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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

EXECUTIVE SESSION

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TUESDAY,

OCTOBER 25, 2005

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The meeting was convened in Room T-2B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:19 a.m.

MEMBERS PRESENT:

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

1       SPEAKERS AND PARTICIPATING NRC STAFF:  
2       DOUGLASS F. EGGLI, M.D., ACMUI  
3       THOMAS H. ESSIG           NMSS/IMNS/MSIB  
4       CINDY M. FLANNERY        NMSS/IMNS/MSIB  
5       SANDRA L. GABRIEL        DNMS, Region I  
6       PATRICIA K. HOLAHAN, Ph.D, NMSS/IMNS/MSIB  
7       ANGELA R. MCINTOSH       NMSS/IMNS/MSIB  
8       MOHAMMAD SABA            NMSS/IMNS/MSIB  
9       SAMI S. SHERBINI, Ph.D, NMSS/IMNS/MSIB  
10      JOHN SZABO                OGC  
11      RONALD E. ZELAC          NMSS/IMNS/MSIB

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ALSO PRESENT:

CHARLES L. MILLER, PhD

JOHN SZABO

DONNA-BETH HOWE

LYNNE A. FAIROBENT

JEAN ST. GERMAIN

ROBERT FORREST

I-N-D-E-X

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23  
24  
25

Page

Introduction . . . . . 5

Opening Remarks . . . . . 8

Status of Guidance on Reducing Doses to  
Members of the Public

    Dr. Sherbini . . . . . 156

RIS on Visitor Dose Limits

    Dr. Sherbini . . . . . 166

Electronic Signatures in Written Directives

    Dr. Howe . . . . . 200

Adjourn

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

CHAIRMAN MALMUD: It's yours, Mr. Essig.

MR. ESSIG: Okay. If other members would kindly take there seats. Mr. Leito.

As designated federal official for this meeting, I am pleased to welcome you to Rockville for the public meeting of the Advisory Committee on the Medical Use of Isotopes.

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

Present today as the alternate designated official is Cynthia Flannery, Team Leader for Medical Radiation Safety.

This is an announced meeting of the committee. It is being held in accordance with the rules and regulations of the Federal Advisory Committee Act. The meeting was announced in September 20th and October 4th, 2005 editions of the Federal Register.

The function of the committee is to advise the staff on issues and questions that arise on the medical use of byproduct material. The committee

1 provides counsel to the staff, but does not determine  
2 or direct the actual decisions of the staff or the  
3 Commission. The NRC solicits the views of the  
4 committee and values them very much.

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

11 As part of the preparation for this  
12 meeting, I have reviewed the agenda for members and  
13 employment interests based on the general nature of  
14 the discussion we're going to have today and tomorrow.  
15 I have not identified any items that will pose a  
16 conflict. Therefore, I see no need for an individual  
17 member of the committee to recuse themselves from the  
18 committee's decision making activities.

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

23 At this point I would like to introduce  
24 the members of the committee that are here today. Dr.  
25 Leon Malmud, Chairman, our health care administrative

1 representative.

2 Dr. David Diamond, radiation oncologist.

3 Dr. Subir Nag, radiation oncologist.

4 Dr. William Van Decker, nuclear  
5 cardiologist.

6 Ms. Sally Schwarz, nuclear pharmacist.

7 Dr. Richard Vetter, radiation safety  
8 officer.

9 Dr. Jeffrey Williamson, therapy physicist.

10 Mr. Ralph Leito, nuclear medicine  
11 physicist.

12 Mr. Edgar Bailey, state representative.

13 Dr. Robert Schenter, who is not here.

14 Dr. Orhan Suleiman, of the Center for Drug  
15 Evaluation and Research of the U.S. Food and Drug  
16 Administration are those who are present.

17 Dr. Douglas Eggli will not be attending  
18 this meeting. Dr. Leon Malmud, Acting Chairperson,  
19 will conduct today's and tomorrow's meeting.

20 Following discussion of each agenda item,  
21 the Chair at his option may entertain comments or  
22 questions from members of the public who are  
23 participating with us today.

24 CHAIRMAN MALMUD: Thank you, Mr. Essig.

25 The opening remarks will now be made by



1 Dr. Miller.

2 DR. MILLER: Good morning. I'd like to  
3 welcome everybody to beautiful, sunny Rockville,  
4 although for Dr. Diamond, I'm sure that he has been  
5 through a little bit more than we have in the last few  
6 days. So I was happy to see that he made it.

7 I would like to welcome the members of the  
8 public to the meeting. I think Tom has said out the  
9 protocol for the meeting and so that we have a very  
10 aggressive agenda this time. So in order to try to  
11 stay on schedule as much as we can, Dr. Malmud, I will  
12 without further ado turn the meeting over to you.

13 CHAIRMAN MALMUD: Thank you.

14 The next item on the agenda is the status  
15 of Board applications and the presenter will be Cindy  
16 Flannery, and with her Dr. Ronald Zelac and Dr. Dona-  
17 Beth Howe.

18 Dr. Flannery.

19 DR. FLANNERY: Thank you.

20 Good morning. Thank you for the  
21 opportunity. I will be opening up the discussion on  
22 the status of the review process for recognition of  
23 the specialty boards.

24 As you know, on March 30th of this year,  
25 the Federal Register announced the change in the NRC

1 requirements for recognition of the specialty boards.  
2 These changes related to the training and experience  
3 requirements that the boards have placed on the  
4 candidates who are seeking board certification.

