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 OPEN SESSION

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

OPEN SESSION

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TUESDAY, APRIL 25, 2006

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The Advisory Committee met at 8:30 a.m. in Balcony B in the Natcher Conference Center, Natcher Building (Building 45), National Institutes of Health, Bethesda, Maryland, LEON S. MALMUD, M.D., Chairman, presiding.

MEMBERS PRESENT:

- LEON S. MALMUD, M.D. Chairman
- EDGAR D. BAILEY Member
- DAVID A. DIAMOND, M.D. Member
- DOUGLAS F. EGGLI, M.D. Member
- RALPH P. LIETO Member
- SUBIR NAG, M.D. Member
- SALLY WAGNER SCHWARZ, R.Ph. Member
- ORHAN H. SULEIMAN, Ph.D. Member
- WILLIAM VAN DECKER, M.D. Member
- RICHARD J. VETTER, Ph.D. Member
- JEFFREY F. WILLIAMSON, Ph.D. Member

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SPEAKERS AND PARTICIPATING NRC STAFF:

THOMAS H. ESSIG, Designated Federal Official,

NMSS/IMNS/MSIB

CYNTHIA M. FLANNERY, NMSS/IMNS/MSIB

ANGELA McINTOSH, NMSS/IMNS/MSIB

CHARLES MILLER, Ph.D., NMSS/IMNS

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I-N-D-E-X

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

(10:44 a.m.)

MR. ESSIG: Okay. As Designated Federal Officer for this meeting, I'm pleased to welcome you to Bethesda for the public meeting of the ACMUI.

My name is Thomas Essig. I am Branch Chief of the Materials Safety and Inspection Branch and have been designated as the federal officer for this Advisory Committee in accordance with 10 CFR Part 7.11.

Present today as the alternate Designated Federal Officer is Cynthia Flannery, Team Leader for Medical Radiation Safety within the Materials Safety and Inspection Branch. Raise your hand, Cindy.

This is an announced meeting of the committee. It is being held in accordance with the rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission. The meeting was announced in the April 11, 2006, edition of the Federal Register, Volume 71.

The function of the committee is to advise the staff on issues and questions that arise during medical use of byproduct material. The committee provides counsel to the staff but does not determine or direct the actual decisions of the staff or the

1 Commission. The NRC solicits the views of the
2 committee and values them very much.

3 I request that whenever possible we try to
4 reach consensus on the various issues that we will
5 discuss today, but I also value minority or dissenting
6 opinions. If you have any such opinions, please allow
7 them to be read into the record.

8 As part of the preparation for this
9 meeting, I have reviewed the agenda for members and
10 employment interests based on the very general nature
11 of the discussion that we are going to have today. I
12 have not identified any items that would pose a
13 conflict. Therefore, I see no need for an individual
14 member to recuse themselves from the committee's
15 decisionmaking activities.

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

20 At this point, I would like to introduce
21 the members of the committee that are here today --
22 Dr. Leon Malmud, Chairman, who is our Health Care
23 Administrator; Dr. David Diamond, Radiation
24 Oncologist; Dr. Subir Nag, Radiation Oncologist; Dr.
25 William Van Decker, Nuclear Cardiologist; Dr. Douglas

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1 Eggli, Nuclear Medicine Physician; Ms. Sally Schwarz,
2 Nuclear Pharmacist; Dr. Richard Vetter, Radiation
3 Safety Officer; Dr. Jeffrey Williamson, Therapy
4 Physicist; Mr. Ralph Lieto, Nuclear Medicine
5 Physicist; Mr. Edgar Bailey, State Representative; and
6 Dr. Orhan Suleiman, the Center for Drug Evaluation and
7 Research. Did I get it right this time, Dr. Suleiman?
8 For the U.S. Food and Drug Administration.

9 Dr. Robert Schenter, who is our Patient
10 Advocate Representative, will not be attending this
11 meeting due to an illness. Dr. Malmud, as the ACMUI
12 Chairperson, will conduct today's meeting. Following
13 a discussion of each agenda item, the chair, at his
14 option, may entertain comments or questions from
15 members of the public who are participating with us
16 today.

17 Dr. Malmud?

18 CHAIRMAN MALMUD: Thank you, Mr. Essig.

19 The next item on the agenda is the opening
20 remarks of Dr. Miller. Dr. Miller.

21 DR. MILLER: Thank you, Dr. Malmud. I'd
22 like to welcome both the committee and the members of
23 the public to our spring meeting. The venue is
24 different today. I apologize to anyone who may have
25 had a hard time finding a place, although I would

1 think that you wouldn't, given the nature of this
2 facility.

3 One of the things that I've noticed in
4 just looking around is, since the configuration of the
5 room is a little bit different, at various points in
6 the meeting members of the public are recognized by
7 the chair, Dr. Malmud, so that they can provide any
8 comments that they want. In order for those comments
9 to get on the record, they have to use a microphone.

10 And I don't -- do we have a microphone
11 available, Mohammed, for the members of the public, or
12 -- okay. We'll try to work to get something there.

13 I don't want to belabor the beginning of
14 the meeting, so I want to get on with turning the
15 meeting back over to Dr. Malmud, the chair, and get to
16 our first topic. So, again, welcome and I appreciate
17 your attendance today.

18 Thank you.

19 CHAIRMAN MALMUD: Thank you, Dr. Miller.

20 The next item on the agenda is the RIS on
21 visitor dose limits to be presented by Dr. Sherbini.
22 Dr. Sherbini will present the draft RIS on rapidly
23 granting exemptions from regulatory dose limits for
24 certain caregivers.

25 MR. ESSIG: I would just preface Dr.

1 Sherbini's remarks with the particular presentation
2 that's included in the members' notebooks has evolved
3 over what was there originally, because originally we
4 were going to present an overview of the proposed RIS.
5 And we received some very good comments from Mr. Ralph
6 Lieto, and so we have restructured.

7 And I would note that he was the only one
8 on the committee -- so I'm going to chastise the rest
9 of you a little bit -- he was the only one on the
10 committee who provided comments on the RIS.

11 PARTICIPANT: (Inaudible comment from an
12 unmiked location.)

13 MR. ESSIG: That's not true. He was the
14 only one that I was aware of. I'm sorry.

15 DR. SHERBINI: We received also from Sally
16 Schwarz.

17 MR. ESSIG: Okay. All right. And Dr.
18 Vetter also submitted comments?

19 MEMBER VETTER: If you are not getting all
20 the comments, there is a problem.

21 MR. ESSIG: Okay.

22 (Laughter.)

23 Thank you for calling that to my
24 attention.

25 For some reason, Mr. Lieto's comments

1 became the most visible ones. So --

2 (Laughter.)

3 MEMBER VETTER: And the by way, I e-mailed
4 Sally the comments I gave to her that didn't get to
5 you.

6 MR. ESSIG: Okay. I apologize, then, for
7 the general chastisement. I was out of order.

8 (Laughter.)

9 PARTICIPANT: You can self-chastise.

10 MR. ESSIG: Yes, yes.

11 (Laughter.)

12 So we have -- because of the comments, we
13 felt it would better serve our interests if we
14 restructured the presentation to focus on the -- give
15 an overview of the RIS and then focus on the issues.

16 Dr. Sherbini?

17 DR. SHERBINI: Thank you, Tom.

18 I will spend just a few minutes giving a
19 background of where this RIS came from, and then
20 concentrate on the comments. The comments were very
21 good, and we know how to address some of them. We
22 don't know how to address the others, and so we'd like
23 your I guess advice on how to resolve these -- the
24 issues that some of these comments raised.

25 Okay. This whole thing started with the

1 incident that occurred a couple of years ago at one of
2 the hospitals in which a member of the public received
3 a dose that was higher than the public dose limit.
4 And after analyzing this case and reviewing the
5 circumstances, the staff wrote a paper to the
6 Commission suggesting that maybe people who take care
7 of patients in a hospital situation should not be
8 subject to dose limits.

9 The Commission liked the idea and approved
10 the idea that we should not put dose limits on
11 caregivers. So the Commission directed us to write
12 guidance on how to do this. They also suggested that
13 rather than leave it open we start with a limit of 20
14 millisieverts, and then go up if the need arises. Our
15 experience so far suggests that 20 millisieverts
16 should be sufficient for most cases.

17 But the method is still open, so that if
18 more is needed it can be obtained. So the 20
19 millisieverts really can be viewed as an
20 administrative limit, if you will, that can be changed
21 as circumstances evolve. We started writing this RIS
22 a few months ago. We have distributed it for review.
23 It's still being reviewed, and the target date to
24 issue this is June of this year. So that's basically
25 the background.

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1 This is one of the comments that we got.
2 We thought when we wrote this that the parallel
3 between the caregiver being exposed to radiation and
4 the patient undergoing treatment is apt. But the
5 comments suggest that it is not a good parallel.

6 The reasoning behind our thought is that
7 the caregiver is viewed as an extension of the
8 patient's treatment requirements. And so the
9 involvement of the caregiver and the exposure to
10 radiation of the caregiver is viewed as contributing
11 to the patient's well being, and that really is the
12 major justification for allowing a member of the
13 public to receive a fairly high dose, that it benefits
14 the patient. If it does not benefit the patient, then
15 we really would not have any justification.

16 So I'm not sure if the committee thinks
17 this is not an apt parameter. Sir?

18 MEMBER WILLIAMSON: Well, I think it does
19 benefit the patient and maybe should say that and just
20 drop the other phrases about the analogy, you know,
21 between the patients actually receiving the treatment
22 and/or diagnostic services to avoid this controversy.
23 I think you can make the point directly without having
24 --

25 DR. SHERBINI: Okay. That --

1 MEMBER WILLIAMSON: -- to defend the
2 analogy.

3 DR. SHERBINI: Okay. We'll make that
4 change, then.

5 This is an issue that we find very
6 difficult to resolve, and we really need your help in
7 that. How do we handle the situation of pregnant
8 women or minors acting as caregivers who may receive
9 high doses? We don't know how to address this, and we
10 would appreciate some advice on that matter.

11 I mean, we had originally thought that we
12 would leave it up to the hospital's policy, the
13 individual hospital's policy, to decide whether
14 pregnant women should or should not be exposed, minors
15 should or should not be exposed, but it's unclear what
16 the best approach should be in this case.

17 CHAIRMAN MALMUD: Dr. Sherbini, is your
18 comment meant to be an open question for discussion?

19 DR. SHERBINI: Yes, we'd like some ideas
20 of how to address this.

21 CHAIRMAN MALMUD: Well, may I precipitate
22 the discussion by saying that there should be no
23 exceptions for pregnant women and children, that they
24 should not be caregivers because of the sensitivity of
25 the fetus and a young child to radiation, which is

1 greater than that of an adult, given the size of the
2 fetus and the developing physiology of the child.

3 DR. SHERBINI: Would it be acceptable to
4 leave this up to the hospital's policy rather than
5 make it an NRC policy?

6 CHAIRMAN MALMUD: Dr. Vetter?

7 MEMBER VETTER: I'd like to differ with
8 the chair. From the standpoint of risk to
9 individuals, we certainly would want to protect
10 pregnant women and minors to much greater extent than
11 we would other adults. But there are two things about
12 this situation that are quite different I think than
13 normal. One is we're looking at an extremely small --
14 I would predict we're looking at an extremely small
15 number of people in the first place, and those who are
16 pregnant and minors would be even a very small number.
17 So we're looking at rare occurrences, I think.

18 The second is I think we need to consider
19 what stimulated all of this in the first place, and
20 that was an individual who you could argue is a
21 caregiver or not in the true sense of the word, who
22 wanted to spend time with her dying parent. So are we
23 going to say a pregnant woman and a minor can't do
24 that? I guess I would say that's going a little bit
25 too far.

1 On the other hand, I think hospitals can
2 take -- there are many, many steps they can take to
3 keep those doses very, very low. But there might --
4 what I'm hesitant about here is making a black and
5 white kind of a rule here that suggests that you would
6 never allow a pregnant woman or a minor -- a minor to
7 get more than 100 or a pregnant woman to get more than
8 even 500, if we use the occupational limit. We would
9 never allow that.

10 I think as a matter of policy, I
11 personally think that's going a little bit too far.

12 CHAIRMAN MALMUD: Dr. Suleiman.

13 MEMBER SULEIMAN: I pretty much concur
14 with Dr. Vetter's comments. I think -- first, I think
15 an informed consent by the caregiver would maybe
16 address some of the liability issues. Second,
17 professionally, I think there is no reason that the
18 doses can't be kept so low that I would argue very
19 strongly that probably the risk to either a child or
20 a pregnant female would be very, very, very
21 negligible. We don't want to get into a risk
22 discussion here.

23 CHAIRMAN MALMUD: Okay.

24 MEMBER SULEIMAN: But I think informed
25 consent and keeping the doses as low as possible would

1 really ensure the safety. And I think what I have
2 said all along is the caregiver really is not -- is
3 neither an occupational worker or a member of the
4 general public, so they should be treated as such. So
5 --

6 CHAIRMAN MALMUD: Okay. Thank you, Dr.
7 Suleiman.

8 The purpose of my initial comment was to
9 stimulate the discussion, which obviously has
10 occurred.

11 (Laughter.)

12 The next element of my question would be:
13 to whom shall this responsibility be given? Shall it
14 be the RSO of the institution involved or another
15 party? Dr. Eggli.

16 MEMBER EGGLI: I think that this certainly
17 needs to be done in consultation with the RSO, and I
18 would actually like to come back to the first question
19 for just a second, which is I think the guidelines
20 that we use in handling accidental exposures of
21 pregnant patients probably apply. And I don't think
22 you'll find anything in any literature anywhere that
23 with exposures in the 10 rem or less range where
24 you'll find any evidence of any long-term adverse
25 fetal outcomes.

1 So I think that setting an arbitrary limit
2 that's low is not beneficial. But I think I like
3 Orhan's concept of the informed consent, and that --
4 I think that that should be a combination of the
5 physician responsible for the radiation exposure to
6 the patient, and the radiation safety officer should
7 clearly -- I think should clearly be involved as well.

8 I don't think it should be just the
9 radiation safety officer. I think the -- that the
10 radiation safety officer probably has no real
11 relationship with the family members, but the treating
12 physician does have a -- in theory should have a
13 relationship with the patient and the family, and that
14 that counseling should come from both the radiation
15 safety officer and the treating physician to put it in
16 a proper perspective.

17 CHAIRMAN MALMUD: Thank you, Dr. Eggli.
18 How would you address the issue of a dying parent with
19 a minor child? Who would sign the informed consent on
20 behalf of the minor child?

21 MEMBER EGGLI: I would -- there would --
22 the likelihood is that if you have a dying parent,
23 there may be yet one surviving parent who could sign
24 that consent for the -- could sign the consent for the
25 minor child. And, in fact, if the dying parent is

1 still legally competent, they are the guardian of that
2 child.

3 CHAIRMAN MALMUD: Thank you.

4 Dr. Nag.

5 MEMBER NAG: I would like to propose that
6 we separate the minor from the pregnant women, because
7 perhaps, you know, they are -- I don't know about the
8 exact dose limit, but there would be some difference
9 between a pregnant woman and a minor.

10 The other thing is although the case that
11 brought this on was about a dying parent with -- and
12 the daughter, the same problem would occur on some of
13 the things I need -- you know, I am exposed to when I
14 treat a child and the mother or the -- you know, the
15 parent wants to be taking care of the child even
16 though the child has a radiation implant in them. And
17 that's something that occurs not very frequently but
18 perhaps once a year or so.

19 CHAIRMAN MALMUD: Other comments? Mr.
20 Lieto.

21 MEMBER LIETO: Getting back to I think
22 what Dr. Sherbini was asking before, he had I think
23 asked the question: should this be something left up
24 to the individual licensees to determine? I would say
25 probably, yes, that would be what we would want to

1 recommend. But I think what needs to be included in
2 this document is some guidance addressing that
3 respective point.

4 I think that the -- that pregnant women
5 and minors as caregivers should be strongly
6 discouraged. The points that, you know, Dr. Vetter --
7 the circumstances that Dr. Vetter brought up I think
8 need to be emphasized, in that, one, these are going
9 to be very, very uncommon situations. And now we're
10 talking about very extremes of an uncommon situation.

11 And do we want to try to establish a
12 guidance document where something might come up once
13 in a five-year period or something like that? I think
14 we'd end up making a guidance document that's going to
15 look at almost every possible variation of our
16 imagination. So I think the guidance should be that
17 it's strongly discouraged unless it's in the best
18 interest of the patient as determined by the
19 licensee's authorized users involved with the patient
20 care.

21 CHAIRMAN MALMUD: Either Dr. Diamond or
22 Dr. Schwarz was next. Dr. Schwarz?

23 MEMBER SCHWARZ: I disagree with Ralph.
24 I think that being a woman and being able to be
25 pregnant, I mean, certainly if I was faced with a

1 situation like this I really wouldn't want to be told
2 that this is not possible. I think that certainly to
3 be careful is the way to proceed.

4 And as far as guidance, maybe it is left
5 up to the hospital. But certainly not that it's
6 strongly discouraged. I mean, it's certainly not
7 going to try to be in that position, but it may occur.
8 And if that would occur, I certainly think that you
9 need to be safe, allow the patient to be safe, but --
10 excuse me, the caregiver to be safe but not to say
11 that that can't occur.

12 CHAIRMAN MALMUD: Thank you.

13 Dr. Diamond.

14 MEMBER DIAMOND: Yes. I would concur with
15 Ralph's position. I believe that in this regulatory
16 issue summary that there can be language included that
17 this type of exposure, particularly to pregnant women
18 and to minors, is to be strongly discouraged, and
19 would be envisioned only under very exceptional
20 circumstances, and that particularly under these
21 circumstances there should be a discussion between the
22 treating physician, with input from the radiation
23 safety officer, with clear discussion regarding the
24 potential risks.

25 And perhaps to go and be more specific

1 would be an example of overregulating, again, given
2 that the number of occurrences expected per year would
3 be less than one, and perhaps maybe one occurrence
4 every fifth or tenth year.

5 CHAIRMAN MALMUD: Okay. Thank you, Dr.
6 Diamond.

7 May I just summarize where we are at the
8 moment? It seems as if we've heard four elements
9 discussed. The first one is that it should be the
10 responsibility of the licensee. The second one is
11 that informed consent is an essential element, either
12 by or on behalf of the minor.

13 The third is that there be safety
14 precautions as part of the process, so that the usual
15 barriers that are constructed -- a lead shield, for
16 example -- for someone who wishes to stay in the room
17 for a prolonged period of time, should be a
18 requirement, as it would be if we were trying to
19 maintain within the existing guidelines.

20 And the last element was not mentioned,
21 but we did discuss it previously, and that is that
22 there should be contemporaneous notification of the
23 regional NRC office that this event is occurring,
24 since it is a very rare event and would not flood the
25 NRC with unnecessary data, but would keep them posted

1 of an unusual situation.

2 Are there other elements, or are there --
3 are there discussions of any of the elements that I've
4 mentioned? Dr. Diamond?

5 MEMBER DIAMOND: Yes. Would you also
6 include as a fifth point that the visitor be badged?

7 CHAIRMAN MALMUD: Okay. Badged. That's
8 a fifth element.

9 And, Dr. Williamson, I think you had your
10 hand up.

11 MEMBER WILLIAMSON: Yes. I think one
12 element that was left out of your summary was the
13 concept of while not forbidding minors and pregnant
14 women to be caregivers, the concept of discouraging
15 them.

16 CHAIRMAN MALMUD: Yes, thank you.

17 Other comments? Mr. Lieto? Was that your
18 hand? Oh, I'm sorry. Dr. Eggli.

19 MEMBER EGGLI: Again, I would like to come
20 back to Sally's comment that we have to pay attention
21 to what the measurable risk is for a child or a
22 pregnant woman. And you'll be hard pressed to find
23 any literature that will quantitate any risk at these
24 low levels, even up to 10 or more rem.

25 And regulating based on absence of

1 information of harm I think is not a good thing here,
2 so that the strongly discouraging minors and pregnant
3 women I think is an overdraw, that there is no
4 evidence in the literature to support this. This is
5 something that I deal with three or four times a year
6 with patients who are exposed at a time that they did
7 not realize they were pregnant. And what is the risk
8 to the fetus?

9 If you want to look at the risk in the
10 first 12 weeks, almost all mutations are lethal and
11 the pregnancy aborts. After that, you can -- and
12 there is nothing in the literature that says that 10
13 rem will do that. Nobody knows what that threshold
14 is, but all early pregnancies, all mutations are
15 lethal.

16 After that point, there is zero evidence
17 that exposures even greater than 10 rem produce any
18 medical effect in the fetus or in the child as the
19 child grows. So I think strongly discouraging flies
20 in the face of all existing evidence.

21 CHAIRMAN MALMUD: Okay. Thank you, Dr.
22 Eggli.

23 Other comments?

24 (No response.)

25 Then, may I once again summarize? And I

1 think I've left a point out, so please add on to my
2 comments if you will. The elements are: number one,
3 that it would be the licensee's responsibility; number
4 two, the licensee would notify the regional NRC of
5 this unusual situation in a contemporaneous fashion;
6 number three, informed consent is an essential
7 element; number four, there would be discouragement of
8 pregnant women and children from participating, but
9 not exclusion as long as they are informed or the
10 responsible guardian of the child is informed; number
11 five, that obviously all safety precautions would be
12 mandated -- lead shielding, distance, etcetera -- to
13 the degree possible.

14 And is there one that I left out?
15 Dosimetry badges. Okay, that was it. It was the
16 badges.

17 So there are six elements in this. I
18 think Dr. Williamson has a comment.

19 MEMBER WILLIAMSON: Some of the elements
20 are common to everybody who is a caregiver, so I don't
21 see why badges should be prescribed. And, you know,
22 I think -- you know, it is made clear there should be
23 some apparatus for monitoring everybody. Also,
24 contemporaneous notification is required for
25 everybody. I don't see why it needs to be

1 specifically mentioned in this case, since everybody
2 is covered.

3 CHAIRMAN MALMUD: Okay. If I may, the
4 reason I included contemporaneous notification is that
5 it's the belief of some of the members of the
6 committee that had there been contemporaneous
7 notification with regard to the incident that
8 precipitated this discussion that the outcome might
9 have been different, since notification after the
10 process is not quite the same and does not give the
11 same opportunities for monitoring by the regional
12 office.

13 MEMBER WILLIAMSON: Dr. Malmud, the whole
14 point of the RIS --

15 CHAIRMAN MALMUD: Go ahead. Dr.
16 Williamson.

17 MEMBER WILLIAMSON: I thought the whole
18 point of the RIS was for anybody that is to be a
19 caregiver that violates the 100 millirem rule there
20 has to be notification in advance of the exposure.

21 CHAIRMAN MALMUD: Okay.

22 MR. ESSIG: Dr. Malmud, I was just going
23 to inquire, would you consider making that -- your
24 five points in the form of a recommendation that --
25 would that seem appropriate?

1 CHAIRMAN MALMUD: Yes. If that would be
2 helpful, I think that in -- in creating --

3 MR. ESSIG: Or a motion?

4 CHAIRMAN MALMUD: In creating exceptions,
5 the more clarity there is to the exception, the more
6 likely is adherence to the exception policy. So
7 that's why I included these elements. And if you
8 wish, I will mention them again as a motion. Is that
9 the pleasure of the committee?

10 In that case, there are -- I'll summarize
11 again. The elements are: number one, that it becomes
12 the responsibility of the licensee; number two, that
13 the licensee will give the regional NRC office
14 contemporaneous notification of this rare exception;
15 number three, informed consent will be required;
16 number four, there will be educated discouragement of
17 pregnant women and children from excessive exposure;
18 number five, that the standard safety precautions will
19 still be in place, despite the fact that we've given
20 exception for the dosimetry; and, number six, that
21 there will be some measure of exposure of the parties.

22 MEMBER VETTER: What was that last one?

23 CHAIRMAN MALMUD: Some measurement of
24 dosimetry badges. Badges.

25 Dr. Vetter asked what the last item was,

1 and he is correct in asking me to clarify it. That
2 the individuals who are the subject of the exception
3 will wear badges.

4 MEMBER VETTER: Okay.

5 CHAIRMAN MALMUD: That's a motion. Is
6 there a second to the motion?

7 MEMBER VETTER: Second.

8 CHAIRMAN MALMUD: Dr. Vetter seconds the
9 motion. Any further discussion? Dr. Miller.

10 DR. MILLER: I would like to further
11 discuss it from a regulator's perspective. One of the
12 points of the motion was prior notification to the
13 NRC, and I guess --

14 MEMBER DIAMOND: Actually, I believe it
15 was concurrent notification.

16 DR. MILLER: Okay.

17 MEMBER DIAMOND: Concurrent.

18 DR. MILLER: Okay. Fair enough.

19 CHAIRMAN MALMUD: I used the word
20 "contemporaneous."

21 DR. MILLER: Okay. But that would still
22 -- that would still mean notification to the NRC that
23 the situation is taking place. And I guess the
24 question I have, Sami, is from a regulator's
25 perspective, would we consider that necessary? Given

1 the fact that, you know, our regulations provide for
2 certain requirements for when notifications had to be
3 made.

4 And I'm just putting the question on the
5 table from a burden perspective, and I would be
6 interested in my staff's view from a regulator's
7 perspective in that regard.

8 DR. SHERBINI: No. We had not initially
9 thought about having the licensee notify us when
10 things like this happen. We were -- basically, once
11 the exception is granted, then the burden is on the
12 licensee to do the right thing without telling us
13 basically, and that's the way it works in some cases
14 that have been -- yes, sir.

15 MEMBER SULEIMAN: Dr. Suleiman. I'm
16 confused. My perception all along was that the NRC
17 wanted to be notified of this. I, however, agree that
18 if you've got these controls in place it is business
19 as usual, unless there is some overlying, serious,
20 something that is -- scenario that is occurring. But
21 I would -- I would agree. Why would you want to
22 bother? It's just an additional bureaucratic step.

23 DR. MILLER: I guess to get it clear,
24 Sami, what we would be looking for is, when such a
25 situation presents itself, that the licensee would

1 seek an exemption?

2 DR. SHERBINI: Well, the exemption in many
3 cases would be issued to the Department rather than to
4 an individual caregiver. So the Department that
5 handles many cases that require such a situation --

6 DR. MILLER: Okay.

7 DR. SHERBINI: -- would have an exemption
8 to expose caregivers when the physician deems it
9 appropriate to do so.

10 DR. MILLER: So it would be a request and
11 an exemption. It would be a blanket exemption for --

12 DR. SHERBINI: Yes.

13 DR. MILLER: -- that licensee, not on a
14 case-specific basis.

15 DR. SHERBINI: That's right. That's
16 right.

17 DR. MILLER: So I guess the question
18 that's on the table, then, is: having sought that
19 exemption, and having successfully got it from us, we
20 would be comfortable that they're putting the right
21 steps in place.

22 DR. SHERBINI: Yes. Yes.

23 DR. MILLER: And if they're putting the
24 right steps in place, then would there be a need for
25 an individual notification every time a specific case

1 came up?

2 DR. SHERBINI: No. There would be
3 inspections to check on the program.

4 DR. MILLER: Okay.

5 DR. SHERBINI: But --

6 DR. MILLER: All right. I think we've
7 heard from our perspective. Now I'd be interested in
8 the committee's reaction.

9 CHAIRMAN MALMUD: The next question -- the
10 next comment was Mr. Lieto's, and then Dr. Vetter's.
11 Mr. Lieto?

12 MEMBER LIETO: Yes. I think there is a
13 little disconnect here. Where Dr. Sherbini is coming
14 from is the assumption that the licensee is going to
15 do this in advance, with the understanding this might
16 occur. I think most of us on the committee side are
17 looking at this. This is going to be a rare event.

18 We don't ever expect it to happen. But
19 when it does, it's going to be something where you may
20 only have hours or less to do anything about it, in
21 terms of notification. And that's where this
22 immediate notification -- I think where Dr. Malmud is
23 coming from. And the example is the incident that
24 initiated all this in 2002, okay, was -- it happened
25 in a matter of hours that same day and included a

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1 holiday.

2 So what -- you know, in those types of
3 circumstances, and where I think this guidance
4 document needs to come from, is both situations, where
5 - the situation where Dr. Sherbini is coming from
6 where the licensee might be doing a lot of these
7 unusual types of research or therapies and wants to
8 get a preapproved type of authorization. But I think
9 it needs to address the situation that initiated this,
10 which was something that happens, you know, that day
11 or overnight.

12 CHAIRMAN MALMUD: Mr. Essig.

13 MR. ESSIG: If I may -- and I'm glad you
14 brought it up, Ralph -- the situation that we're
15 trying to address is the one that is the emergent
16 situation. The one that the licensee anticipates we
17 -- I can give you an example, because it is part of
18 the public record, of the University of Pennsylvania
19 has the license condition -- approval of exposures up
20 to two rem.

21 And they had identified as -- and I've
22 forgotten the exact treatment modality here, but the
23 parent in this case was the one that would receive up
24 to two rem. We approved that as -- approved our
25 regional office granting that exemption, but that was

1 something the licensee knew about ahead of time, and
2 just the nature of the situation prevented them from
3 keeping the dose to the parent to 100 millirem.

4 But that isn't the -- I don't view that as
5 the situation that was the subject of this RIS. The
6 subject of the RIS is the emergent one, where there is
7 -- the licensee finds himself in a situation -- as you
8 noted, the event back in 2002 that triggered all of
9 this was -- it evolved very rapidly, and so I think in
10 this case what we're saying is the Commission has
11 given us the authority to grant an exemption with very
12 little justification for an exposure limit up to two
13 rem for the individual licensee that notifies us that
14 they're in this -- in this situation.

15 If they need to go beyond that in the
16 judgment of the attending physician, then they
17 certainly -- they certainly can. But we would grant
18 a two rem exemption for that emergent situation with
19 very few questions asked. It is more of a
20 notification -- come into our Operations Center --
21 which is our 24/7 point of contact, and then we would
22 follow up the next business day with the licensee.

23 CHAIRMAN MALMUD: Thank you for that
24 clarification, Mr. Essig.

25 MR. ESSIG: And I might add that we are

1 going well beyond the point of this particular slide,
2 which was on the doses to pregnant women and minors.
3 I think we've kind of leaped ahead to some of the
4 other points in the other slides, so -- so maybe
5 before we go much further, Sami, if you want to catch
6 us up to where -- Dr. Vetter had his hand up. Has
7 your point been handled yet?

8 MEMBER VETTER: Well, just very quickly,
9 I think -- maybe I'm the only one that's confused, but
10 I think -- I think this RIS says we must notify the
11 NRC. And, therefore, there is nothing different about
12 what's in his motion. He is just reemphasizing that
13 for a pregnant --

14 DR. SHERBINI: Maybe I should clarify
15 this. Initially, whether it's a request that is
16 issued -- that is put forward to the NRC long term or
17 an emergency request, in either case the initial
18 contact has to be notification of the NRC that the
19 licensee would like to do this.

20 If, as Tom said, you have time, then you
21 can submit an exemption request, and, you know, take
22 your time to discuss with the region what you want to
23 do, etcetera. If you don't have time, it's -- if it's
24 an emergency, then the RIS has provisions where you
25 can just call the NRC, say, "I'm going to do this,"

1 and actually go ahead and do it -- you know, if it's
2 off-hours or whatever.

3 So either case, there has to be a
4 notification initially to the NRC. If it's a one-time
5 case, then after the notification it goes away. If
6 it's not, then it gets added to the license.

7 CHAIRMAN MALMUD: Dr. Williamson?

8 MEMBER WILLIAMSON: Yes. I guess I'm very
9 unclear. I thought this document was applicable in
10 addressing only one-time requests. And every time a
11 patient or their family fell into this situation, a
12 separate emergency request would have to be made.

13 And now I'm hearing from Dr. Sherbini that
14 actually this is describing -- this is a guide to how
15 to prepare a license amendment to implement a standard
16 variance from the regulations that any patient who
17 comes, you could do this to if they've fulfilled these
18 conditions, and you would not have to advise the NRC
19 on a case-by-case basis. Is that correct?

20 DR. SHERBINI: Well, you know, the
21 distinction isn't as sharp as it's stated. In either
22 case, you need an exemption from a certain part of the
23 regulation, either case. The difference is really how
24 you're going to go about doing that. If it's an
25 emergency situation, the RIS says that you have some

1 leeway in doing this in an unusual way.

2 If you do have time, then you do it the
3 usual way that any exemption is requested. You know,
4 you submit an exemption request from any part of the
5 regulation of the NRC and describe it.

6 CHAIRMAN MALMUD: Dr. Sherbini -- this is
7 Malmud -- may I ask, how often do you expect this to
8 occur annually in the United States? Once a year?
9 Ten times a year? A hundred times a year? Order of
10 magnitude.

11 DR. SHERBINI: We estimate that it's less
12 than five times a year.

13 CHAIRMAN MALMUD: Less than five times a
14 year.

15 DR. SHERBINI: Yes.

16 CHAIRMAN MALMUD: That being the case,
17 don't you think that it would be wise for the licensee
18 for a variety of reasons, including the licensee's own
19 interests, not to mention those of the patient and the
20 caregiver, that the NRC be notified that this event is
21 occurring in a timely fashion, meaning when it's
22 necessary?

23 DR. SHERBINI: Well, it's a requirement.
24 If this event is occurring for the first time, then
25 the licensee is essentially going to violate the

1 regulations. Right? And, therefore, the NRC needs to
2 be notified.

3 CHAIRMAN MALMUD: And that's the reason
4 that I made the suggestion. I think it covers all
5 parties well. And though I'm not in favor of
6 excessive regulation, I am concerned that the licensee
7 not put itself in a situation in which it can be
8 criticized for having done something incorrectly --

9 DR. SHERBINI: Yes, sir.

10 CHAIRMAN MALMUD: -- and not having
11 notified the NRC that it was going on, so the NRC
12 could have, in its regional office, offered advice as
13 to how to do it correctly, in a timely fashion.

14 Again, I'm -- my mind is keyed back to the
15 event of 2002, so I'm trying to prevent that. Also,
16 at the same time, human behavior being what it is,
17 it's better that this be an exception. Otherwise, we
18 begin to see exceptions becoming the rule and
19 extending to circumstances that we did not anticipate.

20 Since this is a rare event -- as you
21 estimate, five times a year or fewer events than that
22 -- it would seem to me, though I'm not the NRC, that
23 this is a burden which the NRC could share with us as
24 providers, as licensees.

25 Dr. Suleiman. I'm sorry, who was -- okay.

1 Mr. Bailey.

2 MEMBER BAILEY: I have to put on my
3 regulator's hat, which I guess is what I'm supposed to
4 do. But I'm struck by the lack of information. We've
5 got one case that we know of. Years ago we used to
6 joke that every time something occurred regulators
7 felt like they had to pass a regulation to prevent
8 that occurring in the future or to make that event
9 legal.

10 If we go with this exemption, I don't know
11 why every single therapy license wouldn't come in to
12 have an across-the-board exemption. And having done
13 that, I will say, as would -- I hope I don't insult
14 the doctors, but there are some doctors who would
15 greatly abuse such an exemption.

16 I'm also struck by why we chose -- or why
17 NRC is suggesting two rem when the occupational dose
18 is five rem, and this is probably a one-time
19 occurrence. It's like putting some magic on two rem.

20 If you're going to make it an exemption,
21 then without much having to be done to exercise it, I
22 don't know why it isn't simply in the regulations,
23 that under certain circumstances it can occur, so that
24 they don't have to come in but put a reporting
25 requirement on it, similar to what you do with

1 misadministrations. You don't have to get permission
2 to have a misadministration. All you've got to do is
3 report it.

4 So to me, looking at this situation, we
5 don't even know how many times it occurs. I think it
6 occurs more than we think. It was only brought to
7 your attention. And with the agreement states having
8 80 percent of the licenses, I think you're going to
9 get a lot of different interpretations on how this can
10 be administered. I think it needs to be very clear
11 what's going to happen here.

12 CHAIRMAN MALMUD: Thank you, Mr. Bailey.
13 Dr. Diamond.

14 MEMBER DIAMOND: I'm actually -- I'm
15 interested in the academic discussion, but I'm
16 actually starting to get a little frustrated. This is
17 getting a little silly. Emergency occurrences of the
18 use of radioisotopes for these purposes should
19 basically never happen, because that's what we're
20 talking about.

