to have
12 your license amended.

13 CHAIRMAN MALMUD: Thank you.

14 Lydia Chang has a comment.

15 MS. CHANG: Actually, I just wanted to
16 respond to Mr. Lieto's question. And Andrew is
17 absolutely correct. Within the final rule we also
18 have addressed comment response. And there were quite
19 a few comments asking a similar type of question that
20 you have raised. And our response, it's really
21 consistent with what Andrew said.

22 If your license is so broad to only
23 byproduct material by having the final rule become
24 effective, that byproduct material would in fact
25 include all the NARM material. Therefore, no license

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1 amendment is necessary. So we actually have clarified
2 within all the responses on comments associated with
3 that question.

4 CHAIRMAN MALMUD: Thank you.

5 Thank you again, Mr. Mauer.

6 And we'll move on to Mr. White.

7 MR. WHITE: Actually, I don't have
8 anything to add. Actually, for the transition plan,
9 I don't have anything to add.

10 CHAIRMAN MALMUD: Okay. We'll be going to
11 the guidance.

12 MR. WHITE: Okay.

13 CHAIRMAN MALMUD: Which is your item.

14 MS. TULL: Dr. Malmud, we were actually at
15 a break.

16 CHAIRMAN MALMUD: Ah, then why don't we
17 take the break now. Is that okay with you, Mr. White?

18 MR. WHITE: That would be fine.

19 CHAIRMAN MALMUD: We'll take the break now
20 and return here, let's see, 9:35.

21 (Whereupon, at 9:20 a.m. a recess until
22 9:43 a.m.)

23 CHAIRMAN MALMUD: Thank you all. We'll
24 resume now, and the next item on the agenda is the
25 presentation by Mr. White regarding NARM guidance.

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1 MR. WHITE: Thank you.

2 Yes, I'm going to give you an update of
3 the NARM guidance and what we've been doing. First
4 I'd like to give you an overview.

5 The NARM guidance writing team was
6 established in the summer of 2006, and our purpose was
7 to evaluate and look at all of the NUREG 1556 volumes
8 and determine what volumes would need to be revised
9 based on the new NARM rule.

10 After our review, we determined that the
11 most pressing volume that needed to be revised was
12 Volume 9 and Volume 13. Volume 9 is program specific
13 guidance about medical use licensees, and Volume 13 is
14 the program specific guidance on commercial regular
15 pharmacy licenses.

16 We also determined that we needed a new
17 volume now that we're dealing with accelerator
18 produced materials. So we came up with Volume 21,
19 which is the program specific guidance about
20 possession licenses for production of radioactive
21 material using an accelerator.

22 We did recognize some other volumes that
23 needed to have minor revisions, but those volumes
24 would be done at a later time, but Volumes 9, 13, and
25 21 are the volumes that we wanted to get out pretty

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1 much by the effective date of the NARM rule.

2 During our process of revising and
3 developing the new guidance, we sent out comments,
4 sent out the volumes to the ACMUI, and unfortunately
5 Volumes 9 and 13 we were not able to receive comments
6 because we already went through the Steering
7 Committee, and we asked that the committee would
8 provide comments during the public comment period.

9 But we were able to get comment for Volume
10 21, and Sally provided comments for that.

11 Due to the extension of the rule, we
12 haven't had the public comment period yet. Well,
13 Volume 21 is now in the public comment period, but we
14 never did receive your comments because of the
15 extension of the rule and we had to wait on any other
16 changes until after the rule was, I guess, finalized
17 as far as the second draft.

18 I want to give you the update on Volume
19 13. I'm the volume leader for Volume 13 and Volume
20 21. So I'd like to give you an update on volume 13 as
21 far as what was contained in that volume.

22 We added guidance for facility and
23 equipment specific to PET radiopharmacies giving them
24 a better understanding of what they need to provide.

25 We also provided some additional

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1 radiopharmaceutical safety recommendations because of
2 the handling of higher energy photon emitting
3 radionuclides, and an example of that would be to
4 recommend using pocket dosimeters.

5 We also insured the applicants of where
6 that if they do have discrete sources of Radon 226,
7 that they now need to be identified and licensed by
8 the NRC.

9 In addition to those revisions outside of
10 the NARM, we also saw the need to add the new 313A AMP
11 form to Volume 13, which will be found in Appendix G,
12 and we also revised the appendix on transportation
13 making it less descriptive and a little more general
14 because Department of Transportation changes their
15 regulations, and we were not able to make sure that
16 your guidance was constantly updated to the
17 regulations.

18 For Volume 21, which is the new volume,
19 production of radioactive material using an
20 accelerator, the first thing that was our decision for
21 this guidance or for production rad. materials, that
22 the license would be a separate license, a separate
23 specific possession license, which would be associated
24 with other licenses such as a broad scope or somebody
25 would be something where you would need to provide all

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1 of the information on this production of radioactive
2 material using the accelerator.

3 Also, in our last meeting, we had the term
4 "authorized user" in the guidance, and there was some
5 confusion as that might cause confusion because the
6 medical in Part 35 authorized user is defined
7 specifically, and so what we did is we changed that
8 section to say individuals that are authorized to
9 handle materials, as you will have some person that
10 will be experienced in this and on the production
11 license. So we did make that change.

12 Also, Sally had a concern or mentioned the
13 fact that for activation products, before we mentioned
14 it, you should list all of your products and give an
15 estimated maximum activity. We know that that could
16 be somewhat hard to do for especially the bigger
17 facilities. So we did put in a provision to authorize
18 the one through 83.

19 However, when we go to the broad scope, we
20 had to note that the financial assurance might be
21 higher. So that's why we also wanted to give the
22 option to smaller licensees who might -- you know,
23 they can usually get their information from the
24 manufacturer if they needed to.

25 And another thing that we added since the

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1 last meeting when I spoke is we did add an appendix on
2 the consortium. For those members who produce
3 radioactive materials or to consortium members, we did
4 add some guidance on that. So that can be found in
5 Appendix P.

6 Currently Volume 21 is out for public
7 comment. It was released on May 29th in the Federal
8 Register. The official date on the Federal Register
9 is comments are due back by June 28th. However, we
10 did send out the Website a little bit later. So we
11 will be accepting comments at least until July 5th.
12 We ask that you still provide comments on that.

13 For Volume 13, we expect to release that
14 at the end of this month, and again, we'll have 30
15 days to comment on that. And Volume 9, we're looking
16 at mid-July for that one.

17 We will provide the ACMUI the guidance as
18 soon as we can. It will probably be close to that
19 date. It might be a week or so before, but in general
20 you'll receive a copy when the public comment period
21 starts.

22 And staff will review and adjust the
23 comments, and we hope that the guidance will be
24 finished by the fall of 2007.

25 And that's all for mine. Dr. Howe is

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1 going to give an update on Volume 9. Were there any
2 questions on Volume 13 or 21?

3 CHAIRMAN MALMUD: Are there any questions
4 for Mr. White?

5 (No response.)

6 CHAIRMAN MALMUD: There are none.

7 Dr. Howe.

8 DR. HOWE: Okay. Duane essentially
9 covered two of the volumes, and I have the third
10 volume, and as you know, Volume 9 is quite thick, and
11 what we did was we essentially did surgical revisions
12 to Volume 9, and those revisions are focused very
13 narrowly on the NARM rule, on the new NRC Form 313As,
14 security related information, and minor updates.

15 And you see I have a lot of slides, but
16 that just goes in to kind of fill out some of these
17 topics. For the NARM rule we added the definition of
18 byproduct material. We added sections about
19 addressing the 10 CFR 30.32 authorization for the
20 noncommercial transfer within a consortium, and
21 Duane's Volume 21 addresses noncommercial distribution
22 within the consortium for the educational facilities
23 and the federal facilities, and Volume 9 includes the
24 noncommercial distribution for the medical facilities
25 to other medical facilities.

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1 And since we have changes for
2 noncommercial distribution, we now have conforming
3 changes in the medical use license for this
4 noncommercial distribution. And Lydia went over some
5 of those changes, like you can now use the
6 measurements that are provided by the noncommercial
7 distributor the same way you could use the
8 measurements provided by commercial pharmacy or the
9 drug manufacturer.

10 Implementation, Lydia talked to you
11 earlier, and Andrew talked to you about the act that
12 there are several dates that are important. One is
13 the implementation of the effective date of the rule
14 for federal facilities. There's an implementation 60
15 days later for non-agreement states. It depends on
16 when your waiver is terminated, and as Lydia
17 indicated, those are parts of the regulation. Well,
18 we've added that information into Volume 9 for the
19 medical use licensees.

20 She also indicated that we have new
21 experienced individuals that have used non NRC-
22 regulated material, and we're recognizing them as
23 authorized users, authorized nuclear pharmacists, and
24 so we've added guidance for those individuals.

25 There is now an amendment request. If you

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1 make a change to a 100 or 200 medical use area only if
2 it has to do with moving a PET production unit around
3 in that area or moving a PET transfer delivery line in
4 that area. Otherwise you're still covered under
5 notification and broad scope licenses do not have to
6 either get an amendment or notify NRC of those
7 changes.

8 We added the strontium and the rubidium
9 generators.

10 One of the major things we did in Volume
11 9 is we added a lot of reminders. Volume 9 is a
12 unique document. There are many, many kinds of
13 licensees that are using this document, and they tend
14 to pick it up and use parts that are relevant to them
15 as opposed to the nuclear pharmacy license or the
16 accelerator production where you may start at the
17 beginning and work your way through.

18 So we've added a lot of reminders in
19 various places in Volume 9 that essentially just tell
20 people now non NRC-regulated material and discrete
21 sources of Radium 226 are now regulated by NRC, and
22 remember these are parts of your radiation safety
23 program.

24 That means that in the past occupational
25 dose was only looked at by NRC if there was NRC

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1 material involved. Then you picked up the non NRC-
2 regulated material because of the byproduct material.
3 Well, now the byproduct material has expanded. So if
4 you had an individual that was working primarily with
5 thallium, they are now part of that occupational dose
6 for NRC purposes.

7 We've put references in that there may be
8 some legacy sources out there that were either
9 reviewed or not reviewed by the non-agreement states
10 with non NRC-regulated material in them, and what
11 should licensees do if they have a device that doesn't
12 have a sealed source and device registry.

13 We added a specific leak test for Radium
14 226. In this case we went to nationally recognized
15 standards and exerted the leak test for individual
16 Radium 226 sources where you put them in a vial and
17 then check for radon.

18 If you have a larger device and the source
19 is in the device, then you use the standard leak test
20 that you use for any other device.

21 We also clarified that we don't think
22 there's any medical use of Radium 226 out there now,
23 but the new rule doesn't prohibit it. So we wanted to
24 make it clear that in the past, they've been used for
25 manual brachytherapy. We would consider manual

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1 brachytherapy to be an accepted use because that was
2 used in the past, but if you're using any unsealed
3 Radium 226, that's definitely going to be a 35.1000
4 use, and if you were using Radium 226 for something
5 other than manual brachytherapy, we consider that to
6 be a 35.1000 use also.

7 Jeff.

8 MEMBER WILLIAMSON: What about Radon 222
9 seeds? I don't think there is a radon seed plant in
10 existence, but there are actually more implants
11 probably done with the 20s and 30s with radon than
12 with radium.

13 DR. HOWE: We'll have to deal with that.

14 MEMBER NAG: Now, radium, you get unsealed
15 Radium 226. Now, 226 half-life is so long. It's
16 1600-something years. How can you have unsealed?

17 DR. HOWE: We don't think it's out there.
18 We just put it in to cover the bases to make sure that
19 people didn't start doing something without contacting
20 us, but we don't think anybody is going to use it and
21 we don't think it's out there, Dr. Nag, but we --

22 MEMBER NAG: But I think the next question
23 about radon is if you think about it radon long-range
24 seeds, I think people will still be using it.

25 DR. HOWE: We'll find out.

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1 Yes.

2 MEMBER FISHER: Is the NRC anticipating
3 the use of unsealed Radium 226 or sealed in the form
4 of targets for producing other short-lived alpha
5 emitters?

6 DR. HOWE: That would not be subject to
7 this particular NUREG because this NUREG is the
8 medical use. If it was being used as a target to
9 develop new isotopes, then that would come under
10 Volume 21, which is Duane's. That would be making
11 accelerator produced materials with an accelerator.

12 Okay. In the 30.32(j), which is the
13 authorization for noncommercial transfer, we've added
14 the guidance in Appendix AA. We have a lot of
15 appendices in this volume. That gives you the
16 guidance on how to submit an application for this
17 authorization.

18 Because of the noncommercial transfer that
19 can be done by medical use licensees, we've also added
20 things like you may now be responsible for filling
21 orders and shipping where in the past you were more
22 responsible for ordering materials and receiving. So
23 we've added shipping.

24 And we've also addressed more non-medical
25 uses in users specifically in the guidance. We've

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1 tried to cover the bases that we can think of. In
2 many cases we've put a disclaimer in that says you may
3 have to supplement this, the model procedures, which
4 are always optional for the non-medical uses that you
5 may be involved with.

6 Okay. Lydia told you that our non-users
7 are grandfathered. We revised Appendix C to include
8 these individuals in the T&E submissions for all
9 pathways. We tried to make that a lot clearer how to
10 capture everyone.

11 And also you need professional licensing
12 information for physicians and pharmacists.

13 One of our big changes as far as pages
14 goes would be the introduction of our new NRC Form
15 313As. We had one NRC Form 313A that was developed as
16 a result of our changes in the 2002 rule, and at that
17 point we were told to make minor changes to the form,
18 and the form had to fit about 25 different types of
19 professional individuals. And it was very, very
20 complicated, and the comment we got from everyone was,
21 "Can you do something with the form?"

22 So we made six of them, and we grouped
23 them this way. There's a 313A RSO that covers
24 individuals that are subject to 35.50. There's a 313A
25 AMP that's for 35.51. There's a 313A ANP for 35.55.

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1 We divided up the physicians into three
2 groups, the AUD, D standing for diagnostic. That's
3 the 190, the 290, and the 590 physicians. The AUT; T
4 stands for unsealed therapy. Those are your 390, 392,
5 394, 396 physicians, and the AUS and the S stands for
6 sealed source, and those are your 490, 491 and 690.

7 You had a chance earlier to look at those
8 forms several meetings ago. We put the new forms in
9 Appendix B. We've revised the guidance to go with
10 these forms. That's in Appendix D. The new forms are
11 up on the Website right now.

12 The guidance, we have a minor tweak to
13 that once we get our no legal objection again on the
14 minor tweak, we'll revise that on the Website, too.

15 We also use these sample forms in the
16 sample 35.200 application.

17 Security related information, security is
18 a big issue. We added a section that reminded
19 applicants and licensees that if they are including
20 security related information, they need to mark it
21 appropriately and separate it out. We provided
22 references to the Website that gives further
23 clarification.

24 We marked a diagram, a facility diagram,
25 that showed exactly where the material would be used

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1 and who was located above and below.

2 We also in the sample application for the
3 200 user because it had a facility diagram to say
4 exactly where the material would be used. We marked
5 on the 313 form that it included security related
6 information, and we marked that page in the sample
7 application.

8 Do we also changed the format of all of
9 our sample licenses to remove the NRC logo, to make
10 them look less like official NRC licenses. They
11 contain the same information, but they do not look as
12 much like an NRC license as they did in the past.

13 And then we did some very minor updates.
14 We changed the agreement state numbers in the map. We
15 added federally recognized Indian tribes. We had a
16 number of tables in Appendix U that had typo errors in
17 it that we have corrected, and we've made some other
18 very minor changes.

19 So that's kind of a quick overview for our
20 changes to Volume 9. Are there any questions or
21 comments?

22 CHAIRMAN MALMUD: Questions or comments
23 for Dr. Howe?

24 MR. BHAT: This is Ram Bhat. Can you hear
25 me?

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1 CHAIRMAN MALMUD: Yes. Could you identify
2 yourself, please?

3 MR. BHAT: Okay. Ram Bhat from U.S. Air
4 Force, Bolling Air Force Base.

5 I have a question. U.S. Air Force has
6 several sites which contain Radium 226 and in some
7 buildings. So how do you interface the
8 decommissioning aspects of this Radium 226 which are
9 contaminated with the soil?

10 DR. HOWE: You're talking about
11 decommissioning and this particular talk is not
12 relevant to decommissioning, and I cannot answer that
13 question. We are currently dealing with revisions to
14 the rule and to the guidance and to the statements of
15 consideration in the rule to address Radium 226 that's
16 been used for military uses.

17 And Lydia Chang is the individual that
18 would be able to respond to that, and Lydia is not
19 here right now.

20 PARTICIPANT: Thank you.

21 CHAIRMAN MALMUD: Any other questions or
22 comments?

23 (No response.)

24 CHAIRMAN MALMUD: There being none, thank
25 you, Dr. Howe.

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1 We will next hear from two people who are
2 identified here at TBD, but they will be more
3 specifically identified after they assume their seats.
4 First I believe it's going to be Cindy Flannery.

5 MS. FLANNERY: Yes.

6 CHAIRMAN MALMUD: And there is a handout
7 which you should all have in front of you.

8 MS. FLANNERY: Okay. Good morning. Cindy
9 Flannery.

10 I just have some introductory information
11 before I pass this over to Dr. Williamson, who by
12 nature of his profession and involvement in AAPM task
13 groups has a lot more to say on this topic.

14 Shortly after the last ACMUI meeting in
15 October, NRC had received a couple of requests for NRC
16 to require vendors as well as users to only use Air
17 Kerma Strength in the calibration of brachytherapy
18 sources instead of apparent activity in millicuries.

19 And around the same time that these
20 requests came in, there were also several medical
21 events that had been reported at that time having to
22 do with the confusion of Air Kerma Strength and
23 apparent activity in millicuries. And these errors
24 had resulted in treatment delivery errors.

25 Now, the NRC's regulations for

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1 manufacturing and distribution of sources and devices
2 do not address the units of measurement.

3 Okay. So here's the first E-mail, and the
4 emphasis is mine here with the bold and underline, but
5 the person who had sent in this E-mail explains that
6 the contained activity is necessary for the purpose of
7 transportation; goes on to say that the treatment
8 planning systems, the modern ones, do only use Air
9 Kerma Strength, and that there is no real useful
10 purpose for apparent activity in millicuries, and then
11 ends up by just suggesting that the NRC consider
12 abandoning apparent activity and requiring the vendors
13 to do that also.

14 Here's a second E-mail that just came in
15 a couple days later. Again, the italics and the
16 underlining here, the emphasis is mine. But I just
17 want to point out this first one here, that this
18 individual had personal experience with ordering some
19 brachytherapy sources and having the manufacturer fill
20 that order in the wrong units.

21 And just like in the previous E-mail, the
22 previous slide, this individual is asking NRC to
23 enforce the units of Air Kerma Strength instead of
24 millicuries and apparent activity.

25 So the next couple of slides that I have

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1 here just have some of the more recent medical events
2 that have been reported to the NRC as a result of
3 confusing these two units. So I have them listed here
4 in reverse chronological order and also I had it color
5 coded by the error.

6 So I'm just going to start out with the
7 data entry ones here in pink. So for this first event
8 here that was a data entry error, and the total
9 activity was determined for this patient in
10 millicuries, but the treatment planning system has a
11 default in Air Kerma Strength.

12 So when this individual entered in the
13 activity, the operator didn't actively go and change
14 it to millicuries, and as a result, the treatment
15 planning system calculated a higher number of seeds,
16 and it resulted in a 24 percent increase in dose.

17 And this right here, a more recent one, is
18 another example of a data entry. Some of these events
19 that are listed here were reported in agreement
20 states, and so there's not quite as much information.
21 If it's reported to NRC, it's followed up with a
22 reactive inspection, and we go and gather a lot more
23 information, but as far as the agreement states,
24 that's all handled by the state inspector. So some of
25 them don't have as much information as others.

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1 So I have no more information than just
2 the wrong units of measurement where entered in the
3 treatment planning system.

4 So that's the data entry type of errors.
5 The other one I want to point out here is in purple,
6 and this is where the licensee made an error in
7 ordering, and in this particular case, the licensee or
8 the treatment planning system calculated in units of
9 Air Kerma Strength .5, but when it was ordered, it was
10 ordered in .5 millicuries. So it ended up being a 27
11 percent overdose.

12 The next slide here, exact same type of
13 error. The treatment planning system calculated in
14 Air Kerma Strength, but the licensee ordered it in
15 millicuries. But in this particular case ten patients
16 were affected, and what happened here is this licensee
17 had a new medical physicist come in and saw the error
18 right off the bat, and they found out that there were
19 ten people who were affected by it when investigated
20 it.

21 Okay. So a third type of cause here is
22 where the manufacturer makes an error in filling the
23 order, and the licensee did not realize that when the
24 brachytherapy sources were received. In this one
25 particular case, the licensee had ordered in units of

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1 Air Kerma, but the manufacturer filled the order in
2 units of millicuries. It resulted in an overdose, and
3 then the opposite here, and it resulted in an under
4 dose.

5 MEMBER WILLIAMSON: Do you know if the
6 shipping vials and the certificates were correctly
7 filled out or were they erroneously filled out?

8 MS. FLANNERY: That information was not in
9 the NMED report.

10 MEMBER NAG: I mean, I have had many close
11 misses or I have seen many close misses, and many
12 times the problem is that the person who is giving the
13 order is someone who may not realize that there's a
14 difference between millicurie and Air Kerma Strength.
15 So they make the call, you know. "I want 0.5
16 millicuries," and they have it or the other way
17 around. "I want 0.5 Air Kerma Strength," and the only
18 thing they have is millicuries. So they just put 0.5.

19 And similarly, some of the technologists
20 may not know the difference between the two. No, the
21 physicist would know.

22 So I think it's a very common error. The
23 risk is very high. You know, once we have that
24 knowledge department we said no one is going to use
25 two different things at the same time. Whenever you

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1 have two different units applicable at the same time,
2 you know, the likelihood of mistake is extremely high,
3 especially when the difference is only about 30
4 percent of most isotopes.

5 CHAIRMAN MALMUD: Ralph.

6 MEMBER LIETO: The units here are
7 millicuries or apparent activity; isn't that correct?

8 MS. FLANNERY: That's correct.

9 MEMBER WILLIAMSON: I'll just comment I'm
10 anticipating my own talk. When I was actively doing
11 brachytherapy physics I order hundreds of probably 400
12 seed orders. I never had an erroneous delivery, but
13 that's because of the way I did it. Okay? I insisted
14 on verbal verification and verification in writing by
15 a fax.

16 So before the seeds were delivered, I knew
17 what their intent was to deliver.

18 MEMBER SULEIMAN: I have a question. but
19 you were dealing with one vendor. So you had
20 established a relationship which implied tighter
21 controls. So I think --

22 MEMBER WILLIAMSON: That helps. In fact,
23 we had two vendors, but you're right. There was a
24 very limited number in that era.

25 CHAIRMAN MALMUD: Those two speakers were

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1 Williamson and Suleiman.

2 Any other comment?

3 MS. FLANNERY: Another thing I wanted to
4 point out here is a conversion error, and while some
5 physicists think that the milligram radium equivalent
6 is an obsolete unit, if you look at a very recent
7 event, which just happened a couple of months ago,
8 that same error was made, the exact same error. The
9 conversion from milligram radium equivalent was not
10 done before it was entered into the treatment planning
11 system.

12 In this particular event there were a
13 couple of things that went wrong. One of them was
14 that conversion was not done, but also this is the
15 first time that this licensee had ever used iridium,
16 and the acceptance testing was not done, and so the
17 treatment planning system did not have the correct
18 dose rate factor in for Iridium 192.

19 I had listed several different kinds here,
20 the conversion errors and so forth, but I really want
21 to focus your attention really on the three types of
22 errors here, namely, the data entry error, the error
23 caused by licensees in ordering the seeds, and then
24 also the errors in the manufacturer filling the order
25 and the licensee not catching it once the shipment is

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1 received.

2 So I just want to conclude by reminding
3 everybody that there are no regulatory requirements
4 for using AKS as opposed to apparent activity, but I
5 just want to request of ACMUI is just to provide some
6 input on NRC's role in this, and I guess now having
7 laid out the radiation safety concerns cause by errors
8 infused in the units resulting in unintended adverse
9 consequences, I'll pass this over to Dr. Williamson.

10 CHAIRMAN MALMUD: Thank you, Cindy.

11 MS. FLANNERY: Thank you.

12 MEMBER WILLIAMSON: Thank you, Cindy.

13 What I thought I would do is present a
14 little technical information, place this in some
15 perspective because I think those of you outside of
16 radiation oncology might not appreciate the technical
17 differences and what the physicist does in day-to-day
18 practice to mitigate the errors that can arise from
19 these conversion processes.

20 So I'll discuss the concepts of apparent
21 activity and Air Kerma Strength mainly for low energy
22 seeds in relation both to primary standards and dose
23 calculation; review some of the potential error
24 pathways; talk about some practical techniques for
25 mitigating errors; and discuss some recommendations

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1 for future action.

2 Here are some individuals, some prominent
3 brachytherapy physicists in the community I talked to
4 to get some more current information than I have
5 regarding what the vendor interfaces are like. So
6 I'll talk a little bit about that as well.

7 Okay. So I think that you all know about
8 Palladium 103 and Iodine 125 implants. We now have
9 Cesium 131 as a new addition to this armamentarium.
10 There are now of the order of 50 to 80,000 of these
11 procedures being done annually for prostate cancer.
12 So it is probably at the moment the most frequently
13 practiced indication for brachytherapy. So it is
14 quite important.

15 So how is strength of clinical
16 brachytherapy course determined? And the answer is
17 much in the same way we determine the quantity, the
18 output of a low energy X-ray unit, by measuring the
19 Air Kerma rate on the transverse axis of the seed via
20 an ion chamber. You have a special quantity for
21 representing this measured output, which is defined by
22 the AAPM called Air Kerma Strength, represented by the
23 symbol S_k , and it is equal to the Air Kerma rate in
24 free space on the axis of the source times the square
25 of the distance.

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1 So it has units of microgray meter squared
2 per hour or centigray, centimeter squared per hour,
3 and frequently the special symbol mu is used to
4 represent this mouthful of units. It's kind of a
5 handy set of units because the Air Kerma Strength
6 represents numerically the centigray per hour of that
7 brachytherapy will deliver in tissue, approximately.
8 So it's very closely related to a quantity of clinical
9 interest.

10 This is the primary standard at the
11 National Institute of Standards and Technology that is
12 used for defining Air Kerma Strength for low energy
13 seeds. So it's basically a cylindrically shaped, free
14 air chamber where the seed is -- I don't have a
15 pointer, but this little rotating seed holder is on
16 the other side of this lead barrier, and there's an
17 aperture that defines the beam. So it's a very handy
18 system for defining a -- thank you -- primary standard
19 for Air Kerma Strength individually for each of the
20 now approximately 20 to 25 seed models that are
21 available on the market.

22 So this is apparent activity. I think
23 because of the dominance of nuclear physics in our
24 field, activity-like units are in common use to
25 describe radiation output quantities. So apparent

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1 activity is the activity of a hypothetical, unfiltered
2 point source of the same radionuclide that gives the
3 same Air Kerma Strength as the given source. So it is
4 a basically kind of odd way of stating the Air Kerma
5 Strength or radiation output of a brachytherapy source
6 in multiples of a hypothetical point source.

7 So this has no connection whatsoever to
8 the nuclear medicine standards for activity. It would
9 be inappropriate to measure this in a dose calibrator
10 unless said calibrator were calibrated against the
11 wide angle free air chamber.

12 So one can define it. You divide the Air
13 Kerma Strength by the essentially exposure or Air
14 Kerma rate constant, which is this animal right here.
15 The AAPM has a guidance document which essentially
16 fixes the two constants at standard values of Iodine
17 125 and Palladium 103. So they are very close to one
18 another, 1.27 microgray meter squared per hour per
19 millicurie for iodine, 1.29 for palladium.

20 Hence you can see the origin of the 30
21 percent errors that were described by Cindy.

22 So what does the AAPM say about this?
23 Well, I defined here what "directly traceable
24 calibration" means. This means essentially a source
25 or an instrument calibrated directly, with no

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1 intermediate steps against the wide angle, three-year
2 chamber.

3 Secondarily traceable is mainly what
4 vendors have available and what we as practicing
5 clinical physicists have available in our clinics. It
6 means we specify or measure the Air Kerma Strength of
7 our seeds in an instrument that has been calculated,
8 that doesn't itself have a directly traceable
9 calibration.

10 So what is recommended and required?
11 Well, all clinical sources shall have secondarily
12 traceable Air Kerma Strength calibrations. This is
13 what AAPM recommends. This is what I believe is the
14 intent of 35.432, which is the section on calibration
15 in 35.400. It basically says if the vendor has not
16 provided a secondarily traceable AKS calibration, then
17 you as the end user are responsible for doing so, one
18 or the other.

19 The AAPM goes one step further. It
20 basically says each user should verify the vendor
21 calibrations with secondarily traceable SK
22 measurements. In fact, it gives specific guidelines
23 suggesting that at least ten percent of the sources
24 should be assayed experimentally by the end-using
25 physicist.

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1 Many institutions are doing this. Most
2 institutions that participate in multi-institutional
3 clinical trials do this because they are required as
4 a condition of being credentialed to participate. So
5 most academic institutions and large private practices
6 who put patients on clinical trials for prostate
7 cancer are, in fact, doing this or have the capability
8 of doing this.

9 Okay. So the status of these
10 calibrations, all advisory and scientific groups that
11 have considered the issue recommend unanimously that
12 Air Kerma Strength be used for source ordering,
13 planning, prescription, and recording treatments; that
14 basically apparently millicuries and other obsolete
15 quantities, such as milligram radium equivalence,
16 should not be used.

17 All source vendors and planning software
18 that you can currently purchase allow the use of Air
19 Kerma Strength in a more or less straightforward and
20 transparent way. Source certificates, all that I know
21 of, report both units. The dominant planning system,
22 which is Varian's VariSeed, the user can choose Air
23 Kerma Strength and apparent activity.

24 And when you choose one or the other, the
25 units are displayed clearly both on the interactive

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1 screens and on the printed output of the plan, but
2 this is user choice.

3 Most of the published dosimetry data is
4 Task Group 43 and Air Kerma Strength compliant, as the
5 quantities are normalized in terms of Air Kerma
6 Strength. Virtually all sources that you can purchase
7 have mixed traceable calibrations that meet the intent
8 of 35.432 and the recommendations of the AAPM.

9 The AAPM maintains registry of sources
10 that adhere to its recommendations, which may be of
11 interest to NRC if you haven't looked at this, and as
12 I mentioned, many clinics, most maybe, maintain in-
13 house calibration capabilities for carrying out what
14 is now from the NRC perspective a voluntary
15 verification assay.

16 However, apparent activity in millicurie
17 units is still widely used in clinical practice. I'm
18 discussing only low energy seeds, but in high dose
19 rate brachytherapy, it can be even more confusing
20 because now, you know, there are at least three
21 quantities floating around. There's Air Kerma
22 Strength. There's milligram hours and milligram
23 radium equivalent that are used in some institutions
24 for intracavitary high dose rate brachy, and of
25 course, there are curies and curie seconds that are

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1 used by some institutions. So you do have to really
2 be careful.

3 And here the potential for errors is much
4 larger. They can be a factor of two because the
5 conversion factor from curies and milligram radium
6 equivalence to Air Kerma Strength is a factor of two
7 different for these two quantities, four versus 8.25.

8 Okay. So for implementing the AAPM
9 recommendation for verifying within the individual
10 hospital or clinic the Air Kerma Strength of purchased
11 seeds, most institutions use a dose calibrator or
12 reentrant ionization chamber. This is a cross-section
13 of a common dose calibrator. This is one of the
14 specialized, but more difficult to use reentrant
15 chambers that you can buy specifically for
16 brachytherapy. These instruments need to be
17 calibrated specifically against the Air Kerma standard
18 for the individual source model. You cannot use the
19 same method of transmitting calibrations to end users
20 that's used in nuclear medicine.

21 I will point out this is the major
22 reference, the revised Task Group 43 report that
23 covers, I think, in one single reference all of this
24 material. So for the benefit of the NRC staff who are
25 interested in working on this issue, this is the

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1 document, the most important document to go to.

2 I'll talk about the relationship now to
3 dose calculation. The Task Group 43 report provides
4 a table based dose calculation algorithm that I have
5 managed to condense down into one slide basically what
6 it is.

7 (Laughter.)

8 MEMBER WILLIAMSON: It's very simple. The
9 dose rate from a brachytherapy seed is the Air Kerma
10 Strength times the dose rate constant times inverse
11 square law times a factor that describes the fall-off
12 of dose along the transverse axis due to attenuation
13 and scattering. This is like a depth dose from which
14 inverse square law has been removed. This is an
15 asymmetry constant that corrects for the fact on
16 average that the dose distributions around these seeds
17 is not spherically symmetric.

18 The dose rate constant is maybe the most
19 important one to consider. This is the ratio of dose
20 rate at one centimeter in tissue divided by Air Kerma
21 Strength. This has a value of the order of unity,
22 that is, 1.0 as I mentioned earlier, although the
23 specific value can vary anywhere from about .85 up to
24 about 1.05 for the brachytherapy seeds that have been
25 used in clinical practice.

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1 For a high dose rate brachytherapy source,
2 this would be about 1.11.

3 So this is the only quantity that is
4 affected by the choice of calibration units. So there
5 you have it, the five-minute introduction to the Task
6 Group 43 formalism.

7 So now if we were going to calculate
8 within a treatment planning system dose using Air
9 Kerma Strength, we would just use the equation
10 directly. If we were going to select the menu option
11 that allows you to use apparent activity, the same
12 equation would be used internally, except they would
13 slip in another conversion factor that basically not
14 surprisingly is the ratio of Air Kerma Strength to
15 apparent activity that I had mentioned previously.

16 These two equations would give absolutely
17 identical numerical results if the same factor were
18 used consistently through the process of ordering
19 seeds and planning the implant and reconstructing the
20 delivered dose distribution. So you can obviously see
21 there is a possibility of error if different people
22 involved in different stages of the process don't use
23 a consistent value of this correction factor.

24 Okay. This is hard to see. This is a
25 typical calibration certificate that you would get

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1 from Oncura for the GE Healthcare Model 6711 seed.
2 This is the most widely used iodine seed still today
3 and historically. And so as you can see, it gives the
4 Air Kerma Strength in microgray meters squared per
5 hour, and it gives the apparent activity in
6 millicurie. Two quantities. I think it's very clear.
7 It gives the activity, and it decays it very
8 conveniently to the specified date of the implant.

9 So when you imagine, if you telephone
10 Oncura to order these seeds, you've got to specify
11 three things clearly to them. You've got to specify
12 the date of the implant. You've got to specify the
13 quantity of source strength that you want, and you've
14 got to specify the quantity that you're dealing with.