5 Six months in advance of when Subpart J  
6 was due to expire, which was yesterday, letters were  
7 sent out to 12 different specialty boards and  
8 regarding applying for industry recognition of one or  
9 more of their certification processes. Nine of those  
10 12 specialty boards responded during the period of  
11 July and August applying for recognition of the  
12 certification process.

13 And the last slide, I have a list of the  
14 status of the review process for each of the specialty  
15 boards, but I first just want to go over the  
16 definitions for the four different categories of the  
17 status.

18 The first one is approved, and the status  
19 of approved means that the certification process for  
20 the specialty board has met NRC's criteria for  
21 recognition. The board was contacted. A formal  
22 letter has been sent to the board, and that specialty  
23 board is listed on the Web site.

24 And for your information, I do have copies  
25 of the Web site that lists the boards that are

1 approved up to date.

2           Approvable means that the certification  
3 process meets the criteria for NRC recognition.  
4 However, NRC staff is still waiting for a response  
5 from the specialty board on the date in which the  
6 specialty board will meet or has met to NRC's criteria  
7 for recognition.

8           Under review means that the NRC has  
9 requested additional information from the specialty  
10 board. The information has been received and is  
11 currently under review by NRC staff, and awaiting  
12 input means that the NRC staff is still waiting for  
13 additional information from the board before it can  
14 continue the review process.

15           And in conclusion, this table summarizes  
16 the status for the nine of the 12 specialty boards  
17 that have applied for recognition of their  
18 certification process.

19           That's all I have.

20           DR. NAG: One question. The certification  
21 of the radiologist London, is that from U.K.? Are  
22 they requesting certification?

23           DR. HOWE: Yes. Am I on?

24           Yes, it is from the United Kingdom, and we  
25 sent letters out to those boards that were listed in

1 Subpart J, and they were listed in Subpart J. They  
2 did respond to us back in the summer and asked us,  
3 "What are you sending us this letter for? Will it  
4 benefit our fellows?"

5 And we responded back to them. So at this  
6 point we haven't received an application from them,  
7 but we have received communication from them.

8 And I think Tom Essig would like me to  
9 address one of the questions that you may have, and  
10 that is as we're reviewing the applications, we're  
11 finding that most of the boards are having to make  
12 minor modifications or codifications of their process  
13 that may not be in the information that's available or  
14 that they sent into us.

15 And so to determine a date at which the  
16 board meets the criteria, we're not looking and seeing  
17 when they made the change. We're looking to see if  
18 the change was a substantive change or a codification  
19 of what they were already doing that had not appeared  
20 in writing anywhere.

21 And so if you look at the boards that we  
22 have recognized, we recognized the Board of  
23 Pharmaceutical Specialties for their certification  
24 process for board certified nuclear pharmacists. They  
25 made some changes to their Web site that indicated the

1 information that they were requiring of their  
2 candidates. But they went back and they looked to see  
3 because our rules were more specific than what they  
4 had upon their Web site, and they went back and looked  
5 at the actual candidates that they had taken the test  
6 and had been certified. And they found that all of  
7 their candidates met our criteria, and so they were  
8 able to go back to March 1996, to show when they were  
9 in compliance with our rules, although they made minor  
10 changes to what they're putting on their Web site  
11 requiring candidates.

12 And I think you'll find the same thing is  
13 true with the American Board of Nuclear Medicine.  
14 They now have additional information that matches our  
15 regulations up on their Web site, and they have made  
16 slight revisions to their certification process to  
17 make it easy for us to identify those members that are  
18 certified that meet our criteria.

19 In this case there is a 'Canada' at the  
20 bottom underneath the name of the certification for  
21 those that did not receive their training under an  
22 authorized user from the U.S.. And there is a 'United  
23 States' for those who did receive it under the U.S.,  
24 and they're also going back to look at their  
25 candidates that aren't already authorized users, and

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1 if they're not authorized users, then they'll take  
2 special efforts to make sure they comply with our  
3 regulations and issue them a new certificate.

4 So there are a number of ways that we're  
5 addressing the fact that changes are being made to the  
6 criteria, but those changes may not be really new  
7 changes to the people that are already certified and  
8 methods to distinguish those people that take the test  
9 that meet our criteria, for maybe others that take the  
10 test that don't meet our criteria, which are normally  
11 the foreign applicants.

12 DR. NAG: Since the Subpart J expired  
13 yesterday, what is the exact status of those boards  
14 here who are either under new or awaiting for their  
15 input? I mean, where does this place us today? If  
16 the Subpart J expired yesterday, someone who was  
17 approved or who is board certified by, let's say, the  
18 American Board of Radiology or American Board of  
19 Osteopathic Radiology where most of your use, what is  
20 the exact status today?

21 MS. FLANNERY: You know, as far as the  
22 boards, I mean, if they can demonstrate at a later  
23 date that they met the criteria at an earlier time, we  
24 can indicate that on the Web site. So just because  
25 they're not listed today, when Subpart J expires,

1 doesn't mean that they can't be listed at a later  
2 date.

3 CHAIRMAN MALMUD: Dr. Miller.

4 DR. MILLER: Dr. Nag, I think your  
5 question was, "given the fact that Subpart J expired  
6 yesterday, what is their standing as of today."