21 We're not talking about the planned
22 administration of therapeutic doses of I-131 to a
23 five-year old child with a pediatric thyroid
24 malignancy which has been planned weeks in advance in
25 which the proper steps can be taken. We're talking

1 about the emergency exemption request for these
2 exemptions to visitor dose limits. This should almost
3 never happen.

4 We've been spending a lot of time and a
5 lot of resources talking about one event in 2002. I
6 think we can simply go issue this RIS with some common
7 sense principles. There should be a reporting
8 requirement, so that we can develop an N, the number
9 of occurrences that have occurred in a prospective
10 way. And I think it's time for us to move on.

11 CHAIRMAN MALMUD: Thank you, Dr. Diamond,
12 for your practical approach.

13 Dr. Suleiman.

14 MEMBER SULEIMAN: Well, I was thinking
15 nobody had mentioned reporting, and then Ed and Dr.
16 Diamond both mentioned it. I think it's -- I believe
17 this issue, depending on how you perceive it, is more
18 prevalent than people will admit to. And I think
19 there are a lot of people who receive significant
20 doses and a lot of people who get to visit them.

21 But unless you define -- have some sort of
22 a cutoff in terms of reporting, now everybody is going
23 to start being monitored or looked at. And so maybe
24 the -- for sake of argument, the 20 millisievert is a
25 good number, above which, you know, they'll say,

1 "Well, let's report these to the NRC. We had so many
2 caregivers. We actually receive -- you know, estimate
3 to receive this much exposure or dose." Otherwise,
4 you're going to get lots of reports.

5 And the two was just -- I don't care. You
6 want to use five? You want to use one? I think,
7 again, personally, I feel that anybody who practices
8 good radiation safety should have those doses much
9 lower than that. But out of principle, select a
10 number and require those to be reported to the NRC,
11 you know.

12 But I think this could be codified or come
13 up with a policy or whatever. But if you don't have
14 some sort of a number above which or below which --
15 otherwise, you're going to get overwhelmed with a lot
16 of additional, unnecessary reporting criteria. But I
17 do think this is much more prevalent. It's not just
18 the dying patient. Some of these survive. And so I
19 think a lot of people do visit them, and maybe getting
20 more than you suspect.

21 CHAIRMAN MALMUD: I believe Dr. Eggli was
22 next, and then Dr. Williamson. Dr. Eggli?

23 MEMBER EGGLI: I actually have two points.
24 One is on your motion, Leon. And actually, we have a
25 motion on the floor, moved and seconded, so this is

1 the discussion of a motion. I think on your dosimeter
2 I wouldn't use the term "badge," because I think we
3 want to monitor their exposure in real time. I would
4 just use "dosimeter."

5 And, secondly, I have to agree with Orhan.
6 I recently treated a child for thyroid cancer, and the
7 mother wanted to know why we were placing so many
8 restrictions on her, because the last time the child
9 was treated elsewhere they didn't have any such
10 restrictions about being in the room.

11 (Laughter.)

12 So I'm sure Orhan is correct about the
13 issue of the practice. So I think that the concept,
14 both as a standing exemption as the one granted to
15 CHOP, and the concept of the urgent exemption, are
16 both -- are both needed and are valuable, because it's
17 out there and it's happening all the time.

18 CHAIRMAN MALMUD: Thank you.

19 Dr. Williamson.

20 MEMBER WILLIAMSON: Well, I would
21 recommend that this current RIS be restricted to the
22 single use emergency setting that would then, by
23 definition, require, as Dr. Malmud calls it,
24 contemporaneous notification of everything, including
25 the pregnant women and minor children. And you could

1 ask that that be part of the information that is to be
2 reported if such individuals are involved.

3 And I think it will be after some period
4 of experience. It will be beyond debate, whether
5 there's a large or small number of cases, and you can
6 proceed to develop a rule accordingly on the basis of
7 some empirical experience.

8 CHAIRMAN MALMUD: Thank you, Dr.
9 Williamson. That being the case, it would satisfy the
10 concerns of both Mr. Bailey and Dr. Eggli if we kept
11 the motion as it stood, substituting the word
12 "dosimeter" for "dosimetry" or "badge" and suggested
13 that this be on a case-by-case basis.

14 It would also give the NRC the opportunity
15 to see how many of these cases actually occur
16 nationally, because right now we don't know. And it
17 may be as few as Dr. Sherbini suggests, and,
18 therefore, not terribly burdensome but very
19 informative.

20 So the motion has been moved and seconded.
21 If it's okay with the group, we'll substitute the word
22 "dosimeter" for "badge" or "dosimetry" and recommend
23 that this be on a case-by-case basis, since it is a
24 rather unusual circumstance to the best of our
25 knowledge.

1 All in favor of the motion? Oh, call the
2 motion, excuse me. Oh, Dr. Williamson.

3 MEMBER WILLIAMSON: I'm sorry. I have a
4 question, a point of clarification. I believe your
5 motion is focused exclusively on pregnant women and
6 minor children, and much of the discussion has focused
7 on the general event, which would include adult
8 caregivers. So perhaps you could restate fully the
9 intent of your motion with all the changes.

10 CHAIRMAN MALMUD: In anticipation of the
11 rest of Dr. Sherbini's presentation, which I'm sure
12 includes the subject that you've raised, may I suggest
13 that the motion be inclusive for all caregivers,
14 including pregnant women and minors, and, therefore,
15 an easily understood, clear policy, with no
16 exceptions, which would allow for this unusual
17 circumstance and which we believe all licensees would
18 be able to understand and apply uniformly.

19 With that, is there agreement among the
20 committee that that's how it should stand? Seeing no
21 further discussion, we'll move it forward. All in
22 favor?

23 (Chorus of ayes.)

24 Any opposed?

25 (No response.)

1 Any abstentions?

2 (No response.)

3 It is unanimous. Thank you, Dr. Sherbini.

4 DR. SHERBINI: Thank you, sir. Well,
5 that's it for my presentation.

6 (Laughter.)

7 CHAIRMAN MALMUD: Your presentation was
8 succinct and reached its target. Thank you very much.

9 DR. SHERBINI: Thank you.

10 CHAIRMAN MALMUD: If we may, we'll move on
11 to the next item on the -- oh, excuse me, Mr. Lieto.

12 MEMBER LIETO: Yes. I have, well, more of
13 a general statement in that I have a little bit of a
14 problem saying that we're done here, because I have a
15 real question about whether the RIS is really the way
16 to go about sending out guidance to licensees as
17 opposed to my understanding that the old Reg Guides,
18 which are no longer used, but I guess it's the NUREG
19 is the proper terminology for guidance documents.

20 I think what needs to be developed -- and
21 the draft RIS that we have here is really not a
22 complete guidance document for licensees to follow.
23 And I think as uncommon as these things are going to
24 occur, they're going to go to this Reg Guide and
25 they're going to look for basically a step-by-step

1 procedure or protocol that needs to be followed, what
2 information needs to be provided, and I don't find
3 that as being this type of a document for providing
4 that.

5 I think it's going to generate more
6 questions to the licensee. I think what's here is an
7 excellent, you know, effort, but I don't think it's
8 complete. And as I mentioned also, information
9 statements are, I didn't think, regulatory guidance.
10 I may be wrong, but in looking at the way these --
11 what the definition is for an RIS, that's not what an
12 RIS is defined to do.

13 And so, again, I don't think licensees are
14 going to look for an information statement as a
15 regulatory guidance document.

16 CHAIRMAN MALMUD: Thank you, Mr. Lieto.
17 Are you suggesting that it might be helpful for the
18 NRC staff itself to prepare a one page or less
19 document which says that in those rare exceptions when
20 the limits are to be exceeded the following steps
21 shall be taken -- number one, it is the licensee's
22 responsibility; number two, there should be
23 contemporaneous notification of the regional NRC
24 office of the exception; number three, informed
25 consent will be obtained; number four, discussion with

1 the affected parties will discourage the exposure but
2 not eliminate the exposure for pregnant women and
3 children; number five, that all standard safety
4 precautions for the purposes of reducing radiation
5 exposure will be maintained; and, number six,
6 dosimeter measurements will be obtained, wherever
7 possible, to measure the exposure of the individuals,
8 and that these records will be maintained by the
9 licensee.

10 How does that sound to you? It's brief,
11 it's readable, and it's understandable. At least I
12 believe it's understandable. That was a question to
13 you.

14 MEMBER LIETO: My gut reaction is that
15 it's not going to be a complete enough guidance for
16 licensees in light of what is in this information
17 statement. I think there are some issues about real
18 time monitoring and some other things that I think
19 need to be resolved, because what you're suggesting
20 and what's in this information statement, yours is
21 very succinct and of a brief, general nature, but I
22 think licensees are going to want more along the
23 protocol type of a document to follow in being sure
24 that all the bases are covered, and that they're not
25 incomplete.

1 CHAIRMAN MALMUD: Would you care to give
2 it some thought and come back to us at -- either via
3 e-mail or at a future meeting with some
4 recommendations for what you think would be complete?
5 We've already discussed and moved on the motion, which
6 has been approved. I'm sure the committee would
7 appreciate additional ideas on how to effect this most
8 efficiently.

9 So do you want to give that some thought,
10 and then draft a memo?

11 MR. ESSIG: May I --

12 CHAIRMAN MALMUD: Oh, I'm sorry. Mr.
13 Essig.

14 MR. ESSIG: I might be able to help with
15 Mr. Lieto's concern. The regulatory issue summary is
16 -- as you know, is one of our several different types
17 of generic communications that the NRC has. We have
18 used the RIS as a vehicle for promulgating short-term
19 guidance where it doesn't require a rather detailed
20 discussion. We've done this in several issues related
21 to occupational radiation protection, and so on.

22 The preferred long-term approach would be
23 to fold that document into a more traditional guidance
24 document. In the case of the regulatory program for
25 byproduct materials, the chosen guidance documents are

1 the NUREG 1556 series. And what we could consider as
2 a longer-term solution is taking the guidance from the
3 RIS after maybe some experience with it, deciding
4 whether or not it needed to be amplified or diminished
5 in some way, and then take that experience
6 collectively, sunsetting the RIS and folding it into
7 a NUREG 1556 series, the appropriate one of that
8 serious.

9 So that would be the -- that would be the
10 longer-term solution. But I believe it's consistent
11 with the purpose of the RIS -- and Angela McIntosh is
12 our generic communications coordinator -- and I
13 believe that this would be a legitimate use of a RIS
14 for promulgating the short-term guidance. Getting it
15 into the public domain quickly is the idea.

16 The NUREG 1556, to amend one of those, is
17 a rather significant undertaking. And we have done
18 that, but it involves convening a work group of our
19 regional staff, our headquarters staff, and it's a
20 rather -- a long process to do. And so generally we
21 find ourselves having to be rather picky and choosy
22 which ones we -- which ones we tackle, because of the
23 resources that it consumes to update a 1556 series
24 document.

25 So that would be -- that could be -- so we

1 have a near-term and a long-term approach, and I think
2 the near -- the RIS would be consistent with the near-
3 term approach, and the NUREG 1556 would be a longer
4 term approach.

5 CHAIRMAN MALMUD: Thank you, Mr. Essig.
6 If I understood what you said correctly, what you're
7 saying is this is a new process, let's have some
8 experience with it, see what needs to be altered, if
9 anything, and then refine it further if necessary.

10 MR. ESSIG: Just to clarify, the RIS
11 itself is not a new process. I didn't mean to suggest
12 that. It's just the content of -- this particular
13 subject matter is new, and that we -- it would help us
14 to gain some experience with it, because to -- as Dr.
15 Sherbini noted, we really don't know how many of these
16 are occurring per year.

17 I mean, one could argue that, well, we had
18 the one in 2002, and to our knowledge that has been
19 the only one. But as members have pointed out, there
20 are probably others that have not come to our
21 attention that have been occurring, nonetheless. So
22 we don't know the true volume of these.

23 CHAIRMAN MALMUD: Thank you.

24 I think Dr. Williamson had another
25 comment, then Mr. Bailey. Dr. Williamson?

1 MEMBER WILLIAMSON: Yes. I just wanted to
2 comment that by supporting Dr. Malmud's proposal I am
3 advocating that these six different points be
4 included, you know, as kind of deliverables of the
5 report, or as conditions that it must meet. I do not
6 accept what I understood his contention to be, that
7 his statement he just made, this very short, brief,
8 terse statement can replace the entire RIS.

9 I do believe that there is a value served
10 by describing more fully the basis of the situation
11 and a lot of the details. So I am more in agreement
12 with Mr. Lieto on that point.

13 CHAIRMAN MALMUD: I would only state that
14 my terse summary was not meant to substitute for the
15 RIS, but simply to explain the process.

16 And I think Mr. Bailey was next.

17 MEMBER BAILEY: My concern right now is
18 how this document and this process will impact on the
19 agreement states and the 80 percent of radioactive
20 materials licensees in the United States. Whereas
21 this may work well for guidance for NRC, I think this
22 issue needs to be brought up to the agreement states
23 to get some concept, because some states -- I just ran
24 into a state -- in order to grant an exemption, they
25 have to demonstrate that the practice will result in

1 lower radiation exposure than the regulation itself,
2 which this certainly would not do.

3 And other states -- for instance, I would
4 say I know at least one state where if you wrote to
5 the Director and said, "Hey, I want to do this," and
6 just said, "Hey, I've got this patient," that would be
7 enough. So I really think this needs to be brought up
8 to those -- to the agreement states and get some input
9 on how this is going to impact them or not.

10 CHAIRMAN MALMUD: Mr. Essig?

11 MR. ESSIG: I agree with Mr. Bailey. And,
12 in fact, we have done that. It has probably been two
13 years ago now when the subject was broached during a
14 routine monthly call with the agreement states, and
15 those states who spoke out in favor of -- or that --
16 after understanding the situation, the approach that
17 we are proposing -- I don't know that we had a RIS in
18 mind even at that -- at that point, but we were
19 thinking in terms of guidance versus rule, those two
20 extremes.

21 And those who spoke out -- and they were
22 rather vocal during that call -- favored the guidance
23 approach and, hence, not the rulemaking approach.
24 When we undertake a rulemaking, of course, we have to
25 be cognizant of what the potential volume is going to

1 be of -- and if we don't see -- although the
2 individual issue may have some significance, if the
3 frequency is so low that -- you know, if we're talking
4 less than five per year, then it's -- in many respects
5 it's kind of hard to justify a rulemaking, and that's
6 why we proceed with an exemption to an existing rule.

7 And so I think we can maybe resurface the
8 idea to the monthly call with the agreement states.
9 A couple years ago when we did that the view was that
10 it should be in the form of guidance rather than a
11 rule.

12 CHAIRMAN MALMUD: Thank you, Mr. Essig.

13 May we move on to the next item on the
14 agenda, which is the rulemaking agenda. Mr. Lieto?

15 MEMBER LIETO: Well, you had made -- posed
16 a question or a charge to me about coming back to the
17 committee.

18 CHAIRMAN MALMUD: And Mr. Essig said that
19 his staff would assist you with the process.

20 MEMBER LIETO: Okay. I was going to just
21 say, to close us out, and maybe working with Dr.
22 Sherbini on what has been done so far to come up with
23 something in a precise manner.

24 CHAIRMAN MALMUD: Thank you very much.

25 And thank yo, again, Dr. Sherbini. Never

1 has so much been accomplished with one slide.

2 (Laughter.)

3 The next item on the item is the NARM
4 rulemaking, and Lydia Chang of the NRC Commission will
5 be the presenter.

6 MS. CHANG: Thank you. Again, my name is
7 Lydia Chang. I'm with the Rulemaking Guidance Branch
8 within the NMSS office.

9 Today I just want to an overview of the
10 NARM rulemaking effort. First, I will briefly
11 describe the Energy Policy Act, talk about the waiver
12 that we have published last year, the rulemaking
13 approach, the strategy, our current schedule, and give
14 you an overall summary of the rule and the
15 implementation consideration, and the next step.

16 As you know, the Energy Policy Act of 2005
17 was signed into law on August 8. Within Section
18 651(e) of the Energy Policy Act, it amends the
19 definition of the byproduct material. It also amends
20 the Section 274(b) of the agreement provision of the
21 Act to include such material with an agreement that
22 NRC might decide to enter with the states.

23 It also amends Section 81 of the AEA
24 regarding the disposal of the newly-added byproduct
25 material. It does requite NRC to issue a final

1 regulation within 18 months, which is extremely
2 aggressive. It also allows NRC to grant a time limit
3 waiver.

4 Within the Act, the definition of
5 "byproduct material" is amended to include certain
6 discrete sources of radium-226, and also material made
7 radioactive by use of the particle accelerator such as
8 accelerator-produced radioactive material and any
9 other discrete sources of naturally-occurring
10 radioactive material other than source material that
11 we determine to pose similar threat in radium.

12 As part of the working group, we did not
13 find any such isotopes within the NARM that will be
14 included in the last bullet of that byproduct
15 material. So today's talk will only be focused on
16 radium-226 and also the accelerator-produced
17 radioactive material.

18 The Act also limits the material to only
19 for material produced for commercial, medical, and
20 research activity. So we did not have the whole gamut
21 of NARM. It's still limited somewhat.

22 The Energy Policy Act allows the
23 Commission to grant the waivers, because the Act does
24 not want the new regulation to impact industry
25 immediately. So, therefore, on August 31st NRC did

1 publish a waiver, and I have placed a citation over
2 here.

3 The waiver allows the persons engaged in
4 activity involving NARM to continue with the activity,
5 and also allows the states to continue to regulate the
6 NARM material. As you know, quite a few agreement
7 states already have regulations on their book to
8 regulate such material.

9 The waiver is effective through August 7,
10 2006, for import and export. However, the waiver is
11 effective until August 7, 2009, for other activities
12 related to NARM. NRC may terminate the waiver sooner
13 if it is deemed necessary.

14 Our rulemaking approach is to try to get
15 the other regulators, the agreement states and non-
16 agreement states, early into the process, so we did
17 form a NARM rulemaking working group to working
18 alongside with agreement states to come up with
19 regulations. We also involved various offices from
20 the headquarters, including the state programs,
21 enforcement, OGC. We also involved regional people,
22 so that they can give us the perspective from their
23 day-to-day operations.

24 And, of course, we included quite a few
25 states within our working group. From the states we

1 have representatives from the State of Oregon, Texas,
2 Florida, and a non-agreement state, Michigan. We also
3 include a state representative in our Steering
4 Committee, so, therefore, all the decisions were made
5 with the agreement states.

6 We also try to get the stakeholder
7 involved within the whole process. We had a public
8 meeting in November of last year. We also met with
9 individual federal agencies, including FDA, EPA, NRC
10 -- I mean, EPA and DOE, Department of Homeland
11 Security, and a whole bunch of other folks, to try to
12 understand their concerns.

13 We also included background documentation
14 within our rulemaking website, at least keeping -- to
15 keep the public informed about the rulemaking process.
16 As I said, we had a roundtable public meeting back in
17 November of last year, and here is just a summary.
18 Ralph and Sally both attended the meeting, so they
19 could probably share a lot more with you guys than I.

20 Here is the citation for the rulemaking
21 website we created back in November of last year, and
22 we also published availability notification. Right
23 now, the address is -- it's kind of unique, since it
24 has not been published in the Federal Register. Right
25 now, it's filed under the other rulemaking manual.

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1 Once it's published, then it will be filed under the
2 proposed rule manual.

3 Again, the Energy Policy Act requires NRC
4 to come up with the final rule within 18 months. It
5 does require NRC to consult with the states, and also
6 other stakeholders. They do want us to cooperate with
7 the states and use the model state standards to the
8 maximum extent practicable, and consider their
9 potential impact on the availability of
10 radiopharmaceuticals to physicians and patients.

11 In doing so, our strategy is to try to
12 minimize adding new stuff. In our opinion, the
13 accelerator-produced radionuclides are very similar to
14 reactor-produced radionuclides. Therefore, they
15 should be treated very similar to our existing
16 regulatory framework. So that's our starting point.

17 We also look at the suggested state
18 regulation, which is developed by CRCPD, which also
19 includes NARM and other types of radioactive material.
20 So we try to use that as the standard, since, you
21 know, we do have 50 states, and the regulation might
22 vary form state to state. But SSR does provide a very
23 good, concise, and consolidated state position on NARM
24 rulemaking, so we use that as our second thing to
25 supplement the things that we don't have in our

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1 existing regulation.

2 Since NRC has never regulated cyclotron
3 before, we also kept in mind that Energy Policy Act
4 does limit NRC authority to radionuclides produced for
5 medical, commercial, and research activity.

6 We kind of evaluated, how should we
7 regulate the material that is produced from
8 accelerator, and we actually proposed to the
9 Commission that we should regulate all materials, both
10 intentionally produced and not intentionally produced,
11 such as activated material, only from the accelerators
12 that is designed to produce radioactive material for
13 medical, commercial, and research activities.

14 If the accelerator does not produce
15 material for its intentional purpose, then we do not
16 wish to regulate them. An example of those kind of
17 accelerators are linacs for radiation treatment, so
18 that's -- that's like a very big decision that we have
19 made early on and proposed to our Commission.

20 We also added some minor provisions to
21 supplement the SSRs. We developed a specific
22 requirement for radium-226. It has not -- we
23 understand there is a lot of different kind of
24 material out there that contains radium sources, but
25 there are really no structured approach on how to

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1 regulate them. So we did propose some approach for
2 that.

3 We provide certain grandfather provisions
4 for certain products, and also certain individuals.
5 We also try to recognize FDA's and state programs, so
6 we don't have to reinvent the wheel. We also try to
7 increase inflexibilities within the regulation, so
8 that we would minimize the impact on
9 radiopharmaceutical industries.

10 The current status -- on January 3rd, we
11 sent a draft proposed rule to both the states and
12 ACMUI for an advance review. We did receive comments
13 from them, and was considered and incorporated into
14 the current draft that was forwarded to the Commission
15 March 27th. And we've issued a SECY paper.

16 We did make the draft document available
17 to the public, even though the Commission has not
18 voted on it, and the provisions might change based on
19 the Commission's decision. But we do want to make it
20 available to the public, so that it can take a look,
21 and also to allow extra time.

22 The final rule is required by the statute
23 to be published on February 7, 2007.

24 Right now, I'm just going to summarize the
25 type of changes we have included in the proposed rule.

1 We amended the definition, such as authorized nuclear
2 pharmacist -- I forgot to the bring the byproduct --
3 oh, there is the byproduct material. That was a big
4 one, you know, change the definition of byproduct
5 material. But I just noticed I put it in alphabetical
6 list instead, so we did redefine authorized user,
7 authorized nuclear pharmacist, byproduct material,
8 low-level radioactive waste, and waste.

9 We also added similar definitions within
10 the regulations. A couple of them is actually direct
11 adaption from the SSRs.

12 We also come up with a new definition of
13 discrete source, as required by the EP -- Energy
14 Policy Act. We kind of struggled with the definition
15 quite a bit, and it has gone through several
16 iterations during the drafting of such definition. I
17 guess our primary purpose is that we only want to
18 regulate material that's only designed for medical,
19 commercial, and research activities.

20 And we also do not want to regulate
21 diffused material. So in -- you know, when you put
22 those two concepts in mind, this is a definition that
23 we, along with several federal agencies, has come up
24 with.

25 We have defined a source -- a source with

1 physical properties which is separate and distinct
2 from radiation present in nature, and in which the
3 radionuclide concentration has been increased by human
4 process with the intent that the concentrated material
5 will be used for its radiological property.

6 I guess the last two words are extremely
7 important for the intent to use for radiological
8 properties, because we do not wish to regulate T-
9 norms, such as fertilizers or fly ash, from power
10 generation -- from powerplants of such.

11 Some of the general provisions we
12 recognized during general licenses -- a lot of those
13 general licenses are already within the regulations,
14 so we are basically adding radium to certain
15 provisions within that, and also adding cobalt. We
16 added non-radionuclides to the existing provision. In
17 Schedule B, we added 13 radionuclides and have listed
18 over here.

19 We also added radium to Schedule C, which
20 is the emergency plan requirement. I very much doubt
21 that it would have any impact on the medical
22 community.

23 As for the radium source, we are proposing
24 to have a general license approach. Since we are not
25 certain of how -- how much material is out there and

1 what type of material, and the concentration of the
2 radium within those materials, we are trying to do
3 something like a graded approach.

4 Right now, we are proposing to use a
5 general license for certain antiques, luminescence
6 items that's stored in aircraft. And then, we put
7 some kind of numerical numbers for less than 100 items
8 that's not stored in aircraft, or 50 luminescence
9 items that's not stored in timepieces, and other
10 products containing radionuclides less than one
11 microcurie.

12 And the reason that we want to use this
13 general license approach in exemptions is because it
14 still provides certain protection. It does require
15 that -- the licensee to notify NRC for possible
16 damages. It does require the -- it does require the
17 licensee to dispose of it accordingly, and also
18 prohibit any abandonment or export of such material.

19 And whenever we need information in a
20 written request, they need to respond to us, so that
21 we can address the general license more appropriately
22 in the future.

23 As for the medical use, in our opinion,
24 the non-PET radionuclide drugs -- it's really no
25 different than radionuclides produced in reactors.

1 Therefore, there are no rule text change that's
2 needed. For PET radionuclides, we only make some
3 minor changes in Part 32 and Part 35. We do want to
4 recognize FDA registration -- the register of the PET
5 facilities by FDA or the states.

6 We are allowing non-commercial
7 distribution between medical use, which is -- to us
8 which is kind of important, because that would
9 actually minimize the impact from radiopharmaceutical
10 to be available to patients and to physicians.

11 And we are going to regulate all
12 radionuclides production operations under Part 30 as
13 possession and under Part 32 as distribution. We are
14 including grandfather provisions for certain
15 individuals, so that any authorized user that -- any
16 authorized users that are currently recognized by the
17 agreement state will continue to be recognized.

18 Some of the implementation strategy that
19 we have proposed within the draft rule is to allow 60-
20 day effective day from the publication of the final
21 rule for federal facilities. For other individuals,
22 since the waiver will still be in effect, the
23 effective date will be depending on when the waiver
24 terminated.

25 We are including special provisions that

1 has never been included in the past. In the past, NRC
2 has used enforcement discretions. But for this
3 situation, since we believe that a lot of individuals
4 already have the NARM material in hand, we want to
5 allow them to have specific authority to continue to
6 use material, provided that they continue to use the
7 material safely and comply with other regulations. So
8 we did make a special provision in that aspect.

9 We are requiring the licensee to submit
10 amendments if they already have the NARM material, to
11 submit within six months from the effective day, or
12 within six months from the day of the waiver
13 termination. For any new license applications, such
14 as cyclotron production operations, we want them to
15 submit new license application within a year from the
16 effective day, or within a year from the waiver
17 termination.

18 NRC does plan to terminate the waiver
19 sooner. Once we publish a final rule, we will
20 terminate the waiver for federal facilities and Indian
21 tribes. And then, agreement state termination will
22 depend on when the agreement is updated and when the
23 agreement states submit their certification.

24 For non-agreement states, we are planning
25 to do probably in three batches, depending on the

1 state's intent to enter into agreement, or whether the
2 state has any NARM regulations or not. We are
3 planning to publish all those -- I mean, publish all
4 those in the Federal Register.

5 The transition plan is required within
6 Energy Policy Act, so NRC is -- it's preparing the
7 transition plan right now, and the transition plan --
8 is planning to publish the plan sometimes I guess
9 early next year when the final rule is proposed.

10 Again, the waiver will be terminated in
11 stages, and it will be elaborated within the
12 transition plan, and it will also be published in the
13 Federal Register.

14 The waiver -- if we do not terminate the
15 waiver earlier, then the waiver will automatically
16 expire on August 7, 2009.

17 The next step -- the Commission paper was
18 submitted to the Commission late March, so it's
19 waiting for the Commission to make a decision. I
20 understand that the Commission is planning to have a
21 Commission briefing on May 15th, so perhaps a decision
22 would not be made until after the Commission briefing.

23 Once the Commission gives us directions,
24 then we will revise the proposed rule, and then
25 publish in the Federal Register for 45 comment period.

1 And we are planning to have a public meeting during
2 the public comment period.

3 That concludes my presentation.

4 CHAIRMAN MALMUD: Thank you, Ms. Chang.
5 Are there -- that was great information. Are there
6 any questions or comments? Dr. Williamson.

7 MEMBER WILLIAMSON: Could you please
8 explain the second-to-the-last bullet on slide 4.
9 Produced, extracted, or converted after extraction,
10 before, on, or after August 8, 2005.

11 (Laughter.)

12 I'm having some -- I'm sure it means
13 something, but I'm having --

14 MS. CHANG: Right.

15 MEMBER WILLIAMSON: -- difficulty
16 inferring the intent.

17 MS. CHANG: Right. Actually, this is the
18 language directly from the Energy Policy Act. The
19 Congress' intent is to regulate all materials,
20 regardless when it's produced. And the reason we
21 include the word "on" -- I mean, "before, on, or
22 after" is basically for legal purposes, so that we can
23 regulate them. It's all materials.

24 CHAIRMAN MALMUD: Thank you.

25 Any other questions or comments?

1 MEMBER NAG: Yes.

2 CHAIRMAN MALMUD: Dr. Nag.

3 MEMBER NAG: Yes. I think I might be very
4 stupid, but overall I felt this document really hard
5 to understand. The language is such that it is very
6 hard for me to follow and understand. But maybe
7 that's because I'm very stupid.

8 CHAIRMAN MALMUD: I speak for the
9 committee when I assure you that you are not stupid,
10 and the document is difficult but not impossible. And
11 it is a bit bureaucratic; however, it is addressing a
12 number of regulatory issues which we as physicians
13 might regard as being bureaucratic from our clinical
14 perspective, but it is a document which explains
15 things in detail, perhaps too excess but in detail.

16 But let me assure you that we all have a
17 sense of frustration in tackling a document like this.
18 And we do not challenge your intellect.

19 MS. CHANG: Let me just try to elaborate.
20 Actually, the Federal Register -- it is somewhat
21 cumbersome to review because of the structure. It's
22 a rulemaking process. So the structure of the Federal
23 Register, usually we have a lot of supplemental
24 information that describes all the issues that we have
25 contemplated, and how we come to the proposal.

1 And then, there's also a whole bunch of
2 boilerplate language that's required by other
3 statutory requirements, and then we have the rule text
4 change. So I would suggest if you want to have better
5 understanding of the document, you might want to start
6 with the Commission paper, because that's more, you
7 know, written for average people to understand. And
8 it doesn't have all those legalese stuff, and doesn't
9 have all those rule text type of language.

10 And another thing I would suggest is to
11 just go back -- go to the back of the Federal Register
12 where have all the rule text change proposal, just
13 focus on Part 35 portion. That will probably help you
14 to understand what type of changes that we are
15 recommending.

16 CHAIRMAN MALMUD: Dr. Diamond.

17 MEMBER DIAMOND: Yes. From the medical
18 perspective, the greatest impact, of course, will be
19 on PET radionuclides. So looking at slide number 15,
20 when you're discussing the -- when you're adding the
21 13 NARM radionuclides to Schedule B, exempt
22 quantities, can you -- since I don't have Schedule B
23 in front of me, can you give us a sense of what these
24 exempt quantities are, how they will impact upon the
25 clinical use of PET, and what about the nuclides that

1 you do not list on that slide which are also routinely
2 used for PET imaging?

3 MS. CHANG: Yes. Actually, the 13 NARM
4 radionuclides was added based on SSRs. As you know,
5 with, you know, a year and a half of statutory
6 timeline to come up with the final rule is extremely
7 difficult. The Schedule B table, it's actually for
8 exempt quantities. It lists the concentration below
9 which -- I don't know, I think I might need other
10 people to help me with that.

11 Donna-Beth might be able to help you
12 elaborate, you know, the specific radionuclides exempt
13 quantities.

14 CHAIRMAN MALMUD: Dr. Howe, I see you
15 walking up to the microphone. We would appreciate
16 your input as well.

17 Thank you.

18 DR. HOWE: I think one of the points that
19 you have to keep in mind is that for exempt quantities
20 and exempt concentrations, these materials are not
21 allowed to be used on human beings. They're not
22 allowed to be put into products that are ingested, put
23 on people, or in any cosmetics or other products.

24 So the exempt quantities and exempt
25 concentrations are outside of the medical arena as far

1 as your patient treatment goes. They are quantities
2 that you may be able to use for laboratory-type tests
3 or for quantification of materials.

4 MEMBER DIAMOND: So if I understand you
5 correctly, Donna-Beth, this particular bullet point
6 does not have any applicability to the routine
7 clinical use of PET radionuclides, nor to the use of
8 PET nuclides that are currently being studied in
9 humans for new diagnostic or therapeutic purposes.

10 DR. HOWE: That's correct. Part 35 is the
11 only section in which you can use radioactive
12 materials on or in human beings. And the Part 35
13 already has regulations that permit research for
14 medical use licensees, and that would be 35.6. And
15 that just requires informed consent and institutional
16 review board reviews. Or if you are under research
17 that is already approved or funded by another federal
18 agency, then that federal agency's requirements come
19 in.

20 CHAIRMAN MALMUD: Thank you for clarifying
21 that, Dr. Howe.

22 Are there other questions or comments?
23 Dr. Williamson?

24 MEMBER WILLIAMSON: Well, it's just a very
25 narrow technical question on slide 17. It says non-

1 PET radionuclides in drugs, no rule changes needed.
2 So there is no non-reactor byproduct material that
3 requires special mention in Tables B or C or anything
4 like that? I'm quite surprised at the conclusion,
5 although I'm not a nuclear engineer.

6 DR. HOWE: What we found was that our
7 current regulations are written in such a way that for
8 -- especially for medical use. Just redefining the
9 material as byproduct was all that was needed for the
10 regulations themselves. We did think that the PET
11 production, the PET radionuclides, were a special
12 feature, and so we did add some things to allow for
13 non-commercial distribution of PET radionuclides
14 between medical use licensees.

15 But for the most part, the regulations, as
16 they stand, adding the new material into the
17 definition of "byproduct," there was no need to change
18 the words.

19 CHAIRMAN MALMUD: Thank you, Dr. Howe.

20 Dr. Van Decker.

21 MEMBER VAN DECKER: Thank you, Dr. Malmud.

22 I can assure you, Dr. Nag, that having
23 grown up in north Jersey my ability sometimes to
24 understand language is much worse than anyone else's.

25 (Laughter.)

1 Just a couple of questions. This public
2 meeting I assume, therefore, is going to occur within
3 the next month. Is that kind of --

4 MS. CHANG: It all depends on when the
5 Commission approves the publication of the proposed
6 rule. Once the proposal is published --

7 MEMBER VAN DECKER: So hopefully fairly
8 soon. I was just getting a sense for that. Okay.

9 MS. CHANG: Yes. Once it's published,
10 then we will put out announcements.

11 MEMBER VAN DECKER: Okay. The second
12 question: can you elaborate a little bit for me on
13 the last bullet on slide 17, what that summary was
14 meant to mean?

15 MS. CHANG: Okay. That means any
16 authorized users within agreement state or non-
17 agreement state that's currently only using the NARM
18 material and no other non-NARM material under NRC
19 jurisdiction, which means that we have not been
20 involved in the past. We do want to recognize these
21 individuals, so that they will continue to be
22 authorized users.

23 MEMBER VAN DECKER: Oh, okay.

24 MS. CHANG: Does that make sense?

25 MEMBER VAN DECKER: Actually, yes.

1 (Laughter.)

2 MS. CHANG: Okay. Good.

3 CHAIRMAN MALMUD: Thank you.

4 Dr. Diamond.

5 MEMBER DIAMOND: That was my question.

6 Thank you.

7 CHAIRMAN MALMUD: Dr. Diamond's question
8 was the same as Dr. Van Decker's. Both have been
9 adequately answered by Ms. Chang.

10 Mr. Lieto.

11 MEMBER LIETO: I have a sort of more
12 general question in terms of the whole rulemaking.
13 Are things pretty much on schedule as far as staff was
14 planning with this rulemaking process? And if the
15 rule -- if the Commission delays or, I mean, I should
16 say if they publish it when you expect them to, is
17 that still going to -- is that going to keep things on
18 your timetable? And if not, are there any plans to
19 address possibly not meeting this 18-month timeline?

20 MS. CHANG: Based on our preliminary
21 schedule that was shared with the public back in
22 November, we were hoping that we can publish the
23 proposed rule by the end of this month. Of course,
24 the Commission has not made any decision, so that
25 doesn't look likely. Therefore, there is some

1 schedule slippage.