15 As I understand from talking to my expert
16 consultants, if you do this in writing, you can use
17 either apparent activity or Air Kerma Strength, and
18 the form makes it fairly clear which choice you are
19 making. If you do this on the telephone, Oncura will
20 discuss this only in terms of apparent activity. They
21 expect you to take the initiative as the user to
22 convert it to their unit.

23 Now, when I was doing this some ten years
24 ago, it was even more difficult. First of all, they
25 would only decay it to the Monday closest to your

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1 shipping date. They would not give you the average
2 activity. They would give you the upper and lower
3 bound on the activity group. So you had to sit there
4 with a calculator and not only convert it from Air
5 Kerma Strength to apparent activity, but you'd have to
6 average their upper and lower bound, and you would
7 have to do this decay correction. So there was a lot
8 of possibility for error, and one has to be very
9 careful.

10 Okay. This is the calibration
11 certificate. Well, I'll mention one more thing since
12 I think misinterpreting these certificates can be one
13 of the possible pathways for error. They mention
14 various other conversion factors here that contained
15 activity. The apparent to contained activity
16 conversion factor is buried here in the footnotes to
17 this text. They also tell you what the conversion
18 factor is if you want to express apparent activity in
19 megabecquerels instead of the doubly obsolete
20 millicuries.

21 This is the Theragenics/Bard calibration
22 certificate, and I might mention this is made more
23 complicated by the fact that for palladium especially,
24 there are multiple pathways. You won't have to deal
25 with just Theragenics or Bard, but I believe there are

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1 several other companies that sell this particular
2 seed. They each will have their own telephone
3 interface. So there's a lot more complexity than
4 there used to be.

5 So you can see there are many more
6 quantities here you have to worry about. There's the
7 Air Kerma Strength, the Air Kerma range, the seed
8 activity and its range in megabecquerels, the apparent
9 activity and its range in millicuries. So they have
10 everything here in a nice table. So it is more
11 complicated.

12 Usually the reference date is the implant
13 date, but not necessarily, and you actually have to
14 make steps to make it clear that's how you're
15 specifying it or it could be a different date.

16 The order and quantity, you can use
17 either, but the telephone, they will only accept Air
18 Kerma Strength units. So there is a difference, and
19 this is in general true. There are now 20 different
20 models of seeds you can order, and as an individual
21 user, you need to understand the weaknesses and
22 pitfalls of the vendor's ordering interface that you
23 are dealing with.

24 Okay. So what are some error pathways?
25 I'll give you kind of a diagram here to show you. So,

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1 you know, we go all the way from vendor calibration to
2 institutional calibration to clinical prescription,
3 which usually has to do with making it pre-planned and
4 translating the desired dose that you want to give
5 into some quantity, say, apparent activity; doing the
6 implant; and then performing the dose calculation and
7 seeing what the dose is.

8 So there is a chain of activities here,
9 all of which involve consistently selecting the same
10 quantity or if there is a change in quantity in any
11 one of these steps, properly converting from one to
12 the other.

13 So possible error pathways are we have the
14 vendor for V, the client for C, which usually is the
15 physicist but not necessarily, and the physician who
16 is in our institution certainly not the person who
17 does the ordering. So what are some possible errors?

18 Well, the client order can match the
19 prescription quantity, that is, the P quantity, but
20 not these quantities, and this might not be picked up
21 by these. So there could be a V-C miscommunication.

22 The client order could match the vendor
23 order in quantity, but not the physician's
24 prescription quantity. So the physicist could
25 misunderstand the physician's prescription and order

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1 in Air Kerma Strength instead of apparent millicuries,
2 or the other way around.

3 C, V, and P could all agree on the
4 quantity, but V fills the order with the wrong units.
5 So there would be an operational error on the part of
6 V. Now, V could do this in two different ways. The
7 shipping container and the certificate could clearly
8 specify which quantity it's specified in. So it would
9 be actually from their perspective correct, or it may
10 be incorrect. I think there's two possibilities, and
11 we're not clear which happened.

12 Occasionally the worse error where it's
13 actually mislabeled has happened. There could also
14 be, I think, a reference implant date disagreement.
15 This could be either due to a misunderstanding between
16 the client and the physician or the client and the
17 vendor, and one could wind up with seeds that are
18 erroneously labeled as to date, and this might not be
19 picked up.

20 Okay. At the treatment planning level,
21 the wrong quantity from the V certificate could be
22 input into the computer where one could pick off Air
23 Kerma Strength from the certificate into a computer
24 where the option apparent activity has been selected.

25 One could select the correct activity from

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1 the certification, but select a wrong planning system
2 menu option.

3 Another error could be the wrong
4 conversion factor could be programmed into the
5 software for that particular seed model.

6 Another possibility is an incorrect decay
7 correction to correct for differences between
8 reference and treatment date could be in place. This
9 could be either an error in introducing the half-life
10 into the software or simply erroneous entry of the
11 date into the planning computer.

12 So there's a lot of different error
13 pathways. I'd also like to point out that we could
14 worry a lot about this particular mechanism, but there
15 are many, many other sources of error. One could have
16 the wrong dose rate constant in which would have
17 basically no dependents necessarily on the choice of
18 quantity.

19 So what do we do in clinical practice to
20 avoid this? Well, as I commented earlier, the client
21 must anticipate the vendor ordering system flaws and
22 use redundant communication. So what I always did is
23 I insisted that the vendor repeat back the order to me
24 so that I would hear what it is they had written down
25 to reduce miscommunication.

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1 I would also insist, and we do this today
2 still in my institution even though I'm not the one
3 involved, that they fax a copy of the order to us
4 immediately so that before it's shipped, we can pick
5 up on any error that has been made, and I think this
6 is -- I agree with Dr. Nag -- it has happened more
7 than a few times that it has been incorrect, and this
8 is the place to catch it.

9 Another something else that can be done
10 and is required by 35.457, I believe, which has
11 basically a skeleton set of commissioning tests that
12 have to be done of any brachytherapy dose calculation
13 algorithm.

14 This should catch any systematic flaws in
15 the algorithm or its programming the constant, such as
16 wrong dose rate constant or wrong conversion factor.

17 Another test that one can do is what I
18 call end-to-end testing. So what does this mean?
19 Well, one is following the AAPM recommendations. One
20 will have the capability of verifying via a dose
21 calibrator or reentrant chamber the Air Kerma Strength
22 of any batch of seeds that you order. So a very
23 useful test to do is to basically simulate a
24 treatment. Order an extra seed or take the first set
25 of seeds that you order for a patient, calibrate them,

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1 get the Air Kerma Strength, which is usually fairly
2 clear from the calibration certificate supplied for
3 the chamber that you use, manually calculate the dose
4 rate, then go through the normal clinical process as
5 if you were planning a patient, but do it only for one
6 seed, and compare the calculated dose distribution to
7 the manually calculated dose. And you will be able to
8 pick up any errors due to mishandling these quantities
9 or units throughout the chain of converting from one
10 step to the other. So this is certainly a very good
11 test that I think any physicist would do coming into
12 an institution for the first time.

13 And it is, in fact, what the Radiological
14 Physics Center does when they come and site visit an
15 institution that's participating in multi-
16 institutional clinical trials.

17 Okay. For protection against random
18 errors, I think the best protection is written
19 procedures and forms to capture key data: dates,
20 units, and quantities. So if at the time one is doing
21 the seed assay, for example, has the written
22 prescription information in front of one and the date
23 of the implant, it's very easy to check at the time of
24 seed assay whether an error has been made or all the
25 pieces of paper are together. One can check what's

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1 written on the calibration certificate against the
2 prescription.

3 On the other hand, if the forms are
4 scattered all over the department, the prescription
5 form is in the patient chart and not in the record
6 book in the same physical location where the seeds are
7 received, this may be missed if this is carried around
8 in somebody's head.

9 So one has to have, I think, a rationally
10 designed process. I had mentioned already what one
11 can do to control and understand the vendor ordering
12 interface. I think the third step one can take is to
13 follow the Task Group 56.43 Air Kerma Strength assay
14 recommendations. They're excellent protection against
15 random errors in either labeling the seed product or
16 misinterpreting the certificate or misreading the
17 certificate that comes.

18 The fourth thing that can be done is an
19 independent physics review of the plan per TG-56
20 guidelines. And once a plan has been done, a physics
21 review of the plan would consist of basically checking
22 the source strength printed on the treatment plan
23 against the calibration certificate against the
24 written prescription checking all of the dates and
25 decay and checking via some independent dose

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1 calculation algorithm that the dose distribution
2 computed by the plan is at least approximately
3 correct.

4 So what could I say in terms of
5 conclusions? Well, multiple source strength quantity
6 certainly is a source of potential error. I'll
7 comment though we shouldn't single this one out.
8 There are many, many other sources of error that can
9 creep into the process and will creep into the process
10 in any poorly organized system.

11 And I think one thing I would say is that
12 the regulations do not have a fine enough mesh to
13 basically force a clinic to have a bomb proof system
14 for capturing all errors. This is basically the task
15 of the qualified medical physicist to organize and
16 document the process, design it so that it is very
17 robust against all of these bad things that might
18 happen.

19 So there's really no excuse for, no
20 alternative to having a qualified and experienced
21 individual to take charge of the process and make sure
22 that this and other sorts of errors are mitigated.

23 Okay. So I would say that regulating
24 apparent activity out of existence isn't warranted.
25 You know, as I count up the number of patients

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1 affected by this three to four-year experience
2 reported by Cynthia's handout, there are approximately
3 50. If I doubled the risk, given the number of
4 permanent implant procedures that are done, it's about
5 five times ten to the minus four. So it's fairly
6 small, and many of the errors were caught it sounds
7 like at fairly intermediate points so that the dose
8 delivery errors were only of the order of six percent
9 instead of the full 29 percent or a factor of two.

10 Secondly, I think the community adaptation
11 at least in the short term to outlawing apparent
12 activity since it's so widely used could also cause
13 more errors in the short term. It's maybe better that
14 the community, that the readership within the
15 regulated community keep pushing on the users to
16 gradually abandon this.

17 Fourthly, it's well documented and
18 straightforward, and minimum practice standards should
19 be sufficient to address this problem. Many of them
20 are in the address or alluded to within the
21 regulation, but the regulation never will be a
22 sufficient practice guide and will never be a
23 substitute for following, I think, recommended
24 practice standards.

25 So I think given that this has happened,

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1 a reasonable recommendation or course of action is to
2 draft an information notice highlighting the potential
3 problems and what some of the solutions are.

4 Another action that could be undertaken by
5 the NRC is to have your liaison to the AAPM basically
6 take on the task of discussing this with the
7 brachytherapy subcommittee chairman, who is Dr. Mark
8 Rivard and, you know, ask the AAPM to put on its radar
9 or on its agenda the task for trying to push the users
10 and the users' vendors to promote the use of Air Kerma
11 Strength, I think, on a more consistent and
12 wholehearted basis.

13 I think the structure that exists now to
14 insure that all of the clinical use seeds have
15 adequate dosimetry data sets backing them is
16 essentially a voluntary guideline that the AAPM has
17 put in place through collaboration with NIST and the
18 vendor. So that's worked very well, and I think that
19 if this is thought to be an item of high concern, and
20 we certainly agree we should continue pushing on this,
21 I think they would be in a very good position to do
22 this.

23 That concludes my presentation.

24 CHAIRMAN MALMUD: Thank you, Dr.
25 Williamson, for an extraordinarily detailed and

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1 understandable explanation of errors that have
2 occurred and might occur. There must be some
3 comments. We'll start with Dr. Nag.

4 MEMBER NAG: Yes. You have given a very
5 thorough presentation. I would like to highlight some
6 of the clinical portion. You know, you have done it
7 from a physics standpoint and I'll do it from a
8 clinician's standpoint.

9 A couple of things that have a major
10 element of error I think. If you are going to involve
11 an information notice, you highlight: (a) If there's
12 a change of personnel. But a new physicist comes in.
13 The physicist is used to doing it one way in the other
14 institution. When you come to a new institution, you
15 are going to do another, but maybe the wrong way.

16 Second is when you are changing a vendor,
17 for example each vendor has their own way of doing
18 things. So if you were ordering iodine C from vendor
19 A in millicuries, for example, vendor B might do it
20 another way.

21 So those are two places where you have
22 most -- where -- you know, error can occur many places,
23 but these are two ways that you have the higher risk
24 of making those errors. So I think those are two
25 places you should try to consent.

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1 And then the third thing that although
2 it's possible to use many methods, each institution
3 should use one method. For example, the ideal role
4 everyone should use air kerma strength; that is the
5 idea rule. If you can do it that way, that would be
6 the best, but if that cannot be enforced, at least
7 each institution should do it one way. You cannot
8 have one institution ordering in air kerma one day
9 and millicurie another day. So these are little
10 things that I enforce at my institution.

11 MEMBER WILLIAMSON: That's right. I mean,
12 this whole process within the institution the
13 practitioners have control of, that they should
14 document it and basically do all of the steps in one
15 quantity or the other and minimize the amount of
16 fiddling around with manual calculators. That's really
17 good advice.

18 I agree with all your points.

19 CHAIRMAN MALMUD: Dr. Suleiman?

20 MEMBER SULEIMAN: I have a question. You
21 said that one of the studies or whatever they sampled
22 ten percent of the seeds for accuracy?

23 MEMBER WILLIAMSON: Basic no, I didn't say
24 that. I said that the AAPM recommendation is that two
25 verify the vendor's calibration, the minimum number of

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1 seeds out of a, say, a batch of 100 that you buy that
2 you should measure or assay individually is ten.

3 MEMBER SULEIMAN: Are there any results to
4 share with those how well do those agree or what sort
5 of deviation do people observe when they do such
6 sampling?

7 MEMBER WILLIAMSON: Well, it depends on --

8 MEMBER SULEIMAN: Are they all within five
9 percent, are they off by 25 percent, 50 percent? Just
10 I want to get a --

11 MEMBER WILLIAMSON: No, I can give you --
12 I'd say there have been large errors occasionally
13 reported, but with fairly low probability. The sorts
14 of things that are usually are found are of the order
15 of three to maybe seven percent changes. And to some
16 extent this is due to random fluctuation because, you
17 know, the seed-to-seed variation within a batch of
18 seeds typically has a standard deviation of about two
19 to three percent under the best of circumstances. So
20 if you have a small number of seeds, like for an
21 iodine implant where maybe you might use as few as
22 eight seeds, this can be important and you would want
23 to probably assay every single one of those seeds and
24 maybe consider using your own measured value --

25 MEMBER SULEIMAN: What's the vendor's

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1 stated accuracy? They don't state better than five
2 percent, do they?

3 MEMBER WILLIAMSON: Well, I'm not sure
4 they -- this is a topic of active discussion within
5 the AAPM as to how to improve the uncertainty or
6 reduce the uncertainty of vendor calibrations. I
7 think it's thought to be around 3 to 5 percent under
8 the very best of circumstances. It can be measured
9 with a total uncertainty of about 2 percent within an
10 institution if you're really careful. But, yes, the
11 answer is especially for a small number of seeds, it's
12 about 5 percent.

13 MEMBER NAG: One comment there. Basically
14 I have told my physicists to report to me for any
15 deviation of more than 5 percent, otherwise they don't
16 even report to me. But the other comment that the ten
17 percent assay, the recommendation from AAPM, however,
18 did not like -- when they tell you you don't
19 necessarily have to do it unless you are in a treating
20 institution, you know, it's not mandatory.

21 MEMBER WILLIAMSON: That's correct. I
22 will say that there have been occasionally reports
23 which are much larger than 5 percent deviations. In
24 1997 it was discovered that the main palladium vendor,
25 its calibration precipitously changed, systematically

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1 by 10 percent. This was not noticed by the vendor.
2 This was observed by the users. And this was a fairly
3 serious incident. There have been other incidents
4 which are much rarer and more random of very large
5 deviations.

6 So the answer is that there are random
7 fluctuations of the order of 3 to 5 percent and the
8 AAPM basically says five percent is the limit that you
9 should proceed to rectify the discrepancy before you
10 proceed. But 5 to 10 percent systematic deviations
11 have been noticed and occasionally much large random
12 deviations have been noted due to mislabeling of a
13 shipment.

14 CHAIRMAN MALMUD: I think there was
15 another comment. Dr. Fisher?

16 MEMBER FISHER: Thank you. Darrell
17 Fisher, the patient rights advocate.

18 I do have experience in this area. I do
19 brachytherapy seed order checks for two institutions
20 representing four vendors and one independent
21 treatment planning center in the Seattle area. And so
22 the reason I do seed order checks is for the exact
23 reason that you've pointed out, that there are a
24 number of places where errors can occur. And I would
25 like to concur with all of your points, Dr.

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1 Williamson, the answer to this dilemma is not
2 eliminating the apparent activity unit. It's putting
3 in place a good quality assurance system for checking
4 orders and making sure that when orders are received,
5 they match the order.

6 The independent check of a seed order by
7 a second medical physicist has helped us reduce errors
8 from about ten percent down to zero for the last year
9 and a half. We also revised the order forms for each
10 vendor because the order forms themselves created
11 mistakes and had errors.

12 We do careful matching of dates, times,
13 especially the dates, times, and units. The date the
14 seed is calibrated, the date the seed is intended to
15 be implanted making sure that all the dates are right
16 with patient name, number and other identifiers. Make
17 sure that a QA system is well documented and in place.

18 And now the errors that we notice are in
19 filling the send order, which we try to check when the
20 seed orders arrive. And so I think major problems now
21 that we experience are with getting the order quantity
22 and product at the hospital when it's needed.

23 CHAIRMAN MALMUD: I believe Dr. Welsh had
24 a comment.

25 MEMBER WELSH: So I've heard that there

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1 are so many potential weaknesses in the system and
2 avenues through which errors can occur, such as vendor
3 A might have a different policy from vendor B for
4 iodine-125 and then a different policy may exist for
5 palladium-103, as you mentioned, with the telephone
6 ordering.

7 It seems that the fact that there are so
8 few errors is a testament to the quality of the
9 clients, the physicists and physicians who are
10 involved in all this. The double checking system that
11 I've heard, Dr. Nag's system, Dr. Williamson's
12 approach all seem to be excellent solutions. But it
13 would seem logical that if apparent activity is
14 considered obsolete, why not consider abandoning it at
15 this point?

16 It seems that the estimate of increased
17 errors in the short run may be preventable if this
18 were a very gradual transition. Because it's obvious
19 that there are checks and balances that prevent errors
20 when they are so likely to occur with the current
21 system. Why not just take that extra step out?

22 CHAIRMAN MALMUD: That's a question. Does
23 anyone on the Committee wish to respond? Dr. Fisher?

24 MEMBER FISHER: For compliance with other
25 regulations, transportation of sources and possession

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1 limit.

2 MEMBER NAG: Again, those I think that can
3 be gained, too. Because if you are going to make a
4 systematic approach, then, you know, you have to begin
5 in all the areas.

6 CHAIRMAN MALMUD: Mr. Lieto?

7 MEMBER LIETO: Apparent activity has
8 nothing to do with the transportation. It's the actual
9 activity. So if you take apparent activity out of the
10 equation, you still are going to have the activity
11 that has to be shipped. And actual activity, like I
12 guess maybe there might be some rare legacy type
13 treatment planning systems that might use that value,
14 really the only time you're going to use the shipped
15 activity is simply on your transportation labeling.
16 It doesn't get into the treatment planning system at
17 all. Apparent activity is a different quantity
18 altogether.

19 CHAIRMAN MALMUD: So your comment, Mr.
20 Lieto, is meant to say that the system with the older
21 terminology could be abandoned?

22 MEMBER LIETO: Yes. The apparent activity
23 value, yes.

24 CHAIRMAN MALMUD: Debbie?

25 MEMBER GILLEY: Yes. As far as regulatory

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1 requirements, we don't use apparent activity. We use
2 activity as possession limits, so again we wouldn't
3 have an issue with apparent activity anymore.

4 CHAIRMAN MALMUD: All right. Orhan?

5 MEMBER SULEIMAN: Would a requirement --
6 there's sometimes a role for government in terms of
7 mandatory standards if it's safety related. Would a
8 requirement that such sources have a NIST traceable
9 standard, and therefore you automatically adopt the
10 way NIST is recording that activity and since NIST is
11 pretty much in sync with this AAPM protocol, would
12 that solve the problem?

13 MEMBER WILLIAMSON: No. Because without--
14 you know, there already is the requirement within the
15 35.457 that basically there be essentially this tray.
16 It doesn't say it so many words, but it says industry
17 standards. But basically all of the sources are
18 supplied with NIST traceable calibrations. They may
19 not be the lowest of them, they may not all meet the
20 uncertainty standards we'd all like, but they're
21 there. But the problem is the vendors translate them
22 into other units and quantities. The reason they do
23 that is because the users want them translated into
24 other quantities and units and that's what they use in
25 their institutions.

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1 CHAIRMAN MALMUD: Jeff, I'd like to ask a
2 question. Not being a radiation therapist or
3 physicist. The errors that have occurred, which are
4 of an order of magnitude of concern, not the other
5 errors -- after all seed placement has such an order
6 of magnitude of potential error that these smaller
7 errors may be insignificant. So just addressing the
8 larger errors that have occurred historically, what
9 has been their source of error? Is there --

10 MEMBER WILLIAMSON: Well, I'm not sure I
11 understand the question.

12 CHAIRMAN MALMUD: All right. I'm not
13 being clear.

14 There are clinical errors that are the
15 magnitude of concern?

16 MEMBER WILLIAMSON: Yes.

17 CHAIRMAN MALMUD: But there were not many
18 of them. Of those clinical errors that were of a
19 magnitude of concern, was there a common thread among
20 those?

21 MEMBER WILLIAMSON: I don't -- I think
22 actually to try to answer the question, I think the
23 dominant source of errors that exceeds this -- that is
24 more serious than this kind of error frequency wise,
25 and Sandra or Donna-Beth may correct me. I'm not sure

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1 who is tracking all these errors now. It's geometry.
2 You know, if you get the source in the wrong place,
3 that's going to cause -- has the potential to cause
4 percentage wise a much larger error or catastrophic
5 error than I think these unit conversions. And I
6 think this happens numerically more often than these
7 kinds of errors.

8 The second ranking item of concern I would
9 say is, indeed, treatment planning related errors
10 where somewhere the dose is reckoned incorrectly and
11 a clinical decision is made upon an incorrectly
12 calculated dose rate, which is what I would classify--
13 this would be a subclass of those errors. But there's
14 many more indications and pathways for this error than
15 just this.

16 DR. HOWE: Dr. Malmud, if I could just
17 give a little anecdotal --

18 MR. MOORE: One second. This is Dr.
19 Donna-Beth Howe from the NRC Staff.

20 CHAIRMAN MALMUD: Do you have a mike
21 there, Donna?

22 DR. HOWE: I think I do.

23 CHAIRMAN MALMUD: Go ahead.

24 DR. HOWE: I think I would agree with Jeff
25 Williamson. If we look back at our medical events that

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1 are reported, we have more often than not they're in
2 the wrong place. And generally if you look to see why
3 they're in the wrong place, it's because of improper
4 interpretation of ultrasound. And so I think that's
5 where we get our most severe medical events.

6 CHAIRMAN MALMUD: Thank you.

7 So that's what I suspected. And that
8 being the case, is there really a need to alter any of
9 the procedures in place today with regard to the units
10 when it appears that the errors that have occurred as
11 a result of the units are trivial compared to the
12 errors that have occurred because of human error or
13 physician practice, which is unrelated to these
14 issues?

15 And I'll just make a statement, which is
16 that we can spend enormous amounts of energy and funds
17 on establishing standards which are applicable to
18 maybe two standard deviations or three. Once we get
19 beyond that, there's an extraordinary expense involved
20 both in human effort and in dollars in correcting
21 errors that might occur outside of three sigma.

22 Now in handling airplanes, one is
23 concerned about every incident. But the question here
24 is are we dealing with issues that are clinically
25 significant? I realize that they are numerically of

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1 concern, but do they really have any clinical
2 significance considering the fact that the placement
3 of these therapies is a human skill which has much
4 greater errors associated with it than the errors
5 which appear to have been presented here as being
6 common errors.

7 MEMBER WILLIAMSON: Well, I would agree
8 with your conclusion but not your reasoning. Okay.

9 I think that in an individual patient, a
10 30 percent error can have clinical significance. But
11 what I would say is I think this is one category of
12 errors out of many possible pathways. To be able to
13 do modern brachytherapy with a high level of
14 reliability, safety and accuracy, you need to have a
15 very well organized process and system with double
16 checks built in and qualified personnel to staff it.
17 I don't think that it is the role of the regulation to
18 look at every single detail and say you must do it
19 this way, you must do it this way, you must do it this
20 way. I do think that's not appropriate to regulate
21 this small issue.

22 I think we should take the opportunity to
23 call attention in an information notice to the kind of
24 safety processes and practices that are necessary to
25 mitigate this and other classes of error. And since

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1 this has come up, I think we should do an information
2 notice and draw attention to what is really needed to
3 do this kind of therapy safely. And I think if you
4 have a good process, it doesn't matter whether you use
5 apparent activity or air kerma strength. We'd all
6 prefer that apparent activity and milligram radium
7 equivalence would fade away into the sunset, but you
8 know my job is to design -- or used to be to design
9 systems that are robust enough to work reliably no
10 matter what quantity we use.

11 CHAIRMAN MALMUD: And my question is, "Do
12 physicists currently believe that the system is
13 flawed?" If you asked me as a clinician what I
14 believed was the number one protective element for the
15 patient in this system, it is the presence of a
16 qualified compulsive, attentive physicist.

17 MEMBER WILLIAMSON: And physician.

18 CHAIRMAN MALMUD: Yes. But I mean before
19 it gets to the physician.

20 MEMBER WILLIAMSON: That's true. I'd
21 agree. I wouldn't call the system flawed. I think
22 the flaw is in ourselves because, you know, some
23 institutions have an allegiance to these old-fashioned
24 units and quantities. But I think with a good system
25 it doesn't matter.

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1 CHAIRMAN MALMUD: Dr. Welsh?

2 MEMBER WELSH: I would like to just chime
3 in here reiterating what Dr. Nag pointed out earlier
4 about this system. It could work well if you have a
5 consistent team with a conscientious physician and a
6 compulsive physicist. But if you get a new physicist
7 who may be just as compulsive but not use to that
8 particular system, then the flaws within the system
9 itself become apparent and it becomes far more
10 challenging than it needs to be.

11 MEMBER WILLIAMSON: That's the task of,
12 you know, clinical management to make sure that when
13 you get a new person on board, they are well oriented
14 and, you know, double checked. I think that would be
15 part of the system you'd have to have. And the more
16 the system is carried around in an individual's head
17 instead of written out on paper in the form of a
18 process that more than one person can share, the more
19 likely that is to happen.

20 CHAIRMAN MALMUD: I think Dr. Nag?

21 MEMBER NAG: Yes. See, I have been
22 investigating the medical events the last couple of
23 years. Although not systematic, just from memory I
24 think the largest magnitude of error has been called
25 a misplacement because the physician, whoever this

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1 order it is, an oncologist, did not know enough about
2 ultrasound and thought anything that looks black was
3 the -- that's the largest magnitude. However, in terms
4 of the number of errors I think miscalibration links
5 quite high -- not miscalibration, but
6 misidentification that is oddly the millicurie or
7 apparent millicurie and so forth.

8 For iodine being 30 percent it is not all
9 that bad. It's bad, it's still a misadministration
10 because it's more than 30 percent. But for iridium,
11 it's 1.79, so it's 79 percent difference. So that is
12 a pretty large magnitude and it's not a trivial
13 amount.

14 Unquestionably, I would favor that that
15 means some type of regulatory push to have everything
16 in terms of --

17 CHAIRMAN MALMUD: Again, as a non-
18 radiation therapist, non-radiation therapy physicist,
19 looking at the details of what you've presented, Dr.
20 Williamson, I mean I'm impressed with the detail and
21 the thoughtfulness. What concerns me is how we
22 recommend that a system be changed in some fashion
23 which is not so complex that itself generates
24 unintended consequences.

25 And of the suggestions that I've heard

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1 here today, the one that seems most easily applicable
2 and might reduce the number of errors from the outset
3 is that each institution adhere to one system and one
4 system only of its choice in the beginning. And that
5 that would in theory reduce some of these errors that
6 are occurring for institutions that are currently
7 using two different systems.

8 MEMBER WILLIAMSON: I don't want to make
9 it seem like I'm defending, you know, old-fashioned
10 units. I think what I'm defending -- I'm trying to
11 caution against is making a hard and fast regulation
12 to deal with it. That's very costly. Okay. It's going
13 to take a long time to do it. It may have unintended
14 consequences. It's one sided. It tends to sort of
15 warp one's perspective because, you know, regulation
16 should be made only about very important things.

17

18 I think what we could do that I think is
19 reasonable and would capture both what Dr. Walsh and
20 Dr. Nag and I have been saying, is I think to strongly
21 encourage or recommend institutions and vendors to get
22 with, you know, get on board and use modern quantities
23 and units, really pay attention to this. And I think
24 there are ways to do that that fall short of an
25 explicit regulations which I think is the strongest

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1 possible response that NRC can make to something
2 besides, you know, punishing you know an individual
3 institution. So there would be recommendations in the
4 regulatory guide covering 35.400 that this quantity be
5 used. There can be an information notice pointing out
6 these problems and recommending. There can be efforts
7 to work more closely with the AAPM on a plan to get
8 more compliance with these recommendations to use this
9 quantity that have been on the books now for 20 years.
10 And as the AAPM has a very good track record of
11 bringing the different groups together and getting
12 voluntarily compliance with even more difficult issues
13 than this. Making the transition from older systems
14 of dosimetry to TG-43 was a major achievement of the
15 AAPM and the regulated community. And it was done
16 without any regulatory push from FDA or NRC.

17 CHAIRMAN MALMUD: Dr. Williamson, is that
18 your recommendation that we invite AAPM to send us an
19 informational item regarding what their recommendation
20 is for dealing with this issue?

21 MEMBER WILLIAMSON: Yes.

22 CHAIRMAN MALMUD: May we take that as a
23 motion to this Committee?

24 MEMBER WILLIAMSON: So moved.

25 MEMBER LIETO: Seconded.

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1 CHAIRMAN MALMUD: It has been seconded by
2 Mr. Lieto.

3 Is there any further discussion about
4 asking AAPM to send us a memo which would be a
5 consensus document from AAPM regarding its
6 recommendation for how this specific issue might begin
7 to be addressed? We're not speaking of regulation,
8 we're speaking of transition? Dr. Nag?

9 MEMBER NAG: Yes. AAPM already has a
10 recommendation, though, we don't need a separate one.
11 I mean, they already of their recommendation. I think
12 what we should be doing is say the recommendation, it
13 is recommended that the users follow the AAPM
14 recommendation. The recommendation, though, you were
15 one of the authors of that recommendation.

16 MEMBER WILLIAMSON: Well, I think that the
17 suggestion goes a little further than that. It's
18 basically asking the AAPM to collaborate with NRC in
19 producing an information notice specifically for the
20 regulated community to encourage some motion on this
21 issue.

22 CHAIRMAN MALMUD: Well, but Mr.
23 Williamson--

24 MEMBER NAG: Okay. I would agree with
25 that. Yes.

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1 CHAIRMAN MALMUD: Is that the motion
2 you're seconding?

3 MEMBER LIETO: That was my understanding
4 of the motion and its intent.

5 CHAIRMAN MALMUD: Mr. Moore?

6 MR. MOORE: The Staff, through information
7 that it gets back, can do things such as discuss
8 incidents or talk about what's happened out within the
9 regulated community. It can talk about best practices
10 that institutions may want to adopt. It can put out
11 information that's available and that other
12 organizations have available. But we are limited to
13 some extent in what we can put out through regulatory
14 information statements or information notices. To not
15 put out something that has any appearance of being a
16 requirement or a regulation in the sense that, you
17 know, our general counsel will tell us it can't look
18 like it's a requirement. So we would have to walk a
19 fine line and not using the word "recommendation."

20 We could put out something that another
21 organization may say is a recommendation and say
22 attached is, you know, something that AAPM believes is
23 useable.

24 CHAIRMAN MALMUD: I believe that's exactly
25 what we've been seeking, which is an informational

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1 item from the NRC which incorporates the
2 recommendation from the AAPM, which would be nothing
3 more than an informational item, but it would be
4 distributed because currently I don't think that there
5 is a uniform document that's been distributed to all
6 of the users, is there?

7 MEMBER WILLIAMSON: That's why it's a
8 collaboration because, yes, it has to be something
9 that fits the format of this kind of a information
10 dissemination pathway.

11 CHAIRMAN MALMUD: Mr. Lieto?

12 MEMBER LIETO: Scott, using your own
13 terminology if we specify -- I mean if it's specified
14 in the draft that comes back to the NRC as a result of
15 this motion of using the terminology these are best
16 practices or things of that nature, which essentially
17 are standards, I mean as long as they don't say
18 "recommendation," I mean is that the key not using the
19 word recommendation?

20 MR. MOORE: The Staff can come up with
21 something that would work. And certainly something
22 that AAPM puts out itself, the Staff can forward other
23 agencies' documents and make them available through
24 the use of an information notice or a RIS to the
25 regulated community to make the regulated community

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1 know about good practices, basically.

2 MS. WASTLER: And part of what could be
3 done in the IN is, was as recommended, is to describe
4 some of the errors that we've seen and how they might
5 result and recommend or suggest those best practices,
6 some of which were discussed today that might help
7 eliminate it, you know. Because our goal is to try to
8 minimize if not eliminate events happening no matter
9 what their significance might be.

10 MEMBER WILLIAMSON: Yes.

11 MS. WASTLER: You know, to totally protect
12 health and safety.

13 CHAIRMAN MALMUD: And that's what I think
14 that we're striving for is essentially an
15 informational item --

16 MS. WASTLER: Right.

17 CHAIRMAN MALMUD: -- which incorporates
18 the recommendation of the physicists so that at least
19 the information is distributed and available for the
20 users to incorporate into their practices, but it is
21 not a regulation. It is a transmission of someone
22 else's recommendation.

23 Orhan?

24 MEMBER SULEIMAN: I'm a little conflicted,
25 not a lot conflicted. Because if the purpose was to

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1 inform the vendors to switch over, you've communicated
2 that. If the NRC comes out with an advisory or
3 something that doesn't have the force of standards
4 behind it, the vendors could still ignore you and
5 continue -- why have they ignored you up to now?

6 So my question is maybe the vendors have
7 an ear and they'll go back and they'll standardize the
8 way you like and this problem is solved.

9 MEMBER WILLIAMSON: Because it's the
10 community. It's actually the customers who want it
11 this way, that's why they do it. Vendors typically do
12 things because in response to customer demands and
13 preferences. They don't do it because they're stubborn
14 cusses, you know.

