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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

(ACMUI)

+ + + + +

SUBCOMMITTEE ON TRAINING AND EXPERIENCE REQUIREMENTS

+ + + + +

FRIDAY

JUNE 21, 2002

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ROCKVILLE, MARYLAND

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The Subcommittee met at the Nuclear
Regulatory Commission, Room T2B3, Two White Flint
North, 11545 Rockville Pike, at 8:03 a.m., Dr. Richard
J. Vetter, presiding.

SUBCOMMITTEE MEMBERS PRESENT:

RICHARD J. VETTER, Chairman

JEFFREY A. BRINKER, Member

MANUAL CERQUEIRA, ACMUI Chairman

DAVID A. DIAMOND, Member

RUTH MCBURNEY, Member

JEFFREY WILLIAMSON, Member

JOHN W.N. HICKEY, Designated Federal Official

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1 STAFF PRESENT:

2 ANGELA WILLIAMSON

3 INDA PSYK

4

5 ALSO PRESENT:

6 PHILIP O. ANDERSON, ABR

7 JAMES A. BOXALL, JR., ANSC

8 DR. PAUL CAPP, ABR

9 PAUL CHASE, AOBR/AOBNM

10 LYNNE FAIROBENT, ACR

11 DR. RICHARD FEJKA, BPS/APHA

12 RANDY FENNIN, SEIC

13 ANGELA FURERON-LEE, AAPM

14 SHAWN GOOGINS, ABHP/NIH

15 DR. WILLIAM HENDEE, ABR

16 DONNA BETH HOW, NRC

17 DAVID H. HUSSEY, ASTRO

18 WILLIAM D. NELLIGAN, CBNC

19 M. GARY SAYED, ABSNM

20 KRISTIN SIMONSON

21 DR. DAVID STEIDLEY, ABMP

22 WILLIAM R. UFFELMAN, ESQ., SNM/ABNM

23 DR. WILLIAM VAN DECKER, CBNC

24

25

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

(8:03 a.m.)

1
2
3 CHAIRMAN VETTER: My name is Richard
4 Vetter and I have been appointed by Dr. Cerqueira to
5 be the Chair of this Subcommittee on training and
6 education as it relates to the NEU Part 35. I would
7 like to welcome members of the Subcommittee and Dr.
8 Cerqueira, the NRC staff and our public visitors ,
9 here today.

10 The subcommittee has been working via e-
11 mail to come up with some preliminary recommendations
12 and the purpose of the meeting here today is to
13 discuss those preliminary recommendations and come to
14 a consensus on a recommendation for the training
15 education requirements as spelled out in Part 35.

16 Dr. John Hickey from the NRC, he and his
17 staff have been supporting this activity, and John has
18 some remarks to make this morning.

19 MR. HICKEY: Good morning, and welcome to
20 the NRC. Thank you for attending the meeting. I am
21 the designated Federal official for ACMUI, which means
22 that I have day to day responsibility for the
23 interactions between the committee and the Commission.

24 The function of the ACMUI is to provide
25 advice and recommendations on medical issues to the

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1 NRC, and the Commission appreciates the time that the
2 Committee takes on these matters because they also
3 have very busy schedules at their institutions.

4 This particular session is as Dr. Vetter
5 said, is on training and experience requirements in
6 the NEU Part 35, which was published on April 24th.
7 The new rule has been published in the Federal
8 Register and is available on our website, and there
9 are excerpts in the handouts that are available on the
10 shelves in the back of the room that include the
11 training and experience requirements that were
12 published.

13 Prior to publication the Commission was
14 informed of implementation problems related to
15 training by the ACMUI and by other parties.
16 Therefore, the Commission changed the final rule to
17 retain the old training experience requirements for
18 two years in parallel with the new requirements.

19 And during that two year period the
20 licensees can follow either the older requirements or
21 the new requirements in establishing qualifications
22 for their authorized users and other authorized
23 persons.

24 In addition, the Commission stated that it
25 would work with the medical community to address

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1 implementation problems and work with the ACMUI. So
2 it was in that context that this subcommittee was
3 appointed. And the Commission looks forward to
4 receiving the recommendations of the Committee.

5 And the recommendations will be carefully
6 considered, but I want to emphasize that the
7 recommendations to the Committee do not constitute
8 final action by the Commission. The Commission will
9 still need to determine if the changes will be made,
10 and what changes will be made, and if the changes, if
11 they are made, might not necessarily coincide with the
12 recommendations of the Committee.

13 This is a transcribed public meeting, and
14 so all speakers should keep in mind that they are
15 speaking for the public record, and I will turn the
16 meeting back to Dr. Vetter to introduce the other
17 members of the subcommittee, and proceed with the
18 meeting. Thank you, doctor.

19 CHAIRMAN VETTER: Thank you very much,
20 John. Dr. Cerqueira, in his capacity as Chair of the
21 ACMUI, at our last meeting appointed the subcommittee
22 to address this training and education issue.

23 Members of the Committee, besides myself,
24 are Ruth McBurney, who represents the States; Jeff
25 Williamson, representing Therapy Physicists; David

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1 Diamond, representing Radiation Oncologists; and
2 Jeffrey Brinker, representing Interventional
3 Cardiology.

4 The Committee has worked informally via E-
5 mail and telephone to come up with some preliminary
6 recommendations, and this is our first meeting to
7 actually discuss those recommendations.

8 I will spend just a moment on the agenda,
9 just so that everyone is in agreement here. The plan
10 is to finish by noon or before. We will start by
11 discussing the charter, and just review that very,
12 very briefly, and then discuss the subcommittee
13 recommendations, the goal being to come to a consensus
14 on what those recommendations would be.

15 Now, the preliminary recommendations we
16 have written. I'm sorry, I am getting ahead of myself.
17 And we will discuss those recommendations and we will
18 take a short break mid-morning, and then we will open
19 it up for public comments.

20 Those who wish to make public comments
21 should register. There is a sheet here to register and
22 let the NRC staff know that you do wish to make
23 comments, and then we will open the meeting for these
24 public comments after our break.

25 We do request that public comments be

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1 limited to 10 minutes. And then finally at the end of
2 the meeting hopefully we will have a consensus that we
3 can review, and that consensus will be presented to
4 the ACMUI for further deliberation. Is there anything
5 that we want to say at this point about that, about
6 that timing and so forth?

7 MR. HICKEY: Excuse me, doctor, but if I
8 could just interject. Written comments were accepted
9 prior to this meeting, and there are copies in the
10 back. Those will be part of the record. Any written
11 comments can be left today, and we will accept written
12 comments up until June 28th for consideration by the
13 full committee.

14 And the full committee will be holding a
15 meeting by telecon on July 8th, and that meeting has
16 been announced, and it will be conducted from our
17 auditorium here at the NRC, and people can come to the
18 auditorium to observe that meeting, and Dr. Cerqueira
19 will be here in person to conduct that meeting.

20 CHAIRMAN VETTER: Thank you. So the
21 public has had an opportunity to input to date, and
22 they will have further opportunity for public input
23 after we arrive at our consensus here today. Okay.

24 The charter of the subcommittee was to
25 develop the concept for a draft rule that restores

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1 board certifications as the primary pathway for
2 becoming an authorized medical physicist, radiation
3 safety officer, and authorized user.

4 As the Committee wrestled with that charge
5 to develop some recommendations, there were three
6 areas that basically came out that we needed to focus
7 on. One was the issue of listing boards, and the
8 subcommittee in our preliminary conversations felt
9 that boards should be formally listed, but whether
10 they were listed in the regulations or on the NRC
11 website is a matter that needs to be decided, and
12 perhaps that is more an issue of how that process is
13 facilitated, as opposed to whether it really needs to
14 be in the regulations.

15 The second area was criteria for
16 recognition of boards, and we wrestled with that, and
17 so hopefully our recommendations will reflect those
18 criteria. And then the third was the issue of
19 modality, specific training. Two issues there really,
20 and that is a licensee hiring a new RSO or medical
21 physicist, or whatever, and assuring that that person
22 who might be board certified actually is experienced
23 using the modalities that that licensee is authorized
24 to use.

25 And the second issue is a licensee who has

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1 an authorized medical physicist, RSO, or whatever,
2 that gets a new modality, and then assuring that those
3 people get the appropriate training in the new
4 modality.

5 So that basically was the charge, and as
6 I mentioned, the committee worked by telephone and e-
7 mail to come up with some preliminary recommendations,
8 which we will discuss at this time. Any other
9 comments from members of the subcommittee at this
10 point in time? Yes, Jeff?

11 DR. WILLIAMSON: I am never without words
12 here. I think that there are a couple of categories
13 of individuals that we have not discussed and maybe
14 should. We have not really developed a framework for
15 35.300 modalities, and it is not clear to me whether
16 there are not difficulties with the authorized nuclear
17 pharmacy training and experience, and we should
18 clarify whether that needs to be amended, if only to
19 bring the language in line with the revised category.

20 CHAIRMAN VETTER: I think that is a good
21 point, and I think that my personal perspective is we
22 were charged to work on these three areas, and then
23 secondly to that was the issue of consistently
24 throughout Part 35.

25 So it was our understanding that if we

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1 came up with recommendations for a particular category
2 -- for instance, just a simple one, the listing of the
3 board. Should boards be listed, and they would not be
4 listed in one category and not in another. So it
5 would be consistent all the way across.

6 The same thing for criteria for boards.
7 We would develop general criteria for boards, even if
8 we didn't address a specific category like authorized
9 nuclear pharmacy, and we would expect that our
10 recommendation would be applied across the board.

11 DR. DIAMOND: Just to expand that,
12 Richard. For example, when I was working on 690 for
13 therapeutic uses, we really wanted to try and go and
14 get a consensus on those points, and then the decision
15 would be that once we got that consensus that we would
16 go back and make housekeeping changes for parallel
17 structure, and for example, 392 and 394, and 490, and
18 491. Otherwise, our e-mails would become even more
19 burdensome.

20 CHAIRMAN VETTER: Good point.

21 DR. CERQUEIRA: Another point that has
22 come up is for the RSO. If you are a medical
23 authorized user, should that criteria also allow you
24 to meet the RSO criteria as well, and so I think that
25 kind of needs to be addressed, because as stated, some

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1 of the 290 requirements aren't totally consistent with
2 the RSO requirements.

3 CHAIRMAN VETTER: Okay. When we get to
4 that. That is a good point, and we be sure to mention
5 that. Okay. Well, let's turn to the draft
6 recommendations that we have. If I could just make
7 some preliminary comments, and I might be repeating
8 myself a little bit as we look at these.

9 There are -- and let me just say that the
10 intention was to develop a -- the intention was not to
11 develop regulatory language. However, the
12 recommendations look like regulatory language, and
13 that's because the committee simply wanted to pay
14 attention to detail and not leave some stuff out.

15 But we don't pretend to be those that
16 would write the regulations. So once again, the main
17 thing was that we wanted to make sure that we didn't
18 miss something. So we wrote it in that kind of a
19 format.

20 So on radiation safety officer, we did
21 list the boards and basically just went back to the
22 old list, and we asked ourselves whether or not that
23 list of boards meets our broad criteria, the broad
24 criteria being paragraph B, as certified by a
25 specialty board, whose certification has been

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1 recognized by the commission and requires all
2 diplomats to.

3 And then we have several different
4 categories or criteria that we would expect all of
5 those boards to meet, and we have no reason to believe
6 -- even if we have not looked at those in extreme
7 detail, there is no reason to believe that none of
8 them would meet those criteria.

9 So the issue is -- the primary issue is
10 that there are specific criteria that a specialty
11 board would have to meet in order to be approved to be
12 on the NRC authorized list of boards, the idea again
13 being that anyone who is board certified by one of
14 those boards then would automatically qualify as a
15 person who a license could approve as the radiation
16 safety officer.

17 The alternate pathway then is separate and
18 the board would not have to meet that alternative
19 pathway. Let me say that the way that we have got it
20 worded here, it looks like they are mutually
21 exclusive, and we certainly didn't intend that.

22 Certainly if a board -- and I think it
23 would be reasonable if a board chooses to meet the
24 alternate pathway as one of the criteria, and that
25 certainly has to be acceptable, because that is the

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1 alternate criteria.

2 So we wouldn't want to rule it out. I
3 mean, a board could certainly be listed if it meets
4 those alternative criteria. Then paragraph (b) is an
5 authorized user, and an authorized user of what. We
6 didn't specify there, but we assumed that the next
7 paragraph on modality and specific training would take
8 care of that.

9 So as an authorized user, and authorized
10 medical physicist, authorized nuclear pharmacist,
11 identified on the license, and then second, has
12 experience with radiation safety aspects of similar
13 types. So an authorized user who is approved to us
14 categories under 200 could be the radiation safety
15 officer for those materials, but would not qualify to
16 be the radiation safety officer for 600.

17 The intent was for all of the sections to
18 sort of follow that general theme, that there is a
19 listing of boards that would be maintained somewhere,
20 either in the regulations or on the NRC website, or
21 somewhere, where anyone who is interested in that list
22 of boards could easily access it.

23 And then the criteria would be in the
24 regulations. So the boards would understand what
25 criteria they need to meet, or there is the

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1 alternative pathway, and there is the issue of
2 authorized users, and so forth.

3 And then finally the modality specific
4 training, which I mentioned is intended to assure that
5 even if a person is board certified, they have
6 experience and an understanding of the issues
7 associated with the modalities for which the licensee
8 is authorized. So let me just open it up for comments
9 on radiation safety officer.

10 MS. MCBURNEY: Just a question. If
11 someone were board certified in, for example, nuclear
12 medicine -- for example, the American Osteopathic
13 Board of Nuclear Medicine -- could they be the RSO for
14 therapeutic material?

15 CHAIRMAN VETTER: No, because paragraph
16 (e) says that in addition to all --

17 MS. MCBURNEY: And they have to have the
18 additional training.

19 CHAIRMAN VETTER: Right. So they could be
20 if they had the appropriate training, I guess, yes.
21 That's a good point. So an authorized user in nuclear
22 medicine could be the radiation safety officer that
23 would include therapy, but only if --

24 MS. MCBURNEY: If they are board
25 certified.

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1 CHAIRMAN VETTER: If they are board
2 certified, and they have been trained in the safety
3 aspects of therapy in accordance with paragraph (e).

4 DR. CERQUEIRA: Again, in terms of the
5 cardiology community, the other issue that comes up is
6 the CBNC, which has been recognized in the 290 should
7 be included here as well.

8 CHAIRMAN VETTER: It should be, yes.

9 DR. CERQUEIRA: And for Part C on this,
10 for the 290, we sort of break it down into 700 hours
11 without putting specific hours -- you know, here it
12 has got 200 hours, and we had sort of taken that out
13 at some point.

14 So I think for those people, they may not
15 necessarily meet this criteria if we had the specific
16 200 requirement in there. So there is an
17 inconsistency between those two, and I think we should
18 try to get that rectified.

19 MS. MCBURNEY: But if they are an
20 authorized user, they could be --

21 DR. CERQUEIRA: Well, certainly by board
22 certification, yes.

23 MS. MCBURNEY: And (d).

24 DR. CERQUEIRA: And (d).

25 DR. WILLIAMSON: Yes, paragraph (d), which

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1 says, "is an authorized user, authorized medical
2 physicist, or authorized nuclear pharmacist," there is
3 no presumption that to qualify as an RSO under that
4 provision that you have to meet the board's
5 eligibility requirements if we want to call them that,
6 or board qualification requirements.

7 DR. CERQUEIRA: Okay. So I guess that
8 would do it, and then if we could just basically add
9 the board to the list.

10 DR. WILLIAMSON: But I think there is --
11 I think that Dr. Cerqueira is right. There is a
12 contradiction between (a) and (b) in the proposal.
13 There is not a contradiction between (b) and (d) by
14 definition, and the intent and structure of the old
15 sets of regulations.

16 But we did say in our covering memo that
17 the intent was that the listed boards, explicitly
18 mentioned boards, would meet the broad criteria in
19 (b).

20 CHAIRMAN VETTER: And do you think they
21 don't?

22 DR. WILLIAMSON: Well, that is a question
23 -- I don't think there is any presumption to be, for
24 example, American Board of Radiology certification,
25 does not require you to have six or more years of

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1 responsible professional experience in health physics.
2 So, in that sense I think it would be not appropriate
3 --

4 MS. MCBURNEY: I think that the boards
5 pertaining to radiation safety officer should only be
6 those that are dealing with health physics.

7 DR. WILLIAMSON: I think that that is
8 probably true.

9 MS. MCBURNEY: Because if you are an
10 authorized user, then you go that route.

11 DR. WILLIAMSON: So actually I think maybe
12 the authorized user certifications at the very least
13 should probably be removed from paragraph (a).

14 CHAIRMAN VETTER: Okay. Because those
15 people qualify under paragraph (d).

16 DR. WILLIAMSON: Right. They qualify
17 under paragraph (d). And then, you know, we have to
18 look carefully at paragraph (b), and make sure that it
19 represents kind of the minimum bar for those boards
20 that we do want to include, and I think that at the
21 very least you would want to include the American
22 Board of Health Physics, and probably ABMP
23 certification and medical health physics. And we can
24 discuss whether --

25 MS. MCBURNEY: ABR.

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1 DR. WILLIAMSON: Yes, ABR medical
2 certification in therapeutic radiological physics, and
3 ABMP certification in radiation oncology physics,
4 should be on that list. And we might want to fine
5 tune these criteria so that there would not be an
6 incompatibility between their eligibility
7 requirements.

8 CHAIRMAN VETTER: Okay. So what I am
9 hearing is that the list should be focused on those
10 who qualify -- the list of boards should be those who
11 qualify in basically medical health physics. So that
12 is the approved list of boards.

13 DR. CERQUEIRA: Right.

14 CHAIRMAN VETTER: And they would meet
15 those criteria under (b), but that would not rule out
16 someone who is certified in radiology.

17 MS. MCBURNEY: In theory.

18 CHAIRMAN VETTER: In nuclear medicine to
19 be the RSO, and because they would qualify under (d),
20 they are an authorized user. I think that makes sense.
21 Dr. Brinker or Diamond? So the list that we would be
22 recommending to the NRC, wherever they maintain it,
23 would be focused on health physics, and initially at
24 least we would be crossing off the medical boards.

25 DR. WILLIAMSON: I think if maybe John can

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1 clarify this, but I think the intent of (a) and (b) is
2 to define those individuals who could be RSOs of the
3 very largest licensee organizations is it not?

4 DR. CERQUEIRA: Right, independent of
5 being an authorized physicist or medical physician.

6 DR. WILLIAMSON: Right. So that is what
7 the ultimate function or role of this category that we
8 have to keep in mind.

9 DR. CERQUEIRA: With the provision that
10 there be a sort of specific training in the area in
11 which you are applying, and it is not part of the
12 recognized training requirements.

13 CHAIRMAN VETTER: Okay. I think we have
14 consensus on that. And the criteria for (b) was
15 basically our minimum criteria that currently are
16 required by the American Board of Health Physics, and
17 the American Board of Medical Physics actually
18 requires a Masters Degree.

19 And I am not sure about the American Board
20 of Science and Nuclear Medicine.

21 DR. WILLIAMSON: I don't think that ABMP
22 for Medical Health Physics requires six years
23 experience.

24 MS. MCBURNEY: It does require a Masters.

25 DR. WILLIAMSON: It does require a

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1 Masters?

2 MS. MCBURNEY: I think that can -- I am --

3 CHAIRMAN VETTER: I think that is a minor
4 point, and we can check on that and be sure that we
5 aren't inconsistent with either of those boards.

6 DR. WILLIAMSON: I think that both ABMP
7 and ABR may in some cases accept candidates that have
8 two years. As I recall for ABMP, at the function of
9 what kind of a degree you have, and if you have, for
10 example, a doctoral degree in medical physics, it is
11 a smaller number of years of experience, versus having
12 a Masters Degree not in medical physics, would require
13 the most years of experience. I think four. And I
14 think it is 2 to 4.