2 Right now, we have not evaluated whether
3 that will impact our final publication of the final
4 rule. Once we make that determination, it's most
5 likely that we will ask the Commission for an
6 extension.

7 CHAIRMAN MALMUD: Thank you.

8 Dr. Miller.

9 DR. MILLER: Yes. I'd also like to point
10 out that the Commission has scheduled a meeting with
11 various stakeholders on the Energy Policy Act,
12 scheduled for the 15th of May. I don't know if the
13 Commission will vote on the proposed rule prior to
14 that meeting or not. But as Lydia has pointed out,
15 once the Commission has voted, then we'll have a
16 better perspective on whether or not we can meet the
17 date.

18 We've been trying to march as hard as we
19 can to try to meet the date. They put in a plug for
20 the team that did this. They worked many, many long
21 hours. There were periods where they were in here on
22 weekends until 3:00 or 4:00 in the morning trying to
23 meet these deadlines. It was an extremely ambitious
24 schedule.

25 We had to work very closely with the

1 agreement states, because obviously the agreement
2 states and the non-agreement states have been
3 regulating this material for a long time. We have
4 not, so their insights are extremely important.

5 So we're doing the best we can, Ralph, and
6 we'll have a better handle on it once the Commission
7 has ruled on the proposed rule.

8 CHAIRMAN MALMUD: Thank you, Dr. Miller.

9 The next comment is that of Dr. Vetter,
10 and then a member of the public. Dr. Vetter.

11 MEMBER VETTER: A question. Is it safe to
12 assume that for medical use purposes that this new
13 regulation has minimal or no impact on agreement
14 states?

15 MS. CHANG: That's correct. That's a fair
16 assumption, since agreement states are already
17 regulating NARM material right now.

18 CHAIRMAN MALMUD: We have a member of the
19 public. Would you please introduce yourself before
20 your question or comment? Thank you.

21 MS. FAIROBENT: Yes. Lynne Fairobent with
22 the American Association of Physicists and Medicine.
23 I'm very confused over slide 18. On slide 18, the
24 first thing it says is that there is an effective date
25 of the rule 60 days from the date of publication.

1 That I understand.

2 Then, it says that license amendments or
3 new applications don't need to be submitted until an
4 additional six months or a year after that effective
5 date. Isn't that, in fact, the effective date? This
6 wording is just very different than I've seen from any
7 regulation. I mean, is what you're saying that a
8 license amendment basically would be, let's see, eight
9 months from the date of publication, which would be
10 the effective date for the license amendment?

11 I guess I'm confused over what happens
12 between the effective date and that first six-month
13 period, if you need a license amendment and the
14 effective date and a year later. I've just not seen
15 the wording like this before for effective dates and
16 publication dates. I wonder if you could clarify.

17 MS. CHANG: Sure. If you can think about
18 different individuals in different states, agreement
19 states and non-agreement states, and also federal
20 facilities, we are trying to impose different kinds of
21 dates on different group of people, regardless -- I
22 mean, based on the waiver.

23 You kind of have to separate the effective
24 day. The effective day and the waiver are kind of
25 related to each other. We have an effective day, but

1 the waiver is still in effect. Therefore, the
2 effective day means nothing.

3 DR. HOWE: Lynne, let me try to clarify a
4 little bit. This is a very unique rule in which we
5 have material that is already being used safely and
6 under regulations by many different people out there
7 in agreement states and non-agreement states. One
8 thing we didn't want to do was to stop the use of that
9 material.

10 So we did something very interesting. We
11 put an authorization in the regulations that permits
12 people to continue to use the material, but holds them
13 responsible to meeting all of the requirements in 19,
14 20, 30, all the appropriate parts of the regulation
15 that would apply to this new byproduct material,
16 provided that they, if they need to, submit an
17 amendment request within six months, if they already
18 have an NRC license; or, if they don't have an NRC
19 license, then submit a new application within a year.

20 So the intent is to bridge that period of
21 time in which people would need to get an official
22 document from the NRC. We are holding them
23 responsible for the regulations, i.e. reporting
24 requirements, reporting medical events, reporting
25 overexposures, reporting loss of material, during that

1 timeframe, but we're not going to hold them and issue
2 them citations for not having a license at that point.

3 MS. FAIROBENT: My point is I know what I
4 think the intent was. I don't think it's written
5 clearly enough. And if I am a licensee with a PET
6 facility in the State of Missouri, I have no clue what
7 date I need to submit my brand-new license application
8 to NRC. It appears to me that it's one year plus 60
9 days from the date of publication.

10 I think it would be easier to state it in
11 that manner than to say one year from the effective
12 date, which is 60 days from the date of publication.
13 It may be actually easier to follow when there are
14 actually calendar dates in there, but I think it's
15 very unclear to the licensees or potential licensees
16 at this point as it's written.

17 MS. CHANG: Yes. Actually, once the final
18 rule is published, it would actually have the actual
19 day within the Federal Register, and also within the
20 regulation.

21 CHAIRMAN MALMUD: So, Lydia, are you
22 saying that once it's published, then the final date
23 will be known.

24 MS. CHANG: Right. The Federal Register
25 will automatically insert the dates.

1 CHAIRMAN MALMUD: So the ambiguity will be
2 gone at that point.

3 MS. CHANG: Right.

4 CHAIRMAN MALMUD: Thank you.

5 Is that helpful?

6 MS. FAIROBENT: We'll see.

7 (Laughter.)

8 CHAIRMAN MALMUD: Thank you.

9 Dr. Suleiman.

10 MEMBER SULEIMAN: Just a question, some
11 numbers. Do you have any idea, or do you have an
12 estimate of how many facilities are going to require
13 a new license? That is, those facilities that are
14 probably currently under non -- or not within
15 agreement states that have PET facilities.

16 DR. HOWE: We did some estimates to try to
17 come up with burden for OMB and for regulatory
18 purposes. We think maybe about five percent of the
19 current number of licensees that we have might be a
20 ballpark number for new individuals who will need
21 licenses.

22 We think most people that are licensed,
23 either in NRC states or in agreement states, are
24 already using radioactive material, and, therefore,
25 already have a license. But there might be some

1 people that are, for one reason or another, only using
2 this material and are not licensed at this point.

3 MEMBER SULEIMAN: So five percent is what
4 absolute number?

5 DR. HOWE: We have about 4,000 NRC
6 licensees, and so five percent of that. It's not a
7 very large number.

8 CHAIRMAN MALMUD: Dr. Miller.

9 DR. MILLER: If I can further complicate
10 matters, there's another aspect of this also in that
11 non-agreement states who are currently regulating it
12 may be pushed with this regulation to finally come in
13 and want to become an agreement state. We've got so
14 indication from a couple of states.

15 So along with this, we would also have a
16 possibility of a non-agreement state applying for
17 agreement state status, having that review take place,
18 and if that review were completed prior to the -- you
19 know, the expiration of the waivers, well, then, they
20 wouldn't need an NRC license. They would simply come
21 under the new agreement state agreement.

22 CHAIRMAN MALMUD: Thank you.

23 Are there other comments? Mr. Bailey.

24 MEMBER BAILEY: Lydia, just for
25 clarification, if you had a stand-alone PET facility

1 operating now -- and we'll use Missouri since it seems
2 to be the state of choice today -- who does not
3 currently have an NRC license, under the suggested --
4 or under the proposed regulations, regardless of
5 whether or not the practicing physician, RSO,
6 pharmacist, met the requirements in the regs for
7 byproduct material, they would be deemed to be
8 qualified under the new license?

9 MS. CHANG: They would need to apply for
10 a new license for the production, but individuals were
11 deemed qualified, yes.

12 MEMBER BAILEY: Yes.

13 MS. CHANG: Am I correct, Donna-Beth?

14 DR. HOWE: That's part of our
15 grandfathering process. We are adding to the
16 definitions of authorized user and authorized nuclear
17 pharmacist, that if you were a physician who was using
18 only NARM material then you would be considered --
19 during the effective date of the waiver, then you
20 would be considered an authorized user or an
21 authorized nuclear pharmacist. And so that would
22 cover over for the commercial PET centers also.

23 CHAIRMAN MALMUD: Mr. Bailey has a
24 followup.

25 MEMBER BAILEY: Yes. You said NARM

1 material, but if there is one of those people out
2 there that's still using radium-226, they would also
3 be grandfathered to continue using radium-226?

4 DR. HOWE: That's correct.

5 CHAIRMAN MALMUD: Thank you. And now we
6 know why Missouri is called the Show Me State.

7 (Laughter.)

8 Dr. Schwarz.

9 MEMBER SCHWARZ: Since I am the individual
10 that comes from the State of Missouri, it is a
11 wonderful state. But, for example, which is a real
12 example, we are a broad scope license. We have a PET
13 production facility, and now we'll have to apply, I'm
14 assuming, for a license.

15 Do you know exactly what will be involved
16 in terms of submission of this license for the PET
17 facility? We have three cyclotrons, to add to the
18 problem.

19 DR. HOWE: If your PET facility is in the
20 business of commercial distribution, then --

21 MEMBER SCHWARZ: It is not.

22 DR. HOWE: It is, then, for non-commercial
23 distribution?

24 MEMBER SCHWARZ: That's correct.

25 DR. HOWE: Then, we are permitting non-

1 commercial distribution under Part 30 and Part 35, if
2 you don't need a 32 license. And so it would -- it
3 would be simply adding the radiation safety program
4 that would be associated with that PET production
5 facility to your license.

6 MEMBER SCHWARZ: And if we then --

7 MS. CHANG: They don't have a license,
8 because they are non-agreements.

9 DR. HOWE: Well, her facility has an NRC
10 license. And so you would just amend your -- so you
11 would be going for an amendment.

12 MEMBER SCHWARZ: Just an amendment.

13 CHAIRMAN MALMUD: Does that clarify the
14 issue for you, Dr. Schwarz?

15 MEMBER SCHWARZ: And then, if we were to
16 become a distributor, we would need an additional
17 license, Part 30.

18 DR. HOWE: That's correct. You would need
19 a 3272 medical distribution license.

20 CHAIRMAN MALMUD: Thank you, Dr. Howe, for
21 clarifying that for Dr. Schwarz.

22 There's another comment from a member of
23 the public. Would you please introduce yourself
24 before your comment?

25 MR. BROWN: Roy Brown with CORAR. I'm not

1 sure I really understand the answers here, because the
2 question posed by Ed Bailey really said -- let's take
3 Missouri. That's a great example. In Missouri, now
4 I can operate a PET facility with a cyclotron
5 distributed commercially without an NRC license, and
6 without a state license, because the State of Missouri
7 register does not list -- does not issue a license.

8 So if I have -- I really don't have an
9 authorized user now that's approved on a license. I
10 have what I consider an authorized user, but it's not
11 on a license. So would they still be grandfathered?

12 DR. HOWE: What we've done is we've
13 revised the definition for an authorized user. Now,
14 in this particular case, you're talking about a
15 pharmacy. And so the authorized user is really the
16 authorized nuclear pharmacist.

17 MR. BROWN: Well, yes, but since they
18 don't have an NRC license and don't have a State of
19 Missouri license, they --

20 DR. HOWE: Right.

21 MR. BROWN: Yes, they're qualified, but
22 they're not on a license.

23 DR. HOWE: If you are talking an
24 authorized nuclear -- a nuclear pharmacist, then we
25 have written into our grandfathering procedures, if

1 you are a nuclear pharmacist and you are dealing only
2 with the material that are now under the byproduct,
3 that you would be grandfathered, and you would be
4 considered.

5 And the licensee, just as when we
6 developed the nuclear pharmacy rule back in 1994, we
7 allowed pharmacies to designate their own authorized
8 nuclear pharmacist if they met certain grandfathering
9 criteria. We've added that into 3272.

10 MR. BROWN: No, that's wonderful. I
11 really, really like the grandfathering. I just
12 thought you had to be tied to a license to take
13 advantage of it.

14 DR. HOWE: No, you do not.

15 MR. BROWN: Okay. Great. Thank you.

16 MS. CHANG: And I guess one clarification
17 is that for the authorized user we're allowing them to
18 use notification instead of license amendment as part
19 of the grandfather approach.

20 DR. HOWE: Yes, and there is also the
21 notification provision for the authorized nuclear
22 pharmacist that meets the criteria.

23 Now, I'm not sure how Missouri -- we'll
24 address it in Missouri, because we do have -- for
25 commercial distribution you have to be registered with

1 FDA, whatever that means, or you have to be registered
2 with the state. And so I don't know if the states
3 register the PET facilities as pharmaceutical
4 production facilities or not. So we may have to do
5 some tweaking on that part.

6 CHAIRMAN MALMUD: Thank you, Dr. Howe.

7 I will turn the podium over to -- oh,
8 excuse me. Dr. Schwarz?

9 MEMBER SCHWARZ: In the State of Missouri,
10 I believe that the nuclear pharmacies are all
11 registered as pharmacies in the State of Missouri. So
12 that would be the traditional nuclear pharmacies. The
13 PET facilities are managed in several different --
14 well, two different ways. One is, as a nuclear
15 pharmacy, they are authorized or registered as a state
16 pharmacy, or they're registered as manufacturers which
17 distribute to a nuclear pharmacy.

18 DR. HOWE: I think at this point we've got
19 flexible enough wording in 3272 to capture both of
20 those, but we'll look carefully.

21 CHAIRMAN MALMUD: Thank you.

22 Are there other comments? If not, I will
23 turn the podium back to Mr. Essig for a moment, who
24 will tell us about the next hour.

25 MR. ESSIG: Lunch.

1 (Laughter.)

2 CHAIRMAN MALMUD: Thank you. We have been
3 informed. We'll rejoin at 1:30.

4 MR. ESSIG: And I believe there is
5 adequate lunch facilities here.

6 CHAIRMAN MALMUD: Yes. Out the doors and
7 to your left.

8 MR. ESSIG: To the left?

9 CHAIRMAN MALMUD: Yes.

10 MR. ESSIG: Okay.

11 CHAIRMAN MALMUD: Thank you.

12 (Whereupon, at 12:35 p.m., the
13 proceedings in the foregoing matter
14 recessed for lunch until 1:36 p.m.)

15 CHAIRMAN MALMUD: If I may, I'll call the
16 meeting back to order. And the first item on the
17 agenda will be presented by Roy Brown with CORAR
18 assessment of the new NRC draft rulemaking to
19 implement the Energy Policy Act.

20 This is an open session and we invite Mr.
21 Brown to begin.

22 MR. BROWN: Thank you. Let me start off
23 by thanking the ACMUI for allowing me to speak to you.
24 I know you have a very, very full agenda. And I
25 really appreciate the time you have given me to

1 present our initial thoughts on the rulemaking.

2 Let me also start off by commending the
3 NRC staff. They have done a tremendous amount of work
4 in a short period of time. We actually believe that
5 the 18-month time table on this rulemaking is not very
6 generous and the staff has done an incredible amount
7 of work.

8 Also, it has been very, very helpful that
9 the NRC released the NRC SECY paper. It allowed us to
10 get a chance to review the draft rulemaking before it
11 gets published in the Federal Register. It just gives
12 us a little bit more time to digest everything that is
13 in there. So we really appreciate that. And we would
14 encourage that in the future. I know this is a
15 special circumstance.

16 I'm going to skip this slide. I think
17 most of you know who CORAR is. I'll just briefly say
18 CORAR is a North American Trade Association for the
19 manufacturers and distributors of radionuclides and
20 radiopharmaceuticals. Most of the major manufacturers
21 of these products are members of CORAR. So we are
22 definitely a stakeholder in this whole process.

23 We have had a chance to review this draft
24 rule now but these are only our initial thoughts. We
25 really need to spend some more time on really digging

1 into this in more detail and determining what kind of
2 impact this is going to have on the industry.

3 Let me talk about some of the positive
4 aspects of the rulemaking first. First of all, we
5 think that the NRC's classification of accelerators
6 into three different categories is a very wise
7 decision. We agree with this interpretation. We
8 think that the proton therapy machines, those machines
9 that are not designed to produce material and not
10 being used for that purpose, we don't think there is
11 any reason for the NRC to get involved with those.
12 But what we do, CORAR has long supported NRC getting
13 jurisdiction over the machines that do actually
14 produce products.

15 So we agree with the NRC's classification
16 of these accelerators into three categories. And then
17 writing rulemaking to cover two of those three
18 categories.

19 Also, we agree with the NRC's regulatory
20 policy on uniform regulation, regardless of method of
21 production. They talk about this in some length in
22 the rulemaking. A good example is cobalt-57 which for
23 years now has been -- you can produce cobalt-57 either
24 in a reactor or in a cyclotron. We are glad NRC
25 recognizes they are not going to make any distinction

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1 of how this material gets produced. It will be
2 regulated the same way.

3 So we strongly agree with that philosophy.
4 We feel it is the best way to deal with these
5 radionuclides.

6 Also, we had a little bit of a discussion
7 on this a few minutes ago about grandfathering. We
8 very much agree and very much appreciate the NRC's
9 effort to grandfather in previously qualified,
10 authorized users, or authorized nuclear pharmacists
11 and RSO.

12 It was also very helpful this morning to
13 get clarification that even if someone isn't an
14 authorized user or an authorized nuclear pharmacist on
15 a previous registration but not on the license, they
16 too would be grandfathered in. So we think this is
17 very important. We think this is a big step forward.
18 It will dramatically help the rulemaking.

19 A couple more positive aspects. The way
20 we read this draft rulemaking is looking at Part 30,
21 looking at the emergency planning and the
22 decommissioning funding in Part 30, we don't think
23 those would be triggered by small PET facilities in
24 the draft regulations.

25 Looking at the criteria under Part 30,

1 they don't meet the half life or the quantity
2 designations to require emergency planning or
3 decommissioning funding so we agree with this
4 interpretation. Once again, we think this is a wise
5 move on the NRC's part and we support this.

6 And lastly, the last positive aspect of
7 the rulemaking, before I get into the negative ones,
8 is the NRC's waiver that runs through 2009. Once
9 again, this will allow seamless practice of nuclear
10 medicine and seamless production of these NARM
11 radiopharmaceuticals until all the dust settles on
12 this new rulemaking and it is implemented with a new
13 set of licenses and license amendments.

14 So we think this waiver is a very wise way
15 to go. We think this will create really a seamless
16 effect in the practice of nuclear medicine.

17 Okay, you knew this was coming. Some of
18 the negative aspects, some of the concerns we have
19 with the draft rulemaking. CORAR's big concern all
20 along has been the lack of uniformity in the agreement
21 states. And we don't think that the draft rulemaking
22 has done much to address that.

23 And we recognize a lot of this problem is
24 really not the NRC's problem. It is really an issue
25 with the organization of agreement states and the

1 CRCPD. Although we are very strong supporters of the
2 SSRs, the suggested state regulations, these are
3 really not implemented uniformly among the states.

4 One of the major problems we have is the
5 first bullet point here. In the past, we've had a
6 great deal of difficulty getting new NARM
7 radiopharmaceuticals approved in the agreement states.
8 Some states don't actually go in and do the approval
9 to review a new radiopharmaceutical. And we have some
10 cases where it has been six, nine, ten, eleven months
11 before a new NARM radiopharmaceutical will actually
12 get approved in all 50 states and be able to be used
13 in all 50 states.

14 So we really don't see anything in the new
15 rulemaking that will make that any easier. We were
16 hoping with some higher levels of compatibility, that
17 may bridge us a little bit and create more uniformity.

18 But we don't see anything there.

19 Also, we had raised before -- the second
20 bullet point -- there are some state-specific product
21 approval and labeling requirements. Some states
22 require special labeling and special approval for
23 products to be used in those states. Once again, this
24 refers back to the level of compatibility and frankly
25 we see a lot of the levels of compatibility we would

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1 like to see higher in the draft rule.

2 The third bullet point here, sealed
3 sources and device registries. These are handled
4 differently by different states. The NRC, obviously,
5 does it uniformly. But the NRC does not do it in the
6 same manner as states do. And not all the states
7 handle it the same way. So there is quite a
8 discrepancy still here.

9 And we don't think the draft rule really
10 addresses this. And once again, we know this is not
11 NRC's jurisdiction but we were asking and pleading for
12 NRC's help to try to get more uniformity through this
13 rulemaking.

14 And lastly, all these kind of point to the
15 last bullet point, the level of compatibility we would
16 like to see it higher, Category B in all new areas and
17 even in some of the existing rules to promote more
18 uniformity.

19 A couple more concerns, even though the
20 NRC held a very, very productive workshop back in
21 November that CORAR participated in and quite a few
22 people in this room participated in, regrettably the
23 regulated community really had no interaction with the
24 steering committee, the NMSS, EPA, Energy Policy Act
25 Task Force, or the NARM working group.

1 It would have been nice to have some
2 interaction with that group. We know there was a
3 rulemaking being written. But it would have been nice
4 to work out some of these issues, some of the concerns
5 we have with those groups.

6 Another concern we have is the new fee
7 structure in Part 170. We are afraid this is going to
8 negatively impact some of the small facilities located
9 now in non-agreement states which will now, the
10 future, be under NRC's jurisdiction. In the past they
11 have very, very low fees or in some cases, no fees.
12 In some cases, you know, a five-dollar registration
13 fee in non-agreement states. And now they are going
14 to be subject to pretty heavy NRC fees for license
15 amendments, new license, and license inspections. So
16 we are concerned about the impact on small licensees.

17 Some suggestions on what to do with the
18 draft rulemaking. Once again, we would like to see a
19 higher level of compatibility for both the new
20 regulations and the existing regulations that are on
21 the books for use of radionuclides in medicine.

22 We would also like to see some
23 clarification on how NRC intends to regulate
24 incidentally-produced materials on accelerators. The
25 NRC really addressed in their preamble to the

1 rulemaking. They said they are going to regulate not
2 only the material that you planned to make but the
3 material you don't plan to make, things like zinc-65,
4 europium-152, and -154 in the concrete wells
5 surrounding the bunker.

6 There is really nothing in the rulemaking
7 that talks any more about how NRC plans to regulate
8 this. We realize this may take place in the guidance
9 document but we really haven't seen any guidance
10 document or don't have any indication of what guidance
11 docs will be out there when the rule is finalized. So
12 that would -- any of that information would be
13 helpful.

14 And lastly, although the NRC -- I'm sorry
15 -- although the NRC promoted the use of CRCPD,
16 suggested state regulations, we would like to see
17 strict adherence to them to communicate greater
18 uniformity. And once again, we realize that this is
19 not completely an NRC problem. This is really a
20 problem with the states but we will be making a
21 similar plea to CRCPD and the organization of
22 agreement states.

23 That concludes my comments. Once again,
24 thank you very much for the opportunity to come speak
25 to you this afternoon. And I think we have a few

1 minutes for questions maybe? Okay -- wait a minute,
2 I'm sorry. I have one more slide here. I'm sorry
3 about that.

4 One more suggestion we had is we are
5 encouraging the NRC to take a look at exempting low
6 energy PET cyclotrons. Some of the low energy PET
7 cyclotrons, and once again, I'm talking here about
8 cyclotrons that are less than 11 MeV or less. These
9 are typically self-shielded. And as a result, there
10 is not a high neutron field generated outside the
11 cyclotron. So there is not a lot of neutron activation
12 in the room surrounding the cyclotron.

13 So we think there may be some opportunity
14 to there may be some opportunity here to summarily
15 exempt certain cyclotrons like 11 MeV or less from
16 some of the regulations. And lastly, CORAR would like
17 to see at least one more workshop -- and it was nice
18 to see this morning that, in fact, NRC does have one
19 planned after the rulemaking is published. Now I'm
20 done, thank you.

21 CHAIRMAN MALMUD: Thank you, Mr. Brown.

22 Are there any questions or comments for
23 Mr. Brown?

24 Mr. Lieto?

25 MEMBER LIETO: Mr. Brown, could you

1 clarify in your -- I don't know which slide it is, but
2 under the concerns that you are -- I guess the second
3 bullet there where it says there is no plan to get
4 NARM radiopharmaceuticals into the states faster than
5 the current cumbersome process.

6 Are you saying that each individual state
7 has to approve the accelerator-produced materials now?
8 And that this rulemaking process would not solve that?

9 MR. BROWN: Yes, that's right. Each one
10 of the states has their own process. And some of the
11 states, some of the more progressive states they just
12 say hey, does it have FDA approval? If it does, send
13 us a copy of that, send us a copy of the package
14 insert and a copy of the labels. You are good to go.

15 Other states say well, we have to review
16 it and approve it, look at the radiation shielding,
17 look at the labeling. And jump through several hoops
18 before we can allow it in our state.

19 And let me just give you a short story
20 here. A couple of -- not the last NARM product that
21 was approved but I think two NARM products ago that
22 was approved, the state in which this NARM product was
23 manufactured, refused to review it and approve it for
24 the manufacturer.

25 So the manufacturer -- that state said

1 well, go to an adjoining state. And as long as you
2 have an adjoining state, and that is a state that
3 touches the state the manufacturer was in, as long as
4 you go to an adjoining state and get them to approve
5 it, then we will approve it.

6 While this company went to all four of the
7 adjoining states to the state where is it was
8 manufacturer, three of the four said no, we're not
9 going to do that. One of the four said we will
10 approve it but you have to get another state to
11 review. And then we will review it. Then the third
12 state will approve it.

13 So you had to go through three state
14 approvals o get it approved in the state you were
15 producing it in. And it is that kind of silliness
16 that we are trying to avoid.

17 MEMBER LIETO: Because it would seem like
18 in Part 35, isn't there a specific phraseology that
19 says that if it is an FDA approved --

20 MR. BROWN: For all byproduct material,
21 yes.

22 MEMBER LIETO: Right. Well, this would
23 now fall under that definition. So I think that would
24 solve this problem wouldn't it?

25 MR. BROWN: I don't know. I think we are

1 still going to have a problem with some states wanting
2 more information and wanting specific approval. And
3 right now we have states requiring more than other
4 states do.

5 And I don't see that changing unless the
6 NRC can do something about making it a higher level of
7 compatibility to say, you know, enough of that
8 silliness. If one state approves it, you all should
9 approve it. Like I said, that's what we are looking
10 for is some help from NRC.

11 CHAIRMAN MALMUD: Mr. Bailey?

12 MEMBER BAILEY: Mr. Brown, are you talking
13 about specifically non-agreement states or are you
14 including agreement states and non-agreement states?

15 MR. BROWN: Some of the problem -- most of
16 the problem is with non-agreement states. They are
17 generally the source of the problem. But in some
18 cases, agreement states are problems, too.

19 Yes, the one thing that will occur, and
20 without having any level of compatibility associated
21 with it is that the problem will go away or should go
22 away in the non-agreement states because those states
23 will no longer have authority to regulate their
24 radioactive material.

25 Now I know in the past on some of the PET

1 facilities, the question -- when we got back to the
2 argument of is this a pharmacy or is this a
3 manufacturer, under the pharmacy laws, you could get
4 all kind of differences. But once you go under the
5 manufacturer and have FDA approval, I don't see that
6 that should really be a problem. Maybe I have more
7 confidence than perhaps you do, but I don't think in
8 general agreement states want to argue about things
9 that are already approved by somebody, whether it be
10 NRC or FDA or, for that matter, another state. But
11 this could be a problem. I'm personally not familiar
12 with people doing things except -- particularly when
13 we were looking at some of the new modalities.

14 And I think the problem in many cases was
15 just lack of information about them. And under this
16 new system, I don't see that those kinds of things
17 will occur nearly as much as they have in the past.

18 I agree on the non-agreement states, I
19 think the problem will go away because they will now
20 be NRC states, if you will. But two of those three
21 states I mentioned in the example were agreement
22 states. And said, well, you will have to get somebody
23 else to approve it. And then we will approve it kind
24 of thing.

25 And, you know, if NRC could come up with

1 some leadership and say well, we will approve it. And
2 then all the agreement states will say well, if NRC
3 has approved it, after it has FDA approval, then all
4 the agreement states will approve it. That would be
5 wonderful. Does that make sense?

6 MEMBER BAILEY: Yes, it makes a lot of
7 sense. And I'm just assuming that that will happen.
8 Whereas you have these materials that were out there
9 in never, never land as far as federal government was
10 concerned before, I can understand and I know it
11 occurs that some agreement states don't want to review
12 things or don't feel that they have the staff or the
13 time and they are not getting paid to do that or for
14 whatever reason, it occurred in the sealed source and
15 device registry where NRC actually said if you don't
16 want to do them, then give it back to us.

17 Some states decided they we would retain
18 the right to do the sealed source and device review.
19 But as far as I know, once they are approved by -- and
20 appear in the sealed source and device registry,
21 everybody accepts them with very little change to
22 them. So I think that is where we are going on these
23 pharmaceuticals. I think the real problem before was
24 hey, they are new. And somebody needs to review them.
25 But hey, not me.

1 MR. BROWN: Yes, the manufacturers don't
2 have a problem. We're glad to have anybody review it.
3 We just don't want multiple approvals that take, you
4 know, ten months to get them all from all the states.

5 CHAIRMAN MALMUD: Thank you.

6 MR. BROWN: Thank you.

7 CHAIRMAN MALMUD: We will now move on to
8 the next agenda item which is Part 35 Training and
9 Experience, the Status of Board Applications. It
10 looks as if the presenter will be Cindy Flannery with
11 Donna-Beth Howe and Ron Zelac. And the NRC staff will
12 present that status of applications submitted for
13 recognition by the various specialty boards.

14 MS. FLANNERY: Good afternoon. I'm just
15 going to be providing a status on specialty board
16 recognition and updates since the ACMUI meeting last
17 October. And this first slide here just gives a
18 definition of some terms that are used on the
19 categories in the next slide for the recognition of
20 specialty boards.

21 Approved means that the board has met
22 NRC's criteria. Their certification process has met
23 NRC's criteria and they have been notified via letter
24 that they are recognized and they post it on the NRC's
25 website.

1 Under review means that additional
2 information was requested of the specialty boards by
3 NRC. And that supplemental information has been
4 received and is currently under review.

5 And awaiting input means that that
6 additional information has not yet been received from
7 the board.

8 And this table just lists the nine boards
9 that have submitted applications for recognition of
10 their certification process. Six of those nine boards
11 are currently recognized. And a couple of the boards
12 here, namely the American Board of Radiology and the
13 American Osteopathic Board of Radiology have
14 specialties. And so in the case of the American Board
15 of Radiology, the specialties are in various stages of
16 the review process. But right now the radiation
17 oncology specialty is currently recognized.

18 And this last slide is just a copy of the
19 website where the specialty boards are listed and the
20 sections of the regulations that they are currently
21 recognized under.

22 And that concludes my presentation. And
23 we can open it up for discussion at this time.

24 CHAIRMAN MALMUD: Dr. Williamson?

25 MEMBER WILLIAMSON: Yes, can you explain

1 why the American Board of Radiology is approved for
2 490 and 690 only from January 2007 forward? What is
3 wrong with the certifications issued before that date?

4 MS. FLANNERY: Yes, in the cases of future
5 dates, the boards have had to make changes to their
6 certification process to meet NRC's criteria. And in
7 this particular case, they had to distinguish
8 candidates who have received their work experience
9 under AU and have met NRC's criteria from those who
10 have not. And namely that is for under 390, it is
11 required to obtain work experience under an authorized
12 user. And they had to make changes to their
13 certificate by putting the words AU eligible above the
14 seal of the certificate. And that will go into effect
15 in June of 2007.

16 MEMBER WILLIAMSON: So the sole problem
17 was that the head of the residency program was not an
18 authorized user? Can you explain in more detail what
19 the problem was say for 490 which is brachytherapy?

20 MS. FLANNERY: You mean the program
21 director?

22 MEMBER WILLIAMSON: Yes, I don't
23 understand. So --

24 MS. FLANNERY: It is not always the case
25 that the program director is an authorized user. So

1 in the case of -- if they are involved in the case
2 experience, for example, in 390, the case experience
3 say, for example, the three administrations of iodine-
4 131 just as an example, the person who would be
5 attesting to that case experience may not be an
6 authorized user. It could be a program director
7 became the case experience, it is not required that
8 that attestation be -- the boards are not required to
9 include that as part of their program. That is up to
10 the individual.

11 MEMBER WILLIAMSON: Let's see if I -- I'm
12 still confused. I'm sorry. Can you explain more
13 clearly why radiation oncologist who has gone through
14 an approved residency and presumably done
15 brachytherapy under an authorized user by the laws of
16 the state or the NRC regulations, why their board
17 certification doesn't not count towards becoming an
18 authorized user?

19 MS. FLANNERY: How the application was
20 submitted is just put all the 390, 490, and 690 all
21 together. And didn't separate them. Does that answer
22 your question? I'm sorry.

23 MEMBER WILLIAMSON: No, it does not. So
24 for 490 -- which is 400 -- 35 400, which is
25 brachytherapy --

1 MS. FLANNERY: Right.

2 MEMBER WILLIAMSON: -- if I understand,
3 you are concerned that there are some diplomats of the
4 American Board of Radiology that never had
5 brachytherapy training? Never had case experience
6 with brachytherapy? And the reason you reject all
7 board certificates before 2007 is because you think
8 the American Board of Radiology was not adequately
9 tracking that? I'm really not clear what you are
10 saying.

11 MS. FLANNERY: In the example I was giving
12 before, I was referring to 390.

13 MEMBER WILLIAMSON: Yes. I'm talking
14 about 400. My last three questions have been about
15 400.

16 MS. FLANNERY: Okay. As far as the
17 application, the 480, 690, and 390 were just all put
18 together. The application did not separate them. So
19 somebody who is certified in radiation oncology would
20 meet all three of those criteria, in 390, 490, and
21 690. And they weren't separated.

22 And so the board had put -- I guess
23 requested that as an effective date.

24 MEMBER WILLIAMSON: What do you mean was
25 not separated? What was not separated? Why whom?

1 MS. FLANNERY: The Board submitted the
2 application for 390, 490, and 690 all together. And
3 the 390 criteria could not be met until June of 2007.

4 CHAIRMAN MALMUD: Dr. Vetter was next.
5 And then Dr. Diamond.

6 MEMBER VETTER: Several of these boards
7 have recertification requirements so I'll just pick
8 mine. I'm certified by the American Board of Health
9 Physics. And every four years I need to get
10 recertified. So if I am recertified after January 1
11 of 2006, am I qualified under this rule?

12 MS. FLANNERY: Under --

13 MEMBER VETTER: This says certification
14 after June -- January 1 of 2006 for training for
15 radiation safety officer.

16 MS. FLANNERY: No.

17 MEMBER VETTER: And if the answer is no,
18 which I anticipated it would be, what can the board do
19 to rectify that? In fact, if you look at my
20 experience or the experience of the physicists who
21 work for me, they all far exceed -- because of their
22 current experience, they far exceed the requirements
23 but they took the boards before January 1 of 2006. So
24 shouldn't these boards be able to rectify that in the
25 sense of recognizing the experience that these

1 individuals now have?

2 MS. FLANNERY: The board could, on a case-
3 by-case basis, on behalf of the individual say that
4 the individual has met the criteria. But not for an
5 entire year unless they looked at all the individuals
6 who have received their certification in that year.
7 That's the only way it could be done.

8 Or if the board is willing to do it, they
9 could conduct that review on a base-by-case basis.

10 MEMBER WILLIAMSON: All right. Under the
11 current structure, that makes sense to me that one of
12 my physicists who has 20 years experience doing about
13 everything you can do in medical health physics and is
14 certified by the American Board of Health Physics
15 previously but now under my supervision has worked
16 with HDR and gamma knife and you know, you name it,
17 they have worked with it, on a case-by-case basis,
18 that individual, it seems to me, should be able to get
19 approved under this process, as long as the board has
20 established with you a procedure whereby they would
21 individually examine that person's record as part of
22 their recertification process. Does that make sense?
23 Am I making myself clear?

24 MS. FLANNERY: Yes. The American Board of
25 Health Physics, for example, had to make some changes

1 to meet the criteria. And the effective date in this
2 case would be January 1, 2006. The only other option
3 if the Board is not able to review it on a case-by-
4 case basis, would be for that individual to get
5 recognized by the alternate pathway, which is
6 submitting documentation for the training and the
7 experience.

8 MEMBER WILLIAMSON: Just one more brief
9 question. Is the mechanism currently in place for
10 boards to do that? Or is this something that they
11 would have to propose to the NRC? Because it seems to
12 me there are plenty of -- I think the same thing would
13 hold true of other boards, too. There are lots of
14 people out there who are currently qualified under the
15 way that the boards are currently defied -- that is
16 you define the requirements for each board. They
17 evaluate the candidates.