15 MEMBER SULEIMAN: Maybe the fact that
16 you've appeared today and made this presentation may
17 be sufficient initiative to solve the problem?

18 MEMBER WILLIAMSON: I think the fact that
19 -- well, I suggested a two pronged approach. I think
20 making it appear an item of regulatory concern, which
21 an information notice does, will bring more attention
22 to it.

23 I also suggested, I don't know if Dr.
24 Zelac is still is the -- are you the liaison to the
25 TPC, the Therapy Physics Committee of the AAPM?

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1 DR. ZELAC: Yes, I am.

2 CHAIRMAN MALMUD: For the record, Dr.
3 Zelac's indicating yes. Yes.

4 MEMBER WILLIAMSON: Okay. That's very
5 good. Well, I would recommend a second recommendation.
6 That is Dr. Zelac take this issue to the TPC Committee
7 and basically see if the AAPM has interest in trying
8 to promote uniformity on this issue. I think that if
9 it's properly discussed in advance with the Chairman
10 of the appropriate subcommittee that I indicated, I
11 think you will find that the AAPM is interested and
12 might have some ideas that fall short of an explicit
13 regulation or trying to promote more unanimity.

14 CHAIRMAN MALMUD: Is that a corollary to
15 your motion?

16 MEMBER WILLIAMSON: Yes.

17 CHAIRMAN MALMUD: Mr. Lieto, do you second
18 that corollary, or would you like them to be two
19 separate issues?

20 MEMBER LIETO: Can I answer it?

21 CHAIRMAN MALMUD: Please do.

22 MEMBER LIETO: I think that's unnecessary.
23 I think it's pretty obvious because it's medical
24 physicists that have been raising the issue regarding
25 the difference in the units. And I think there's

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1 already that interest in the AAPM community.

2 So I think the information notice of the
3 motion is going to incorporate all the aspects that
4 Dr. Williamson has stated. And I think rather than
5 weigh it down with corollaries, that we just leave it
6 as was so nicely put originally and move on.

7 CHAIRMAN MALMUD: Well, Mr. Lieto prefers
8 to leave the motion as it stood without weighing it
9 down with Dr. Zelac, who is not that heavy a weight.
10 So is there further discussion? Ms. Gilley?

11 MEMBER GILLEY: I don't want to muddy the
12 waters, but there are 34 agreement states that might
13 like to participate in this information notice also.
14 And since it's not going to be a regulatory
15 requirement at the federal level, I would like
16 consideration to be given that we also include them as
17 another partner in this activity.

18 CHAIRMAN MALMUD: Thank you for reminding
19 us of that. Thank you.

20 MR. MOORE: We would coordinate the
21 information notice with the agreement states.

22 CHAIRMAN MALMUD: All right. There is a
23 recommendation on the table. Shall we call the vote
24 for the recommendation?

25 All in favor? Any opposed? Any

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1 abstentions?

2 You have receive unanimous approval of
3 your recommendation, Mr. Williamson. And thank you
4 again for a very clear well thought out presentation,
5 as usual.

6 Is this your last presentation before --

7 MEMBER WILLIAMSON: This is my last
8 presentation, yes.

9 (Applause).

10 MS. WASTLER: Perfect timing.

11 CHAIRMAN MALMUD: I hope that you will
12 notice that the Chairman has brought the Committee to
13 the conclusion of the morning session at precisely
14 11:29. Lunch is extended by one minute.

15 We'll see you back here at 12:30 for a
16 discussion of specialty boards. Thank you.

17 (Whereupon, the Committee was adjourned,
18 to reconvene this same day at 12:32 p.m.)

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1 A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

2 12:32 p.m.

3 CHAIRMAN MALMUD: We are going to begin
4 this afternoon's session with Cindy Flannery, who is
5 going to speak to us about an update regarding the
6 approval status of specialty boards. However, we will
7 wait for a few more people to join us at the table.
8 Thank you. Cindy, you are on.

9 MS. FLANNERY: Good afternoon. This is
10 just a brief informational presentation to provide the
11 status of recognition of the specialty boards as well
12 as provide updates to the boards that are already
13 currently listed since this topic was last presented
14 at the October ACMUI meeting.

15 This right here is a list of the boards
16 that are recognized thus far. Each time I have given
17 this update at the three previous ACMUI meetings,
18 there have been nine specialty boards that have
19 submitted applications. But since the October ACMUI
20 meeting, we have now added a tenth to that list. That
21 is the last one here, the Certification Board of
22 Nuclear Endocrinology.

23 They just submitted an application a
24 couple of months ago. The NRC staff went back to
25 them, requested some additional information, which

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1 they have submitted. And it is with NRC staff right
2 now for review.

3 The only other board right now that is not
4 yet recognized is the second to the bottom there, the
5 American Board of Medical Physics. Their status has
6 remained unchanged for a little over a year and a half
7 now.

8 Early on in the process, they submitted an
9 application. NRC went back to them, requested some
10 additional information. And we are still awaiting
11 that supplemental information from ABMP.

12 Having said that, they have expressed an
13 interest very recently to us that they are interested
14 in pursuing and continuing the recognition process.

15 So that covers the only two boards that
16 are not yet recognized of the ten that have applied.
17 Now, as far as changes to the currently recognized
18 boards since the last ACMUI meeting, there have been
19 changes to two of the specialties in the American
20 Board of Radiology, namely the diagnostic radiology
21 and the radiologic physics specialties. And at the
22 request of ACMUI, NRC has gone to the ABR and asked
23 them what they can do about recognizing their
24 diplomates who have obtained their certification prior
25 to the recognition date.

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1 And those two specialties that I have
2 mentioned have proposed some methods for reviewing the
3 qualifications of those diplomates who have obtained
4 their certification prior to the effective date.

5 And this right here is just the different
6 sections of recognition.

7 Yes?

8 MEMBER LIETO: I am a little confused.
9 Maybe it's just the table setup.

10 MS. FLANNERY: Okay.

11 MEMBER LIETO: Under your ABR, American
12 Board of Radiology and Radiological Physics was
13 comprehensive. And I hope somebody from the board
14 will correct me if I'm wrong. It was no longer
15 offered and hasn't been for a few years.

16 Those are the others. Now, granted they
17 are the RSO applications, but those are the specific
18 specialties of certification listed under it. The two
19 you have listed up above it are the same as the two
20 that are listed below the third one. Am I making
21 sense? I don't have a pointer.

22 MS. FLANNERY: These three, these are
23 subspecialties of the radiologic physics.

24 MEMBER LIETO: No. Your certificate will
25 say American Board of Radiology Diagnostic

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1 Radiological Physics, American Board of Radiology
2 Medical Nuclear Physics. There's no radiologic
3 physics in the certificate. It's not a specialty of
4 certification.

5 There used to be analogous to maybe the
6 American Board of Health Physics comprehensive. If
7 you got radiological physics, it meant you were
8 competent in all three specialties, which I don't
9 believe is offered any longer. Is that correct?

10 CHAIRMAN MALMUD: Microphone and introduce
11 yourself.

12 DR. MORIN: I am Richard Morin, the
13 diagnostic radiologic physics trustee for the ABR.
14 The way it is categorized like that, I think, Ralph,
15 is because within the ABR, we have three areas in
16 which we certify: radiation oncology, diagnostic
17 radiology, and radiologic physics.

18 So radiologic physics just refers to the
19 overall area of where the physicists are, but you're
20 quite right. We don't have an exam any longer in
21 radiological physics.

22 MEMBER LIETO: But the first two listed
23 are the same as the two specialties listed underneath.

24 DR. MORIN: They are only physicists.

25 MEMBER LIETO: I'm sorry. Okay. Got you.

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1 MS. FLANNERY: As far as the method that
2 ABR has proposed for these specialties was to review
3 the qualifications of the diplomates and amend their
4 certificates to say either AMP-eligible or
5 RSO-eligible above the seal of the certificate.

6 So right now the therapeutic radiological
7 physics is recognized under 35.51, which is the
8 training and experience for authorized medical
9 physicists. So their certificates can only say
10 AMP-eligible on them; whereas, the other two are
11 listed under 35.50, which if you look on the next
12 page, it's for RSO.

13 Their certificates if they meet the
14 qualifications of the training and experience
15 requirements, I should say, then their certificates
16 will read RSO-eligible on them. So that's what they
17 have proposed.

18 And they're going to review on a
19 case-by-case basis the qualification of those
20 diplomates at the request of the individual and amend
21 their certificates accordingly.

22 CHAIRMAN MALMUD: Dr. Williamson?

23 MEMBER WILLIAMSON: Could you review,
24 Cindy, for a moment what were the major reasons for
25 rejecting each of the ABR categories prior to June

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1 2007 or 2006, as the case may be, what the ethical --

2 MS. FLANNERY: As relates to all three of
3 the specialties --

4 MEMBER WILLIAMSON: Yes.

5 MS. FLANNERY: -- or just the physics?

6 MEMBER WILLIAMSON: All of them.

7 MS. FLANNERY: Well, there are various
8 reasons. One of them is because some of the
9 diplomates have received their training and experience
10 or their work experience, I should say, in the
11 Canadian program. And the way NRC's regulations are
12 written, it needs to be their work experience as an
13 AU, which for the most part means somebody practicing
14 in the U.S. or listed on a U.S. license. So that is
15 one of the reasons.

16 I think there may have been some reasons
17 for what was on the exam itself because NRC
18 regulations would specify what the exam content must
19 include.

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

22 MS. FLANNERY: And I think that's all I
23 can think of right now. There may have been other
24 reasons.

25 MEMBER WILLIAMSON: I am trying to think.

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1 So let me ask more specifically, then. For
2 therapeutic radiological physics, for being an
3 authorized medical physicist, what was the grounds for
4 rejecting those certificates prior to June 2007?

5 MS. FLANNERY: I think one of the reasons
6 is for the Canadian program. And I don't know. Maybe
7 somebody from the ABR could answer that question. I
8 don't know. What's been expressed to me is that there
9 are some reasons why even some of the diplomates who
10 will be certified after the recognition date of June
11 2007 will not meet, but it has not been really
12 conveyed to me as to why they can't meet NRC's current
13 criteria.

14 CHAIRMAN MALMUD: Dr. Nag?

15 MEMBER NAG: What about radiation
16 oncologists who are board-certified in radiation
17 oncology prior to June 2007? Would they be able to
18 handle the 390, the unsealed radioisotopes because
19 previously although that was included in the
20 curriculum, it did not really have those things
21 specified?

22 MS. FLANNERY: That has been brought to
23 the American Board of Radiology. And a request has
24 been submitted. But what NRC has proposed is to break
25 it down, instead of including 390, 490, and 690

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1 altogether, to break it down.

2 So, say, for example, if they can
3 demonstrate that their diplomates from a previous year
4 prior to June 2007 can meet NRC's current criteria
5 for, let's just say, 490, they could do that. So 390,
6 490, and 690 can have different dates.

7 Now, the message that has been conveyed to
8 me is that they're going to do that and provide the
9 dates, but it has not been submitted yet. So I think
10 for the 390 what happened is that they had to make
11 changes to the certification process to meet NRC's
12 current criteria.

13 So I don't think this June 2007 date can
14 be changed for 390. However, 490 and 690, it can.

15 MEMBER NAG: Now, for the 690, one
16 question has been that if you did gamma knife in one
17 use a long time ago and haven't done it for a while
18 but you're still in therapy and now going back to a
19 new institution and it's been more than seven years,
20 how you're going to handle those. I think those are
21 becoming the questions to handle. Do we have any
22 solutions yet?

23 MS. FLANNERY: I guess I'll look to some
24 of the other NRC staff here, but I think it has been
25 longer than seven years they would need to demonstrate

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1 some training and experience in that modality.

2 And then the ABR, I mean, depending on if
3 they were recognized, for example, or listed to review
4 the qualifications of the diplomates who got certified
5 prior to the effective date, the ABR could do the
6 review, see if their qualifications meet NRC's current
7 criteria. But, you know, they could also apply to the
8 region, and the review could be done that way.

9 Training and experience would need to be
10 obtained within that modality the last seven years.

11 CHAIRMAN MALMUD: Other questions? Yes?

12 MEMBER EGGLI: Doug Eggli. I have, I
13 guess, a question for representatives of the American
14 Board of Radiology for Diagnostic Radiology. The
15 current approval is for 290 and 292. Yet, the
16 training and experience requirements for 394 with the
17 exception of the case experience are virtually
18 identical.

19 My residents now are going out grumpy
20 about with their board certification not qualifying
21 them under 394. Does the board intend to have 394
22 added since essentially all you have to do is get the
23 case experience if you have met the other T&E
24 requirements?

25 DR. ALDERSON: I am Phil Alderson. I am

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1 the President of the American Board of Radiology. And
2 I am in diagnostic radiology and nuclear medicine. So
3 I will attempt to answer Dr. Eggli's question.

4 Our understanding, not the same as what
5 you have just said, was that in order to be qualified
6 under the higher level of radioiodine, it took quite
7 a bit more training, not just a little more case
8 experience.

9 MEMBER EGGLI: If the total training
10 requirement under 394 -- under 390 is 200 hours, but
11 under 394 is 80 hours and they're achieving those 80
12 hours as they qualify for 392, all they need is case
13 experience as I read the regulation. Can the staff
14 help me on this?

15 DR. ALDERSON: You will have to refer that
16 back to the NRC for some interpretation of the
17 regulations and what was required. It was our
18 understanding that a lot more training would be
19 required for the higher doses. Accordingly, we felt
20 in radiology residencies, that would be hard to
21 achieve and, therefore, we went with a smaller amount
22 of training.

23 And we currently have no idea about trying
24 to change that, but we would, of course, if we had
25 misunderstood the regulations.

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1 MEMBER EGGLI: But 390 is the category
2 that requires the 200 hours of training for a broader
3 spectrum of therapeutic nuclear medicine but 394 is
4 radioiodine in ranges higher than 33 millicuries and
5 the regulation says the didactic and laboratory
6 requirement is.

7 MS. FLANNERY: Unless, Ron, you could
8 answer that?

9 CHAIRMAN MALMUD: Dr. Zelac, are you able
10 to address the question?

11 DR. ZELAC: Yes, sir.

12 CHAIRMAN MALMUD: Thank you.

13 DR. ZELAC: If the requirement, we're
14 talking specifically 392 and 394, the requirement in
15 each case is 80 hours. However the phrasing is, it's
16 80 hours.

17 MEMBER EGGLI: Didactic and laboratory.

18
19 DR. ZELAC: Thank you. And in each case,
20 it requires patient experience --

21 MEMBER EGGLI: Right.

22
23 DR. ZELAC: -- for three cases.

24 MEMBER EGGLI: Right.

25

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1 DR. ZELAC: So unless there was some
2 significant difference in the information being
3 presented for less than 33 millicuries versus more
4 than 33 millicuries, the training should suffice for
5 both.

6 MEMBER EGGLI: The training for handling
7 greater than 33 millicuries qualitatively is
8 identical. Quantitatively we put a little bit more
9 emphasis on some of the spills, some of the exposure.
10 But qualitatively the knowledge, the mathematics, the
11 basic radiation biology, the health physics are
12 identical between 392 and 394. It's sort of it's a
13 function of quantity of emphasis, rather than quality
14 of knowledge.

15 DR. ZELAC: So what you're basically
16 saying is that if the classroom and laboratory
17 training were directed towards --

18 MEMBER EGGLI: Three ninety-four.

19

20 DR. ZELAC: -- 394, it --

21 MEMBER EGGLI: It would satisfy all of the
22 requirements --

23 DR. ZELAC: That's correct.

24 MEMBER EGGLI: -- of 392.

25 DR. ZELAC: That's correct.

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1 MEMBER EGGLI: And then all you would need
2 would be three cases.

3 In my practice, clinically we are a
4 thyroid cancer practice, rather than a hyperthyroid
5 practice. And my residents come out with 15 or 20
6 cases of experience with thyroid cancer and 5 or 6
7 with hyperthyroid disease. And then they want to know
8 why they can't get a preceptor statement that
9 qualifies them for Part 394 therapies.

10 I hope I am not misrepresenting this
11 wrong, but I have read the regulations several times.

12 MS. FLANNERY: I think it's also a matter
13 of whether -- the programs that they're in, say a
14 four-month program, for example, are they going to get
15 an opportunity to do three cases of iodine 131
16 administrations greater than --

17 MEMBER EGGLI: In my practice, in that
18 four-month period, they will do twice as many thyroid
19 cancers as hyperthyroids. They will do twice as many
20 cases greater than 33 millicuries. And under 33
21 millicuries, we log their experience, but at the end,
22 it doesn't go anywhere because the current ABR/AU
23 status doesn't apply to Part 394.

24 I think the answer is in many practices
25 yes. Even if all of the practices don't do that, is

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1 there any reason to constrain those who can get there
2 by not having 394 for ABR diplomate?

3 MS. FLANNERY: The question would be, is
4 the ABR requiring that of all of their programs?

5 MEMBER EGGLI: The training that ABR is
6 requiring very effectively targets the T&E for 394.
7 As I understand what ABR is asking you to train our
8 residents to, I think it qualifies for 394 with the
9 exception of the case experience.

10 DR. ALDERSON: Were the ABR to understand
11 this in the way it has been expressed today, we might
12 apply to include 394. But to answer Ms. Flannery's
13 question directly, no, we are not now requiring all
14 programs to do what would be required for 394. They
15 are required only to have three thyroid therapies, not
16 six. And they can be either lower or higher. But
17 they are not required to have what is needed in 394
18 because of the way the regulation has been interpreted
19 to us previously. But we would have to do further
20 paperwork and reapply if there is a new understanding.

21 CHAIRMAN MALMUD: Dr. Zelac?

22 DR. ZELAC: One thing to be added -- and
23 this is the reason I wanted to take a look at the
24 regulation -- under 392, one qualification to be
25 automatically authorized for 392 is to be authorized

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1 for 394. So if you are authorized for 394, you are
2 automatically good for 392, meaning less than 33
3 millicuries as well. So if the target were to prepare
4 for 394, that would cover both.

5 DR. ALDERSON: So it is clear that --

6 MEMBER EGGLI: Can I ask a clarifying
7 question? If they qualified under 394 with 3 cases of
8 greater than 33 millicurie, would it automatically
9 qualify them for 392 so they wouldn't have to have an
10 additional three cases of less than 33?

11 DR. ZELAC: Yes, yes.

12 DR. ALDERSON: So the question in the
13 field -- and this was the issue when the board
14 originally determined how to approach this -- is not
15 among the big programs. It's quite clear that that
16 can be met. It's among all the small programs and
17 whether they, in fact, can get their residents the
18 experience required at the higher dose levels. That
19 was the issue, and that is why we went the way we did.

20 MEMBER EGGLI: Could ABR apply in such
21 away that they could offer 394 if the program can meet
22 the threshold or do all ABR programs have to meet that
23 threshold?

24 MS. FLANNERY: I think all programs would
25 have to meet that. Is that correct?

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1 MEMBER WILLIAMSON: I think that that is
2 true for the board certification pathway. The
3 resident could always apply under the alternate
4 pathway. I think it would be somewhat difficult. To
5 add parenthetically, at Washington University, where
6 I was on the faculty for some years, for example, it's
7 radiation oncology that does all of the radioiodine
8 applications for a malignant indication. So unless a
9 diagnostic radiology resident sought out the
10 additional case experience, they would not normally
11 get that.

12 CHAIRMAN MALMUD: Dr. Howe has a comment.

13 DR. HOWE: The ABR could put things on its
14 certification that would recognize, let NRC recognize,
15 the person was eligible for 394. And they could put
16 something on that certification that NRC could look at
17 and see they were only eligible for 392. It is their
18 choice as to what they do because we have
19 distinguishing things on other certifications for
20 other boards.

21 MEMBER EGGLI: Thank you, Dr. Howe.

22 CHAIRMAN MALMUD: Does Dr. Howe's comment
23 answer the concern?

24 MEMBER EGGLI: It answers my question.

25 CHAIRMAN MALMUD: It answers your

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1 question. Okay. Dr. Eggli says it answers his
2 question. So now we may move on to the next question.
3 I saw a hand. Sally Schwarz?

4 MEMBER SCHWARZ: Okay. I have a question
5 about the pharmaceutical specialties. I know
6 originally we were approved for both 35.55 and 35.50.
7 And I'm curious as to why the ability to become an RSO
8 for a pharmacy practice --

9 MS. ROYBAL: Excuse me. I'm sorry to
10 interrupt, but we cannot really hear some people.
11 Some people talk so low we cannot hear the questions.

12 MEMBER NAG: Sally, I think you need to
13 bring the microphone to your --

14 MS. ROYBAL: We are on the maximum here
15 volume, and we can't hear the questions and sometimes
16 the answers.

17 CHAIRMAN MALMUD: Thank you. We will ask
18 Ms. Schwarz to move the microphone closer.

19 MEMBER SCHWARZ: Excuse me. I am asking
20 a question in regard to the Board of Pharmaceutical
21 Specialties. Our status allows authorized nuclear
22 pharmacists 35.55. And before the review, the actual
23 acceptance of boards, we were allowed 35.50 status as
24 well if we were board-certified by the Board of
25 Pharmaceutical Specialties. And I'm wondering why

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1 that never came through as a status for the Board of
2 Pharmaceutical Specialties.

3 MS. FLANNERY: It really hasn't for any of
4 the boards just because under 35.50 there's a pathway
5 for authorizing individuals. So that means authorized
6 users, authorized medical physicists, and authorized
7 nuclear pharmacists. That is a pathway.

8 So if you are AMP or ANP and AU, you can
9 become an RSO. So they don't need to be specifically
10 listed under 35.50.

11 MEMBER SCHWARZ: But are you saying by the
12 alternate pathway or by virtue of our specialty?

13 MS. FLANNERY: Well, it would depend on
14 what pathway you applied for that authorization in the
15 first place. So if you're an AMP, for example, then
16 you can become an RSO by virtue of being an AMP.

17 MEMBER SCHWARZ: ANP.

18 MS. FLANNERY: Then you wouldn't have to
19 submit, you know, the training and experience --

20 MEMBER SCHWARZ: Right.

21 MS. FLANNERY: -- or submit the
22 documentation that you would have to under the
23 alternate pathway.

24 MEMBER SCHWARZ: So, in other words, if
25 you are board-certified by the Board of Pharmaceutical

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1 Specialties, you could then submit eligibility to
2 become an RSO?

3 MS. FLANNERY: Right. You could submit
4 your certificate to show that you are an ANP. Then
5 you could get listed as an ANP on the license and an
6 RSO.

7 MEMBER SCHWARZ: Thank you.

8 MS. FLANNERY: Does that make sense?

9 MEMBER SCHWARZ: Yes.

10 MS. FLANNERY: Okay.

11 CHAIRMAN MALMUD: Does that mean that a
12 pharmacist ANP can automatically apply to be a
13 pharmacist RSO once having been certified as an ANP?

14 MS. FLANNERY: A certified nuclear
15 pharmacist, we want to get to be an ANP on the
16 license, the authorized nuclear pharmacist. They
17 could apply under the certification pathway. And then
18 they could also pursue being an RSO, which one of the
19 pathways for being an RSO is to be an ANP. So it
20 would be a matter of submitting a copy of the board's
21 certificate. Is that correct? Am I stating that
22 right?

23 PARTICIPANT: And also they would require
24 a preceptor.

25 DR. HOWE: For the ANP, the certification

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1 pathway, like every other pathway, is a board
2 certification that's listed by the NRC on its Web site
3 and an attestation that the training has been complete
4 and the person can function independently as an ANP.

5 And then if you're applying for an RSO,
6 the pathway is 35.50(c)(2), which is you are already
7 an ANP. And currently our regulations take you down
8 to (d), which says you have an attestation that you
9 are an ANP, essentially you are an ANP, and that you
10 can function independently as an RSO, and that
11 preceptor comes from an RSO.

12 MEMBER SCHWARZ: And we do need a second
13 attestation statement from an RSO in order to be able
14 to be an RSO.

15 DR. HOWE: That's the current
16 interpretation of the regulations.

17 DR. ZELAC: But if I can -- this is Ron
18 Zelac. If I can address that issue? We at NRC, as
19 you on the Advisory Committee, are very well-aware
20 that this is something that was not intended, not in
21 the past, and ought not to be there. And our intent
22 is to go the direction of removing the requirement for
23 an attestation for an authorized individual, be it AU,
24 AMP, or ANP, to get a second attestation when seeking
25 authorization as an RSO.

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1 What will remain, what is there now, is
2 the need to have specific training relative to that
3 for which you wish to have RSO responsibilities. But
4 that can be documented in another way, and an
5 attestation will not be required.

6 But Donna-Beth is correct. At the moment
7 it is.

8 MEMBER SCHWARZ: And, Ron, how much longer
9 will it take to make that change? Excuse me. How
10 much additional time will be required to make that
11 change?

12 DR. HOWE: This is Donna-Beth Howe. You
13 will be hearing this tomorrow in my presentation. So
14 it's one of the potential changes to Part 35. We have
15 a rulemaking that should be starting this summer that
16 will address issues that you heard before for changes
17 to 35. The length of time it takes for it to become
18 final we can't tell you, but there is rulemaking in
19 the process.

20 MEMBER SCHWARZ: Thank you.

21 CHAIRMAN MALMUD: Other questions for
22 Cindy Flannery? Dr. Williamson?

23 MEMBER WILLIAMSON: What is the status of
24 the AAPM petition for rulemaking, which would
25 generalize or liberalize the 35.57 grandfathering

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1 clause to pick up most of the diplomates, I think,
2 before October 2005 if I'm not mistaken.

3 MS. FLANNERY: I don't think I am in the
4 best position now to answer that question. And I
5 don't know if it was the intent to cover that now
6 under this part or under the next item in the agenda.
7 What would be the appropriate place to do that?

8 DR. RATHBUN: Excuse me for interrupting,
9 Cindy. Yes. In the next session, we can discuss the
10 status. But, unfortunately, we will not be able to
11 discuss the petition itself.

12 MS. FLANNERY: Thank you.

13 CHAIRMAN MALMUD: Mr. Lieto?

14 MEMBER LIETO: Yes. This was specifically
15 asked and addressed prior to this meeting, what the
16 status of the three petitions affecting medical use
17 was. I got generalized statements answers to the
18 first two. And the issue regarding the AAPM petition
19 it was specifically indicated to me was going to be
20 addressed in this session.

21 And I think to tell this group now that
22 they have got to wait, especially when we have got a
23 large body out here of people that are here for this
24 specific purpose, I think it kind of gets to a large
25 portion of the problems that we're addressing here

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1 because there's a large number of people. And
2 contrary to staff's opinion, there are a number of
3 people out there that are not applying because of
4 these deadlines or these start dates that are put out
5 there. And so you have a lot of medical physicists
6 and some health physicists for RSOs that are being
7 adversely affected by these dates.

8 So I think it would be nice to have an
9 update as to what the status of that is. And to say
10 it's in a working group and can't be addressed I think
11 is not very helpful.

12 MS. WASTLER: Mr. Lieto, I apologize. I
13 realize that it is not satisfactory. But the process
14 that we have requires us to not disclose. It's all
15 pre-decisional information. And so we cannot discuss
16 the, say, suggestions, proposals that are going on in
17 the working group in an open forum.

18 Ron can address when we feel that we would
19 be able to. And I know that is not satisfactory. I
20 mean, I think folks want answers. But we have a
21 responsibility to complete our process, put the
22 recommendation to management, and then it be, you
23 know, the resolution of that be, made public.

24 But, Ron, could you address where we are
25 on that, please?

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1 DR. ZELAC: My name comes up because I am
2 the representative from the medical radiation safety
3 team to the working group that's considering the
4 petition. It was anticipated that there would be
5 great interest in knowing what the status of this
6 petition was at the moment. And that has been
7 conveyed to the chairman of the working group, who is
8 in a position to make a statement as to where we are
9 and what the timetable is and where we seem to be
10 going.

11 The gentleman's name is Mr. Ed Lohr, and
12 he's in the audience. And he can handle it from this
13 point on.

14 MR. Lohr: Hi. I know I am new to you
15 folks. I am a health physicist. And I work in
16 rulemaking. I'm the team leader for this Ritenour
17 petition that you all are referring to.

18 What I can tell you, as Sandy said, is
19 very limited. However, we did receive the petition in
20 September. It was published in the Federal Register
21 November 1st for public comments, closed on the 16th
22 of January.

23 There was 165 public comments received.
24 A working group was formed. I am the team leader. We
25 are diligently working on the petition. We anticipate

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1 by the end of the summer to have resolution of it.

2 Other than that, I'm not sure what else I
3 can share with this group.

4 MR. MOORE: This is Scott Moore. If I may
5 provide some more information, our petition review
6 process is a formalized regulatory process within the
7 agency. When we receive petitions for rulemaking,
8 they're docketed within the agency. And we put it out
9 for formal comment to the public. And we get comments
10 back that are docketed and that are on the record. So
11 it has a legal standing within the agency.

12 If we discuss it in an open setting and we
13 take additional comments on it then, then we would be
14 obligated to consider those comments as well as part
15 of the petition review process.

16 And so we take the comments. And then the
17 petition review process is closed then, and the
18 petition working group considers those comments, all
19 of those comments and the incoming petition, as part
20 of the petition review process.

21 The petition working group considers those
22 and makes a recommendation to the petition review
23 board. There's an actual board within the agency.
24 The petition review board meets. And, as Mr. Lohr
25 just told you, it ought to meet sometime I believe in

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1 the August time frame and come to some conclusion.
2 And then it will issue a decision back to the
3 petitioner on the resolution of the petition itself.

4 So it's a formal regulatory process that
5 happens within the agency.

6 CHAIRMAN MALMUD: Thank you.

7 Dr. Welsh?

8 MEMBER WELSH: I have a general question
9 about what I see on your chart there. In radiation
10 oncology, American Board of Radiology, recognition
11 date is June 2007. My question is about the
12 recertification process. If somebody is recertified
13 in 2007, does that mean that they are recertified with
14 their certificate when they had it in, say, 2000 or is
15 it now 2007 board certification?

16 MS. FLANNERY: It would be anybody who
17 obtained their certification after the June 2007 date.
18 It's not applicable to the recertification. They
19 would have to meet NRC's current criteria.

20 And right now, you know, you can see on
21 some of these I have an asterisk. And what that
22 indicates are the boards, the specialties, that are
23 doing a review of the individuals' qualifications on
24 a case-by-case basis.

25 Right now they are not doing that for

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1 radiation oncology, but they are, of course, say, for
2 example, diagnostic radiology. In that case they
3 could go back, review the qualifications. And if that
4 individual meets NRC's current training and experience
5 criteria, then they could reissue a certificate and
6 the person could apply for authorization under the
7 certification pathway.

8 CHAIRMAN MALMUD: Does that address your
9 question, Dr. Welsh?

10 MEMBER WELSH: Somewhat.

11 CHAIRMAN MALMUD: Other questions or
12 comments for Cindy Flannery?

13 MS. FLANNERY: Thank you.

14 CHAIRMAN MALMUD: Hearing none, thank you.

15 A question is asked. And that is, can the
16 subject be discussed in a closed executive session?

17 MR. MOORE: Is there a need for it?

18 CHAIRMAN MALMUD: Yes.

19 MR. MOORE: I don't know.

20 MS. WASTLER: We will have to ask that
21 question. I'm not sure.

22 CHAIRMAN MALMUD: Thank you. Perhaps you
23 can let me know when you get the answer to it.

24 MS. WASTLER: Yes, I will.

25 CHAIRMAN MALMUD: The next item on the

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1 agenda is the T&E implementation issues. And this is
2 going to be a discussion which you are going to
3 monitor for us.

4 DR. RATHBUN: Yes, sir.

5 CHAIRMAN MALMUD: Thank you.

6 DR. RATHBUN: You're welcome.

7 All right. Let me introduce myself. My
8 name is Patricia Rathbun. And I do work for the NRC.
9 However, I do not work in this area or certainly
10 haven't in the past ten years. So please think of me
11 as a neutral person who is here.

12 I understand that this is a very tough
13 issue. And I also understand, as Ralph pointed out,
14 there are lots of people in this room who have lots of
15 knowledge. And so we're trying to establish a
16 methodology here whereby we can tap the expertise in
17 the room.

18 And so essentially I am going to pass out
19 now a very brief agenda, which will just kind of show
20 because I realize this is a little bit different than
21 we normally do things. So we'll have a little
22 different type of meeting. I think there's enough for
23 everyone.

24 Our purpose here is to collect data. It's
25 not to resolve any issues. And I know that in a

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1 professional group like this with many experts -- and
2 I always want to do this -- we want to immediately
3 jump and fix the issue. What is the question? What
4 is the answer? Let's answer it, and let's get on with
5 it.

6 I'm going to ask your indulgence to work
7 with me. So if you've gotten your handout now,
8 really, I'm just trying to take the administrative
9 burden off here and put it on myself. And if I
10 understand correctly, if you've gotten it, what we've
11 received so far is we have some written statements.
12 We will also have some other types of statements. And
13 we also have people on the phone.

14 So if you could take just a minute and
15 take a look at the agenda? Our goal again is to hear
16 from as wide a variety of stakeholders as is possible.
17 And we would like positive as well as negative
18 experience if that is plausible on this part of Part
19 35.

20 The ground rules, which I would like to
21 try and hold to, would be to start on time, stay on
22 time, and stop on time. Having said that, we are
23 starting at 1;15. So we'll adjust that accordingly.
24 I had planned on having a break at 2:30. And I had
25 planned on coming back from 2:45 to 5:00 and truly

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1 ending at 5:00 o'clock out of respect for people's
2 schedules.

3 The rest I think one thing that is going
4 to be a problem is that once an issue has been
5 addressed and hopefully captured, we'll try not to go
6 back too often. It's especially difficult because we
7 have people on the phone. So you have to try and get
8 the -- and we will put the issues in writing up in
9 front of you.

10 Okay. Having said that now, Ashley will
11 be typing what she hears you say. Watch the board.
12 If it's wrong, you tell me, and we'll fix it.

13 If you look now at part 3, the
14 presentation of examples, I want to start with the
15 written statements that have already been provided to
16 the NRC, then go to the telephone, and then take the
17 comments from the rest of you in here.

18 Before we do that, I would like to hear
19 from the people on the telephone who is out there.
20 Speak up, and we'll just handle it.

21 MR. RATLIFF: Richard Ratliff with the
22 Texas Department of State Health Services.

23 DR. RATHBUN: Okay. Thank you.

24 MR. SCHMIDT: Paul Schmidt representing
25 the Organization of Agreement States.

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1 DR. RATHBUN: I didn't hear that. Oh,
2 Paul. Hi, Paul.