7 DR. NAG: Today, yes.

8 MS. FLANNERY: Sorry. I didn't understand  
9 the question.

10 PARTICIPANT: It's not that they can't go  
11 back and become in good standing, but I think since it  
12 expired yesterday if they're not in good standing  
13 today and had been approved --

14 DR. NAG: Then let's say -- exactly. If  
15 today someone is applying, what are you going to do  
16 today because, you know, maybe three months from now  
17 they will send in applications that will meet the  
18 criteria, but today if someone is applying, what can  
19 you do?

20 MS. FLANNERY: If somebody submitted, say,  
21 an amendment request asking to add this individual who  
22 is certified by the ABR, they would not be able to,  
23 you know, get approved under the certification  
24 pathway. They would have to get approved by the  
25 training and experience pathway until such time the

1 ABR can be listed.

2 DR. NAG: Now, since all sent out at least  
3 80 or 90 percent of all the authorized users will be  
4 coming to the ABR certification, I don't think this is  
5 an acceptable condition to be placed then because you  
6 are going to be by default trying to do everyone by  
7 the alternate pathway rather than the board  
8 certification pathway.

9 DR. HOWE: I think the assumption is that  
10 we're currently reviewing the ABR application, and  
11 that we will be eventually approving it, and when we  
12 do approve it, we'll find a date at which it is in  
13 compliance with our rule, and that date may be prior  
14 to October 24th, and we're expecting it to be a short  
15 period of time between October 24th and when the  
16 approval comes through.

17 And it is only those individuals that are  
18 applying in that short period of time that are  
19 affected, but Subpart J, when we did the new rule back  
20 in April, was scheduled to disappear on October 24th,  
21 and --

22 DR. NAG: But we have at least from August  
23 10th and July 26th and July 29th -- these are the  
24 three when you are going to have a lot of  
25 applications. Is there any way we can either speed it



1 up between about two or three months?

2 DR. HOWE: We sent them a letter  
3 requesting additional information, and they did not  
4 submit that additional information til the last week.

5 DR. NAG: Do we have an example of what  
6 these additional information are? We may be able to  
7 push some of these things also through our own direct  
8 connection if we know what some of the concerns are  
9 because this is a very, very important thing where the  
10 Subpart J has already expired.

11 MS. FLANNERY: Some of the examples, they  
12 would list some topics for required training or some  
13 topics for work experience or number of hours, and  
14 they just weren't specific enough.

15 CHAIRMAN MALMUD: Dr. Williamson?

16 MS. FLANNERY: That's a common example of  
17 additional information. It's just more of a  
18 clarification.

19 CHAIRMAN MALMUD: Go ahead.

20 DR. WILLIAMSON: From what I'm hearing, it  
21 sounds like not all individuals who are board  
22 certified, who have been certified by the American  
23 Board of Radiology, will be included in this pathway,  
24 and that there are certain segments of the certified  
25 professional community that will be excluded from this

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1 pathway.

2           Could you explain case by case within the  
3 ABR framework which individuals or groups of  
4 individuals are going to so be excluded and what the  
5 issues are? Because, yo know, numerous concerns have  
6 been expressed to me by members of the community about  
7 this process.

8           DR. HOWE: I don't think we're far enough  
9 in the review to know what groups will be excluded,  
10 but I can give you an example of the American Board of  
11 Nuclear Medicine. In the American Board of Nuclear  
12 Medicine, there is a residency program, and the  
13 residency program in our requirements, there are two  
14 accreditation boards for the residency program.

15           They had a third accreditation board, and  
16 then if you look at the requirements for 100 and 200,  
17 the actual work experience that's also required under  
18 the board certification pathway had to be given under  
19 the supervision of an authorized user, and those  
20 individuals that were receiving their training in  
21 Canada were not getting their training under an  
22 authorized user.

23           So the Canadian group is open to take the  
24 examination, but they don't meet the requirements in  
25 35-190 or 290. So the board put a notation on the

1 bottom of the certificate, one United States, the  
2 other Canada so that we would see exactly who met our  
3 requirements. So we are not holding the boards to any  
4 requirements other than what's in our regulation.

5 Another example would be the cardiology  
6 group. They have foreign individuals that take their  
7 examination, but they issue two different  
8 certificates. One certificate is for those  
9 cardiologists residing in the United States. They  
10 meet the criteria of coming under the supervised work  
11 experience of authorized users. The ones that do not  
12 reside in the United States don't meet that criteria.  
13 They take the same examination. They pass, they fail,  
14 but we have a way of telling who meets our criteria  
15 and who doesn't.

16 So that is an example of distinction  
17 between groups, but we can't discuss the American  
18 Board of Radiology.

19 CHAIRMAN MALMUD: Thank you, Dr. Howe.

20 Dr. Zelac.

21 DR. ZELAC: Yes. To answer your question  
22 specifically, additional information was requested  
23 from that particular board, the American Board of  
24 Radiology, after the application was submitted and  
25 reviewed. In turn, the board did supply additional

1 information, but just very, very recently.

2 We are in the process of reviewing the  
3 additional information to be sure that, in fact, it  
4 does satisfy the requested need to show conformity of  
5 the program or programs actually with the current  
6 regulations.

7 The presumption that there may be  
8 certified individuals who will not be accepted is  
9 premature. If the program in effect as described  
10 meets the criteria and if it is essentially, as  
11 pointed out by Dr. Howe earlier, one that has been in  
12 effect for a considerable period of time, all of the  
13 diplomates since the program that is described was  
14 established will be eligible.