18 These candidates who were certified years
19 ago and now have all of this experience working under
20 an authorized user or an RSO or medical physicists, if
21 they were to take the boards today, they would
22 qualify. The fact of the matter is they took it a
23 long time ago. And it is only because they took it a
24 long time ago that they don't qualify.

25 So if there is a mechanism for the boards

1 to individually review and approve those individuals
2 when they go in to get recertified, it seems to me it
3 would make a lot of sense. But I don't know if that
4 currently exists, if that opportunity exists, or do we
5 have to create a new mechanism or how do we look at
6 that?

7 MS. FLANNERY: I don't know of any boards
8 who are currently doing that. But the NRC would
9 recognize that if the board could speak on their
10 behalf to say that they meet NRC's criteria, that that
11 individual meets NRC's criteria. But I don't -- I
12 can't speak for the boards and I don't know that any
13 -- we are willing to do that at this point.

14 DR. BETH-HOWE: I did the American Board
15 of Nuclear Medicine. And in their application, they
16 had to change some of their criteria to make it clear
17 that they would meet. But what they also believed was
18 that most of their candidates in previous years would
19 meet the criteria even though those criteria were not
20 the criteria listed in previous years.

21 So they have essentially agreed that they
22 will go back to individuals that are not authorized
23 users, reevaluate what their criteria was and if they,
24 in fact, did meet our existing criteria today, they
25 would modify their certificate to put the designation

1 that is on their certificates now that indicate that
2 they are eligible to be authorized users. And part of
3 their problem was that they have individuals that take
4 examination that are not trained in the U.S. and,
5 therefore, their training isn't under an authorized
6 user.

7 But they have committed to going back and
8 reviewing individual criteria to see if they meet our
9 existing criteria today. And so they will go back and
10 retrospectively add that to their certificate.

11 I don't think we have had any other boards
12 that have agreed to do that. We did talk to the
13 American Board of Health Physics and they were offered
14 the opportunity to do the same thing but they haven't
15 come back to us with that.

16 CHAIRMAN MALMUD: Dr. Diamond?

17 MEMBER DIAMOND: So Cynthia, tell me what
18 will happen to the radiation oncology trainees who are
19 expecting to become Board certified by the American
20 Board of Radiology and Radiation Oncology in June
21 2006.

22 MS. FLANNERY: The option for these
23 diplomats would be to apply for authorized user status
24 under the alternate pathway which is the training and
25 experience pathway.

1 CHAIRMAN MALMUD: Does that answer your
2 question Dr. Diamond?

3 MEMBER DIAMOND: It answers it. It
4 doesn't make me very happy.

5 CHAIRMAN MALMUD: Could you explain why it
6 doesn't make you happy?

7 MEMBER DIAMOND: Because my understanding
8 is that the diplomats who are anticipating -- those
9 who are expecting to become diplomats in June 2006 by
10 virtue of their training programs, having been
11 modified to meet the new regulations as enumerated,
12 should have already met all those criteria. And I
13 guess your point is you do not think that those
14 criteria have been met. Is that correct? I'm trying
15 got specifically tease out what is special about these
16 2006 diplomats that is causing the problem in
17 radiation oncology and what are we going to do with
18 these 200 individuals in June 2006 when they are
19 hoping to get jobs which is right around the corner.

20 MS. FLANNERY: The ABR has had to make
21 changes to their certification process in order to
22 meet NRC's criteria. And the date that was applied by
23 the ABR was they could make those changes in the next
24 round, which is June of 2007. And so really the only
25 other option would be the training, experience pathway

1 or unless as I mentioned earlier, if the board is
2 willing on a case-by-case basis and on behalf of the
3 individual to state that the individual has met NRC's
4 criteria, those are the only two options.

5 MEMBER WILLIAMSON: In your communications
6 with the American Board of Radiology, in which they
7 made these comments to you, was it clear to all
8 parties that there was going to be this mess two
9 months from now? I'm just -- I'm the pragmatic guy on
10 the panel. And, you know, these doctors are expecting
11 to get jobs. And you are telling me that from now
12 until -- they are expecting to start those jobs on
13 July 1st, 2006. They are going to be able to go
14 thorough this paperwork to become authorized users for
15 all of these uses?

16 MS. FLANNERY: I don't think I could
17 answer that question for the board at this time.

18 CHAIRMAN MALMUD: This is Dr. Malmud.
19 When we discussed this issue over the past several
20 years, we were concerned that the NRC process was
21 essentially imposing upon the boards criteria for
22 board certification by requiring that the boards train
23 the residents for the alternate pathway since, by
24 definition, a certain percentage of residents would
25 not pass the boards. And, therefore, would require

1 the alternate pathway to be authorized users.

2 Or would take the boards at such a time
3 that was delayed and, therefore, could not be
4 authorized users by virtue of the boards not yet
5 having board certification. Now I don't recall the
6 precise outcome of that discussion except our concern
7 about it. But I worked on the assumption that for
8 those who did not pass the boards or who had not taken
9 the boards and therefore could not use the board
10 pathway to certification that if their training
11 supervisor certified that they had the requisite
12 experience required under the alternate pathway, that
13 they could be authorized users.

14 Am I correct so far? So that the answer
15 to that was an affirmative nod from the three persons
16 giving this session.

17 So, therefore, the question boils down,
18 Dr. Diamond, to whether or not in their training they
19 received the training requirements of the alternate
20 pathway.

21 The training requirements of the alternate
22 pathway, I assumed -- and this is an assumption and
23 not a fact -- were being met by the American Board of
24 Radiology but yet though they were being met, they
25 were not being documented in a fashion up to that

1 point which would necessarily be adequate for the
2 successor to the training program should the
3 individual leave and the training program director no
4 longer be there.

5 And that our concern was for the future.
6 But that the current training program directors, who
7 would have just graduated or these individuals who are
8 now going to enter practice could certify truthfully
9 that these individuals had received the requisite
10 training under the alternate pathway.

11 It's a long way of saying that my
12 assumption was we would not interfere with the ability
13 of these young physicians who just finished their
14 board certification training but not yet sat for the
15 boards to practice and become authorized users if
16 their training program directors would simply certify
17 correctly and honestly that these individuals had
18 received the training requirements according to the
19 alternate pathway.

20 Am I okay so far? Okay. Is that a
21 problem? Do you think that will present a problem Dr.
22 Diamond, Dr. Nag for those who are finishing radiation
23 oncology training?

24 MEMBER DIAMOND: I can't speak for a
25 program director. I think that the logic that you

1 spell out I follow. I think it boiled down to the
2 fact that the letter communicating to NRC from ABR
3 indicated that they would be able to certify that all
4 of their programs would meet all the enumerated
5 requirements in 2007 as opposed to this 2006 cycle.

6 An I would hope that the training
7 programs, having access to all these enumerator
8 requirements for some period of time would have
9 already modified their training to meet all of the
10 criteria for the alternate pathway. So I would hope
11 that there will be no problem in that these preceptors
12 can correctly and honestly certify that those points
13 have been made.

14 But it is going to generate a lot of
15 consternation. So do you have any thoughts on this?

16 MEMBER NAG: I think there will be a
17 period where you will have to use the alternate
18 pathway. But I think the specialty board to place all
19 the requirement by 2007 so that one year we will have
20 a problem.

21 MEMBER DIAMOND: So Subir, since you are
22 closer to the academic centers than I am, do you think
23 that the training programs have instituted the
24 required changes to their training programs so that
25 the diplomats in 2006 will, in fact, have met all of

1 the criteria of the alternate pathway? And that their
2 preceptors can correctly and honestly attest?

3 MEMBER NAG: Yes.

4 MEMBER DIAMOND: So that this may be a
5 non-issue?

6 MEMBER NAG: Yes, I have seen at least our
7 training program and a few others, I don't know about
8 all -- but they do have all the NRC -- so they will
9 have to go through the alternate pathway.

10 MEMBER DIAMOND: Okay -- so maybe I made
11 too much of an issue over a technical point that is
12 actually moot. I hope that you are correct.

13 CHAIRMAN MALMUD: If I may, Dr. Diamond,
14 it is not a moot issue in that if the program director
15 certifies that the individual not yet board certified
16 has met the T&E requirements under the alternate
17 pathway, that will be reviewed on an individual case-
18 by-case basis. And the additional workload falls to
19 the NRC staff for this transition of about a year or
20 so.

21 MEMBER DIAMOND: And also not only the
22 additional workload but also remembering that from a
23 pragmatic point of view, many of these individuals are
24 going to be moving and applying for jobs and trying to
25 buy their first homes and so forth.

1 And if you don't have an authorized user
2 designation, let's say you are in a non-agreement
3 state, you can't work. You don't work, you don't get
4 paid. There is going to be -- this is a very short
5 time horizon. And I'm just wondering -- there is not
6 a representative of the American Board of Radiology
7 here today. But I'm wondering if the trainees that
8 are getting ready to graduate are aware of this
9 specific issue.

10 CHAIRMAN MALMUD: If I may, I can't speak
11 for the trainees but I think Dr. Zelac has a comment
12 which probably relates back to a discussion we had
13 some months ago. Dr. Zelac?

14 DR. ZELAC: Well, actually I wanted to
15 address the specific point that Dr. Diamond just
16 raised. These newly completed residents now seeking
17 their first positions can certainly go to institutions
18 where there is an authorized user and for the time
19 that it takes for their application to be reviewed
20 before they can also be added to the license as
21 authorized users, they can certainly act and perform
22 their functions under the supervision of an existing
23 authorized user. The rules allow for that.

24 MEMBER DIAMOND: Right. I think the main
25 issue is individuals who are entering small clinics in

1 non-agreement states I think is the key issue at hand.

2 DR. ZELAC: If there is no existing
3 authorized user at the facility, yes. That would be
4 a difficulty. And there would be some time required
5 for them first to complete their application and
6 submit it and clearly some time required for the
7 review of the application. But on the review side, it
8 ought to be quick because all of their information is
9 basically current.

10 MEMBER NAG: Another practical point and
11 that is when you finish your education and you are in
12 a job, at that point you are not board certified. So
13 you do have that one year or so from the time you
14 finish your licensing until the time you are board
15 certified.

16 CHAIRMAN MALMUD: You are, of course,
17 correct, Dr. Nag, and that is the issue that we were
18 concerned about for those who had finished training
19 but were not yet board certified. And that is why we
20 discussed the fact that the training programs will
21 have to train to the level of the alternate pathway or
22 their graduates, the trainees upon completion of
23 training, may have a problem in becoming authorized
24 users if they have not had the requisite experience.

25 And though I am not a program director any

1 longer, it is obvious to me from the behavior of the
2 residents in our program, that they are fully aware of
3 the changes that are occurring and have rushed back to
4 me for certification that they, for example, in
5 radiology, that they had the requisite experience in
6 the use of iodine-131 for the treatment of thyroid
7 cancer and hypothyroidism. So our resident group is
8 aware of it.

9 And how aware the other residents are
10 throughout the country, I'm not sure. But the new
11 guidelines were published as of October of '05, as I
12 recall. And, therefore, they was adequate notice in
13 addition, the leadership of the American Board of
14 Radiology was aware of it. And has discussed it. And
15 it has been discussed also at the AUR. So I suspect
16 that most residents in radiology are hustling around.

17 What is happening in radiation oncology,
18 I can't address since I have no familiarity with it
19 all.

20 Dr. Williamson?

21 MEMBER WILLIAMSON: Well, I guess I am
22 concerned that many of the previous diplomats of the
23 American Board of Radiology and Radiation Oncology
24 will not be able to meet the alternate pathway
25 requirements. The alternate pathway requirements were

1 intentionally made more prescriptive and burdensome
2 than the requirements for board eligibility. For
3 example, enumerating the number of hours of didactic
4 training versus practical training. In addition, the
5 sections 400, 600, 300 -- 400 and 600, excuse me,
6 specify that the 500 hours must be spent with specific
7 modalities such as HDR or gamma stereotactic or
8 cobalt-60 teletherapy.

9 So I would say a diplomat who was maybe
10 treating lung cancer -- a diplomat of 1995 who is
11 treating lung cancer for seven years or some long
12 period of time and wanted to switch to neuro would not
13 be able to become an authorized user of gamma
14 stereotactic without presumably going back and having
15 500 hours of additional training.

16 Whereas if the application would have been
17 approved without this date qualification, there would
18 be no problem. So I think it is more also than just
19 an impact on individual practitioners. There is a
20 serious shortage of radiation oncologists and medical
21 physicists in the country, estimated to be of the
22 order of 20 percent.

23 CHAIRMAN MALMUD: Would you care to
24 comment on that issue Dr. Zelac or Dr. Howe?

25 DR. ZELAC: Dr. Williamson is quite

1 correct in terms of the alternate pathway requirements
2 being more prescriptive than those under the board
3 certification pathway. If for no other reason that
4 the hours of didactic classroom and laboratory are
5 specified under the alternate pathway where it is not
6 under the board certification pathway. In terms of
7 what type of experience an individual gets in
8 fulfilling their qualification for the total hours, it
9 really depends on the modalities that they are
10 interested in.

11 They are going to be getting their
12 training and work experience in one of them. And
13 presumably -- or at least one, and it is in at least
14 that one that they will be seeking their
15 authorization, not for the others. It is not that
16 they have to get it in all three, for example.

17 MEMBER WILLIAMSON: The question was, if
18 I can be permitted a follow is someone who has an
19 older board certificate whose training program
20 included only manual brachytherapy now in 2007 moves
21 to a small institution where they have to be in charge
22 of HDR brachytherapy, what do they do?

23 PARTICIPANT: Well, clearly they would be
24 qualified to do the manual brachytherapy and would
25 seek authorization under 400, meaning they have met

1 the qualifications under 490. In terms of 690, before
2 they could be qualified, meaning authorized to do that
3 type of work and they haven't done it before, you
4 should get additional training. That's reasonable.

5 CHAIRMAN MALMUD: Wouldn't they also
6 require credentialing by the institution at which they
7 are going to practice this new modality for
8 themselves? And wouldn't the credentialing require
9 some experience? That question is addressed to Dr.
10 Williamson.

11 MEMBER WILLIAMSON: Well, I imagine so but
12 the issue is with board certification, this retraining
13 is left to the discretion of the physician who is
14 presumed to be a professional and able to develop a
15 self-directed training program as is necessary to move
16 to a new modality.

17 Now it will be prescribed -- the criteria
18 aren't clear whereas if the board certification prior
19 to 2007 were accepted, the person to change fields
20 would only have to show the additional technical and
21 safety training which is required of all AUs
22 regardless of which pathway they use.

23 CHAIRMAN MALMUD: Dr. Eggli?

24 MEMBER EGGLE: For training requirements
25 for diplomats of the American Board of Nuclear

1 Medicine, I think their training program is long
2 enough and robust enough that they have no problem.
3 However for diplomats of the American Board of
4 Radiology, particularly for those who are graduating
5 in 2006, it is a real scramble to get in the 80 hours
6 of classroom and didactic by the time they graduate.

7 And there may be a whole bunch of 2006
8 diplomats of the American Board of Radiology who could
9 functionally be disenfranchised because there is just
10 not enough time left in their residency between when
11 -- well, between when ABR understood what the
12 regulation was and was actually going into effect and
13 time left to implement it.

14 So I think there are going to be a whole
15 bunch of people who are graduating this year who are
16 diplomats of the American Board of Radiology who may
17 well turn out to be disenfranchised because there is
18 just not enough time to -- not to get the 700 hours in
19 because that has been understood. But to get the 80
20 hours of classroom and laboratory experience into
21 their curriculum before they graduate, I think there
22 is a real serious challenge for those diplomats.

23 CHAIRMAN MALMUD: Dr. Howe:

24 DR. BETH-HOWE: Just kind of a word of
25 warning. When you are thinking about credentialing,

1 not all of these authorized users are going into
2 facilities that do credentialing. They may be going
3 into private practice. d so credentialing in not
4 something that you can fall back on all of the time.

5 CHAIRMAN MALMUD: You are correct. That's
6 a good point. Thank you.

7 It sounds as if there may be an
8 opportunity for some entrepreneurial physicists in the
9 field to rev up a course or two for those graduates of
10 training programs who have not met the training
11 requirements by June of `06.

12 Dr. Eggli?

13 MEMBER EGGLI: It actually turns out
14 several entrepreneurial folk are doing that and
15 offering web-based interactive training. However, for
16 most of our residents, the cost of that is
17 prohibitive.

18 CHAIRMAN MALMUD: Thank you.

19 MEMBER EGGLI: It is up to 8,000 dollars
20 per individual.

21 CHAIRMAN MALMUD: Sounds as if they need
22 some competition with a lower-priced product of equal
23 quality of course.

24 Dr. Zelac?

25 DR. ZELAC: If I can add just a couple

1 more words to the question that Dr. Williamson had
2 raised before. The individual who was previously
3 certified, who has been authorized using
4 brachytherapy, implant brachytherapy, and now goes to
5 a facility at which they wanted to do HDR, for
6 example.

7 The qualifications that they would have
8 had to have met for board certification initially when
9 they got it would have included the same requirements
10 in terms of the three-year residency that exist both
11 in 490 and in 690. So if they were qualified under
12 490, they would meet most of the qualifications under
13 690 as it is written today.

14 The one thing that was added intentionally
15 on the advice of this advisory committee was that such
16 individuals who now wanted to get into a new modality
17 would have to receive specific training in that new
18 modality under an appropriate person before they could
19 get approval to do it.

20 But the length of the training is not
21 specified. It is simply some additional training
22 which is felt to be appropriate be it from the
23 manufacturer, be it from an involved physicist, be it
24 from an involved authorized user. Wherever the source
25 of the training was, it had to cover certain things

1 which are enumerated in the very last section of 690.

2 And I'll quote, "has received training in
3 device operation, safety procedures, and clinical use
4 for the types of use for which the authorization is
5 sought." And then it tells how this training
6 requirement can be satisfied.

7 So this person, in fact, is not going to
8 have to spend years or go through a laborious process
9 in order to, if you will, extend their existing
10 authorization to cover the new modality in 690.

11 CHAIRMAN MALMUD: Thank you, Dr. Zelac.
12 Is that Dr. Eggli's -- no, I'm sorry. I keep
13 confusing your arms.

14 (Laughter.)

15 CHAIRMAN MALMUD: Mr. Lieto?

16 MEMBER LIETO: I guess I'm am still a
17 little bit bothered and confused about the status of
18 diplomats before the dates here. Let's say, for
19 example, and this is, I guess, maybe to carry on with
20 what Dr. Vetter started, say an RSO that was American
21 Board of Health Physics certified in 2004 or a nuclear
22 medicine physician applying for 190 who is approved in
23 2004.

24 Their board certifications, according to
25 this, even though they met the NRC requirements at

1 that time to be an authorized user or an RSO, because
2 of this magic date, those criteria and credentials are
3 no longer good enough to be an RSO or an authorized
4 user simply because of that effective date of the
5 rules.

6 And I guess I'm trying to understand how
7 we are supposed to explain this to those diplomats.

8 DR. BETH-HOWE: Your supposition is
9 correct. The problem is that our regulation didn't
10 come into effect until 2005. And so there may have
11 been changes between what the boards approved in 2002
12 versus what the boards -- not approved but what the
13 boards were seeking for their candidates prior to the
14 candidates that are listed here on our website.

15 In some cases, the boards -- like the
16 American Board of Nuclear Medicine -- they have gone
17 back and they have made a commitment that they will
18 review the criteria for their individuals to see if
19 they meet our existing criteria. And if so, they will
20 give them a new certificate.

21 But you have to keep in mind that one
22 reason there are dates here is because the boards had
23 to make changes to their acceptance criteria of
24 individuals to sit for the board to meet our criteria.
25 So some of the people in those earlier dates don't

1 meet our criteria. Some of the people in the previous
2 dates do.

3 MEMBER LIETO: But --

4 DR. BETH-HOWE: And the NRC decided that
5 we -- when they did the rule in 2002, they did not
6 grandfather the boards. They said the boards will
7 have to be reviewed from this point forward.

8 MEMBER LIETO: But the understanding was
9 that those diplomats would have been AUs or RSOs under
10 the rules that were in effect at that time. If they
11 were able to be an authorized user or an RSO at that
12 time, they met NRC criteria up until that date.

13 How can you say that after that date
14 because you changed the rules that they are no longer
15 allowed to become an authorized user or an RSO?

16 DR. BETH-HOWE: That's what changing our
17 rules did. It changed the criteria.

18 MEMBER LIETO: But you can't change the
19 rules and then say everybody before hand who met the
20 criteria are no longer acceptable. And that's the
21 point I'm trying to make. You are kind of saying that
22 you are going to hold people accountable for what has
23 changed in the future as to what the criteria under
24 which they got certified when that certification was
25 perfectly acceptable.

1 DR. ZELAC: Consider this, if the
2 individual who was trained previously had been active
3 and had applied to become authorized, they certainly
4 would have met the criteria and been authorized at
5 that point in time because their training comported
6 with the requirements at that time.

7 That same individual who chose or did not
8 apply to become authorized at that point in time and
9 waited, now the criteria are different. The criteria
10 that they have to meet now are not the same as they
11 were previously. And that doesn't guarantee that the
12 training and experience or certification that they got
13 previously is going to meet the current criteria.

14 The holdover, of course, was Subpart J -

15 MEMBER LIETO: But the problem, Ron --

16 DR. ZELAC: -- until it disappeared.

17 MEMBER LIETO: The RSO is a classic
18 example. It is your requirement that you can only
19 have one RSO on the license. I think if it was up to
20 us, we would have multiples on the license.

21 DR. ZELAC: Well, we're not talking about
22 people that were grandfathered, because clearly,
23 people that had made their application --

24 MEMBER LIETO: But they couldn't.

25 DR. ZELAC: But the people that had been

1 authorized and were named on licenses were
2 grandfathered over. Those people that, for whatever
3 reason, had not been named on a license at the time of
4 the transition and then chose to apply later have to
5 meet the new criteria. Otherwise, we'll never make a
6 change.

7 MEMBER LIETO: But that's my whole point.
8 The NRC set up the process that wouldn't allow these
9 people to be named.

10 DR. ZELAC: The Commission, when it
11 reviewed the change in training and experience
12 requirements, said specifically that all the boards
13 that had been previously recognized would have to be
14 re-evaluated so that it was clear that the criteria
15 being required of their candidates by those boards
16 would meet the current criteria. This was the
17 decision of the Commission, not staff. The date at
18 which a board's process for examining their candidates
19 is effective, as indicated on what's on the website,
20 is what the board tells us. We don't tell the board
21 well, we think it was effective as of such and such a
22 time. The board says here are the -- okay, our
23 criteria now meet your's. Fine. And these same
24 criteria were in effect for the last ten years, so
25 anybody from 1996 forward is good. And we'll say

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1 fine, that's great. So 1996 will appear on the
2 website.

3 CHAIRMAN MALMUD: Mr. Bailey.

4 MEMBER BAILEY: If I read this correctly,
5 there's not a certified health physicist in the United
6 States or Canada who meets the requirements to be an
7 RSO today. They cannot go by the first pathway. Is
8 that correct? Because none of them have been
9 certified since January 1, 2006. However, all of the
10 requirements listed for this certifying board have
11 been in place for more than 20 years. Dr. Vetter and
12 I have both served on the American Board of Health
13 Physics. All of these requirements have been met for
14 a long time.

15 There has been created a pathway where a
16 certified health physicist has to have six years
17 experience, but if I decide to go to a tech school and
18 take four three-hour courses and work for a year, I
19 can be an RSO. So what that, in effect, does; why
20 would some facility go out and hire a Dr. Vetter when
21 they could hire someone as their RSO who only has
22 maybe not even an associate degree and one year's
23 experience. This is an inadvertent thing, I think,
24 that happened, but it's not a good thing.

25 DR. BETH-HOWE: When we reviewed the

1 American Board of Health Physics to see what their
2 criteria were, their criteria didn't match our
3 criteria with respect to certain degree programs. And
4 also, I believe some of them didn't require - I think
5 maybe they didn't require a Bachelor's Degree or
6 something.

7 MEMBER BAILEY: The American Board of
8 Health Physics has required a Bachelor's Degree since
9 about 1990, at the very latest, that it's been
10 required. They're in the same subjects. They're six
11 years of experience necessary, and I'll give an
12 example of some really strange thing that can happen.
13 Because I chose not to work in a hospital, I'll have
14 to go back and take those 12 semester hours and work
15 under somebody before I can be an RSO in a hospital.
16 I could have very easily maybe gone to work in a
17 hospital, but I didn't.

18 DR. BETH-HOWE: But the Board criteria
19 were not the same as the current criteria. And when
20 the board came in, they have not to-date been able to
21 say we meet the NRC criteria from 1990 forward. They
22 have that option, but they haven't gone back and
23 reviewed.

24 MEMBER BAILEY: I was in on some of those
25 early discussions with the board, and there was a

1 requirement in there at that time that the experience
2 part of it had to be hospital-based to be an RSO. And
3 it was true that the American Board of Health Physics
4 did not have specific questions every single year on
5 medical health physics, although I'd be hard-pressed
6 to find a year they didn't. But as it came out in the
7 regs, what the boards had to meet, they certainly have
8 met. Now if they need to go back and say hey, we want
9 to make it retroactive to when we required a
10 Bachelor's Degree, would that be an easy thing for
11 them to do?

12 DR. BETH-HOWE: Other boards have done
13 that.

14 MEMBER BAILEY: So that's a yes.

15 DR. BETH-HOWE: That's a yes.

16 MEMBER BAILEY: Okay. Thank you.

17 DR. ZELAC: If I could add one comment;
18 what Dr. Vetter had been suggesting before, that as a
19 service to its diplomats, a particular board could
20 choose to examine the qualifications that a particular
21 person had submitted when they sought to become
22 certified and see if those qualifications match the
23 current requirements. Clearly, a letter from the
24 board that said that this person's certification
25 matches your current requirements should be adequate.

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1 I don't know any reason why it wouldn't be adequate
2 for that person to become authorized based on that as
3 their training and experience credential. But again,
4 that's a decision on the part of the board to do as a
5 service to its diplomats.

6 Now I have discussed this with some of the
7 ABHP current members, and they were reasonably
8 agreeable to this being something that a board ought
9 to be doing, and in that case, would be willing to do.

10 CHAIRMAN MALMUD: Thank you, Dr. Zelac.
11 That certainly delivers a message, which would be
12 useful to those diplomats of that board, and would be
13 in the hands of that board's leadership. Thank you.
14 I think Dr. Williamson had another comment.

15 MEMBER WILLIAMSON: Can you update the
16 ACMUI on the status of applications for authorized
17 medical physicists?

18 MS. FLANNERY: We are discussing this
19 because there are two different boards that have
20 applied, and we're discussing which one. As far as
21 the American Board of Radiology, right now we are
22 waiting for some information that we have requested.
23 And then as far as the ABMP, we're waiting for
24 information from that board, as well. So we can't
25 continue the review process until that supplemental

1 information has been supplied to us.

2 CHAIRMAN MALMUD: Thank you. Does that
3 answer your question, Dr. Williamson?

4 MEMBER WILLIAMSON: Well, in a manner of
5 speaking, I suppose. It's a formal answer.

6 CHAIRMAN MALMUD: Thank you. Are there
7 any other questions or comments regarding this subject
8 for these three presenters? If not, thank you very
9 much. We'll move on to the next item on the agenda.
10 Dr. Zelac.

11 DR. ZELAC: Dr. Sherbini had, as you well
12 know, only presented a couple of slides on what was a
13 very involved and lengthy topic. I've got more slides
14 on what should be a very simple, and straightforward,
15 and easy matter to handle. I think we'll be able to
16 get through this one hopefully quite quickly.

17 There was a rule change for authorized
18 users seeking RSO status, and I want to just review it
19 with you to be sure that you are aware of it. It's
20 understandable as to what was done, the rationale
21 behind why it was done is a little more involved, but
22 let's go and see where we get to.

23 In order to become an RSO under current
24 NRC requirements and regulations, in Part 10 CFR
25 35.50, Training for Radiation Safety Officer, one has

1 to satisfy three separate requirements. First is
2 having general training and experience. Second is
3 having training specific to RSO responsibilities that
4 will be undertaken. And third is the submission of an
5 RSO attestation of qualifications from a preceptor.

6 The first point, the general T&E for RSO
7 responsibilities - I've listed there on the slide the
8 different pathways that one can follow in order to
9 satisfy those training and experience requirements.
10 The first, and I'll just leave off the 35.50 - (a) (1)
11 is essentially the health physics certification
12 pathway; (a) (2) is the diagnostic medical physics
13 physicist certification pathway; (b) is the alternate
14 pathway, which can be followed, of course, by anyone;
15 (c) (1) is the pathway for therapeutic medical
16 physicists who are not named as authorized medical
17 physicists on license. For example, a facility at
18 which the physicist is doing implant brachytherapy
19 only, not doing HDR, not doing Gamma Knife, not doing
20 teletherapy; so, therefore, they're not named on the
21 license as an authorized medical physicist, because
22 those are the only things, except for Strontium-90
23 source calibration, for which an authorized medical
24 physicist is required. So (c) (1) is the pathway for
25 certified therapeutic medical physicists who are not

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1 essentially named on a license as an AMP. And the
2 last pathway, (c)(2), is for authorized individuals,
3 the authorized user, the authorized nuclear
4 pharmacist, the authorized medical physicist. Again,
5 different pathways for training and experience.

6 You'll notice that the last requirement
7 listed on the slide is the preceptor RSO attestation
8 of qualifications. And I simply want to go into that
9 now for a moment. The basis for this requirement -
10 the Staff Requirements Memorandum, SRM, for the
11 proposed rule on medical use of byproduct material
12 recognition of specialty boards had the following two
13 statements in it.

14 "In addition, the Commission has approved
15 the recommendation of the Advisory Committee
16 concerning the preceptor statement." And here's the
17 meat - "A preceptor statement is required from
18 individuals, regardless of the training pathway
19 chosen." So a preceptor statement would be required
20 for individuals going down the (a)(1) pathway, the
21 (a)(2) pathway, the (b) pathway, the (c)(1) pathway,
22 or the (c)(2) pathway. Regardless of what pathway of
23 training and experience you sought RSO status, you
24 would have to supply a preceptor statement. And
25 you'll notice I included those that were authorized

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1 users, authorized medical physicists, and authorized
2 nuclear pharmacists. Dick.

3 MEMBER VETTER: If I may ask a quick
4 question while you're on that subject; you need a
5 preceptor statement from whom? So if the authorized
6 user wants to be the RSO, who provides the preceptor
7 statement for the RSO portion?

8 DR. ZELAC: The preceptor statement has to
9 come from an RSO. And, specifically, I'll pull it out
10 and we'll see what the exact wording is. This is
11 Section 35.50(d), the preceptor requirement. "Has
12 obtained written attestation signed by a preceptor RSO
13 that the individual has satisfactorily completed the
14 requirements in Paragraph E, which we'll get to in a
15 minute, and in Paragraphs" - and then the different
16 T&E pathways are named. "And has achieved a level of
17 radiation safety knowledge sufficient to function
18 independently as an RSO for a medical use licensee."
19 So that's the preceptor has to attest to, and the
20 person who has to do it is a preceptor RSO. Does that
21 mean at the same facility? No. It does mean a
22 preceptor, someone who is named on a license, an NRC
23 license as an RSO, or the way we operate, it could be
24 named on agreement state license as an RSO and still
25 qualify.

1 MEMBER VETTER: So, hypothetically, if an
2 authorized user at an academic medical center, so they
3 had their own RSO, moved to a private practice and
4 wanted to be the RSO at that private practice, he
5 needs to get a preceptor statement from the authorized
6 user from that academic medical center?

7 DR. ZELAC: No, he needs to get a
8 preceptor statement from the RSO at that academic
9 medical center.

10 MEMBER VETTER: I'm sorry, that's what I
11 meant. From the RSO --

12 DR. ZELAC: Or from any RSO.

13 MEMBER VETTER: All right. But he has not
14 been practicing under that RSO. He's been an
15 authorized user there.

16 DR. ZELAC: He or she has been at that
17 facility working with materials, and presumably, has
18 demonstrated their ability through that work
19 experience to not only use the materials, but use them
20 in a safe manner, which respects all the requirements
21 to do that. If the RSO is willing to attest to that,
22 and Section E, which we haven't gotten to yet, and the
23 RSO thinks that this person should be able to handle
24 the RSO responsibilities at their other new facility,
25 they would sign it. If they don't on any one of those

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1 counts, they won't, and the person has to seek their
2 attestation somewhere else, or fill in the blanks in
3 terms of the requirements that the preceptor RSO
4 designated hasn't felt that they satisfied yet, by
5 getting additional training, for example.

6 The current rule, or the rule that was
7 current until recently, meaning in January, had a
8 problem in interpretation. It listed the various
9 training and experience pathways, (a) (1), (a) (2), (b),
10 and (c) (3), but it didn't list (c) (2). That meant -
11 (c) (2), again, is for the authorized individuals.
12 That meant that an authorized user, for example, who
13 wanted to be named as the RSO, would also have to
14 satisfy the training and experience requirements in
15 one of the other pathways. This wasn't by design.
16 When the rule was put together, it was thought
17 perfectly obvious that there shouldn't have to be an
18 attestation to the fact that this person was an
19 authorized user, for example, because that clearly
20 appeared on a license already. Why does somebody have
21 to attest to that when it's already documented? But
22 our counsel told us that if (c) (2), that particular
23 pathway wasn't there, wasn't named explicitly in the
24 rule language, that the authorized individual seeking
25 to become the RSO would have to meet the

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1 qualifications for one of the other pathways, as well
2 as being an authorized individual already.

3 The fix, simply, as I said, this was a
4 very simple thing, the fix was simply to add (c)(2) to
5 the list of training and experience pathways in the
6 preceptor Section D. So what I had read before, which
7 says - and, again, this is the preceptor requirement -
8 "Has obtained written attestation signed by a
9 preceptor RSO that the individual has satisfactorily
10 completed the requirements in Paragraph E", which
11 we'll get to in a minute, and in Paragraphs" - and
12 then it had the listings of the various sections, we
13 added (c)(2) to that section. So that meant, in turn,
14 that when a preceptor RSO now provided the
15 attestation, what were they attesting to? First, that
16 the individual is authorized on the licensee's NRC
17 license as an AMP, ANP, or AU. Secondly, that the
18 individual has completed the specific RSO training
19 described in 35.50(e), which we'll get to in a minute.
20 And finally, the overall statement of qualification
21 that the individual "has achieved a level of radiation
22 safety knowledge sufficient to function independently
23 as an RSO for a medical use licensee."

24 So that was the fix, and so just to finish
25 up the tale, so to speak, let me show you specifically

1 what is required in terms of the specific RSO
2 training. We already went through this in terms of
3 the added training for the authorized user under 690,
4 but this is what the requirement for added training is
5 for the RSO.

6 And this is simply quoting from the
7 requirement for added training that appears in
8 35.50(e), "Training in the radiation safety regulatory
9 issues and emergency procedures or the types of use
10 for which a licensee seeks approval. This can be
11 satisfied by completing training that is supervised by
12 an RSO, an AMP, an ANP, or AU, as appropriate, who is
13 authorized for the types of use for which the licensee
14 is seeking approval." So it's pretty straightforward,
15 it's pretty direct, it's pretty pragmatic in terms of
16 what this added requirement is that an AU has to
17 fulfill before they can, in fact, become the RSO, and
18 have a preceptor sign-off, essentially, that they are
19 qualified to do so.

20 Anything further that we want to cover on
21 this issue?

22 CHAIRMAN MALMUD: Are there any questions,
23 comments, or discussion for Dr. Zelac? I see none.
24 Any from the public? Oh, Dr. Vetter.

25 MEMBER VETTER: I'm still kind of thinking

1 about this. Well, the example I had used before is a
2 real one, where I received a telephone call from a
3 physicist from an academic medical center, an
4 authorized user had moved from that center to a
5 private practice, and they needed an RSO. And under
6 the old rules, he qualified as an RSO. They sent the
7 package in to Region I, Region I said he did not
8 qualify as an RSO under these rules, so the AU went
9 back to the academic medical center to get the RSO to
10 sign a preceptor statement, and the RSO said you
11 didn't practice under me; and, therefore, I will not
12 sign the preceptor statement.