3 MR. SCHMIDT: Hi.

4 DR. RATHBUN: Anybody else?

5 MR. STEVENS: Mike Stevens with the
6 Florida Bureau of Radiation Control.

7 MS. ROYBAL: Margaret Roybal and Daniela
8 Bowman with New Mexico Radiation Control Bureau.

9 DR. RATHBUN: Welcome. Okay. So, then,
10 when you speak, we have to remember to identify
11 ourselves because this meeting is being transcribed.
12 So when you are speaking on the phone, please say your
13 name first for the transcriber.

14 All right. Who would like to give the
15 first written statement? Who were the statements
16 from?

17 MS. TULL: SNM.

18 DR. RATHBUN: Okay. Thank you.

19 MR. BEVEN: Thank you. Terence Beven
20 representing SNM. We appreciate the opportunity to
21 comment on the training and experience requirements.
22 I would like to just highlight some of the items which
23 are of interest to us.

24 SNM supports the removal of the preceptor
25 for those in the board certification pathway. The

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1 American Association of Physicists and Medicine and
2 other groups discuss this in greater detail in their
3 various written statements.

4 SNM recommends that the NRC and ACMUI
5 review the impact of the effective date concept. AAPM
6 and other groups also discuss this in greater detail.
7 SNM is concerned that it's unclear what is required of
8 a physician who completed a residency program more
9 than seven years ago and now decides to apply for
10 authorized user status. Specifically, do they have to
11 repeat all of their training? And if not, if they
12 worked in a nuclear medicine lab after they completed
13 their training, would this ongoing experience mean
14 that they had met the seven-year requirement?

15 The 200 hours of classroom and lab
16 training required in 10 CFR 35.390 cannot be justified
17 since this is nearly a complete overlap of 80 hours of
18 classroom and lab training required by this
19 regulation; specifically as an example I-131 therapy,
20 which has been mentioned, below 30 millicuries and
21 greater than 30 millicuries.

22 A syllabus of materials to be covered by
23 classroom and lab exercises could be developed
24 conjointly by the NRC and professional educators. I'm
25 sure the boards and the residency review committees

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1 would appreciate the opportunity to participate in
2 such a process.

3 SNM believes the certification boards
4 should determine the acceptable training methods for
5 the education of physicians regarding activities such
6 as eluting the generation system, performing,
7 measuring, and testing of the A08, processing the A08
8 reagent kits to prepare radioactive drugs, and
9 administering radioactive agents. Recent
10 clarifications have stated that the only acceptable
11 method of training for these various tasks is
12 physical, hands-on.

13 We are also concerned that our Canadian
14 members may be problematic insofar as meeting the T&E
15 requirements. Individual physicians trained in Canada
16 if they did not receive their training under the
17 supervision of an authorized user may not be
18 qualified. Ideally, there should be a defined pathway
19 by which a Canadian nuclear medicine physician could
20 meet the new T&E criteria without necessarily being
21 trained by a U.S. NRC-licensed user.

22 A potential good approach would be that a
23 Canadian physician should have their training verified
24 by an authorized user in the U.S. and that they should
25 also be required to take a few hours of additional

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1 training to confirm they are knowledgeable in these
2 areas.

3 In closing, SNM appreciates the
4 opportunity to share our perspective on the
5 implementation of Part 35.10 of the requirements. And
6 we hope that this discussion is the beginning of a
7 long-term dialogue between the NRC, ACMUI,
8 certification boards, professional societies, and
9 other stakeholders. We fully support NRC's efforts to
10 work closely with all stakeholders and particularly
11 educators to enhance the clarification and
12 implementation of the various T&E requirements.

13 Thank you.

14 DR. RATHBUN: Thank you so much for doing
15 that. And if I could just get you to help me a little
16 bit with sort of the key points? That was a lot of
17 information for Ashley to hear. So could you help me
18 with some categories that I want to put up here? The
19 first one we got, remove the preceptor statements.

20 MR. BEVEN: Yes.

21 DR. RATHBUN: Review the impact of the
22 effective date.

23 MR. BEVEN: Yes.

24 DR. RATHBUN: And clarify the
25 requirements for a physician to complete the residency

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1 program. I think you had a few more.

2 MR. BEVEN: The Canadian members.

3 DR. RATHBUN: The Canadian. And I know we
4 have the letter, but I want to be sure that everybody
5 in the room also knows what's in your talk.

6 MR. BEVEN: I think that encompasses all
7 of our bullets.

8 DR. RATHBUN: Okay. Thank you so much.
9 Okay. What is the next one?

10 CHAIRMAN MALMUD: There is another issue.

11 DR. RATHBUN: Oh, I'm sorry. Okay.

12 CHAIRMAN MALMUD: The 200-hour.

13 DR. RATHBUN: Okay. Thank you.

14 CHAIRMAN MALMUD: And included in that
15 200-hour in parentheses is the question of developing
16 a syllabus.

17 DR. RATHBUN: Thank you. And the next --
18 I'm sorry?

19 PARTICIPANT: There's one other item.

20 MEMBER LIETO: This is Ralph Lieto. I
21 think there was one other one, and that was having to
22 use live generators to demonstrate acceptable
23 training.

24 CHAIRMAN MALMUD: All right. That was
25 part of --

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1 MEMBER LIETO: It's supposed to be a part
2 of the 200-hour?

3 CHAIRMAN MALMUD: It's separate, but okay.
4 We'll make it a separate item. It really refers to
5 the current prescriptive requirements of the NRC,
6 which really tread on the traditional turf of the
7 specialty boards, which determine that which is
8 required for their trainees.

9 DR. RATHBUN: This is really what we're
10 putting on, isn't it? This is the key point.

11 CHAIRMAN MALMUD: This is an example of
12 what is perceived currently --

13 DR. RATHBUN: Right.

14 CHAIRMAN MALMUD: -- to be overly
15 prescriptive --

16 DR. RATHBUN: Right.

17 CHAIRMAN MALMUD: -- since the average
18 nuclear physician, nuclear radiologist, nuclear
19 cardiologist has no need to and no day-to-day
20 experience in eluting generators.

21 DR. RATHBUN: Okay.

22 PARTICIPANT: We're getting it together.

23 DR. RATHBUN: Okay. What's the next
24 letter we got? AAPM? If I'm going too fast, you stop
25 me.

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1 CHAIRMAN MALMUD: Well, are we staying
2 with the issues that relate to nuclear medicine
3 training? Is that the first topic?

4 DR. RATHBUN: No. What I really --

5 CHAIRMAN MALMUD: Go through the letters?

6 DR. RATHBUN: I think so.

7 CHAIRMAN MALMUD: Okay.

8 DR. RATHBUN: And then after we hear from
9 each one, let's see what our real topics are.

10 CHAIRMAN MALMUD: Okay.

11 DR. RATHBUN: Is that right? Okay.

12 CHAIRMAN MALMUD: Then we have another
13 member of the public. Would you introduce yourself,
14 please?

15 MR. WHITE: I am Gerald White. I'm the
16 President-Elect of the American Association of
17 Physicists in Medicine. And, for the record, we
18 represent 6,500 medical physicists in the United
19 States and Canada.

20 I would like to discuss a written document
21 that we sent that is a summary of discussions held at
22 a meeting of stakeholders that you have in front of
23 you and also a document that was a letter written by
24 the AAPM to Commissioner Klein.

25 I will do some bullet points here. I

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1 think maybe one thing that we would like to make plain
2 is that the original idea of listing the boards on the
3 Web site was a good one. But earlier today someone
4 talked about unintended consequences of regulation.
5 And this is an incredible series of unintended
6 consequences, as is demonstrated by the packed
7 audience here today of educators, physicians,
8 physicists, other professionals who have given several
9 days of their time and hundreds of hours prior to this
10 to sort out this mess that we're in.

11 We have a uniform professional agreement,
12 although some disagreement perhaps on the details,
13 that there are serious problems with this process.
14 And we hope that both the NRC and the ACMUI will agree
15 with that as well. There is increasing complexity and
16 no benefit.

17 We have a number of work-arounds that have
18 been proposed by the staff. And they are in many
19 cases analogous to traveling from Philadelphia to New
20 York by way of New Orleans, Los Angeles, and Seattle.
21 It's possible, but it creates no benefit to the public
22 and doesn't enhance radiation safety.

23 We have agreement with the preceptor
24 statement problem, that essentially in the board
25 certification pathway context, it is redundant.

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1 During the application process for the boards, there
2 are multiple sign-offs by physician proctors, although
3 perhaps not in exactly the format that NRC would like.
4 There is an examination process and proctored clinical
5 experience that make the preceptor statement
6 completely unnecessary in the board certification
7 pathway.

8 And, for reasons that we have detailed in
9 the letter, it is also problematic to obtain these
10 statements because preceptors are reluctant to sign in
11 the method that NRC requests.

12 The issue of marginalizing the certifying
13 boards by virtue of both the preceptor statement and
14 what we call the failure to grandfather those people
15 who were previously board-certified is a significant
16 issue.

17 The issue of effective date of board
18 recognition was not discussed and not anticipated
19 during the lengthy multi-year process that AAPM and
20 other organizations participated in with this group in
21 developing the regulations.

22 To give you an example of one of the
23 places where the silliness, if I can use that word,
24 has really manifest. Can you put that? Is that an
25 allowed word on the --

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1 DR. RATHBUN: It's a good word for me.

2 MR. WHITE: There is a statement that
3 describes how one can use board certification to be a
4 supervisor of an educational program for aspiring
5 AMPs. And the requirements for that are that the
6 person has been certified by a specialty board
7 recognized by the NRC or agreement state.

8 However, to be an AMP, you have to be
9 certified by a specialty board whose certification
10 process has been recognized by the NRC. Simple
11 one-word difference. And in the former case, all
12 board certificates issued by the ABR qualify, but in
13 the latter case, none prior to 2007 do. No one
14 anticipated that sort of distinction, and it certainly
15 makes no sense in the radiation protection context.

16 We have talked a lot about the potential
17 difficulties in the letter here about people becoming
18 authorized medical physicists due to the way
19 authorized medical physicist has become a recent
20 construct, the difficulty of physicists becoming RSOs
21 because there's only one RSO on the license, compared
22 to physician AUs, where there may be multiple folks in
23 that category.

24 And I won't go through all of those
25 particular objections but just to say again that there

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1 were people who were qualified by their board
2 certificate prior to October of 2005. And the next
3 month, same person, same board certification suddenly
4 are not qualified. It makes no sense from a public
5 health standpoint.

6 I would like the Committee and the NRC to
7 consider the Occam's Razor principle that --

8 DR. RATHBUN: Oh no, not that.

9 MR. WHITE: Yes. Well, but in this case
10 I think it's not only applicable. I think it's the
11 key to the solution.

12 And I'll note that the AAPM has a petition
13 for rulemaking, which I know cannot, dare not be
14 discussed in this context. But we feel that the
15 petition for rulemaking provides an Occam's Razor-type
16 solution. It doesn't take us from Philadelphia to New
17 York by way of the West Coast.

18 And it's certainly something that we think
19 that the Commission and this Committee should support.
20 And we're hoping that the Committee will support the
21 actions requested in this petition sometime today
22 before we leave.

23 These issues need to be resolved. We need
24 to have pathways for resolution, hopefully within the
25 NRC or outside of the NRC. But these need to be

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1 resolved. And I think there is uniform professional
2 agreement on that.

3 DR. RATHBUN: Okay. Thank you very much.

4 I think we will go back after the next
5 statement because I am starting to hear some overlap.
6 We can put these issues out. Even if they are in the
7 petition and they are brought up in this venue, we can
8 discuss them.

9 What is the next one? We just had two.
10 All right. Going out to the telephone, is there
11 anybody out there who has a prepared statement to
12 make?

13 (No response.)

14 DR. RATHBUN: Okay. All right. Then
15 let's go back, then, to this.

16 CHAIRMAN MALMUD: Are you able to hear us
17 on the phone? I think there are four external
18 parties.

19 MR. RATLIFF: Yes. This is Richard
20 Ratliff, Texas Department of State Health Services.
21 I just have a short statement from our Texas Radiation
22 Advisory Board, governor-appointed advisory board,
23 requesting that the NRC and the Committee change the
24 requirement 35.392, training for oral administration
25 of sodium iodide 131 from a category B to a category

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1 C compatibility.

2 DR. RATHBUN: Okay. I have written that
3 down. The Texas Board of -- how do you say it?

4 PARTICIPANT: Texas Advisory Board.

5 DR. RATHBUN: Advisory Board recommends
6 that the requirement in 35.392 be changed from a
7 category B to a category C compatibility. Is that
8 right?

9 MR. RATLIFF: Yes.

10 DR. RATHBUN: Okay.

11 MEMBER NAG: Can someone amplify on what
12 that change means from a B to a C?

13 DR. RATHBUN: Okay.

14 CHAIRMAN MALMUD: Can you in Texas tell us
15 what you are trying to achieve?

16 MR. RATLIFF: Yes, sir. This is Richard
17 Ratliff again. Currently our Texas regulations for
18 controlled radiation have been stricter than the NRC's
19 training and experience. And this would allow us to
20 continue having stricter requirements requiring ACGME
21 training for all physicians who would use iodine in
22 therapy.

23 CHAIRMAN MALMUD: Thank you for clarifying
24 your position.

25 DR. RATHBUN: The concept of a category B

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1 and a category C, is that something we should talk
2 about here?

3 MEMBER NAG: I have no idea what that
4 means.

5 DR. RATHBUN: Have you heard of that
6 before? Okay. Who is here?

7 CHAIRMAN MALMUD: Please clarify.

8 DR. RATHBUN: Yes. Okay. I am looking
9 for a victim.

10 (Laughter.)

11 DR. RATHBUN: Where are all of my victims
12 when I need them?

13 MR. MOORE: Yes. I'll try to answer it.

14 DR. RATHBUN: Okay.

15 MR. MOORE: And, Debbie, help me if I
16 don't get the exact words.

17 (Laughter.)

18 DR. RATHBUN: There's my victim.

19 MR. MOORE: The category B level of
20 compatibility means that the agreement states for a
21 regulation that's passed by NRC will have regulations
22 within the agreement states that is essentially
23 identical to NRC's regulations. It doesn't have to be
24 verbatim, but it does have to be essentially identical
25 to the regulation that NRC passes.

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1 Category C has to have the essential
2 objectives of the regulations that NRC has. And so
3 the agreement state may pass something that's
4 different, but it meets the same objectives of the
5 same, which means the state could be more restrictive
6 than NRC's regulations.

7 For instance, in the area of training and
8 experience, it could require more hours of training or
9 could require additional evidence that the training
10 has been taken or that kind of stuff but still meets
11 the same objectives, which is to show that the
12 training and experience has been taken and obtained.
13 Does that explain it?

14 DR. RATHBUN: Did you have anything to add
15 to that, Debbie?

16 MEMBER GILLEY: I believe this particular
17 -- Debbie Gilley -- incident has to do with iodine for
18 thyroid carcinoma or for therapeutic applications.
19 And under Subpart J, a limited number of hours were
20 required for physicians that do that, though the
21 potential risk for harms may be greater than the
22 diagnostic nuclear medicine physicians doing
23 diagnostic studies.

24 So some of the states have indicated that
25 they would like to have more training and education

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1 for those people doing therapeutic applications than
2 what is currently required in the regulations.

3 DR. RATHBUN: Texas, is that okay with
4 you? Does that characterize your issue?

5 MR. RATLIFF: Yes.

6 DR. RATHBUN: Good. Okay. Anything else?

7 CHAIRMAN MALMUD: Any other external
8 stakeholders who are on this phone conversation who
9 wish to make a comment?

10 (No response.)

11 CHAIRMAN MALMUD: If not, we will move on.

12 DR. RATHBUN: We have one more.

13 CHAIRMAN MALMUD: Here, but we are done
14 with the phone entries.

15 DR. RATHBUN: It sounds like, yes.

16 CHAIRMAN MALMUD: Thank you.

17 DR. RATHBUN: Thank you.

18 CHAIRMAN MALMUD: Member of the public?

19 MS. MARTIN: Thank you very much.

20 CHAIRMAN MALMUD: Please introduce
21 yourself.

22 MS. MARTIN: My name is Melissa Martin.
23 I am here today representing the American College of
24 Radiology. I have served for the last six years as
25 Chairman of the Government Relations Committee of the

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1 ACR's Medical Physics Commission.

2 For those who aren't aware -- but I am
3 sure everyone in this room is -- the ACR represents
4 32,000 members. So when we're discussing our
5 organization, we are a large part of what is affected
6 by these rules and regulations.

7 The ACR has been a very active participant
8 with the NRC throughout this development and
9 implementation of the T&E requirements. It is our
10 belief that the current NRC staff's implementation of
11 this rule is inconsistent with the understandings and
12 deliberations that were part of the rulemaking
13 process.

14 We basically have three areas of concern.
15 And these should be very consistent with what you have
16 already heard. Number one, there are no health or
17 safety concerns raised by permitting those persons who
18 were deemed competent to practice on or before October
19 24th, 2005 to continue to practice. Imposing
20 additional regulatory burdens upon these individuals
21 is unwarranted.

22 Number two, the notion that recognized
23 status for approved boards will have an effective date
24 was not contemplated prior to the rule becoming
25 finalized. This interpretation, along with the delays

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1 in recognizing certifying boards, has been problematic
2 for both authorized users and others, who were not
3 eligible for grandfathering and, yet, sat for their
4 board exams before the board's effective date.

5 Number three, the ACR recognizes the
6 unique difficulties faced by medical physicists
7 relative to grandfathering. It is a fact that the
8 term "authorized medical physicist," this concept is
9 relatively new in many states. And, therefore, the
10 opportunity to be grandfathered is limited. And the
11 licensees have only listed a single RSO on their
12 license.

13 The next concern, we recommend that the
14 NRC should develop a mechanism to ensure that all
15 individuals seeking authorized status who are
16 adversely affected by this effective date constrict be
17 given the opportunity to come in under the board
18 certification pathway.

19 One other area of our concern is the
20 preceptor requirement. The preceptor requirement has
21 proven to be extremely problematic in practice. There
22 is significant concern about the potential among
23 potential preceptors as to the liability they face in
24 attesting to the qualifications of others.

25 We are faced with a difficult choice. The

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1 preceptor must either sign a statement and risk the
2 personal, professional, and potentially economic
3 ramifications of signing or agreeing to sign a
4 statement and accept the potential liability thereof.

5 We have been made aware that it is not
6 consistent application in documenting the requirements
7 for these preceptor statements. Some areas are
8 requiring facilities to further substantiate the
9 assertions made in preceptor statements.

10 Our recommendation is that preceptor
11 statements are redundant given the thoroughness of the
12 board certification process and should not be required
13 for those members that are already certified by the
14 American Board of Radiology in any of the categories.

15 The other item that we would like to bring
16 up is the attention of the shortage of qualified
17 personnel to function as radiation safety officers
18 under the current construct. The RSO shortage is
19 caused by an implementation of the rule and is
20 severely stressing the system to the point that some
21 facilities will have no one qualified to be RSO with
22 the current requirements.

23 What this is forcing is that some RSOs are
24 being asked to be listed on several facilities'
25 licenses. The question is, how many facilities can an

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1 RSO adequately serve?

2 So we would recommend that the ideas
3 already given be adopted by the NRC. Thank you very
4 much.

5 DR. RATHBUN: Thank you.

6 Could you help me on this one? It was
7 your one just before the shortage of qualified RSOs.
8 Could you say that one again for me?

9 MS. MARTIN: Is that relative to the
10 preceptor statement or the RSO?

11 MEMBER EGGLI: It was actually captured in
12 number 7.

13 DR. RATHBUN: Okay. All right. So we're
14 doing better. We're on the same wavelength here.
15 Okay.

16 Having done this, then, is there anybody
17 else in the room who would like to pose an issue?
18 We'll come back, and we'll go through possible
19 solutions, but I would like to make sure we get all of
20 the issues out. Yes, sir?

21 MEMBER NAG: Yes. This is Dr. Nag,
22 radiation oncology. In radiation oncology, we have
23 the manual that is the 400 and then the 600, which is
24 the high-dose rate brachytherapy and gamma knife.

25 If someone is recently board-certified, it

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1 is not a problem. However, the problem is that many
2 people will graduate or have graduated some time ago.
3 And then they have worked on something, not worked on
4 something.

5 And then let's take an example of someone
6 who graduated seven or eight years ago, had training
7 in all of the modalities, worked on one of those
8 modalities but in that institution did not work on the
9 HDR.

10 Now he goes to another university or
11 another place and now wants to do the HDR. Then he is
12 told that "You haven't had this for seven years. And,
13 therefore, you have to retrain on HDR," which is easy
14 enough. You do a few cases of HDR. You show the
15 recentness.

16 And then you are now told that because
17 it's more than seven years, you have to do all of the
18 other training, which is not fair because they have
19 been taking care of other parts of radiation oncology.

20 So it is something that we have to show,
21 but one possibility is that if you are board-certified
22 and, again, no matter what, if you have to show your
23 recent training, you don't have to show the recentness
24 of all the 700 hours, but that component, for example,
25 HDR or gamma knife, you just have to show that you

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1 have had some recent training in that component.

2 That's one solution. You might think of
3 other things.

4 DR. RATHBUN: So are you saying if you
5 are, say, working on gamma knife and then you
6 transferred and you wanted to work on an HDR, you
7 wouldn't be able to do that? Is that what you are
8 telling me?

9 MEMBER NAG: At least that is how it has
10 been interpreted.

11 DR. RATHBUN: Okay.

12 MEMBER NAG: That is how, you know, some
13 states and well as some NRC offices are interpreting
14 it.

15 DR. RATHBUN: Is that something that would
16 have happened in an agreement state situation? Have
17 you heard of that, Debbie?

18 MEMBER GILLEY: I have not heard of that
19 being an issue.

20 MEMBER NAG: I have given a written
21 statement to the NRC last week of the actual happening
22 and the order of events it went through.

23 DR. RATHBUN: Okay. Okay.

24 MEMBER NAG: So that is in your file.

25 DR. RATHBUN: Good. Excellent. Okay.

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1 That's exactly what we want is a specific example.

2 MR. MOWER: I am Herb Mower. I am
3 Chairman of the American College of Medical Physics,
4 in addition to the things that Gerry White mentioned
5 from the AAPM, which we cosigned the letter.

6 Relative to the preceptor, which there are
7 various concerns about, if somebody has been working
8 and board-certified prior to the cutoff date but in
9 the period prior to that had done the right number of
10 hours and whatnot but their preceptor is either in an
11 institution which is addressed in here which does not
12 allow you to say more than somebody attendant there
13 or, worse yet, the preceptor is, in the words of the
14 TV series, six feet under. What do we do in a
15 situation like that?

16 And no one else has addressed the fact of
17 a preceptor who is no longer with us. And what does
18 that do to the person who went through the program?
19 Do we expect them to start all over again in order to
20 get a new preceptor who would be working with them?

21 DR. RATHBUN: So you said if his preceptor
22 was gone six feet under, leave that alone. How does
23 he or she become certified?

24 MR. MOWER: How do they get the preceptor
25 statement, right.

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1 DR. RATHBUN: How they get the preceptor
2 statement. That's an interesting point.

3 DR. BROGA: Good afternoon. My name is
4 Dean Broga. I'm the RSO at VCU. I will not speak on
5 behalf of any societies but more in a problem of a
6 physicist working in the field.

7 The problem of the RSO has become a big
8 issue in community hospitals and smaller outpatient
9 facilities, which would be counting a large number of
10 licensees now, with physicians with limited
11 experience.

12 And, as Melissa mentioned earlier, a lot
13 of pressure has been put on existing RSOs to cover
14 these facilities, even though they may go there
15 infrequently. This has been an approach taken by the
16 NRC to solve this problem. Otherwise we would be
17 shutting a lot of facilities down.

18 I would like to see it change so that they
19 identify some kind of RSO in training at that facility
20 who is being covered by an RSO but not have another
21 RSO named as responsible person.

22 I feel it really puts us in a very big
23 bind to be covering a facility where we only may be
24 able to get to every three months when there is a
25 person on site who could be named as an RSO in

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1 training or whatever who has much more authority on a
2 day-to-day basis. Unfortunately, that is the model
3 that is occurring right now in a lot of facilities.

4 DR. RATHBUN: And presumably as a result
5 of the implementation --

6 DR. BROGA: It's a problem that I have had
7 two or three cardiologists who want to leave a group
8 to start their own outpatient office and they ask me
9 about getting a license. I say, "Well, okay. The
10 biggest, first problem you have is who is going to be
11 the RSO."

12 Especially if you are a break-away
13 cardiologist and the group you are leaving is not
14 sympathetic to your move, they are not going to sign
15 anything. So, you know, I have had a couple of people
16 who did not break away because they couldn't get an
17 RSO, which is unfortunate.

18 DR. RATHBUN: Okay. That's really
19 interesting. Okay. All right.

20 MR. MOWER: If I could just do a point of
21 clarification? If you go back to me, I'm not Rick
22 Morin. I'm Herb Mower, M-o-w-e-r, same as power
23 mower.

24 (Laughter.)

25 MR. MOWER: I said my name is Rick Morin.

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1 (Laughter.)

2 DR. RATHBUN: Unfortunately, you caught
3 Ashley over there stealthily doing that. That's one
4 of our really big tricks.

5 Yes, sir?

6 MEMBER EGGLI: I think as you cycle back
7 to something that appeared in several of the issues,
8 one issue that needs to be dealt with is preceptor
9 liability or at least perceived liability on the part
10 of preceptor.

11 As a person who does about 15 of these a
12 year, I understand what those comments were. And that
13 touches in several of the areas. And the ability to
14 get preceptor statements is that the preceptor is
15 perceived as a significant liability issue.

16 And the preceptor wants to be -- which I
17 think was NRC's intent -- very sure of the people that
18 are preceptoring. But preceptor liability is a major
19 contributor to a lot of the topics that we're seeing
20 listed.

21 DR. RATHBUN: It's kind of like being a
22 kindergarten teacher, I guess. The most serious thing
23 you do is hurt somebody's kid. Okay.

24 DR. BROGA: Can I comment on that?

25 DR. RATHBUN: Sure.

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1 CHAIRMAN MALMUD: Come to the microphone
2 and introduce yourself.

3 DR. RATHBUN: Say your name.

4 DR. BROGA: Dean Broga again. I think
5 that is a huge problem. We know the NRC has
6 prosecuted people for signing preceptor statements
7 erroneously. It is in the records. It's not a
8 question that it hasn't happened. And that was when
9 you were attesting training and experience, not
10 competency. That statement says competency.

11 And the third statement in that thing
12 about the regulations and emergency preparedness and
13 so forth, it's poorly delineated. I have no idea what
14 it means.

15 If someone were to ask me to sign a
16 statement about their competency and I have some
17 liability in it, there's a great hesitance on my part
18 to do it.

19 And so we have gone from saying "training
20 and experience" to "They are competent to do this
21 job." And then we have ambiguous statements that
22 don't delineate what we're really covering.

23 There is a number of major medical
24 facilities that are having problems with this.

25 DR. RATHBUN: Okay. I think we've got

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1 this one.

2 CHAIRMAN MALMUD: If I may, I would like
3 to put a little historical perspective on this. The
4 members of the Committee will all recall that, I
5 believe, to a man and to a woman, we all protested the
6 use of the word "competency."

7 We can attest to the fact that an
8 individual has received certain levels of training and
9 that he or she appears to have absorbed that training.
10 We cannot attest to an individual's competency. An
11 individual who is competent today may be totally
12 incompetent tomorrow or may commit an act tomorrow
13 which betrays his training.

14 Coming from Philadelphia, where there are
15 more lawyers than there are educators, I can tell you
16 that putting a statement down as to someone else's
17 competency leaves the training program director or the
18 attester potentially liable. And it is not a
19 worthwhile gamble, not in Philadelphia.

20 DR. RATHBUN: Dr. Eggli?

21 MEMBER EGGLI: In the original discussion
22 and consideration, I think that when we got to this,
23 one of the concepts that we had sort of agreed to was
24 that we could attest to mastery of a body of
25 knowledge, as opposed to competency.

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1 I actually thought that that is how the
2 final reg would be written at the time, but competency
3 sneaked back in there. We just looked at the various
4 sections of the reg, and the word "competency" is in
5 there.

6 I think it's easier to attest the mastery
7 of a body of knowledge than it is to attest the
8 competency because I can test for mastery of a body of
9 knowledge. As already said, I have no idea how to
10 test for competency.

11 DR. RATHBUN: Right, right.

12 CHAIRMAN MALMUD: And it should be in the
13 minutes that the members of this Committee protested
14 the use of the word "competency." And we were assured
15 that it probably would not appear. And, yet, it did
16 appear.

17 As the Chair of the ACMUI, I must tell you
18 that I am distressed and disappointed that something
19 that was unanimously opposed by the members of the
20 ACMUI was ignored at the time of the final writing of
21 the document.

22 It's as if we don't exist. If our purpose
23 is to participate and to give you our opinions, for
24 them to be ignored totally, then I believe we are a
25 purposeless committee and should be dissolved.

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1 MEMBER NAG: So be it.

2 DR. RATHBUN: I can sympathize with your
3 feelings. To dismiss it is the worst feeling.

4 CHAIRMAN MALMUD: I believe I am speaking
5 on behalf of the entire membership.

6 DR. RATHBUN: Am I getting everybody
7 showing their hands on this?

8 CHAIRMAN MALMUD: Do you want a show of
9 hands?

10 MEMBER NAG: Yes.

11 DR. RATHBUN: Yes.

12 (Whereupon, there was a show of hands.)

13 CHAIRMAN MALMUD: Everyone who was on the
14 Committee at the time agrees.

15 DR. RATHBUN: Okay.

16 CHAIRMAN MALMUD: And we regard that as a
17 betrayal.

18 DR. RATHBUN: Okay. I can understand
19 that.

20 CHAIRMAN MALMUD: Strong words but strong
21 feelings.

22 DR. RATHBUN: Well, it's clearly very
23 important.

24 CHAIRMAN MALMUD: Because we're
25 interfering with the practice of medicine and

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1 certification of individuals. Some actions which are
2 taken to protect the public actually have the opposite
3 effect.

4 For example, if there is a shortage,
5 different subject, if there is a shortage of RSOs and
6 RSOs are, therefore, require, those who are certified,
7 are required to cover more than one institution, we
8 have diluted the competency.

9 We have not improved the competency
10 because the individual who is the RSO for three or
11 four or five or six or more institutions cannot be
12 physically there all the time. That's not progress.
13 That's regression.

14 So we have to look at the unintended
15 consequences of some of these actions that are taken
16 with all of the good intention in the world but are
17 not responsive to the advice given by this Committee,
18 which I recognize is an advisory committee.

19 But if our advice is worth nothing, tell
20 us. And we have better ways of spending our time.

21 DR. RATHBUN: Well, did you want to
22 respond to that?

23 MR. MOORE: The Advisory Committee's
24 advice is certainly important to the agency. And we
25 can go back and look at the record and see what

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1 happened, but we certainly do value your advice.

2 One of the things that we haven't brought
3 out much in this discussion is the agreement states'
4 views on the training and experience requirements
5 beyond what the Texas Radiation Advisory Board's
6 position is on the one compatibility issue.

7 And I remember when we were promulgating
8 Part 35. The states played an important role and had
9 some fairly strong views. And so, you know, we do
10 have Debbie Gilley, the Chair of the CRCPD, and Paul
11 Schmidt, the Chair of the Organization of Agreement
12 States, on the phone and other agreement state
13 representatives on the phone.

14 Now, I wonder if any of you all would like
15 to bring in a state perspective on the T&E
16 requirements and talk about any of the state-specific
17 issues.

18 DR. RATHBUN: Okay. Paul, could you go
19 first on this one? Paul?

20 MR. SCHMIDT: Yes, I'm here.

21 DR. RATHBUN: Okay. Could you speak to
22 this issue a little bit?

23 MR. SCHMIDT: I'm going to have to keep it
24 somewhat general here.

25 DR. RATHBUN: Okay.

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1 MR. SCHMIDT: There's another individual
2 I was hoping was going to be on this phone who could
3 speak to it much more specifically. I don't believe
4 they are, though, from what I have heard.

5 DR. RATHBUN: Okay. Well, Debbie is here.
6 And we thought that we would let you go first.

7 MEMBER GILLEY: Thank you so much.

8 MR. SCHMIDT: I would be happy to have
9 Debbie go first.

10 (Laughter.)

11 DR. RATHBUN: You want Debbie to go first.
12 Okay.

13 MEMBER GILLEY: Well, let me take it from
14 a personal state perspective first. There are four
15 states that have medical physicist licensure laws.
16 They are very prescriptive licensure laws. And for
17 that, those four states, there are going to be some
18 compatibility issues that are going to come up because
19 there is statutory language that requires certain
20 qualifications for a therapeutic medical physicist.
21 State of Florida will have difficulty meeting the
22 attestation requirement and the preceptoring
23 requirement as it's currently in Part 35.

24 So that very little world is the State of
25 Florida. I believe Texas may have some issues, New

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1 York and Hawaii also. Of course, it is not an
2 agreement state, but they also have medical physics
3 licensure law.

4 The agreement states did participate in
5 this activity all along. And they did try to bring --
6 I'll choose my words carefully here -- a common sense
7 approach to this. The way we have been working for
8 many years appeared to be working fine with us with
9 the board recognitions as they were identified prior
10 to 2005 or prior to Part 35 implementation.

11 So the compatibility issue B was a
12 surprise to us later on in the process. So with all
13 of those comments, we were led down the path, much
14 like the ACMUI was, with how things were going before
15 we saw what was the final product and the final
16 compatibility.

17 DR. RATHBUN: Okay. It looks like we will
18 have no trouble setting the issues out. I know we
19 aren't going to get the solutions, but we can set the
20 issues out.

21 Okay. Dr. Malmud, did you want to add
22 something right now?

23 CHAIRMAN MALMUD: No. I just wanted to
24 recognize Dr. Van Decker.

25 DR. RATHBUN: Okay. Thank you.

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1 MEMBER VAN DECKER: I just wanted to add
2 a comment to the compatibility B issue from the
3 provider perspective. Obviously providers sometimes
4 go from state to state in their careers. And so from
5 the provider issue, it would certainly be a more
6 reasonable thing to have a uniform status for T&E
7 across the nation that is reasonable and acceptable to
8 everyone than to go state to state and find out you
9 can do something in one state but if you cross the
10 border, you can't do it in another state. It's
11 problematic.

12 DR. RATHBUN: That's a good point. Thank
13 you. So you run across the border and practice
14 medicine.

15 CHAIRMAN MALMUD: Dr. Williamson wanted to
16 be recognized.

17 MEMBER WILLIAMSON: And I think to comment
18 that if one looks at the record of past ACMUI
19 deliberations, we have strongly been in favor of a
20 uniform regulatory apparatus and not allowing
21 individual states to penalize providers more than
22 other states, which it sounds like Texas would like to
23 do, have more strict -- you know, we might be in this
24 setting more empathetic to states who wish to have
25 better work-arounds than the NRC does, but --

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1 (Laughter.)