15 CHAIRMAN VETTER: We can check on that.
16 We can check on that.

17 DR. CERQUEIRA: Richard, under (b) (3), it
18 sort of comes again to the written certification and
19 what does that mean. You know, part of the charge of
20 the committee was that the preceptor concept should be
21 modified to become documentation of successful
22 completion of a training program, rather than a
23 testimony to clinical competence.

24 CHAIRMAN VETTER: Right.

25 DR. CERQUEIRA: And we had tried, you

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1 know, during the initial discussions over the course
2 of the last six years, we wanted to put a little bit
3 of bite into the preceptor statement, in the sense
4 that we didn't want people to just sit through a
5 program, but that they have had some mastery of the
6 material, and whether competence is too strong a word.

7 But at some point, we are going to have to
8 deal with or address the issue of whether just having
9 completed a program, versus some requirement for the
10 preceptor who is signing for this person, and saying
11 that this person not only has completed the program,
12 but has mastered the material in some way.

13 DR. CERQUEIRA: That is what the exam
14 does.

15 CHAIRMAN VETTER: That is what the exam
16 does, but this is the alternative pathway.

17 DR. CERQUEIRA: No.

18 MS. MCBURNEY: No, this is the requirement
19 of (a).

20 CHAIRMAN VETTER: Okay.

21 DR. WILLIAMSON: Perhaps you should delate
22 paragraph (b)(3). Why is it necessary to have a
23 preceptor statement in the board certification
24 criteria if they are already passing an exam. Isn't
25 that a sufficient credential?

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1 DR. CERQUEIRA: We will come back to that
2 later on, because in order -- you know, what are the
3 eligibility criteria for the board, and are we going
4 to require some sort of a preceptor statement as to
5 mastery of the material.

6 MS. MCBURNEY: Most board certifications
7 do require some sort of reference or supervisor
8 reference, or something like that.

9 CHAIRMAN VETTER: They do, but I think the
10 point for us to wrestle with would be whether or not
11 we want someone to testify that in fact the person was
12 around going through some training, or did they simply
13 read a book.

14 It is a matter of being in contact with
15 the material, and with the environment, because that
16 would be the issue. Do we think that the regulations
17 should require that, or --

18 DR. DIAMOND: I see that kind of like a
19 letter of reference almost that that person was around
20 performing that supervised experience, because again
21 at this point they are not in a formal degree program,
22 let's say, if they are going through
23 (b) (2).

24 You need someone to sign off that this
25 person was there and they did fulfill these

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1 responsibilities.

2 CHAIRMAN VETTER: Right. Okay. Well, let
3 me present sort of a principle by which we may be able
4 to decide what to do, but I think the principle is, is
5 that the boards as currently configured that are
6 nominally accepted as valid credentials for these
7 roles are doing a good job, and that there is no
8 threat to public safety by virtue of these boards not
9 working well.

10 So therefore we should not or we are not
11 in the business of imposing criteria that forces them
12 to make certain changes. I mean, the NRC should only
13 do that if they believe there is a threat to public
14 safety from the existing credentialing system.

15 So I think that the consequence of this
16 principle, if we accept it, is that we want to very
17 carefully -- that we want to recommend to the staff
18 that they very carefully tailor the wording of this
19 preceptor statement so that inadvertently well-
20 functioning boards that do a good job of identifying
21 competent practitioners aren't inadvertently excluded
22 from the process.

23 So maybe we can sort of leave it to the
24 staff to worksmith this according to the ball of the
25 principle that I just articulated.

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1 DR. WILLIAMSON: Right. I agree with that.
2 But if the consensus to leave that paragraph 3 in
3 there or delete it?

4 DR. DIAMOND: I would suggest leaving it
5 in.

6 CHAIRMAN VETTER: Okay.

7 DR. DIAMOND: I think it serves a useful
8 function.

9 CHAIRMAN VETTER: Okay.

10 DR. CERQUEIRA: Getting back to Jeff's
11 point then, so if we take it out of the board
12 requirements do we want to leave it in for the
13 alternative pathways? So that if somebody is meeting
14 this by training and experience, that sort of
15 preceptor statement, which doesn't require board
16 certification, would put a little bit more pressure on
17 the person certifying them, and not only that they
18 have sat through the program, but they have been in
19 the environment and have some master.

20 DR. WILLIAMSON: I think that is
21 reasonable, since they are not taking an examination,
22 and this is not a formal or structured certification
23 mechanism, that there be more teeth in the board free,
24 or boardless alternative pathway requirements.

25 But I think that we have to recognize that

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1 the board requirements and the alternative pathway
2 requirements can be different.

3 So a more or a tougher preceptor statement
4 would probably be warranted in that.

5 DR. DIAMOND: I would concur with that.
6 For example, in 690, we tried to use language such
7 that the alternative pathway was a little more
8 prescriptive, and a little more enumerative if you
9 will, of these details.

10 CHAIRMAN VETTER: Okay. So we are
11 recommending that to the alternative pathway we add
12 some sort of written certification or preceptor
13 statement, something of that sort. All right. Moving
14 on, and we need to move through these reasonably
15 quickly. We can't spend all day on this particular
16 section.

17 And let's do or focus a moment on
18 paragraph (e), because this would be something similar
19 throughout. Simply saying that whoever this
20 individual is who the license wants to appoint as
21 radiation safety officer needs to have experience.

22 We don't specify or we don't get into
23 detail what that is, and I guess I don't think we
24 should. That should be left to guidance. But we
25 specify that the individual must have training and

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1 experience in the materials that are being used by the
2 licensee, and if they don't have it, there is a
3 pathway to get it.

4 For instance, you get a new modality. If
5 a licensee gets gamma knife and has not had one
6 before, then the radiation safety officer can get
7 training in the emergency preparedness, et cetera,
8 from the authorized medical physicist, or another RSO
9 who is authorized to use that material. Jeff.

10 DR. WILLIAMSON: Yeah, I think we should
11 recognize that the level and intensity of training for
12 an RSO is different than what would be required for an
13 authorized, an authorized medical physicist.

14 There is on presumption that the RSO is a
15 hands-on person and has to operate the device and
16 treat patients. They are kind of a level up in the
17 management structure, and so that is one point. I
18 think the second point is that to my knowledge there
19 really are not formal mechanisms or training programs.

20 I don't believe other than supplying
21 installation guides and licensing guides for these
22 devices that the vendors really don't provide a
23 mechanism that gives the appropriate introduction.

24 And so I think we should be on the record
25 as stating that in defense of the vagueness or

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1 looseness of these requirements.

2 DR. CERQUEIRA: I guess in terms of (b) as
3 well, we are saying that it is supervised by an
4 authorized medical physicist or radiation safety
5 office. And in the case of diagnostics, could that
6 supervision be by an authorized user physician?

7 DR. WILLIAMSON: I think that is a good
8 point.

9 CHAIRMAN VETTER: Sure. I think so. So
10 we will add, "or authorized user" in there.

11 DR. WILLIAMSON: Probably as appropriate
12 maybe should be also put in there.

13 DR. CERQUEIRA: Yes, to make certain that
14 if you are an authorized user for diagnostics, then
15 you are not going to train somebody in therapeutics.

16 DR. WILLIAMSON: That's right.

17 CHAIRMAN VETTER: So AU/AMP, or radiation
18 safety officer, as appropriate.

19 CHAIRMAN VETTER: Good point. Other
20 discuss on paragraph (e)? Okay. So we will add
21 authorized user as appropriate. All right. Let's
22 move on to training for authorized medical physicist.

23 And once again, trying to carry the same
24 theme through the entire recommendations, first would
25 be a listing of the boards. Jeff, do you want to --

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1 and again we don't want to nitpick on words that carry
2 the basic concept through.

3 So on the listing of the boards that would
4 be maintained by the NRC, this would be limited to
5 boards that certify medical physicists specifically.

6 DR. WILLIAMSON: That's right. So, we
7 would define the general phrase, "radiation oncology
8 physics," which refers to the core material covered by
9 paragraph (a), those boards.

10 CHAIRMAN VETTER: Right. Do you want to
11 explain why (b) is different? Why is--

12 DR. WILLIAMSON: You mean why is (b) a
13 separate paragraph?

14 CHAIRMAN VETTER: Yes.

15 DR. WILLIAMSON: It could be changed, but
16 it is because the American Board of Radiology has
17 historically had a number of credentials, and some of
18 them very broad. So, for example, radiological
19 physics actually includes examinations in nuclear
20 medicine, radiation oncology, and diagnostic x-ray
21 imaging.

22 So it was just time saving. You know,
23 there were four board certifications maintained by the
24 ABR, and so I made an ABR section, and then an ABMP.
25 But we could change it and have paragraph (a).

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1 CHAIRMAN VETTER: I don't think we need to
2 worry about level of detail.

3 DR. WILLIAMSON: It is detail, and I don't
4 think it is important.

5 CHAIRMAN VETTER: I agree.

6 DR. WILLIAMSON: But we could collapse (a)
7 and (b) into one paragraph if that were desired. No
8 problem.

9 CHAIRMAN VETTER: Well, they probably
10 won't be in the regulations anyway. They will be
11 maintained on a separate list. And so just that it is
12 clear what the intent is. So the intent is the
13 American Board of Radiology and those four areas, the
14 American Board of Medical Physics, and Radiation
15 Oncology Physics.

16 DR. WILLIAMSON: That's correct.

17 MS. MCBURNEY: And just again, and pardon
18 my ignorance, but are we then saying that if the
19 physician is certified by the ABR that they could then
20 quality as an authorized medical physicist?

21 DR. WILLIAMSON: No.

22 MS. MCBURNEY: So there is a separate ABR
23 examination for a physicist?

24 DR. WILLIAMSON: That's correct

25 MS. MCBURNEY: And is there some way that

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1 we can separate that out? Otherwise, it could be
2 somewhat ambiguous.

3 CHAIRMAN VETTER: They are there, those
4 four areas.

5 MS. MCBURNEY: It says these things.

6 DR. WILLIAMSON: It says specifically
7 therapeutic radiological physics; roentgen ray and
8 gamma ray physics.

9 DR. CERQUEIRA: But those are separate
10 examinations that are given?

11 DR. WILLIAMSON: Yes.

12 DR. CERQUEIRA: They are? Okay.

13 DR. WILLIAMSON: Well, it is very similar
14 to the old Part 35

15 CHAIRMAN VETTER: Okay. Let's move on to
16 paragraph (c). These are the general requirements
17 that we would expect, or our general criteria that we
18 would expect to recognize a board. Do you want to say
19 anything about that, Jeff?

20 DR. WILLIAMSON: Yes. I will mention that
21 there are -- there is a move in radiation oncology to
22 have formal two year clinical training programs, which
23 we call radiation oncology physics residences. But
24 they are not widespread, and I don't think the market
25 penetration of those training vehicles is great enough

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1 that they could form the basis of a regulation at this
2 time.

3 So this was quite a difficult task to
4 figure out what to do. So I went through and I
5 compared the ABMP and ABR eligibility requirements and
6 tried to distill the common subset, which is basically
7 a graduate degree in a physical science or
8 engineering, a Masters Degree, and a minimum of two
9 years of supervised experience.

10 And to make sure that this was experience
11 in an appropriate facility, I included in here that it
12 had to occur in a radiation oncology facility that
13 provides mega-voltage external beam therapy and
14 brachytherapy.

15 And that I further, to make sure that this
16 experience doesn't occur in Bermuda, or some place
17 that does not follow customary -- and I mean no slam
18 against Bermuda.

19 But some place that does not follow the
20 standards of practice characteristic of North America,
21 and that I put that it had to be under the direction
22 of physicians who meet the requirements of 35.400 or
23 600, which would have effectively I think limited it
24 to experience in the U.S.

25 And so how to do this certainly is open to

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1 debate, and whether Canada should be included, for
2 example, and Europe. I don't know how exactly. So
3 there is an issue there that I want to point out, and
4 that is why I included this paragraph (c)(2)(ii),
5 because otherwise I felt that some very marginal
6 experience in something peripherally related to health
7 care could be substituted, and I didn't want that.

8 And so the intent was to restrict this
9 training and experience that occurs in a reasonable
10 full-service radiation oncology department.

11 DR. DIAMOND: So, Jeff, right now the
12 specialty boards that are granting this radiation
13 oncology physics certification, is it just ABR, or
14 ABMP, or --

15 DR. WILLIAMSON: Well, ABR and ABMP both
16 have diplomates that are in the field. Recently there
17 has been a negotiation between ABR and ABMP, and ABMP
18 is going to not in the future certify radiation
19 oncology physicists in competition with the AABR.

20 DR. DIAMOND: And you did not want to
21 enumerate ABR or ABMP in this paragraph because it may
22 be evolving to include other certified positions?

23 DR. WILLIAMSON: Well, the whole purpose
24 of paragraph (c) is to allow for other certification
25 mechanisms that might arise in the future. You know,

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1 we had made the decision, or it was suggested to us
2 that one way or another we had to include broad
3 criteria that defined what were acceptable boards in
4 the different areas.

5 And to do that by enumerating physics
6 boards would be a circular definition. So you can't
7 define what is an acceptable radiation oncology
8 physics board by saying it is one of these boards.
9 You have to have an independent list of criteria. So
10 I made an independent list.

11 It doesn't mention physics certification
12 or any specific certification mechanism. It
13 indirectly by 35.400 and 600 reference refers to the
14 certification of the authorized users presumably, but
15 they could be alternative pathway physicians, too.

16 Then finally pass as an examination
17 administered by diplomats of the board in questions
18 that assesses the following broad list of functions
19 and skills.

20 MS. MCBURNEY: The term megavoltage,
21 external being therapy, would that include materials?

22 DR. WILLIAMSON: It would include
23 materials, but it would include linacs, and I think
24 that is important because there are actually very few
25 cobalt 60 teletherapy units operating in the country,

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1 and it would be completely unrealistic to expect that
2 physicists, authorized medical physicists for taking
3 care of Cobalt 60 teletherapy would have Cobalt 60 in
4 their training experience, and this is one of the
5 central efficiencies of the old set of requirements
6 that I think we were asked to address.

7 CHAIRMAN VETTER: All right. And then the
8 alternate pathway is pretty much as it was before, and
9 you do have the written certification from the
10 supervising medical physicist.

11 DR. WILLIAMSON: Yes, and I put here
12 satisfactorily completed.

13 CHAIRMAN VETTER: Right.

14 DR. WILLIAMSON: And I assume that means
15 more than just sleeping or sitting there.

16 CHAIRMAN VETTER: Right.

17 DR. WILLIAMSON: And again we could debate
18 exactly how that --

19 MS. MCBURNEY: Usually there is an exam
20 involved in that training.

21 DR. WILLIAMSON: -- should be. But this
22 is the alternate pathway, and so there is not
23 necessarily an exam. Remember that there is no --

24 MS. MCBURNEY: Right, it is not board
25 certification, but a lot of times with training there

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1 is some sort --

2 DR. WILLIAMSON: Only in a formal
3 structured program, and again we talk about requiring
4 a physics residency here, but I really do think that
5 would be contrary to the intent of either the old or
6 current set of regulations.

7 CHAIRMAN VETTER: Any other comments on
8 the alternative pathway? Okay. Then paragraph (e) is
9 the modality specific training. Any comments there,
10 Jeff?

11 DR. WILLIAMSON: Just to say that the
12 basis was to put the burden of defining the content of
13 this curriculum really on the vendor, and use the sort
14 of training that the vendor typically supplies to a
15 new purchaser of a unit. This will of course vary
16 with the type of unit.

17 For HDR, it may be on the order of several
18 days, and for stereotactic it is a week usually at a
19 facility treating patients, or for Cobalt 60, it might
20 be an hour.

21 MS. MCBURNEY: I would suggest removing
22 the phrase, "that is equivalent to instruction
23 provided by the vendor to new customers," because I
24 think it is covered in the next sentence. Whereas, if
25 you just say in addition to meeting the requirements

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1 of (a), (b), (c), or (d), an authorized medical
2 physicist must have training in the modality for which
3 authorization is sought, that includes device
4 operation, safety procedures, clinical use, and
5 operational treatment planning system.

6 And then I think the next sentence that
7 this may be satisfied by a training program provided,
8 et cetera.

9 CHAIRMAN VETTER: I agree. I think that
10 is a good point. In the first sentence, we don't want
11 to limit it to some level of vendor provides. We
12 might want to exceed that.

13 DR. WILLIAMSON: All right. So just
14 strike, "that is equivalent to instruction provided by
15 the vendor to new customers."

16 MS. MCBURNEY: Right.

17 CHAIRMAN VETTER: And then the second
18 sentence allows that pathway for other training
19 through the vendor. Other questions on (e)? Yes,
20 John.

21 MR. HICKEY: I wanted to go back to (c)
22 when we are done with (e).

23 CHAIRMAN VETTER: Okay. Any other
24 questions on (e)? All right.

25 MR. HICKEY: I wasn't clear. Paragraph

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1 (c) would not have a written certification, but
2 paragraph (d) would?

3 DR. WILLIAMSON: Well, as I think we have
4 made -- we have decided by consensus that some kind of
5 a letter addressing the performance of the candidate
6 for the board examination is required.

7 MR. HICKEY: Okay. Because it seems to me
8 when someone presents their credentials that they
9 provide some testament that they actually have
10 completed those credentials.

11 DR. WILLIAMSON: That's correct, and I
12 think that both physics boards that I have experience
13 with would have no difficulty meeting or in fact do
14 require letters of reference to attest to their
15 satisfactory completion of this experience.

16 So we could put it in there. At the time
17 that I did this, I didn't think it was necessary
18 because the examination seemed to be a substitute for
19 assessing confidence.

20 CHAIRMAN VETTER: So we will put something
21 in. Go ahead.

22 DR. CERQUEIRA: The default statement that
23 seems to be coming out that we have both for the 290,
24 as well as for the medical physicist, is that the
25 individual has satisfactorily completed the training

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1 and experience described above.

2 So do we feel that is the way that we want
3 to go, rather than saying it is competent or is
4 mastered?

5 DR. DIAMOND: Yes.

6 DR. CERQUEIRA: So we basically would make
7 it uniform for all RSOs, medical physicists, and
8 authorized users?

9 DR. DIAMOND: I think that is good
10 verbiage to use.

11 CHAIRMAN VETTER: Okay. Just looking to
12 know that or for some one to testify that in fact a
13 person really was here, and really did train.

14 DR. WILLIAMSON: And did an acceptable and
15 satisfactory job, and wasn't incompetent, I think.
16 You know, satisfactorily completed, it seems to be a
17 broad enough statement, I hope. Maybe in the public
18 comments the representatives of the different board
19 organizations can address this, but if we go back to
20 the principle I enunciated we want, whatever the
21 verbiage is.

22 It has to be common enough that all of the
23 boards that are currently accepted as credentialing
24 those functions would be able to satisfy that
25 requirement.

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1 CHAIRMAN VETTER: Well, if we use as an
2 example the current preceptor statement, or I'm sorry,
3 the old -- yeah, the current preceptor statement that
4 is required by the NRC, it simply lists the hours of
5 training and the number of generators alluded, and
6 that sort of thing, and it is signed by the preceptor.

7 The preceptor doesn't have to testify
8 whether the person did a good job, a bad job, an
9 indifferent job, but completed those requirements.

10 DR. CERQUEIRA: I think what this does,
11 and again when we started this process we wanted to
12 take the NRC out of the practice of medicine, or
13 responsibility upon the boards, or the physician, or
14 medical physicist.

15 And I guess this will do it. Basically,
16 the NRC will accept either the boards or a statement
17 from an authorized user, but it really makes it
18 incumbent upon the boards to make certain that the
19 people have had some mastery or competence of the
20 material.

21 CHAIRMAN VETTER: So satisfactorily
22 completed. Those are the words that we are looking
23 for? Does that sound okay?

24 DR. CERQUEIRA: Yes. But I guess the
25 public comments will be important later on.

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1 CHAIRMAN VETTER: Right.