13 Now I don't know what -- you said there
14 may be some alternative mechanisms for obtaining the
15 appropriate training and get certified, not certified,
16 have an RSO attest to this individual's competence to
17 do radiation safety. And I don't know if this is a
18 big problem or not, but here's an individual who is
19 practicing nuclear medicine in an academic medical
20 center. True, he wasn't working for the RSO, or
21 working under the RSO or anything. But like you said
22 earlier, obviously, he's been working safely for many
23 years, but the RSO there was uncomfortable signing a
24 preceptor statement saying this authorized user would
25 be a good RSO because he didn't work directly with

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1 him, so it sort of left him in a lurch, and I don't
2 know what the answer to that is.

3 DR. ZELAC: So the RSO wasn't sufficiently
4 familiar with this person's qualifications?

5 MEMBER VETTER: I don't know any of the
6 individual. All I know is the RSO would not sign
7 because the authorized user didn't practice under the
8 RSO. In other words, the RSO didn't supervise the
9 authorized user in a radiation safety capacity; and,
10 therefore, he would not attest to his ability to be an
11 RSO.

12 DR. ZELAC: If the RSO had any knowledge
13 of the authorized user's competence or experience, I
14 think he was probably going beyond what he or she
15 should have in terms of refusal. Again, if they felt
16 that this person -- if they couldn't sign a preceptor
17 statement, attestation because they believed that this
18 person had not had any specific training, they may
19 have had a lot of work experience, but they didn't
20 have any specific training relative to RSO
21 responsibilities, one would expect that a reasonable
22 working relationship, they could have gotten something
23 done in short order and satisfied, if you will, the
24 RSO.

25 The alternative was for this person to

1 seek some specific training under an authorized
2 whomever for the type of work for which they wish to
3 be the RSO, and get that person, if it happened to be
4 an RSO, to sign, or the RSO at that facility to sign
5 the preceptor statement. There are pathways, and
6 that's the point, that the additional requirement for
7 training is not onerous in terms of fulfilling it,
8 even if the person hasn't necessarily done everything
9 that they might need to serve as the RSO; if they
10 haven't had that as part of their work experience as
11 an authorized something else, they can easily get it.

12 CHAIRMAN MALMUD: Dr. Eggli.

13 MEMBER EGGLI: I actually had a similar
14 sort of phone call. I don't know if it was the same
15 individuals, but it was the same situation. And I
16 think the comment I would like to make is that
17 authorized individuals in the new environment are
18 awfully protective of what they put their signature
19 on, because essentially, the new regulations make
20 those authorized individuals liable, in a sense, for
21 that signature on that piece of paper. Maybe it's
22 always been that way, but I think there's a new
23 heightened sense of not just responsibility, but
24 liability for signing as an authorized individual when
25 you sign somebody's preceptor statement. And I can

1 understand the health physicist's reluctance, the
2 RSO's reluctance to sign that statement because,
3 essentially, the person didn't work for them, they
4 didn't supervise them, the experience they had wasn't
5 under the supervision of that individual. And if you
6 want to get real rigid about the interpretation of the
7 regulation, you shouldn't be writing a preceptor for
8 that individual. And I think there's a whole new
9 heightened sense of both responsibility and liability
10 associated with an authorized individual putting their
11 name on a preceptor statement. And I think that's
12 going to be one of the consequences of the regulation.

13 DR. ZELAC: Recognize that in this case
14 for an RSO, it has to be a preceptor RSO who makes the
15 signature on the attestation. For authorized users,
16 in general, you're right, it could be another
17 authorized user signing the preceptor statement. But
18 in this case, it's the RSO, an RSOs have always had
19 that, if you will, liability hanging over their heads,
20 or at least for the recent past in the last couple of
21 decades, have had that thought in mind, or should have
22 had that thought in mind before they sign or do
23 anything.

24 CHAIRMAN MALMUD: Dr. Williamson, then Mr.
25 Lieto.

1 MEMBER WILLIAMSON: I believe I'm familiar
2 with this case, as well, and I don't believe that the
3 RSO took issue with the adequacy of the training of
4 the individual, but simply did not participate in it,
5 and felt uncomfortable attesting to the fact that the
6 individual was able to independently practice, because
7 this person had no direct knowledge of this person's
8 capability functioning under those circumstances.

9 The way the regulation is written, it's
10 more global. It doesn't ask you to examine the CV of
11 the person and determine whether this person has
12 adequate credentials. It asks you to attest to the
13 independent ability. And I emphasize, I think this is
14 a rather daunting task or duty set forth for us for
15 our colleagues, regardless of what kind of authorized
16 person we might be; especially when you consider the
17 chilling impact of, I think, some of our earlier
18 deliberations today.

19 MEMBER LIETO: Well, I guess Jeff stole a
20 little bit of my thunder there, but I think what Ron
21 was talking about in terms of the RSO's attestation;
22 this is something entirely new. Physicians in the past
23 have been signing preceptors for other authorized
24 users via the alternate pathway for many years, but
25 for RSOs, AMPs, nuclear pharmacists, they've not had

1 to do this before. And so there's not any sort of
2 guidelines out there as to okay, what do I need to
3 look at before -- if I did not provide that training,
4 what do I need to look at before I can make an
5 attestation in good faith that this person can
6 function? Is it a CV review, do you quiz previous
7 employers, or do you just sit down with the guy and
8 get a gut feeling as to I think this guy knows what
9 he's talking about? And there's just not really any
10 good, shall we say, guidelines out there, and it's all
11 new.

12 DR. ZELAC: The one comment I'd make is
13 that in the case -- the RSO is particularly difficult
14 because you've got an RSO who is attesting for an
15 authorized something else, user, medical physicist,
16 nuclear pharmacist. It's not as if it's an authorized
17 user attesting for a potential authorized user, or an
18 authorized medical physicist attesting for a potential
19 another authorized medical physicist, so this is kind
20 of a hybrid situation, if you will, and I understand
21 that there can be difficulties with that type of an
22 arrangement.

23 To my knowledge, we haven't had responses
24 from the regions who, of course, are having to handle
25 on a day-to-day basis a great volume of difficulties

1 in this regard, but that doesn't mean that things are
2 not happening that simply don't get that far because
3 somebody won't attest.

4 MEMBER BAILEY: What I hear you saying is
5 what we used to call brother-in-lawing it. And I
6 really hope you're not going the direction you're
7 talking about, because I know in at least two states
8 that I've worked for, we have turned back preceptor
9 statements because the individual did not have
10 experience working with that person, and this was for
11 Aus. We insisted that they have someone who had
12 direct knowledge of that individual's capabilities and
13 so forth. You cannot hire a new cardiologist, if you
14 have private practice, and be the AU or do the
15 preceptor statement for that AU. And I think you'll
16 find that is not uncommon in many states, so we're
17 going to have two different systems, where one, if you
18 can get somebody to sign the paper, you're in. The
19 other one where they're really still going to be
20 questioning whether the individual signing the
21 preceptor statement even knows the individual.

22 DR. ZELAC: Dr. Malmud, if I can comment.
23 When the current training and experience rules were
24 being formulated, one thing that was considered was
25 the fact that the person who might provide the

1 attestation may not necessarily have been the one
2 under whom the training was actually provided. That
3 doesn't mean that the person signing the attestation
4 would be unfamiliar with the qualifications of the
5 person for whom they were signing, but they would not
6 necessarily have to have been the supervisor for the
7 work experience, or for that matter, for the classroom
8 and laboratory training that had been accumulated by
9 this person. And it was for that reason that the
10 preceptor definition which exists now in 35.2 includes
11 the work "verify", so such a person who was going to
12 serve as the preceptor could look at documentation and
13 credentialing, and whatever else provided by the
14 applicant, and decide on their own if they felt
15 comfortable enough with that information, plus their
16 personal knowledge, hopefully have such thing, of the
17 person in order to sign the attestation. So yes, in
18 one sense, if there are states which are specifically
19 requiring that the training be provided by the person
20 signing the attestation, or the work experience be
21 accumulated under the person signing the attestation,
22 NRC requirements are different.

23 MEMBER SULEIMAN: Perhaps either some
24 guidance or some examples that spell out a little bit
25 more specifically prescriptively attestation

1 preceptor. Until you've worked with somebody or
2 worked under somebody, or had somebody work for you
3 directly and see their work, I mean, there's a real
4 disconnect sometimes.

5 DR. ZELAC: I understand, but this gets to
6 the point of someone signing something, essentially,
7 without having the appropriate knowledge to do so,
8 whether we intent, or malevolent nature, whatever it
9 is. And Dr. Eggli made this point before, there's a
10 lot at stake when you're putting your name on a
11 document.

12 MEMBER SULEIMAN: But if it isn't
13 standardized somehow, somehow, you're going to have
14 tremendous inconsistency among different regions and
15 different facilities. I mean, that's my concern. Is
16 there anything that would help level the playing field
17 in terms of the attestors, and the preceptors, and so
18 on, without having different interpretations by
19 different people based on their personality or
20 experience?

21 DR. ZELAC: I can't speak to it directly
22 because I don't remember, but I can tell you that the
23 NUREG 15.56 Volume 9, which is Medical Use, was
24 updated at the time that the training and experience
25 rule was coming into effect, so that they would both

1 be available at the same time. Whether that specific
2 point that you have raised has been included in terms
3 of providing some specific guidance to preceptors, I
4 can't say, but 15.56-9 will undergo some changes in
5 the future, in the not distant future, and perhaps
6 something like that would be appropriate.

7 CHAIRMAN MALMUD: Dr. Vetter.

8 MEMBER VETTER: That may be difficult
9 because I'm sure there are some academic medical
10 centers where the RSO does not get to know every
11 resident, simply can't. They're huge programs, and
12 even if the RSO is providing some lectures and that
13 person is sitting there listening, on the basis of
14 some lectures, what can you tell, or the person
15 sitting there listening, what can you tell? They
16 stayed awake.

17 DR. ZELAC: Well, the other thing, too, is
18 that what you're describing, the residents typically
19 would not be named on the license as authorized users.
20 Am I correct?

21 MEMBER VETTER: I'm sorry, let me clarify.
22 I'm thinking when the resident has completed training,
23 and they want to take a package of paperwork with
24 them, including a preceptor statement from their
25 authorized user that they practiced under and the RSO

1 because they're going into a small practice. And the
2 RSO may not even know who that person is. Now what
3 kind of guidance are you going to write for that RSO?

4 DR. ZELAC: Well, one could say that the
5 RSO could look to the authorized user who is signing
6 the preceptor statement for that intention. And if
7 you're satisfied that this person seems to be
8 functioning satisfactorily, I will be, too.

9 MEMBER VETTER: Actually, that's what I
10 had in mind. If this come to me and I have to sign,
11 the authorized user is going to send me a letter
12 saying the same thing. So I'm going to depend on the
13 authorized user's evaluation and judgment of that
14 individual.

15 DR. ZELAC: Right.

16 CHAIRMAN MALMUD: Who was next? Dr.
17 Williamson.

18 MEMBER WILLIAMSON: Yes. I guess
19 regarding the compatibility in the agreement states
20 versus non-agreement states, isn't this level of
21 Compatibility B - wouldn't the agreement states be
22 forced to accept the same interpretation as NRC?

23 DR. ZELAC: Mr. Bailey is shaking his head
24 no, and I think he's reflecting the point of view of
25 many of those persons who are associated with

1 agreement state programs. However, the training and
2 experience that became effective in October of 2005
3 has a compatibility level of B for training and
4 experience.

5 MEMBER BAILEY: But not for definitions.

6 DR. ZELAC: But not for definitions, so we
7 have some issues to resolve.

8 CHAIRMAN MALMUD: I have a question, and
9 that is as follows. Beginning with this year, June of
10 '06, it would sound to me as if the wise thing to do
11 is to provide each trainee upon his or her completion
12 of training, with several statements, one with regard
13 to being an authorized user, one with regard to being
14 an RSO, if that's what they're interested in or have
15 trained in, as well as their diploma having completed
16 their residency. So in leaving a program, one should
17 have at least three documents, and perhaps with
18 respect to therapy, a fourth document.

19 DR. ZELAC: That sounds like a very
20 appropriate approach for those that are involved with
21 training programs.

22 CHAIRMAN MALMUD: So that for those of us
23 in training programs, we should be using the belt and
24 suspenders approach, meaning give them everything you
25 think they may need to keep their pants up, not

1 knowing what's coming along. How do we spread that
2 word quickly, for at least those who are finishing now
3 moving forward? Is this actually a recommendation?
4 And should we be the ones making the recommendation?
5 How is the information to be transmitted? It's almost
6 as if we're doing a disservice to training somebody,
7 allowing him or her to complete the training, and not
8 giving the documentation they might require in the
9 event that we drop dead and can no longer certify that
10 they received the direct training experience with us
11 that they had.

12 MEMBER NAG: I think they may be a good
13 idea, but the thing is, what we review, like all the
14 program, just like the board, and tell the individual
15 in a practical problem you may wish to discuss this
16 with your training programs.

17 CHAIRMAN MALMUD: Thank you, Dr. Nag. But
18 I'm still concerned about those who are finishing
19 training this year and who will finish training next
20 year. When I separated from the Air Force, they told
21 me that there was a document that I might need some
22 day, and I should keep a copy of it. And lo and
23 behold, I required it this year, some 30-some years
24 after having completed my term in the Air Force. And
25 I have saved that document, there it was. I pulled it

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1 out, xeroxed it, and sent it off. I suspect that we
2 would be very wise to protect those whom we are
3 training by suggesting that they leave with certain
4 documents. And it would be very useful if we sitting
5 here today can decide what those documents should be.

6 A physician finishing training, whether a
7 radiation oncologist, a radiologist, or nuclear
8 physician, would require board certification. That's
9 the target, that's the goal. And what other documents
10 should that individual be prepared to have in the
11 event that he or she may need them in the distant or
12 near future? What would you recommend?

13 DR. ZELAC: Well, recognize with respect
14 to the board certifications that on the request of the
15 boards the requirement for them to receive from their
16 candidates a certification was removed, and that
17 requirement for an attestation under the new
18 terminology was placed on the individual who is
19 applying to become authorized. So with respect to the
20 board's involvement, that's probably not the way to
21 go, because they've begged off, essentially, from
22 getting involved with anything relating specifically
23 to the kind of attestation being required by NRC or
24 agreement states, presumably.

25 CHAIRMAN MALMUD: I agree with you, Ron.

1 In addition, the individual may be one of those small
2 minority that never achieves board certification.

3 DR. ZELAC: Right.

4 CHAIRMAN MALMUD: So we really have to
5 satisfy the alternate pathway. Now let's assume that
6 the trainees are finishing and must satisfy the
7 alternate pathway in addition to the board
8 certification, if they're able to achieve it. What
9 documents should we really be recommending that those
10 individuals carry with them and keep in a safe place
11 into the future?

12 DR. ZELAC: Well, again, you're addressing
13 and rightfully so, those people that are in training
14 programs right now, those people are finishing up
15 their training programs very soon.

16 CHAIRMAN MALMUD: Correct.

17 DR. ZELAC: If those people are going to
18 seek in the near future authorized status, or RSO
19 status, or both, they will need, of course, the
20 attestations that are covered in the various sections,
21 and they should have an easy pathway to getting them
22 because everything that they have accumulated in the
23 way of training and experience is recent. However, if
24 those same individuals finishing now should decide
25 that they are not going to seek the status for five

1 years or their circumstances are such that they don't,
2 what would they need? They'd need exactly the same
3 documents, except it would be easier to get them now
4 than to go back five years from now and try to obtain
5 the same attestations from the same people. If you're
6 an authorized user in one of the categories for
7 authorized use, it's the attestation from an
8 authorized user in the same category. If it's an
9 authorized medical physicist, it's an attestation from
10 an authorized medical physicist. If it's for an
11 authorized nuclear pharmacist, again, it's an
12 attestation from an authorized nuclear pharmacist, and
13 if you're seeking RSO status, it's a preceptor
14 statement, an attestation from preceptor RSO.

15 CHAIRMAN MALMUD: Now the first three are
16 clear. Let's go to the last one, the statement from
17 the RSO. What would the RSO have required of the
18 radiology resident in order to give the radiology
19 resident an attestation of RSO status? Since
20 numerically the largest number of trainees each year
21 is made up of radiologists, what should that
22 individual carry with him or with her from the RSO in
23 the event that that individual would become the RSO at
24 a small hospital or clinic in a remote area, in
25 addition to practicing radiology?

1 DR. ZELAC: The individual seeking RSO
2 status has to follow one of the pathways that exists
3 in the current rule in order to satisfy the training
4 and experience requirements. This person that you're
5 speaking of, the person is becoming an authorized
6 user, for example, will have gone through the
7 appropriate training and experience requirements to
8 become an authorized user. That's fine. And they
9 will be presumably applying for a license -- to be
10 named on a license, to be authorized on a license. If
11 that's the case, they would probably be following the
12 authorized user pathway. They're not going to be
13 following the health physics certification pathway.
14 That wasn't the way they came, the training that
15 they've had, nor would they be following either one of
16 the medical physicist certification pathways, either
17 diagnostic or therapeutic. So those are out, and not
18 to be considered. What's left is the alternate
19 pathway, and its specific requirements, so you could
20 have someone attest to the fact that they've fulfilled
21 those specific requirements listed in the alternate
22 pathway, or if they were already named on a license,
23 or expected to be named on a license as an authorized
24 user - follow what we were just discussing, which is
25 the (c) (2) pathway for authorized individuals, that

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1 the individual is named on a license as one of these
2 authorized persons, and they've had the specific
3 training in Section E, which we went over, and this is
4 a value judgment on the part of the preceptor that
5 they are qualified to be the RSO for what they wish to
6 be responsible for.

7 CHAIRMAN MALMUD: Okay. Thank you. I
8 believe we have -- oh, Dick, and then we have a member
9 of the public.

10 MEMBER VETTER: Okay. Just one quick
11 question. Does the letter of attestation have an
12 expiration date on it?

13 DR. ZELAC: That has not come up. I see
14 no reason why it would have to have any stale dating
15 associated with it.

16 DR. BETH-HOWE: The training and
17 experience.

18 DR. ZELAC: That's another issue, but that
19 has to do with meeting the qualifications of the
20 current rule in terms of becoming authorized to begin
21 with. The training and experience has to be within
22 the past seven years.

23 DR. BETH-HOWE: The comment was that the
24 recent training and experience would take place, so if
25 you had an attestation that was, say, 25 years old and

1 you hadn't practiced for 25 years, we would probably
2 look for something more recent as an attestation.

3 DR. ZELAC: Yes.

4 CHAIRMAN MALMUD: Thank you, Dr. Howe. We
5 do have a member of the public who's been waiting to
6 speak. Would you please introduce yourself and then
7 make your presentation. Thank you.

8 MR. WHITE: Thank you. I'm Gerald White,
9 and I'm representing the American Association of
10 Physicists in Medicine. And I have yet some
11 additional comments to make on the training and
12 experience issues, as applies to medical physicists.
13 And you have a written statement in front of you,
14 which is much more complete than the brief talk I'm
15 going to give today.

16 I do want to say that AAPM understands the
17 Commissioners' desire for a change in the board
18 recognition process, and we understand that it was the
19 Commissioners' desire not to provide a mechanism by
20 which the boards were grandfathered. But we do not
21 believe that the Commissioners had in mind the lack or
22 creating a class of previous diplomats who were unable
23 to use their certificates to become qualified in the
24 future.

25 We believe that it's been clear in the

1 recent months that the regulatory language and
2 application process for the boards has been seriously
3 flawed. The process is going on very slowly, and that
4 has impacted the ability of the people to become
5 recognized on licenses.

6 In the printed material you have some
7 statements, one from Commissioner Merrifield, where he
8 notes that the existing specialty boards, although did
9 not meet -- they've met the intent of the required
10 training, even if they did not meet the exact wording
11 in the regulations. I've also quoted from an NRC
12 statement that says, "If an individual holds
13 certification from a board for which the NRC or
14 agreement state withdraws recognition, the
15 certification will be considered valid if it was
16 granted during the time interval that the board
17 certification process was recognized." The AAPM would
18 like the Committee to consider that spirit in applying
19 this process to medical physicists who were previously
20 certified.

21 I note that the process impacts medical
22 physicists more profoundly than other specialties.
23 Unlike authorized users, the status of authorized
24 medical physicists is a recent construct, so the
25 opportunities for grandfathering were limited. In

1 addition, you've already heard, and I'll say again,
2 radiation safety officers, there is but one in an
3 institution, so the opportunity for a medical
4 physicist who had been practicing even for a great
5 many years to become a radiation safety officer, was
6 limited. Dr. Zelac referred to people who had waited
7 until it was too late to apply; but, in fact, for
8 medical physicists, it's not that we were dithering in
9 the brew pub or the lab, the opportunities just did
10 not exist. The entities or the singularity RSO
11 position places undue burdens on the grandfather
12 process for us.

13 I'll also note there's been much
14 discussion about alternate pathways. Alternate
15 pathways, while it is theoretically possible, can be
16 very difficult to achieve for AMPs and RSOs whose
17 training occurred a number of years ago for reasons
18 that have been previously discussed. And also, it
19 should not be necessary for an individual who has
20 previously been qualified or had a board certification
21 that was recognized by the NRC to have to create the
22 alternative pathway documentation which can be
23 burdensome.

24 I also note that as Dr. Diamond mentioned,
25 this is going to create a classification of

1 individuals, practitioners who will be "difficult to
2 license". We'll find it that they'll be at a
3 competitive disadvantage with their peers. I also note
4 that this status will follow, for recent diplomats,
5 will follow for their entire careers. Dr. Diamond
6 raised the issue of the ABR diplomats in therapeutic
7 radiation oncology. That's not an issue that just
8 applies to these folks in the first year or two when
9 they get their first license. They will be on the
10 alternative pathway qualification route, I believe,
11 for their entire career, so every time they change
12 jobs, they're going to have to re-justify their
13 license or status. So we're asking the NRC staff to
14 take whatever steps are necessary to see that previous
15 diplomats of ABR and ABMP boards are recognized
16 without the construct of effective date. The
17 effective date construct had never been seriously
18 discussed in all the years that this topic has come up
19 at the ACMUI, and we think it's an unnecessary
20 impediment.

21 Lastly, we note in the document that you
22 have that many agreement states have come to a set of
23 successful procedures that will overcome these
24 obstacles, and we would like the NRC to follow their
25 lead and create procedures whereby authorized medical

1 physicists and RSOs can be named based on previously
2 existing board certification, not grandfathering the
3 boards, but recognizing previously approved
4 certificates.

5 CHAIRMAN MALMUD: Thank you, Dr. White.
6 Any discussion? So concisely, you are asking that the
7 individuals be grandfathered, not the board itself,
8 but the individuals. Is that correct?

9 DR. WHITE: Yes. And we're asking that it
10 be done in a practical fashion. We've heard a lot of
11 suggestions here today about case-by-case review by
12 various boards. That sort of thing is just
13 practically impossible. There are probably a thousand
14 diplomats in physics of the American Board of
15 Radiology, and their situation needs to be addressed
16 as a group, I think.

17 CHAIRMAN MALMUD: Do you have a suggestion
18 for how that might be achieved?

19 DR. WHITE: I don't. And I had thought
20 about making suggestions, but I think the first goal
21 is to get an agreement that a problem exists, and it
22 needs to be solved. What I'm hearing today is that a
23 problem doesn't really exist, and there are a great
24 many work-arounds by which one can be certified. And
25 I think that both of those things are false. The

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1 problem exists, and there are no easy solutions.

2 What states have done, is issued an
3 additional time, and states have additional years to
4 adopt these changes. And during that additional time,
5 physicists can apply for these RSO and authorized
6 medical physicists positions under the old rules. The
7 problem we have in the NRC world is that the old rules
8 expired before the new boards were approved, and
9 that's unique in the NRC formalism. And I think it's
10 an error.

11 CHAIRMAN MALMUD: Thank you. Mr. Lieto.

12 MEMBER LIETO: Well, I guess I would --
13 maybe the statement that Mr. White presented here
14 about a possible, I don't want to say fix, but maybe
15 at least for previous diplomats the statement that in
16 the NRC document about procedures, that if an
17 individual holds certification from a board for which
18 the NRC or agreement state withdraws recognition, the
19 certification will be considered valid if it was
20 granted during the time that the board certification
21 process was recognized. And to me, it looks like a
22 way around the problem and concern that we've been
23 expressing repeatedly with previous diplomats being
24 recognized.

25 CHAIRMAN MALMUD: Dr. Williamson.

1 MEMBER WILLIAMSON: Well, I think the full
2 story is not in. We don't -- the NRC staff is very
3 tight-lipped on what's going on about the AMP
4 certification. But I think what has happened to
5 radiation oncologists suggests we are on the verge of
6 an unmitigated disaster with board certification,
7 round two. If I point out some history; we went to
8 the Commission three years ago complaining basically,
9 what a disaster the new Part 35 Training and
10 Experience requirements were, that it was going to
11 cause chaos, shortages, all sorts of problems because
12 previously well-accepted and qualified boards will no
13 longer be accepted as default credentials, and
14 everybody will have to go through the alternative
15 pathway. This was accepted and the Staff Requirements
16 Memorandum came out that we were to try again. And
17 here we are. I think we're on the verge of having to
18 admit we've failed the community again.

19 CHAIRMAN MALMUD: May I ask a question of
20 the group; and that is, who is opposed to granting
21 continuing privileges to those who already have them?
22 What constituency is arguing against continuing the
23 certification of the individuals who already are
24 certified? Who has spoken against it? Who has
25 concerns that something untoward will happen to a

1 patient as a result of continuing certification for
2 those who already have it? Has anyone? Dr. Holahan.

3 DR. HOLAHAN: The problem is, as has been
4 said, they weren't previously listed on a license, so
5 I think that's the problem that we were trying to fix,
6 because only authorized medical physicists who are
7 listed on licenses were teletherapy physicists. There
8 was no other authorized medical physicist prior to
9 this new rule that was specified on a license.

10 CHAIRMAN MALMUD: Mr. Lieto.

11 MEMBER LIETO: Well, I'd like to say, the
12 problem is even worse than that because only a
13 minority of the states were even teletherapy
14 physicists listed, and those were only the non-
15 agreement states. Most agreement states did not even
16 list them, so even though there had been in the
17 process of NRC regulations that teletherapy physicists
18 be listed on NRC licenses, the agreement states were
19 under no obligation, and many of them did not list
20 physicists on their agreement state licenses. And I
21 can tell you from personal experience, these are
22 problems in getting an AMP approved now that that has
23 generated.

24 CHAIRMAN MALMUD: If I may, I'll restate
25 my question. Other than the issue of bookkeeping,

1 documentation, of having been on a previous license,
2 what risk to the public do we perceive in continuing
3 the licensure of those who have been practicing? What
4 risk is there? What evidence is there that a single
5 patient has been harmed by such an individual, whose
6 license will be essentially revoked with this new
7 regulation? Is there anyone who is aware of any
8 single instance in which a patient has been harmed?
9 Dr. Nag.

10 MEMBER NAG: No. I mean, I was going to
11 say something else. I was going to say that one
12 possibility that the Subpart J that expired October of
13 2005, one possible fix is that Subpart J be extended
14 until this new board certification takes over in June
15 of 2007, so that between October of 2005 through June
16 of 2007, the regulation of Subpart J be continued.
17 That might be a possible solution.

18 CHAIRMAN MALMUD: Dr. Nag, does that solve
19 the problem or delay resolving it?

20 MEMBER NAG: It will solve the problem
21 because the problem now is what is happening the
22 graduates who are graduating in 2006 June, or some
23 people graduate in late 2006, so it will solve those.

24 CHAIRMAN MALMUD: Is that the only
25 problem, though? Mr. White, is that the only problem,

1 those who are graduating in `06, or will graduate in
2 `07?

3 MR. WHITE: No, it's not.

4 CHAIRMAN MALMUD: Would you please restate
5 what you perceive the problem to be?

6 MR. WHITE: Well, let me answer the
7 question, if I may, why that doesn't solve the
8 problem. For radiation safety officers, you still
9 have the issue that there is but one RSO in a facility
10 in most states; although, in some states they have
11 things called associate or assistant RSOs. And I can
12 tell you that we have 12 of them on our license just
13 to avoid this problem. But it also affects people who
14 are in the pipeline for RSO, and the existing RSO
15 doesn't want to step aside just to have a junior
16 person named to get on the license.

17 If the extension period lasted long enough
18 so that practicing medical physicists could get on a
19 license as an AMP, if the construct existed long
20 enough, that would ameliorate the problem. It would
21 still put us in the same position as some of the Rad
22 Oncs having to constantly justify your alternate
23 pathway if you fail to get on a license in time, if
24 you were the procrastinator that Dr. Zelac described.
25 So I think then you have a paperwork burden with no

1 benefit to the public, but it would certainly be a
2 better situation than what we have now. It's not a
3 solution.

4 CHAIRMAN MALMUD: So that the answer to my
5 question is that Dr. Nag's suggestion would give time
6 for those who need to address any perceived
7 deficiencies to do so by `07.

8 MEMBER NAG: I was meaning for the
9 radiation oncologists. I was not addressing the RSO
10 problem. The solution I was giving was for radiation
11 oncology, and I think that would solve the problem for
12 the radiation oncology.

13 CHAIRMAN MALMUD: Would that solve the
14 problem for the radiation oncology community as a
15 whole, or only for those who are finishing training in
16 `06 or '07, Dr. Nag?

17 MEMBER NAG: I think it should solve the
18 overall radiation oncology problem.

19 CHAIRMAN MALMUD: Thanks. Dr. Diamond,
20 would you agree that that would solve the radiation
21 oncology problem for `06 and `07, which is the only
22 problem that you see with this change of
23 interpretation of regulations?

24 MEMBER DIAMOND: I'm sorry. I was just
25 outside. I didn't --

1 CHAIRMAN MALMUD: All right. Dr. Nag
2 suggested that the problem with regard to the
3 radiation oncologist specialty could be resolved if -
4 is it Subpart J - were extended to October of `07;
5 therefore, allowing those who are currently in the
6 pipeline or who will be completing their training by
7 `07, to meet the new criteria; and, therefore, not
8 preventing them from practicing without restrictions.

9 MEMBER DIAMOND: Since I'm the pragmatic
10 guy, I asked myself how many people are being
11 affected? Once again, it's my impression that the
12 only individuals being affected will be those
13 individuals finishing their training programs in 2006,
14 who will be operating in clinics where there is not an
15 authorized user, and who desire to use manual
16 brachytherapy, 35.390 uses, and so forth. I think the
17 easiest solution is just to let them know right now
18 that they need to go and have complete and thorough
19 documentation that they have met all the relevant
20 criteria to which they've been trained, and not go
21 through a process of trying to extend Subpart J.

22 CHAIRMAN MALMUD: Dr. Williamson, do you
23 have a third opinion?

24 MEMBER WILLIAMSON: I do, indeed. Yes, I
25 am reviewing 35.690, and respond to a previous comment

1 of Dr. Zelac's, that 35.400 training would satisfy the
2 35.600 requirement. Well, anyway, I think it's
3 incorrect. It specifies here that, "The structured
4 educational program has to contain 500 hours of work
5 experience under the supervision of an authorized user
6 who meets the requirements in 35.690 or before October
7 2005, 35.960, at a medical institution involving" -
8 and then it lists all sorts of things you have to do
9 that are specific to the devices regulated by 35.600.
10 So no, I don't think any old ordinary radiation
11 oncology residency would satisfy this requirement via
12 the alternative pathway. So I think there's a second
13 group of individuals that is older diplomats who wish
14 to switch from the modalities they were trained in to
15 Gamma Stereotactic, or HDR, as it appears in their
16 institution, and they would be in trouble because they
17 do not have this 500 hours under the supervision of
18 somebody who was 35.690 AU, or had the devices at the
19 time at the institution.

20 MEMBER DIAMOND: Excuse me, Jeff. If my
21 understanding is correct, you're saying that you have
22 a substantial concern because you're concerned about
23 the authorized user prior to October 2005, who is now
24 changing his or her practice to take on a new modality
25 use, such as a 690 use for gamma stereotactic, and

1 your feeling is that according to the letter of the
2 law, that would entail 500 hours of such experience,
3 as opposed to just going through the specific vendor
4 training, which is designed to be flexible. And I'm
5 confused, because I thought Dr. Zelac specifically
6 spoke to that point and held a different opinion.

7 MEMBER WILLIAMSON: Yes. I am disagreeing
8 with Dr. Zelac. I think his point is true of those who
9 qualify for AU via the certification pathway only.

10 CHAIRMAN MALMUD: Is Dr. Zelac still here?

11 DR. ZELAC: Oh, yes.

12 CHAIRMAN MALMUD: Ron, your name is being
13 dragged about. Would you please clarify what you said
14 so that you can reassure Dr. Williamson of your
15 position.

16 MEMBER DIAMOND: Just tell us, is Dr.
17 Diamond right, or Dr. Williamson right.

18 DR. ZELAC: My comments were clearly at
19 the podium in response to questions without taking the
20 trouble to look specifically at what was listed in the
21 requirements. If Dr. Williamson indicates that that
22 it wouldn't be fulfilled, I'm inclined to say that
23 perhaps the wording suggests that. On the other hand,
24 an authorized user for radiation oncology, it seems
25 reasonable, and I'd like to be able to look more

1 carefully, it seems reasonable that such a person
2 would be able to add a modality without having to
3 acquire that much additional experience. I reserve
4 comment until I've had a chance to take a look
5 specifically. But since I have the microphone, if I
6 can make an additional comment in response to part of
7 what Mr. White had said. Is that okay?

8 CHAIRMAN MALMUD: Please do, Dr. Zelac.

9 DR. ZELAC: The example was given of
10 someone who would become a radiation oncology
11 authorized user via the alternate pathway, having to
12 reassemble all of this information time after time as
13 they move from one institution to another. Once
14 they're named on a license as an authorized user, they
15 can use that as their credential towards being named
16 as an authorized user on another license. They do not
17 have to recreate the entire background. Their
18 authorized status becomes their document of
19 verification, or it should, to go from one licensee to
20 another.

21 There are exceptions. I know that we, for
22 example, at NRC will accept authorized status from an
23 agreement state; whereas, some of the agreement states
24 anyway will not accept NRC authorized status in order
25 to name an individual as authorized in their

1 jurisdictions.

2 DR. BETH-HOWE: Ron, I don't think the
3 regs say that, though, explicitly.

4 DR. ZELAC: Say what?

5 CHAIRMAN MALMUD: Someone made a comment
6 that I couldn't hear, and did not introduce --

7 MS. FAIROBENT: Dr. Malmud, Lynne
8 Fairobent, AAPM, also. I don't believe that the
9 regulations specifically say that if you come in under
10 the alternate pathway and you get on one license, and
11 you move to another, it will be recognized. I think
12 that that's something that is open. I think it was
13 clearly the intent that that would happen, but I don't
14 think it specifically is documented in that manner.

15 CHAIRMAN MALMUD: Dr. Howe, do you --

16 DR. ZELAC: We are in disagreement,
17 because I am sure that a person in an NRC state who
18 achieved authorized status on one license can use that
19 listing as an authorized individual to do exactly the
20 same work at another licensee's facility.

21 CHAIRMAN MALMUD: Dr. Howe.

22 DR. BETH-HOWE: This is Dr. Howe. And
23 that's included in the definition in 35.2 of an
24 authorized user. The definition is that you meet the
25 requirements for the alternate pathway, or that you

1 are already listed on a license for that use. And it
2 pertains also to the medical physicist, and the
3 nuclear pharmacist, so it is in regulation, and it is
4 across the board for NRC.

5 CHAIRMAN MALMUD: Thank you, Dr. Howe.
6 Having heard the reassurances of both Dr. Howe and Dr.
7 Zelac regarding this issue, is there any more concern
8 about it? Good. Oh, there is concern. You know, I
9 was -- in my former role as the Dean and Vice
10 President of a university, I worked more with lawyers
11 than with physicians. And the one thing the lawyers
12 taught me was that when you've won a battle, be quiet.
13 Anything you say from there on will only damage your
14 position. Now you have two highly respected members
15 of the NRC staff, Dr. Howe and Dr. Zelac, who have
16 assured you - are you sure you want to continue this
17 discussion, and to what goal? Mr. Lieto.

18 MEMBER LIETO: I will restate my point in
19 that I don't dispute their claims about the authorized
20 users. I do dispute that that occurs for the
21 physicists. Physicists are not named on licenses in
22 most agreement states, so that transfer does not occur
23 because they aren't named. I will concede the fact
24 that if they are named on an NRC license, that that is
25 usually accepted by the agreement state, but that does

1 not mean that they will be named on that agreement
2 state license.

