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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

ROBERT L. O'CONNELL, NMSS/IMNS/MSIB

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.

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

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

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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.



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

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

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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

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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 1<sup>st</sup>, 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

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 25<sup>th</sup>, 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



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

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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, were  
24 I am, and I was the host, in April, just a couple of  
25 weeks ago and we identified the various controversial

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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.



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

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

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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

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.)