2 DR. CERQUEIRA: And to see what the boards
3 can tell us.

4 CHAIRMAN VETTER: Okay. John, did that
5 answer your question?

6 MR. HICKEY: Yes, thank you.

7 CHAIRMAN VETTER: Okay. Jeff, any -- I
8 guess that takes care of your section, right?

9 DR. WILLIAMSON: Yes.

10 CHAIRMAN VETTER: Moving on to 35.190,
11 training for uptake, dilution, and excretion studies.
12 Ruth.

13 MS. MCBURNEY: Okay. The first section
14 there is just to put back in the boards that had
15 previously been accepted for uptake, dilution, and
16 excretion studies.

17 These would be the board certification
18 requirements for acceptance of a board. The question
19 here arises for consistency do we want to add
20 requirements for some sort of residency, or have that
21 as an optional pathway for acceptance of the board
22 certification process.

23 Otherwise, it would just be a board
24 certification whose process includes the requirement
25 for (b) (1), and success completion of the exams, and

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1 has been recognized by the commission. So that is
2 basically just a minimum of 60 hours training
3 experience.

4 And certification by an authorized user
5 that the person has successfully completed those
6 requirements.

7 CHAIRMAN VETTER: So the question that you
8 were asking under paragraph (b) was whether we thought
9 a residency should be completed?

10 MS. MCBURNEY: Option.

11 CHAIRMAN VETTER: Oh, an option.

12 MS. MCBURNEY: Or an option for uptake and
13 dilutions, since these are low risk.

14 CHAIRMAN VETTER: So they have completed
15 a residency and approved by the American --

16 MS. MCBURNEY: Nuclear Medicine.

17 CHAIRMAN VETTER: Right.

18 DR. CERQUEIRA: But I guess that would
19 sort of look at people who have completed a residency,
20 but are not necessarily board certified, but wouldn't
21 they meet the requirements under (d)?

22 MS. MCBURNEY: Oh, yeah. The question is
23 of course that the residency should include those 60
24 hours and a minimum of that, but whether we want to
25 put into rule space an option would be that one has

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1 completed something similar to what is in --

2 DR. WILLIAMSON: If you look at subpart
3 (j) 35.190, it has three options. You can be
4 certified in one of the listed boards, or (b), have
5 the classroom and training experience, et cetera, as
6 listed here, or (c), have successfully completed a six
7 month training program in nuclear medicine as part of
8 a training program that has been approved by, et
9 cetera, et cetera.

10 It seems to me that we should probably
11 follow the old regulation.

12 DR. CERQUEIRA: But there are no six month
13 training programs in nuclear medicine. I mean, that
14 has been pointed out quite often.

15 MS. MCBURNEY: Right. That is an issue.

16 CHAIRMAN VETTER: But as I interpret the
17 question, do we think it is appropriate for a new
18 medical specialty board to come along to certify
19 candidates for 190, and the only requirements for the
20 board are that you have 60 hours of training
21 experience?

22 MS. MCBURNEY: I don't know that any
23 specialty board is going to come along to do that.

24 CHAIRMAN VETTER: And we don't know what
25 anyone might do, might or might not do. So I guess

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1 the question is do we feel that would be appropriate
2 if that in fact -- that they are meeting the minimum
3 requirements for the alternate pathway.

4 MS. MCBURNEY: It will become more
5 important when we get to 290.

6 CHAIRMAN VETTER: Right. But the way it
7 reads now, a board could come along to offer a
8 specialty specification. Even ABR could offer a
9 specialty certification in 190. Of course, ABR
10 requires more than that.

11 But let's say a new board would come along
12 and only require 60 hours of training experience to
13 qualify for the board.

14 DR. WILLIAMSON: Well, this individual
15 would have a medical degree, and has to have completed
16 an internship just to have basic licensure, right?

17 CHAIRMAN VETTER: Right.

18 DR. WILLIAMSON: Basic licensure as a
19 practicing physician, and so is this uptake and
20 dilution considered sufficiently low risk that the
21 NRC does not have to require them to have a residency
22 in something? I guess that is the issue.

23 CHAIRMAN VETTER: Right. I am not arguing
24 that one way or another. I just wanted us to feel
25 comfortable with what this says. This says a board

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1 could do that.

2 DR. WILLIAMSON: I think Dr. Cerqueira is
3 the closest to a nuclear medicine practitioner. What
4 do you think?

5 DR. CERQUEIRA: I would feel uncomfortable
6 having somebody with a one year internship as is only
7 medical training, be able to use this, even if they
8 met the hourly requirements. I just don't know how --

9 MS. MCBURNEY: Well, I guess the medical
10 specialty board whose certification process requires
11 the successful completion of a residency program in
12 nuclear medicine, approved by --

13 CHAIRMAN VETTER: Well, again, we need to
14 focus on the safety aspects, and not --

15 DR. WILLIAMSON: Right.

16 MS. MCBURNEY: And the board certification
17 process and not the alternate pathway.

18 DR. WILLIAMSON: Well, let me be a
19 contrary in here for a minute. I think that when back
20 when, in the last six years, the ACMUI and the NRC
21 made a determination that nuclear medicine type
22 imaging applications, and those areas using relatively
23 small doses of radioactivity, were considered
24 sufficiently low risk that all the NRC had to concern
25 itself with was the technical and safety training of

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1 the individual, and not the clinical competency,
2 whether they will competently execute these dilution
3 and uptake procedures, and so on.

4 And so it seems to me that our scope is to
5 fix problems, and not to overturn major -- how should
6 I say -- principles that were decided on long ago as
7 being the basis of these regulations. So it would
8 seem to me that since neither the old regulation that
9 the NEU Part 35 has superseded, nor the NEU Part 35,
10 requires a residency in something.

11 And that we should look very carefully at
12 this, and ask the NRC to produce a list of what kinds
13 of specialists have availed themselves of 35-190, and
14 make sure that we are not unnecessarily
15 disenfranchising some segment of the practicing
16 community, unless there really is a public health
17 issue at stake.

18 MS. MCBURNEY: I think like a lot of
19 endocrinologists and so forth, and clinical
20 pathologists, go through the alternate pathway
21 usually.

22 DR. CERQUEIRA: I think we also decided
23 that we would leave a lot of this up to credentialing
24 bodies at hospitals at the State level.

25 DR. DIAMOND: Exactly.

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1 DR. WILLIAMSON: That's right.

2 DR. DIAMOND: I was just going to make the
3 point in response to what Manny said that in a
4 circumstance where you have some disillusioned
5 individual that just finished an internship in
6 pediatrics and wants to go and start doing these
7 studies that there is no way that any credentialing
8 subcommittee in a hospital is ever going to grant
9 privileges to do this.

10 CHAIRMAN VETTER: So I guess we are okay
11 with the way that it is.

12 MS. MCBURNEY: Okay. So that covers the
13 certification, and certainly if they are an authorized
14 user under 290 or 390, they can do the 190 stuff.
15 Once again, (d) with alternate pathway, requires some
16 sort of written certification that the individual has
17 satisfactorily completed the requirement. And then to
18 290.

19 DR. CERQUEIRA: So I guess we are all
20 comfortable with the concept that if a cardiologist
21 meets the 290 that he is not going to be treating
22 patients for thyroid disease, but that is going to be
23 sort of regulated by the medical community.

24 CHAIRMAN VETTER: Right.

25 DR. BRINKER: But this isn't treatment?

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1 MS. MCBURNEY: Right.

2 CHAIRMAN VETTER: No.

3 MS. MCBURNEY: Going on to 290 then. One
4 again in (a) was the certifications that had been
5 accepted in the old rule, and then (b), certified by
6 a medical specialty board. The certification process
7 includes the minimum training experience that is in
8 alternate pathway.

9 The question becomes here do I add an
10 option for a residency program in nuclear medicine.
11 Of course, the residency program would include all the
12 training experience requirements in (b) probably if it
13 was --

14 DR. WILLIAMSON: Wait. I'm not sure I
15 understand your question.

16 MS. MCBURNEY: Okay. In 690, Dr. Diamond
17 has included a residency program as a requirement.

18 DR. WILLIAMSON: That's right.

19 MS. MCBURNEY: The question is do we want
20 to add a residency program in nuclear medicine as an
21 optional --

22 DR. WILLIAMSON: As a criteria --

23 MS. MCBURNEY: For criteria for a board
24 certification process acceptance.

25 DR. WILLIAMSON: I would make the same

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1 argument that I did for 190, that we went through this
2 ad infinitum for two years, and decided that the break
3 point was 200 versus 300 and above, and for 200 and
4 100, we were not going to require a demonstration of
5 clinical competence, and that the requirements should
6 focus more on safety, and technical competence, and
7 handing, et cetera.

8 And I am afraid that if we open that up
9 again that it will cause a big controversy, because
10 that took a lot of effort, and compromise, and
11 negotiation, to sort out.

12 So it seems to me that we should apply the
13 principle that if it is not broken, let's not fix it.

14 CHAIRMAN VETTER: And so we are okay with
15 the way it is worded now. Anyone disagree with that
16 and the way that it is worded now?

17 DR. WILLIAMSON: I think we do need to
18 make sure that we have identified all the things that
19 are broken, and make sure that these changes do fix
20 it. And it is obvious from the comments that some of
21 these things are very controversial with the
22 community.

23 MS. MCBURNEY: And then going along with
24 that, and this sort of went back and forth, but the
25 nuclear cardiology certification in nuclear cardiology

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1 does include all of those requirements.

2 Now, the fact that they are limited by
3 their scope of practice -- and not under a license,
4 but under what they are doing in practice would be
5 just nuclear cardiology.

6 DR. CERQUEIRA: The practice of medicine
7 would probably propose the appropriate restrictions on
8 it.

9 MS. MCBURNEY: And then you would be going
10 after in-bone scans and that sort of thing.

11 DR. CERQUEIRA: Right.

12 DR. WILLIAMSON: Yeah, I agree with that.

13 MS. MCBURNEY: Since we are focusing just
14 on the radiation safety issue and handling techniques.

15 CHAIRMAN VETTER: Okay. Continuing on, is
16 there anything else?

17 MS. MCBURNEY: Let's see. (d)(1) with
18 parallel structure, and having the certification by
19 the preceptor that they meet the requirements in
20 (d)(1).

21 CHAIRMAN VETTER: Right.

22 DR. WILLIAMSON: Now, are we -- do we know
23 whether all these certification boards in fact do meet
24 the proposed requirements in (d)(1), or have we fixed
25 the problem for --

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1 MS. MCBURNEY: Oh, of the current board?

2 DR. WILLIAMSON: Yeah, of the current
3 boards. For example, diagnostic radiology by the
4 American Board of Radiology. Would their eligibility
5 requirements include the requirements in (e) (1)?

6 MS. MCBURNEY: Has the NRC --

7 DR. WILLIAMSON: John, could you maybe
8 fill us in on that?

9 MS. MCBURNEY: On what requirements each
10 of these boards has?

11 MR. HICKEY: Yeah, and I think don't I can
12 do that off the top of my head. The only one I recall
13 is the Board of Nuclear Medicine meets the
14 requirements, except that there is a possible question
15 about the preceptor statement.

16 But I might be able to check during the
17 break to see what the other ones are and where we are
18 on those.

19 MS. MCBURNEY: Okay.

20 MR. HICKEY: I would also ask again on
21 paragraph (b) for both 190 and 290, is there going to
22 be a requirement for some sort of a certification that
23 the training was completed?

24 MS. MCBURNEY: Yes. Oh, I see what you
25 mean, because (d) (1) --

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1 DR. CERQUEIRA: You mean a preceptor's
2 statement?

3 DR. WILLIAMSON: Well, it depends on how
4 you define a preceptor statement, but it was what
5 before we were calling a preceptor statement.

6 MS. MCBURNEY: Rather than (d)(2).

7 DR. WILLIAMSON: So why don't you just
8 paragraph (d), and delete or cross out the (1).

9 MS. MCBURNEY: Both 190 and 290 and cross
10 out the one?

11 DR. WILLIAMSON: Yeah.

12 CHAIRMAN VETTER: In that regard, I would
13 like to -- I don't want to get into a long detailed
14 discussion of this, but relative to the option of a
15 residency, why don't we allow the boards to require
16 either a residency or (d)?

17 MS. MCBURNEY: That way if there is some
18 question on the number of hours, and if it is a
19 residency --

20 CHAIRMAN VETTER: So the American Board of
21 Radiology would not have to determine that in fact the
22 person had 700 hours of training, but that they had in
23 fact completed the residency?

24 MS. MCBURNEY: A two year residency
25 program.

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1 DR. WILLIAMSON: Do we know that this is
2 a problem that we have to fix? I thought 700 hours
3 was selected because it is the number of hours that a
4 radiology resident typically spends in nuclear
5 medicine. I am not a specialist --

6 DR. CERQUEIRA: Yeah, I think that is how
7 it was decided. There was a lot of discussion about
8 whether to put in specific hourly requirements for the
9 classroom, and didactic it, and come up with like 80
10 hours at one point.

11 But then I think the Nuclear Medicine
12 Society basically felt that it should just be 700
13 hours in the environment. And I think that is what
14 the radiologists are required to do, 6 months, 4 to 6
15 months.

16 MS. MCBURNEY: Maybe we could get into
17 from the board's comment period.

18 CHAIRMAN VETTER: We will ask that during
19 the comment period.

20 DR. WILLIAMSON: Again, I think we should
21 be careful and not change it.

22 MS. MCBURNEY: But even if it is an option

23 CHAIRMAN VETTER: What I am trying to do
24 is to add some flexibility to the process for the
25 boards.

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1 MS. MCBURNEY: Right.

2 DR. WILLIAMSON: Well, you want to make
3 sure that somebody doesn't substitute a pathology
4 residency or something.

5 MS. MCBURNEY: No, it would be a residency
6 in nuclear medicine or in radiology.

7 CHAIRMAN VETTER: And approved by ACGME.
8 We will ask that question later as to what would be --
9 whether or not that would be problematic. Okay. So
10 mainly the only changes under (b)(1), to include the
11 requirements of the entire paragraph (d).

12 MS. MCBURNEY: Yes, and the same with back
13 on 190, the same way.

14 MR. HICKEY: Dr. Vetter, on that change,
15 I just want to point out that that paragraph calls for
16 the certifier to be an authorized user. So you just
17 need to make sure that is your intent.

18 CHAIRMAN VETTER: Good point. I think
19 that is their intent isn't it?

20 MS. MCBURNEY: I believe so.

21 DR. WILLIAMSON: Do we want it to be an
22 authorized user, or someone who meets the requirements
23 for an authorized user?

24 CHAIRMAN VETTER: Why wouldn't it be an
25 authorized user?

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1 DR. CERQUEIRA: Right. I think --

2 MS. MCBURNEY: To provide the training?

3 DR. CERQUEIRA: I think we all felt that
4 being an authorized user was essential. Otherwise,
5 there is no way of identifying that that person has
6 the hourly requirements to sign off.

7 CHAIRMAN VETTER: Everybody okay with
8 that? Then let's move ahead to 35.690, training for
9 use of remote after-loader units, teletherapy units,
10 and gamma stereotactic radiosurgery units. Dr.
11 Diamond.

12 DR. DIAMOND: Okay. Yes. So, again the
13 general framework of this is authorized user status
14 granted through a board pathway, which is paragraph
15 (a), and board alternate pathway, paragraph (b). The
16 currently approved boards are listed in paragraph (c).

17 And then a specific delineation for
18 modality specific training in Part (d). Problems or
19 changes in paragraph (a) would be the fact that
20 currently certification requires the successful
21 completion of a three year residency programming
22 radiation oncology approved by the residency review
23 committee on the ACGME.

24 It was pointed out to me that all of the
25 American Radiation Oncology Residency Programs have

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1 now moved to four years. However, if you change that
2 verbiage from a 3 to 4 years, that may not be
3 consistent with some of the foreign boards that are
4 currently recognized; Canada, the World College, and
5 Great Britain.

6 So my suggestion would be to leave it at
7 3 years to prevent that problem.

8 MS. MCBURNEY: At a minimum.

9 CHAIRMAN VETTER: Add the word minimum?
10 A minimum of?

11 DR. DIAMOND: A minimum, that's fine.
12 Continuing on that same paragraph (a)(1), is this is
13 the only section that we have discussed thus far in
14 which we do not delineate that the residency program
15 must satisfy the requirements enumerated in paragraph
16 (b)(1), and in the final draft, which we are looking
17 at today, several members of my stakeholder community
18 said that it became onerous on the residency programs
19 to keep track of the number of hours of classroom time
20 and laboratory training, and suggested that that
21 specific reference be deleted.

22 I don't have a specific problem in
23 removing that language, except that it makes this
24 inconsistent with the other sections that we have just
25 discussed.

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1 DR. WILLIAMSON: I am confused. I don't
2 think so. It is not with medical physics.

3 DR. DIAMOND: If you take a look --

4 CHAIRMAN VETTER: It is consistent with
5 the diagnostic.

6 DR. DIAMOND: Correct.

7 CHAIRMAN VETTER: But not with the RSO or
8 authorized medical physics.

9 DR. DIAMOND: That's correct.

10 DR. CERQUEIRA: I think it's fine.

11 DR. DIAMOND: Okay. I am just pointing
12 out key differences. We included the examination of
13 paragraph (a)(2), and the alternate pathway is
14 essentially unchanged from the current regulation.

15 Going on to paragraph (b)(2), that is
16 unchanged. And paragraph (b)(3) is the preceptor
17 statement, which has the parallel verbiage of having
18 written certification that the individual has,
19 "satisfactorily completed."

20 So that is parallel to what we discussed
21 a few moments ago, and the caveats there is that the
22 written certification must be signed by a preceptor
23 who meets or who has experience in that particular
24 modality.

25 In other words, you need to have that

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1 preceptor statement signed by someone who knows what
2 they are doing in that particular area.

3 CHAIRMAN VETTER: Right.

4 DR. DIAMOND: It would be ridiculous to
5 have a preceptor statement signed that this person has
6 satisfactorily completed training in the use of
7 gammaknife when that person who is offering that
8 statement has never seen a gammaknife unit.

9 So that is why that is written in that
10 fashion. Paragraph (c) represents to the best of my
11 knowledge the board's currently recognized by the
12 commission, and we would probably want to modify that
13 to be specific, and that it is radiation oncology
14 training within ABR, the American Osteopathic Board of
15 Radiology, and so forth.

16 In other words, to make it clear that
17 someone can't just be a diplomate of the ABR in
18 diagnostics.

19 MS. MCBURNEY: It has to be in whatever it
20 is.

21 DR. DIAMOND: Right.

22 MS. MCBURNEY: Radiation oncology.

23 DR. DIAMOND: Right. Radiation oncology
24 training in.

25 DR. WILLIAMSON: Why did you choose to --

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1 you know, all the other statements have up front as
2 option (a) board certification in X, Y, or Z by so and
3 so, and you have kind of put it down here in (c).

4 CHAIRMAN VETTER: It won't really matter
5 because they are not going to be in the regulation.
6 They are going to be listed separately from the
7 regulations.

8 DR. WILLIAMSON: Well, we don't know that.
9 That was something to be discussed wasn't it?

10 CHAIRMAN VETTER: We were going to discuss
11 that, right. Well, we are not writing the regulation
12 either.

13 MS. MCBURNEY: Right, and they will do the
14 parallel work.

15 CHAIRMAN VETTER: If the NRC wants to
16 maintain them in the regulation, they will place them
17 in whatever paragraph they wish.

18 DR. DIAMOND: And finally in paragraph
19 (d), my only suggestion for the modality specific
20 training paragraph is that the second paragraph, which
21 states that this includes training in device
22 operation, common safety procedures, common clinical
23 use, and so forth, I would just go and end the
24 sentence there, and delete the phrase, "that is
25 equivalent to that instruction provided by the vendor

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1 to new customers."

2 MS. MCBURNEY: Right.

3 DR. DIAMOND: And with the same rationale
4 that was discussed a few moments ago. So I think that
5 is a good start for us. I would again remind the
6 staff that if these principles are accepted, that we
7 need to go back and make parallel changes to other
8 sections, including 392, paragraph (c)(3); 394,
9 paragraph (c)(3); 490, paragraphs (a) and (b)(3); and
10 491, paragraph (b)(3).