2 MEMBER WILLIAMSON: -- to make things
3 worse than they are now seems like just
4 incomprehensible.

5 MEMBER GILLEY: May I respond? Again, if
6 we had the old Subpart J and it was not a
7 compatibility theme, the new Part 35, many states
8 would have remained the same as it was prior to the
9 implementation of Part 35. And you would have had
10 less restrictions, what is currently required of NRC.

11 DR. RATHBUN: Okay. When we come to the
12 part where we talk about solutions to some of these
13 things, I suspect that we will have some things to say
14 about that, how that came about.

15 Yes, Dr. Eggli?

16 MEMBER EGGLI: I would like to give the
17 other side of Dr. Van Decker's comment. Again, as I'm
18 a purveyor of preceptor statements, I guess is the way
19 I appear here, I preceptor about 15 people a year.
20 And I get calls from people who several years later
21 are moving to another state. And now the requirements
22 are different. And the training program that they
23 were in was not designed to meet the requirements of
24 the most restrictive of the agreement states.

25 And we have to tell these people they

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1 can't practice anymore because I cannot write them a
2 preceptor statement for the state that they want to
3 move for because our program wasn't designed to meet
4 the most restrictive of preceptor requirements among
5 the 34 agreement states. And it ends up being a
6 serious problem for the individual practitioners as
7 they try to move from state to state.

8 So Bill was talking about it from the side
9 of the affected individual. I see it from the side of
10 the purveyor, who has to essentially tell these people
11 that I'm changing their career choices because I can't
12 write in a preceptor statement.

13 DR. RATHBUN: So the categorization is
14 also making this issue more complex. Do we have
15 somebody on the phone who wants to talk?

16 (No response.)

17 DR. RATHBUN: Okay. Debbie?

18 MEMBER GILLEY: Just saying that there is
19 reciprocity between states and the agreement states
20 and NRC. So there are other mechanisms through
21 reciprocities by being listed on a license and a
22 non-agreement state or another agreement state and
23 coming into the new state versus using reciprocity as
24 the basis.

25 MEMBER EGGLI: Yes. Sadly sometimes these

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1 are first-time licenses for these individuals.

2 MEMBER GILLEY: And they're working at
3 broad-scope licenses that don't list them on a
4 license, --

5 MEMBER EGGLI: Yes.

6 MEMBER GILLEY: -- as I understand it.

7 MEMBER EGGLI: Yes.

8 DR. RATHBUN: Okay.

9 MEMBER NAG: I'm again Subir Nag,
10 radiation oncology. Radiation oncologists have two
11 major roles. One is external therapy. The other is
12 radiation implant of brachytherapy.

13 Not all radiation oncologists do both
14 equally. Most people do more external and less
15 brachytherapy. And if the regulations are
16 overburdensome, more and more radiation oncologists
17 will do less and less brachytherapy.

18 So that you are going to see brachytherapy
19 disappearing. Although medically it's very useful,
20 many radiation oncologists choose not to do these and
21 let their license lapse.

22 So I think if the NRC is not really -- you
23 may make some of the procedures not available because
24 people just don't want to go through this. And this
25 is a real possibility.

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1 And I will be presenting even in
2 brachytherapy an alternative tomorrow that may make
3 some people choose not to use radioactive implants.

4 DR. RATHBUN: Okay. So that may result in
5 changing the way somebody practices medicine. Is that
6 what you are saying?

7 MEMBER NAG: Yes.

8 DR. RATHBUN: Okay. Is there anybody else
9 in the back of the room who would like to speak? All
10 right. We'll put you in line behind this gentleman.

11 MR. LAMBERT: My name is Kent Lambert.
12 I'm here representing the American Board of Health
13 Physics. Because I understand that these proceedings
14 are transcribed verbatim and because I know my
15 limitations as a public speaker and because, as Mark
16 Twain once said and I quote, it takes more than three
17 weeks to prepare a good impromptu speech, --

18 (Laughter.)

19 MR. LAMBERT: -- I have prepared remarks.
20 The American Board of Health Physics was formed in
21 1958 and has granted over 2,000 certifications in
22 health physics over the last 48 years. Over 1,300
23 certified individuals are still active. Under current
24 regulations, only 53 certified individuals are
25 eligible to be a radiation safety officer based on

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1 their certification.

2 It's apparent that the certification board
3 requirements of part 35 were modeled after the ABHP
4 certification requirements. However, minor
5 differences between the two sets of requirements
6 prevent a blanket assertion by the American Board of
7 Health Physics that all of us diplomates prior to 2005
8 meet these requirements.

9 As a result, the current regulations
10 require that individuals certified prior to 2005 by
11 the American Board of Health Physics use a so-called
12 alternate pathway to become an RSO.

13 Consequently, it's more difficult for
14 individuals who have more post-certification
15 experience to become RSO than it is for recently
16 certified individuals, who by definition have less
17 work experience. As Lieutenant Commander Spock would
18 say, that is not logical.

19 The current regulations imply that
20 individuals certified prior to 2005 are less capable
21 of performing as radiation safety officer than those
22 certified subsequently.

23 However, there's no evidence to support
24 that premise. Therefore, the additional steps of
25 using the alternative pathway pose a burden upon

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1 individuals and licensees without a corresponding
2 increase in public or worker health and safety.

3 And I have to skip all that part about Dr.
4 Ritenour's petition. So I've got --

5 DR. RATHBUN: Did Mr. Spock say anything
6 else?

7 (Laughter.)

8 DR. RATHBUN: This is a joke because I
9 have a dog named Mr. Spock.

10 MR. LAMBERT: In summary -- okay. Then I
11 can go ahead. Dr. Ritenour's position offers a
12 solution to these issues. And by amending the
13 existing regulations to recognize individuals who are
14 certified by a board that was listed in Subpart J of
15 the old regulations for radiation safety officer, the
16 NRC would allow safety professionals that were
17 previously considered qualified to serve as radiation
18 safety officer on a medical use license to do so
19 without any additional hurdles.

20 The ABHP recognizes that Ritenour's
21 petition specifically focuses on the American Board of
22 Radiology and American Board of Medical Physics in
23 this discussion. However, the actual language, which
24 I just stated, is much more general. And, as such, it
25 includes recognition of individuals certified by the

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1 American Board of Health Physics.

2 In summary, the American Board of Health
3 Physics believes that as its current certificate
4 process effectively determines the competence of
5 professional health physicists, so did its past
6 processes.

7 Individuals certified by ABHP, both before
8 and after 2005, have demonstrated that they possess a
9 substantive foundation in health physics through study
10 and professional experience. And they have
11 demonstrated technical competence through successfully
12 completing the ABHP certification exam.

13 These credentials should be recognized by
14 the NRC as sufficient for the individual to serve as
15 radiation safety officer without discriminating based
16 on a date of certification.

17 DR. RATHBUN: Thank you.

18 DR. BROGA: Dean Broga. And as someone
19 certified by the ABHP, the ABR, and the ABMP for over
20 30 years, I would like to ditto that remark.

21 DR. RATHBUN: It looks like you are the
22 answer to the problem.

23 DR. BROGA: My other concern is that the
24 staff has now broken out the RSO at test stations to
25 categorical areas. And this can create a huge problem

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1 for new categories being added at a licensee.

2 For instance, the RSO for a gamma knife is
3 broken out. So if a community hospital that is using
4 one of its oncologists as an RSO because they have no
5 full-time physicist there now wants to add a gamma
6 knife, that physician is going to have to go through
7 some other gamma knife somewhere in the United States,
8 convince the RSO there to take him under his wing for
9 some period of time undefined, and then to attest to
10 him. I think that's a huge problem. And it may limit
11 the scope of what a lot of facilities can do.

12 A couple of people have asked me about
13 this already, even just adding seeds. And I said,
14 "You have an authorized physician user RSO. This is
15 a huge problem to get them named and attested to to
16 use these materials."

17 The more esoteric or the newer the
18 practice or the procedure that is being implemented,
19 the bigger the problem is going to be. The first
20 facility is obviously going to have to have the Adam
21 and Eve concept. Who is going to be the RSO for there
22 is no RSO to attest to you? And then everybody else
23 who wants to be an RSO added all over the country are
24 going to have to go to that facility to get attested
25 to, which seems to me traceably burdensome for the

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1 medical facilities.

2 DR. RATHBUN: Dr. Malmud?

3 CHAIRMAN MALMUD: May I ask a question of
4 our guest?

5 DR. BROGA: Yes.

6 CHAIRMAN MALMUD: And that is, how would
7 you propose that physicists be certified as competent
8 RSOs and in new technologies such as the gamma knife?
9 I mean, it's an issue that we have always dealt with
10 historically. And I'm not taking a position on it.
11 As we add a new technology, we somehow learn it on the
12 job, by sometimes visiting other institutions.

13 What would you propose to protect the
14 public from the application of new technology, in
15 which those who are applying it have no evidence of
16 experience?

17 DR. BROGA: I believe that with almost any
18 new -- first of all, the principles of radiation
19 protection and safety haven't changed for any of these
20 methodologies. They may be new treatment
21 methodologies, but the basic concepts of shielding
22 time, distance, interlocks do not change.

23 And most of the people who are
24 board-certified and/or previously had historical
25 experience can certainly work with the manufacturers

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1 to learn the variance in concepts here, as would be
2 the physicist requiring to get manufacturers' training
3 as well as the physician to get manufacturers'
4 training when the new modality is brought in.

5 I don't know why a similar concept can't
6 be taken for the radiation safety officers. There are
7 certainly other people, not necessarily RSOs, who
8 could provide that training.

9 CHAIRMAN MALMUD: So you are suggesting
10 that the system as it has stood in place for decades
11 is actually functioning well and shouldn't be altered,
12 namely that those of us who are practitioners, those
13 of us who are physicists learn the new technology on
14 the job with the database and the knowledge base that
15 we have had over the years and that we now employ with
16 the new technique?

17 DR. BROGA: I believe that is what I am
18 saying. And I believe that is only proven by
19 inspection.

20 CHAIRMAN MALMUD: That is what I wanted to
21 hear you say. Thank you. So you believe that the
22 system as it was was not proven to be defective.

23 DR. BROGA: I don't know where it was
24 broken, but that was never pointed out to me before,
25 sir.

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1 CHAIRMAN MALMUD: Thank you.

2 DR. RATHBUN: Okay. Thank you.

3 MR. MOWER: Herb Mower. That's M-o-w-e-r.

4 (Laughter.)

5 MR. MOWER: American College of Medical
6 Physics. Following up on what Dean Broga said, one of
7 the things that we learned as we were being trained
8 for our profession is not how to by rote apply two
9 plus two equals four but how to think to adapt those
10 things that we have learned to new situations, which
11 can also be new modalities. That's part of the
12 process of being a professional.

13 The regulations that had come out with
14 strict programs. And I don't believe there's any
15 strong documentation to show that they were previous
16 programs that needed to be addressed or corrected.

17 I think the NRC's goals should be to
18 provide access to the greatest number of people, to
19 the highest quality diagnostic and therapeutic
20 procedures while supporting good radiation safety
21 practices. And with the rules as they have come out,
22 I feel that it is going to very much limit this
23 process for many of our people.

24 DR. RATHBUN: So you are telling me if it
25 wasn't broken, it shouldn't have been fixed?

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1 MR. MOWER: One can always improve, but
2 one should not break that which is not broken.

3 DR. RATHBUN: Okay.

4 MEMBER WILLIAMSON: It is Jeff Williamson,
5 member of the ACMUI. Yes, in fact, I think with any
6 new regulation, there is supposed to be some process
7 -- I think the OMB requires it -- that the burden on
8 the regulated community be balanced against the
9 benefit. And I think I am told now that in order for
10 this regulation, this T&E regulation, to work, the ABR
11 is going to have to review thousands of old
12 applications for board certification that were
13 previously filed over the years, including mine, as it
14 turns out, since I do not satisfy the recency of
15 training requirement.

16 DR. RATHBUN: You didn't make that yet?

17 MEMBER WILLIAMSON: No. That's right.
18 They are going to bill the individual certificate
19 holders for this process. This was a cost I'm sure
20 that was not anticipated in the OMB analysis. So, you
21 know, I think there is a strong I would presume
22 regulatory basis or legal basis for going back and
23 scrutinizing this concept of effective date of
24 certification approval because this was not a concept
25 that was considered in the original deliberations and

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1 I'm sure was not part of that analysis. That's point
2 one, I believe.

3 I also would like to point out that the
4 ACMUI Subcommittee on Training and Experience was the
5 group that, perhaps now to our discredit, drafted the
6 original rule language for what is now the current
7 training and experience requirement.

8 Unfortunately, there were some small
9 changes made, a few words here and there that were
10 inserted, both I'm sure through the machinations of
11 the staff as well as the Commission. One has already
12 been alluded, the use of the word "competency."

13 And I think the second point I would like
14 to make is that historically the intent of the ACMUI
15 in drafting this rule language was that the existing
16 Subpart J boards, almost without exception, should be
17 approved without question.

18 We made every effort to try to diligently
19 parrot what we thought was a reasonably general gloss
20 on the eligibility requirements for both the ABR, the
21 ABMP, and other certifying organizations. We also
22 made the initial recommendation that the Subpart J
23 legacy boards be hard-wired into the regulation and
24 that the case-by-case review commence only with new
25 boards that might materialize or in reverse could be

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1 exercised if an existing board appeared to be
2 deviating from their past practices and constituting
3 a new source of health and safety concern.

4 This was, unfortunately, ignored and
5 removed, which defeated the whole purpose and I think
6 has essentially caused all of this complexity because
7 of interpretation of a few words.

8

9 could be exercised

10 DR. RATHBUN: Let me make sure. And I am
11 new to this. What you're telling me is, in your
12 working group, these were issues that you had kind of
13 worked out. And when you saw the ensuing rule, you
14 saw words come in or things that didn't go the way you
15 thought they were going. Is that what you're telling
16 me?

17 MEMBER WILLIAMSON: That's correct. I'm
18 sure that as an Advisory Committee, what we thought
19 has no official standing or legal standing --

20 DR. RATHBUN: That's right.

21 MEMBER WILLIAMSON: -- in this matter, but
22 this was, for the record, the intent.

23 DR. RATHBUN: The group.

24 MEMBER WILLIAMSON: And this was the
25 original language was crafted with these assumptions

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1 made in mind basically.

2 DR. RATHBUN: Okay.

3 MEMBER WILLIAMSON: And the words were no
4 longer adequate when the assumptions were changed.

5 DR. RATHBUN: Okay.

6 MEMBER WILLIAMSON: The language was no
7 longer adequate to ensure the goals of the regulation
8 once the various protections grandfathering
9 protections were stripped out by the Commission.

10 DR. RATHBUN: Okay. You said put
11 grandfathering down here, too.

12 CHAIRMAN MALMUD: Mr. Lieto wanted to make
13 a comment.

14 DR. RATHBUN: Yes, sir.

15 MEMBER LIETO: Well, actually, it's just
16 to follow up a point that Jeff's made in that another
17 item that this Committee opposed, not on one occasion
18 but on several, was the preceptor statement. We were
19 opposed to it.

20 The only place we saw that was meant to be
21 in the alternate pathway, where training and
22 experience had to be submitted and that there was an
23 added station by an individual, that they had
24 documentation that that information is accurate and
25 complete. It was never meant to be tied to the board

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1 certification route.

2 And, like I said, it was not on one
3 occasion but more than one where this went all the way
4 up to the commissioners, where we were mandated that
5 this had to be in there.

6 And so I guess it kinds of gets back to
7 we're like a prophet in our own land. And what we say
8 seems to not bear a lot of weight. And we need the
9 input of the regulated community to come here and say
10 that maybe there was some validity to what we said
11 several years ago.

12 DR. RATHBUN: Dr. Eggli?

13 MEMBER EGGLI: If I may complete the
14 circle that they have started here --

15 (Laughter.)

16 MEMBER EGGLI: -- by saying that the
17 intent of the alternate pathway was to allow qualified
18 people who were not board-certified to become
19 authorized users.

20 Now what we have created is a whole bunch
21 of board-certified people who can't become authorized
22 users by the board certification pathway. We have
23 created approximately a two-year gap of
24 disenfranchised people between the effective date in
25 October 2005 and when the boards qualified and then,

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1 finally, because of the liability now associated with
2 the prescriptive attestation, the alternate pathway,
3 which could salvage all of these people, is
4 functionally dead because preceptors will not write an
5 alternate pathway statement because of liability.

6 Since the new regulation came into effect,
7 I have not written a single alternate pathway
8 preceptor statement and will not.

9 DR. RATHBUN: That's pretty clear. Okay.
10 All right. What I think I would like to do next is to
11 be --

12 CHAIRMAN MALMUD: May I --

13 DR. RATHBUN: Sure.

14 CHAIRMAN MALMUD: I think there is one
15 other point that we discussed. I apologize --

16 DR. RATHBUN: That's okay.

17 CHAIRMAN MALMUD: -- for perhaps being
18 redundant. The alternate pathway route is one that
19 about 20 percent of radiology residents must take
20 because they will not have passed their boards first
21 go-around. So the alternate pathway requirements turn
22 out to be requirements that the board itself must
23 adhere to, recognizing that about 20 percent of its
24 graduates will have a gap between completion of their
25 residencies and board certification, assuming that

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1 they will pass the boards on the second go-around.

2 Therefore, the boards must teach to the
3 alternate pathway. Therefore, the NRC in a de facto
4 means has established the academic criteria for the
5 boards.

6 If the boards must teach to the alternate
7 pathway, then the NRC has established the teaching
8 requirements. Some of these teaching requirements are
9 not logical and cannot be met by the board.

10 I think we have reached an accommodation
11 with regard to the definition of the number of hours
12 required of training for radiology residents -- I'm
13 speaking of radiology residents now -- and that their
14 experience can include clinical work as well as
15 didactic lectures.

16 Otherwise the didactic lectures in a
17 definition that was debated in this Committee some
18 months ago would have taken up the entire time of
19 their training period in nuclear medicine. And they
20 would have had no clinical experience in nuclear
21 medicine in order to satisfy the requirements for
22 nuclear medicine, physics, and radiopharmacy.

23 I think we have reached an accommodation
24 on that issue.

25 DR. RATHBUN: It sounds like you did on

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1 that.

2 CHAIRMAN MALMUD: But my point is that the
3 alternate pathway has converted from an assistance to
4 a liability in terms of getting the radiology
5 residents', who do constitute the largest group of
6 residents finishing each year, eligibility for
7 authorized user status.

8 And, interestingly, the states that would
9 be most negatively affected by this are the states
10 which demanded higher standards to begin with because
11 they are the ones who will not have radiologists able
12 to take positions in small departments -- I think one
13 of the states referred to these as Mom and Pop
14 operations -- because they cannot get authorized user
15 status.

16 So there is this unintended consequence of
17 good intentions driven by the state, not driven by the
18 NRC but responded to by the NRC on behalf of the
19 states. And that's the history of how this evolved.

20 DR. RATHBUN: Okay.

21 CHAIRMAN MALMUD: It was a classic case of
22 the tail wagging the dog.

23 I'm sorry. I think you have --

24 MR. MOORE: Yes.

25 DR. RATHBUN: Scott. Okay. Good.

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1 MR. MOORE: Dr. Malmud, that's an issue,
2 you know, that you and the Committee have brought up
3 consistently for a number of years, including when the
4 Part 35 was being developed.

5 And we certainly recognize that it's an
6 impact of the regulations that we're aware of, but it
7 certainly was not an intent of the regulations.

8 CHAIRMAN MALMUD: Correct.

9 MR. MOORE: The regulations recognize
10 three alternatives for practicing grandfathering,
11 board certification, or the alternate pathway. And
12 the programs that the boards come up with on their own
13 are those that the boards choose to develop, whether
14 they choose to go with that that's required by the
15 alternate pathway because numbers of graduates don't
16 pass or can't apply is a decision that the boards
17 themselves make. We recognize that it does lead to an
18 impact of the way the regulations are written.

19 CHAIRMAN MALMUD: I agree with you up to
20 the point where you say it's a matter for the boards
21 to choose. The boards' hands are tied into the
22 standards of the alternate pathway. If the boards
23 recognize the reality -- and they do -- that about 20
24 percent of their graduates will not pass the boards
25 the first year.

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1 If that's the case, then 20 percent of the
2 residents coming out will not be qualified to be
3 authorized users except through the alternate pathway.

4 If that's the case, then the boards must
5 teach to the alternate pathway. Otherwise, 20 percent
6 of our residency graduates in diagnostic radiology we
7 know will not be authorized users to staff these small
8 departments scattered in these Western states that
9 seem to be most concerned about this issue.

10 So that it was an unintended consequence.
11 And I said very clearly not the intent of the NRC but
12 a response of the NRC to this requirement. In fact,
13 the boards must teach to the NRC requirements or 20
14 percent of their trainees will not be able to take
15 positions in small departments and be authorized users
16 within and until they're board-certified unless the
17 board itself has met the standards of the NRC.

18 And the standards of the NRC became
19 extremely prescriptive. That prescriptive standard of
20 the NRC basically told the boards "This is what you
21 are going to teach or 20 percent of your graduates
22 will not be authorized users, eligible to be
23 authorized users."

24 MR. MOORE: Right.

25 CHAIRMAN MALMUD: This creates a status of

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1 conflict between the mission of the NRC, which is,
2 correctly, the protection of both users and the public
3 from unnecessary radiation risk and intrusion into
4 what should be taught by the boards, which I believe
5 the boards have done a good job in for the last 60 or
6 70 years. Nothing is perfect, but they have done a
7 good job.

8 MR. MOORE: Thank you.

9 CHAIRMAN MALMUD: And now we have lined up
10 with the boards being told "This is what you will
11 teach," not that we, the NRC, wish to do this to you,
12 but a couple of states have concerns. Those concerns
13 are addressed by us. And in addressing the concerns
14 of a couple of states, we are now going to flip it and
15 become the academic adviser to the boards,
16 unintentionally, an unintended consequence;
17 nevertheless, one that we have to live with.

18 I believe we worked out a solution to that
19 in how we define the number of hours that are going to
20 be taught to radiology residents in their rotations
21 through nuclear medicine. They're less prescriptive
22 now. They don't demand didactic classroom hours.

23 However, it is the way things evolve. And
24 the same thing appears to be a problem for the
25 physicists in a different way. And, of course, the

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1 most disappointing thing has been the assertion of a
2 word that we all agreed would not be there.

3 That is a betrayal of the confidence of
4 the Committee in making a recommendation since the
5 Committee was very specific, repetitively so in kind
6 terms in more robust discussions, to use a term that's
7 favored now in Washington, in our opposition to that
8 word. And, yet, the word somehow appeared. That is
9 a big disappointment for us.

10 Dr. Nag?

11 MEMBER NAG: Yes. And I listened to what
12 you said. It's not only the alternative pathway. The
13 NRC is basically telling the board that we will
14 recognize you only if you have these in the
15 curriculum.

16 So it's not only for the alternative
17 pathway. It's for the board itself because if the
18 board did not have all of those requirements, the
19 board would not be recognized. And, therefore, to
20 take that into recognition, the board has to
21 incorporate all of that into their curriculum.

22 CHAIRMAN MALMUD: Are you speaking to the
23 Radiology Board or the radiation oncologists?

24 MEMBER NAG: Radiation Oncology Board.

25 CHAIRMAN MALMUD: Because in radiology, I

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1 think there was a collegiality on the part of the
2 American Board of Radiology in saying, "Yes, we agree
3 we should teach A, B, C, and D. But don't tell us how
4 many hours specifically of each."

5 I think that was the spirit, not the
6 specific words but that was the spirit. I thought
7 that the boards were trying to be as collegial as
8 possible.

9 MEMBER NAG: Yes.

10 CHAIRMAN MALMUD: But when it became
11 prescriptive as to the number of hours in classroom
12 versus definition of didactic, then it became truly
13 intrusive and obstructive to the goals that we wanted
14 to achieve.

15 But I think there was a collegiality
16 demonstrated on that issue between the NRC itself and
17 the board in trying to achieve an agreement that was
18 workable, I hope.

19 MEMBER NAG: My point was that you're
20 saying that it was only to meet those 50 percent who
21 are not board-certified. But even those who are
22 board-certified, the American Board of Radiology has
23 to incorporate all the NRC requirements so that they
24 would become recognized by the NRC. That's all the
25 point I'm trying to make.

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1 CHAIRMAN MALMUD: Yes. I agree with your
2 point except I think that I'm speaking on behalf of
3 the ABR. Perhaps I shouldn't. I was impressed with
4 their collegiality in wanting to respond to the
5 request of the NRC in teaching things but not in being
6 prescriptive as to the numbers of hours and what the
7 definition is of a didactic session. I think that's
8 where the differences lay.

9 I think that that issue was resolved. The
10 issue that was not resolved -- I think that issue was
11 resolved, but the issue that was not resolved was the
12 insertion of the word "competency" again. When we
13 protested in every way humanly possible, it didn't
14 belong there.

15 MEMBER NAG: We have an ABR representative
16 behind you.

17 CHAIRMAN MALMUD: Please speak on behalf
18 of the ABR.

19 DR. MORIN: I am Richard Morin for ABR
20 trustee. I just want to amplify Dr. Malmud's comments
21 in one area that the Advisory Board may not be
22 familiar with. The board itself doesn't demand
23 curriculum in everything else that it does. It's the
24 Radiology Residency Review Committee that defines the
25 curriculum. This is really an exception.

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1 And the board did go out of their way.
2 And any certification board in general doesn't define
3 the curriculum. It's the practice or the
4 professionals in that field that generate what the job
5 is. A test content outline is developed from that.
6 The curriculum flows from that. And then the board is
7 responsive to what is the nature of the job.

8 Now, this was a big exception. And I
9 think I will pass on your remarks to the president at
10 the time that was quite collegial, I think.

11 And so this is a major, major effort. And
12 it does have downstream ramifications for
13 professionals as they leave their residencies.

14 DR. ALDERSON: Phil Alderson, President of
15 the American Board of Radiology. I wanted to amplify
16 that comment a bit further and provide one
17 clarification. For first-time takers of the American
18 Board of Radiology, only about ten percent fail, not
19 20.

20 But, in fact, the points made by Dr. Morin
21 are quite correct. It was the programs that had to
22 accommodate. The board through a broad communication
23 matrix nationwide made it quite clear that it would
24 accept only the types of training that you have been
25 discussing, the more rigorous types of training. And

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1 if those weren't provided, then we would not authorize
2 as an authorized user eligible person any radiology
3 diplomate. So the RRCs in the programs had to provide
4 that level of activity.

5 And to say how it exacerbated the problem
6 of availability that you have been discussing, in
7 fact, some programs did not. Some programs
8 acknowledged that they could not provide that
9 particular level. And so they told the board that our
10 own diplomates or our own candidates will not, in
11 fact, be AU-eligible.

12 And so, in fact, it was even worse than
13 the problem Dr. Malmud pointed out, but many, many
14 more radiology residents around the country aren't
15 able to do this in any regard.

16 DR. ROYAL: My name is Henry Royal. I'm
17 the Executive Director of the American Board of
18 Nuclear Medicine. And I just wanted to also confirm
19 what Leon said, the effect of these regulations on the
20 training requirements that boards impose.

21 If there is any rationale behind the --
22 for example, if we look at 35.390, if there is any
23 rationale behind asking for 200 hours of classroom and
24 laboratory training in 390, then the boards would want
25 to provide that training, but one of the problems is,

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1 as we have heard today, that there is a lot of overlap
2 between the 80 hours for 390, the 80 hours for 394,
3 the 80 hours for 396. And it is hard to understand
4 where the 200 hours come from.

5 So, on the one hand, the boards would like
6 to meet these requirements because we would like to
7 believe that there was some rationale --

8 DR. RATHBUN: Person on the phone, could
9 you identify yourself? Hello?

10 DR. METTER: I am from the Texas Radiation
11 Advisory Board, a member on the Medical Committee from
12 Texas. And we have also our Vice Chair of the Texas
13 Radiation Advisory Board for Texas, Dr. Ian Hamilton.
14 And I'm Dr. Darlene Metter.

15 DR. RATHBUN: Okay. Can we just hold your
16 comments here because we have a gentleman from the
17 American Board of Nuclear Medicine speaking. And then
18 I'll come back to you.

19 DR. METTER: Yes. Thank you.

20 DR. HAMILTON: Sorry. We didn't realize
21 we were making comments. We weren't sure we were
22 hooked up.

23 DR. RATHBUN: Okay. We'll get back to you
24 in just a minute.

25 DR. METTER: Thank you.

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1 DR. ROYAL: So the bottom line is that the
2 regulations for classroom and laboratory do affect the
3 boards and the boards' requirements.

4 MEMBER NAG: Before you leave, could you
5 clarify what you meant by you support Dr. Leon Malmud?
6 He made a lot of comments. So which portion of that
7 are you supporting?

8 (Laughter.)

9 MEMBER NAG: Could you be more specific?
10 I think that would help the matter. I want to be
11 specific.

12 DR. ROYAL: The specific thing that I was
13 supporting him on is that the training and education
14 requirements do affect what boards then include in
15 their regulations. So, even though the NRC
16 regulations say that the boards are not required to
17 meet the classroom and laboratory standards for the
18 alternative pathway, the actual reality is that they
19 feel that they must meet those requirements.

20 MEMBER NAG: I said basically the same
21 thing. You know, I am glad that you are pointing that
22 out.

23 DR. RATHBUN: Should we hear from those
24 people on the phone? All right. Texas, could you now
25 give your talk or your comment?

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1 DR. METTER: Okay. Dr. Hamilton, did you
2 want to make a comment or did you want me to make my
3 comments?

4 DR. HAMILTON: Go ahead and make your
5 comments. Yes. Dr. Metter has been very succinct in
6 stating our position and helping Mr. Ford, our chair,
7 and myself put our position statements together along
8 with Kim Howard, who is the chair of our Medical
9 Subcommittee. Go ahead.

10 DR. METTER: Well, I had four specific
11 concerns. And I agree with Dr. Royal regarding the
12 maintaining the training and experience requirements
13 as they need to be strict because we are dealing with
14 therapy of a radionuclide, particularly I-131, that is
15 really one of the most serious radiopharmaceutical we
16 use routinely for therapy in nuclear medicine.

17 And my first comment would be that the
18 current proposal has a major impact on the standard of
19 patient care and public safety. The ACGME, which is
20 our accrediting body for our training programs, sets
21 and monitors the training requirements. And we
22 maintain a tight relationship with our board
23 certification requirements, as Dr. Royal has said.
24 And it does ensure a quality standard for patient
25 care.

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1 If we allow certification to be a
2 non-standard or generic training process, you really
3 have an unknown quality of training you receive and,
4 hence, the question of quality of patient care,
5 particularly likely if you lowered the standards of
6 training and experience.

7 And also with this unconfirmed standard,
8 you are unable to confirm the fulfillment of the
9 training requirements other than a certificate, which
10 can be made by any organization.

11 Number two, the major inherent differences
12 between therapeutic and diagnostic procedures are very
13 important because diagnostic procedures use routinely
14 a low energy short half-life tracer, namely
15 technetium. And our therapy that is being in question
16 is sodium iodide, which is a long half-life, high
17 energy radionuclide that has gamma and beta emissions
18 and actually can destroy tissues and if used in the
19 wrong amount can actually kill the patients by
20 destroying their bone marrow.

21 And if someone doesn't understand this,
22 that training and experience is the most important
23 part of therapy with radioactive sodium iodide, then
24 they really should not be doing this procedure.

25 Number three is that the proposal for the

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1 training and experience that is being proposed is
2 really a passive learning experience. And currently
3 in our ACGME-accredited institutions, we do both
4 passive and active training. And we confirm our
5 individual learning the information through exams,
6 either at the end of the course, our annual in-service
7 exam or through board certification, that has the
8 individual physicians on this very important
9 information.

10 And some of these courses that have been
11 proposed are eight consecutive days of ten-hour days
12 in physics. And unless you really, really like
13 physics, I think after one hour, it's going to be very
14 questionable how much you have learned after just one
15 hour.

16 And there have been studies shown that
17 people sitting and learning in a classroom only retain
18 about 20 percent of that knowledge at the end of one
19 hour. And this decreases exponentially over time.

20 DR. RATHBUN: This is why you're getting
21 a break shortly. This is a great statement.

22 DR. METTER: And I have just a couple of
23 more. The financial impact if you have
24 nonstandardized programs, who will actually check them
25 and monitor them? Right now the ACGME currently

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1 monitors and trains in the training programs with
2 regular site visits and reviews. And this is very
3 costly.

4 I just was at an ACGME meeting yesterday.
5 And I asked one of the chairs what it cost just for
6 them to review 30 programs. And it's \$45,000 for the
7 ACGME just to mix 2 days' review of 30 programs. So
8 it's going to be very costly for the taxpayers to
9 monitor and review these processes to ensure a quality
10 standard of training and experience.

11 And, lastly, access to basic science and
12 training and experience needs to be through an
13 accredited institution. And these institutions are
14 available all throughout the country. And, like for
15 our institution, I do not know of any time where we
16 have refused to accept people from outside to come and
17 participate on a preceptorship regarding our training
18 and experience in radiology or in nuclear medicine.

19 And that's what I have to say.

20 DR. RATHBUN: Okay. Dr. Metter, Dr.
21 Malmud has a comment for you.

22 CHAIRMAN MALMUD: Dr. Metter?

23 DR. METTER: Yes?

24 CHAIRMAN MALMUD: May I ask, what is your
25 recommendation to the Committee? I understood each of

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1 the points that you made, but I am not sure I
2 understand what you wanted to achieve.

3 DR. METTER: What I want to achieve is to
4 maintain a high quality of the standards for training
5 and experience for an authorized user. And I believe
6 depending what category -- are you for 35.390 or
7 35.292 or 35.294?

8 It's just that I would like to maintain a
9 high standard of quality of training and experience
10 for the authorized user being attained in ACGME
11 institutions to assure the quality of training and
12 experience of the authorized user because of the
13 hazards of therapy for I-131.

14 DR. RATHBUN: And is the real issue we're
15 talking about here the compatibility category?

16 DR. METTER: And the compatibility is not
17 compatible, correct. These are people. This is not
18 interstate industry. And lowering the standards would
19 be wrong. It would majorly impact on patient care and
20 the public safety.

21 CHAIRMAN MALMUD: Dr. Metter?

22 DR. METTER: Yes?

23 CHAIRMAN MALMUD: We thank you very much
24 for your comments. We fully agree with you that
25 standards should not be lowered and that we do feel a

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1 strong sense of responsibility for the health and
2 welfare of both the public and the providers. And we
3 are very supportive of your maintaining those
4 standards.

5 DR. METTER: Thank you.

6 DR. HAMILTON: Thank you very much. All
7 we are worried about is the gate-keeping, like Dr.
8 Metter has stated, and to maintain that safety that we
9 are all talking about.