15 So that's part of the process in dealing  
16 with the boards, to find out when the program which is  
17 being described which we deem to be acceptable in  
18 terms of matching the regulations requirements was  
19 established, and that's the date that gets put into  
20 the Web site along with the recognition of that  
21 board's certification process.

22 So in summary, we cannot presume at this  
23 time that there will be individuals certified by the  
24 ABR whose certifications will not be acceptable.  
25 Until we get some information back from the ABR as to

1 when its program as described was established, it's  
2 premature to presume anything.

3 CHAIRMAN MALMUD: Mr. Bailey.

4 MR. BAILEY: Since I come from a segment  
5 that licenses 80 percent of the radioactive material  
6 users in the country, am I correct that agreement  
7 states who put someone on the license as an authorized  
8 user, those people will automatically be accepted as  
9 authorized users by NRC?

10 DR. HOWE: Right now the agreement states  
11 have three years to implement the revisions to Part 35  
12 that were made final in April of 2005, and so until  
13 April of 2008, the agreement states, unless they  
14 revise their regulations to conform with the current  
15 Part 35, can still use Subpart J or what they're using  
16 to recognize authorized users, and NRC recognizes  
17 people that are recognized as authorized users as  
18 authorized users for the same medical use.

19 So if you are a physician on an agreement  
20 state license for the same medical use, then you can  
21 be recognized by the NRC.

22 MR. BAILEY: And does that also apply or  
23 how will you take into account those states that, for  
24 instance, license physicists? Will those  
25 automatically be recognized if it's a state licensure,

1 as opposed to a board certification?

2 DR. HOWE: We have a definition of an  
3 authorized user, an authorized medical physicist, and  
4 an authorized nuclear pharmacist, and those  
5 definitions include individuals that are currently on  
6 licenses that recognize them for that use for the  
7 materials which they're authorized.

8 So if you have a medical physicist on an  
9 agreement statement license that's recognized for 600  
10 uses because that's where we name medical physicists  
11 or for Strontium I applicator, then we would accept  
12 them as existing authorized users or a medical  
13 physicist or pharmacist.

14 MR. BAILEY: I was referring to a  
15 different type of licensure. I was talking about  
16 professional licensure, not named on a materials  
17 license necessarily.

18 DR. HOWE: This only addresses board  
19 certification routes.

20 MR. BAILEY: So you would not recognize  
21 state licensure, say, in medical physics?

22 DR. HOWE: Medical physicists are not  
23 required to be stated licensed, and so we would not.

24 MR. BAILEY: They are in some states.

25 DR. HOWE: By the NRC.

1 MR. BAILEY: Right.

2 DR. HOWE: The criteria to be an authorized  
3 medical physicist does not include licensure. Some  
4 states do license them, but not -- so they would have  
5 to meet our requirements or be listed on an agreement  
6 state license or already listed on an NRC license  
7 because the training and experience rule grandfathers  
8 those individuals that are already recognized.

9 CHAIRMAN MALMUD: Does that answer your  
10 question, Mr. Bailey?

11 MR. BAILEY: Yeah, but not very  
12 satisfactorily because if you have a state law that  
13 says somebody is something in that state and then you  
14 pass a federal regulation that says they have to meet  
15 some other requirement, I think there's a little bit  
16 of conflict there.

17 DR. HOWE: But does your state, when it  
18 calls someone a medical physicist, does it include  
19 normal diagnostic physics? Does it include  
20 brachytherapy physics? Does it include things that  
21 are outside of what we're looking at?

22 We can only judge a physicist based on how  
23 we list an authorized medical physicist. There are  
24 many, many areas that a physicist can function in that  
25 that are beyond our authorizations.

1 MR. BAILEY: I think in different states  
2 there are different categories in how those are broken  
3 down, and I would assume, although I don't know  
4 specifically, that someone who is licensed as a  
5 therapy medical physicist should be able to meet the  
6 requirements.

7 But are you going to go do each of the  
8 state boards that do license physicists, some of whom  
9 may not be board certified?

10 And I would give an example. There might  
11 be someone, for example, in the State of Texas, which  
12 does license physicists, who's working at a VA  
13 hospital in Texas as a therapy medical physicist.

14 DR. HOWE: And if there is a physicist  
15 that's working at the VA, that physicist needs to come  
16 under our NRC requirements to be listed as an  
17 authorized medical physicist on that VA permit because  
18 the VA is a master materials licensee, and so they  
19 have to follow the NRC requirements.

20 So they would be listed on an NRC license  
21 as a medical physicist if they met our requirements.  
22 But we don't require our medical physicists to be  
23 licensed.

24 MR. BAILEY: Oh, you do not?

25 DR. HOWE: We do require our doctors to be



1 licensed. We require our pharmacists and our  
2 physicians to be licensed. They don't have to be  
3 licensed in the state in which they practice, but they  
4 do have to be licensed. That's in our definition.

5 CHAIRMAN MALMUD: Does that clarify the  
6 issue for you, Mr. Bailey?

7 Thank you. Thank you, Dr. Howe.

8 Dr. Nag.

9 DR. NAG: Since the states have three  
10 years to comply, how does this ruling apply to the  
11 states? I mean, October 24th the Subpart J expired  
12 for the NRC. You know, if you are board certified in  
13 one of the agreement states, do you have until October  
14 24th of 2008 for this thing to be applicable or how  
15 does it apply in the agreement states?

16 DR. HOWE: It depends on what the  
17 individual agreement state has done. There are some  
18 agreement states that may be implementing the new rule  
19 quicker than 2008. There may be other agreement  
20 states that won't be able to implement the new rule  
21 until 2008. So it depends on what the agreement state  
22 is doing.