3 CHAIRMAN MALMUD: Thank you for that
4 information. Now I think that Dr. Eggli was next.

5 MEMBER EGGLI: And my comment comes back
6 to Subir's, because although I represent Organized
7 Nuclear Medicine, there is an orphan child who isn't
8 sitting at this table, which is diagnostic radiology,
9 and somebody has to speak for diagnostic radiology.
10 And there is an analogy to the Social Security's notch
11 babies, which were people who were born between 1917
12 and 1922 who have reduced benefits for their whole
13 life just because they happened to be born during that
14 time. And so that the 2006 graduates of radiology
15 programs are going to be notch babies who are
16 potentially disenfranchised. Extending Subpart J
17 until the American Board of Radiology meets all of the
18 requirements would take care of that subgroup, the
19 same as it would take care of the subgroup that Subir
20 was talking about. And, again, the issue is
21 documenting not the 700 hours, but documenting the 80
22 hours of classroom and didactic, which is required for
23 alternate pathway, but not required for the board
24 certification pathway, so we've changed rules
25 midstream. And I'm used to this, because I spent 10

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1 years in the Army, they always changed rules midstream
2 on me. As a matter of fact, I went in with an
3 obligation of two years, four months, and twelve days,
4 and because they changed rules so often, it took me
5 ten years to pay back that obligation, so I understand
6 changing rules midstream. But we have a group of
7 potentially disenfranchised people, and they are the
8 rat in the snake's belly. This year, 1,600 graduates
9 will happen. The vast majority of them will go into
10 private practice. There are 125 academic medical
11 centers in this country, and based on statistics
12 published by the Association of Chairs of Academic
13 Radiology Departments, there are at least six job
14 openings in each of the 125 academic medical centers
15 which can't be filled. And with 1,600 graduates every
16 year, that tells you how few go into academic medicine
17 every year, so all of these people are going out into
18 private practice. So out of that 1,600, probably all
19 but 100, and probably all but 50 will be affected by
20 this change where their programs are going to have
21 trouble documenting the alternate pathway for them.
22 Extending Subpart J until the board is clearly in
23 compliance with the letter of the law, as opposed to
24 the spirit of the law, would avoid this potential
25 catastrophe for 1,500 people.

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1 CHAIRMAN MALMUD: Now having heard this
2 discussion which it's true, I recognize it's going
3 overtime, but it's very important. Having heard the
4 discussion - oh, okay. I was going to suggest, is
5 there anyone here who would not support a motion that
6 with respect to radiation oncology and radiology, that
7 we recommend in the strongest terms that Subpart J be
8 extended through October of '07? Dr. Miller.

9 DR. MILLER: Seeking the wisdom of your
10 earlier counsel about dealing with lawyers, I'd like
11 to point out before you enter such a motion, that it's
12 not a simple matter of extending Subpart J. Subpart
13 J has expired last October. Since Subpart J has
14 expired, it's not like we did a year and a half ago or
15 two years ago, where we simply sought approval from
16 the Commission to extend it. What we are basically
17 dealing with then, is promulgating a new rule, since
18 there is no Subpart J that currently exists as a
19 federal regulation. The time that it would take to do
20 that may be longer than the time that's going to be
21 needed to get to 2007. That's my professional
22 opinion.

23 CHAIRMAN MALMUD: Do you have an opinion
24 regarding a means of resolving this difficulty?

25 DR. MILLER: It was stated earlier, I

1 think, in one of the comments of a member of the
2 public that the agreement states seem to have some
3 solution that would work around this. All I can offer
4 at this point in time is to try to entertain the
5 agreements states and the CRCPD to see if there's
6 something we can do to resolve the dilemma. I think
7 from my perspective, and I think from Dr. Holahan's
8 perspective, we recognize that this is a dilemma,
9 especially for medical physicists. And especially in
10 light of the fact that through no fault of their own,
11 they weren't named on licenses. And it seems to be
12 from the evidence that was presented today, that
13 there's a large number that are in that situation.
14 And correct me if I'm misspeaking, but I think the
15 concern would be that they would be disenfranchised,
16 so we need to think about a practical solution.

17 I don't think the staff has an answer to
18 that question today, and I think that's something I
19 need to ask my staff to try to work on. And I would
20 commit to try to engage the states to see if we can
21 come up with a practical solution.

22 MEMBER DIAMOND: Dr. Diamond. Since it
23 was I who brought up this issue forty-five minutes or
24 an hour ago when I asked a question regarding the June
25 2007 issue, I think to summarize, I don't think

1 additional rulemaking to satisfy this conundrum is
2 going to be practical. I'm disappointed that the ABR
3 was not able to go and make its necessary or requisite
4 modifications to address those diplomats finishing in
5 June 2006, so again the question is, for those
6 individuals who are going specifically to non-
7 agreement states and who will be working in clinics
8 where there's not an authorized user working in
9 conjunction with them, what can be done? I don't have
10 an answer today. There may be some training programs
11 where the diplomats will be able to honestly document
12 that they have met all of the enumerated requirements.
13 There may be other trainees that won't be able to do
14 that. I think we need to go and engage the American
15 Board of Radiology and have a discussion with them.
16 I don't think it can be solved here at this venue.

17 CHAIRMAN MALMUD: Dr. Williamson. I
18 believe Mr. Bailey had his hand up first, then Dr.
19 Williamson. Mr. Bailey. Is that okay with you?

20 MEMBER WILLIAMSON: Yes, of course.

21 MEMBER BAILEY: The question of agreement
22 states not adding physicists to the license - I think
23 about a year ago, I sent some data because CRCPD was
24 meeting at the same time, or whatever. That sort of
25 few the attention of the agreement states to what was

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1 going to be happening, and I think many of the
2 agreement states in their responses at that time
3 indicated that they were going to start doing it. And
4 I know in California we did go in and add some.

5 The remedy, I think, that's been
6 mentioned, and so I'm hoping that that's not as big a
7 problem now, and I'd be happy to query them again to
8 see what the status is. Another issue that was
9 brought up was that the agreement states seemed to be
10 able to work around this problem. And I think part of
11 that is because the agreement states haven't adopted
12 these regulations yet. They had three years from the
13 time, and certainly, we're now in what year, point 8
14 or something of that three-year period on T&E. So in
15 the meantime, we're waiting for the next shoe to drop
16 in the continuing saga of T&E and NRC.

17 The other thing, and I would just throw it
18 out, and I may get something thrown at me, is that it
19 seems to me that there is a process for an exemption
20 to a regulation. And I don't see why these people
21 could not apply for an exemption to those requirements
22 for an authorized user. And if NRC had a bent toward
23 doing that, they could, I would think, certainly grant
24 that exemption for an individual person.

25 And the last point, and I'll shut up, is

1 that someone did mention that some agreement states
2 have been adding assistant RSOs for years, or at least
3 for some time. I know in California we basically said
4 that if you had a large facility, you must have at
5 least one assistant RSO, because we felt that those
6 facilities that were operating 24/7 could not possibly
7 have coverage, particularly during vacations and so
8 forth, so at least in California, a lot of the
9 licenses did have assistant RSOs on them, which I
10 presume, although I guess I should ask, would be
11 accepted as an RSO.

12 CHAIRMAN MALMUD: Thank you. Dr. Zelac
13 and Dr. Williamson. Dr. Zelac's comments may address
14 your concern, Dr. Williamson, so if I may, I'll ask
15 Dr. Zelac to make his comments first.

16 DR. ZELAC: Thank you. Two things.
17 First, with respect to medical physicists and being
18 named on licenses, and being able to essentially
19 grandfather as the agreement states change their
20 requirements. It was, and Mr. Bailey is correct,
21 approximately a year ago that discussions on this
22 issue were raised. And there were several suggestions
23 that were offered at that time to the agreement states
24 for them to alleviate potential problems down the
25 road. The first of those was that as licenses were

1 being written or amended, that at that point in time
2 the medical physicist be named on the license.
3 Another was that some states have created lists of
4 qualified experts in various fields, and the state
5 could essentially take action to recognize all of
6 those individuals en masse in a group as the
7 equivalent of being listed on a license, because the
8 whole purpose of having such list was that such
9 individuals, when named by a potential licensee as
10 their physicist, would be automatically accepted,
11 whether they were named on the license or not. So
12 there were various suggestions that had been made over
13 a year ago, or perhaps a year ago, for the agreement
14 states to work towards alleviating what could be a
15 large problem when their regulations finally come into
16 agreement with our's. That was the first point. And
17 if you'll indulge me, I'll just finish up.

18 With respect to what Dr. Williamson was
19 questioning on my earlier statement, my statement, I
20 think, holds. I am not retracting it, primarily
21 because the example that he had given and was
22 discussing was for an individual who had been
23 previously certified in radiation oncology, and had
24 been practicing and named on a license. Now such an
25 individual then would only have to consider, if you

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1 will, the certification pathway. And for both 490 and
2 for 690, the certification pathway requirements are
3 the same. There are no differences. The examination
4 typically would cover both brachytherapy and devices,
5 so the person who had been previously certified would
6 have had some testing on devices, as well as on source
7 use. They would have gone through the same three-year
8 residency program, and on that basis, being qualified
9 to 490 would mean that they could become qualified
10 under 690 for one of the devices that are covered in
11 690, as long as they had the additional training
12 covered in Section C, which is the additional section.

13 MEMBER WILLIAMSON: That would make sense
14 if the board certification were accepted as a pathway
15 for authorized usership at that time. But by
16 hypothesis and, indeed, fact, that is not so. The
17 individual is recognized as an authorized user for
18 brachytherapy say in 1995 by virtue of a regulation
19 which is no longer on the books and not recognized as
20 having any implications for grandfathering today. It
21 is now stated that board certification only after
22 January 1st, 2007 is relevant.

23 DR. ZELAC: But my point was, just to
24 reiterate, that the individual who is named already on
25 a license, they got there by board certification,

1 that's fine. But they're already named on the
2 license. We're talking about extending their scope of
3 usage to include a new modality, and for that they
4 should only need additional training.

5 MEMBER WILLIAMSON: That's 35.57, but it
6 says only for the same kind of use.

7 MEMBER NAG: I suggest we move on, because
8 this -- I don't think we're going to end this any time
9 soon.

10 CHAIRMAN MALMUD: Thank you, Dr. Nag.

11 MEMBER WILLIAMSON: But that's not the one
12 I wish to make. That was a response to comment on one
13 of my earlier. My comment is, I think we should ask
14 for an audience before the Commission and air this
15 whole problem. It may well be that we might just have
16 to admit failure.

17 MEMBER DIAMOND: Leon, I still think that
18 we should engage in formal communication with the
19 American Board of Radiology so that we can go and best
20 define the nature and the scope of this alleged
21 difficulty.

22 CHAIRMAN MALMUD: I'm not certain which of
23 the difficulties you're referring to. It seems to me
24 that we've listed three difficulties. One is, the
25 radiation oncologists who are finishing training, and

1 their need to be authorized users without having to
2 get passed the boards. Therefore, they would have to
3 have satisfied the T&E requirements under the
4 alternate pathway. Some will not have done that.

5 The second one is the radiology residents
6 who will be finishing with the same problem. The
7 third is the issue of physicists, whether they receive
8 their physics training under the ABR or another route,
9 and what their status is. And it looks as if, in
10 terms of crises, the crisis that may be the largest of
11 all requiring individual attention is the issue of the
12 physicists who, in a sense, are being disenfranchised.

13 MEMBER DIAMOND: If I may respond to your
14 first two points.

15 CHAIRMAN MALMUD: Yes.

16 MEMBER DIAMOND: I think that we need to
17 send two letters to the American Board of Radiology
18 asking how they, as a board, suggest addressing the
19 issue, firstly, of radiation oncology trainees who
20 will be completing in June 2006, who desire to
21 practice 390, 490, 690 uses in non-agreement states in
22 clinics where there's not an authorized user. Ask
23 them how they've decided to address the problem, and
24 then repeat a similar letter to the American Board of
25 Radiology specifically for diagnostic medicine, how

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1 will the issue of trainees finishing in June 2006 who
2 wish to practice 390 uses, who may not be able to
3 document the 80 hours that Dr. Eggli has discussed,
4 what solution is proposed, again practicing in non-
5 agreement states where there's not an authorized user
6 also practicing.

7 CHAIRMAN MALMUD: On those two issues, who
8 has been communicating with these two boards, who in
9 the NRC? To whom are the ABR - who are they writing
10 to, and who's responding to them?

11 MS. FLANNERY: That would be.

12 CHAIRMAN MALMUD: Okay. So do you think
13 that it would be worthwhile drafting two such letters?

14 MS. FLANNERY: Yes. As I mentioned
15 before, the reason why it has a future date of June
16 2007 is because the ABR Radiation Oncology specialty
17 could not meet the criteria in 390. So we could
18 possibly go to the board and see if that was the case
19 for 490 and 690, that would be a possibility, and
20 contacting the board that way.

21 CHAIRMAN MALMUD: Would that satisfy your
22 suggestion, Dr. Diamond?

23 MEMBER DIAMOND: I think it would be an
24 extraordinarily useful exercise to contact the board
25 and ask the specific question that I outlined a few

1 moments ago, and ask how they suggest solving the
2 problem. And perhaps, in the interim since you've
3 last had communication with the board, perhaps they've
4 been able to submit additional information or data
5 that would allay some of our concerns regarding the
6 490 and 690 uses, at a minimum.

7 CHAIRMAN MALMUD: All right. So you are
8 suggesting two such letters be drafted, one of the
9 American Board of Radiology, one to the American Board
10 of Radiation Oncology.

11 MEMBER DIAMOND: No, no. American Board
12 of Radiology with respect to radiation oncology, and
13 a second to the American Board of Radiology with
14 respect to diagnostic --

15 CHAIRMAN MALMUD: Diagnostic radiology.
16 Ralph, Mr. Lieto, you have a comment about that?

17 MEMBER LIETO: Just a question for
18 Cynthia. Does the ABR understand, or I should say do
19 they recognize that what they've put forth so far will
20 disenfranchise previous diplomats? Do they understand
21 that, or are they just kind of looking at the future
22 and trying to address a future issue?

23 MS. FLANNERY: I think that was a question
24 that Dr. Diamond had asked earlier, and I don't know
25 the answer to that. I'm sorry.

1 MEMBER DIAMOND: Ralph, I bet that when
2 they were issuing this material in response to the
3 staff's questions, someone probably neglected this
4 specific issue that was highlighted and brought to our
5 attention an hour ago, as the start of our
6 conversation. Just a guess.

7 CHAIRMAN MALMUD: Well, it certainly is a
8 worthwhile effort to get those two letters off as
9 quickly as possible, if you're in agreement that those
10 can be written.

11 PARTICIPANT: Dr. Malmud, I think Dr.
12 Diamond is suggesting letters written from the ACMUI,
13 not necessarily the staff. Is that correct, Dr.
14 Diamond?

15 MEMBER DIAMOND: I did not specify.
16 Perhaps it would be best for Ms. Flannery to be the
17 author of the letters since she has the ongoing
18 communication. The ACMUI does not have the ongoing
19 line of communication with the ABR. Although,
20 certainly, we as individuals could contact them.

21 CHAIRMAN MALMUD: Dr. Miller.

22 DR. MILLER: May I offer a practical
23 solution?

24 CHAIRMAN MALMUD: Please do.

25 DR. MILLER: Would it be acceptable to the

1 ACMUI for the NRC staff to send such a letter, but
2 note in the letter at the recommendation of ACMUI we
3 are sending you this letter? I think that would
4 satisfy all concerns.

5 CHAIRMAN MALMUD: That would satisfy us.
6 Thank you. Could that letter go out soon?

7 MS. FLANNERY: I don't see a problem with
8 that.

9 CHAIRMAN MALMUD: Okay. So we'll assume
10 that that letter will go out to the ABR with regard to
11 radiation oncology and diagnostic radiology. All
12 right. So that begins to address two of the issues.
13 The third issue remains, and that is the concern about
14 the status of the physicists. Dr. Miller.

15 DR. MILLER: Yes. Dr. Holahan has raised
16 an interesting point. There seems to be a lot of
17 interest in getting a letter out quickly, but then the
18 question becomes does the ACMUI want to review the
19 letter before it goes out to assure that its
20 recommendations are accurately reflected so that we're
21 not back at a table later saying that the staff
22 mischaracterized what your intentions would be.

23 CHAIRMAN MALMUD: Dr. Vetter says that
24 Malmud could review it, and Malmud would be happy to
25 review it with Dr. Diamond, since it was his

1 suggestion. We could do that very quickly as soon as
2 the letter is drafted.

3 MS. FLANNERY: Okay.

4 DR. MILLER: Thank you.

5 CHAIRMAN MALMUD: That takes us to the
6 other issue, which is of concern, and that is the
7 status of physicists. What we do not wish to do is be
8 a part of a process which disenfranchises people who
9 are currently practicing, and puts patients at risk
10 for not having adequate physicists to manage the
11 clinical operations. Nobody in this room wishes to be
12 a part of such a process, whether they are ACMUI, the
13 public, or I'm sure the staff of the NRC, so how do we
14 resolve this? Does anyone have a constructive
15 suggestion, rather than replaying the problem? Let
16 the record show we're met with silence so far. I
17 think a member of the public has something to
18 contribute. That's Mr. White.

19 MR. WHITE: I'm not sure I have a
20 definitive suggestion on the spur of the moment, but
21 I'd first like to recognize that there appears to be
22 general agreement that there is a problem that needs
23 to be solved. And secondly, I heard two potential
24 suggestions, each of which I'm sure have difficulties
25 associated with them. One is something analogous to

1 an extension of Subpart J, which brings with it a lot
2 of rulemaking overhead, although from the point of the
3 American Association of Physicists in Medicine, that's
4 overhead that would accrue to the NRC and staff,
5 rather than to our organization and our members, so
6 it's not quite as objectionable on this side of the
7 microphone as the other. But there are some temporal
8 difficulties with that.

9 The other is some discussion of an
10 exemption process, or some sort of interim - I'm not
11 sure in the regulatory world how that might happen.
12 And then the third is maybe a further review of what
13 some states have done in this regard; although, I will
14 say in the states that I'm familiar with, those
15 changes have been done in the rulemaking space, which
16 is much easier in the state world oftentimes than in
17 the federal world. But I think if there is a general
18 agreement that there's a problem that needs to be
19 solved, we can find some way to do it. I'm just not
20 sure that it's this afternoon.

21 CHAIRMAN MALMUD: I think that we've
22 reached an agreement that there's a problem. We've
23 also been told that we cannot resurrect Part J, and
24 that it is not Lazarus, and we don't have that power,
25 so that that's not a viable solution. Therefore,

1 other means of solving the problem need to be brought
2 forth in order not to interrupt the quality of
3 healthcare. It's also been my experience with this
4 Committee within the last year that the NRC staff, Dr.
5 Howe, Dr. Zelac, have, in a sense, been more
6 charitable toward a variance and an exemption for a
7 physicist practicing offshore if I remember correctly
8 than the staff was, than the ACMUI was. So I wonder
9 if, in fact, we should be turning back to the wisdom
10 of Drs. Howe and Zelac, and asking them if they have
11 a solution proposed, since they were more
12 understanding of the special needs of the physicist
13 than this Committee was last time I recall the subject
14 coming forward. Dr. Howe, I'm putting you on the
15 spot.

16 DR. BETH-HOWE: I don't think I have a
17 solution now. I think one of the things that we need
18 to think about is how big is the problem, because
19 we've now had essentially authorized medical
20 physicists, at least in NRC states, for the last -
21 since 2002, and they're only recognized for HDR units
22 and Gamma Knife units. And so, I don't think -- and
23 we're looking at a larger number of Gamma Knife units,
24 but certainly not a huge number of Gamma Knife units,
25 so I'm not sure we have as much of a problem with the

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1 Gamma Knife. And I'm not so sure on the HDR. We
2 haven't recognized an authorized medical physicist for
3 the manual brachytherapy, which I think is probably a
4 larger program, so we don't have a problem for
5 authorized medical physicists for the manual
6 brachytherapy, so I think one of the things we'd have
7 to answer is how big a problem is it, first. And I'm
8 not sure we know that answer right now.

9 CHAIRMAN MALMUD: Would you recommend that
10 we wait and see, and then deal with it on a case-by-
11 case basis as it arises?

12 DR. BETH-HOWE: I think we certainly have
13 more flexibility to do that than any other path,
14 because I don't think there would be that many
15 exemptions that we would be considering.

16 CHAIRMAN MALMUD: Thank you. Mr. Lieto,
17 Dr. Williamson, this relates to physicists. Are the
18 two of you agreeable to see what happens, and then let
19 NRC staff deal with it on a case-by-case basis, as it
20 arises?

21 MEMBER WILLIAMSON: I think we could maybe
22 make it known to the regulated community that if
23 troubles like this do come up, that the NRC does have
24 a mechanism to grant variances from T&E rules, as you
25 pointed out before and some of us were not very

1 charitable, I guess, to all the requesters, but
2 perhaps we could turn over a new leaf and even a large
3 batch of cases like this could be reviewed
4 expeditiously, and a decision rendered, or enough
5 precedents set that the staff would feel comfortable
6 running an exemption process even without our
7 assistance in each case.

8 CHAIRMAN MALMUD: Rather than promising a
9 solution, could you communicate that the NRC will
10 investigate a solution in order to address the issue?

11 MEMBER WILLIAMSON: I would just say, I
12 think maybe this is the best idea. And I think the
13 representatives of the AAPM maybe have heard that
14 there is a mechanism for submitting petitions to this
15 body. Is that correct?

16 DR. HOLAHAN: I'd be cautious -- well,
17 are you saying petitions for rulemaking, or --

18 MEMBER WILLIAMSON: No, petitions for
19 granting an exemption or variance from the written
20 language of the T&E requirement.

21 DR. HOLAHAN: Then it's an application.
22 I'd just like to clarify, it's an application.

23 MEMBER WILLIAMSON: But an individual
24 licensee can make such an application. It does not
25 have to be approved by the region to come to

1 headquarters, does it?

2 CHAIRMAN MALMUD: Dr. Howe.

3 DR. BETH-HOWE: Yes, it would have to come
4 to headquarters. I wanted to make another point, and
5 I think it's something we may not be focusing on right
6 now; and that is that there are several mechanisms to
7 become an authorized medical physicist. One of them
8 is being recognized as an authorized medical physicist
9 by a broad scope license. That's independent of
10 whether the state puts the individual on a limited
11 specific license, and I would think that most of your
12 authorized medical physicists, because of the HDR
13 units and the Gamma Knife units, which is what we're
14 recognizing them for, are probably broad scope
15 licensees. And so, if the broad scope licensee
16 recognize them as an authorized medical physicist,
17 then they would be recognized under NRC's definition
18 of an authorized medical physicist.

19 CHAIRMAN MALMUD: Mr. Lieto.

20 DR. BETH-HOWE: Also, an MML permittee.

21 MEMBER LIETO: I would really strongly
22 take issue with your comment that most of the HDR work
23 is at broad scope licenses. HDR is replacing manual
24 brachytherapy in just leaps and bounds in community
25 hospitals. There are some community hospitals setting

1 up mobile services. It's the exact opposite of the
2 case that most HDR is done in broad scope licenses. I
3 think my guess would be that -- not guess, my strong
4 belief is that it's the exact opposite.

5 CHAIRMAN MALMUD: Well, then we will wait
6 and see as each individual case arises, and NRC staff
7 has the opportunity to see the scope of the problem
8 and to work out a mechanism for dealing with it. It
9 looks as if that's the best we're able to come up with
10 today.

11 MR. ESSIG: Dr. Malmud, Mr. White and Dr.
12 Zelac are waiting.

13 CHAIRMAN MALMUD: Oh, excuse me. Mr.
14 White.

15 MR. WHITE: Thank you. I'd just like to
16 suggest that the process you describe would be eagerly
17 embraced by the AAPM if we were able to see some set
18 of criteria by which the exemption requests would be
19 judged; that is, if there were some sort of formal or
20 informal guidance to the staff that physicists could
21 look at and feel confident or not confident.

22 Secondly, I'll point out that this solves
23 only the problem of authorized medical physicists.
24 The problem of RSO remains, and it will remain an
25 issue for about 25 years until physicists who are

1 certified prior to 2006 retire, so we still need some
2 way to people who are certified prior, assuming that
3 the ABR gains status with a date of 2006, we're still
4 going to have a cadre of physicists who are going to
5 go on for a quarter of a century who need to have this
6 issue resolved, and I'm not sure how to do that. If
7 it's the exemption process, perhaps we should talk
8 about that, but we need to look at both RSO and AMP.

9 CHAIRMAN MALMUD: Thank you for clarifying
10 the long-term issue, as well. And we will ask NRC
11 staff to look at that latter problem, since we do not
12 seem, as the ACMUI, to have the ability to resolve it,
13 except to offer advice if a solution is proposed to
14 us. Dr. Zelac.

15 DR. ZELAC: Just some quick observations
16 on the problem. We've been in the new training and
17 experience rule for five months, which is relatively
18 short time. However, within that five months, the
19 number of cases which have come up which have required
20 exemption request consideration have been virtually
21 zero with respect to physicists. Very few physicists
22 have been coming forth whose credentials didn't match
23 the current requirements, and had to have an exemption
24 request considered.

25 The second thing is that with respect to

1 Mr. White's comments about having some idea what the
2 guidelines would be, this is one of the suggestions
3 that I had actually made to the American Board of
4 Health Physics through one of its members, that a
5 person essentially serve as a test case and apply for
6 an exemption in such a way that we could at least
7 establish some what seem to be reasonable guidelines
8 for granting such an exemption. I think that would
9 have utility. It's not to say that the result of one
10 specific can automatically be extended to many others,
11 but at least it would provide some framework for
12 consideration of others, and some feedback to the user
13 community as to what might be reasonable in terms of
14 seeking an exemption.

15 CHAIRMAN MALMUD: Thank you for that
16 suggestion, Dr. Zelac. I hope that if the AAPM is
17 preparing a test case that they prepare a test case
18 which will be persuasive and select the test case very
19 carefully. We'll move on to the next item on the
20 agenda, which was to have been what - the break?

21 We have a choice - we can take a break,
22 take a five-minute just stand up and walk around, or
23 just continue on? I've minutes. The suggestions were
24 made for five minutes, and that's five.

25 (Whereupon, the proceedings went off the

1 record at 4:23 p.m. and went back on the record at
2 4:37 p.m.)

3 CHAIRMAN MALMUD: We'll begin the
4 afternoon session and first there are some issues that
5 Mr. Essig wants to bring forth. Tom?

6 MR. ESSIG: Yes, just to point out that if
7 you look at the agenda, we have Items 12 -- 11, 12,
8 and 13 on the agenda and it's now 4:35 and those were
9 to have started at 3:00 o'clock. So what we're
10 proposing doing is the last presentation of the day
11 which was going to be a working session with Mr. Lieto
12 to help prepare his slides and all, we will do that
13 tomorrow morning and so that we would have sessions 11
14 and 12 yet this afternoon, plus the five-minute
15 session, Dr. Malmud, that you mentioned by the other
16 presenter.

17 And then tomorrow morning Session 14 will
18 go on as currently scheduled. Session 15 will be done
19 in summary fashion, that is the status of medical
20 events. That will take 15 minutes, thereby freeing up
21 30 minutes. And the other 30 minutes that we would
22 free up would come from the closing session or
23 administrative closing action item review which has
24 budgeted 45. We'll cut that to 15, freeing up another
25 30 minutes, giving us a total of 60 minutes freed up.

1 We'll take the 60 minutes, put it in the time slot
2 right after presentation 15, so from 9:00 until 10:00
3 will be the work session with Mr. Lieto and then the
4 break will be from 10:00 to 10:15 and then 10:15 to
5 11:15 will be Session 16 or, I'm sorry, 10:15 to 11:45
6 will be Session 16. And then Session 17 will be 11:45
7 till noon.

8 I can reiterate that tomorrow morning, but
9 I just wanted to put people who are maybe concerned
10 about this afternoon's session and how late we were
11 going to finish. So, we can proceed.

12 CHAIRMAN MALMUD: Will Mohammed give us a
13 new printout for tomorrow of the new agenda?

14 MALE PARTICIPANT: Yes.

15 CHAIRMAN MALMUD: Thank you. All right,
16 if I may, we have a member of the public, Dr. Salem
17 who is here from Chicago and to whom we had promised
18 five minutes on the agenda a little bit earlier today
19 and I'll ask him to give his presentation. You can
20 come up to the front if you wish, Dr. Salem. Yes.
21 And Dr. Salem is an interventional radiologist at
22 Northwestern University and has about five minutes of
23 comments to share with us. Dr. Salem.

24 DR. SALEM: Thank you, Mr. Chairman,
25 members of the panel. Thank you for the opportunity

1 to speak. I just have an approximately five-minute
2 commentary to make. My name is Riad Salem. I'm an
3 interventional radiologist at Northwestern University
4 in Chicago, Robert H. Lurie Comprehensive Cancer
5 Center. I'm Board certified in radiology by the
6 American Board of Radiology and fellowship trained in
7 interventional radiology. I'm an authorized user of
8 Y90 microspheres. I'm accompanied by Dr. Robbie
9 Murphy, interventional radiologist, M.D. Anderson
10 Cancer Center and Vanessa Gates, certified medical
11 nuclear physicists.

12 This statement is made on behalf of the
13 Society of Interventional Radiology, SIR. The Society
14 of Interventional Radiology is a non-profit, national
15 scientific organization of more than 4,000 physicians
16 and allied healthcare professionals committed to
17 improving the health and quality of life through the
18 practice of vascular and interventional radiology.
19 Before I continue, I would like to disclose that I am
20 a consultant for MDS Nordion, manufacturer of
21 TheraSphere, and I have lectured for Sirtex Medical,
22 manufacturer of SirSpheres. Dr. Murphy is a proctor
23 for SirSpheres. I would like to speak about my
24 experience with Y90 microspheres.

25 As of today, I have successfully performed

1 over 850 infusions of Y90 microsphere therapy as the
2 authorized user. In this capacity as authorized user,
3 I performed all aspects of clinical patient
4 assessment, eligibility for treatment, dosimetry and
5 long-term follow-up. We continue to have a busy
6 clinical practice and we average 28 to 30 cases per
7 month. We continue to publish the safety and efficacy
8 of this data supporting the treating -- the usage of
9 Y90 for the treatment of liver tumors.

10 The SIR is interested in collaborating
11 with the NRC as well as the societies representing
12 radiation oncology and nuclear medicine to recognize
13 interventional radiologists as qualified authorized
14 users for Y90 microspheres. The SIR is concerned with
15 the public transcripts from the meeting held in
16 October 2004 and April 2005 discussing the topic of
17 Y90 microspheres. It is unclear why the significance
18 of the interventional radiology role was downplayed.
19 In fact, it does not appear that interventional
20 radiology had any input in the decision making process
21 for Y90 microsphere regulation given the pivotal role
22 the play in the treatment process.

23 We would like to briefly discuss arguments
24 supporting interventional radiologists as the
25 authorized user for Y90 microsphere therapy. One,

1 interventional radiologists are certified by the
2 American Board of Radiology which includes 960 hours
3 of compulsory nuclear medicine training during
4 residency. Furthermore, as part of their residency
5 training, interventional radiologists must complete
6 mandatory didactic physics training, including
7 radiation biology, radiation physics and radiation
8 safety.

9 Two, Y90 microsphere therapy has been
10 available commercially in the US for six years. IR's
11 have been at the forefront of Y90 research. Of the
12 last 50 peer reviewed publications and book chapters,
13 more than 55 percent were generated by the
14 interventional radiology community. In fact, current
15 clinical research endeavors are underway to study the
16 effects of radioactive microspheres for the treatment
17 of liver tumors. These physician led efforts as
18 principal investigators and as investigational device
19 exemptions are being held by interventional
20 radiologists.

21 Three, one of the arguments for radiation
22 oncologists as the authorized user stems from the fact
23 that Y90 microsphere are classified as ACL source or
24 radiation delivery device by the FDA. However, we
25 believe this classification alone should not

1 determined who should be an authorized user for Y90
2 microsphere therapy, since it ignores the unique
3 delivery methodology for this device. Y90 microsphere
4 treatment is a process unlike other brachytherapy
5 modalities in that it is not performed through a
6 needle placed into position like prostate seeds
7 injected into a closed cavity like leucite or after
8 loaded into the lumen of a stationary catheter by an
9 automated system, example, coronary brachytherapy.

10 Trans-arterial microsphere delivery
11 depends on the knowledge of vascular anatomy. Central
12 factors in insuring target delivery of Y90
13 microspheres are intro-procedural precession of the
14 anatomy, dynamic changes in the capacitiveness of the
15 hepatic vascular bed, catheter infusion pressure and
16 angiographic end points to avoid significant adverse
17 events such as stasis. These scales are intrinsic to
18 the practice of interventional radiology.

19 Four, restricting authorized user status
20 to a radiation oncologist has resulted in limiting
21 access of this therapy to patients. To my knowledge,
22 there have been several hospitals unable to offer this
23 treatment option given the difficulties and the
24 simultaneous availability of IR's and non-IR AU's in
25 the procedure suite at the time of dose delivery. And

1 finally, I would like to discuss possibly one of the
2 most compelling arguments for interventional
3 radiologists as AU's. As part of their regulatory
4 approval, both manufacturers of Y90 microspheres,
5 Nordion and Sirtex require users to undergo training
6 for usage of Y90 that encompasses dosimetry, patient
7 selection, infusion techniques and clinical follow-up.
8 As of today, April 25th, the training of authorized
9 users is being performed exclusively by interventional
10 radiologists with the exception of one radiation
11 oncologist.

12 As previously stated by members of this
13 committee, the role of this committee is not to
14 dictate the medical use and practice of Y90
15 microspheres but to regulate the handling of the
16 radioactive material in a medical setting. We agree
17 with this statement. However, given the reasons
18 above, the infusion of Y90 microspheres share
19 significant features of pharmaceutical delivery. We
20 would like to emphasize, therefore, that
21 interventional radiology offers the expertise for Y90
22 microsphere use and that this specialty should not be
23 excluded. In conclusion, the committee clearly
24 recognizes the requirement for collaborative efforts
25 between multiple modalities for successful use of Y90

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1 microsphere therapy. This is evident given its
2 continued classification as 35.1000.

3 Hence, we believe the training and
4 experience required for this emerging technology
5 should also reflect its hybrid status. We would like
6 to advocate that one, the training requirements for
7 this modality not be limited to 35.490 which
8 essentially mandates three years of radiation oncology
9 residency and two, interventional radiologists, by
10 virtue of their training and experience, be authorized
11 users for Y90 microspheres, a recognition that is
12 commensurate with prevailing clinical practice and
13 ultimately supported by the fact that as of today,
14 radiation oncologists and nuclear medicines are being
15 trained by interventional radiologists.

16 In closing, I thank the panel for the
17 opportunity to provide comments and I'm pleased to be
18 open for questions that it may have. Thank you.

19 CHAIRMAN MALMUD: Thank you, Dr. Salem.
20 Are there questions for Dr. Salem? Dr. Eggli and then
21 Dr. Diamond.

22 MEMBER EGGLI: Actually, David has his
23 hand up first.

24 MEMBER DIAMOND: I'm just going to ask a
25 brief question because I think in Doug's presentation,

1 mine and perhaps Subir's we're going to address a lot
2 of these issues but my one question to Dr. Salem is,
3 are there instances right now where board certified
4 interventional radiologists, who obviously, are
5 authorized users for 35.390 uses are not being granted
6 a use status? Is that what you're telling me?

7 DR. SALEM: Yes, that is correct.

8 MEMBER DIAMOND: Where did that happen?

9 DR. SALEM: Where did that happen or when
10 did that happen?

11 MEMBER DIAMOND: Can you give us some
12 details?

13 DR. SALEM: At hospitals, most hospitals
14 that I'm aware of are not recognizing interventional
15 radiologists as authorized users. They are mandating
16 that it be a radiation oncologist and in some places,
17 nuclear medicine physicians.

18 MEMBER DIAMOND: Okay, but this is a very
19 important distinction. It is not a hospital's
20 determination as to who is an authorized user or not.
21 That's the Nuclear Regulatory Commission's statutory
22 authority. I think what you're referring to is
23 hospital, credentialing hospital privileges. Is that
24 more specific?