11 And just as far as language regarding
12 competency and just minor housekeeping changes.

13 CHAIRMAN VETTER: Okay. Ruth.

14 MS. MCBURNEY: I guess parallel language
15 in 300 as well.

16 DR. WILLIAMSON: Yeah, and in that there
17 are going to be some more substantive issues.

18 CHAIRMAN VETTER: Okay. Questions for Dr.
19 Diamond? Good job.

20 DR. DIAMOND: Thank you.

21 CHAIRMAN VETTER: Okay. And then the other
22 issue that we were simply asked to consider and I
23 think we all agreed, that we simply want consistency
24 in all of the sections relative to requirements, or
25 criteria, that is, that boards would need to meet in

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1 order to be listed, or whether or not we need to look
2 at each one of those and go through and develop
3 criteria is another matter.

4 We were not asked to address nuclear
5 pharmacist, authorized nuclear pharmacist, for
6 example. But we would expect that it would simply be
7 consistent throughout, and the same for the other, the
8 radiopharmaceutical therapy.

9 We would want consistency in those
10 sections as well, but we were not asked to address
11 them specifically. But that takes us through those
12 sections that we were asked to address. John.

13 MR. HICKEY: Yes. If I could just ask one
14 question back on 690. Again, on the preceptor
15 statement, I believe there still are questions that
16 are parallel to the concerns about the medical
17 physicist.

18 As written, I believe that the authorized
19 user -- first of all, the authorized user would sign
20 the preceptor statement. And second of all, there
21 would have to be coverage of each type of unit. So in
22 order for someone to be certified on a gammaknife,
23 they would have to have training on the gammaknife and
24 the preceptor would have to be authorized for the
25 gammaknife.

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1 And all of this would have to be part of
2 the board process in order for the board to be
3 recognized, and I think there are some issues there
4 that parallel the issues that were raised with the
5 medical physicists.

6 CHAIRMAN VETTER: Right. That's a good
7 point. We don't mean to constrain the boards to that
8 point, to that extent. We want to be sure to capture
9 all of the requirements for training in the paragraph
10 that addresses training in specific modalities.

11 But we don't mean to constrain the boards
12 to require that everyone who is going to be certified
13 have gammaknife experience.

14 DR. WILLIAMSON: I don't think that Dr.
15 Diamond's write-up does that. He basically gives the
16 requirements for boards in Section D of 35.690(a).
17 And I think what needs to be done to make it parallel
18 to the others is that you have to add a four, and it
19 includes a preceptor statement testifying to
20 satisfactory completion of the above-requirements.

21 MS. MCBURNEY: Of the residency.

22 DR. WILLIAMSON: Yes, basically the
23 residency. But the intent is to -- and the
24 description of what the examination contents include,
25 they include radionuclide handling, and stereotactic

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1 radiosurgery, high and low dose brachytherapy, which
2 are all topics that the boards do cover.

3 But then the contact with actual units and
4 actual experience with a given unit is cast on to
5 Section D, the modality specific training. So in that
6 sense it is parallel to the medical physicist. And it
7 is only in the alternative pathway, Section B, where
8 the preceptor is attesting to specific competence of
9 the physician in the modality being requested.

10 And that is also similar for the medical
11 physicist, and seems consistent with our principal
12 that the non-board certification route alternate
13 pathway requirements can be a little stiffer and more
14 focused than the broader requirements of the boards.

15 MS. MCBURNEY: Does the board
16 certification require that the residency -- that
17 whoever is in charge of the residency program, send in
18 a letter?

19 DR. DIAMOND: Yes, your residency program
20 director has to send in a letter.

21 MS. MCBURNEY: So if we add that as a
22 requirement under the board certification process, a
23 written statement of the completion of (a)(1) --

24 DR. DIAMOND: Right, and so we will make
25 that (a)(4), preceptor statement, which could be

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1 interpreted to be a residency program director
2 statement indicating or certifying that the above
3 requirements have been satisfactorily met.

4 MR. HICKEY: Thank you.

5 DR. CERQUEIRA: And John, I guess the
6 staff is going to go through the minutes and all of
7 these changes will be put into the revised version of
8 this.

9 And I think it is really incumbent upon us
10 before the main meeting on July 8th that we go through
11 it and check it, especially all of the ands or ors, as
12 well as the parallel nature between the various
13 groups.

14 CHAIRMAN VETTER: Right. I think they are
15 expecting us to provide a report to you, that this
16 subcommittee would provide a report to you with those
17 changes in it.

18 DR. CERQUEIRA: Right.

19 MR. HICKEY: Yes, and we can assist with
20 the administrative review, in terms of noting
21 editorial inconsistencies and things like that.

22 DR. CERQUEIRA: Well, we have got like two
23 weeks.

24 CHAIRMAN VETTER: Right. So it is not a
25 lot of time. That takes us through the sections that

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1 we were asked to address. Are there any other
2 additions or questions on these sections? If not,
3 John, are there any other additions or questions at
4 this point from you?

5 I know that you have not had a chance, or
6 you and your staff have not had a chance to discuss
7 any changes that we have made here. But any questions
8 at this point?

9 MR. HICKEY: No, I think the discussions
10 and conclusions this morning hold together very well.
11 I want to emphasize though that the subcommittee
12 recommendations should be clear on the list, or on the
13 issue of the listing of the boards, and the rationale.

14 It is my understanding that the
15 subcommittee believes that all of the boards should be
16 reevaluated against criteria, and there should not be
17 any presumption that any boards that are currently
18 listed in Part 35 meet the criteria, and that those
19 have to be reevaluated.

20 And there will be a lot of people who are
21 not in this meeting that will be asking that question;
22 is there any presumption that any board that was
23 listed in the old rule does not have to be reviewed
24 again.

25 CHAIRMAN VETTER: We are a little ahead of

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1 schedule, and so let's go ahead and discuss that point
2 right now.

3 DR. WILLIAMSON: Well, I argued for the
4 explicit mentioning or listening of the currently
5 recognized or accepted boards in the revised rule
6 making that might come out of this. So we had I guess
7 a tentative consensus that was reasonable, or at least
8 we would go with that initially.

9 But I would agree that there was also the
10 presumption that to be so listed that the listed
11 boards would have to meet the broad criteria for being
12 an eligible board.

13 But the rationale was that as part of the
14 package of writing this regulation that it would force
15 the NRC and the staff to go through and comb the
16 eligibility criteria of these boards very carefully
17 and compare them against the proposed criteria. So
18 that a terrible error wouldn't happen again as it has
19 happened now with the recently published rule.

20 And secondly that as soon as the rule hits
21 the streets, then those boards are mentioned, and so
22 there would be no disruption. So that is the
23 rationale from my perspective.

24 CHAIRMAN VETTER: Ruth.

25 MS. MCBURNEY: Given that information and

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1 that all of these are going to have to be relooked at
2 to see if they meet the new criteria, and going back
3 to 35.50, the way the written certification of the
4 supervising or RSO that an individual completed for
5 training and experience, would the American Board of
6 Health Physics still meet that.

7 CHAIRMAN VETTER: Yes.

8 MS. MCBURNEY: Because it doesn't mention
9 that it is specific in medical physics.

10 DR. WILLIAMSON: Right. Well, this is
11 health physics now?

12 MS. MCBURNEY: Yes, in (b).

13 CHAIRMAN VETTER: It says professional
14 experience, and it does not say professional
15 experience in medical.

16 MS. MCBURNEY: Right. Because I think
17 they do require a residency signed by the supervisor.

18 CHAIRMAN VETTER: They do. They require
19 2 or 3 residences, yes, and one of them signed by the
20 supervisor. And the American Board of Medical Physics
21 is somewhat similar to that.

22 MS. MCBURNEY: Yes.

23 DR. DIAMOND: I must happened to note,
24 Richard, that when I was doing paragraph (c), which
25 enumerated the boards, included was the American

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1 Osteopathic Board of Radiology. I am not even sure if
2 the American Osteopathic Board of Radiology has a
3 radiation oncology training program in existence. I
4 don't know, but I am not aware of it offhand.

5 CHAIRMAN VETTER: I think that gets back
6 to John's point. We would not presume that any board
7 at this point in time meets these criteria. This
8 would require the NRC staff to go back out to the
9 boards, and similar to what they did before, two years
10 ago, and ask them do you meet these requirements, and
11 demonstrate that you do.

12 And presumably they would be able to
13 simply send the literature back to the NRC, the
14 literature that the candidates received that spell out
15 what is expected of the candidate, and what the
16 minimum requirements are.

17 DR. CERQUEIRA: Yeah, I think we do have
18 a history on this, in the sense that Bob Ayres was
19 sort of detailed to go through the boards, and there
20 were some issues that arose more related to the
21 preceptor statement rather than the content was my
22 understanding.

23 But we really need to look at that, and if
24 David brings up the point that the American
25 Osteopathic Board of Radiology, that if they don't

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1 provide that training, then they definitely should not
2 be listed, because it really opens this up.

3 DR. WILLIAMSON: Well, if they don't
4 provide the training, then nobody will be a diplomate
5 of their board, and it is kind of a moot point. I
6 mean, it does no harm. It sort of is unnecessary.

7 But the one concern that I have is that
8 this process of the American Board of Radiology
9 applying or trying to get a definitive answer from the
10 NRC about whether they are going to be recognized or
11 not has taken two years, and to my knowledge, still
12 the boards do not have definitive answers and have not
13 -- and so this is a major reason why I would like to
14 see the reasonable collection of boards listed up
15 front in the regulation, because it will stop all this
16 nonsense, and it will force them in the process of
17 crafting this regulation to ensure that there is not
18 a contradiction between those board eligibility
19 requirements.

20 And to give them an opportunity to fine-
21 tune these criteria so that everything will work out,
22 and I am afraid that if they just ignore that issue,
23 and go ahead with some criteria, some little
24 conjunction, or disjunction, or some turn of phrase,
25 will be incorrect.

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1 And then we will find ourselves in the
2 position that the Office of General Counsel, based on
3 some legal technicality, disenfranchises some part of
4 the community for no reason at all.

5 So this way by putting or listing the
6 board's explicitly, the task of once and for all
7 definitively figuring out if these criteria fit the
8 boards will be done before the rule is cast in
9 concrete.

10 CHAIRMAN VETTER: We will actually arrive
11 at our answer to that question at the end of the day
12 after we have heard public comment, but are there any
13 other comments at this point in time that anybody
14 would like to make in that regard? John.

15 MR. HICKEY: I just wanted to add that
16 there are a couple of boards that have told us that
17 they do not want to request recognition until they
18 know what the criteria are.

19 CHAIRMAN VETTER: Right. Okay. Good
20 point. Any other comments or questions at this point
21 in time? If not, we will take our break 15 minutes
22 early, and when we come back from the break, we will
23 hearing public comments.

24 So once again, any members of the public
25 who wish to make comment, if you have not already

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1 registered with the NRC, be sure that you do that.

2 DR. CERQUEIRA: We should check just to be
3 sure, because we are changing the schedule, and there
4 may be people that are coming and expecting to start
5 at a certain time. So by starting early --

6 CHAIRMAN VETTER: That is a very good
7 point.

8 MR. HICKEY: Let's get the list and read
9 it off and take attendance here.

10 DR. CERQUEIRA: Just to make sure that
11 everybody is here. And basically we are going to have
12 quite a long period, and so if people --

13 CHAIRMAN VETTER: They will still have
14 time. But let's look anyway. Let's look at the list
15 and let's see if those people who have registered are
16 in fact here, and then we will take our break and get
17 to the public comment when we come back.

18 (Discussion off the record.)

19 CHAIRMAN VETTER: We did not give specific
20 times for anyone to speak. We simply said they needed
21 to sign up to speak and they would be given up to 10
22 minutes. Now we have eight people signed up. So that
23 would be 80 minutes.

24 So we are hoping that people wouldn't take
25 a full 10 minutes, but could we just see if these

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1 people are here. William Van Decker?

2 MR. VAN DECKER: Yes.

3 CHAIRMAN VETTER: William Hendee?

4 MR. HENDEE: Yes.

5 CHAIRMAN VETTER: David Steidley?

6 MR. STEIDLEY: Yes.

7 CHAIRMAN VETTER: Paul Capp?

8 MR. CAPP: Yes.

9 CHAIRMAN VETTER: Richard Fejka?

10 MR. FEJKA: Here.

11 CHAIRMAN VETTER: Gary Sayed?

12 MR. SAYED: Yes.

13 CHAIRMAN VETTER: Bill Uffelman?

14 MR. UFFELMAN: Yes.

15 CHAIRMAN VETTER: Paul Chase?

16 MR. CHASE: Yes.

17 CHAIRMAN VETTER: Okay. They are all

18 here. So what we will do is come back at a quarter-

19 to, and have a 15 minute break, and come back and

20 begin hearing public comment from Dr. William Van

21 Decker.

22 (Whereupon, the Subcommittee meeting was

23 recessed at 9:30 a.m., and resumed at 9:45 a.m.)

24 CHAIRMAN VETTER: Okay. Here we are all

25 back again. Thank you all very much. We are at the

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1 point in the agenda where we are ready to receive
2 public comments.

3 We now have nine people signed up, and we
4 had originally said you have up to 10 minutes, and you
5 still do have up to 10 minutes, but we would urge you
6 if you can make your points in less time than that to
7 do so.

8 We would also ask that you leave a minute
9 or so for the subcommittee to ask you questions, and
10 if you could do that, please. The first person who
11 has signed up is Dr. William Van Decker. His
12 affiliation is with the CBNC. Dr. Van Decker.

13 MR. HICKEY: Let me suggest that the
14 speakers join us up at the table for more comfortable.

15 CHAIRMAN VETTER: That would be good, yes.

16 DR. VAN DECKER: Good morning. As an
17 affected stakeholder in this process, I want to thank
18 both the NRC and the ACMUI subcommittee for allowing
19 us to be present today. I would just like to touch on
20 five quick points if I could.

21 Number One, the CBNC would like to thank
22 the NRC for its written May 21st, 2002 notification
23 that the Board meets the requirements for being an
24 authorized user, the board has worked very hard over
25 the past few years to make sure that this is true, and

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1 we appreciate that in writing, and we appreciate the
2 ACMUI Subcommittee recognizing that in its drafts for
3 where we are going from here.

4 Secondly, we wanted to note with some
5 bemusement that the CBNC has always been aboard and
6 has had strict criteria that a person sitting for
7 authorized user status before sitting, because it had
8 not had board status in the old subpart (j).

9 And therefore we want everyone to at least
10 notice now how exactly and painstaking a process this
11 can be if that is part of the issue going in. But it
12 is something that we have done for years, and so it is
13 not that much of an issue, per se.

14 The third point that I would like to make
15 is at least a thought provoking point. In regards to
16 .290, if you look at the current draft, passing a
17 board actually makes the alternative pathway as a
18 building block for authorized usership actually moot.

19 Because just passing the board on to
20 itself will give you the ability to be an authorized
21 user. Therefore, I think it is important obviously
22 that all the boards have relatively industry standard
23 means for sitting the boards.

24 I also want to raise the point to remember
25 that whatever the boards are now, they may not be 10

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1 years from now, and assist them where we try to do
2 innovative things for patient care.

3 So a board changing its criteria five
4 years from now, and another one changing its criteria
5 eight years from now, by the end of 10 years, you may
6 have multiple boards with multiple boards, with
7 multiple diversity of how you become an authorized
8 user.

9 And some consideration needs to be given
10 to how you address that type of a consideration. The
11 fourth point that I wanted to touch on I think was
12 touched on quite heavily this morning, and so I won't
13 spend too much time on it, but that was the issue of
14 radiation safety officership.

15 We are a little less bemused by the fact
16 that the draft specifically lists 11 different boards,
17 which is a fairly diverse community, and did not list
18 CBNC.

19 We recognize that most people involved in
20 nuclear cardiology would have been covered under the
21 nondescript paragraph (d) for that use. But certainly
22 an authorized user should be able to be the RSO for a
23 single modality diagnostic imaging type setup, if that
24 is what their expertise is in, and if they should so
25 desire.

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1 And leaving that board out, and just to
2 point out the political sensitivities of life, and
3 make somebody feel like a second citizen to somebody
4 else whose board is listed in some way.

5 And I think that happens in any of the
6 different categories when you begin to board lists.
7 And the last thing that you want to do is look like
8 you are restricting the scope or practice of medicine
9 in ways that are beyond just radiation safety, and I
10 think that is something that we all need to keep in
11 mind as we go about dealing with this type of
12 situation.

13 And I guess that is the last point that I
14 want to talk about, is number five. Coming from a
15 constituency who has always sensed in some way that
16 subpart (j) was used as an unequal restriction of the
17 scope of practice among physicians, and this may be a
18 point to remember when we talk about having alternate
19 pathways with more teeth and quotes from those people
20 who are quotes are already in.

21 And we are particularly sensitive to rule
22 wording, and that really places the NRC in the
23 position of regulating the practice of medicine.
24 Certainly we have had a lot of workshops on the
25 guidance and inspection documents, and talking about

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1 being more risk informed and performance based, and
2 how we just go through inspections, and guidance, and
3 licensing.

4 I think we need to be taking that same
5 type of thoughtful process to everything else that we
6 do. The key role here is that the NRC wants safe
7 authorized users, and not to be involved in the
8 regulation of medicine.

9 And therefore any wording of any ruling
10 must allow room for new paradigms, for patient care,
11 and even new boards that meet industry standards,
12 remembering where we have come from.

13 And new training and experience for
14 emerging technologies. That will be thought out in
15 the future since it is -- and perhaps such as
16 intervascular brachy, and that the alternative
17 pathways should not be super restrictive to the
18 practice of medicine, but should looked at as building
19 blocks to the other boards.

20 And anything less than that probably begs
21 for stagnation and antitrust arguments as board shift
22 criteria as time goes by and everything else, and I
23 think we should just be trying to do this in an
24 appropriate manner for everyone involved in the
25 community. And I think that I will end my comments on

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1 that note, and I thank You very much for the time.

2 CHAIRMAN VETTER: Thank you, Dr. Van
3 Decker. I appreciate it very much. Does anyone on
4 the subcommittee have questions or comments?

5 DR. WILLIAMSON: Well, we certainly
6 apologize for inadvertently leaving out your board,
7 and I think you can see that we have reversed our
8 mistake by taking all of the specialty physician
9 imaging boards out, and that was not the intent.

10 DR. VAN DECKER: I understand that it was
11 not the intent, but I am just trying to say that we
12 recognize how difficult this is once you start listing
13 specific things as to who you include and exclude kind
14 of thing.

15 DR. WILLIAMSON: Let me ask my question.
16 The way the proposed. draft statements are worded now,
17 it says that you can be an authorized user if you are
18 a diplomate of one of these listed boards, or a
19 diplomate of a recognized board meeting the following
20 broad criteria.

21 And then we do have to work on the problem
22 of how to make sure that the listed boards maintained
23 their adherence to that criteria. But would you find
24 the combination of those two statements acceptable
25 from the scenario or the perspective of your board and

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1 the struggle that it has had to be recognized?

2 Do you think that this sort of alternate
3 board pathway is a reasonable framework for
4 recognizing new boards that come along in a field?

5 DR. VAN DECKER: I think that in all
6 things the devil is in the details, and so as long as
7 the review process is reasonable, and that there is a
8 clear cut building block of what needs to be there and
9 what doesn't need to be there, and that that building
10 block is not four times the standard for whatever
11 anyone else in the rule is, that that is something
12 that could probably be worked with.

13 CHAIRMAN VETTER: Any other questions?
14 Manny?

15 DR. CERQUEIRA: You brought up one item
16 about change in requirements for boards, and I guess
17 once we started listing boards, we are assuming that
18 there is a criteria for -- that eligibility criteria
19 is going to stay the same.

20 And I guess in terms of the committee, do
21 we have any mechanism in place which would allow us to
22 look if a board all of a sudden decides that they are
23 not going to have requirements for certain things?

24 Is there some way that we can take them
25 off the list and do we need to develop some sort of a

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1 process for that.