23 If they have not implemented the new rule,  
24 then Subpart J still exists with that agreement state.

25 DR. NAG: So in many agreement states

1 there may have until October of 2008 or is it October  
2 of 2008 or April --

3 DR. HOWE: April

4 DR. NAG: -- of 2008?

5 DR. HOWE: April of 2008.

6 DR. ZELAC: Essentially, an individual  
7 applying for recognition in addition to a license in  
8 an agreement state has to satisfy the requirements in  
9 that agreement state. In most of the agreement  
10 states, the regulations do mirror what was in Subpart  
11 J.

12 CHAIRMAN MALMUD: Dr. Williamson.

13 DR. WILLIAMSON: Could you describe what  
14 subgroups of certified health physicists are excluded  
15 from the recognition pathway, the board recognition  
16 pathway?

17 DR. HOWE: I think it's too early to say.  
18 We're currently working with the American Board of  
19 Health Physics, for them to give us a date at which  
20 they meet the requirements in the current Part 35, and  
21 we are expecting that they may be able to do as some  
22 of the other boards have done. They may change their  
23 requirements to meet the new rule, but they may also  
24 be able to go back and look at who is certified and  
25 see that those individuals may, in fact, meet our new

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1 rule, and so --

2 DR. WILLIAMSON: What is the requirement  
3 that they don't meet, since every effort was made to  
4 craft this new regulation so that it would match, you  
5 know, the current practices of the boards?

6 This was the underlying intent. So I'm  
7 very concerned when you tell me now that there are  
8 potentially large segments of certified professionals  
9 that will be excluded from this pathway, you know.  
10 Reports have come to me from various representatives  
11 of boards and the scientific societies involved in  
12 these processes that, you know, excessively literal  
13 interpretations of the regulations, including, for  
14 example, refusing to recognize radiological sciences  
15 as being a medical physics degree and so forth.  
16 Concerns like this have been raised.

17 I just would like some assurance this is  
18 not the case.

19 DR. HOWE: I don't believe we have said  
20 radiological sciences was not a physical science. The  
21 criteria for certification under what we would call  
22 the health physics pathway because there are two  
23 different pathways for a radiation safety officer.  
24 One is the diagnostic nuclear medicine medical  
25 physicist. The other is the health physics, and that

1 is that they have a Bachelor or graduate's degree from  
2 an accredited college or university in physical  
3 science or engineering or biological science with a  
4 minimum of 20 college credits in physical science.

5 So physical science is a very general  
6 term, and we have been asked in the past to look at a  
7 list of things that you may not be able to make a  
8 determination whether it was a physical science or  
9 not, and we've got back to that particular board and  
10 said, "We can't make that determination. We're  
11 assuming that the board, when it looks at the  
12 transcripts from that group, will be able to tell  
13 whether that particular degree really is physical  
14 science." Because the title itself just does not  
15 allow us to make a broad category decision.

16 But the boards are supposed to require  
17 that they be in physical science, and if it's in a  
18 physical science no matter what its name is they  
19 should be able to recognize it.

20 MR. LEITO: So if I interpret what you're  
21 saying, that you're leaving it to the board to make  
22 that decision that it meets that requirement, and if  
23 they do and they accept the candidate, then you're  
24 deferring to the board. You're not trying to say,  
25 well, we disagree with you and we don't consider that

1 a physical science. Therefore, we don't recognize  
2 that candidate.

3 DR. HOWE: I think it's very clear that we  
4 do not consider engineering a physical science, and we  
5 do not consider biological science a physical science,  
6 and you'll see that in those areas where an  
7 engineering degree is appropriate, it says  
8 engineering. It says physical science, engineering,  
9 and then biologic with hours of physical science.

10 So that hasn't been an issue yet because  
11 those are in the radiation safety officer. They're  
12 also -- I don't know if they're in the medical physics  
13 one or not.

14 CHAIRMAN MALMUD: Mr. Leito.

15 MR. LEITO; Well, two points. One, I've  
16 got to really underscore what Jeff said, that we made  
17 every effort in crafting the words and the intent so  
18 that this would not set into a new criterion, that  
19 we'd have this transition that would be as smooth as  
20 possible and as general as possible. There was no  
21 intent that these were meant to be extremely  
22 prescriptive interpretations of the words.

23 The second point is that I'm getting real  
24 mixed signals here because what Ron had alluded to was  
25 that if a board that has existed, let's say the

1 American Board of Radiology now comes in and provides  
2 the criteria to demonstrate that, the new criteria are  
3 met; that any previous candidates that may have not  
4 been listed as authorized users were going to be --  
5 that certification would be recognized.

6 What I'm hearing from you, Dona-Beth, is  
7 that if a person was board certified, let's say by the  
8 American Board of Radiology in the year 2000, was not  
9 listed as an authorized user, now comes and applies  
10 via their board certification to be an authorized user  
11 because of the new criteria, and let's say the board's  
12 criteria are established, let's say, as of today; they  
13 aren't going to be recognized as an authorized user  
14 via the board certification, and that is really 180  
15 degrees from whatever was intended in this process.

16 So I don't know. Like I said, I'm getting  
17 mixed signals and I don't know which ones were  
18 supposed to be followed here.