25 DR. SALEM: Yes, sir, if you're asking

1 about 35.399, I do not know --

2 MEMBER DIAMOND: Yes, that's a very
3 different issue that we'll talk about.

4 DR. SALEM: Okay, I do not know the
5 answer.

6 CHAIRMAN MALMUD: Dr. Eggli?

7 MEMBER EGGLI: I think that we don't have
8 any trouble and I think both David and I will support
9 the concept, we are not looking at titles of
10 individuals. We are looking at authorization status
11 and I think we will argue that any user who is
12 authorized for Part 300 or Part 400 uses has
13 demonstrated that they have adequate qualifications
14 and there's no reason why an interventional
15 radiologist can't be an authorized user for Part 300
16 uses.

17 Many of them are trained for that. Many
18 of them actually leave their radiology residencies
19 with preceptor statements that qualify them as Part
20 300, the general Part 300, not 392 or 394, but Part
21 300 uses.

22 CHAIRMAN MALMUD: Dr. Eggli, are you
23 saying that from your understanding that they can be
24 authorized users if they experience that training
25 during their residency?

1 MEMBER EGGLI: I think what we're going to
2 be talking about is recommendations that we are making
3 to the ACMUI generally and hopefully ACMUI to NRC as
4 to what are reasonable training requirements for uses
5 of therapeutic microspheres. That's the issue that
6 we're going to address.

7 MEMBER NAG: Dr. Malmud?

8 CHAIRMAN MALMUD: Yes, Dr. Nag.

9 MEMBER NAG: Yeah, since there are going
10 to be three more presentations on the same issue and
11 all of them are going to basically talk about the same
12 thing, shouldn't we have the discussion after the
13 three presentations?

14 CHAIRMAN MALMUD: You mean, should this
15 speaker have come after the others?

16 MEMBER NAG: Yes.

17 CHAIRMAN MALMUD: Yes, but this speaker
18 has to catch a flight back to Chicago and we didn't
19 expect that we would be this late. Other comments?
20 Mr. Lieto? Where is the speaker?

21 MEMBER LIETO: Actually, it was a converse
22 of Dr. Diamond's question; are you aware of any
23 interventional radiologists that have been approved as
24 authorized users?

25 DR. SALEM: Yes.

1 MEMBER LIETO: And were these only under
2 broad scope licenses?

3 DR. SALEM: Yes, to my knowledge, yes.

4 MEMBER LIETO: Okay, thank you.

5 CHAIRMAN MALMUD: Any other questions or
6 comments for Dr. Salem? If not, thank you, Dr. Salem.
7 We have heard your position and it will be considered
8 as the discussion goes on into the afternoon. You're
9 more than welcome to remain if you can catch an
10 alternate flight.

11 Dr. Diamond.

12 MEMBER DIAMOND: Thank you. I was asked
13 by the Chairman as Dr. Eggli, to have a few comments
14 regarding training and experience issues in the use of
15 hepatic arterial microspheres and to present a
16 personal perspective. I'd like to preface my remarks
17 by saying that this does not have the imprimatur of
18 the entire radiation oncology organized community but
19 it is my perspective, although I think that many of
20 the community do, in fact, share it. At the
21 conclusion of these presentations, I believe Dr. Nag
22 is going to update us on a recent meeting that he
23 hosted at Ohio State University from the so-called
24 REBOC, the Radio-Embolization Brachytherapy Oncology
25 Consortium. Is that correct?

1 Okay, and the REBOC Consortium's
2 recommendations were not available by the time I
3 needed to submit these slides but I think we will have
4 some consensus. How do I -- I think Polonius said
5 brevity is the soul of wit, so let's try and move it
6 along.

7 Very good. So as we've discussed our
8 charge is simply to provide advice to the
9 Commissioners and staff on medical and technical
10 issues that arise in the regulated use of byproduct
11 material. Our concern is public safety. Was we've
12 talked about for many years, our interest is -- we
13 have no interest in the so-called practice of medicine
14 which is the purview of the medical community, per se.
15 So microsphere therapy is a medical device. Well, as
16 we've discussed many times here, the manufacturer
17 specifically opted to go through the FDA device, not
18 the drug pathway for approval and it was this fact and
19 not any radiation safety considerations that was the
20 premise for FDA regulation as a medical device.

21 Is it a brachytherapy modality, yes, of
22 course. Physically, these are encapsulated sealed
23 sources but as we've discussed many times here from a
24 regulatory viewpoint, it is problematic to place these
25 under the manual brachytherapy meaning the 35.490

1 rubric for many examples. Number one, one cannot
2 count the number of individual sources and we know
3 that each Sir-Sphere vial for example, contains 40 to
4 80 million spheres. And further, this is also
5 problematic because Technetium 99 microspheres have
6 been used for some time in nuclear medicine and have
7 never been regulated in this particular manner.

8 The current guidance that we've heard in
9 the past from Donna Beth and her colleagues has been
10 that these -- that this particular modality is now
11 fallen under the emerging technology section, 35.1000
12 and current NRC guidance specifically recognizes
13 35.490, manual brachytherapy AU's with specific vendor
14 training as authorized for this purpose and the
15 question, therefore, was should the guidance be
16 modified specifically to allow nuclear medicine
17 authorized users and for that matter specific -- and
18 for that matter, 35.390 users of any particular title
19 to use the modality.

20 I believe back in 2003 there was an
21 initial joint letter between the Society of Nuclear
22 Medicine, the American College of Radiology, ASTRO and
23 the AAPM in which this draft recommended that both
24 physicians certified in nuclear medicine who have met
25 35.390 training and those certified in radiation

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1 oncology who have met 35.490 uses be authorized for
2 this particular use.

3 My personal recommendation is that I
4 concur that both nuclear medicine 35.390 AU's and
5 radiation oncology 35.490 AU's have the technical
6 training and experience to safely handle and
7 administer hepatic microspheres, and I would also
8 submit that titles aside, diagnostic radiologists with
9 35.390 authorized user status also have the technical
10 training and the technical experience to safely handle
11 and administer these microspheres.

12 In summary, though outside the purview of
13 the Nuclear Regulatory Commission, I strongly support
14 efforts by which the professional societies develop
15 guidelines which promote optimal patient care through
16 a defined multi-specialty team approach analogous to
17 what we've done in the past with vascular
18 brachytherapy when it first came through. We have a
19 lot of experience in approaching these new modalities.
20 I will point out that patient screening and treatment
21 planning are complex and most of these patients have
22 been heavily pre-treated with chemotherapy and
23 externally with radiotherapy. And as such, it is in
24 the medical community's best interest to develop
25 working documents that talk about the roles of

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1 radiation oncologists, interventional radiologists and
2 nuclear medicine physicians. With respect to our
3 previous speaker, I think he had a little bit of a
4 misunderstanding. Any authorized user with 35.390
5 background by this approach, should be authorized to
6 actually deliver this modality. The question is,
7 whether it be an interventional radiologists, whether
8 it be a nuclear medicine physician, whether it be a
9 radiation oncologist, I think the individual question
10 is, should that person, in fact, do it and I hold the
11 same position I've held in many other modalities in
12 the past, which is it's a particular individual's
13 interest and expertise which is the main determinant
14 in the community level who should be doing this
15 because I think we all agree that 35.390 users, 35.490
16 users all have the technical experience and background
17 to do it.

18 And again, that really is outside the
19 purview of the NRC and that's what I -- and that's why
20 I'm pleased to see organizations such as the REBOC
21 consortium discussing these issues, and I think this
22 is an example where I and Doug are in marked
23 agreement. So thank you very much. And this actually
24 will be the last presentation I make to this August
25 body and I thank all of you for all of these -- over

1 the past eight years the outstanding public service
2 that you all have afforded to us. Appreciate it.

3 CHAIRMAN MALMUD: Thank you, Dr. Diamond.

4 (Applause)

5 CHAIRMAN MALMUD: The next item on the
6 agenda is the presentation -- I turned it off, didn't
7 I? The next item on the agenda is the presentation by
8 Dr. Eggli.

9 MEMBER DIAMOND: Mr. Chairman, I just want
10 to let you know that I may have to leave before the
11 entirety of this particular topic is completed, so my
12 apologies if I have to leave while Subir or the
13 discussion are still going on.

14 CHAIRMAN MALMUD: Well, if you have to
15 leave before Doug finishes his presentation, I'll take
16 the opportunity to once again thank you for eight
17 years of service to the NRC and to the public and for
18 all of your contributions to the constructive activity
19 of this committee. Thank you again.

20 MEMBER EGGLI: My conclusion is going to
21 be exactly the same as David's. I'm going to raise a
22 couple of different questions, which I think need to
23 be discussed but it doesn't change ultimately the
24 conclusions. I don't know that I need to spend a lot
25 of time belaboring this but basically there

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1 therapeutic microspheres have features that are
2 similar to brachytherapy devices. They have features
3 that are similar to unsealed sources and they are
4 regulated right now in the Part 1000 New Technologies.
5 Basically the similarity is to typical radiation --
6 brachytherapy sources. They're registered as
7 brachytherapy sources. They're either sealed in glass
8 beads or in resins. The differences is the sources
9 don't have serial numbers and they are too numerous to
10 count.

11 The sources behave like large particles
12 which have been used in nuclear medicine for years.
13 Spills are handled like unsealed sources. The patient
14 distribution and dosimetry studies use nuclear
15 medicine techniques and the administration is similar
16 to the intra-arterial administration of MAA which has
17 been used for evaluating chemotherapy to the liver and
18 hepatic carcinomas and metastasies for long, long
19 time.

20 Again, there are differences. They are
21 technically brachytherapy sources and they are sealed.
22 The bottom line in training issues is that any
23 experienced therapeutic physician trained for either
24 300 or Part 400 uses can be safely trained to handle
25 therapeutic microspheres. The nuclear medicine

1 physicians can learn the appropriate dosimetry
2 techniques. The radiation oncologists, many now, are
3 trained in Part 300 uses as part of their residencies,
4 but those who weren't initially can be trained to
5 manage unsealed sources.

6 The question that I raised are three cases
7 enough to be considered adequately trained? I don't
8 know the answer to that. I would think that as risk
9 increased, it's reasonable to increase the experience
10 required for independent use. And again, that can, I
11 think, be a discussion point. It's kind of like
12 prunes; are three enough or six too many. But the
13 question is, what is the right amount of training.
14 And I don't think that that amount of training varies
15 for some class of users. Part 300 users, Part 400
16 users have the same kinds of training and experience
17 requirement. I think that training programs should be
18 designed conjointly, I've said by oncologists and
19 nuclear medicine physicians, but maybe what I should
20 say are Part 300 and Part 400 users, to determine what
21 are the appropriate training requirements. The 300
22 people can sort of contribute the concept of what's an
23 appropriate training requirement for those
24 characteristics of microspheres that are related to
25 300 uses. The 400, the people trained and experienced

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1 in Part 400 uses can contribute what they feel are
2 appropriate training and experience requirements that
3 suit the 400 requirements.

4 I've listed some possibilities.
5 Basically, everybody that's a 300 or 400 user is well
6 trained in the basic knowledge of biology, the basic
7 physics, the basic mathematics and radioactivity.
8 Everybody needs to develop experience with the
9 administration devices. The practical experience in
10 radiation safety as applied to unsealed sources is
11 something that can be learned without a whole lot of
12 difficulty. The use of dose calibrator surveying
13 packages for contamination, detection of
14 contamination, cleanup of radioactive spills are all
15 basic techniques that easy cross-training can be
16 provided for.

17 Nuclear medicine physicians may need some
18 experience in dosimetry theory, techniques and
19 calculations, those who don't do dosimetries currently
20 and they, again, need experience with administration
21 devices. So my recommendation, again, a personal
22 recommendation but again, I think follows along with
23 everything I've seen so far is that with appropriate
24 training, authorized users for both Subpart 300 and
25 Subpart 400 uses should be able to obtain authorized

1 user status for therapeutic microspheres. Appropriate
2 training requirements need to be defined for these
3 users and appropriate experience levels need to be
4 determined.

5 CHAIRMAN MALMUD: Thank you, Dr. Eggli.
6 It sounds as if you and Dr. Diamond are in complete
7 agreement.

8 MEMBER EGGLI: I think so. The only
9 difference is I've raised questions about what the
10 requirements should be but otherwise philosophically,
11 I think we're in complete agreement.

12 CHAIRMAN MALMUD: Thank you.

13 MEMBER DIAMOND: Mr. Chair, I think the
14 important issue is, Doug and I are in complete
15 agreement that 300 and 400 users both have the
16 technical experience to safely handle and administer
17 this. I think we also both agree that who is actually
18 doing this is a question of medical practice which is
19 outside the NRC purview and I think we thirdly agree
20 that these type of discussions that Subir are going to
21 bring to our attention is really the best for optimal
22 patient care. This is a complex treatment
23 technically. These are very, very sick patients.
24 There are a lot of issues regarding how these patients
25 are being followed and we -- and I'm sure we're all in

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1 agreement that's it really how these patients are
2 optimally cared for which is the real issue that needs
3 to be tackled.

4 MEMBER EGGLI: And again, I am in full
5 agreement with everything that Dr. Diamond has just
6 said.

7 CHAIRMAN MALMUD: We will now hear from
8 Dr. Nag. Dr. Nag.

9 MEMBER NAG: Thank you very much. I will
10 presenting it more from the viewpoint of the REBOC
11 committee and as a user of yttrium-90 microspheres.
12 Basically, about a year ago there was an yttrium-90
13 meeting and during the meeting we came up with the
14 idea that there should be a consensus panel because
15 the indication, techniques and so on for yttrium-90
16 microsphere was so varied and there was no
17 standardization.

18 So we formed the Radioembolization
19 Brachytherapy Oncology Consortium or REBOC which is an
20 independent group and it has expertise from the field
21 of medical oncology, surgical oncology, radiation
22 oncology, nuclear medicine and interventional
23 radiology. Well, we decided to meet in Columbus, where
24 I am, and I was the host, in April, just a couple of
25 weeks ago and we identified the various controversial

1 areas and we made them clinical guidelines.

2 The members of the REBOC panel, there was
3 12 of us, represented the various specialties and also
4 there were official representation from various
5 societies like MES, the Brachytherapy Society, Society
6 of Nuclear Medicine and so on. We made a number of
7 recommendations. I don't have time to go through all
8 the recommendations; however, I have sent a summary of
9 the recommendations to the ACMUI panel members by e-
10 mail. We have now finalized the whole report. We
11 have sent out the report to various external viewers
12 for their comments before we send it out for
13 publication.

14 Some of the summary there is sufficient
15 evidence to support the safety and efficacy of Y-90
16 and that the patient should be rendered it by a multi-
17 disciplinary team and not by single individuals. And
18 the candidates should be patients with unreceptable
19 primary or metastatic disease who have predominantly
20 a liver disease with a life expectancy of greater than
21 three months and absolute are those whose pre-
22 treatment MAA scan showed potential of more than 30
23 gray shunt to the lung and those that show lower GI
24 tract that cannot be corrected by catheter
25 embolization techniques. Relative (indiscernible) are

1 those with poor liver function and even worse of all
2 elevated bilirubin level. We do need angiographic
3 techniques and therefore, it would be very important
4 and we have to embolize the hepatic threshold or the
5 hepatic artery that (indiscernible).

6 If you have bilobar disease, you can
7 either do a single whole liver infusion or sequential
8 unilobar treatment and those with unilobar disease
9 received therapy only to the hepatic lobe. The dose
10 estimation using the surface area method the method of
11 choice rather than other alternate methods and glass
12 microsphere the calculations is supplied by the
13 manufacturer recommended. And we felt that by virtue
14 of the rating, certification and involvement, and
15 contribution of Y-90 microsphere, the following
16 disciplines are qualified to use Y-90 microsphere;
17 radiation oncologists, nuclear medicine physicians,
18 and interventional radiology and in terms of the
19 licensing the 35.390 and the 35.490. And I think
20 that's a very brief, the summary from the REBOC group.

21 CHAIRMAN MALMUD: Thank you, Dr. Nag. It
22 sounds as if you are in agreement also. Dr. Diamond.

23 MEMBER DIAMOND: Yes, I'd just like to
24 congratulate Dr. Nag for putting that meeting
25 together. I think it's very helpful and very

1 important. One comment I would like to make is that
2 now that we are in agreement on so many topics, one
3 concern I do have, and again, this is not really the
4 purview of the advisory committee but it's something
5 I want to put out to the consortium, to the REBOC
6 panel, what I do not want to see happening is I do not
7 want to see for example, interventional radiologists
8 in community hospitals performing this type of
9 procedure on an infrequent basis without a very, very
10 thorough pre-procedure evaluation of the patient or
11 without a commitment to long-term followup.

12 In other words, I have no concerns that an
13 interventional radiologist who is a 390 authorized
14 user is safely trained to handle this particular
15 modality. And at some of these large centers I'm
16 impressed by the numbers of patients that are being
17 treated, but my concern is the potential that at
18 community centers, these patients could not -- my
19 concern is that there could be a potential that they
20 are not being adequately evaluated beforehand and that
21 they are not being adequately followed in longitudinal
22 fashion. Again, this is not the purview of this
23 committee, but I'm just putting this out as my little
24 input for your REBOC panel.

25 They need intensive follow-up. They need

1 intensive pre-treatment evaluation for optimal patient
2 care.

3 MEMBER NAG: That is where the multi-
4 disciplinary approach takes place. In many places it
5 is done by either surgical oncologists or the medical
6 oncologists, so it is a multi-disciplinary between
7 nuclear medicine. In many places, nuclear medicine
8 may give the dose, but the follow-up is done by
9 medical oncologists and so on.

10 CHAIRMAN MALMUD: Thank you. Dr.
11 Williamson.

12 MEMBER WILLIAMSON: I would like to
13 congratulate all three speakers on I guess speaking
14 with one voice on this matter. I would like to take
15 one issue with one minor comment Dr. Diamond mentioned
16 and that is that clinical competence has no role in
17 the determination of training and experience. And
18 I'll go back. I've been on the committee a long time
19 since the early 1990s when we first began the
20 discussion of how to revise Part 35. And it was at
21 35.300 where the break point fell.

22 35.200 and 100 was fell to patients and
23 public safety had very minor dependence, if any, on
24 clinical competence but that as we moved up from 300,
25 400 and 600, the issues of the ability to properly

1 select patients itself began to assume greater and
2 greater public health significance.

3 CHAIRMAN MALMUD: Thank you. Other
4 comments? Dr. Eggli?

5 MEMBER EGGLI: Again, I would like to
6 congratulate Dr. Nag and the REBOC committee for a
7 well-measured and well-thought out recommendation. I
8 think that their emphasis on a multi-disciplinary
9 approach is very important. I think this is becoming
10 widely accepted in large medical centers but may not
11 have drifted out, way out into the community and as we
12 look at this, to re-emphasize Dr. Diamond's point that
13 people with interest and ability will do a good job,
14 but people who are under pressure in a small community
15 setting might be pressured to do this in the absence
16 of a multi-disciplinary team. And again, I think
17 patient care, although again, our primary issue isn't
18 patient care, but patient care is best facilitated by
19 these multi-disciplinary teams.

20 And I would again, congratulate Dr. Nag
21 and his committee for their acknowledgment of this
22 reality.

23 CHAIRMAN MALMUD: Thank you. I believe
24 that our member of the public has another comment.
25 Dr. Salem?

1 MEMBER NAG: By the way, if any of you
2 want to be an official viewer of the document, I'll be
3 glad to send it to you and you can be a viewer. If
4 any of you have any interest, put up your hand I can
5 send it to you.

6 CHAIRMAN MALMUD: Thank you. Dr. Salem.

7 DR. SALEM: Yeah, I just wanted to echo
8 the comments made by the panel. Indeed in the
9 training process when physicians want to learn how to
10 use this type of therapy, it is almost exactly what
11 Dr. Diamond was saying, that we emphasize the clinical
12 follow-up, the assessment, the multi-disciplinary
13 approach because this is a significant advancement in
14 the liver and the treatment of liver cancers and that
15 is the only model that we push or we advocate and we
16 recommend for the use of Y-90 microspheres.

17 CHAIRMAN MALMUD: Thank you. Dr. Salem,
18 in your institution, with whom do you collaborate in
19 the performance of these studies; radiation
20 oncologists, medical oncologists or nuclear physician
21 or none of them?

22 DR. SALEM: We work very closely with
23 medical nuclear physics, so nuclear medicine is really
24 the team that we work with and we collaborate with
25 nuclear medicine, not radiation oncology in our

1 institution.

2 CHAIRMAN MALMUD: So the dosimetry is done
3 by the medical physicists.

4 DR. SALEM: Myself and the medical
5 physicist, that's correct, confirmed by the medical
6 physicist.

7 CHAIRMAN MALMUD: And the medical
8 physicist is associated with the section of nuclear
9 medicine?

10 DR. SALEM: That is correct.

11 CHAIRMAN MALMUD: Thank you. Other
12 comments from the public or from members of the
13 committee? Now, having heard what we've heard, what
14 are we expected to do as a result of being so well-
15 informed with such a consensus of opinions? Was there
16 action that was desired?

17 MEMBER NAG: I think --

18 CHAIRMAN MALMUD: Dr. Nag?

19 MEMBER NAG: Yeah, I think right now the
20 way the wording of the NRC rule is, that it only 490
21 physicians are allowed to be authorized users other
22 than the broad scope licensee. Am I not right? So
23 I mean, I think the panel or the ACMUI members are
24 telling otherwise.

25 CHAIRMAN MALMUD: Thank you. May we move

1 onto the next item on the agenda? Mr. Lieto?

2 MEMBER LIETO: I think we need to make
3 some formal recommendations to change the guidance
4 document that's out on the website. And I guess I'll
5 get the ball rolling here, hopefully, I'll get it
6 right. But I think the first thing would be a motion
7 to amend the guidance for the Y-90 microspheres to
8 include physicians approved under Part 390 as
9 authorized users for the Y-90 microspheres.

10 MALE PARTICIPANT: (Inaudible)

11 MEMBER LIETO: I think those are already
12 listed, so this would be in addition to the --

13 CHAIRMAN MALMUD: The motion that Mr.
14 Lieto is making would increase the authorization from
15 490 users to 390 users and is there a second to that
16 motion?

17 MEMBER WILLIAMSON: Second.

18 MEMBER NAG: Before that --

19 CHAIRMAN MALMUD: Dr. Williamson seconded
20 it. Now, there's discussion. Dr. Eggli --

21 MEMBER EGGLI: No, I was just going to
22 second it as well.

23 CHAIRMAN MALMUD: Okay, now I believe that
24 Dr. Howe had a comment that she wished to make.

25 DR. HOWE: Yeah, I'm hoping during part of

1 your discussion you'll talk about what you think the
2 adequate training and experience will be and also
3 discuss whether you think there's a role for the
4 medical physicist in here, not necessarily the HDR
5 gamma knife medical physicist but as our colleague
6 there said, he has a medical physicist that assists
7 him in calculating dosimetry. So is there a role for
8 a physicist in this one, too?

9 CHAIRMAN MALMUD: Having heard Dr. Howe's
10 first question, what do we think requirements should
11 be and number two, what's the role of the physicist.
12 Dr. Eggli?

13 MEMBER EGGLI: I think the multi-
14 disciplinary team needs to contain someone who is
15 comfortable with the appropriate dosimetry. I'm not
16 sure it necessarily has to be an authorized medical
17 physicist but clearly someone with both experience and
18 comfort at the dosimetry technique needs to be a
19 member of the multi-disciplinary team. In my own
20 case, I would welcome the medical physicist but I'm
21 not sure that that should be an absolute requirement.
22 There should be a requirement for that experience to
23 be in the team.

24 DR. HOWE: Could you expand on what you
25 would consider that experience to be?

1 MEMBER EGGLI: I think that again, the
2 experiences with dosimetry that's related to the
3 administration of microspheres.

4 DR. HOWE: Would a dosimetrist, as more of
5 a technician, would that be acceptable or do you want
6 a higher level of --

7 MEMBER EGGLI: I'm not sure that -- being
8 from the nuclear medicine world rather than the
9 radiation oncology world, I don't understand either
10 the skill set or the distinction between someone who
11 is simply -- who is a dosimetrist for external beam
12 sources and a medical physicist. I would suspect that
13 a dosimetrist doesn't have the necessary experience
14 with small particles and that a medical physicist
15 probably would be a more appropriate person but I
16 would ask Subir to speak to that.

17 CHAIRMAN MALMUD: Dr. Nag?

18 MEMBER NAG: Yeah. Actually, I think for
19 the yttrium-90, first of all, the physical presence of
20 a physicist is not required unlike the -- you know,
21 unlike gamma knife and HDRs. I don't think it would
22 require the physical presence. I think you need
23 physics input as part of the multi-disciplined team
24 just like a medical oncologist and a radiation
25 oncology and a surgical oncologist are part of the

1 team. The calculation for the yttrium-90 is
2 reasonably easy, you know, you could just leave it as
3 medical input rather than having, you know, AMP
4 meaning --

5 CHAIRMAN MALMUD: Dr. Nag, would that mean
6 that an interventional radiologist and a physics
7 technician would be adequate to provide this service?

8 MEMBER NAG: Many places it's dosimetrist
9 and whether the nuclear medicine type of dosimetrist
10 or the radiation oncologist kind of dosimetrist fills
11 the role.

12 MEMBER NAG: I'm sorry, I didn't
13 understand.

14 MEMBER NAG: Dosimetrist.

15 CHAIRMAN MALMUD: A technician dosimetrist
16 or a physicist dosimetrist?

17 MEMBER NAG: All dosimetry I think comes
18 from the physics side.

19 CHAIRMAN MALMUD: All right, so it would
20 be a physicist and an interventional radiologist, that
21 would be a sufficient team?

22 MEMBER NAG: That's part of the team,
23 because then from the medical input, either a medical
24 oncologist or a surgical oncologist, plays into the
25 team.

1 CHAIRMAN MALMUD: Okay, thank you. Dr.
2 Williamson, you had a comment?

3 MEMBER WILLIAMSON: Yeah, I don't think --
4 if you're going to put in the guidance that input of
5 a physicist or somebody who's an expert at unsealed
6 dose calculations is needed, a dosimetrist is the
7 wrong person. A dosimetrist may be trained by a
8 physicist to carry out the procedures but is not in a
9 position, it's not in their training to be able to
10 devise such procedures.

11 CHAIRMAN MALMUD: Dr. Suleiman?

12 MEMBER SULEIMAN: What you need is
13 somebody who understands the formal kinetic properties
14 of the drug and if it's all going to go to the liver,
15 you're fine but if it doesn't, so you need somebody
16 who understands imaging sufficiently to identify the
17 bio-distribution, clearance and uptake of the
18 administered drug and from that, you're traditional
19 nuclear medicine type calculations, but these are
20 therapeutic doses, so as somebody once said, you can
21 be off by two or three with a diagnostic, but here I
22 think it's much more critical. The person you need,
23 whether they're a physicist or dosimetrist is somebody
24 very knowledgeable, is going to be somebody that if
25 there's a problem that pops up, where did it go and

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1 how much of the yttrium landed there, and how much
2 dose is the individual getting. So I don't think you
3 should take this cavalierly and I think that's why I
4 think they're using the MAA to sort of get an idea
5 pre-yttrium-90 what the distribution is, similar, I
6 think to the Bexar and Zeblen drugs where you're
7 trying to predict what the distribution is before you
8 administer the therapy. So I don't think people
9 should take this lightly. I don't know what the
10 individual is, but I think this inter-disciplinary
11 team approach is clearly important. Some of our
12 pharmacologists understand this much better than
13 sometimes the physicists.

14 I'm concerned that you have the
15 appropriate technical expertise and I'm not so sure
16 you can label any profession as being sufficiently
17 knowledgeable to deliver that. So I don't think this
18 is a trivial issue.

19 CHAIRMAN MALMUD: If I may, the
20 credentialing process of the institution that provides
21 the service would be one which would require the skill
22 sets that you are discussing, but I don't think that
23 addresses Dr. Howe's question which is what training
24 do we believe is necessary for any of the individuals
25 or an individual in this team to provide the service.

1 Was that your question, Dr. Howe?

2 DR. HOWE: Yes, it was. I think we
3 recognize that when we have it over in 490 we
4 generally have a physicist available there also. When
5 we move into 390, we may or may not have a physicist.
6 Is that person really necessary? Who is it that gives
7 that extra support?

8 CHAIRMAN MALMUD: Mr. Lieto?

9 MEMBER LIETO: There's really three
10 issues, I think before us. The first is, I think we
11 need to vote on the motion. The second one, I think,
12 would be to address do we want to include in the
13 guidance a multi-disciplinary team of interventional
14 radiologists, radiation oncologists, nuclear medicine
15 and then I think the third thing would be to address
16 the specific training components maybe, I think that
17 Dr. Eggli addressed; how many cases should this
18 involve in terms of the training and maybe some of the
19 specific aspects of dosimetry and so forth.

20 So if I could, I'd like to maybe vote on
21 the motion that's before us and then we could maybe
22 move on to the other two points. Does that sound
23 reasonable?

24 CHAIRMAN MALMUD: The motion before us is?

25 MEMBER LIETO: The motion before us is to

1 amend the regulatory guidance on the NRC website for
2 Y-90 microspheres to add Part 390 authorized users.

3 CHAIRMAN MALMUD: And that motion was
4 seconded by Dr. Williamson, as I recall. Any further
5 discussion of that motion? All in favor? Any
6 opposed? Any abstentions? It's unanimous.
7 Congratulations. The next part of your statement
8 related to --

9 MEMBER LIETO: The --

10 CHAIRMAN MALMUD: T&E?

11 MEMBER LIETO: The team -- should a team
12 components be specified on the regulatory guidance.

13 CHAIRMAN MALMUD: All right, Dr. Vetter.

14 MEMBER VETTER: I'm not personally in
15 favor of becoming that specific. I think each
16 hospital has to decide who makes up the best team and
17 their case. In one case it might be interventional
18 radiologists and nuclear medicine. In another case,
19 it might be radiation oncology. So I'm not convinced
20 that we should be that specific.

21 CHAIRMAN MALMUD: Thank you, Dr. Vetter.
22 I have a question. Is there ever a situation in
23 which this procedure would be performed without the
24 participation of an interventional radiologist? No,
25 so could we define the team, therefore, as an

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1 interventional radiologist, plus someone who has
2 expertise in the handling of radio-pharmaceuticals
3 and/or particles? Dr. Eggli?

4 MEMBER EGGLI: Yeah, you sort of stole my
5 thunder there with my hand up in the air. I think
6 what we should be defining are the required skill sets
7 and not the required individuals and I think you've in
8 a generic fashion, touched on those skill sets
9 necessary. You need someone skilled at placing a
10 catheter. You need someone who has experience with
11 particle therapies and you need someone who has
12 experience with the dosimetry calculations associated
13 with the delivery of particle therapies. And that
14 individual has training credentials for either Part
15 300 or Part 400 uses.

16 CHAIRMAN MALMUD: So that you are
17 recommending that the team consist of an individual
18 who is skilled at placing the catheter.

19 MEMBER EGGLI: Yes.

20 CHAIRMAN MALMUD: An individual who is
21 skilled in understanding the radiation dosimetry.

22 MEMBER EGGLI: Yes.

23 CHAIRMAN MALMUD: An individual who's
24 skilled in understanding the pharmacologic
25 implications of the administration of these particles.

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1 MEMBER EGGLI: Yes, and part of the
2 dosimetry part includes the ability to use the nuclear
3 medicine computers to do the dosimetry calculations as
4 well.

5 CHAIRMAN MALMUD: That's getting kind of
6 specific. You want to talk about the dosimetry.

7 MEMBER EGGLI: Yeah, that's skill in the
8 dosimetry.

9 CHAIRMAN MALMUD: So the skills are the
10 placement of the catheter, the calculation of the
11 radiation burden and the understanding of the pharm --

12 MEMBER EGGLI: Well, the experience with
13 unsealed source therapy.

14 CHAIRMAN MALMUD: The oncologist and
15 techni --

16 MEMBER NAG: Yeah, one more. And someone
17 with expertise in the knowledge of pharmacologic
18 knowledge of liver cancer or how liver cancer behave,
19 so you do need some oncology input, whether it be a
20 medical oncologist, a radiation oncologist or a
21 surgical oncologist to be part of the team.

22 CHAIRMAN MALMUD: That would be therapy,
23 generically and oncologist, it could be radiation,
24 medical or surgical. So it's oncology, placement of
25 the catheter and the radiation dosimetry, those three

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1 elements?

2 MEMBER EGGLI: Safe handling of unsealed
3 sources.

4 CHAIRMAN MALMUD: All right.

5 MEMBER EGGLI: Because you can be -- you
6 can be expert in calculating the dosimetry and not
7 have experience in handling unsealed sources.

8 CHAIRMAN MALMUD: Right. So those are the
9 four elements. Now, we get back to Dr. Howe's
10 question which is still on the table. Dr. Howe?

11 DR. HOWE: Well, I was just going to ask
12 a question and that is, I'm not sure I understand why
13 pharmacology is important here because in this case,
14 you have a sealed source that will get embedded in a
15 capillary bed and you do not have -- you do not have
16 a molecule that goes and interacts with any system.
17 You have just a radiation emitter.

18 That's why we put it in manual
19 brachytherapy is because it is radiation.

20 MEMBER EGGLI: I disagree. The resin
21 leaks so you do have to consider physiology. If you
22 only use the glass beads, I believe you're correct,
23 but the resin leaks. You'll find the stuff in the
24 urine after a resin treatment. So the resin leaks.
25 So you have to understand the physiology of where else

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1 you're going to get radiation exposure in the body if
2 you're going to use the resin microspheres.

3 CHAIRMAN MALMUD: Does that answer your
4 question, Dr. Howe?

5 DR. HOWE: That does at insight to my
6 question, yes.

7 CHAIRMAN MALMUD: Thank you. Dr.
8 Suleiman.

9 MEMBER SULEIMAN: Regarding the
10 pharmacokinetics or to be more simple the bio-
11 distribution, the ability to determine the bio-
12 distribution from available images, I mean, it's very
13 easy to misinterpret and if there are complications,
14 again, in the REBOC think that I picked up on, they
15 actually are using MAA to sort of predict if that
16 patient, how it's going to distribute. So you just
17 can't look up the dose distribution from some text
18 book. I mean, it's going to be different. These are
19 patients that are pathologically serious compromised.

20 DR. HOWE: I think we recognize that when
21 you're doing this procedure, there is a diagnostic
22 nuclear medicine aspect to it, which would be done by
23 a 35.200 physician and that is the initial monitoring
24 to see what kind of shunting that you might have, but
25 we're separating that, because that is a traditional

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1 nuclear medicine procedure done by traditional nuclear
2 medicine from the actual administration of the yttrium
3 microspheres and so we're just looking at the yttrium
4 microsphere administration assuming that the licensee
5 knows they have to use a 200 physician for the other
6 part.

7 CHAIRMAN MALMUD: Dr. Eggli?

8 MEMBER EGGLI: I don't think that can be
9 a 200 user because that's where the dosimetry
10 calculation is coming from is the micro -- is the MAA
11 distribution study. So I think that distribution
12 study needs to be supervised by a 300 rather than a
13 200 user.

14 DR. HOWE: And that may be true but the
15 administration doesn't have to be by a 300 user. But
16 certainly that's part of the dosimetry.

17 MEMBER EGGLI: Well, but in reality, you
18 wouldn't separate the person who's going to administer
19 the MAA from the person who's going to use that
20 information to calculate the dosimetry. Those are --
21 that's going to use proprietary nuclear medicine
22 equipment, proprietary nuclear medicine software to
23 come up with some of those numbers. So I would be
24 reluctant to say this is a 200 -- a Part 200 user
25 activity. I think it is part of the dosimetry of the

1 administration of microspheres and that should be --
2 in this case should be a 300 rather than a 200 user.

3 DR. HOWE: Okay.

4 CHAIRMAN MALMUD: We have a member of the
5 public who's been very patiently waiting to make some
6 comments. Would you please introduce yourself?

7 MS. WARBICK: Thank you. My name is Ann
8 Warbick. I work in regulatory affairs at MDS Nordion.
9 We're the manufacturer of the yttrium-90 glass
10 microspheres and I wanted to point out to you just to
11 give you a little bit of background that very early
12 on, we realized that training and education of the new
13 users was extremely important as you've already eluded
14 to this. So what we did was we established a Center
15 of Excellence in the United States and our Center of
16 Excellence, you may not be surprised, is managed by
17 Dr. Riad Salem. He has a wealth of information and
18 knowledge that he's gleaned from using these
19 microspheres and treating patients.