2 CHAIRMAN VETTER: David, did you --

3 DR. DIAMOND: I was just thinking of the
4 same thing as Dr. Van Decker was speaking. There are
5 a lot of advantages to enumerating the boards for
6 clarify sake, and for removal of all of these
7 nitpicking questions that may occur.

8 But then you have to have a mechanism for
9 updating them, and for deleting boards should they
10 for some reason they not adhere to. So if you are
11 going to do that, it works both ways.

12 DR. WILLIAMSON: Well, I have a
13 suggestion. Actually, we could put in that paragraph
14 (a) that it is certified by Board X, by Board Y, Board
15 Z, et cetera, provided that the diplomates sitting for
16 these boards adhere to the minimum requirements in
17 paragraph (b).

18 CHAIRMAN VETTER: Yeah, I don't think that
19 we have to worry about the words, but the point is
20 well taken.

21 DR. WILLIAMSON: And that would
22 automatically nullify, even though they are mentioned
23 explicitly, that if they somehow change the residency
24 requirement from 2 to 3 years, it would automatically
25 disqualify those diplomates.

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1 CHAIRMAN VETTER: And the point is well
2 taken. We don't want words in here that would
3 restrict the growth of the profession.

4 DR. VAN DECKER: And new paradigms. And
5 this just jogged my memory. This residency issue is
6 frequently a matter of clinical competence and time of
7 patient selections, da da, da da, da da. And I think
8 that the goal here is to be focused on what is the
9 radiation safety, and what makes the States and the
10 NRC comfortable that a physician can appropriately
11 handle ionizing radiation.

12 And coming from the City of Philadelphia,
13 I can guarantee that if you want to worry about
14 clinical competence, there are plenty of lawyers who
15 will find you. I guarantee.

16 CHAIRMAN VETTER: Okay. Thank you very
17 much, Dr. Van Decker.

18 DR. VAN DECKER: Thank you very much.

19 CHAIRMAN VETTER: Dr. William Hendee,
20 representing the American Board of Radiology.

21 DR. HENDEE: I would like to ask that Dr.
22 Capp join me and we will do ours together.

23 CHAIRMAN VETTER: That will be wonderful.

24 DR. HENDEE: And Dr. Capp has a very brief
25 statement.

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1 CHAIRMAN VETTER: Sure.

2 DR. HENDEE: So that will cut down one of
3 your speakers.

4 CHAIRMAN VETTER: Okay.

5 DR. CAPP: Thank you. My name is Paul
6 Capp, and I am the Executive Director of the American
7 Board of Radiology and have been for nine years, and
8 the former president of the board prior to that time.
9 I am an old physicist from way back, and then went
10 into nuclear physics.

11 And then I realized that I wasn't bright
12 enough and so I had to go into medicine. So, if you
13 will excuse me for that, but I speak as a medical
14 doctor and a radiologist.

15 I don't have to tell this group that our
16 board from way back realized that the serious effects
17 of radiation caused the board beginning in 1934 to
18 start examining in 1934 about radiation effects.

19 And so it has been high on our list in the
20 examination process over the many, many years. So
21 much so that in 1947, and in view of the increasing
22 technology, we brought in physicists to the board at
23 that time and started the certification process in
24 radiologic physics.

25 And which is still recognized today by the

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1 ABMS, and that is important. The ABMS is medical
2 board's only, but the ABMS has allowed for the ABR to
3 continue to certify radiologic physics up until this
4 day.

5 Whereas, they do not allow certification
6 for non-physicians in any other field except for
7 medical genetics due to many, many other reasons. We
8 think so seriously about this topic that we have
9 separate examinations in the diagnostic radiology
10 today, and we have a three hour examination, written
11 examination, in both radiologic physics and radio
12 biology for the diagnostic resident who has just
13 completed five years of training.

14 And in radiation oncology, we have a three
15 hour examination in radiologic physic, and therapy,
16 and a three hour examination in radiobiology, besides
17 the basic science clinical examination.

18 And this of course all precedes the oral
19 examination that occurs if they are successful with
20 the written examinations. So we are very serious
21 about radiation safety, and we have specific
22 examination committees.

23 Dr. David Hussey from San Antonio, who is
24 the head of the examination committee in radiation
25 oncology, and he feels strong enough, and he is here

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1 in the audience today, to perhaps answer your
2 questions.

3 And Dr. Phil Alderson from Columbia is in
4 the audience who runs our nuclear medicine section,
5 and Dr. Steve Thomas is here, who is a nuclear
6 physicist, in charge of the nuclear medicine part, and
7 he is representing another or wearing another hat, and
8 representing the AAPM.

9 And I am pleased to say on our board of
10 trustees we have three physicists, which is unusual
11 for a medical board, but that is also how strongly we
12 feel about this topic. And I am pleased to say that
13 we are probably the only medical board in existence
14 that has a non-physician as president now.

15 So our president for the next two years is
16 Dr. Bill Hendee, who will give the points that we
17 would like to get across. Bill.

18 DR. HENDEE: Thank you, Paul. I think
19 everyone in this group and so there is no point in
20 telling you who I am, other than the fact that I did
21 want to mention one credential that you may not know
22 about.

23 I am the secretary of the National Patient
24 Safety Foundation and a founding board member , and I
25 wanted to state that just so you will know that in

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1 addition to coming at this from a professional point
2 of view as a medical physicist, and health physicist,
3 I also come at it from the point of view of having a
4 great interest in the protection of the health and
5 safety of patients who are provided health care in
6 institutions across the country.

7 It is a pleasure for me to be here as
8 well, and I am here to state the unqualified support
9 of the American Board of Radiology for the June 14th
10 statement that has been developed by this group, by
11 the ACMU subcommittee, and which has been discussed
12 here today.

13 This statement restores board
14 certification as the default pathway for individuals
15 to become authorized as radiation safety officers, and
16 medical physicists, and nuclear pharmacists, and
17 authorized users of byproduct material.

18 We endorse this restoration of board
19 certification as the default pathway. We strongly
20 encourage the acceptance of each of the certification
21 of boards that are identified in these subcommittee's
22 report as they relate to Parts 35.50, 35.51, and
23 35.190, and 35.290, and 35.690.

24 And we would also point out that we would
25 also hope that they would be identified as they

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1 pertain to other relevant sections in the revised Part
2 35, and that would include Parts 35.390, 35.490, and
3 35.590.

4 In the development of the position of
5 support for the subcommittee's report, the American
6 Board of Radiology consulted three other certification
7 boards; the American Board of Health Physics, and the
8 American Board of Medical Physics, and the American
9 Board of Scientists in Nuclear Medicine.

10 All of these boards are represented here
11 today, and you will hear from all three; David
12 Steidley representing the ABMP, and Gary Sayed
13 representing the American Board of Scientists in
14 Nuclear Medicine, and Shawn Googins representing the
15 American Board of Health Physics.

16 I am pleased to tell you that these three
17 certification boards have joined with the ABR in
18 unqualified support of your statement. In arriving at
19 this position of unqualified endorsement of your
20 report, the ABR and the other boards examined the five
21 assumptions on page one of the subcommittee's report,
22 and we agree with these assumptions and acknowledge
23 that the boards specifically identified in your report
24 meet the criteria referenced in the second assumption
25 of your subcommittee's report on page one.

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1 Why did the American Board of Radiology
2 and its companion boards feel strongly that about
3 board certification as the default pathway? There are
4 several reasons and here are some of them.

5 And I will express these on behalf of the
6 American Board of Radiology, and the other committees
7 can make their own statements. As you have already
8 hear, the ABR has spent 80 years defining the criteria
9 for the safe and efficacious use of ionizing
10 radiation, including radiation from byproduct
11 materials in diagnostic and therapeutic medicine.

12 These criteria are infused into the
13 certification examination process and by extension
14 into the education and training programs for
15 diagnostic radiologists, nuclear radiologists,
16 radiation oncologists, and medical physicists.

17 Certification by the ABR is a direct
18 indicator that the individual is technically competent
19 to use ionizing radiation safely to diagnose and treat
20 disease, and in the case of medical physicists, to
21 provide medical physics and radiation protection
22 services in a safe and responsible manner.

23 The ABR and its companion boards recognize
24 the futility of attempting to equate competence with
25 hours of training and experience in any discipline,

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1 and an acknowledgement that is shared by virtually all
2 experts in higher education.

3 Consequently the ABR and its companion
4 boards do not wish to accommodate a specific
5 requirement of hours of training and experience,
6 because we think it is not relevant to the evaluation
7 of competence.

8 Further, the ABR and its companion boards
9 wish to assure the NRC that board certification is a
10 more acceptable criteria than hours of training and
11 experience in evaluating the competence of individuals
12 using radiation for the diagnostic and therapeutic
13 diagnosis and treatment of disease in humans.

14 Now, as I have listened to your
15 deliberations today, there are three issues that I
16 would like to comment on specifically. The first has
17 to do with the discussion of Part 35.50, training for
18 radiation safety officers, at which there was some
19 discussion about the desirability of removing from the
20 list of qualified certification boards, the American
21 Board of Radiology.

22 We believe that would be a mistake,
23 because if you remove the American Board of Radiology
24 as a default pathway to become a radiation safety
25 officer for individuals, especially for individuals

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1 training in medical physics, then the only way that a
2 medical physicist could serve as a radiation safety
3 officer is to meet the definition of authorized user,
4 which is confined to radiation oncology physicist.

5 But the American Board of Radiology
6 certifies not only radiation oncology physicist, but
7 it also certifies medical nuclear physicists, who are
8 extremely well qualified to serve as a radiation
9 protection or radiation safety officer in
10 institutions.

11 And it also certifies diagnostic
12 radiologic physics, who have a lot of training in
13 radiation protection and radiation safety, and for
14 small hospitals that don't have an extensive program
15 in radiation oncology, they might be the best choice
16 to serve as a radiation safety officer.

17 So we would ask that you reexamine that
18 discussion to be sure that you don't disenfranchise
19 individuals who could do a great service to the
20 community by removing the American Board of Radiology
21 as a default pathway for certification, leading to
22 recognition as a radiation protection officer.

23 My second point comes to the discussion
24 about letters of reference and whether those letters
25 of reference should address whether an individual has

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1 completed a training program, has satisfactorily
2 completed a training program, or has competently
3 completed a training program.

4 And we obviously have had great discussion
5 about this within the American Board of Radiology.
6 Our belief is, number one, that it is the
7 certification process that assures competence, and not
8 a letter of reference from an individual.

9 And therefore, we don't pay much attention
10 to letters that attest to competence. We want letters
11 that attest to what can quantitatively be evaluated by
12 an individual, namely the degree of training and
13 whether it has been completed or not.

14 We don't know what satisfactorily
15 completed means as compared to completed. If you want
16 to leave satisfactorily in there, I suspect that it
17 will be interpreted as completed.

18 Another issue is that if someone were to
19 write a letter that stated that an individual is not
20 competent, we would not pay much attention to that
21 letter, because once again it is the certification
22 process that evaluates competence and not letters.

23 And we do not want an individual to be
24 accepted or rejected into the certification process
25 based upon the opinion of one individual evaluating

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1 competence. And if we did and rejected the individual
2 on the basis of letters that declared that he was
3 competent, I suspect that we would be ending up in
4 court because we had disenfranchised a potential
5 applicant from practicing his profession.

6 So I think that letters of attestation or
7 letters of reference really have to only address those
8 things that can be evaluated by people in a
9 quantitative way.

10 There was a discussion on Part 35.290
11 related the certification and diagnostic radiology by
12 the American Board of Radiology by the American Board
13 of Radiology, meet the requirements of Section d-1 in
14 Part 35.290.

15 And I would like to say an unqualified
16 yes, as we have already stated in a letter dated June
17 26th, 2000 from Dr. Paul Capp, the executive director
18 of the ABR, to mr. Donald Cool of the NRC staff, and
19 in which we addressed specifically that specific
20 question.

21 I think that all of us here -- the Nuclear
22 Regulatory Commission, the American Board of
23 Radiology, the ACMUI, and its subcommittee, all the
24 companion boards to the ABR. We all share a common
25 objective.

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1 The common objective is using ionizing
2 radiation safely and effectively in the diagnostic and
3 therapeutic applications of human disease. And we
4 propose that the NRC and the professions work together
5 as we are now towards this objective to improve human
6 health, medical diagnosis, and therapy.

7 A good start, a very good start in this
8 direction by the NRC, would be the acceptance of the
9 statements of its own subcommittee of the advisory
10 committee on the medical use of isotopes related to
11 the training and experience requirements, and we would
12 like to thank this subcommittee for your hard work.

13 We think you have done a great service to
14 the people of this country, and what you have
15 accomplished through this statement, and we appreciate
16 it very much. Thank you.

17 CHAIRMAN VETTER: Thank you, Dr. HENDEE.
18 Anyone have questions for Dr. HENDEE or Dr. Capp?
19 Yes, Ruth.

20 MS. MCBURNEY: One of the MRC staff
21 persons brought up that if the certification process
22 requires a signature by an authorized user attesting
23 to the completion of the training and experience
24 requirements that that might pose a problem.

25 What sort of letters of reference are

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1 required for sitting for the diagnostic board?

2 DR. HENDEE: At the present time, we
3 require two letters of competence, and I can ask Dr.
4 Capp to address this as well. They are letters from
5 individuals who are certified by the American Board of
6 Radiology.

7 MS. MCBURNEY: And they would already be
8 authorized users or maybe be qualified as authorized
9 users, maybe if they are program directors, or
10 something like that.

11 DR. CAPP: If you are talking about, say
12 diagnostic radiologists.

13 MS. MCBURNEY: Diagnostic, right, the 290
14 physicians.

15 DR. CAPP: At the present time, as in most
16 ABMS boards, the program director is required to sign
17 off, and in our particular application, the program
18 director must state that an individual is
19 professionally qualified, is the term that we use.

20 Now, in the 193 diagnostic radiology
21 programs in this country, virtually all of them have
22 multiple individuals who could be qualified to be
23 authorized users. So I am sure that they have one,
24 two, or three in each institution.

25 MS. MCBURNEY: So the wording of that is

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1 not a problem.

2 DR. CAPP: It is not a problem, except on
3 the other hand most program directors in diagnostic
4 radiology are probably not authorized users, because
5 there are people in nuclear medicine, or a radiation
6 safety officer, a health physicist, et cetera, fulfill
7 those criteria.

8 And so what we would have to do would be
9 to put another line in there, and so the signatures
10 that would be required would be not only the program
11 director, but an authorized user if that is your
12 intent.

13 CHAIRMAN VETTER: But the program director
14 would be as equally qualified as the authorized user
15 to testify that the individual had completed the
16 training?

17 DR. CAPP: Yes.

18 MS. MCBURNEY: So we could add some
19 wording there.

20 DR. CAPP: Yes, program director, or
21 authorized user. Go ahead.

22 DR. DIAMOND: Well, I was just going to
23 state that if the program director must already make
24 an attestation for that candidate to be professionally
25 qualified to sit for the boards, then it is entirely

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1 moot to add another sentence.

2 For example, what we were going to do in
3 paragraph (a)(4), a preceptor statement or residency
4 program statement, which is entirely redundant and
5 moot as far as I can tell. My question for Dr. HENDEE
6 would be would you also recommend based upon the
7 grounds that you cited that a preceptor statement be
8 deleted from the alternate pathway?

9 You made an argument for deleting a
10 preceptor statement from the board certification
11 pathway, and would you recommend on the same
12 principles delineated from the alternate pathway?

13 DR. HENDEE: I wasn't making a statement
14 to delete the preceptor statement. I was making a
15 statement that says that the preceptor statement
16 should verify that the individual has completed the
17 required training, and we do require preceptor
18 statements as you have already heard for entrance into
19 the certification examination.

20 My comment was on asking that individual
21 to attest to the competence of the individual, and I
22 think that is not a wise thing to do.

23 DR. DIAMOND: All right. So, for example,
24 the language that is currently there, which is,
25 "satisfactorily completed," you just told us that that

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1 is meaningless to you, and --

2 DR. HENDEE: Completed is not meaningless,
3 but satisfactorily completed, and I don't know what
4 satisfactorily means in that context.

5 MS. MCBURNEY: I think that means that
6 they didn't fail.

7 DR. HENDEE: Well, if they failed, they
8 would not have completed it, right? I mean, you can
9 leave satisfactorily in there. I don't think it is a
10 big issue. Competently is the issue.

11 CHAIRMAN VETTER: Jeff.

12 DR. WILLIAMSON: Well, two comments. I
13 think in 35.290, we should be really careful not to
14 overly define the qualifications of the preceptor so
15 that we get the radiology boards in trouble. I think
16 it is nitpicking, and there is no reason to do that.

17 And I think that in the description of the
18 broad criteria for being an acceptable board, we have
19 to make it general enough that a residency program
20 director who is primarily a diagnostic radiologist,
21 and who had been overseeing the program, that that
22 person's statement can be accepted as a preceptor
23 statement.

24 The second comment, because I think that
25 Dr. Hendee is right, and we should go back and look at

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1 the RSO category, and do something to address the
2 possibility of these specialty physics certifications
3 being able to practice as RSOs, at least in limited
4 context, and I think he is absolutely right.

5 CHAIRMAN VETTER: I agree, and I wanted to
6 ask a question with regard to your radiological
7 physics exams, do you have two exams; one for
8 diagnostic, and one for oncology?

9 DR. HENDEE: We have three exams actually.
10 We have one for diagnostic radiologic physicists, and
11 we have another exam for medical nuclear physicists,
12 and we have another exam for radiation oncology
13 physicist.

14 There is a part one, which is common to
15 those, but then there is a Part II written exam, and
16 an oral exam, and they are separate exams all the way
17 through.

18 CHAIRMAN VETTER: So relative to 35.50, it
19 is those three subspecialities that we are talking
20 about?

21 DR. HENDEE: Yes. Right.

22 CHAIRMAN VETTER: Thank you.

23 DR. WILLIAMSON: And I think somehow we
24 need to distinguish between an RSO that has broad
25 authority to be an RSO for a broad scope licensee,

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1 versus an RSO who is limited to kind of single
2 modalities or some smaller collection of modalities.

3 MS. MCBURNEY: For example, for a
4 radiation oncology program that is separate from a
5 large hospital, a lot of times the medical physicist
6 is also the radiation safety officer.

7 CHAIRMAN VETTER: Good point. Okay.
8 Other questions for Dr. Hendee or Dr. Capp? Thank you
9 both very much. We appreciate you taking the time to
10 come here and address us. Thank you. Next is Dr.
11 David Steidley, representing the American Board of
12 Medical Physics.

13 DR. STEIDLEY: Good morning.

14 CHAIRMAN VETTER: Good morning.

15 DR. STEIDLEY: My name is David Steidley,
16 and for identification purposes only, I am the Chief
17 Physicist, as well as Radiation Safety Officer, at St.
18 Barnabus Medical Center, in Livingston, New Jersey.
19 I am a Diplomate of the American Board of Radiology,
20 of the American Board of Medical Physics, the American
21 Board of Health Physics.

22 I am a Fellow of the American College of
23 Radiology, and a Fellow of the American Association of
24 Physicists in Medicine. I am here today in my role as
25 a member of the Board of Directors of the American

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1 Board of Medical Physics, and I also serve there as
2 their panel chair for medical health physics.

3 The official position of the American
4 Board of Medical Physics is identical to the American
5 Board of Radiology as expressed minutes ago by Dr.
6 Hendee.

7 I would like to stress the painstaking
8 path that our board has laid out for its diplomates.
9 You must have an advanced degree. You must have
10 multiple years of experience. You have to have
11 letters of reference.

12 You have to pass a rather arduous written
13 exam, which is divided into two parts, and you have a
14 notoriously difficult two hour examination before a
15 panel of three experts.

16 Only then do you become qualified, and are
17 able to be a diplomate on the American Board of
18 Medical Physics. We have heard a number of hours of
19 training and education bandied about -- 200 hours, 500
20 hours, 700 hours.

21 A typical candidate here has a minimum of
22 16,000 hours of training and experience. So I think
23 those other numbers pale in comparison. So given all
24 this background, I think you have to conclude that we
25 need a default pathway that says you are boarded.