19 DR. HOWE: I think Ron can answer this,  
20 but I think we're both saying the same thing.

21 DR. ZELAC: Just to answer both your  
22 concern and what was expressed by Dr. Williamson. We  
23 all know that a huge amount of effort was put in both  
24 by the Advisory Committee and the staff to craft a  
25 rule that would satisfy the need for recognition of

1 those individuals who were board certified by the  
2 existing boards, because those people who had been  
3 board certified and were users had certainly been  
4 recognized to be qualified and competent and certainly  
5 adequately prepared to do the jobs.

6 So, first of all, just to acknowledge,  
7 yes, there was a huge amount of effort and, yes, the  
8 intent was to have a regulation in place that would in  
9 many cases mirror the requirements of the existing  
10 boards. I think that's kind of a given from the past.

11 The thing that we're trying to do with the  
12 boards is to have them indicate to us when the  
13 programs, which were the ones that were in effect at  
14 the time the regulation was being established and upon  
15 which the regulation was mirrored, when those program  
16 were established. Was the program, for example, the  
17 ABHP that we reviewed and will probably -- it's an  
18 approvable status at the moment, isn't it? Yeah, it's  
19 not up as approved, but it's approvable.

20 When was that program established? Last  
21 year, five years ago, 15 years ago?

22 DR. HOWE: Two years from now.

23 DR. ZELAC: Yeah. Well, whatever it is --

24 DR. HOWE: It's a spectrum.

25 DR. ZELAC: -- that's what we're looking

1 for so that that date goes in as well as the name of  
2 the board's process, and so all of the diplomates from  
3 that date forward will be recognized as long as that's  
4 the process that the board uses.

5 It's very possible that there will be  
6 individuals -- you gave the example -- who came in  
7 under a program that didn't meet the criteria that are  
8 in effect now by that board and are not reflected in  
9 the regulations. If those people come in, they'll  
10 have to be by the alternate pathway if they're not  
11 already authorized individuals.

12 MR. LEITO: What you're saying is that  
13 you're basically disenfranchising those people that  
14 met board certification requirements at the time. So  
15 if they met the board certification requirements at  
16 the time that those rules were in effect, you're now  
17 saying, "Well, because we didn't list you on a board  
18 or on a license, you can't be listed as an authorized  
19 user." Is that correct? That's correct. Oh, boy.

20 DR. NAG: I would like to introduce a  
21 motion.

22 CHAIRMAN MALMUD: Dr. Nag.

23 DR. NAG: Yeah, I would like to introduce  
24 a motion. I am very much concerned that the expiree  
25 of Subpart J yesterday we need to avoid, and we



1 haven't solved some of the problem. In fact, nine out  
2 of the 12 boards have not internally solved. They're  
3 under review. Others are awaiting further input.

4 So I would like to make the following  
5 motion: that Subpart J, although it expired October  
6 24th, be extended by a period of either six months or  
7 one year.-- we can discuss that -- to allow the NRC  
8 officials and the boards to resolve some of the  
9 problems. Otherwise we are going to be faced with  
10 multiple problems.

11 You know, this is the motion I'd like to  
12 place on the table.

13 CHAIRMAN MALMUD: Dr. Nag has made a  
14 motion. Is there a second to his motion?

15 (No response.)

16 CHAIRMAN MALMUD: There being no second to  
17 the motion, the motion doesn't carry forward.

18 Mr. Bailey had his hand up for a while.

19 MR. BAILEY: I was disturbed by the  
20 statement that engineering was not a physical science.

21 DR. HOWE: Engineering is an applied  
22 science

23 MR. BAILEY: I would beg to differ with  
24 you, having two engineering degrees and having courses  
25 that were listed as either physics or engineering,

1 depending upon which school you were enrolled in and  
2 chemistry courses that were the same way.

3 DR. HOWE: I think you'll find that where  
4 we have a requirement for a physical science, we also  
5 add "or engineering," and so you are not  
6 disenfranchised. You are included in the particular  
7 area where those are addressed.

8 MR. BAILEY: I thought you said for RSOs,  
9 "engineering" would not count.

10 DR. HOWE: No. For an RSO it can be in  
11 physical science or engineering or biological science  
12 with 20 --

13 MR. BAILEY: Okay.

14 DR. HOWE: -- credit hours in physical  
15 science. So the engineers are included.

16 DR. WILLIAMSON: But not biologists who  
17 have engineering courses instead of physical  
18 sciences.

19 MR. BAILEY: Right.

20 DR. WILLIAMSON: Is that what's  
21 disenfranchised?

22 DR. HOWE: That's disenfranchised.

23 DR. WILLIAMSON: All right. Well, I think  
24 I do have a motion I would like to make.

25 CHAIRMAN MALMUD: Dr. Williamson.

1 DR. WILLIAMSON: I think that I would like  
2 the details of the process to be made clear on the  
3 presumption that an excessively literalist and narrow  
4 minded interpretation of the words in this rule have  
5 been made by the NRC staff, and that needlessly, you  
6 know, various segments of the certified professional  
7 population are going to be excluded from the board  
8 certification pathway.

9 So I think that you've been very  
10 circumspect, and it seems to me reluctant to give us  
11 any details of what's going on, and I'm very  
12 concerned.

13 So my motion is to the effect that, you  
14 know, I think the process you're going through needs  
15 to be reviewed by us in some more detail so that we  
16 can, you know, verify whether there really are, in  
17 fact, some substantial efficiencies and discrepancies  
18 between the board certification process and the rule  
19 or is this just sort of an artifact of excessive  
20 literalism?