10 DR. RATHBUN: Okay. Let's take Dr. Eggli
11 and then Dr. Nag and then Dr. Williamson.

12 MEMBER EGGLI: First of all, I want to
13 address Society of Nuclear Medicine's comment on the
14 200-hour requirement for Part 390. I think the 200
15 hours is a bit over the top. I think I am on the
16 record as having said that back at the original
17 considerations.

18 It doesn't take 200 hours to learn the
19 radiation safety part of high-dose iodine therapy.
20 The part that, in fact, the 200 hours detracts from is
21 the clinical decision-making, the patient evaluation,
22 the therapy planning, which are the key parts of
23 administering radioactive iodine to a patient with
24 thyroid cancer or, in fact, any other therapeutic
25 application of radiopharmaceuticals.

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1 either Dr. Alderson for the American Board of
2 Radiology or Dr. Royal for the American Board of
3 Nuclear Medicine to comment on what they consider the
4 important parts of the learning experience here.

5 DR. RATHBUN: Hold on here. We're getting
6 out of process. I need to --

7 MEMBER NAG: That's fine.

8 DR. RATHBUN: Okay. You're okay?

9 MEMBER NAG: I will back off.

10 DR. RATHBUN: Are you going to back off?
11 Because I promised you next. And then I need to get
12 Scott. And then I need to get --

13 MEMBER WILLIAMSON: Since we have spent
14 this time discussing the State of Texas' objections to
15 the current training and experience requirement, I
16 wish somebody would make it clear what it is in the
17 current regulation they object to.

18 DR. RATHBUN: Okay. I think State of
19 Texas is talking, really, about the compatibility
20 category. And I --

21 MEMBER WILLIAMSON: What is in their view
22 incompatible with the existing requirement? What is
23 it they want to do that the current requirement
24 doesn't do? It just would be helpful if they would
25 lay out briefly what is the material dispute here,

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1 material basis of the dispute.

2 DR. RATHBUN: Here is my problem. I'm
3 looking at a bunch of really tired people. And what
4 I would really like you to do is to go away and take
5 a break.

6 (Laughter.)

7 DR. RATHBUN: I think that would be better
8 because let me tell you what Ashley and I would like
9 to do during the break is to review our notes and put
10 the issues out in order because I think we have come
11 to a point where we have kind of run through all of
12 our issues.

13 I realize we need clarification from
14 Texas, but I think that might be we could shift, then,
15 from listing the issues or the areas of problem to
16 some potential solutions. And that might work.

17 Okay. You can be my last speaker before
18 the break.

19 DR. ALDERSON: All right. This is Dr.
20 Alderson at request from Dr. Eggli's comments. I'll
21 make it very brief. I just want to say that I
22 strongly support and I think the American Board of
23 Radiology would strongly support what he had to say.
24 It is hard to believe that in a clinical environment
25 anything could be ALARA without a good sense of

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1 clinical judgment about when radiation should be used
2 and how it should be used.

3 DR. RATHBUN: Okay. With that, I'm going
4 to declare a break. And I would like if you all could
5 come back at 3:00 o'clock.

6 (Whereupon, the foregoing matter went off
7 the record at 2:44 p.m. and went back on
8 the record at 3:08 p.m.)

9 CHAIRMAN MALMUD: Ladies and gentlemen, we
10 are ready to resume our session, and we look forward
11 to another active, stimulating, and robust discussion.

12 DR. RATHBUN: Okay. Can you all hear me?
13 Can you hear me now?

14 PARTICIPANT: Yes.

15 DR. RATHBUN: All right.

16 DR. HAMILTON: Before you start, can you
17 hear us in Texas?

18 PARTICIPANT: Maybe.

19 (Laughter.)

20 DR. METTER: Yes, we can.

21 DR. HAMILTON: Good. Okay. We want to
22 make sure that we're plugged in. Thank you. Now we
23 can start.

24 DR. RATHBUN: Thank you.

25 Okay. What we tried to do quickly at the

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1 break was to go through the issues and try to get
2 them, you know, into one standard list. So let's just
3 go through them. This is not by order of importance
4 or anything else. It's just how it came out in the
5 discussion.

6 Okay. Number one, the preceptor statement
7 has associated with it liability, redundancy,
8 inconsistent application, and we did hear you about
9 the word "competency," and understand.

10 Okay. A lot of the -- yes.

11 MEMBER WILLIAMSON: Well, there was
12 another point in that --

13 DR. RATHBUN: Okay.

14 MEMBER WILLIAMSON: -- it asks you from
15 time to time to attest to the unattestable --

16 DR. RATHBUN: Okay.

17 MEMBER WILLIAMSON: -- because of, you
18 know, changes in technology.

19 DR. RATHBUN: Attest to the unattestable.

20 MEMBER WILLIAMSON: It asks you to
21 represent competency of individuals --

22 DR. RATHBUN: Okay.

23 MEMBER WILLIAMSON: -- in areas where you
24 have no experience with it.

25 DR. RATHBUN: And that ties to that,

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1 doesn't it?

2 MEMBER WILLIAMSON: Well, that's
3 different.

4 DR. RATHBUN: Okay. Okay. I like that,
5 too. Maybe it's not a word, actually.

6 (Laughter.)

7 DR. RATHBUN: Incomprehensible. We'll
8 make it up. Okay. Very clearly -- yes, sir.

9 DR. BROGA: You didn't include the
10 difficulty of obtaining it with more esoteric users.

11 DR. RATHBUN: Okay. Oh, wait. We're out
12 of control. Can you -- we're out of control, because
13 the translator/reporter doesn't know who's talking.

14 PARTICIPANT: We're getting a lot of echo.

15 PARTICIPANT: We are getting it here in
16 Texas as well. Tremendous echo.

17 DR. BROGA: Dean Broga. I just wanted to
18 add the --

19 PARTICIPANT: Here in Texas we can still
20 understand.

21 DR. RATHBUN: One second. Person on the
22 phone, could you guys hold again? Could you hold just
23 a second and we'll come right back to you.

24 (Off the record discussion.)

25 DR. RATHBUN: We're going to send you,

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1 Richard, the list.

2 MR. RATLIFF: Yes, that would be helpful.

3 DR. RATHBUN: Excuse me?

4 MR. RATLIFF: Yes, that would be good.

5 Thank you.

6 (Off the record discussion.)

7 (Applause.)

8 DR. RATHBUN: Okay.

9 DR. BROGA: Do I have to say that live?

10 I wanted to make sure we added the difficulty
11 obtaining attestation for more esoteric uses.

12 DR. RATHBUN: Okay. More esoteric uses.

13 MS. WASTLER: Difficulty of obtaining.

14 DR. RATHBUN: Difficulty of obtaining
15 same. Difficulty of obtaining same -- difficulty of
16 obtaining certain -- that's all right.

17 MS. TULL: Is this what we want?

18 DR. RATHBUN: Okay. Is that looking good?

19 PARTICIPANT: Yes.

20 PARTICIPANT: That's fine.

21 DR. RATHBUN: Okay. The impact of the
22 effective date, is that too neutral, or would you like
23 to add some words to that?

24 (Off the record comments.)

25 DR. RATHBUN: Okay, 200 hours. All right,

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1 it's interesting. Now Texas, we're getting into No.
2 5, the compatibility issue. And would you like to
3 give us your position again?

4 MR. RATLIFF: Yes, this is Richard Ratler.
5 Dr. Metter and Dr. Ian Hamilton have been on the line.
6 But our Radiation Advisory Board's position was that
7 our regulations as they currently exist were more
8 stringent, especially on the therapy; and when the NRC
9 changed the compatibility from compatibility C to
10 compatibility B, it has impacted our ability to keep
11 our regulations in the way that the Radiation Advisory
12 Board felt they should be.

13 DR. HAMILTON: That's exactly the point we
14 were trying make. Thank you, Richard.

15 DR. RATHBUN: All right. Hang on a
16 second.

17 (Off the record comment.)

18 DR. RATHBUN: All right. I'm sorry. We
19 were sending you another email. Could you just say
20 that again and Andrew is here. So he can help with
21 the compatibility categories. Would you say it again,
22 Richard?

23 MR. RATLIFF: Yes. You know when we
24 developed our rules, changed them on medical, we have
25 stricter requirements on iodine therapy and when the

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1 compatibility category was changed from a C which
2 would let us continue to a category B, that has
3 limited our ability to remain compatible by keeping
4 our rules with the stricter requirements.

5 DR. RATHBUN: Okay. Scott, you're going
6 to address that further, aren't you, the states'
7 position, but it doesn't have to be right now.

8 MR. MOORE: Not now.

9 DR. RATHBUN: Okay. Dr. Malmud.

10 CHAIRMAN MALMUD: This is Leon Malmud.
11 May I ask you a question in Texas?

12 MR. RATLIFF: Yes.

13 CHAIRMAN MALMUD: Can you give a concrete
14 example of how something has been altered with respect
15 to your imposing more strict requirements than the NRC
16 has?

17 MR. RATLIFF: Yes. What our current roles
18 require is the actual training. You can't go the 80
19 hours. You have to have your training at ACGME
20 approved facilities.

21 CHAIRMAN MALMUD: They can't do the
22 commercial courses for physics.

23 MR. RATLIFF: There is no alternative
24 pathway like you've seen in the NRC rules for the
25 therapy.

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1 CHAIRMAN MALMUD: I'm still -- Can you
2 give me a concrete example?

3 MR. RATLIFF: Well, basically what we have
4 is physicians many times come in who have not had the
5 training in all of the didactic and clinical but they
6 want to come in to the alternative pathway and think
7 they meet that requirement. So we take each of those
8 cases individually to the medical committee of our
9 Texas Radiation Advisory Board for them to look at the
10 training to determine even though it may meet the NRC
11 requirements, is it adequate for what our medical
12 advisory board feels would be acceptable.

13 MR. MOORE: This is Scott. To answer Dr.
14 Malmud's question, Richard, you're saying that Texas
15 would require for the 80 hours ACGME training.

16 MR. RATLIFF: Correct.

17 MR. MOORE: And NRC's requirements would
18 only require 80 hours. So you're saying in Texas
19 those 80 hours would have to be received in an ACGME
20 training program.

21 MR. RATLIFF: Training program.

22 CHAIRMAN MALMUD: Now under the --

23 PARTICIPANT: Hold it. If I had to move
24 the category here --

25 MR. MOORE: But that's going an example of

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1 where Texas has more restrictive standards than NRC
2 standards.

3 CHAIRMAN MALMUD: How are we interfering
4 with your ability to have stricter standards if you
5 want?

6 MR. MOORE: That's compatibility.

7 MR. RATLIFF: When the Commission
8 developed their compatibility levels, a compatibility
9 C allows agreement states to be more stringent. But
10 when you go to compatibility B you're looking at
11 trans-boundary indications and you have to be almost
12 identical. so you cannot be stricter than the NRC
13 requirement.

14 CHAIRMAN MALMUD: I see. Thank you.

15 MEMBER NAG: This is Dr. Nag. Do you have
16 examples of physicians who have done this in our
17 states and are already doing it in other states, but
18 they move to Texas and now they cannot practice in
19 Texas? And if so, what do you do with them?

20 MR. RATLIFF: Typically, it's been
21 endocrinologists who want to do hyperthyroidism
22 treating who have not had the ACGME training and so we
23 will bring the application forward to our medical
24 committee of our Texas Radiation Advisory Board to
25 have them review the qualifications of the individual

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1 physician to determine should we add them to a
2 license.

3 PARTICIPANT: I don't think that's the
4 question.

5 MEMBER NAG: My question was they were
6 doing hyperthyroid treatments the day before that in
7 Ohio and California and they moved now to your
8 wonderful state of Texas and now is he out of a job or
9 can he practice?

10 MR. RATLIFF: Correct. That's why they
11 would have to go through the process of having us take
12 it to our Radiation Advisory Board to determine do
13 they -- Since they don't meet our standards that in
14 rule, are they acceptable and should we put them on
15 the license?

16 DR. METTER: We would take it on -- This
17 is Darlene Metter. We would take it on an individual
18 case-by-case basis. If they are on a broad license
19 and are on the license as an authorized user, there
20 really shouldn't be a problem.

21 DR. HAMILTON: They just have to come
22 before the Board.

23 DR. METTER: Correct. And it's on a case-
24 by-case basis.

25 DR. RATHBUN: Would you like me to move

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1 on, Dr. Malmud?

2 CHAIRMAN MALMUD: Please do.

3 DR. RATHBUN: Okay. Let's go down to
4 grandfathering and the situation where preceptor might
5 not be available. You might never get a new
6 statement. RSO requirements, I don't know that we
7 flushed this one out because there was a lot of
8 discussion around that.

9 MEMBER NAG: I think, No. 6.

10 DR. RATHBUN: Yes.

11 MEMBER NAG: Those two are separate issues

12 --

13 DR. RATHBUN: Okay. So that's seven.

14 MEMBER NAG: Yes. Separate things.

15 DR. RATHBUN: Fine. Okay, and -- Okay.

16 (Off the record comments.)

17 DR. RATHBUN: All right. Let's flush out
18 eight a little bit more because we didn't get it all
19 up there or now nine.

20 PARTICIPANT: Eight.

21 DR. RATHBUN: Eight. Yes, ma'am?

22 MS. FAIROBENT: Yes, Lynne Fairobent with
23 AAPM. Can you just go back up to six? I just want to
24 be sure that the grandfathering of diplomats is also
25 tied to the effective date assignment of Board

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1 recognition. It is an issue that was captured by the
2 AAPM petition to recognize individuals who had been
3 certified by boards that had been previously listed in
4 Subpart J. So they are tied together, but they are
5 separate items. But I really would like maybe a sub-
6 item under the grandfathering of diplomats that also
7 reflects the effective date assignment problems.

8 DR. RATHBUN: All right. Tell Ashley
9 exactly what you want her to put there.

10 NS, FAIROBENT: Ashley, I would just list
11 petition for Rule 35-20 and it's the issues that are
12 specified in the Ritenour petition, PRM-3520. That's
13 the PRM number for the Ritenour petition.

14 DR. RATHBUN: Okay. Thank you. Any other
15 comments? Yes sir?

16 MR. WHITE: Gerald White, American
17 Association of Physicists and Medicine. I'm sorry.
18 You left the compatibility number just a bit quickly
19 unexpectedly. There is an issue between the B and C
20 compatibility having to do with licensure of medical
21 physicists in states.

22 DR. RATHBUN: Right.

23 MR. WHITE: And if that could go on the
24 list as well. We can talk about that.

25 DR. RATHBUN: As a result of the B. All

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1 right. The RSO. I don't have my notes right now, but
2 could you all expand that or do you like it the way it
3 is? The seven year recency of training.

4 MEMBER NAG: I think that needs to be
5 subcategorize as training in each modality -- recency
6 of training in part 35.390 or 35.490.

7 DR. RATHBUN: Right. Modalities.

8 MEMBER NAG: With each individual type of
9 procedure.

10 DR. RATHBUN: Okay. Procedure such as
11 gamma knife, HDR.

12 MEMBER NAG: Yes.

13 DR. RATHBUN: All right. I know what I'm
14 thinking about. Go back up on the RSO. We're now
15 having a shortage of RSOs.

16 MEMBER EGGLI: That relates to the one per
17 license.

18 DR. RATHBUN: Okay. Yes, ma'am?

19 MS. MARTIN: Do you want me to add?

20 DR. RATHBUN: Yes.

21 MS. MARTIN: This is Melissa Martin. Go
22 back to your RSO question please. One item that we
23 didn't really reiterate but I know it has come to my
24 attention just as practicing as an RSO. One of the
25 questions is if you look at new qualifications, in

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1 other words, someone recently certified effective June
2 `07 is now qualified to be RSO in medical physics for
3 their particular specialty. So, in other words, a
4 nuclear medicine physicist would be qualified to
5 practice radiation safety in nuclear medicine physics
6 only. I would go back to the problem of one per
7 license and shortage because most community hospitals
8 have one RSO. That person is supposed to cover
9 therapy and nuclear medicine and I'm not giving you an
10 answer. I'm just saying it is a problem when you say
11 that that person to be RSO has to be broad certified
12 in every category and that would be whether it's a
13 nuclear medicine physician or radiation oncologist,
14 how we're going to handle that. But I think that's a
15 real problem.

16 DR. RATHBUN: Okay. How would you have us
17 word that? Can you help us word that? Sometime --

18 MS. MARTIN: Cross categories training.

19 PARTICIPANT: Cross modality.

20 MS. MARTIN: Or cross modality training.

21 DR. RATHBUN: Okay.

22 (Off the record discussion.)

23 MEMBER WILLIAMSON: Jeff Williamson. Does
24 the concept that's the statement preceptor statement

25 --

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1 DR. RATHBUN: Yes.

2 MEMBER WILLIAMSON: -- cover the issue of
3 having to have two preceptor statements if you come in
4 under the AMP/AU route?

5 DR. RATHBUN: Let's put the in there.

6 MEMBER WILLIAMSON: That they have not
7 only a preceptor statement for your first primary --

8 DR. RATHBUN: We need to put that in.

9 MEMBER WILLIAMSON: Okay.

10 DR. BROGA: I would like to go back to two
11 things perhaps to add onto what Melissa said. Dean
12 Broga, by the way. We used to have a category on the
13 license called Assistant RSO. I understand the
14 concept to have one individual identified as RSO who
15 is looking at the overall program especially when
16 there's a complexity of modalities involved. But
17 there is still a need to have someone who understands
18 each of the modalities. I don't know why we can't
19 have one RSO and a subgroup of assistant RSOs assigned
20 responsibility in specific areas which also allows
21 them documentation of time and training to be named
22 RSO as was done in the old way the NRC handled it.

23 The other issue that I brought up earlier
24 is the one that I think is a problem at a lot of small
25 outpatient facilities, a lot of small community

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1 hospitals, is when one RSO leaves and they have no one
2 qualified. You're presently forcing consultants to
3 take on the role of RSO when they're only there
4 infrequency. I'd rather have an RSO in training or
5 somebody or even assistant RSO named under that who
6 was more onsite responsible because it's very hard
7 when you're 300 miles away to deal with problems on a
8 day-to-day basis.

9 DR. RATHBUN: Okay. So you want to talk
10 about an assistant RSO.

11 DR. BROGA: And assistant RSO and/or some
12 kind of RSO responsibility in training.

13 DR. RATHBUN: Okay.

14 DR. BROGA: I don't know the terminology
15 where there's another RSO overseeing him, but that
16 RSO is not totally responsible for a facility he is
17 300 miles away from.

18 DR. RATHBUN: After we get through this
19 list, we're going to get a chance to put all the fixes
20 up there that you want.

21 DR. BROGA: Okay. Great.

22 MS. TULL: Does this go in the fixes?

23 DR. RATHBUN: That's a fix, yes. The fix
24 is in.

25 MEMBER WILLIAMSON: Where do we put the,

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1 I think what was expressed earlier, sense that this is
2 inherently unfair that a whole group of practitioners
3 that once were considered to be eligible in a very
4 straightforward way to be AMPs, etc., now have to go
5 through a much more complex and costly and time-
6 consuming --

7 DR. RATHBUN: Post-2005. So let's go back
8 up to the 2006.

9 PARTICIPANT: That's the grandfathering.
10 Wouldn't you say that a grandfathering issue?

11 MEMBER WILLIAMSON: Yes. Right. I'd say
12 kind of unfairness.

13 DR. RATHBUN: Okay.

14 MEMBER WILLIAMSON: Lack of a balance
15 between cost and benefit.

16 DR. RATHBUN: Okay.

17 (Off the record comments.)

18 MS. WASTLER: We have it at the very end,
19 isn't it?

20 MEMBER WILLIAMSON: I don't know.

21 MS. WASTLER: Yes, the last one.

22 DR. RATHBUN: There we go.

23 MEMBER WILLIAMSON: Okay. There it is.
24 Okay. Good.

25 DR. RATHBUN: Okay. Seven years, go down

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1 to nine. We have that. Nine, is that now -- That's
2 all right. How about 10?

3 MR. MOORE: I have a follow-on on 10.

4 DR. RATHBUN: Okay.

5 MR. MOORE: I think that 10 accurately
6 describes some of what we talked about. But deriving
7 from 10 when Part 35 T&E requirements were being
8 developed, there was an intense dialogue for a long
9 period of time between the agreement states and NRC
10 about the prescriptiveness of the requirements that
11 were needed in the regulations with the agreement
12 states arguing for more prescriptiveness being needed
13 and NRC trying to strike a balance between a call for
14 a prescriptiveness and the ACMUI's views on what were
15 needed in the T&E requirements.

16 It might be helpful with the ACMUI
17 assembled here if we could get some of the thoughts
18 out from the agreement states if anybody can
19 articulate those about what the agreement states face
20 and why they thought prescriptiveness was needed since
21 there are certainly some unintended consequences that
22 we're seeing now. at least since we have everybody
23 assembled, it might help to bring those forward and
24 get the whole discussion happening in one place. Does
25 Paul or Debbie, do you all want to talk about that?

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1 MEMBER GILLEY: One of the reasons the
2 agreement states like that is that we don't all have
3 medical advisory boards that can determine whether or
4 not the people are qualified. So if there are
5 prescriptive requirements as far as number of hours in
6 each particular subject matter, it makes it a lot
7 easier on us to deem that those people have met the
8 minimum requirements. That was ease of availability,
9 lack of having the technical expertise to make those
10 judgment calls as much as Texas has.

11 DR. RATHBUN: Richard, are you out there?
12 Richard?

13 MR. RATLIFF: Yes. They keep cutting out
14 on us.

15 DR. RATHBUN: Okay. Can you help with
16 Scott's question?

17 MR. RATLIFF: Well, yes. The main things
18 we've seen because of the change in the rule on
19 training and experience like I said is how we have
20 many people who because we have not changed our rules
21 yet don't qualify. We have to go through the process
22 of going back and forth to the advisory board to
23 double-check to see do they consider them acceptable.

24 We also in Texas have a -- We license
25 medical physicists. So we have a problem because we

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1 have state legislation that's put in effect a medical
2 physics program and now we're faced with the NRC rule
3 that doesn't recognize those and we have a conflict
4 there.

5 DR. RATHBUN: I'm jumping ahead, but when
6 we come back to this, let's talk about what would be
7 the fix.

8 MR. RATLIFF: Sounds good.

9 DR. RATHBUN: Okay. So we have 11.

10 (Off the record comment.)

11 DR. RATHBUN: I'm sorry.

12 CHAIRMAN MALMUD: I would make a
13 suggestion and that is that board certification should
14 be sufficient.

15 DR. RATHBUN: Fine.

16 CHAIRMAN MALMUD: If the person is not
17 board certified, all they need is a statement from the
18 director of the training program that attests to the
19 fact that the individual has completed the residency
20 in preparation for the boards and is qualified to sit
21 for the boards. That's it. Because that's really
22 what a residency director does is to attest that the
23 individual has had the requisite education and is now
24 qualified to sit for the boards.

25 So all right. If only ten percent of the

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1 residents are not going to pass the boards, this will
2 encompass the ten percent who don't pass in the first
3 go-around. I thought the number was 20 percent, but
4 I'm corrected. It's ten percent for the first go-
5 around, but it's probably larger than that to include
6 those who are taking the boards for the second time.

7 AP: Yes, it's about five to seven percent
8 larger.

9 CHAIRMAN MALMUD: All right. So it's
10 about 15 percent. That's a fair compromise.

11 (Laughter.)

12 CHAIRMAN MALMUD: So it's 15 percent and
13 I believe that most, if not all, residency training
14 program directors would be willing to attest that the
15 individual has completed the training and is able to
16 sit for the boards. How is that?

17 MEMBER GILLEY: Clarification. We were
18 never looking at minimum number of hours for those
19 people who were board certified. The 200/500 hours
20 were alternative pathways.

21 CHAIRMAN MALMUD: Yes, and I'm suggesting
22 that the alternative pathway is defective in that it
23 has unintentionally become the standard of training
24 and therefore, we could get around that by accepting
25 either board certification or a statement from the

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1 training program director that the individual has
2 completed the training program and is not able to sit
3 for the boards. That's it. That means that we would
4 have accepted, we being the NRC, the training program
5 standards as being the standard. Now would the states
6 accept that too?

7 MEMBER GILLEY: We would accept what was
8 Subpart J which the alternative pathway doesn't have
9 to be done in a medical educational program. There
10 are other ways of becoming adding to a license other
11 than going through your educational program as a
12 physician in training. So there --

13 CHAIRMAN MALMUD: I'm sorry. I was
14 speaking to the issue, the large issue, of radiology
15 residencies.

16 MEMBER GILLEY: Okay. That was never in
17 -- The only time that alternative pathway came into
18 play prior to the implementation of the new Part 35
19 was if the radiologist wished to get put on the
20 license prior to board certification. In your
21 program, it wasn't always acceptable, but there is a
22 subset of people that go to a private, 200-hour
23 educational program and then they convince their
24 medical institution that a radiologist can receptor
25 them for their 500 hours of clinical experience that

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1 are not associated with a residency program. That is
2 a pathway that they can get put on a license.

3 A lot of cardiologists early on, this was
4 their pathway for getting on a license. So there's a
5 subset of people that that is why we wanted the
6 prescriptive language. We were not interested in the
7 prescriptive language for the board certification. We
8 didn't think that problem was -- that that was a
9 problem. But we did want some prescriptive language
10 for those individuals that were not in a radiology,
11 nuclear medicine, radiation therapy program. Well, I
12 can't include radiation therapy. They are completely
13 separate, but to be able to do those procedures.

14 CHAIRMAN MALMUD: I see. I didn't realize
15 it was possible to practice radiology without being
16 trained in radiology.

17 MEMBER GILLEY: The early on nuclear
18 cardiologists were in a program like that. There is
19 a couple of formalized training programs to get the
20 200 hours by going for four or five weeks for a 40
21 hour week course and then you can at your medical
22 institution with the approval of your radiation safety
23 committee set up a preceptor program and you can
24 actually get your hours and be signed off on
25 authorized users.

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1 DR. METTER: I'm sorry. We're having
2 problems with the audio where you're cutting in and
3 out.

4 MEMBER GILLEY: I speak loud.

5 PARTICIPANT: Don't need a mike.

6 PARTICIPANT: We, too.

7 CHAIRMAN MALMUD: Can you hear me?

8 DR. METTER: Yes.

9 CHAIRMAN MALMUD: We'll try and ask each
10 of our speakers to hold the microphone closer to their
11 mouths.

12 DR. METTER: Thank you.

13 MEMBER GILLEY: Okay. Can you hear me
14 now?

15 DR. METTER: Yes.

16 MEMBER GILLEY: Okay. Debbie Gilley with
17 CRCPD/OAS/State of Florida. In the current
18 regulation, not the current, the old regulations of
19 Subpart J prior to the implementation of 2005 Part 35
20 T&E there was a mechanism available for any physician
21 who wanted to go through the 200 hours of classroom
22 experience and get 500 hours of work experience to be
23 put on the license as an authorized user for
24 diagnostic nuclear medicine and many of the earlier
25 nuclear cardiologists, this is the pathway that they

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1 took because there was not board certification
2 available for them. They were cardiologists that
3 attended a five or six week training program and they
4 were also approved by their radiation safety committee
5 and they had an authorized user that preceptored them
6 and that is the area that the agreement states with
7 the rewrite of Part 35 was interested in keeping very
8 prescriptive. They wanted the minimum amount of
9 education that was required in the 200 hours of
10 didactic training and they also wanted the work
11 experience to be there. So those are different issues
12 than the residency program that you've been referring
13 to where you have 10, 15, 20, however many people that
14 need to be put on by alternative pathway.

15 CHAIRMAN MALMUD: Okay.

16 DR. RATHBUN: Okay. So I think we are
17 down to 11. We did that. Okay. Are there any issues
18 that you think we missed? Yes.

19 MS. MARTIN: And maybe I just didn't see
20 it. Melissa Martin. Did you get the Canadian?

21 DR. RATHBUN: Yes, we did.

22 MS. MARTIN: Then I slept. Sorry.

23 DR. RATHBUN: Yes. Got it. Okay. Well,
24 now we come to the good part. Let's figure out and I
25 think in this discussion some of the NRC staff will

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1 speak and speak to perhaps if they have a fix in mind
2 or things that you haven't learned about yet. But
3 let's now proceed to figure out how we're going to fix
4 these issues. So let's go to one.

5 MS. TULL: I'm sorry. I was --

6 DR. RATHBUN: Let's go to one. One.

7 There you go. Okay. Is there anything that the NRC
8 wants to say about one? That would be you, Ron.

9 (Laughter.)

10 DR. ZELAC: Two things. Not to be
11 pointing fingers or trying to place blame, but we have
12 to keep in mind that what we as a agency do reflects
13 what our Commissioners tell us will be. We can put
14 forth suggestions, proposals, ideas, but the bottom
15 line is the Commissioners want something and that's
16 the way it goes. Now if it turns that it's not
17 satisfactory for whatever reasons, there's always
18 obviously the option of making changes. However, what
19 we did in the case of the preceptor statement was what
20 the Commission told us to do in terms of the staff.

21 This is, I will quote from the Staff
22 Requirements Memorandum that came out from the
23 Commission in February of 2003. "In addition, the
24 preceptor statement should remain as written in the
25 final Part 35 rule," meaning the 2002 rule which, of

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1 course included the word "competency," which included,
2 in fact, the word "certify" but that was changed to "a
3 test."

4 "The staff should clarify that the
5 preceptor language does not require an attestation of
6 general clinical competency but does require
7 sufficient attestation to demonstrate that the
8 candidate has the knowledge to fulfill the duties of
9 the position for which the certification is sought.
10 This form of attestation should be preserved for both
11 pathways of certification, i.e., through board
12 certification or through training and experience."

13 So the Commission was very clear. The
14 2002 rule which was viewed by everyone as faulted was
15 to be changed. The preceptor statement, however,
16 would remain, would remain applicable to both the
17 board's cert pathway and the alternative pathway and
18 would speak of attestation as opposed to certification
19 and was intended to not be dealing with or not be
20 referring to or not be implied to apply to clinical
21 competency but simply adequacy of knowledge to fill
22 the duties of the position for which certification is
23 sought.

24 DR. RATHBUN: Comments?

25 CHAIRMAN MALMUD: Ralph?

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1 MEMBER LIETO: I don't know if we're at a
2 position to just offer other solutions even in light
3 of what Dr. Zelac has pointed out, but my
4 recommendation would be that the attestation be
5 removed from the board certification pathway and the
6 intent, I think, all along was that it would be for
7 the alternative pathway because originally, in the
8 origin Part 35 for 2002, the only place an attestation
9 had to be was for an authorized user coming in under
10 the alternative pathway. Anybody else coming in under
11 an alternative pathway did not have to have an
12 attestation. Well, we didn't have ANP but the therapy
13 physicists and so forth. So to me, it's sort of a
14 compromise in the sense that any alternative pathway
15 requires an attestation, but that the board
16 certification route because of the redundancy that's
17 been pointed out earlier really is not necessary.

18 DR. RATHBUN: Yes. Dr. Williamson.

19 MEMBER WILLIAMSON: Yes. I do recall the
20 events that Dr. Zelac has related, but I would say
21 that's a political problem and the solution would be
22 to go back to the Commission and say it's not working.

23 DR. RATHBUN: Scott, what is our mechanism
24 for that?

25 MR. MOORE: We can always go back into the

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1 Commission with a proposed change to the rule based on
2 experience. We would have to have a basis to do that
3 obviously. I guess I have a question for Mr. Lieto.
4 The question would be this. We've talked about the
5 unintended consequences of the alternative pathway
6 becoming the de facto requirements for the board
7 certification. Could you go back actually for a
8 second? If we remove the attestation from the board
9 certification pathway, but if we kept attestation
10 requirement in the alternative pathway, would it, in
11 fact, then still become a de facto requirement for
12 everybody going through a program where they all need
13 one, in fact, to get through the program because they
14 may, in fact, not pass the boards?

15 DR. RATHBUN: Dr. Eggli.

16 MEMBER EGGLI: Well, as a writer of
17 preceptor statements, I don't write preceptor
18 statements until I know whether or not they've passed
19 the boards. So that helps me in that pathway. I
20 think the idea that you have to deal with the whole
21 issue of the reluctance of preceptors to preceptor the
22 alternative pathway and I think if the word
23 "competency" is changed to "mastering of a body of
24 knowledge," that would make preceptors a little less
25 reluctant to preceptor an individual.

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1 And then again, we have to go back to the
2 issue that the agreement state wanted
3 prescriptiveness, but if you could make the
4 alternative pathway a bit less prescriptive and say
5 the attestation of the preceptor covers the ambiguity
6 in the prescriptiveness of the alternative pathway,
7 again that could solve some of the problem, I think.

8 MR. MOORE: That helps.

9 DR. RATHBUN: Ron and then Dr. Malmud.

10 DR. ZELAC: Several things. First, to get
11 back to what Ralph was saying, the 2002 rule did
12 require preceptor statement for the board cert
13 pathway. It did require preceptor statement for the
14 alternative pathway and that's from what I read
15 previously is what the Commission wanted retained.

16 MR. MOORE: Right.

17 DR. ZELAC: Second --

18 MR. MOORE: But they've asked could we
19 present it back to the Commission and --

20 DR. ZELAC: I understand that.

21 MR. MOORE: Right.

22 DR. ZELAC: Okay. Secondly, the current
23 Part 35 specifically for the RSO has one attestation
24 which does not include the word "competency" and
25 that's for the radiation safety officer. So it could,

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1 in fact, perhaps serve as a model for modifying the
2 others similarly.

3 I'll let you read what the current rule is
4 with respect to attestation for the radiation safety
5 officer. This is in 35.50(d). "Has obtained written
6 attestation signed by a preceptor RSO that the
7 individual has satisfactorily completed the
8 requirements in paragraph E" which, in fact, as a
9 reminder, are the additional specific training
10 requirements, and in paragraphs A(1) and A(2) and so
11 forth which refers to the other pathways in which one
12 can become an RSO and here's where we're getting to
13 the good stuff, "and has achieved a level of radiation
14 safety knowledge sufficient to function independently
15 as an RSO for a medical use license." There is
16 nothing about competency. It's about obtaining a
17 sufficient -- a level of radiation safety knowledge
18 sufficient to function independently.

19 DR. RATHBUN: Dr. Malmud.

20 CHAIRMAN MALMUD: Ron, when you read the
21 other statement about competency, did I hear that it
22 didn't mean -- it was competency, but it didn't mean
23 competency?

24 DR. ZELAC: It did not mean clinical
25 competency. That was understood by the Commission and

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1 it was intended to be conveyed.