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1 And I am happy to see that this committee
2 is making progress in restoring that, and in
3 conclusion then, I think that we can say that we stand
4 totally in support of your subcommittee's draft of
5 614.02 on training and experience as amended today.
6 Thank you.

7 CHAIRMAN VETTER: Thank you, Dr. Steidley.
8 Any questions for Dr. Steidley? You said years of
9 experience. Could you be more specific about that?
10 A person needs an advanced degree, and so a minimum of
11 a Masters degree.

12 DR. STEIDLEY: That's correct.

13 CHAIRMAN VETTER: And so many years of
14 experience.

15 DR. STEIDLEY: Yes. It depends on the --
16 if you have a Ph.D., the experience is four years in
17 order to sit for Part III; and it then takes an
18 additional year for you to go into the oral
19 examination. So with a Ph.D., you would need a
20 minimum of five years.

21 Now, if you do a specific Ph.D. in medical
22 physics, and there only a handful of programs that
23 have that requirement, it is a total of four years.
24 But most of your work at that point, if you are in one
25 of those programs will be hospital related.

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1 Your research project will probably or
2 undoubtedly have something to do with medical physics.
3 So you are quite a bit more involved than a standard
4 candidate taking a Ph.D. in physics. We lightened
5 that up.

6 If you come from a medical physics program
7 that is accredited, and now you are talking just 2 or
8 3 in the country, then we would reduce it to a total
9 of 3 years. And with Masters degree candidates, you
10 have to add about 2 years to each of those numbers, in
11 terms of total experience.

12 CHAIRMAN VETTER: So with a Masters, a
13 minimum would be five years experience, plus a Masters
14 degree?

15 DR. STEIDLEY: Well, if you are in an
16 accredited medical physics program, you could get away
17 with as little as 4 years after you have got your
18 Masters degree. But if you are in an accredited
19 Masters physics program, those 2 or 3 years that you
20 have spent have been just 100 percent medical physics.

21 CHAIRMAN VETTER: And for the medical
22 health physics?

23 DR. STEIDLEY: The same

24 DR. WILLIAMSON: And for -- this is years
25 of experience before you can successfully apply to

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1 take the first level of the written exam?

2 DR. STEIDLEY: We have -- well, for the
3 part one exam --

4 DR. WILLIAMSON: Yes, the Part I test.

5 DR. STEIDLEY: -- you don't need to have
6 professional experience. It is a generalized test.
7 Then for Part II, you would have to wait another 4
8 years, but that is not a usual pathway.

9 CHAIRMAN VETTER: Other questions?

10 DR. WILLIAMSON: Well, one question. How
11 does this compare to the ABR?

12 DR. STEIDLEY: Excuse me?

13 DR. WILLIAMSON: How does the years of
14 experience for ABMP compare to the American Board of
15 Radiology for radiation oncology physics?

16 DR. STEIDLEY: I don't think I could speak
17 to an exact comparison.

18 CHAIRMAN VETTER: Are Dr. Hendee or Capps
19 still here that could answer that for us?

20 DR. HENDEE: Okay. I could answer that.
21 The question is what are the experience requirements
22 or the total requirements for certification in
23 radiology oncology physics by the American Board of
24 Radiology, and the answer is that you have to have
25 three years of experience.

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1 If you have a Masters degree, you can
2 count up to six months of that education towards the
3 three years, provided that it is real experience in
4 the clinic as part of your educational process.

5 If you have a Ph.D., and the Ph.D. and the
6 Masters have to be of course in relevant scientific
7 fields, then you can count up to 12 months towards the
8 3 year requirement, but again it has to be in clinical
9 relevant experience as part of your education and
10 training.

11 CHAIRMAN VETTER: Okay. Thank you. Any
12 other questions for Dr. Steidley? Thank you very much
13 for taking the time to come here and visit with us
14 here today. The next on the list is Dr. Richard
15 Fejka, representing the Board of BPS and APHA. That
16 is pharmacist.

17 DR. FEJKA: Good morning, and thank you
18 for the opportunity to appear in front of the board
19 and offer some comment. Specifically, I am here
20 representing the Board of Pharmaceutical Specialties,
21 and specifically their nuclear pharmacy specialty
22 council.

23 As well as a dual hat of representing the
24 American Pharmaceutical association. Specifically,
25 myself, I am a practicing nuclear pharmacist for the

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1 past 21 years, and I am board certified, and I am
2 currently serve as a member of the Nuclear Pharmacy
3 Specialty Council within BPS.

4 Although the subcommittee was not
5 specifically asked to deal with the training and
6 experience requirements for an authorized nuclear
7 pharmacist, in reviewing the proposed regs that were
8 submitted here for radiation safety officers,
9 authorized medical physicists, and training for
10 authorized users, we are encouraged to see that board
11 certification is listed, specifically listed, and that
12 it is an excellent move to list particular boards as
13 being or meeting the qualifications to become
14 authorized.

15 However, the aspect of putting a preceptor
16 statement into a board, we are not so sure that it
17 meets the requirements that we see as authorizing
18 someone to be a board certified nuclear pharmacist.

19 As Dr. Williamson stated, if you sit to
20 take an examination and don't pass, obviously you are
21 not going to become board certified. And in our
22 particular case for recognizing, and we are sitting to
23 become board certified in nuclear pharmacy, we require
24 a minimum of 4,000 hours of T&E, which far exceeds the
25 NRC's statement of 700 hours.

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1 So obviously one could become recognized
2 as an authorized nuclear pharmacist under the proposed
3 NRC regs if you just meet the 700 hours. But board
4 certification is also another area which could
5 represent that pharmacist who truly wants to go above
6 and beyond the minimum, and to state that you
7 understand the work that you do, and that you are a
8 recognized expert in your field.

9 As a nuclear pharmacist, and representing
10 APHA, the alternative pathroad that was proposed in
11 the April 24th regs of 700 hours is acceptable to us
12 for meeting the requirements of mathematics and
13 chemistry, and the manipulation of pharmaseuticals,
14 and to be able to safely operate a nuclear pharmacy.

15 And the preceptor statement there
16 certainly is appropriate, and as a nuclear pharmacist,
17 again, I believe that we wouldn't have any real
18 problem with accepting that.

19 As a possibility to recognize future
20 boards, although being in the field for this large
21 numbers of years that I have practiced, I understand
22 the importance that the NRC would want to be able to
23 have criteria to recognize future boards.

24 And maybe to do that, certainly be a
25 member of the Board of Pharmaceutical Specialties, we

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1 have as a minimum our 4,000 hours, and maybe that
2 might be an acceptable figure to use.

3 But as Ms. McBurney stated in her review
4 of the proposed draft regulations, a board that would
5 meet the NRC's minimal requirements of 700 hours in
6 the various areas of training might be a standard
7 whereby the NRC could use to judge future boards that
8 were to come down and be recognized.

9 That basically summarizes what I wanted to
10 state with regard to nuclear pharmacists, but since we
11 are not sort of, so to speak, dangling out there, we
12 are not exactly sure finally what the NRC is going to
13 state.

14 We have the April 24th regs, and we have
15 the regulatory guide, Chapter 9, which lists specific
16 things, but does not go into detail as to what was
17 proposed here that the subcommittee was specifically
18 asked to look at.

19 So again as a nuclear pharmacist, we
20 certainly would be encouraged or would like to see
21 what the final draft, the final rules, would come down
22 as it affects us. But if you use what this committee
23 did as an example of what we might be able to be
24 applied to, to specifically put back the Board of
25 Pharmaceutical Specialties for recognition without a

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1 preceptor statement, would be acceptable.

2 And the other alternative pathways to
3 being recognized as an authorized nuclear pharmacist
4 of the 700 hours would be acceptable to us also.

5 CHAIRMAN VETTER: Thank you very much, Dr.
6 Fejka. Questions?

7 MS. MCBURNEY: I think we mentioned
8 earlier that we would recommend that the NRC make
9 similar consistent ruling language throughout all this
10 T&E requirements.

11 DR. FEJKA: I did hear that, and I was
12 encouraged to hear that from a member. But once
13 again, with some speculation or apprehension until we
14 see the final rules, at least we are encouraged to see
15 that if we are treated similar to the other authorized
16 user areas, then we probably will be happy.

17 MS. MCBURNEY: Good.

18 CHAIRMAN VETTER: A couple of questions.

19 DR. FEJKA: Sure.

20 CHAIRMAN VETTER: Focusing on the
21 preceptor statement first of all. It is going to be
22 our recommendation that -- or at least the sense that
23 I have so far is that our recommendation is that we
24 not require boards to require candidates to provide a
25 preceptor statement that testifies to their

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1 competency.

2 But rather that they have completed a
3 training program, and could you tell me what you mean
4 by a preceptor statement?

5 DR. FEJKA: Well, that was again a thing
6 in the April 24th publication, and in Reg Guide 9, the
7 proposed Reg Guide 9. It was, I'm sure, exactly what
8 that meant to us. Now we have had further information
9 that delineates that the NRC basically was concerned
10 about an individual from the radiation safety
11 standpoint.

12 Now, the preceptor statement, and trying
13 to apply that with regard to our certification
14 examination, since to sit for it requires 4,000 hours,
15 two years of training in the area of nuclear pharmacy,
16 we would think that somebody who would become board
17 certified would eventually learn something concerning
18 radiation safety issues.

19 CHAIRMAN VETTER: I'm sorry, but I just
20 would like a very specific answer as to whether or not
21 you would object to a statement that required
22 candidates to provide the board with a letter that
23 said they had in fact completed the training, or do
24 you assure that in some other way?

25 DR. FEJKA: We assure that in some other

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1 way. If you sit for our exam and you don't pass it,
2 you don't become board certified. But the alternative
3 is that before you would even get to our examination,
4 that you would have the NRC's 700 hours of experience.

5 MS. MCBURNEY: But you don't require a
6 statement from the training institute?

7 DR. FEJKA: No, because the training that
8 a pharmacist would have, 4,000 hours, two years, could
9 occur over working at several different facilities.
10 And again not having much to go upon as to what or who
11 would certify, who would sign ultimately saying that
12 you worked and satisfactorily met the requirements --

13 MS. MCBURNEY: So they would just self-
14 attest to it?

15 DR. FEJKA: Self-attestment is another
16 thing, and maybe it could work, but if you don't pass
17 the tests --

18 CHAIRMAN VETTER: But you do have a
19 mechanism that demonstrates that the individual has
20 completed the training; is that correct?

21 MS. MCBURNEY: Just the exam.

22 DR. WILLIAMSON: Do you have some way to
23 verify that they completed the stated number of hours
24 of training?

25 DR. FEJKA: Okay. We ask them to attest

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1 to that either through providing evidence of taking
2 course work, of where they have worked in their
3 experience, and what facilities, and whether or not
4 they have gone on to take graduate level programs or
5 degrees.

6 So to that extent, we have that
7 requirement. The Board of Pharmaceutical Specialties
8 did submit that to the NRC and the NRC felt that we
9 met the requirement, providing the information with
10 regard that our board is a satisfactory board.

11 However, their comments did come back that
12 the preceptor statement was missing. And it is that
13 preceptor statement that we feel under the pathway
14 that would exist, 700 hours, comes before our
15 examination.

16 You could maybe go that way. However, if
17 you did choose to become board certified and not an
18 authorized nuclear pharmacist first, although I can't
19 understand someone would go down that pathway first,
20 that it might serve as a moot point.

21 CHAIRMAN VETTER: Okay. Other questions?
22 So your minimum requirements are basically two years
23 of training in nuclear pharmacy?

24 DR. FEJKA: To become board certified.

25 CHAIRMAN VETTER: To become board

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1 certified, right. Okay. If there are no other
2 questions, thank you very much, Dr. Fejka.

3 DR. FEJKA: Thank you.

4 CHAIRMAN VETTER: I appreciate you coming
5 here today to visit with us. And next on our list is
6 Gary Sayed, representing the American Board of Science
7 and Nuclear Medicine.

8 MR. SAYED: Good morning. For reference,
9 I am Gary Sayed, Professor of Diagnostic Imaging at
10 Thomas Jefferson University, in Philadelphia. I am
11 the past president of the American Board of Science
12 and Nuclear Medicine, and I am here to inform you that
13 the formal position of the American Board of Science
14 and Nuclear Medicine is identical to the position
15 expressed by Dr. Hendee on behalf of the American
16 Board of Radiology.

17 The ABSNM is a board established and
18 founded to certify scientists by the Society of
19 Nuclear Medicine, the American College of Nuclear
20 Physicians, and the American College of Nuclear
21 Medicine.

22 The board has been certifying scientists
23 in radiation protection, medical nuclear physics, and
24 nuclear pharmaceutical science, for the past 25 years.
25 In order to sit for the examination, the candidates

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1 with a Masters degree are required to provide letters
2 of evidence from two preceptors, one of whom must be
3 a certified nuclear medicine scientist; and the other
4 a board certified nuclear medicine physician for 5
5 years of training.

6 And for the Ph.D. candidates, we require
7 3 years of experience. In closing, I would like to
8 thank you for this opportunity to participate in this
9 process.

10 CHAIRMAN VETTER: Thank you very much.
11 Questions? Yes, Jeff?

12 DR. WILLIAMSON: For what category in Part
13 35 would your certification be applicable; to just
14 radiation safety officer?

15 MR. SAYED: Specifically for 35.50, yes.

16 DR. WILLIAMSON: And probably for nuclear
17 medicine applications, and not broad scope licensees?
18 Or would you claim that one of your diplomates could
19 be an RSO for a broad scope licensing?

20 MR. SAYED: Yes. Under Part 35.50, as
21 RSOs for broad scope licenses, particularly our
22 diplomates who are certified in the radiation
23 protection specialty.

24 CHAIRMAN VETTER: And does your board
25 assure or does your board examine in any safety

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1 aspects of radiation therapy?

2 MR. SAYED: Yes. The radiation protection
3 exam covers all aspects of radiation safety practice
4 in nuclear medicine, particularly with respect to
5 safety practice in nuclear medicine, particularly with
6 respect to unsealed sources involving therapeutic
7 applications.

8 DR. WILLIAMSON: But not brachy therapy?

9 MR. SAYED: No, we don't cover that.

10 DR. WILLIAMSON: Or Cobalt 60 teletherapy?

11 MR. SAYED: No.

12 MS. MCBURNEY: And then under that, they
13 would need to go into items under 35.50 about the
14 other --

15 CHAIRMAN VETTER: We do have a mechanism
16 to cover that. They would have to have modality
17 specific training in those areas over and above their
18 board exam?

19 MR. SAYED: That's right.

20 CHAIRMAN VETTER: Now, could you review
21 again what the minimum requirements are? Three years
22 experience, plus a Ph.D.?

23 MR. SAYED: For candidates who have or
24 whose terminal degree is a Masters degree, we require
25 five years of experience.

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1 CHAIRMAN VETTER: Okay. And do you allow
2 anyone with a Bachelors degree to sit for your exam?

3 MR. SAYED: The minimum academic
4 requirement is a Masters degree.

5 CHAIRMAN VETTER: Okay. Thank you. Any
6 other questions for Dr. Sayed? If not, thank you very
7 much for coming and visiting with us today. And next
8 on our list is Bill Uffelman from the Society of
9 Nuclear Medicine, the American Board of Nuclear
10 Medicine.

11 MR. UFFELMAN: I am Bill Uffelman, and I
12 am General Counsel and Director of Public Affairs of
13 the Society of Nuclear Medicine and I guess by default
14 I am appearing for the American Board of Nuclear
15 Medicine as they did not send anybody today.

16 As an attorney, my comment on all of this
17 is that words do matter. Particularly, I have concern
18 over the presumption that a program director's
19 signature does satisfy the preceptor requirement.

20 I would want to see language that
21 specifically says that. The grandfathering in 35.57
22 -- my concern is that the preexisting board
23 certifications, because those conceivably a board for
24 whatever reason may not choose to meet the new
25 requirements, but somebody who is currently working

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1 under the old board certification, that they in fact
2 somehow don't lose their status.

3 I mean, the irony is that they were good
4 enough in the old rule, but not perhaps they are not
5 good enough. And at the same time, there is a seven
6 year recentness of training requirements. Somebody in
7 fact may have been an RSO, and may have been gone into
8 academia, and that they are not an RSO.

9 But they are teaching the course that is
10 training the people to be the new people, and I guess
11 perhaps obtaining continuing education in the whole
12 process, or a lifetime of education.

13 But in fact that they could return to that
14 status, because the way that the language is currently
15 written, it says that you have to be an RSO today, and
16 you have to be a teletherapy or medical physicist.

17 You have to be a nuclear pharmacist today
18 on somebody's license, when in fact whatever path you
19 follow you may have moved off of the license at this
20 moment in time.

21 Then I guess my last comment may be very
22 specific and probably could be asked away from this,
23 but I will ask it on the record. John, the timing on
24 some of this, the ABSNM and ABMN were both given until
25 Monday to respond to the letters that you sent them.

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1 I got back from L.A. last night from our
2 annual meeting of the Society of Nuclear Medicine, and
3 I know that our office is closed today and that there
4 is nobody there cranking out a letter for Monday.

5 You did get an e-mail or an e-mail was
6 sent from ABNM, which I believe as I read it, at least
7 responds to the two specific questions that you asked,
8 and Gary of course has gone on the record on behalf of
9 ABSNM, and I would ask that until we can get actual
10 signed letters in with those documents be considered,
11 and those statements be considered sufficient to
12 respond to your questions.

13 MR. HICKEY: Yes, that's fine, and I
14 wanted to clarify that anybody who wants to submit
15 comments for consideration by the subcommittee or the
16 full committee has until June 28th to submit those
17 comments.

18 MR. UFFELMAN: As far as my letter to you,
19 you can respond at any time.

20 MR. HICKEY: Okay. Thank you very much.

21 CHAIRMAN VETTER: Thank you very much, Mr.
22 Uffelman. Questions?

23 MR. UFFELMAN: Yes, Ma'am?

24 MS. MCBURNEY: Just a comment on this
25 recentness of training, and that has been one of the

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1 issues that we have been grappling with, and I don't
2 know if they are addressed in the new NRC rules.
3 John, do you know?

4 MR. UFFELMAN: John, 35.159.

5 MR. HICKEY: It is there.

6 MS. MCBURNEY: Okay.

7 MR. UFFELMAN: It has been seven years.

8 MR. HICKEY: It is there.

9 MS. MCBURNEY: Because we do have some
10 people returning to different aspects of user status,
11 or RSO status that have been out of it for a while.

12 DR. WILLIAMSON: Well, it says seven
13 years, or the individual must have had related and
14 continuing education and experience since the required
15 training and experience was required.

16 CHAIRMAN VETTER: Well, that is not in our
17 charge, but we will certainly pass that comment on,
18 right.

19 MR. UFFELMAN: I think it is, and it is
20 obviously related, and you are worried about the new
21 people coming in and I am worried about the people who
22 are already here.

23 CHAIRMAN VETTER: Absolutely. Right. Any
24 other questions for Mr. Uffelman? If not, thank you
25 very much. We appreciate you coming over to visit

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1 with us. Next on our list is Paul Chase from the
2 American Osteopathic Board of Radiology.

3 MR. CHASE: Dr. Vetter and members of the
4 committee, I am happy to be here to make some
5 comments. I am Paul Chase, and I am Chairman of
6 Radiology at the South Jersey Hospital System. I am
7 the radiation safety officer for the system, and I am
8 not on the Board of Osteopathic Radiology, but I am
9 here representing the American Osteopathic Board of
10 Radiology, and the American Osteopathic Board of
11 Nuclear Medicine.

12 I am on the Board of Nuclear Medicine. I
13 am the past president of the College of Radiology, and
14 I am certified by the American Osteopathic Board of
15 Radiology, by the American Osteopathic Board of
16 Nuclear Medicine, and by the American Board of Nuclear
17 Medicine.

18 The American Osteopathic Boards have a
19 long history of working together with the NRC. We go
20 back to 1982, when our diagnostic boards were actually
21 the first boards recognized by the NRC in Categories
22 1 and 2.