20 Whenever a new physician is interested in
21 using our microspheres, we send them to Dr. Salem's
22 site where they receive a full orientation. They
23 receive lectures on mechanisms of actions, radiation
24 dosimetry, all the basic background that will -- that
25 they'll need in order to do that job. We already know

1 that they have a good medical background to start off
2 with, so we've given them a little bit more.

3 And as well, Dr. Salem does treatments,
4 does several treatments the day that they're visiting
5 his site. After the treatments are completed, three
6 different visits are made to the physician's site. We
7 have proctors at our company that travel from Canada
8 to different sites in the United States to proctor the
9 different hospital sites and provide them with
10 assistance. And if they need additional assistance,
11 well, we're there for them.

12 Now, as the hospitals set up their first
13 patients, I wanted you to also know that Dr. Salem
14 works with them. He helps them to understand any
15 issues that they have, screening the patients, you
16 know, anything that might be an issue for them,
17 dosimetry, that sort of thing. So he will work with
18 them to help them do those first three patients. And
19 if they need additional help we're there for them as
20 well. I think Vanessa Gates wanted to make a few
21 comments. She's the physicist that works on the team
22 and it is definitely a team approach and I think
23 that's what Dr. Salem's team does stress when visitors
24 come to his site, that it must be a team approach, as
25 you've already eluded to this. Thank you.

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1 CHAIRMAN MALMUD: Thank you. Now I have
2 a question. Does this mean that in practical terms,
3 that this therapy could be administered by an
4 interventional radiologist and a radiation oncologist
5 absent input from nuclear medicine or by an
6 interventional radiologist plus a nuclear physician
7 absent radiation oncology? Is that an acceptable
8 pairing? Whose arm is that? Dr. Eggli?

9 MEMBER EGGLI: Again, I think we need to
10 go back to the skill set. I don't think you say it
11 has to be an interventional radiologist and a nuclear
12 medicine doc or an interventional radiologist and a
13 radiation oncologist. I think you just need to make
14 sure that the defined skill sets are available. I
15 would not want to put a sub-specialty label on those
16 skill sets.

17 CHAIRMAN MALMUD: All right, I believe Dr.
18 Salem had a comment. Dr. Salem?

19 DR. SALEM: Yes. I completely agree. I'm
20 not sure that we would want to label all the specific
21 skill sets but at minimum, I think you pointed out
22 that every patient that is evaluated for this, needs
23 to have nuclear medicine input by virtue of the
24 diagnostic and the dosimetry portion. So nuclear
25 medicine plays an integral role in this based on the

1 MAA scanning for gastrointestinal shunting or lung
2 shunting.

3 CHAIRMAN MALMUD: May I ask another
4 question? That is, who manages these very sick
5 patients when they come in with all of the sequelae of
6 their disease?

7 MEMBER NAG: Again, may I answer that?

8 CHAIRMAN MALMUD: Yes, I was hoping you
9 would.

10 MEMBER NAG: Okay, it depends, again, on
11 the various hospital. From a practical standpoint,
12 in our center, if they need to be admitted, post-
13 therapy for any complication they're usually admitted
14 by the medical oncologist or the surgical oncologist.
15 In some places, the radiation oncologist would admit
16 in places where radiation oncologists have admitting
17 privileges. Now, it depends and the immediate post-op
18 period they're looked after usually by the
19 interventional radiologist within the first two to
20 three hours.

21 CHAIRMAN MALMUD: Thank you.

22 DR. SALEM: If I could add a comment, Mr.
23 Chairman, I think the cornerstone of the management
24 of, for example, the hepatocellular carcinoma patient
25 is the medical oncologist and the hepatologist with

1 our without the transplant team. So those two form
2 the basis. From there, I think what happens is they
3 are out-sourced for various therapies for certain
4 periods of time, so the patients that get sent to say
5 surgery or radiation oncology or interventional
6 radiology, get sent there for therapy, whatever that
7 therapy is for a period of months.

8 So for example, our hepatoma patients we
9 follow for six to nine months at which time they are
10 returned to the medical oncologist or the hepatologist
11 for chronic long-term care, given as you point out,
12 they have significant core morbidities.

13 CHAIRMAN MALMUD: Thank you. May I ask
14 Dr. Howe, are you satisfied with an understanding of
15 what the skill sets are that are required and with
16 respect to the Nuclear Regulatory Commission's
17 concerns?

18 DR. HOWE: I think so and I think part of
19 it is that you've defined skill sets not individuals
20 and so it could be one person or two people that
21 contain all of these skill sets. One of the thoughts
22 that I had was that perhaps one of our best ways to
23 define adequate training would be a preceptor
24 attestation which is the same mechanism that we use
25 for all other authorized users and would put the focus

1 on the person that's providing the preceptor training
2 to sign off on the individual as being competent to
3 function.

4 CHAIRMAN MALMUD: The current regs require
5 three cases for I-131 therapy. Is there a number
6 that's recommended to achieve a degree of competence
7 in this therapy?

8 MEMBER NAG: Yes.

9 DR. HOWE: From what I'm hearing it's
10 sounds as if the training that's provided by the
11 manufacturer at say the Center of Excellence is a
12 number of cases and then there's also a follow-up at
13 the individual hospital because you have unique
14 situations with different team members.

15 CHAIRMAN MALMUD: I was wondering if there
16 was a specific number. Dr. Nag.

17 MEMBER NAG: Yeah, I believe again, that
18 number 3 that we have in the regs but there are many
19 factors. One is the MDS Nordion and the other is
20 Sirtex and both of them have preceptor training. Both
21 of them will not allow you to do any yttrium-90
22 therapy until you have been precepted on at least
23 three cases, I believe.

24 CHAIRMAN MALMUD: So three is a consistent
25 number. It satisfies the standards that were

1 established for I-131 therapy. It satisfies that
2 which the manufacturer of the product is using
3 currently and is that the number that visitors to your
4 program, Dr. Salem, at Northwestern, generally receive
5 before you're willing to certify them?

6 DR. SALEM: Yes, sir, Mr. Chairman. What
7 happens is they usually see two to three cases, but
8 once they leave our institution, the manufacturer
9 physically sends proctors for the actual
10 administration portion the physics portion, added
11 support for nuclear medicine and they do an extra
12 three cases, so it is quite comprehensive.

13 CHAIRMAN MALMUD: Thank you. Dr.
14 Suleiman, you have a pained expression on your face.
15 Would you like to say something?

16 MEMBER SULEIMAN: I wasn't planning on it,
17 but I'm not going to pass up the opportunity. I think
18 the iodine therapy is much simpler relative to this
19 and I think just philosophically, I think three sounds
20 to me is too few.

21 CHAIRMAN MALMUD: We appreciate your
22 opinion. Dr. Eggli?

23 MEMBER EGGLI: That was the concern that
24 I'd actually raised in my presentation, you know, are
25 three really enough. It sounds like what they're

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1 doing is their training three and preceptoring three
2 for a total of six. I'm personally much more
3 comfortable with that kind of level of involvement.
4 It's sort of the old see one, do one and then maybe
5 teach one at some point, but I think that you're under
6 close supervision participating in three. And then
7 under still fairly close supervision, you are being
8 mentored on three more the way the vendor currently
9 has it set up.

10 I think I'm personally comfortable with
11 that and I would agree with Orhan's statement that
12 this is more complex than some of the radio-iodine
13 therapies which speaks to why this would go into 390
14 rather than 392 or 394, because the bar is higher for
15 a physician practicing for -- training requirement for
16 390 than it is for 392 or 394, so I think that's
17 appropriate in raising the bar a little on the
18 training and experience requirement, I think, is
19 commensurate with that, with that increased risk level
20 associated with that training. I think I would be --
21 I am comfortable with the approach that the vendor is
22 suggesting which is three and three.

23 CHAIRMAN MALMUD: So you're more
24 comfortable with six, three plus three, and Dr.
25 Suleiman looks less pained with three plus three. And

1 Dr. Salem, is that a practical number, three plus
2 three?

3 DR. SALEM: The three of six, I don't know
4 if that concerns me more than the fact of putting a
5 strict guidance and regulation on -- I don't know what
6 the first three means. I mean, we have a Center of
7 Excellence and we provide training. I don't know what
8 other vendors or manufacturers are performing. I
9 don't know what that means for other patients.

10 CHAIRMAN MALMUD: At your Center of
11 Excellence, how many cases does an individual see
12 who's visiting your Center of Excellence with that
13 intention --

14 DR. SALEM: It will range between two and
15 five.

16 CHAIRMAN MALMUD: Two and five.

17 DR. SALEM: There is no strict number that
18 we follow. The strict number that I believe the
19 manufacturers both follow and I fully support is three
20 of the proctored at their own site, at their own
21 institution, ironing out all of the technical nuances
22 that are required for this therapy at their own site.
23 The three for the manufacturer at the site, I believe
24 is solid and compulsory. The other ones, I think, are
25 a benefit. I don't know how easy or difficult it is

1 to mandate people actually see infusions before
2 actually starting them.

3 CHAIRMAN MALMUD: The reason that I'm
4 pursuing this is, if there are going to be guidelines,
5 the guidelines have to have firm numbers and it seems
6 to me that we have this active discussion ongoing now.
7 This is a time to make a recommendation.

8 DR. SALEM: I believe if I could make a
9 recommendation that three on site proctored infusions
10 is reasonable.

11 MEMBER NAG: Dr. Malmud?

12 CHAIRMAN MALMUD: Dr. Nag?

13 MEMBER NAG: I mean, having done these
14 procedures, I feel the -- I agree with Dr. Salem. The
15 practical experience of having proctored in your own
16 institution under your own environment is much more
17 important than visiting someplace and seeing what
18 others are doing. And you know, I believe that three
19 proctored cases in your own institution is what I
20 would go by.

21 CHAIRMAN MALMUD: Well, I'm sorry, I'm
22 puzzled. How can one have three proctored cases in
23 one's own institution when one hasn't done them
24 before?

25 MEMBER NAG: Because what happens is that

1 the -- let's say I would go over to a place where they
2 are going to do a new case. I would be there from the
3 beginning. I would coach them or Dr. Salem would go
4 and Dr. Salem would coach them from the beginning.
5 They're there from the beginning of the day to the end
6 of the day and they do that for at least three cases
7 and therefore, all the practical problems that come up
8 are solved right there.

9 CHAIRMAN MALMUD: Dr. Howe.

10 DR. HOWE: I think possibly one solution
11 to this is to think about it in terms of training and
12 work experience. And we could put cases in the
13 training aspect which would be the vendor training, so
14 people have a chance to see the experienced person
15 using and then put three cases in the supervised work
16 experience. So that we could meet both things at the
17 same time, because I would hate to see this be a
18 lecture part of training devoid of patient care on the
19 first part.

20 CHAIRMAN MALMUD: So from the Nuclear
21 Regulatory Commission perspective, it would be three
22 supervised cases plus -- three proctored cases, is
23 that the term, plus additional experience with regard
24 to the radiation issues. We're not discussing
25 credentialing here. That's a hospital issue, but from

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1 the radiation perspective a minimum of three cases.

2 DR. HOWE: I'm looking more at possibly
3 six cases, three being in the training aspect of it
4 and then three being in the supervised work experience
5 under the supervision of an authorized user that can
6 do this procedure.

7 CHAIRMAN MALMUD: Thank you, I would --
8 Dr. Vetter?

9 MEMBER VETTER: Well, why are we -- it
10 sounds like we're increasing the requirements and the
11 question I would have is why are we increasing the
12 requirements? Currently, it's three proctored cases.

13 DR. HOWE: I think part of the reason is
14 that this is a complicated procedure that has many
15 places where things can go wrong, just mechanically
16 and with the material itself. So it's not your
17 typical therapy administration.

18 MEMBER VETTER: But what is causing us to
19 want to increase the required number of cases?

20 CHAIRMAN MALMUD: In other words, have
21 there been any problems which would cause the minimum
22 number to increase from the three that you have been
23 using, Dr. Salem? Have you had any unusual
24 circumstances that you --

25 DR. SALEM: No, I don't think so. I think

1 the ability of a site to see another hospital, see how
2 they do this, is extremely helpful for hospitals. But
3 I don't want to forget -- we don't want to forget the
4 fact that we don't want to take that aspect for
5 granted. It is not easy to find centers where you can
6 find this type of training and this type of
7 experience. And so the most -- the common denominator
8 is at the own institution with a trained authorized
9 user or therapist that uses this therapy that can
10 literally navigate that site and hospital through
11 their own process from A to Z.

12 You can theoretically train a site if you
13 had an onsite authorized user in three day's time,
14 having three or four or five patients to treat where
15 all of these things are done. I think I am concerned
16 about imposing this other training elsewhere because
17 of the logistics and the ability to perform that.

18 CHAIRMAN MALMUD: When someone leaves your
19 program, do you feel satisfied that he or she has had
20 adequate experience in seeing three cases?

21 DR. SALEM: Absolutely. When they leave
22 my program, I'm comfortable that they are ready to
23 start.

24 CHAIRMAN MALMUD: With three cases.

25 DR. SALEM: They are ready to start their

1 own program, but they nevertheless need significant
2 hand-holding and support by the manufacturers.

3 CHAIRMAN MALMUD: Yes. Dr. Schwarz, I
4 think was next.

5 MEMBER SCHWARZ: I just have a question
6 similar. Are there documented misadministrations,
7 have there been problems with this particular modality
8 that you're thinking that we need more cases?

9 DR. HOWE: Yes, we have had a number of
10 misadministrations and we've had a number of problems
11 in the delivery of the microspheres into the patient
12 and we've had all aspects of it, but with SirSphere
13 and with TheraSphere. So it does have a track record
14 as being a kind of a unique procedure that needs
15 special care and there are differences between the two
16 devices that people need to be aware of when they are
17 administering the different kinds of spheres.

18 MEMBER SCHWARZ: So you are thinking that
19 additional training -- I mean -- would be a good
20 thing. That three hands-on cases plus possibly three
21 observed cases.

22 CHAIRMAN MALMUD: I think Dr. Vetter's
23 question still remains unanswered. Would you care to
24 say something, Dr. Vetter?

25 MEMBER VETTER: Yeah, just briefly. Once

1 again, I recognize it's a complicated procedure. I
2 know there have been problems, especially early on,
3 but what is the current root cause of the problems and
4 can it be tied to a lack of training? I'm not arguing
5 it ought to be three or six. What I'm arguing is, we
6 ought to have a good reason for increasing the number
7 of cases if we're going to increase the number of
8 cases. So if there's a root cause tied to the lack of
9 training, that's a reason to increase the number of
10 cases.

11 CHAIRMAN MALMUD: Dr. Williamson was next.

12 MEMBER WILLIAMSON: I just have a simple
13 question of fact. In the current vendor supplied
14 training protocols for both agents, is the proctor
15 necessarily an authorized user or is it just a
16 technical representative from the company?

17 MEMBER NAG: No, it's an authorized user,
18 someone who is doing it every day.

19 MEMBER LIETO: My interpretation is that
20 what's occurring is that, say in Dr. Salem's case is
21 that these individuals come. They observe the
22 performance of three procedures going through all the
23 motions, if you will, of what needs to be done and how
24 it's done and so forth. Then they go to their
25 institution and perform the procedures proctored by

1 the manufacturer's representative. Okay, and so I
2 think what Donna Beth is recommending is just simply,
3 I don't want to say codifying it but putting it into
4 the guidance document is that there would be these
5 three cases under an authorized user in which they go
6 through training and experience -- through training.
7 They then go to their institution and actually
8 experience performing these procedures proctored by --
9 another three procedures proctored by -- very closely
10 by the manufacturer vendor rep. That's my
11 understanding of what they've been saying, which would
12 be, I think the six cases we're talking about but
13 really isn't any different than what's been done.

14 MEMBER NAG: I don't think that's so. The
15 proctors are authorized users. They're either
16 radiation oncologists or interventional radiologists
17 who have done a large number of this procedure. They
18 are not just technical representatives. So they are
19 proctoring who have done a lot of cases themselves,
20 they're authorized users.

21 MEMBER LIETO: But the authorizes user of
22 the licensee that's performing the procedure okay,
23 that's the three cases done on their own -- at the
24 licensee's site, not the three cases -- they're not
25 doing procedures at Dr. Salem's site. He's doing them

1 and they're basically monitoring sort of like, if you
2 will, shadowing his staff and so forth. So I think
3 the actual hands-on doing it, okay, is the three
4 proctored cases at the licensee's site.

5 MEMBER NAG: Right.

6 MEMBER LIETO: So that's where the
7 experience come is, not -- and the training is
8 occurring in the first three cases. So I think what
9 we're talking about are three training cases, three
10 experience cases.

11 MEMBER NAG: But I think there are two
12 different manufacturers and they do not necessarily do
13 it the same way. And --

14 MEMBER LIETO: That's understood. What
15 I'm saying is, the recommendation, I think, should be
16 that we have the same thing regardless of the
17 manufacturer of the microspheres so that the NRC can
18 put this into their guidance.

19 MEMBER NAG: Right, but I think the
20 important -- from a practical standpoint, and I have
21 seen and I have done it and have be proctor also. The
22 important component is the proctoring at your own site
23 because that's where you learn all the practical
24 problems that can go wrong. The other thing, you
25 know, we had the yttrium-90 symposium series that goes

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1 on for two days. Many of those things are the
2 theoretical part, but the practical part is they
3 proctored things that you have in your own
4 institution.

5 CHAIRMAN MALMUD: Dr. Nag, are you
6 recommending that three cases be seen at the original
7 site and that two be proctored at the home
8 institution?

9 MEMBER NAG: No, three be proctored at the
10 home institution.

11 CHAIRMAN MALMUD: Three plus three is your
12 recommendation.

13 MEMBER NAG: No, the other three is really
14 not the important component. The three that is in
15 your own institution is the important component.

16 CHAIRMAN MALMUD: So you are recommending
17 three at one's own institution.

18 MEMBER NAG: Yes.

19 CHAIRMAN MALMUD: And who would be the
20 proctor, the manufacturer's representative?

21 MEMBER NAG: No, the proctors are
22 authorized users that the manufacturers send. I mean,
23 they're sent by the manufacturers but they are not
24 technicians. They are authorized users from other
25 sites.

1 CHAIRMAN MALMUD: Is that a practical
2 solution in terms of the willingness of the
3 manufacturer to do this and the expense associated
4 with the physician coming to the site? I'm just
5 asking a question. We have a member of the public.

6 DR. MURPHY: Mr. Chairman, thank you very
7 much. My name is Dr. Rodney Murphy from MD Anderson.
8 I'm an interventional radiologist and I'm a proctor
9 for Sirtex Medical. Dr. Salem is a proctor for
10 Therasphere Medical or MDS Nordion, manufacturer of
11 Therasphere. Sirtex Medical is a different approach.
12 They do not have a Center of Excellence and proctors
13 go out the individual sites. I am not an authorized
14 user. I am a proctor for Sirtex Medical and the
15 majority of proctors are not authorized users. And
16 they're there in a shadowing capacity. So we're there
17 to assist and answer questions till we feel that they
18 are comfortable where they can actually the procedure
19 on their own. I just want to add a little perspective
20 on what's actually happening, the reality. So there
21 is no Center of Excellence for the other manufacturer.
22 So it's three cases, proctored at their home
23 institution.

24 CHAIRMAN MALMUD: Thank you. That's three
25 cases proctored at their own institution but not by an

1 authorized user.

2 DR. MURPHY: That is correct.

3 CHAIRMAN MALMUD: Thank you.

4 DR. MURPHY: And I do not necessarily
5 follow up on the issue of whether or not these three
6 cases have been proctored. In other words, the
7 manufacturer follows up on the number of proctorings
8 at that unusual site. When I go out to proctor a case
9 there may be only one case on that particular day and
10 on subsequent days another proctor may come out to
11 necessarily proctor additional cases in order to
12 achieve a minimal threshold number of three.

13 CHAIRMAN MALMUD: Then if I understand
14 you, it's three cases proctored by the manufacturer
15 with the manufacturer keeping the record of the three
16 cases having been proctored.

17 DR. MURPHY: Correct.

18 CHAIRMAN MALMUD: And these are not by
19 authorized users, necessarily.

20 DR. MURPHY: Correct.

21 CHAIRMAN MALMUD: They can be but they're
22 not necessarily.

23 DR. MURPHY: Yes, that is correct.

24 CHAIRMAN MALMUD: And Dr. Salem is nodding
25 his head in agreement, I see.

1 DR. SALEM: Yes, if I can just add, the
2 reason for the authorized user distinction is because
3 I'm fortunate to be authorized user in my state. Dr.
4 Murphy is equally qualified as I am to be an
5 authorized user and it varies from state to state. So
6 he could be an authorized user.

7 CHAIRMAN MALMUD: So if one were to
8 continue the practices that the two of you have
9 introduced with respect to the two companies that you
10 work with, it would be three cases proctored at the
11 institution that wishes to do the procedure with the
12 proctor not necessarily being but an authorized user.

13 DR. SALEM: But a representative of the
14 company, yes, sir.

15 CHAIRMAN MALMUD: Thank you. That should
16 answer the question as to what's been happening thus
17 far which would help NRC establish policy for what
18 will happen in the future. Did anyone else wish to
19 make a comment about this issue. Time, yes. Oh, Dr.
20 Williamson.

21 MEMBER WILLIAMSON: Well, I'm wondering
22 what the qualifications of the proctor should be, just
23 experienced physicians?

24 CHAIRMAN MALMUD: If I may, it would seem
25 to me that the qualifications of the proctor should be

1 someone who has the experience of greater than three
2 cases.

3 MEMBER WILLIAMSON: And not an authorized
4 user, because that won't be practical it sounds like.

5 CHAIRMAN MALMUD: It sounds like it has
6 not been an authorized user at least on one instance
7 and it may not be practical for the individual to be
8 the authorized user if these are relatively young
9 physicians and who have not necessarily wish to be
10 authorized users themselves being at large teaching
11 institutions.

12 MEMBER NAG: The reason because they're
13 not authorized user is as of now the NRC rule is that
14 only 490 are authorized user for Y-90. Once the new
15 rule comes in, both nuclear medicine physicians and
16 interventional radiologists, who will have experience
17 in 390 would also be authorized user. These are all
18 physicians who are doing it every -- you know, who are
19 doing it routinely but they are not necessarily
20 authorized user because of the NRC rule.

21 CHAIRMAN MALMUD: I believe Dr. Vetter
22 wishes to make a comment.

23 MEMBER VETTER: Just a quick one. Just
24 remember that you can't do this without an
25 interventional radiologist and that might give you a

1 clue as to why so many of them are the proctors.

2 CHAIRMAN MALMUD: You are, of course,
3 correct. The other thing we should recognize is that
4 while our goal is to achieve radiation safety
5 practices which are in the best interest of the
6 patients, we don't want to create hurdles which will
7 prevent this procedure from being used broadly to the
8 betterment of patient care. We are running far
9 behind. If I may, I'll take the Chairmans'
10 prerogative and close discussion on this issue right
11 now.

12 Thank you, we'll move on. I wish to thank
13 the members of the public who participated in this
14 discussion. Your input was very valuable, thank you.
15 If we may, we'll move on now to Item Number 12, which
16 is Proposed Breast Brachytherapy Using I-125 Seeds,
17 and the presenter will be Michael Cutrer. Did I
18 pronounce it correctly?

19 DR. CUTRER: Yes, you did.

20 CHAIRMAN MALMUD: Thank you. With North
21 American Scientific and he will present to the ACMUI
22 the proposed breast brachytherapy using I-125 and the
23 associated shielding issues. Mr. Cutrer.

24 DR. CUTRER: Thank you, Mr. Chairman and
25 members of the committee. I appreciate the

1 opportunity here today to introduce to you a -- what
2 we feel is an exciting new option in the treatment of
3 accelerated partial breast irradiation using
4 brachytherapy. I think everyone here will agree that
5 the best part of my presentation today is that it's
6 the last one, if I understand the schedule correctly.

7 I apologize that some of this presentation
8 was done for individuals that were significantly less
9 technical than the committee, so I can bypass a lot of
10 this in the interest of time, but there is definitely
11 a need for the accelerated partial breast radiation
12 and a need for new options. The primary driver for
13 that is that whole breast irradiation is taking six to
14 eight weeks. The accelerated partial breast
15 irradiation options that are currently out there
16 provide a number of important options, primarily one
17 being that patients are able to initiate their
18 chemotherapy earlier as opposed to waiting the six to
19 eight weeks for the treatment time.

20 With accelerated partial breast we've seen
21 a number of Phase 2 studies that are supporting its
22 use. We're seeing that the majority of the
23 recurrences in these patients that are undergoing
24 lumpectomies are in or near the tumor bed, which was
25 the driver for accelerated partial breast in the first

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1 place. The two current methods that are out there,
2 one is using multiple catheters, 15 or 20 catheters
3 placed in the breast, high dose rate treatment being
4 used to treat these patients, coming in twice a day
5 for five days for their treatment.

6 The challenges there obviously are that
7 it's invasive. It's not easy to learn. It is high
8 dose rate only at the present time. There has been
9 low dose rate treatments having been done historically
10 but the treatment time was 96 hours and so it was
11 certainly not logistically possible for widespread
12 adoption. Skin dose was also an issue with low dose
13 rate because the breast would shift over that course
14 of time.

15 The other challenges, that it does require
16 the capital investment of the high dose rate system.
17 There is also a balloon catheter out there, I'm sure
18 many of you are familiar with the mammosite (phonetic)
19 device. It certainly is more elegant from the
20 standpoint that it is a single incision and placement.
21 It forces the resection cavity to conform to the
22 balloon as opposed to conforming to the resection
23 cavity. Some of the concerns there are that it does
24 put compression in areas of the breast and the tumor
25 bed and restricts blood flow to those areas.

1 So the challenges there are that it's non-
2 conformal. The inflation can cause areas of hypoxia.
3 The seroma or air in the device itself can lead to
4 areas of less superior deployment. There have been
5 balloon ruptures. There's only a signal luman in
6 which to place the high dose rate source. So it does
7 restrict the conformality that a physicist or
8 radiation oncologist could provide if there were
9 greater catheters for them to use for the high dose
10 rate treatment.

11 What we wanted to do was to blend what is
12 good about the two existing systems; the first one
13 being that it's a single site placement and that
14 there's a single incision. There's not multiple
15 incisions being made. There are multiple channels
16 that allow for maximum dose conformity, whether it is
17 high dose rate or low dose rate. What I approached
18 our state health department with and then ultimately
19 was directed to the NRC to get additional guidance was
20 from the low dose rate perspective, what are some of
21 the challenges or recommendations or concerns that the
22 group might have.

23 So we also wanted to avoid any possibility
24 of rupture. We wanted it to be conformal to the
25 resection cavity, not forced conformality around the

1 device and not compress tissue. Essentially, what we
2 have is a device that when it arrives at the site is
3 compressed. It has eight to 12 catheters that are
4 compressed there. And you'll see on the back end
5 here, those little sliders, if you will, allow for you
6 to do a secondary deployment. So this would be the
7 initial deployment in the resection cavity and then
8 the device, this little hand-held plier would be
9 removed. Each of these sliders can be adjusted so
10 that the device not conforms to the tumor bed as
11 opposed to forcing conformality around the device
12 itself.

13 So you would have multiple channels. High
14 dose rate or low dose rate or a combination of either
15 of those. In the scenarios where the resection cavity
16 is very near the chest wall, you might opt for low
17 dose rate there and high dose rate further out.
18 Similarly, if it's very near the skin surface, you
19 might be able to utilize a combination therapy as
20 well. However, having multiple channels will allow
21 for greater flexibility.

22 The device in the case of low dose rate,
23 the patient would simply go home with this device
24 capped. There are no catheters that would be outside
25 the breast. In the case of high dose rate, we

1 envision an adaptor that would go on so similarly
2 patients would go home with just the cap, not a number
3 of catheters or even a single catheter hanging out of
4 the breast. The low dose rate application, the
5 drivers for low dose rate are the continuous dosing
6 and improved biological effectiveness. The reduced
7 dose to healthy tissue. There is no shielded facility
8 required specifically for using Iodine 125. The
9 convenience, we are looking at a number of areas that
10 are of importance.

11 Identification on the patient in the event
12 this patient were in an accident, they need to -- you
13 know, people need to know that they need to have this
14 device removed in a specific time frame. So there
15 needs to be identification. This is also shielding
16 for these patients in some cases. The data that we --
17 the preliminary data that we have seen, as you can
18 imagine with Iodine 125 is very specific to the depth
19 that it is in the tissue.

20 Patient education prior to release is
21 certainly going to be critical. There are a number of
22 existing surgical garments that are out there and a
23 number of shielding materials that can be used.
24 Demron, lead, bismouth, all of these can be
25 incorporated into devices. The one here on this far

1 side here is a device that has been -- we have a
2 manufacturer that can make these devices using demron
3 or the bismouth device so that there is complete
4 shielding if it's necessary. It's lightweight.
5 There's no need, necessarily, for patients to be
6 wearing anything that's excessive or bulky. And
7 again, we think it's important that patient education
8 and physician training be part of this introduction.

9 So again, some very preliminary
10 measurements; we are estimating that we could be using
11 as much as 300 millicuries of iodine, so certainly if
12 there was absolutely no shielding on a patient where
13 it is very near the surface, five millimeter depth,
14 the dose is high. With bismouth or demron, we can
15 reduce that significantly. At a meter those dose
16 rates, as you would expect, would drop off
17 significantly and can be shielded effectively to zero.

18 So what we're looking to do again, is to
19 bring what is good about the two existing methods into
20 one device. We actually just received FDA approval
21 today on the low dose rate applicator and we're
22 looking to roll this out later this year in the
23 November time frame.

24 Obviously, there are a number of important
25 drivers here but the primary one being accelerated

1 partial breast eradication is something that is coming
2 into the mainstream for a variety of reasons. There
3 are two Phase 3 trials that are currently ongoing.
4 Reimbursement is in place and I also believe that
5 there is a significant opportunity outside of the US
6 as well. That's it, as quickly as I could do it.

7 CHAIRMAN MALMUD: Thank you. Dr.
8 Williamson.

9 MEMBER WILLIAMSON: So the sole regulatory
10 issues before us is, this is a modality that would
11 require a temporary implant patient to be released
12 from the hospital and come back at some point in 96
13 hours to have the sources removed. Other than that,
14 it would be handled completely under 35?

15 DR. MURPHY: Correct, and the high dose
16 rate application, obviously, the patient is in the
17 hospital or in the free-standing center. In the low
18 dose rate application, much like with the ocular
19 myeloma patients, where they're treated with the
20 Iodine 125, placed in the eye and then they are
21 released for some time period.

22 CHAIRMAN MALMUD: Dr. Howe.

23 DR. HOWE: I think the issue here is that
24 the low dose rate patient, can they be released under
25 35.75 without additional shielding required and then

1 how do we insure that the patient complies with any
2 additional shielding requirements, because the sources
3 are left in place and the question is, 35.75. And it
4 appears as if you need additional shielding in order
5 to release anybody under 35.75. So that is the real
6 issue here.

7 DR. MURPHY: We think that that is the
8 case probably in the majority of cases. Where the
9 resection cavity is near the chest wall, large breasts
10 small resection, it is possible that that patient is
11 not going to need additional shielding, but by far the
12 majority of them will to some degree.

13 CHAIRMAN MALMUD: Malmud. The guidelines
14 that we give to patients who receive I-131 therapy and
15 who go home on an outpatient basis are existent.
16 Wouldn't similar guidelines be applicable but even
17 less so because of the range of the I-125?

18 DR. HOWE: The issue is with the 131
19 patients that you're releasing, you don't require
20 additional shielding and so in this case, you're only
21 -- they may only be able to allow them to be released
22 if the shielding is in place and remains in place.

23 CHAIRMAN MALMUD: Dr. Nag?

24 MEMBER NAG: Yeah, I think the issue here
25 is exactly similar to the OI myeloma patient treated

1 with I-125 where we have I-125 placed on the eye.
2 Many places do them in the hospital for two or three
3 or four days. Some send them home as an outpatient.
4 And what we do is we measure and see if the exposure
5 rate is more than 0.2 or something, we put a shielding
6 in place and we send them home with instructions to
7 keep the shielding on their eye. So I think similar
8 instructions can be done with these patients.

9 DR. CUTRER: Right. In this case, what
10 we felt was important was that as the manufacturer, we
11 also offer options for the shielding as opposed to
12 leaving it just strictly up to the physician in that
13 any of the surgical garments that I showed or we can
14 incorporate the bismouth material or the demron which
15 is very flexible and can actually be cut and put into
16 the surgical garments very easily.

17 CHAIRMAN MALMUD: Dr. Williamson.

18 MEMBER WILLIAMSON: Well, I think the
19 conditions for release of 35.75 are clear. It doesn't
20 specify that it needs to be a permanent implant or
21 unsealed radioactive source. It just says that the
22 dose equivalent has to be less than 500 millirentgen,
23 period. And it would seem the only issue might be, I
24 suppose, that the ancillary requirements for
25 documentation and patient instruction don't cover the

1 shielding, if that's necessary, so that would be the
2 only like one little paragraph added to 35-1000 would
3 do it.

4 CHAIRMAN MALMUD: Mr. Lieto?

5 MEMBER LIETO: Could you go back to the
6 slide that shows the shielding and the dose rates that
7 -- it was a table, yeah, right there. How long are
8 these sources left in?

9 DR. CUTRER: The typical treatment for
10 accelerated partial breast today using the mammosite
11 device in high dose rate is five days. So what we
12 would envision here is that this is a dose that is
13 going to be delivered continuously over a five-day
14 period.

15 MEMBER LIETO: So they would come back and
16 then it would be removed.

17 DR. CUTRER: Right, and while the -- you
18 know, one scenario would be the patient comes in on
19 Monday morning and they come back Friday afternoon and
20 it's removed but the reality is from initial
21 conversations with physicians is that certainly
22 initially they're going to want to see that patient
23 more frequently.

24 MEMBER LIETO: You know, looking at some
25 of these numbers, I would say that, you know, with

1 even the thinnest shielding involved, you know,
2 releasing these patients with, as Jeff pointed out,
3 you know, precautions and guidance to be followed over
4 a five-day period probably is not unreasonable and I
5 would say that they could -- you know, I don't see the
6 problem with releasing these under 35.75.

7 CHAIRMAN MALMUD: Dr. Nag.

8 MEMBER NAG: Although for high dose rate
9 given over five days, because it's high dose rate, you
10 can only give it two times a day. For LDR, very
11 easily three to four days, so for LDR I think that
12 could be more like four days in most places. In the
13 eye patch it's as many as seven day, most of our eye
14 plant is done in three to four days.

15 DR. CUTRER: Right, and we can certainly
16 adjust that with activity levels that are in the same
17 activity range as the eye plant patients.

18 CHAIRMAN MALMUD: Dr. Vetter?

19 MEMBER VETTER: Does the NRC have any
20 experience relative to the compliance with wearing the
21 shield for eye plant patients? To the best of my
22 knowledge, patient compliance is excellent, so there
23 would be no reason to believe patient compliance
24 wouldn't be excellent here as well.

25 CHAIRMAN MALMUD: Any other comments?

1 Thank you very much.

2 DR. CUTRER: Thank you.

3 CHAIRMAN MALMUD: Is there any action that
4 needs to be taken? Mr. Lieto?

5 MEMBER LIETO: I think NRC was looking for
6 some recommendation from us on this and I would say
7 that -- I would say that these patients being released
8 with these shields in place and following the written
9 instruction and requirements of Part 35.75 there would
10 be no problem in releasing them with the activities --
11 up to the activities that were mentioned.

12 CHAIRMAN MALMUD: So you recommend that
13 this go forward. Is there a second to the motion?

14 MEMBER WILLIAMSON: Second.

15 CHAIRMAN MALMUD: Second by Dr.
16 Williamson. All in favor?

17 (Aye)

18 CHAIRMAN MALMUD: Any opposed? Any
19 abstentions? It carries unanimously. Thank you very
20 much. May I make a motion for adjournment for the
21 day? We will recover and meet tomorrow at 8:00 a.m.

22 MR. ESSIG: Yes, we will, but it's in a
23 different room remember, Room E1 and E2.

24 (Whereupon, at 6:18 p.m. the above-
25 entitled matter concluded.)