2 CHAIRMAN MALMUD: It states that in black
3 and white.

4 DR. ZELAC: In black and white.

5 CHAIRMAN MALMUD: For purposes of that
6 statement, competency does not mean clinical
7 competency.

8 DR. ZELAC: Indeed, it does.

9 CHAIRMAN MALMUD: And therefore, one would
10 assume that a training program director couldn't be
11 sued -- Well, the basis of a suit is the desire to
12 sue, but one would assume that it would be without
13 much merit to sue someone when competency doesn't mean
14 competency according to that statement. I mean, words
15 mean what they're defined as and here it says that
16 competency does not mean clinical competency.

17 DR. ZELAC: It does not. The intent was
18 the person was competent in the radiation safety
19 aspects of that work which they were being authorized
20 for.

21 CHAIRMAN MALMUD: Thank you.

22 DR. RATHBUN: Dr. Williamson.

23 MEMBER WILLIAMSON: So would you be more
24 comfortable certifying somebody's physics skills in
25 competency to be safe in treating patients as opposed

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1 to certifying their clinical competent?

2 MR. MOORE: No.

3 CHAIRMAN MALMUD: No, I don't think that
4 I'm --

5 MEMBER WILLIAMSON: Competency does mean
6 competency, but it means competency in a narrower
7 range of activities than you imagine.

8 CHAIRMAN MALMUD: I know.

9 MEMBER WILLIAMSON: But competency is
10 still competency.

11 DR. ZELAC: That's why I was referring to
12 the RSO attestation as it exists today which does not
13 include the word "competency" --

14 CHAIRMAN MALMUD: No.

15 DR. ZELAC: -- as a possible model.

16 DR. RATHBUN: Donna-Beth wants to speak.

17 DR. HOWE: One possible solution would be
18 to add the competency definition that the Commission
19 believed it was defining to the rule. In other words,
20 the Commission --

21 CHAIRMAN MALMUD: Couldn't hear you.
22 Sorry.

23 DR. HOWE: The Commission in its SRM wrote
24 a definition of competency. That would be another
25 solution.

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1 CHAIRMAN MALMUD: Yes.

2 DR. RATHBUN: Thank you, Donna-Beth. Dr.
3 Nag.

4 MEMBER NAG: I remember the conversation
5 we've had when the ACMUI met directly with the
6 Commissioners and we had brought this up and I don't
7 know which of the commissioner, but one of the
8 commissioners said it is fine. We don't have to have
9 the word. They still wanted a preceptor statement,
10 but the word "competency" could not be there. It
11 would be to attest to having a body of knowledge. So
12 I think what you are talking about in the RSO that
13 would also be translated to the other so that the word
14 "competency" would not be there would make people more
15 -- or would make them more comfortable to sign the
16 preceptor statement.

17 DR. RATHBUN: I think Cindy would like to
18 add something.

19 MS. FLANNERY: Cindy Flannery. I just
20 want to follow up on something that Donna-Beth said
21 with the SRM and I just want to read you something
22 from the Statements of Consideration. It states that
23 "the preceptor statement should remain as written in
24 the current regulations" as stated by the Commission.
25 "However, the Commission emphasized that the preceptor

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1 language does not require an attestation of general
2 clinical competency but requires sufficient
3 attestation to demonstrate that the candidate has the
4 knowledge to fulfill the duties of the position for
5 which certification is sought." And I think that's
6 the definition that Donna-Beth was suggesting could be
7 put in.

8 (Off the record comments.)

9 MR. MOORE: What it really comes down to
10 is will that provide a level of comfort for people to
11 sign preceptor statements and we don't know the answer
12 to that.

13 CHAIRMAN MALMUD: I think it depends on
14 the individual. It gives me comfort. It doesn't give
15 Dr. Eggli sufficient comfort and it doesn't appear to
16 give either Dr. Williamson or Mr. Lieto any comfort.

17 MR. MOORE: Then it doesn't solve the
18 problem.

19 CHAIRMAN MALMUD: I thought it was a
20 clever means of dealing with the issue that Donna-Beth
21 raised.

22 DR. RATHBUN: Dr. Eggli.

23 MEMBER EGGLI: It's half of the key
24 component.

25 DR. RATHBUN: Okay.

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1 MEMBER EGGLI: The other half is the
2 prescriptiveness of the alternative pathway and if
3 that could be loosen up a bit and then say that the
4 attestation of a body of knowledge.

5 DR. RATHBUN: Right.

6 MEMBER EGGLI: Historically, in
7 regulation, you define what that body of knowledge is.
8 The question is do you need to attach a specific
9 number of hours because there are some people that are
10 going to spend 80 hours on this and never master the
11 body of knowledge. Some people are going to master
12 the body of knowledge with ten hours effort.

13 What I'm comfortable with is an
14 attestation that the individual has mastered a body of
15 knowledge because we can document that objectively
16 through testing that they have mastered a body of
17 knowledge. What I prefer not to have is a
18 prescription on how I impart and test that body of
19 knowledge. Tell me what the topics are that you want
20 me to teach, but allow me to design a curriculum which
21 meets that need and then I will attest to mastery of
22 that body of knowledge because I again for whoever
23 comes back and looks at me, whether it's NRC or an
24 individual candidate later, I will documentation that
25 they have, in fact, achieved mastery of the body of

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1 knowledge via a testing process.

2 DR. RATHBUN: Should we take the comment
3 in the back and then take --

4 MR. WHITE: Gerald White, AAPM. A couple
5 comments. One is I'd just like to use the Occam's
6 Razor Rule again and say that what's under discussion
7 here is how to fix something, at least, for the board
8 certification pathway that is redundant and
9 unnecessary and I believe the commissioners could come
10 to that understanding as well.

11 Secondly, I'd like to say that this is not
12 just an issue for, even if the grandfather issue is
13 fixed for the physicians, it's not just for the first
14 time you get on a license. It's every time a
15 physician is placed on a license through their entire
16 career by a mechanism other than already on a license
17 and just to make it clear again, just because a
18 physician in on a license doesn't mean they can use
19 that license to get on the next license and there are
20 issues of accessibility, record keeping. I could go
21 through all the reasons.

22 DR. RATHBUN: How would we word that fix?

23 MR. WHITE: I think the fix would be to
24 remove this requirement from the board certification
25 pathway and that would solve the problem for the

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1 majority of physicians.

2 DR. RATHBUN: Dr. Williamson.

3 MEMBER WILLIAMSON: Yes, I would like to
4 expand on that a bit. I think this conversation has
5 been confined to basically writing preceptor
6 statements for young physicians that have just gone
7 through the training experience. And so older
8 practitioners who need to be basically have new
9 preceptor statements to attest to their current level
10 of knowledge mastery, who is to sign that? There is
11 no formal testing process within the physics community
12 to do that. When a person who was your student 20
13 years ago needs to show mastery of a body of material
14 for a new modality, who is to sign that?

15 Certainly, the old preceptor from 20
16 years, that falls under the category of attesting to
17 the unattestable. So I would have to agree with Mr.
18 White. I think the simplest thing is to drop it
19 barring some sort of demonstration that it's improving
20 public safety. There is a lot of cost associated with
21 going through this.

22 DR. RATHBUN: And I promised Dr. Nag he
23 could be next, but then Ron would be after him.

24 MEMBER NAG: Just to point to one is
25 similar to what Jeff said is that if the person is

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1 board certified, then the board cert is the pathway.
2 You don't need any other thing. But the second point
3 is with Dr. Eggli for those who are not board
4 certified if you need the alternative pathway, I think
5 I disagree with that. It would be easier to attest to
6 the fact that someone has undergone so many hours of
7 this and so many hours of that. It may be more
8 difficult to attest to the fact that the person has
9 this wealth of knowledge because you can test some of
10 it. You can't test everything. You only test, how
11 many, 40 or 50 questions. So it may be easier for the
12 person who are not board certified to say, "I attest
13 to the fact that that person has undergone 200 hours
14 of this and 80 hours of that." That might be right.
15 So I disagree you there.

16 DR. RATHBUN: Ron.

17 DR. ZELAC: Three things. First, relating
18 to the question that had come up about the alternative
19 pathway, it's important to note that there's nothing
20 new about having specific requirements in an
21 alternative pathway. Those have existed in the NRC
22 regulations since at least 1985. So everybody has
23 been functioning with those things for well over a
24 quarter of a century presumably satisfactorily.

25 Second, with respect to the comment from

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1 Mr. White concerning preceptors not being, or maybe
2 Dr. Williamson, with preceptors not being available or
3 not being available for new modalities, there is not
4 a requirement that the preceptor be the one who
5 provided the training. There is a requirement that
6 someone who is functioning in a particular role as an
7 authorized individual can verify by whatever means
8 they choose that you as the person they are signing
9 for have had the appropriate training and experience
10 and secondly, that you're a reasonable person to take
11 on similar responsibilities and act independently.

12 And I'd like to very briefly in support of
13 that position that I just stated quote from the
14 Statements of Consideration for the 2005 rule, the one
15 that we are now discussing. This is in response and
16 this is essentially the NRC basis for requiring
17 preceptor statements. This was in response to a
18 comment. I will not read the comment, but I will read
19 portions of the response and if you can bear with me,
20 this is slightly long, but I think it will help with
21 where we are in terms of what the agency's position
22 has and at this point continues to be, speaking for
23 the Commission which I shouldn't do.

24 "The NRC continues to rely on preceptor
25 statements to determine if an individual has

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1 satisfactorily completed requirements for T&E and has
2 a level of knowledge sufficient to serve as an RSO,
3 AMP, ANP or AU. The NRC believes that it is essential
4 to have individuals who are familiar with the duties
5 of RSOs, AMPs, ANPs and AUs through personal
6 experience to serve as preceptors. Individuals who
7 serve in these positions are best qualified to attest
8 that an individual has achieved a level of competency
9 sufficient to function independently as" the same
10 list.

11 Further down in the answer, the response,
12 "The NRC," and this hasn't come up yet, but it may
13 well, "The NRC does not agree that removing the
14 requirement to acquire a preceptor statement would
15 minimize the delay in approvals of individuals to
16 serve as" these authorized folk "because other means
17 would have to be used to evaluate the competency of
18 these individuals which would increase the amount of
19 time needed for these approvals." And what's being
20 referred to, although not explicitly stated, was
21 possibly examinations, possibly course reviews and
22 certifications, both of which were options that had
23 been considered as alternatives to the preceptor
24 statement.

25 And I'm getting close to the end, but if

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1 you can bear with me, I think this might be helpful.
2 "The NRC," and this has to deal with various
3 preceptors attesting for one person, "The NRC accepts
4 multiple preceptor statements from licensees in these
5 circumstances. As indicated under the discussion of
6 comments, the word "the" was removed from the
7 phrase...to help clarify that more than one individual
8 may serve as a preceptor."

9 And finally, this is specifically speaking
10 of RSOs. "The adequacy of T&E for individuals to
11 serve as RSOs is insured by requirements in the final
12 rule for a preceptor statement and for training in
13 radiation safety, regulatory issues and emergency
14 procedures for the types of use for which a licensee
15 seeks approval." Now this is getting at the specific
16 requirements in Section 35.50(e), the training that's
17 specific and you note also that similar specific
18 requirements were inserted as part of this rule for
19 both authorized medical physicists and for therapeutic
20 radiation oncologists, again, at the direction and
21 request of the advisory committees. I call that to
22 your attention.

23 DR. RATHBUN: Now, so what is the real
24 root of those disconnect? Let's go to the back.

25 DR. BROGA: I think part of the problem

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1 and it's apparent that we're not going to change the
2 way the regulations are written now.

3 DR. RATHBUN: Now you don't know that yet.

4 DR. BROGA: Well, we're not going to
5 change it tomorrow and probably not for a year the way
6 the process goes.

7 DR. RATHBUN: You know we can't do that.

8 DR. BROGA: But you asked what the real
9 problem is and that's what I'm going to get to. We've
10 had preceptor statements associated with this process
11 for years. I think the change in the terminology has
12 raised some paranoia as to what is going to be the
13 applicable implication of this in the field. When you
14 attest to somebody's competency or their training
15 skills with this expanded definition, you wonder
16 what's going to happen a year from now when you show
17 you to do a inspection and one of your radiology
18 residents who's asked about a linearity test said,
19 "Well, I'm not sure I really understood that."

20 Now what is my liability for signing that
21 statement? I think that's what a lot of us are
22 concerned about. It's very difficult to assess the
23 total competency in this broad scope of area when you
24 have, in some cases, minimal contact with this person
25 to the depth you're talking about. What's going to

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1 happen to me when that happens is what we're worried
2 about.

3 DR. RATHBUN: Ron, do you have an answer
4 for that?

5 DR. ZELAC: No.

6 DR. RATHBUN: Okay.

7 (Laughter.)

8 DR. RATHBUN: Okay. I'm going to take Dr.
9 -- At least, he's honest. Dr. Williamson. Dr. Welsh
10 and then we'll go back to the back of the room.

11 MEMBER WILLIAMSON: Well, I think this is
12 a reasonable concern because for RSOs especially for
13 a physician if an RSO is supposed to sign this, the
14 RSO may not have had any contact with the training of
15 a particular resident in this regard. So if NRC
16 wanted to insist on retaining this requirement,
17 perhaps they should investigate some method of
18 granting preceptors immunity from civil and criminal
19 prosecution. Honestly. I think that's almost what is
20 needed because if an incident happens, a serious
21 incident happens, with a person who has been given
22 authorized status based on someone's preceptor
23 statement, my guess is if a serious incident like the
24 HDR source loss in 1991 occurred, there would probably
25 be a witch hunt and go after anybody that had anything

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1 to do with this case.

2 DR. RATHBUN: It's usually us that they go
3 after.

4 MEMBER WILLIAMSON: Well, that's your
5 perception but I think that --

6 DR. RATHBUN: I think we have a paranoia,
7 too.

8 MEMBER WILLIAMSON: Yes, we're paranoid,
9 too.

10 DR. RATHBUN: Right.

11 MEMBER WILLIAMSON: Because we're laying
12 our reputations on the line and if something bad
13 happens, what happens? Then basically, Dr. Zelac read
14 the phrase "by any means you feel necessary." Well,
15 what are those means? What's considered adequate?

16 DR. RATHBUN: Okay.

17 MEMBER WILLIAMSON: This is a rather
18 difficult area.

19 DR. RATHBUN: Okay. I have a comment here
20 from Sandi that is saying to me, "How do you plan to
21 handle this discussion given that it's 4:00 p.m. and
22 we're only on issue one?"

23 (Laughter.)

24 MS. WASTLER: A practicality.

25 DR. RATHBUN: Which is usually what I say

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1 to the people. I guess I got too interested in the
2 subject. So I guess -- I don't know what to do.
3 Let's take these two gentlemen and then let's -- Oh,
4 I forgot you. Okay, and then let's kind of
5 reconnoiter and decide what we want to do. Dr. Welsh,
6 I'm sorry.

7 MEMBER WELSH: I have a suggestion
8 regarding that second sentence there, the change
9 "competency" to "master of a body of knowledge." To
10 my mind, neither one of them is really satisfactory.
11 Competency has obviously raised the sense of paranoia
12 or at least an appropriate level of concern about the
13 possibility of prosecution.

14 Mastery of a body of knowledge is also not
15 adequate because if this is somebody that's just
16 failed the board exam, I'd have a hard time saying
17 that this person has mastered a body of knowledge and
18 there's my attestation. Why not just keep things very
19 bare minimum to what is factual and that is this
20 individual has met the minimum training and experience
21 requirements and that's it? Because that is something
22 that you can say and it would probably not lead to any
23 kind of legal ramifications down the road should that
24 individual prove incompetent or not demonstrate a true
25 mastery of the body of knowledge.

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1 DR. RATHBUN: "Has met" seems to be a
2 pretty deep thing to say.

3 MEMBER WELSH: "Has met the minimum
4 training experience" is something I think we could
5 feel comfortable signing.

6 DR. RATHBUN: Right. Let's take the two
7 gentlemen out there and then we'll --

8 MR. HAFTY: Bruce Hafty from American
9 Board of Radiology and I'll also speak with respect to
10 my role as the Vice Chair of the ROC in Radiation
11 Oncology. We've already heard that the program
12 requirements have been modified to fulfill NRC
13 regulations or guidelines, etc. So once a person --
14 And this is in support of eliminating the preceptor
15 statement for board certified individuals. They've
16 already gone through an approved program. At the end
17 of that -- And all of those requirements in that
18 program fulfill NRC requirements and in the end, the
19 program director attests to a statement that they
20 fulfilled those requirements. Actually, also attests
21 to their competency because we have to do that as part
22 of ACGME rules.

23 So in fact for the clinical folks anyway,
24 we've attested to the fact that they've been through
25 these requirements and they've fulfilled them and they

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1 are competent to practice independently which is part
2 of the standard language. So that is my statement
3 that I would support elimination of the preceptor
4 statement which is redundant for those who have been
5 through this process.

6 DR. RATHBUN: Okay.

7 DR. ALDERSON: This is Dr. Alderson again
8 and I also speak in favor of eliminating this
9 requirement for those who have the board pathway and
10 I'm going to make an analogy but I'm not going to
11 burden the board with this analogy. So this is
12 strictly my own thought about an analogy.

13 I tried to think of a simple program that
14 we all deal with that's government regulated, that has
15 risk, that's associated with frequent renewals and the
16 obvious one is drivers' licenses. So think to
17 yourself. What would happen if every time you had to
18 renew your driver's license somebody had to sign that
19 you were, they had to train you and then say you were
20 competent to drive. Think how they would feel about
21 that. Every seven years you go back in and if your
22 record is clean and you all have records because when
23 medical incidents occur you know about them, so if the
24 record is clean and you have a license, you get a new
25 license. So if you have a board certification and

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1 your record is clean, you ought to be able to get back
2 in there.

3 If you move to a new state, well, then the
4 states have different regulations within a narrow
5 corridor and people easily get their license and go
6 back to driving if they're safe. You could do the
7 same thing. So I think that other government programs
8 that have major states' rights' issues in them have
9 been able to be resolved in a simple way that
10 satisfies the people. I think you all ought to be
11 able to do the same thing.

12 DR. RATHBUN: Okay. Dr. Malmud, let's
13 talk about what we might want to do next. We have --
14 How many do we have?

15 MS. TULL: Eleven.

16 DR. RATHBUN: Eleven I believe.

17 MEMBER NAG: One hour each.

18 DR. RATHBUN: Is there any --

19 MS. WASTLER: This topic just by the
20 discussion we've had is very important to a lot of
21 people for a lot of different reasons and we are faced
22 with the situation where up to this point not all the
23 agreement states have implemented this particular
24 requirement.

25 DR. RATHBUN: Right.

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1 MS. WASTLER: So in reality, we have a
2 situation that under the NRC auspices we have about 20
3 percent of the licensees. The agreement states have
4 80 percent. So many of the agreement states haven't
5 implemented this rule.

6 So this was an opportune time to find out
7 exactly what these implementation issues are. We're
8 very, very committed to finding out where the problems
9 are, why there are problems, and discuss from all our
10 different perspectives how we can move forward to try
11 to resolve these issues in various different
12 mechanisms. This is very important from our
13 perspective and in all of yours.

14 So I don't want to shorten this
15 discussion, but I want to be fair and make sure
16 because some people came today for this very
17 discussion. I don't know that moving it to tomorrow
18 is an alternative. Those people that came -- You
19 know, we have a full day agenda tomorrow. So there
20 are people that are going to come tomorrow that want
21 to do topics.

22 That's the rationale for raising this now.
23 It's quite clear that we have a lot more to talk
24 about. There's a lot of good ideas, a lot of good
25 thoughts, out there that we want to capture, but I

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1 think we need to figure out -- take a moment now and
2 try to figure out how we're going to complete this
3 task that we set forward.

4 Obviously, we didn't factor sufficient
5 time into the process. So that's where I was coming
6 from in raising the question.

7 MEMBER NAG: Are we allowed to stay in
8 this room after 5:00 p.m.?

9 MS. WASTLER: Yes. We have the
10 opportunity to stay later. But the fact that we're on
11 one and there's eleven and you said an hour for each
12 topic, I don't know that that would go over real well
13 with a lot of folks in the audience. So I just wanted
14 to say -- just wanted to raise it so that we could get
15 some kind of agreement what might work best. I will
16 leave that to Pat to raise.

17 DR. RATHBUN: Well, we have some options.
18 Honestly in all the years I've done facilitation, I
19 don't think it will do any good to go past 5:00 p.m.
20 People will get tired. People will get bored and I
21 think we need to end where we said we were going to
22 end.

23 We can, the staff can, look at these
24 issues and try to come up with what would have been
25 our answers. You know what that is. It's just

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1 another rule. Right? So we like that. Okay. Dr.
2 Malmud.

3 MS. WASTLER: I purposefully want to hear
4 what they have to say.

5 DR. RATHBUN: Yes.

6 CHAIRMAN MALMUD: May I suggest that we
7 try and reach closure on this first item?

8 DR. RATHBUN: Yes.

9 CHAIRMAN MALMUD: Now we know now a couple
10 of facts that have been reviewed for us very
11 eloquently by members of the staff. Number one, the
12 Commission itself wants the term "competence" in
13 there. That's been made very clear to us. That's the
14 Commission.

15 DR. ZELAC: No. They want the
16 attestation.

17 MEMBER NAG: No. That's not it. They
18 want the preceptor statement.

19 CHAIRMAN MALMUD: To include the word
20 "competence." But their definition of the word
21 "competence" is not clinical competence.

22 DR. ZELAC: What I had read from the
23 statements of -- from the staff requirements
24 memorandum was a directive from the Commission to
25 staff to keep the preceptor statement unchanged which

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1 meant that it was to remain the same as it was in the
2 2002 rule which did for all of the categories except
3 RSO include the word "competency."

4 CHAIRMAN MALMUD: So the NRC Commission
5 wants the preceptor statement to stay and wants the
6 word "competency" in there but defines competency not
7 as clinical competency. So that is something that
8 they want and we recommend and they heard us and they
9 decided that's what they wanted. Okay.

10 I feel unthreatened by statement in which
11 the record indicates that the word "competence"
12 doesn't mean clinical competence because I couldn't
13 even assure you of my own clinical competence next
14 week. I mean, who know what will happen to me? The
15 point is that that satisfies me, but it may not
16 satisfy everybody else.

17 And Donna-Beth had an idea which was also
18 one which helped to accommodate a solution. It is
19 true. It is not the straight line between two points.
20 It may be a spiral. But, nevertheless, it does get to
21 the other point for me.

22 And the other part of that was, that first
23 issue, the prescriptiveness in the -- Well, maybe
24 that's not a part of it. Is that part of the issue
25 about the alternative pathway? Yes. Is that the

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1 prescriptive issue simply be to the body of knowledge,
2 not to the number of hours in a lab working with a
3 well-type counter, etc. and eluting a generator. I
4 mean, the specifics should be given to the individual
5 training programs to deal with.

6 I sat in in an unrelated issue at a
7 hearing at the Commonwealth of Pennsylvania in which
8 some of the legislators wanted to dictate the
9 curriculum for our universities and the presidents
10 said no. A state-related university. The president
11 said no. It's an intrusion into the academic world
12 and the answer is no. And there was a threat that
13 they cut the funds and he said, "Then cut them, but
14 the answer is no."

15 I believe this is a similar issue, not of
16 such great significance, not of equal significance,
17 but a similar issue. The training of physicians has
18 traditionally been in the hands of these residency
19 training programs. They've done a good job. Let them
20 continue to do it. Specify you need to have -- you
21 want them to be able to train -- If you want us to
22 train our residents so that they're competent or have
23 a fund of knowledge so they can practice, fine, we'll
24 do that. But just don't tell us it has to be six
25 hours eluting a generator and X hours doing something

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1 else and zero hours reading scans. That's not
2 practical. It's just not practical. Will it work?
3 It can't work. No one will sign on it.

4 Now I also know, and we haven't discussed
5 here, but I also know that there was a rumor that
6 someone some years ago said that they were signing
7 attestation forms and didn't even adhere to them.
8 It's just a matter of paperwork and that raised the
9 hackles of everyone who was concerned about it, other
10 program directors, the NRC. If someone is going to do
11 something which is not truthful and honest, that
12 individual will have to pay the consequences. But it
13 doesn't seem to me that the whole world has to pay the
14 consequences and if someone is discovered not adhering
15 to the rules, no one will go after him or her more
16 aggressively than the American boards or the NRC.

17 DR. RATHBUN: Right.

18 CHAIRMAN MALMUD: So I don't think that we
19 can practice based upon a statement that one person
20 might have said which might have been an accurate
21 description of his behavior, but is unethical.

22 DR. RATHBUN: Would you like to address
23 next, Dr. Williamson?

24 MEMBER WILLIAMSON: Yes. With all due
25 respect, I think that the consensus point of view is

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1 that we should go back to the Commission and ask them
2 to drop the preceptor requirement, at least, from the
3 board certification pathway, possibly from the
4 alternative pathway or write a far more restricted and
5 focused one and I think that we could debate all
6 evening to try to reach consensus.

7 DR. RATHBUN: Right.

8 MEMBER WILLIAMSON: I think we should call
9 the question and essentially vote on which of the two
10 alternatives.

11 CHAIRMAN MALMUD: Sally.

12 MEMBER SCHWARZ: I just have a statement
13 to make. I think that the --

14 DR. RATHBUN: Get closer to the
15 microphone.

16 CHAIRMAN MALMUD: You have to reach Texas.

17 MEMBER SCHWARZ: I think that we should go
18 ahead as Jeff just stated because I think what's
19 happened today is not usual precedence. The public is
20 here, I mean, in regard to a problem that exists in
21 the community and I think with that the staff goes
22 back to the Commission and asks essentially that this
23 be repaired, that it is a problem in the community,
24 that there is something that was not broken and it was
25 repaired and now it is broken.

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1 I think that we have different
2 commissioners that will begin as well. Possibly they
3 will have a different point of view as we approach
4 them. But I think that as the staff can take back the
5 communities' concerns as well as ACMUI's previous
6 statements, I think we are certainly being backed up
7 by the community and the next step the community has
8 is the Congress and to me, it seems more effective
9 that all of these people are interested and concerned
10 to come here.

11 DR. RATHBUN: Okay.

12 CHAIRMAN MALMUD: Debbie.

13 MEMBER GILLEY: Could I please, Dr. Zelac,
14 what the date is on those statements of consideration?

15 DR. ZELAC: Yes, March 30, 2005.

16 MEMBER GILLEY: Well, we have some new
17 commissioners since that time. So I think the makeup
18 of the commissioners are such that there may be
19 interest at reviewing this.

20 CHAIRMAN MALMUD: Sally, can you make a
21 motion?

22 MEMBER SCHWARZ: Sure. I would like to
23 move that essentially we do remove the attestation
24 from the board competency review completely. Excuse
25 me. I'm not speaking well. I'd like to move that

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1 remove the attestation from the board certification
2 process and essentially that we then rewrite the
3 attestation to remove "competency" and change it to
4 "mastery of a body of knowledge" for the alternative
5 pathway.

6 MEMBER NAG: Not mastery. I thought we
7 already mentioned mastery of the body of knowledge,
8 but minimum hours of --

9 MEMBER SCHWARZ: Yes, the minimum hours.

10 MEMBER NAG: "Met minimum training and
11 experience requirement."

12 MEMBER SCHWARZ: Yes. "Met the minimum
13 training and experience requirement."

14 CHAIRMAN MALMUD: That's a motion. Is
15 there a second to the motion?

16 MEMBER NAG: Second.

17 CHAIRMAN MALMUD: Any further discussion?
18 (No response.)

19 CHAIRMAN MALMUD: All in favor?
20 (Show of hands.)

21 CHAIRMAN MALMUD: Is it unanimous or was
22 there an abstention?

23 MEMBER GILLEY: I'm the guest. I don't
24 know that I get a right to vote.

25 CHAIRMAN MALMUD: Okay.

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1 MEMBER GILLEY: I'll vote if I can but I
2 don't think I can.

3 DR. RATHBUN: Sorry. You can't vote.

4 CHAIRMAN MALMUD: All of us who are
5 members?

6 (Show of hands.)

7 CHAIRMAN MALMUD: Okay. It's unanimous.

8 MS. TULL: Dr. Malmud, this is actually a
9 clarification. Is that correct to strike through
10 that? That is not to be included in the motion.

11 CHAIRMAN MALMUD: That is correct to
12 strike through it.

13 MEMBER NAG: Let's see. Change
14 "competency" too.

15 DR. RATHBUN: "Competency" too.

16 MEMBER NAG: Yes.

17 MS. TULL: Okay.

18 CHAIRMAN MALMUD: Change "competency" to
19 "has met the minimum training requirements."

20 MS. TULL: Thank you.

21 CHAIRMAN MALMUD: Thank you. Okay. So
22 we've closed on that first issue. Now let's move
23 forward.

24 MS. WASTLER: That's very good.

25 CHAIRMAN MALMUD: What's the second issue?

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1 Impact of the effective date, that apparently is a
2 significant issue. We have to -- Is there a motion
3 regarding that?

4 MEMBER LIETO: I think -- I don't know how
5 to maybe state this as a motion, but the intent is, I
6 think, that the NRC needs to get out of credentialing
7 boards. The whole process that originally was the
8 intent for the alternative pathway of describing
9 boards when they decoupled -- I should back up. When
10 they decoupled the boards from Part 35 and wanted to
11 list them on web pages, the intent was to establish
12 the criteria in order to get listed. The effective
13 date was never part of that discussion and the very
14 descriptions used to describe the boards that would
15 get listed have now, in effect, actually precluded the
16 board certifications before that listing. So it's
17 almost been used against them.

18 I think as Kent Lambert pointed out
19 earlier for the American Board of Health Physics. I
20 mean, the model that we started with for describing
21 these boards and now it's almost a minority of those
22 individuals that can actually get -- whose boards are
23 being recognized.

24 CHAIRMAN MALMUD: Are you recommending
25 that all those who had board certification be

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1 grandfathered?

2 MEMBER LIETO: Yes.

3 CHAIRMAN MALMUD: Is that a motion?

4 MEMBER LIETO: So moved.

5 CHAIRMAN MALMUD: Is there a second?

6 MEMBER WILLIAMSON: Second.

7 CHAIRMAN MALMUD: Discussion?

8 (No response.)

9 CHAIRMAN MALMUD: All in favor?

10 MEMBER GILLEY: I have a clarification.

11 Are we going back to subpart J again?

12 CHAIRMAN MALMUD: Yes.

13 PARTICIPANT: It's effectively subpart J.

14 MEMBER GILLEY: Thank you. Okay.

15 CHAIRMAN MALMUD: All in favor?

16 (Show of hands.)

17 CHAIRMAN MALMUD: Any opposed?

18 (No response.)

19 CHAIRMAN MALMUD: Any abstentions?

20 (No response.)

21 CHAIRMAN MALMUD: It's unanimous. Next,
22 item number three.

23 (Laughter.)

24 MS. FAIROBENT: Lynne Fairobent with AAPM.

25 Just a question to follow-up Debbie's question

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1 regarding whether or not we're going back to subpart
2 J. I think, that as again to get back to the AAPM
3 petition, we were very careful in writing the text of
4 that petition to not preclude any other board who may
5 have been granted recognized status that was not
6 originally part of subpart J to continue to be
7 recognized under the board pathway and specifically
8 I'm talking about the Nuclear Cardiology Board because
9 they were not originally in subpart J. So I just
10 throw that out for your consideration.

11 CHAIRMAN MALMUD: The motion did not refer
12 to subpart J at all. The motion was that all of those
13 who were certified be grandfathered regardless of
14 their board.

15 MEMBER GILLEY: Then all I suggest is that
16 there be a mechanism to add new boards as more boards
17 become available so that we don't lock ourselves down.

18 MS. FAIROBENT: Yes.

19 MEMBER GILLEY: I don't know of any, but

20 --

21 CHAIRMAN MALMUD: That would be a separate
22 issue.

23 MEMBER GILLEY: Right.

24 MR. MOORE: May I ask a point of
25 clarification?

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1 CHAIRMAN MALMUD: Please.

2 MR. MOORE: Would that have the effect of
3 essentially removing 35.59, the --

4 DR. RATHBUN: That's the old subpart --

5 CHAIRMAN MALMUD: If I may, I would leave
6 it to the NRC staff which has excellent lawyers in it
7 to figure out which regulations are going to apply.
8 This body believes that those who have been board
9 certified should not have their board certification
10 interfered with. That is the spirit of this body and
11 that is the intent of this motion unless I interpreted
12 it incorrectly. And let the NRC which has a wealth of
13 staff to deal with this figure out how they're going
14 to put it into one pot or another. But clearly, this
15 is interfering with the practice of medicine and the
16 delivery of health care to patients which is what
17 we're concerned about. Item number three.

18 DR. METTER: Can I make a comment from
19 Texas?

20 CHAIRMAN MALMUD: Yes please

21 DR. METTER: I'd like to make a comment
22 that the board -- There are 24 boards that are
23 recognized by the American Board of Medical
24 Specialties and the American Board of Nuclear
25 Cardiology is a self-appointed board and it's not, I

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1 believe, part of the American Board of Medical
2 Specialties and I just wanted to make that comment.

3 (Off the record comments.)

4 CHAIRMAN MALMUD: Thank you for your
5 information.

6 MEMBER EGGLI: I would like to make one
7 additional comment about that if I might, item number
8 two.

9 CHAIRMAN MALMUD: Dr. Eggli.

10 MEMBER EGGLI: I think the intent of the
11 motion was not to disenfranchise any board currently
12 recognized but to cover the gap between October 24,
13 2005 and when the boards are currently recognized.

14 MR. MOORE: We understand.

15 MS. WASTLER: We understand that.

16 MEMBER EGGLI: Okay.

17 CHAIRMAN MALMUD: Item number three was
18 200 hours. Does someone want to pursue that?

19 MEMBER NAG: Before that, I think Part
20 35.59 should be taken off under number two because
21 that has the recency of training over the last seven
22 years and I think it should be a recommendation that
23 that need not apply.

24 (Off the record comments.)

25 MEMBER LIETO: Yes. I think, isn't

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1 grandfathering one of the points farther down?

2 (Chorus of yes.)

3 MEMBER LIETO: All right. Maybe could we
4 address it then?

5 MEMBER WILLIAMSON: I think there's a
6 recency of training bullet as well that will come.

7 (Chorus of yes.)

8 MEMBER WILLIAMSON: I think that does need
9 to be discussed.

10 CHAIRMAN MALMUD: We'll get to that one.

11 DR. RATHBUN: That's No. 9.

12 MEMBER NAG: Those can be similar. They
13 have some similarity.

14 CHAIRMAN MALMUD: That's item number nine.
15 Can we move down the list and move down to that one?

16 MEMBER NAG: Okay.

17 CHAIRMAN MALMUD: Okay. Number three, 200
18 hours. Who wants to describe that and make a motion?
19 Dr. Eggli.

20 MEMBER EGGLI: The description of the
21 issue is that for Subpart 390 200 hours is excessive
22 radiation safety training, the basic concepts of
23 radiation safety. Although there are some small areas
24 of domain knowledge that are required for each of the
25 modalities, 200 hours is an excessive safety training

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1 program in that for Part 390 again, when we originally
2 discussed this in ACMUI we recommended somewhere
3 between 50 and 80 hours for a Part 390 and that 200
4 hours is kind of over the top and basically, I can't
5 design a training program that will productively
6 consume 200 hours of safe handling and basic
7 knowledge.