23 And radiation oncology in categories five
24 -- or in Groups 5 and 6 at that time. Over the years
25 our basic standards for training have been modified,

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1 always trying to keep up with the requirements of the
2 NRC.

3 For example, at that time in 1982, I
4 believe that they changed the requirements from 3
5 months to 6 six months of training, and we increased
6 our training to six months at that time.

7 In the osteopathic profession, the
8 American Osteopathic Association is the certifying
9 board. The training requirements are established by
10 the College of Radiology. Certification, however, and
11 examination is by the boards. In the college we have
12 a committee called the EESC, Education, Evaluation and
13 Standards Committee.

14 And that committee sets the training
15 requirements, and submits those to the committee, and
16 to that Board of the College, and they then go to the
17 Committee on Post-Graduate Training of the AOA, and
18 eventually to the Board of Osteopathic Specialists.

19 But the power to certify comes from the
20 American Osteopathic Association. Neither the Boards
21 nor the College are autonomous. In a letter just a
22 day or so ago, we are asking for -- and I won't go
23 through the whole letter, but again we have been
24 certifying since 1940 in radiology, but the names of
25 the boards have changed over those years.

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1 And we are included in most of the
2 sections in the NRC requirements for authorized users,
3 but we need to have some updating in Category 35.930
4 and 35.940, and 35.950, and 35.960. And I think --
5 and I am not going to go through that, as the letter
6 is on file, but most of it has to do with housekeeping
7 and bringing things up to date.

8 I would like to support all the comments
9 that were made by Dr. Hendee and by Dr. Capp, and also
10 say that the American Osteopathic Board of Radiology
11 has been working with the ABR to keep our standards
12 and requirements for examination at that level.

13 Now, as regards to the radiation oncology
14 question, I don't think there are any programs, Dr.
15 Diamond, in radiation oncology at this time, but I
16 would say that it is very important to keep the board
17 qualification in there in order to protect those
18 people that are already certified.

19 The basic standards are available, and I
20 would be happy to provide those to you for diagnostic
21 radiology and radiation oncology, and even if there
22 are no programs, they are constantly being updated,
23 and they were updated in '99, and 2000, and 2001, and
24 they are available for review at any time.

25 Pam Smith is our executive director, and

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1 she would be happy to work with anybody in the NRC
2 program. Thank you.

3 CHAIRMAN VETTER: Thank you, Dr. Chase.
4 Any questions? Jeff.

5 DR. WILLIAMSON: I think in the proposed
6 draft rule language for authorized user of 35.600
7 modality, specifies that the boards have to require of
8 the candidates who sit for the examination a three
9 year residency that is approved by the radiation
10 oncology residency review committee of the ACGME. Do
11 you meet the language of that standard for your
12 radiation oncology?

13 I was looking at that
14 and I think further down doesn't it mention the
15 osteopathic boards?

16 MR. CHASE: The osteopathic boards are
17 listed I think in Part A, aren't they, as one of the
18 explicitly recognized boards and then Part B, or
19 whatever, as I can't remember the numbers, lists the
20 broad criteria that all the boards, both current and
21 future, have to meet.

22 And the major requirement that is in there
23 is the three year residency requirement. So my
24 question to you is --

25 DR. WILLIAMSON: Yes, we do, because it is

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1 a four year program.

2 DR. DIAMOND: ACGME.

3 DR. WILLIAMSON: ACGME.

4 MR. CHASE: No, it would not be recognized
5 by the ACGME because like I said initially the power
6 to board certify in our situation comes from the
7 American Osteopathic Association.

8 CHAIRMAN VETTER: It is a different
9 pathway.

10 MR. CHASE: It is a different pathway.

11 DR. WILLIAMSON: Okay. So if we want to
12 fully recognized the osteopathic credential in
13 radiation oncology, we might have to modify that
14 paragraph. That is my point.

15 MS. MCBURNEY: There is the -- what was
16 it, the C-O-P-T?

17 MR. CHASE: Yes, the Committee on Post-
18 Graduate Training.

19 MS. MCBURNEY: Right. The osteopathic
20 equivalent.

21 DR. DIAMOND: What was that again?

22 MR. CHASE: The Committee on Post-Graduate
23 Training.

24 MS. MCBURNEY: C-O-P-T-A-O-A.

25 DR. DIAMOND: The Committee on Post-

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1 Graduate Training?

2 MS. MCBURNEY: Or the Council on -- the
3 Committee or Council on Post-Doctoral Training at the
4 American Osteopathic Association. We have that in our
5 Texas rules.

6 MR. CHASE: I am glad you mentioned that.
7 If I can make one more comment. It is very important
8 for us to have recognition at the Federal level
9 because in those States that are not agreement States,
10 they will look to the Federal Register for how they
11 are going to act.

12 We had that problem in Rhode Island, where
13 there was no recognition at all, and there were only
14 two osteopathic radiologists in that State, they would
15 not have been able to practice nuclear medicine.

16 CHAIRMAN VETTER: Okay. Other questions
17 for Dr. Chase? If not, thank you very much for coming
18 to visit with us today. And our last registered
19 speaker is John Googins, representing the American
20 Board of Health Physics.

21 MR. GOOGINS: Good morning. I am Shawn
22 Coogins, a member of the Board of American Health
23 Physics, and I will keep my comments brief. For the
24 record, I would like to note that at the June 14th and
25 June 15th, 2002 meeting of the American Board of

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1 Health Physics, we unanimously endorsed the ACMUI
2 Subcommittee draft recommendations on training and
3 experience requirements.

4 I would strongly urge the NRC to accept
5 the recommendations of this subcommittee. As far as
6 some brief requirements for certification at the
7 American Board of Health Physics, requires for someone
8 to be able to sit for the exam, a minimum of a
9 Bachelors degree and six years of experience, which
10 not strangely enough on the Part B requirements may be
11 substituted no more than two years of experience for
12 an advanced degree in health physics.

13 As far as the statement regarding written
14 certification from a supervising physicist or RSO, the
15 board certification requirements do have requirements
16 for recommendations and signatures, and evaluation of
17 the training and experience requirements for the
18 individual to be able to just sit for the
19 certification exam.

20 CHAIRMAN VETTER: Thank you very much.
21 Questions for Mr. Googins? Jeff.

22 DR. WILLIAMSON: Does the examination
23 cover modality specific issues of radiation oncology,
24 nuclear medicine, and so on? Is there any content
25 that the candidates are expected to master?

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1 MR. GOOGINS: Yes, the examination covers
2 a number of what we call domains of practice, which
3 cover anything from oncology, nuclear medicine,
4 general biomedical research, that the individual is
5 expected to know and be able to sit to pass the
6 examination.

7 One thing for the record to note is that
8 when an individual practices in a particular area the
9 code of ethics that the American Board of Health
10 Physics requires everyone to sign requires them to not
11 practice in an area which they are not competent to
12 practice in.

13 DR. WILLIAMSON: Do you have an opinion
14 about how we should phrase the requirement for
15 modality specific training and education? Do you like
16 the one that we have?

17 MR. GOOGINS: Personally, I think that as
18 far as modality specific, that is really covered
19 within the inherent ethics statement that we sign for
20 people to be able to practice and supervise a specific
21 modality. So I don't have a particular problem with
22 the statement as it is written.

23 MS. MCBURNEY: I think as you mentioned
24 that the Code of Ethics and the requirements, and for
25 the modality specific training, would involve the

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1 radiation safety regulatory issues, and emergency
2 procedures, and clinical -- some sort of knowledge of
3 the clinical procedures of any modality they would not
4 have had previously.

5 MR. GOOGINS: Correct.

6 CHAIRMAN VETTER: So your code of ethics
7 basically would require someone who is certified by
8 your board, if they are working at a medical center,
9 and you get gammaknife, they requires that they get
10 the training in order to properly serve as Radiation
11 Safety Officers for that modality.

12 MR. GOOGINS: That is correct.

13 CHAIRMAN VETTER: Okay. Other questions
14 for Mr. Googins? I thank you very much, and I
15 appreciate you taking your time to come visit with us.

16 MR. GOOGINS: Thank you very much. That
17 comes to the end of our list, and just let me make
18 sure that I have not missed anyone. Is there anyone
19 who had signed up with the NRC to speak today and who
20 I have missed?

21 (No audible response.)

22 CHAIRMAN VETTER: If not, I would like to
23 take this opportunity to thank all of you. We know
24 that you all have very busy schedules, and we know
25 that this topic is important to you, but it is very

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1 important to us, and we absolutely needed your input,
2 and we very sincerely appreciate you taking the time
3 to come here to visit with us here today.

4 The next -- let's get back to our agenda
5 and see where we are here. The next item, I believe,
6 is the additional discussion. The summary of meeting
7 -- I'm sorry, additional discussion. So we have
8 according to the schedule about 45 minutes to further
9 discuss.

10 And with the input that we received from
11 the members of the professional community, are there
12 issues that the subcommittee would like to discuss and
13 air out a little bit more?

14 MS. MCBURNEY: I think we can go back and
15 revisit the types of certification that would be
16 accepted for the radiation safety officer, or rather
17 the types of board certification.

18 I think that we had eliminated all except
19 those that were in health physics, but after hearing
20 the comments, I think the ABR physics certifications
21 probably would be --

22 CHAIRMAN VETTER: And ABSNM as well.

23 MS. MCBURNEY: ABSNM, yes. Right.

24 CHAIRMAN VETTER: So basically what we are
25 looking for on our list are boards who specifically

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1 examine in medical or health physics, to list them
2 there, and if --

3 MS. MCBURNEY: And partly aimed at
4 authorized user status.

5 CHAIRMAN VETTER: And basically that's it,
6 and remove those that are aimed specifically at
7 authorized user status and nuclear pharmacy, because
8 that would -- there is an alternate pathway for them.

9 DR. CERQUEIRA: Richard, let me just ask
10 a sort of procedural question from John in terms of
11 the issue of whether to list the boards or what we had
12 decided in the past was to let the NRC have a listing
13 of boards that would not be specifically detailed in
14 the Federal regulations.

15 So if we have a published rule in the
16 Federal Register which lists boards, and then if we
17 want to add another board, do we then have to go back
18 to this whole revision process to the Federal
19 Registrar, or how would that be handled?

20 MR. HICKEY: Well, the way the old rule is
21 that you would have to go through the full rule making
22 process to add a board. But there is a way to write
23 the rule that it will list -- the rule could say these
24 are the currently listed boards, and they are
25 acceptable boards, and they are acceptable, plus any

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1 other board that is subsequently recognized.

2 So that could be handled administratively
3 without having to go through the rule making process.

4 DR. WILLIAMSON: That would address many
5 of the concerns of the community if we could do it
6 like that, so that when the package is submitted it is
7 very clear who qualifies and who doesn't.

8 CHAIRMAN VETTER: Okay. So for 35.50,
9 paragraph (a), we are going to recommend that the
10 boards that are currently considered to be listed, of
11 course we have to confirm that in fact they do meet
12 paragraph (b).

13 But those that we would recommend be
14 considered for the original list would be those that
15 examine in health physics and medical physics. And
16 nuclear medical physics as well; the American Board of
17 Science and Nuclear Medicine.

18 DR. WILLIAMSON: Well, I think it is more
19 complicated than this. It seems to me that there is
20 an ambiguity in this regulation, and actually the two
21 preceding regulations, too.

22 My impression seems to be that (a), and
23 (b), and (c), really define the minimum criteria for
24 who can be the RSO in the most complex of
25 institutions.

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1 And that the broad scope licensees that
2 have the full range of modalities, and it sounds like
3 to me that some of these certifications are very
4 focused on certain modalities, such as -- and it
5 sounded to me like the American Board of Science and
6 Nuclear Medicine, Dr. Sayed had stated that they did
7 not examine for knowledge --

8 MS. MCBURNEY: On sealed sources.

9 DR. WILLIAMSON: On sealed sources, or in
10 radiation oncology, and I am not sure compared to the
11 American Board of Health Physics that that
12 certification is appropriate without qualification.

13 Maybe one could make the same arguments
14 for the American Board of Radiology certifications in
15 Nuclear Medicine Physics, and in Diagnostic X-Ray
16 Imaging, that those should be limited to those uses,
17 which are not in the content of the examination.

18 So I am not sure exactly how to do it, but
19 it seems to me that we need to create a category of
20 RSO that is focused on more limited range of byproduct
21 medical services.

22 CHAIRMAN VETTER: Well, I think it would
23 be my position that the purpose of listing the boards
24 is to list those that examine candidates to determine
25 that they are competent to practice medical health

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1 physics without knowing all modalities.

2 MS. MCBURNEY: Right.

3 CHAIRMAN VETTER: And Paragraph (e)
4 captures that.

5 MS. MCBURNEY: Right.

6 CHAIRMAN VETTER: Also, the purpose is not
7 to distinguish between a small medical licensee and a
8 broad scope, and that is what guidance is for. So
9 this would just satisfy that if you want to be an RSO,
10 there are several ways that you can do it.

11 One of the ways is to be certified by this
12 board and have modality specific training, if that is
13 required.

14 MS. MCBURNEY: Because basically in
15 radiation safety what you are really wanting is what
16 do you want the certification to cover, and basic
17 radiation protection and instrumentation, and
18 mathematics, and radioactivity, and radiation biology,
19 and shielding, and those sorts of things, without
20 getting into a lot of the medical physics, the
21 treatment planning, and those sorts of things, because
22 those are not included in radiation safety.

23 DR. WILLIAMSON: Okay. So then maybe what
24 all needs to be done is to remove American Board of
25 Radiology and replace it by a more detailed list of

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1 physics boards.

2 CHAIRMAN VETTER: Right.

3 DR. WILLIAMSON: And ABR certification and
4 therapeutic radiological physics, and in nuclear
5 medicine, and the diagnostic x-ray, et cetera.

6 MS. MCBURNEY: Right.

7 DR. WILLIAMSON: And take away the
8 physician authorized user boards from this list
9 altogether.

10 CHAIRMAN VETTER: Right.

11 DR. CERQUEIRA: But we did accept the fact
12 that authorized physician users would be eligible to
13 be RSOs.

14 MS. MCBURNEY: Right, and that is under
15 (d).

16 DR. CERQUEIRA: Okay.

17 DR. WILLIAMSON: Okay. So that seems like
18 a reasonable argument. Then the Part B or paragraph
19 (b) requirements have to be looked at very carefully.

20 MS. MCBURNEY: Yes, in conjunction with
21 those.

22 DR. WILLIAMSON: And not so specifically
23 focused on American Board of Health Physics that the
24 other ones failed to quality.

25 CHAIRMAN VETTER: Right. We need to look

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1 at the years of experience, and that is the main one,
2 I think. And then under (c) we are going to add what
3 we have been calling a preceptor statement, a
4 statement that would ask that the candidate provide
5 evidence that they have in fact completed some
6 training.

7 DR. CERQUEIRA: And so we have agreed that
8 we are going to just have completed training rather
9 than satisfactorily completed, or competently
10 completed?

11 DR. DIAMOND: Or professionally qualified.

12 MS. MCBURNEY: Well, I think you can
13 define this as satisfactorily completed.

14 DR. CERQUEIRA: But Dr. Hendee said or
15 made the point that that would be very difficult to
16 do.

17 CHAIRMAN VETTER: What does that mean?
18 They completed it certainly for the boards, and he was
19 referring to I think on behalf of the boards.

20 DR. CERQUEIRA: And he didn't answer the
21 question for the alternative pathways.

22 CHAIRMAN VETTER: Well, for the
23 alternatives, that is up to us, and that is different.

24 DR. WILLIAMSON: I think there is more
25 flexibility, and I think it is reasonable that all of

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1 the speakers have indicated that board certification
2 subjects the candidates to certain rigorous standards,
3 and for someone who has not gone through that process
4 to have a slightly stronger teeth in the preceptor
5 statement doesn't seem unreasonable to me.

6 DR. DIAMOND: Right.

7 DR. WILLIAMSON: But it does seem to me
8 that we want to craft a preceptor statement fairly
9 carefully so that based on the legal technicalities
10 that we don't exclude boards unnecessarily for no good
11 public health reasons.

12 DR. DIAMOND: I have a couple of questions
13 or comments. Firstly, fairly shortly there will be a
14 process beginning whereby the currently enumerated
15 boards will be reviewed by the NRC to ensure that they
16 meet the current standards.

17 How is the NRC going to respond to a board
18 that doesn't have a residency training program? Does
19 that mean anything to you? For example, when the AOB
20 submits to you its requirements in its training
21 program, will it be of any concern to you that they
22 don't have a residency training program, or is that
23 really a non-issue to you?

24 MR. HICKEY: Well, if the criteria don't
25 state that that is a requirement, then that will not

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1 be a concern, in the sense that as part of our process
2 of listening to the ACGME and making the final
3 decision we will have decided that that is not a
4 criteria to make the decision.

5 DR. DIAMOND: Okay.

6 MR. HICKEY: Now, there may be individual
7 people inside and outside the NRC that might be
8 concerned about it, but it would not be the basis for
9 the decision.

10 DR. DIAMOND: All right. My second
11 question is with the language that we are adopting as
12 an example, if you go and take a look at Section
13 35.390, unsealed byproduct material for which
14 (inaudible) is required go down to paragraph (b) (2)?

15 As an example, with parallel language,
16 this is parental administration of -- this is actually
17 for iodine 131. Currently, it writes that the
18 individual has satisfactorily completed the
19 requirements of the above paragraph, and has achieved
20 a level of competency sufficient to function
21 independently as an authorized user.

22 My sense is that phraseology of level of
23 competency can be deleted, and completely struck out.
24 Fine. Number 3, just since we are all together, I
25 think what we will do is for 35.690, based upon what

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1 we talked about, I think the best place to put this
2 preceptor/residency program statement, is actually not
3 in (a) (4), but put that directly under (a) (1), just as
4 a writing issue, a preceptor for residency program,
5 director statement, that the above requirements have
6 satisfactorily been met.

7 It makes no sense to put it as a paragraph
8 (a) (4) if that person has no bearing on whether a
9 certification has been recognized by the Commission
10 and so forth.

11 MS. MCBURNEY: Right. And those being
12 part of those requirements.

13 DR. DIAMOND: Right. And lastly if based
14 upon what John just mentioned about AOB, and it
15 really not being an issue to him, and that they don't
16 have a current radiation oncology training program.

17 And probably the best place to include the
18 Council on Post-Graduate Training of the American
19 Osteopathic Organization would be on paragraph (a) (1),
20 and this included residency review committee of the
21 ACGME, or -- and that is probably the best place to do
22 it.

23 CHAIRMAN VETTER: Excellent point.

24 DR. DIAMOND: I am just trying to save us
25 some e-mails.

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1 CHAIRMAN VETTER: Right.

2 MS. MCBURNEY: We had heard comments that
3 the person signing off on the training experience for
4 board certification might not be an authorized user,
5 but they might be the program director for a residency
6 program.

7 So I was thinking that we may need to add
8 language in 190 and 290 that to allow for that in Item
9 (d) (2). Right now we have, "has obtained written
10 certification signed by a preceptor or authorized user
11 that meets the requirements."

12 CHAIRMAN VETTER: We could say preceptor,
13 or. Is there something better than program director?
14 Residency director

15 DR. WILLIAMSON: Training program
16 director?

17 MS. MCBURNEY: Well, a training program
18 director could be --

19 DR. WILLIAMSON: Well, let me ask a
20 question. Is this for the criteria for accepting a
21 board as a credentialing process or the alternative
22 pathways?

23 MS. MCBURNEY: Both, because now that we
24 are saying includes all the requirements of paragraph
25 (d), unless we break that out.

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1 DR. WILLIAMSON: And probably authorized
2 user, or residency program director, would be
3 reasonable and would cover both cases. Now, I am
4 wondering --

5 MS. MCBURNEY: Now, will those program
6 directors meet the requirements of 35.190, 290, or
7 390, or should we put that after --

8 CHAIRMAN VETTER: We are not asking that
9 they do.

10 MS. MCBURNEY: Okay. So that would come
11 after the 190, 290, 390.

12 CHAIRMAN VETTER: That's a good point

13 MS. MCBURNEY: Or equivalent.

14 MR. HICKEY: Could I just clarify? Is
15 that -- is the term, residency program director, that
16 is a recognized term that everyone will understand
17 what that means?