21 CHAIRMAN MALMUD: Dr. Williamson, would  
22 you care to rephrase your --

23 (Laughter.)

24 CHAIRMAN MALMUD: -- motion with fewer  
25 adjectives?

1 DR. WILLIAMSON: Yes, I'll try. It's a  
2 very difficult one. The ACMUI requests that a more  
3 detailed explanation be given for each form of board  
4 certification that when deemed approvable excludes  
5 past or current diplomates of that board from the  
6 board certification pathway.

7 CHAIRMAN MALMUD: Dr. Williamson has made  
8 a motion. Is there a second to that motion?

9 MR. LEITO: I'll second.

10 CHAIRMAN MALMUD: Mr. Leito seconds the  
11 motion.

12 Is there discussion of the motion?

13 DR. VETTER: I'm not sure whether you can  
14 answer this because it depends on what the boards have  
15 told you, but if an individual was originally  
16 certified, let's say, in 1975 and the board requires  
17 recertification every six years and they have been  
18 keeping up to date on that, when was it that they were  
19 last board certified? Which date are you using? Is  
20 it the '75 date or is it a more recent one when their  
21 certification was renewed?

22 CHAIRMAN MALMUD: That's a question to NRC  
23 staff.

24 DR. ZELAC: That question has not come up.

25 DR. VETTER: Well, I would contend that

1 they have been -- you know, you had talked about  
2 dates. How far back does the process go? I would  
3 contend that it only needs to go back no more  
4 certainly than six years ago when they were renewed.  
5 So, you know, whether they were certified, it doesn't  
6 matter when they were certified in the past. It was  
7 renewed, and the last renewal date. So I don't think  
8 boards have to go back and include all of these people  
9 forever. That's why I don't think we need to worry  
10 about Subpart J. I think people who have been  
11 recertified are, in fact, qualified under the new Part  
12 35.

13 DR. ZELAC: I wouldn't necessarily  
14 disagree with you, but I'm not going to say that  
15 that's going to be the interpretation that our General  
16 Counsel has. Are you looking for any feedback at this  
17 point? I mean, we're all around the table. Are you  
18 looking for any feedback from us as to what's going on  
19 here?

20 PARTICIPANTS: Yes.

21 CHAIRMAN MALMUD: Dr. Zelac, you've hit  
22 right --

23 DR. WILLIAMSON: That's the point of my  
24 motion.

25 DR. ZELAC: Rather than too much formalism

1 here, why don't we just get into what's going on?

2 DR. WILLIAMSON: Well, please, we've been  
3 trying to step around the question and pry information  
4 from you. That's why I made the motion.

5 DR. ZELAC: The Federal Register notice  
6 for the revisions to Part 35, the training and  
7 experience, were published on March 30th in the  
8 Federal Register to be effective one month afterwards,  
9 April 29th.

10 As soon as the publication came out in the  
11 Federal Register, the procedures that would be  
12 utilized by staff in reviewing applications were sent  
13 out in written form to all of the boards. That was in  
14 Cindy's first slide on April 4th, I believe, or 9th.  
15 Very early in April letters went out to all the board  
16 with about seven pages, which had to do not only with  
17 reviews of the applications that would be put in and  
18 what should be in those applications and the format  
19 for making those applications, but also the procedures  
20 that would be followed in reviewing any changes to  
21 board procedures in the future, when a particular  
22 board might be delisted and the reasons for doing so.  
23 All of that was made available in early April.

24 Along with that was a suggestion that  
25 boards, particularly those whose programs were not at

1 that point recognized, but all of the boards that were  
2 interested in being recognized submit their  
3 applications ASAP, but 'please' by suggested August  
4 15th at the latest.

5 So that's kind of where we stood in terms  
6 of how we would do. So the procedures that would be  
7 followed are in written form. They were reviewed  
8 extensively and revised, and they're out there and  
9 they are, in fact, up on the Web site and have been  
10 since early April.

11 So what we do in terms of looking at and  
12 reviewing applications from boards is there to be  
13 seen.

14 Secondly, the applications come in. They  
15 are initially reviewed. If there are obvious  
16 deficiencies in the information, it simply doesn't  
17 address the requirements that exist in the rule. Then  
18 the board is so notified. If an application comes in  
19 and it is apparent that the board is attempting to  
20 satisfy or at least provide information relating to  
21 the requirements in the rule, but there are some  
22 questions as to when something came into play, when it  
23 was established, what it actually means, you know, the  
24 requirement for the hours or whatever, then the board  
25 is contacted for supplementary information, and then

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1 when supplied, that information is reviewed.

2 Oftentimes this back and forth between  
3 staff and the board takes place initially verbally,  
4 direct telephone conversations or via E-mails. At the  
5 point when the board is satisfied that they have  
6 sufficiently complete information to supplement their  
7 initial application, then they send it in in a formal  
8 letter to Mr. Essig. That along with the original  
9 letter or that as a substitute for the original letter  
10 serves as the basis for that board's process being  
11 recognized and that board being listed on the Web  
12 site.

13 Is there anything else? Yes.

14 CHAIRMAN MALMUD: Dr. Williamson.

15 DR. WILLIAMSON: The point of my motion is  
16 to learn more of the details of why segments of board  
17 certified or subgroups of board certified  
18 professionals are being excluded from the  
19 certification pathway.