8 The basic core knowledge is the same
9 across all of the radiation safety. I need a little
10 bit of domain knowledge for each of the modalities,
11 but I can do that in far less than 200 hours of
12 training. If we have to do it to comply, it will be
13 Mickey-Mouse time spent not doing anything really
14 productive and useful. It will just be marking the
15 clock.

16 And again, I think that what needs to
17 happen is that we should specify the content to be
18 mastered, not the number of hours spent on it. This
19 is the same as you would down the board certified
20 pathway. You have to design training programs that
21 teach the basic concepts that you need to learn to
22 safely and effectively administer therapeutic
23 treatment with open sources.

24 CHAIRMAN MALMUD: Dr. Williamson.

25 MEMBER WILLIAMSON: This gets to maybe a

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1 broader philosophical difference between the 200/300
2 versus 400/600 domains. As I recall 400 and 600
3 explicitly allowed for a more rigorous and
4 prescriptive alterative pathway; whereas, in 200 and
5 300 and 100, I think that you tried to make the
6 criteria for recognition of a board in the alternative
7 pathway requirements, you said, is one and the same.
8 Is that not correct? And are you --

9 DR. ZELAC: That's not correct.

10 MEMBER WILLIAMSON: That's not correct.
11 Okay.

12 DR. ZELAC: No. For 490 and for 690, the
13 requirement for the board certification pathway does
14 not get into subjects, does not get into lengths of
15 time. It simply says you've gone through a residency
16 program.

17 MEMBER WILLIAMSON: That's what I said,
18 but I believe that 200 and 300 don't do that.

19 DR. ZELAC: That's correct.

20 MEMBER WILLIAMSON: I think 200 and 300
21 are the opposite. They link the alternative pathway
22 with the content of the ACGME, the residency training
23 and experience. So are you proposing more
24 fundamentally that those be decoupled?

25 MEMBER EGGLI: Well, what I guess what I

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1 would be proposing is that the material to be mastered
2 can be prescribed. But again, the amount of time it
3 takes to master that material should not be prescribed
4 and that, in fact, I don't think I can design 200
5 hours of useful education to cover this and not waste
6 a lot of time. And again, I would ask any -- I don't
7 know if I can, but I would ask Dr. Royal if he could
8 address that issue from the American Board of Nuclear
9 Medicine.

10 MEMBER WILLIAMSON: So to clarify my -- to
11 answer my question, you basically -- This is a change
12 you propose for both the alternative pathway and the
13 board certification pathway.

14 MEMBER EGGLI: No, 200 hours is not
15 imposed in the board certification pathway.

16 MEMBER WILLIAMSON: I see.

17 MEMBER EGGLI: It's only right now imposed
18 in the alternative pathway. But if the boards have to
19 train to the alternative pathway level of training,
20 then it becomes a de factor requirements for the
21 board.

22 (Off the record comments.)

23 MR. ROYAL: So I would just make the
24 comment that when Deb was talking about these number
25 of hours, she referred to them in the alternative

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1 pathway as being the minimum number of hours that were
2 required.

3 MEMBER GILLEY: For a non-residential
4 program. This is not a residency program.

5 MR. ROYAL: But it's hard to -- From a
6 board's point of view, if this is perceived as the
7 minimum amount of training for the alternative
8 pathway, it's hard to understand why someone who is in
9 the board certification pathway would not also require
10 this minimum amount of training. So when you say 200
11 hours for 390 for the alternative pathway, it's hard
12 for the boards to ignore that.

13 One of my fundamental problems with it is
14 it's irrational. We had this discussion early in the
15 afternoon about the 80 hours for 392 and the 80 hours
16 for 394 and I thought I heard everyone say "Well,
17 those are the same 80 hours." And yet, if you do 390,
18 you're supposed to do 200 hours. But if the 80 hours
19 for 392 and 394 are the same 80 hours, then somehow
20 you're supposed to do 80 more hours for 396. It's
21 hard to understand with all of that overlap how you
22 could possibly get to 200 hours. So I think the
23 regulations just don't add up mathematically.

24 CHAIRMAN MALMUD: Yes?

25 MR. MOORE: I would just like to say on

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1 this issue that the staff will certainly look at and
2 value any guidance that we receive from the ACMUI.
3 But when we were developing Part 35, the issue of how
4 many hours and especially the 200 hour mark was a
5 serious sticking point with the agreement states.

6 We had extensive evaluation of what should
7 be the appropriate number of hours. We went back.
8 The staff had a working group that went back and
9 looked at the amount of training that was offered in
10 general training programs and found that 200 was a
11 general amount that was available outside.

12 I think that we would certainly value any
13 input from the ACMUI and look at it. But we will have
14 an extremely tough time with agreement states if there
15 is a change in this to remove a number of hours
16 entirely and not specify a number of hours.

17 CHAIRMAN MALMUD: Dr. Eggli.

18 MEMBER EGGLI: When this came up in the
19 final review, Ed Bailey who was the state
20 representative at the time said, in fact, it wasn't
21 all 34 agreement states, that it was driven by two
22 agreement states who were particularly insistent and
23 the rest kind of went along. That was what he
24 reported back to this committee.

25 So I'm not convinced that this burns in

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1 the heart of all agreement states, but we know from Ed
2 Bailey that it did in two particular agreement states.
3 And maybe Debbie could address that issue or Paul.

4 MEMBER GILLEY: We do suggest to state
5 regulations. We have a subpart G that is the
6 equivalent or parallel to NRC's Part 35 and that has
7 been adopted and approved by the Conference of
8 Radiation Control Program directors with that 200
9 hours in place there. The 200 hours is nothing new.
10 That again has been since 1988. We required that for
11 alternative pathways. This is not a new requirement
12 because of Part 35. It is an existing requirement and
13 it is not driven for those residency programs for
14 nuclear medicine or radiology. It's that other subset
15 of programs that are out there and there are private
16 companies that provide this training and that is where
17 that oversight comes from, is required. It's for
18 those organizations.

19 DR. RATHBUN: Lynne.

20 MS. FAIROBENT: Lynne Fairobent, AAPM. As
21 with some of the ACMUI members, I think I've been at
22 every public meeting where these points have been
23 discussed since probably 1991 or so, 1995. A couple
24 of things that maybe will get us out of this dilemma
25 for the 200 hours in the Part 200 and 300 series of

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1 regulations. Perhaps what we should look at now is,
2 and I hate to say this, but a three-fold-type criteria
3 where you have the board pathway and we develop
4 language similar to what was done in 400 and 600 to
5 recognize those individuals that come out of approved
6 residency programs for nuclear medicine and then have
7 an alternative pathway for individuals who are not
8 coming through approved residency programs to get to
9 Debbie's point of where the original basis for the 200
10 hours came from.

11 That was not looked at or discussed during
12 the development of the rule. Because if you remember,
13 the number of hours that OAS proposed was at the 11th
14 hour between the draft and the final rule and was
15 truly not put out for public comment officially to
16 comment on the number of hours that came out in the
17 final regulation other than the minimum 30 day period
18 of when a final rule appears.

19 So perhaps we should really go back and
20 investigate if there is a way in which to develop
21 language to recognize the bona fide residency programs
22 in this area and then an alternative pathway if
23 someone is not coming through residency programs.

24 DR. RATHBUN: Scott.

25 MR. MOORE: Lynne, to the fairness of the

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1 Organization of the Agreement States and to the ACMUI,
2 it's NRC's practice to provide the draft final rule
3 and the draft proposed rule to both the Organization
4 of Agreement States and to the ACMUI in pre-decisional
5 form to both the ACMUI and the OAS and that's why they
6 see it in pre-decisional form and comment back to us
7 on it, the ACMUI and OAS.

8 MS. FAIROBENT: Right, but, Scott, my
9 point was the number of hours was never put out in a
10 public forum for the public to have an opportunity to
11 comment on the 200 hours. If you go back and look at
12 the record, it appeared between the publication of the
13 draft rule for comment and the final rule that was
14 pre-decisional and provided to ACMUI and the agreement
15 states to comment on it. It was only at the ACMUI
16 meeting discussing this that there was any public
17 discussion on the origin or the basis of the number of
18 hours being input into the final rule.

19 DR. RATHBUN: Let's --

20 MEMBER LIETO: This is Ralph Lieto. I
21 just wanted to support what Lynne just said because we
22 actually had a teleconference on this very issue
23 because it was such a substantive change from what had
24 been proposed from the get-go. When it had gone
25 through advanced notice through proposed, there was

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1 never those specific hours and then they come in. It
2 really took everybody quite off-guard. So in all
3 fairness, the regulated community, the stakeholders,
4 did not have the opportunity to see those changes and
5 comment on them before they became final rule.

6 DR. RATHBUN: Dr. Welsh.

7 MEMBER WELSH: I might be reiterating
8 what's already been said here, but I would like to
9 advocate --

10 DR. RATHBUN: Dr. Welsh, could you bring
11 the microphone closer? Thank you.

12 MEMBER WELSH: I'd like to advocate a bit
13 of caution here because the 200 hours is something
14 that might be appropriate for those who are not board
15 certified or who have not gone through residency
16 training. If you remove something that is strict and
17 stringent, it opens up the pathway for those who are
18 not trained in nuclear medicine/radiation oncology to
19 seek a weekend course or a two week course that gets
20 X number of hours in but would not meet our standards
21 for administering radiopharmaceuticals and although
22 200 hours might seem excessive, it's something that's
23 probably easily met in reality during the residency
24 training and I would advocate that we don't say
25 anything about number of hours if somebody is board

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1 certified. But if somebody has failed to meet board
2 certification, this might not be inappropriate.

3 CHAIRMAN MALMUD: Dr. Williamson.

4 MEMBER WILLIAMSON: Well, I think it was
5 Ralph's motion, correct, you put in the table? Who
6 put the motion on the table?

7 MR. MOORE: I don't think there's one on
8 this one.

9 CHAIRMAN MALMUD: There is no motion on
10 the table.

11 (Off the record comments.)

12 MEMBER WILLIAMSON: I would move that we
13 proposed amending the 200 and 300 series of training
14 and experience requirements to include a three-level
15 requirement as proposed by Lynne Fairobent that
16 includes board certification pathway which requires
17 a residency, an approved residency. And with the
18 residency or the certification exam, only the content
19 to be mastered would be specified and the third level
20 would be the alternative pathway II which would be
21 training and experience acquired outside of an
22 approved residency program that would retain the 200
23 hour requirement. Alternative pathway I would be
24 successful completion of an approved residency
25 program.

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1 So there would be more complicated
2 alternative pathway requirement. Alternative I would
3 be residency program. Alternative II would be the
4 more prescriptive pathway as currently written.

5 CHAIRMAN MALMUD: Dr. Van Decker.

6 MEMBER VAN DECKER: I don't know the
7 answer to all of this stuff and as we all know, this
8 has been talked about for decades now. But I'm a
9 little bit concerned about making multiple levels of
10 ways to do things when we're really concerned about
11 how complicated things are right now.

12 I would suggest that this piece of the
13 topic be thought about some and some thoughtful
14 comments came back after people do some thinking. But
15 I'm a little bit nervous about multiple levels of
16 different things going on. But I do agree that
17 obviously prescription is not necessarily the answer
18 to a lot of situations.

19 DR. RATHBUN: Dr. Fisher, Dr. Nag and then
20 I have to take a small break because we have to read
21 something into the record.

22 MEMBER FISHER: This is Darrell Fisher.
23 In my simplistic view, the way the text reads under
24 35.50 if you simply deleted "200 hours of" the text
25 goes on to read "classroom and laboratory training in

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1 the following areas" and then those areas are well
2 described. I think that's sufficient without being
3 prescriptive on the number of hours.

4 DR. RATHBUN: Dr. Nag.

5 MEMBER NAG: I see here seeing 35, 200 and
6 300, I think the requirement was only 300. The 200 is
7 simple --

8 MEMBER EGGLI: The 200 is 80 hours. The
9 300 is 200 hours.

10 MEMBER NAG: Yes. So I just think we need
11 to have 200 in there and then being 35.39 in fact
12 should be 35.39 -- if I'm correct.

13 CHAIRMAN MALMUD: Someone else who had a
14 comment?

15 DR. ZELAC: Yes.

16 DR. RATHBUN: Ron.

17 DR. ZELAC: A quick one. It's more of a
18 comment and a question. Dr. Eggli, what would you
19 think of 120 hours? No, I'm serious. There is a
20 basis for my asking this.

21 MEMBER EGGLI: I understand this is a
22 little bit of Let's Make A Deal that the requirements
23 should be -- I can see where you're coming from that
24 the requirement ought to be greater than Part 200, but
25 maybe then, you're bowing to the 300 hours for Part

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1 390 being excessive. You know, the bottom line is I
2 guess we work with what the regulation is. But for
3 me, again, I thought 80 was excessive for Subpart 200
4 training in 290.

5 I can put together a nice training program
6 that I think meets all the needs of Part 390 in 80
7 hours of training or so. I don't advocate specifying
8 the number of hours, but if we could get there, I'll
9 take some relief.

10 DR. ZELAC: The reason I asked it in that
11 way is that there was when the 2002 rule was being
12 crafted I think a general consensus that 80 hours for
13 therapeutic use was not sufficient and that was going
14 to be raised and the question was what to raise it to
15 and the thought was that an individual who would be
16 spending four months in a department or approximately
17 700 hours would have ample opportunity to learn
18 hopefully both the radiation safety aspects and
19 adequate number of clinical skills to be able to
20 function effectively and independently. So the 2002
21 rule, in fact, for the alternative pathway came out
22 with 700 hours, no specification separately for
23 classroom and laboratory.

24 MEMBER EGGLI: Right.

25 DR. ZELAC: And that's, in fact, what was

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1 in the proposed change for Part 35 in 2005 as well.
2 The reason I mention 120 hours was when the 2002 rule
3 was being crafted there was a survey done as to just
4 what the length of the classroom and laboratory
5 experience was and it turned out that it was 120 hours
6 and so it was basically going to be "Well, you have
7 120 hours of classroom and lab and the remainder to
8 get to 700 hours would be in the clinical setting
9 which would cover radiation safety, but other aspects
10 as well."

11 MEMBER EGGLI: Again, I would favor
12 whatever form of relief from the 200 hours can be
13 obtained.

14 DR. RATHBUN: Okay. Would you have a
15 motion on the table?

16 CHAIRMAN MALMUD: There isn't a motion on
17 the table.

18 MEMBER WILLIAMSON: There is a motion.

19 CHAIRMAN MALMUD: It's not been seconded.
20 Who made the motion?

21 MEMBER WILLIAMSON: I made the motion.

22 CHAIRMAN MALMUD: What was the motion?

23 MEMBER WILLIAMSON: The motion was that
24 there be a three-level training and experience
25 requirement for 35.300, board certification,

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1 alternative pathway with a clinical approved residency
2 and alternative pathway with non-approve residency
3 training.

4 CHAIRMAN MALMUD: Is there a second to
5 that motion? Are you seconding it?

6 MEMBER WELSH: I'm seconding it.

7 CHAIRMAN MALMUD: Dr. Welsh seconds it.
8 Is there any further discussion of that motion?

9 (No response.)

10 CHAIRMAN MALMUD: All in favor of that
11 motion?

12 (Show of hands.)

13 CHAIRMAN MALMUD: All opposed?

14 (Show of hands.)

15 CHAIRMAN MALMUD: It doesn't carry. May
16 I make a motion?

17 DR. RATHBUN: Yes.

18 CHAIRMAN MALMUD: That the number -- That
19 we, first of all, not use the word "excessive" with
20 regard to the 200. Two hundred is more than
21 sufficient but it's not excessive. We could never had
22 excessive training.

23 (Laughter.)

24 CHAIRMAN MALMUD: That we feel that the
25 training requirements could be met adequately with 120

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1 hours and that that is our recommendation that the 200
2 be changed to 120 because that is what training
3 program directors feel is more than sufficient to meet
4 the training requirements in the type of physics we're
5 talking about. So that's the motion.

6 DR. RATHBUN: Does somebody second his
7 motion?

8 MEMBER EGGLI: I'll second it.

9 CHAIRMAN MALMUD: Dr. Eggli seconds it.
10 Any further discussion of that motion? Yes. Dr.
11 Welsh.

12 MEMBER WELSH: Is that 120 hours part of
13 the 700 hours of clinical experience in the field of
14 nuclear medicine?

15 CHAIRMAN MALMUD: Yes. And the 120, by
16 the way, if you take the average college course, it's
17 about 12 weeks, three hours a week, 36 hours. So
18 we're talking about over a year and a half of a
19 college course in nuclear medicine and physics. I
20 think that's more than sufficient.

21 MEMBER WILLIAMSON: That's quite a bit.

22 CHAIRMAN MALMUD: But it's not -- Yes,
23 it's more than sufficient but not so little that
24 somebody could walk through the back door and say, "I
25 took the course in Las Vegas last week and I meet the

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1 hours. I was up day and night doing it." Because
2 there is a risk that the standards are taken to the
3 minimum, that someone may take advantage of them and
4 that would not be in the public welfare. So that's
5 why I suggested the 120.

6 MEMBER NAG: Yes. I think there is a big
7 difference between the number of hours as part of a
8 residency training program requirement because during
9 that residency training you are also learning other
10 things that help you make the decision and a
11 standalone course where you have no knowledge of what
12 radiation is.

13 CHAIRMAN MALMUD: There is a motion on the
14 floor. Any further discussion?

15 (No response.)

16 CHAIRMAN MALMUD: Anyone in favor of the
17 motion?

18 (Show of hands.)

19 CHAIRMAN MALMUD: All those opposed?

20 (Show of hands.)

21 CHAIRMAN MALMUD: Any abstentions?

22 (No response.)

23 CHAIRMAN MALMUD: I guess two oppose.

24 DR. RATHBUN: Motion carries.

25 CHAIRMAN MALMUD: Motion carries.

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1 DR. RATHBUN: All right. I need to do two
2 things. Cindy needs to read something into the record
3 and does this have to be done today?

4 MS. FLANNERY: Yes.

5 DR. RATHBUN: All right. Then start
6 reading.

7 MS. FLANNERY: Thank you. I just wanted
8 to make an announcement for the ACMUI and have this go
9 on public record. Just a very short time ago, you
10 received a couple of letters. They are dated April 26
11 of this year and June 11. I just wanted to ask that
12 you treat these as pre-decisional and handle them just
13 like you would any other pre-decisional documents that
14 you would get via email or in your binders which is
15 basically to not release them until they have -- until
16 such time that they've been publicly released. So
17 thank you, Pat, for giving me a minute to say that.

18 DR. RATHBUN: You're welcome. Okay.

19 CHAIRMAN MALMUD: And Ashley has a very
20 brief statement, too, regarding travel folders.

21 MS. TULL: Really quickly. There are
22 folders for all the ACMUI members with your names on
23 the front. They have your pay vouchers and your
24 travel expense sheet. If you guys can take a look at
25 those this evening, try to fill them out. Anywhere

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1 that's highlighted needs a signature. I'll need this
2 back at the end of the meeting tomorrow.

3 CHAIRMAN MALMUD: Thank you.

4 MS. TULL: Thanks.

5 MEMBER NAG: Ashley. Yes. For the pay
6 vouchers, it's for the two weeks starting from
7 yesterday which means we can submit that a week from
8 now because otherwise we wouldn't know what we are
9 doing next week. You will have difficulty trying to
10 reconcile it.

11 MS. TULL: You are correct, but if you can
12 fill in or give me a signature on anything. There are
13 instructions on that. If you can just take a look at
14 it please.

15 DR. RATHBUN: Okay. As really as a
16 neutral outsider, what I am seeing here is if we had
17 an ACMUI viewpoint on these issues because you were
18 making the motions, I think if we had that, I think
19 the NRC would have a better chance then of going
20 forward and trying to work out some kind of solution.
21 I don't know quite how to do that. I don't really
22 want to backtrack to do this. We could do it, I
23 guess, by letter. I don't know the process well
24 enough.

25 I also see though that we have an

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1 agreement state issue, not issue, but in other words,
2 challenge. Well, we have a new family that's come on
3 board here in our office and we're trying to work that
4 out. So we're going to need some kind of consensus
5 from the agreement states. Ashley.

6 MS. TULL: This is Ashley Tull. As far as
7 logistics, ACMUI does have teleconference.

8 DR. RATHBUN: Okay.

9 MS. TULL: This is something that needs to
10 carry over. In the past, we have done this where
11 ACMUI would call in and I guess we need to include the
12 agreement states.

13 DR. RATHBUN: Okay.

14 MS. TULL: So when we do have a
15 teleconference venue.

16 DR. RATHBUN: Now is that something that
17 would be agreeable?

18 MS. TULL: Yes.

19 DR. RATHBUN: Yes sir.

20 MEMBER WILLIAMSON: I think to deal with
21 the other nine issues in the next five minutes is
22 obviously a logistic impossibility.

23 DR. RATHBUN: It won't work.

24 MEMBER WILLIAMSON: And I think if this is
25 considered important which I think it should be --

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1 DR. RATHBUN: Yes.

2 MEMBER WILLIAMSON: -- I would recommend
3 that probably a noticed telephone conference which all
4 the same individuals might be willing to convene.

5 DR. RATHBUN: Right.

6 MEMBER WILLIAMSON: And we could carry on
7 the discussion for a longer period of time.

8 DR. RATHBUN: Yes.

9 MEMBER WILLIAMSON: Rather a separately
10 noticed physical meeting.

11 DR. RATHBUN: Something like that because
12 we are well ahead of the game because we now have a
13 list of the issues.

14 (Off the record discussion at same time.)

15 DR. RATHBUN: And before you really had an
16 amorphous set of comments. So I think we're better
17 off than we were when we started and I think there is
18 a path forward. Yes ma'am. Sally.

19 MEMBER SCHWARZ: And as a corollary, the
20 public can be included in this conference.

21 DR. RATHBUN: Sure. So then -- Yes ma'am.
22 I could be wrong because I don't know any procedures.
23 Go ahead.

24 MS. TULL: The answer is to Sally's
25 question is yes.

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1 (Off the record comment.)

2 DR. RATHBUN: So having said that --

3 MEMBER SCHWARZ: I believe they have to
4 email someone to be on the list for the
5 teleconference.

6 MS. TULL: It will publicly noticed in the
7 *Federal Register*. So that's how everyone could find
8 out about it.

9 MEMBER EGGLI: Now we have to email you to
10 get the passcode and the number.

11 MS. TULL: Yes.

12 DR. RATHBUN: Right.

13 MS. TULL: So I can control the number of
14 lines.

15 MEMBER EGGLI: Right.

16 DR. RATHBUN: Dr. Malmud, is this
17 something that is okay with you?

18 CHAIRMAN MALMUD: Absolutely.

19 DR. RATHBUN: Okay. All right.

20 MS. WASTLER: Actually, you indicated was
21 to control the number of lines. That's not what I'm
22 trying to control is the number of lines. It's to
23 make sure we have sufficient number of lines.

24 MEMBER EGGLI: To get enough.

25 MS. TULL: Yes. Obtain.

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1 MS. WASTLER: So that we don't exclude
2 somebody. That's why it's important for us to know
3 you is who is going to call in so we can make sure we
4 have all our bases covered and somebody doesn't keep
5 dialing and going "I can't get in."

6 MEMBER SULEIMAN: This will require
7 another FR notice. Right?

8 (Chorus of yes.)

9 MS. WASTLER: Yes it will.

10 MEMBER NAG: The only concern I have is
11 that ACMUI has made a number of these statements
12 before and we have been totally ignored. Are we going
13 to be ignored again? If we are, I'll refuse to
14 participate.

15 DR. RATHBUN: -- and that's what they
16 brought me in because they've selected an outside
17 facilitator and it's my responsibility to make sure
18 that the things you said here get worked on. So as
19 far as I'm concerned, the answer is you are not going
20 to be ignored.

21 MR. MOORE: I would also say that while
22 the ACMUI's position last time was not accepted in the
23 final analysis by the Commission, its advice and input
24 was certainly not ignored. The staff certainly took
25 the input and has provided that information up and

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1 will diligently continue to do that. So we heard you
2 today say that maybe it's time to readdress this issue
3 with the Commission and ask that the Commission relook
4 at the issue of preceptor statements given the new
5 experience. So we do hear you and I want you all to
6 know that your advice is not being ignored.

7 I have a few administrative issues.

8 DR. RATHBUN: Okay. So we've agreed that
9 we're going to continue. I did want to hear from Ron.

10 DR. ZELAC: That was exactly what I was
11 going to suggest.

12 DR. RATHBUN: Okay. And in some cases,
13 Ron has done a lot of research on this and so I would
14 like to see you put something into these questions,
15 maybe things we try or something like that, to move us
16 another step forward. Yes sir.

17 DR. BROGA: Dean Broga. The RSO issue is
18 a looming issue for thousands of community hospitals.
19 We have an ambiguity that if you're an agreement state
20 an authorized user can become an RSO immediately and
21 not in the rest of the NRC states. Will there be time
22 tomorrow morning in the RSO discussion to talk about
23 that?

24 DR. RATHBUN: If that's acceptable to Dr.
25 Malmud. We could spend a little time in the morning

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1 on that.

2 DR. BROGA: I mean, this affects
3 radiologists, Society of Nuclear Medicine,
4 cardiologists.

5 DR. RATHBUN: And the public.

6 DR. BROGA: It's all of them that's
7 affected by that.

8 DR. RATHBUN: The health and safety of the
9 public. So if Dr. Malmud would.

10 CHAIRMAN MALMUD: By all means.

11 MS. WASTLER: I would point out that Mr.
12 Lieto is already on the schedule to talk about the
13 issue of having one RSO on a license.

14 DR. RATHBUN: Good. Excellent. Okay.

15 (Off the record comments.)

16 DR. RATHBUN: All right. Donna-Beth.

17 DR. HOWE: I'm also on the schedule
18 tomorrow to talk about some potential changes to Part
19 35.

20 DR. RATHBUN: Okay.

21 DR. HOWE: And there are some issues in
22 there that are included in the potential changes to
23 Part 35.

24 DR. RATHBUN: So you might have some
25 proposed changes that would resolve some of these

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1 issues. Is that what you're telling us?

2 DR. HOWE: Into a user need memo that will
3 go to the rulemaking group this summer.

4 DR. RATHBUN: Okay. All right. Then with
5 that and with Dr. Malmud's permission, I was going to
6 close this part and then go -- I want to go ahead and
7 close this session and -- Yes.

8 DR. ZELAC: One very, very quick thing.
9 I have to confess that when I was asked about what
10 Dean Broga had been talking about, if I had a
11 response, I wasn't paying attention and that I think
12 had to do with retribution in case you were assigning
13 preceptor statements inappropriately. There is
14 something in the March 30, 2005 rule addressing that
15 specifically. If an individual is authorized as
16 whatever and signed a preceptor statement and the
17 person that he signs for turns out to not be
18 satisfactory, that has no bearing at all on the
19 person's status as an authorized individual. However,
20 if the individual signs a preceptor statement
21 knowingly false, that's another issue entirely.

22 DR. RATHBUN: All right. This is going to
23 be covered. Okay. Donna-Beth, we'll get it tomorrow.
24 Now again, I want to thank you. This was quite a
25 challenge and I appreciate all of your help, Dr.

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1 Malmud for picking up the ball when I dropped it and
2 everyone. So with that, I'm going to close the
3 meeting and turn it over to Scott.

4 CHAIRMAN MALMUD: Before you do that, we
5 want to thank you for your help and your
6 participation. Thank you.

7 (Applause.)

8 MR. MOORE: Thank you, Pat. Thank you,
9 Dr. Malmud. I have three quick administrative items.
10 In March, the Commission gave staff direction through
11 a staff requirements memorandum which is the way the
12 Commission gives staff written directions to follow up
13 on to work with the agreement states to develop a plan
14 for fingerprinting the recipients of orders of IC,
15 increased control orders, and it tasked the staff to
16 work with the agreement states to develop such a plan
17 and have it in place by and have the requirements in
18 place by September.

19 NRC has formed a working group with the
20 agreement states to develop such a plan and is moving
21 to do that. It will have some effect on the medical
22 community, especially hospitals that have things like
23 blood irradiators or large gamma knives, large
24 sources, essentially, those hospitals that have
25 received increased control orders or legally binding

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1 requirements from agreement states that have increased
2 controls in them.

3 We think it would be appropriate to brief
4 the ACMUI on these efforts that are going forward. We
5 need to set up such a briefing at some time in the
6 near future, sometime over the summer and we'll have
7 a follow-on to do that. Sandi and her staff will set
8 such a briefing.

9 We want to make you aware of it at this
10 point, but let you know that that will have to be done
11 through a separate briefing. It wasn't far enough
12 along when we prepared the agenda for this meeting
13 which was back, I think, at th start of May to get it
14 onto this meeting's agenda.

15 The second item is this. The Commission
16 recently was briefed in a meeting, we called it the
17 AARM meeting, as part of a review of operational
18 events and data. As part of that discussion, we
19 received direction in that meeting and then we expect
20 to receive written direction afterwards that we're
21 being asked to work towards a goal of or we're being
22 tasked to work towards a goal of minimizing, if not
23 eliminating, therapeutic medical events to prevent
24 injuries from nuclear medicine. We expect that the
25 Commission will tell us to do that.

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1 We will need to engage ACMUI in a
2 discussion of that. There was a discussion that came
3 out during the Commission briefing on those events.
4 The number of such events are fairly low. That came
5 out during the discussion, but as part of the
6 discussion, we were told to work towards a goal of
7 minimizing, if not eliminating, therapeutic medical
8 events and so we will need to engage ACMUI on such a
9 discussion. We'll need to have a further follow-on
10 discussion with ACMUI on that issue. Mr. Lieto.

11 MEMBER LIETO: A point of clarification.
12 Were these medical events that were classified as
13 abnormal occurrences raising the issue or just medical
14 events in general?

15 MS. WASTLER: As I recall the specific
16 events that were in question were fetal doses and then
17 what we have seen at the point or I guess what's under
18 potential added discussions of the Commission is I
19 think it's a broader topic and so it's talking about
20 events in general, not necessarily abnormal.

21 MR. MOORE: Not just AOs but --

22 MS. WASTLER: Not just AOs.

23 MR. MOORE: But reportable events. Okay.

24 MEMBER LIETO: Because I think the
25 committee is already on record as regarding medical

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1 events and improvements that could go towards that
2 issue regarding sodium iodide in 131 therapies which
3 those two fetal dose events were resulting from. So
4 I think we've already made recommendations on that.
5 It's just a matter of those getting --

6 MS. WASTLER: I would recognize -- I mean
7 the committee has been very helpful.

8 MEMBER LIETO: Okay.

9 MS. WASTLER: And they reviewed several
10 INs that we've put out based on events that have taken
11 place. I think the Commission may not be aware of
12 those individual cases. So it's an opportunity to
13 make them aware, but I think in general our goal is
14 always to have the number of events zero. That's a
15 great goal, but we're talking about human nature and
16 individuals and --

17 MEMBER WILLIAMSON: To insist on a goal of
18 zero means spending infinite resources to preclude
19 error.

20 MS. WASTLER: But if there are fixes that
21 we can -- But there are always ways we can improve
22 things and if there are things or there are activities
23 out there or processes out there where we could make
24 simple fixes -- we talked about this morning in your
25 presentation potential things that we could do with

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1 regards with Air Kerma and putting an IN out there.
2 That would be an opportunity for us to maybe educate,
3 maybe change someone's thoughts with regards to a QA
4 process that would improve the process and therefore
5 possibly eliminate some of the events or minimize
6 them.

7 MEMBER WILLIAMSON: But you are already
8 doing that.

9 MS. WASTLER: I realize that, but the
10 Commission -- I think that's the question that we
11 have to raise, that the Commission is asking us to
12 look at.

13 MR. MOORE: In raising it with you, I
14 wanted you to be aware of the meeting that was held
15 with the Commission. It went over events, not just
16 medical events, events across the board in the whole
17 materials area and as part of that discussion, it came
18 out that the staff should work towards a goal of
19 minimizing, if not eliminating, events in general, but
20 also therapeutic medical events. So they gave us
21 specific feedback in that area and we want to work
22 through the ACMUI to do that.

23 We already, we believe, we the staff
24 believe, that we're already working through the ACMUI
25 to do so. We brief you on events. We receive

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1 feedback from you on how we can do that. But as we
2 move forward on such direction from the Commission, we
3 want to make sure that we do that in coordination with
4 the ACMUI and that the staff not just develop
5 something independently and go back and answer the
6 question.

7 MEMBER NAG: Why is it only for nuclear
8 medicine? I mean, that's the same for any other
9 radiation application with quality for --

10 MR. MOORE: I think the Commission
11 intended that broadly. I didn't think they meant it
12 specifically.

13 (Off the record comments.)

14 MR. MOORE: Okay. The third issue is
15 this. The committee asked about a briefing. There
16 was a question from Dr. Eggli through Dr. Malmud if
17 you could be briefed in a closed meeting on the
18 petition for rulemaking from the AAPM.

19 At this point, we're still looking into
20 it. We raised the issue with our legal counsel. They
21 are looking at it. There are some things they have to
22 look at regarding the Federal Advisory Committee Act.
23 The ACMUI is a federal advisory committee to the
24 agency and they have to look at it and make sure we
25 don't violate the FACA rules.

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1 But the staff's preference is that we
2 would be able brief the advisory committee in some
3 manner on it in a closed session, if possible, if we
4 can legally do that. So we will try to find a way
5 that we can give a briefing to either the ACMUI or a
6 subgroup of the ACMUI which may be possible under FACA
7 and if we can do that, we would like to do that. So
8 we will pursue it with our legal counsel and find out
9 if we can. But we will go forward and continue to
10 look into that.

11 Unfortunately, I will not be able to meet
12 tomorrow. I'm out of the agency tomorrow and Sandi
13 will be here for you as your Federal Official. Thank
14 you very much, Dr. Malmud.

15 CHAIRMAN MALMUD: Thank you.

16 MS. WASTLER: Dr. Malmud, I'll turn the
17 meeting back to you, sir.

18 CHAIRMAN MALMUD: I'm going to just ask to
19 adjourn the meeting and hope to see you all here at
20 8:00 a.m. tomorrow morning. Thank you for a very
21 intense, long day. Off the record.

22 (Whereupon, at 5:08 p.m., the above-
23 entitled matter was concluded.)

24

25