18 DR. DIAMOND: Yes. So, Dick, what is our
19 next step?

20 CHAIRMAN VETTER: The next step is that we
21 have a conference call coming up and I would assume
22 that before that time that we should each go back and
23 craft a revised verbiage for each of the sections that
24 we have discussed, and resubmit them to you.

25 DR. DIAMOND: Would that be helpful?

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1 CHAIRMAN VETTER: Right. Our next step
2 was to -- that when we are finished with our
3 discussion here, go have lunch, and then come back and
4 meet unofficially to talk about the mechanics of that,
5 and how exactly we would take care of all of that.

6 MS. MCBURNEY: And some time-lines.

7 CHAIRMAN VETTER: And remind ourselves,
8 and have the NRC staff remind us what the deadlines
9 are and when we have to have things done, because we
10 are going to need to have to write a report to Dr.
11 Cerqueira and the ACMUI with what our recommendations
12 are. And then we will be done.

13 And then they will meet by conference call
14 on July 8th, or we will.

15 DR. DIAMOND: And then is the next step
16 after that to start working on guidelines for these
17 details of board recognition. In other words, we were
18 having a discussion before about having to have
19 language for allowing boards to have evolutionary
20 changes.

21 I think Dr. Van Decker was alluding to
22 that. Do we need to do any work along those lines?

23 CHAIRMAN VETTER: Our subcommittee does
24 not.

25 DR. DIAMOND: Okay.

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1 CHAIRMAN VETTER: Our charge is --

2 MS. MCBURNEY: This is it.

3 CHAIRMAN VETTER: So ACMUI will have to
4 determine whether or not we want to do more in that
5 regard. Any further discussion at this point? Yes,
6 Jeff.

7 DR. WILLIAMSON: Is this an appropriate
8 time to raise the issue of 35.300?

9 CHAIRMAN VETTER: Sure.

10 DR. WILLIAMSON: Okay.

11 CHAIRMAN VETTER: In terms of consistency?

12 DR. WILLIAMSON: Yes. Well, I think that
13 some decision has to be made about the role of the
14 radiation oncologist as an authorized user for radio-
15 pharmaceuticals.

16 So I think we should think about that, and
17 consider making a recommendation to the ACMUI and to
18 the NRC about that. In the past, the old regulation
19 included ABR certification and radiation oncology as
20 one of the default credentials.

21 In the new regulation, the one that was
22 just published in April. None of the boards were
23 listed, and a far more focused set of requirements
24 were put in that had the 700 hours of training and so
25 on, and for the full unqualified right to practice

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1 radiopharmaceutical therapy.

2 You know, 12 cases, a case experience of
3 12 cases distributed in four different categories is
4 required, and then of course there were the single
5 indication, more focused authorized users.

6 And I think we should give some
7 consideration when we make the list of boards for
8 35.300 that we consider including certification in
9 radiation oncology because there are a number of
10 radiation oncologists that are very involved in the
11 development of radio-immunotherapy.

12 And depending upon how nuclear medicine
13 service is structured in various institutions, such as
14 ours, for example, the radiation oncologist actually
15 do administer all of the radionuclide therapy for
16 malignant indications, and nuclear medicine does it
17 for benign indications.

18 So one option is to think about the
19 pattern that we have developed, which is board
20 certification meeting these criteria, or alternative
21 pathway, and modality specific experience.

22 So what we might do is craft the list of
23 boards to include radiation oncology and have the 700
24 hours and so on that make it general. And then put as
25 the "and" the 12 cases.

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1 DR. DIAMOND: Would you enumerate the
2 boards in this case again?

3 DR. WILLIAMSON: Yes, if we are going to
4 do it with the others, we have to do it for this. So
5 I think we need to make a decision about whether to
6 recommend radiation oncology as was done in the past.

7 DR. DIAMOND: I think we need to do that,
8 because as we change 690, some of those changes by the
9 letter of the law may not allow you to do some of the
10 things in 35.390. So we will have to make that
11 change.

12 MS. MCBURNEY: Does radiation oncology and
13 board certification include radiopharmaceutical
14 therapy?

15 DR. DIAMOND: You are examined in that,
16 and it depends on your residency training program how
17 much experience you have. Where I trained, for
18 example, we do all the therapeutic radionuclide
19 administration.

20 So , for example, in my particular
21 training program, I had extensive experience in the
22 use of iodine for thyroid cancer, and some of the
23 newer agents such as Zevalin and Bexxar for the use of
24 refractory recurring non-Hodgkins lymphoma.

25 And in other training programs, you may be

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1 not exposed to that. You will certainly be examined
2 on it, but you won't have hands-on experience. Again,
3 one of the other reasons that it is so important to
4 have this modality specific training, we don't want a
5 physician who may have passed a board on what these
6 agents represent, and how they are used, has never
7 seen it or handled it before, and all of a sudden is
8 starting to use it, unless they have had some
9 experience and some oversight in their use.

10 MS. MCBURNEY: Now, we are facing it in
11 Texas with the introduction of some of these newer
12 therapeutic drugs, such as the zevalin and the bexxar.

13 DR. DIAMOND: And the other thing is that
14 I really don't think it is a turf issue at all,
15 because again we are not in the business of saying who
16 can and can't do it at a particular institution. That
17 is the physicians of institutions themselves that have
18 to work it out. This is simply a matter of being
19 authorized.

20 DR. WILLIAMSON: So you would support then
21 having as the modality specific "and" clause, the
22 distribution of the 12 cases as is given in the
23 current regulations on top of all of the
24 certifications?

25 DR. DIAMOND: Yeah, I think so.

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1 DR. WILLIAMSON: So we have a broad
2 agreement and we could write that paragraph in that
3 way.

4 MS. MCBURNEY: Okay.

5 CHAIRMAN VETTER: Yes. Other comments?
6 If we don't have any other comments, I am going to
7 suggest that John Hickey be given the opportunity to
8 make any comments he has, and then I would suggest
9 that we take an early lunch, and then come back and
10 talk about the details of what our next steps are, and
11 the mechanics, and so forth.

12 DR. DIAMOND: Richard, would it be
13 inappropriate to perhaps suggest that since it is so
14 early to just move on before breaking, because that
15 may allow some of us to catch an earlier flight home?

16 CHAIRMAN VETTER: Sure. We can do that.

17 DR. CERQUEIRA: Is that going to be an
18 open meeting or is that the committee?

19 CHAIRMAN VETTER: That's just the
20 committee.

21 DR. DIAMOND: That's just the committee.

22 CHAIRMAN VETTER: Will that work, John?

23 MR. HICKEY: Well, if you want to
24 continue, we will just continue to keep transcribing
25 the meeting. There is on reason to stop the

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1 continuity. I am not sure how long it will take.

2 CHAIRMAN VETTER: Okay.

3 MR. HICKEY: As far as your -- to give me
4 the opportunity just to make some remarks, I think the
5 discussion from my perspective -- and I think I can
6 speak on behalf of the staff, has gone well this
7 morning. I think you have hit on the key issues.

8 In particular, you have addressed the
9 issue of preceptors, which affects almost all of the
10 boards, and the issue of different modalities, and I
11 think that you have come up with some good ways to
12 address that.

13 I think you are also positioned on what
14 you are going to recommend as far as listing the
15 boards. I can't predict how that will actually come
16 out, but I view that more as an administrative issue,
17 rather than a substantive issue.

18 I think you have gone a long way in
19 addressing the substantive issues, and you have some
20 constructive and viable ways to address those.

21 CHAIRMAN VETTER: Well, the first issue is
22 that each of us doing some minor revisions. It looks
23 to me like it is minor, minor revisions of each of our
24 sections, and then sending those to the entire
25 subcommittee.

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1 And as long as we don't have any debate on
2 those minor issues, I will simply assemble all of
3 those and forward those to Dr. Cerqueira for the ACMUI
4 conference call on July 8th.

5 So that is the first issue. The second
6 issue is the issue of continuity, and I guess I would
7 raise the question do we need to draft sections for
8 390 and so forth, or can we assume that our intent is
9 going to be carried forward, or will ACMUI draft
10 those, or what?

11 We weren't specifically asked to address
12 those issues, but only to address the issue of
13 continuity.

14 DR. DIAMOND: It is probably -- and not
15 that I have a particular desire to do any more work
16 than I need to, but it is probably useful for me to go
17 and work on 390 and send out a draft, and let us fine
18 tune it around. It goes much faster that way.

19 DR. WILLIAMSON: I think it would be wise
20 given the complexity of the 300 that it we take it on
21 and at least come up with a draft.

22 CHAIRMAN VETTER: So which sections need
23 to be done yet? There is a 390?

24 MS. MCBURNEY: There is a 390, the
25 radiopharmaceutical therapy.

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1 CHAIRMAN VETTER: Radiopharmaceutical
2 therapy, right.

3 MS. MCBURNEY: Right. And Dr. Diamond --

4 DR. DIAMOND: Right, 390. I have a whole
5 list of them.

6 DR. WILLIAMSON: And we have a 490?

7 DR. DIAMOND: So there is a 390 that needs
8 some extensive work actually. And 392.

9 MS. MCBURNEY: And that is?

10 DR. DIAMOND: And 392 would be just the
11 competency issue. So, 392, paragraph (c)(3), which is
12 just deleting the level of competency phrase. Then I
13 have 394, paragraph (c)(3), which is the same exact
14 thing. Then I found 490.

15 MS. MCBURNEY: And 490 being?

16 DR. WILLIAMSON: Brachytherapy.

17 DR. DIAMOND: Brachytherapy. Which is
18 (b)3), level of competency, and also you would have to
19 go and change that parallel structure, right?

20 MS. MCBURNEY: Right.

21 DR. WILLIAMSON: I actually think that the
22 392 and 394 are going to be as much work as 390,
23 because one you have the pattern of all of the boards,
24 you have got to do it the same way.

25 DR. DIAMOND: Right. It is going to be

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1 just repetition.

2 DR. WILLIAMSON: You can sort of recopy
3 it, I think.

4 DR. DIAMOND: Right. Right. I will do
5 that, and so that was 490.

6 DR. WILLIAMSON: And then there is 500.

7 DR. DIAMOND: And 491, again level of
8 competency for -- and I am going to use Strontium-90,
9 and that is paragraph (e)(3). I was really bored on
10 the plane.

11 DR. WILLIAMSON: You have a lot of work.

12 CHAIRMAN VETTER: Are you volunteering to
13 do all of this?

14 DR. DIAMOND: Well, once you do it once,
15 you can cut and paste.

16 MS. MCBURNEY: Yes, cut and paste.

17 DR. WILLIAMSON: And then 590.

18 DR. DIAMOND: I may have created myself as
19 the only authorized user for most of these modalities.

20 MR. HICKEY: Dr. Vetter, if I could just
21 make a suggestion. If it turns out that you are
22 running into time problems in wording the rules, if
23 you could at least state what the principles and
24 objectives, and rationale are that you are trying to
25 get out with 390, and 490.

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1 And at least the full committee could deal
2 with that, and then the staff could follow up with the
3 committee.

4 MS. MCBURNEY: Right. Is anybody going to
5 do anything with the nuclear pharmacy issue?

6 CHAIRMAN VETTER: Yes, that is what I was
7 hoping to ask, because that issue was brought up, and
8 do we need to make any changes as a result of the
9 presentation?

10 MS. MCBURNEY: Apparently they have done
11 a preceptor issue on the acceptance of --

12 CHAIRMAN VETTER: Right. You have someone
13 at your institution --

14 DR. WILLIAMSON: Yes, maybe I could speak
15 with Sally Schwartz. It seems to me that we ought to
16 do something. It seems unreasonable to discredit or
17 marginalize the nuclear pharmacy board on what seems
18 to be a technicality, and I suspect that they have
19 good reasons for not requiring or requiring what they
20 do.

21 And again unless there is a major public
22 health issue with the way that they do it, it would
23 probably behoove the NRC to adapt to them, rather than
24 try to force the community just for technical legal
25 reasons to conform to them.

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1 So maybe I can talk with Sally and see if
2 she can work up something.

3 CHAIRMAN VETTER: Right. If you could
4 visit with her, and you are volunteering to look at
5 all of those other sections during --

6 DR. WILLIAMSON: I think that someone else
7 should take on 500.

8 CHAIRMAN VETTER: Yes, that is the
9 diagnosis. Would yo be willing to do that, Ruth?
10 That one is fairly straight forward, I think.

11 DR. WILLIAMSON: With the exception of the
12 190 and 290 series, where we have agreed that we are
13 going to include in the criteria for recognizing
14 boards, a preceptor statement that states satisfactory
15 completion of a training program, I guess.

16 Many of the statements, or some of them
17 anyway, have that the preceptor must be a diplomate of
18 the board in question. Is that reasonable or
19 unreasonable, or should we delete that?

20 Or is this a technical detail that we
21 should leave for the staff to work out?

22 DR. CERQUEIRA: We probably should leave
23 it out, because we are dealing with the radiation
24 safety aspects and that is sort of what we are
25 concentrating on.

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1 DR. WILLIAMSON: For the therapeutic
2 applications, let me remind you that the ACMUI made
3 the determination in its recommendations that you
4 could not separate safety from clinical competence,
5 and that the proper selection of patients, and not
6 giving high doses of radiation to wrong patients and
7 so forth, resulted in the fact that safety and
8 competence were sort of bound together.

9 So this is mainly an issue, I think -- and
10 I specifically excluded 190 and 290, where the
11 alternative pathway and the board recognition criteria
12 are really the same. But for the therapeutic
13 modalities, they are different.

14 CHAIRMAN VETTER: So how would it leave it
15 then? You would require a preceptor statement if the
16 person had completed the program.

17 DR. WILLIAMSON: Right. A preceptor who
18 is a diplomate of the board in question tests to
19 satisfactory completion of the training program by the
20 applicant. I mean, that is how it is written now, the
21 authorized medical physicist one.

22 CHAIRMAN VETTER: Could it be a program
23 director who is not necessarily boarded? I mean, we
24 have kind of allowed that for the radiology.

25 DR. WILLIAMSON: Well, you see, medical

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1 physics is an exception, where the formal structured
2 training program is not a uniformly available
3 structure.

4 CHAIRMAN VETTER: So we are talking just
5 about the physicist rather than the authorized user?

6 DR. WILLIAMSON: Well, for the physicist,
7 it is very special, and I thought -- I think for the
8 physicist that you can make a really good case that it
9 should be there, because it is one of the few items
10 that really determines the structure, or places some
11 bounds on the training program. So I think it is very
12 reasonable to have it there.

13 CHAIRMAN VETTER: For the physicist.

14 DR. WILLIAMSON: For the physicist. For
15 the physician, I am not sure that it really matters.
16 I don't think so, because really the weight of the
17 regulation, or the regulation really relies on the
18 residency review committee to ensure that it is a
19 proper training program.

20 CHAIRMAN VETTER: Okay.

21 DR. WILLIAMSON: So we leave it for the
22 physicist, I guess, who is the consensus.

23 CHAIRMAN VETTER: Okay. Deadlines.
24 Working backwards, we need this material for the
25 conference call, and also for publications. So when

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1 do we need a report to whom?

2 MR. HICKEY: We would like to have it to
3 me by the 28th, next Friday.

4 MS. MCBURNEY: So does that mean that we
5 would need to get it to you by the 25th?

6 CHAIRMAN VETTER: Yes, I would say that I
7 would like to have everything by Wednesday, and
8 preferably earlier to give us a chance to react to
9 anything.

10 DR. WILLIAMSON: So Tuesday is what date?

11 MS. MCBURNEY: The 25th.

12 DR. CERQUEIRA: The 25th.

13 CHAIRMAN VETTER: The 25th, by five
14 o'clock.

15 DR. CERQUEIRA: Eastern Standard Time.

16 DR. WILLIAMSON: Now, another general
17 question. You know, the bulk of our report is
18 actually draft language. Is there a need for some
19 more discursive or explanatory material that discusses
20 the rationale, or are you prepared to synthesize
21 something based on all the comments that are made, or
22 do we need to expand the first couple of pages?

23 MS. MCBURNEY: Or would that be after July
24 9th?

25 MR. HICKEY: I would say maybe a few more

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1 sentences in the front to address the rationale is
2 appropriate, but not an extensive -- I think you did
3 a good job of preparing a short introduction, and then
4 the wording as illustrations, the way it is drafted
5 now.

6 DR. WILLIAMSON: So that has to be done by
7 the 25th, too?

8 CHAIRMAN VETTER: Right. I will take that
9 assignment, and I will expand that a little bit to
10 take into account what we have done here today.

11 MS. MCBURNEY: And the public comments?

12 DR. WILLIAMSON: Do we need to react to
13 the public comments?

14 CHAIRMAN VETTER: We all have those, and
15 we have all heard them, and we all have copies of the
16 written. I think when we write our sections that we
17 need to review those.

18 DR. WILLIAMSON: But do we need to --

19 MR. HICKEY: You don't need to document or
20 respond specifically to the comments. You just have
21 to consider them as part of your process.

22 CHAIRMAN VETTER: Okay. The plan, David,
23 is for us to -- for those of us who are doing some
24 writing, to have it to me by five o'clock next
25 Tuesday, at 5:00 p.m. Eastern Time, Tuesday. And if

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1 it goes over into the evening, then that would be
2 okay.

3 I will assemble everything in the form of
4 a report, and get it to you by five o'clock Wednesday.
5 You will have Thursday to react, and by five o'clock
6 on Thursday, you need to send an e-mail to John
7 Hickey. He needs it by the 28th.

8 DR. DIAMOND: Should these e-mails that we
9 send back, should they be directed just to the
10 subcommittee, or should they should be sent, CC'd, to
11 the other organizations that have provided comment
12 already

13 CHAIRMAN VETTER: No, just the
14 subcommittee.

15 DR. WILLIAMSON: And the NRC.

16 CHAIRMAN VETTER: Well, just like we have
17 been doing before. We have been copying the staff.

18 MR. HICKEY: After Dr. Vetter transmits it
19 to us, we will transmit it to the attendees, and
20 speakers, and stakeholders, and put it up on our
21 website, and then it will be ready to go on July 8th
22 for the full committee.

23 DR. CERQUEIRA: Now, John, once Dick has
24 finished his portion, it would be good for the staff
25 to go through to look for consistency. Again, the

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1 "ands" or "or" requirements that are in there. Is
2 that possible?

3 MR. HICKEY: Yes, we will do that. I
4 don't think that we can do that before we post it, but
5 we can note that by the time that the full committee
6 meets, or even after if necessary.

7 MS. MCBURNEY: And fix those editorials.

8 CHAIRMAN VETTER: So are we okay with all
9 of that? Questions? If there aren't any questions,
10 I think we are done aren't we?

11 DR. CERQUEIRA: Yes.

12 MR. HICKEY: Okay.

13 CHAIRMAN VETTER: Thank you all very much.
14 You have been an extremely task-focused subcommittee,
15 and I appreciate that very much, and we have not
16 wandered too far astray I don't think. And we are
17 going to have our job done on time.

18 MS. MCBURNEY: And under budget.

19 CHAIRMAN VETTER: Was there a budget?

20 DR. WILLIAMSON: Actually, there is some
21 money involved?

22 MS. MCBURNEY: No.

23 CHAIRMAN VETTER: Okay. So in terms of
24 adjourning the meeting, I want to thank all of you for
25 all the time that you put on, and for the time that

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1 you will continue to put in on it. I would like to
2 thank the support of the NRC staff. I have had
3 extremely good support from John Hickey, and Linda
4 Psyk in moving materials around, and getting us the
5 public comments, and all that sort of thing.

6 And I would also like to officially thank
7 the members of the public who took their time or the
8 time out of their day to come here and share their
9 perspectives with us. If there are no other comments,
10 the meeting is adjourned.

11 (Whereupon, at 11:35 a.m., the meeting was
12 concluded.)

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