20 DR. ZELAC: Well, that was my point  
21 initially.

22 DR. WILLIAMSON: I would like to know --

23 DR. ZELAC: They're not.

24 DR. WILLIAMSON: -- precisely which groups  
25 are being excluded in each of the categories and why.



1 In what form, what is the reason that they fail to  
2 meet the stated criteria in the rule?

3 That's what I'm asking because I'm  
4 concerned that you are dismissing and disenfranchising  
5 groups for essentially silly reasons; that, for  
6 example, I teach a transport theory course that in  
7 most institutions with a nuclear engineering program  
8 would be a nuclear engineering course. In my  
9 institution it's a physics course.

10 It is essentially hard core radiation  
11 physics at a very abstract level, and I think by  
12 anybody's estimation would be a reasonable course to  
13 bring forward for satisfying a course requirement in  
14 physical science.

15 And so if these are the reasons why, if  
16 your other reasons are like this, I'm going to be and  
17 my whole community will be very distressed that for  
18 essentially silly little reasons, you know, some harm  
19 is being done to a subgroup of professionals, and so  
20 I've heard nothing to dispel my concern.

21 DR. ZELAC: What we go on in terms of  
22 reviewing an application is what the board says. Now,  
23 if the board says that we are going to satisfy the  
24 requirements in 3050(a)(2) and they specifically  
25 outline that, yes, we are going to satisfy this, this,

1 this and the other thing, and what's up on their Web  
2 site, because most boards do have a Web site, reflects  
3 that, they're good. There's nothing more to be said.

4 We're not going to look at specific  
5 courses from particular candidate individuals. The  
6 board has made a statement that we will meet your  
7 criteria, and this is what we're telling our  
8 candidates you have to have in order for us to accept  
9 you as a candidate for recognition, and you know,  
10 that's it.

11 And if the board says that to us and the  
12 board says that to its candidates, that's it. End of  
13 story. Their program is recognized.

14 CHAIRMAN MALMUD: Dr. Nag.

15 DR. NAG: Yes, I'd probably like to ask  
16 Tom perhaps. We are discussing details of what  
17 mechanism and what are the points made by some of the  
18 boards may not have met the requirement and so on. On  
19 a broader picture what I would like to know is, is it  
20 possible to have a temporary fix until all of the  
21 approval percents have been resolved so, that the  
22 board certification pathway (being the default  
23 pathway) still continues to exist because my major  
24 concern is that expired yesterday; and yes, we will  
25 have a lot of problems still going on. But we need

1 something that is a temporary fix that will allow a  
2 board certification person to be a default pathway  
3 until the issues are resolved.

4 Can you suggest some mechanism to  
5 temporarily fix that?

6 CHAIRMAN MALMUD: Dr. Diamond.

7 DR. DIAMOND: So if I can understand you  
8 correctly, your concern is what happens if next year  
9 at this time ABR has not been approved and what  
10 happens to all of the diplomates?

11 DR. NAG: Or even tomorrow.

12 DR. DIAMOND: Okay. Let me just -- I want  
13 to make sure I understand it clearly. So let's take  
14 the example of the radiation oncology trainees who are  
15 going to be finishing up their programs in May and  
16 June of 2006. Those individuals, provided they have  
17 passed their written examinations, will sit for their  
18 oral examinations in the fall of 2006, and provided  
19 those individuals pass, at that point they will become  
20 diplomates of the American Board of Radiology.

21 Do we have any reason at this point to be  
22 concerned that the American Board of Radiology working  
23 in good faith with the staff is going to have any  
24 problems before the fall of 2006 such that the crop of  
25 ABR candidates could possibly be board certified, but

1 not become AUs?

2 I think that's the main issue that Subir  
3 and I would have on this particular issue.

4 And then to continue that, I'm not really  
5 sure what's going on with the American Society of  
6 Clinical Endocrinologists, but again, let's say they  
7 have a crop of candidates finishing their fellowships  
8 in May and June of 2006. I don't know when they take  
9 their boards, but you know, are they working with you  
10 in good faith to resolve that or are we going to have  
11 a situation where we have a whole crop of new  
12 endocrinology fellows who are not going to be  
13 authorized for their iodine uses?

14 DR. ZELAC: Let me speak to the latter  
15 portion of your question. The American Association of  
16 Clinical Endocrinologists does not at this point have  
17 a board certification program. They had inquired when  
18 they became aware of the direction that the  
19 regulations were going about the possibility of  
20 establishing such a board and asked us to provide them  
21 with information as it progressed on the process  
22 involved so that they could consider it and make a  
23 determination.

24 DR. DIAMOND: So if I understand you  
25 correctly then, the endocrinologists that use I-131

1 for uses that we discussed, they go through  
2 essentially an alternate pathway to become AUs. Is  
3 that --

4 DR. ZELAC: That's correct.

5 DR. DIAMOND: All right. So that's really  
6 a non-issue then.

7 DR. ZELAC: That's right, and that's why  
8 there isn't concern at this point that there's been no  
9 response back from them.

10 DR. DIAMOND: Because I'm a practical guy.  
11 I'm interested in practical issues. So, again,  
12 getting back to the ABR, do we have any concern that  
13 the ABR working in good faith with the staff would be  
14 in a situation whereby in the fall of 2006 they're not  
15 listed as approved and then we have a real mess on our  
16 hands regarding a whole crop of, for example,  
17 radiation oncologists that could not be authorized  
18 users.

19 DR. NAG: And we don't even have to go as  
20 forward as the fall of 2006. What about the problem  
21 of someone who became board certified as of this year,  
22 2005, has not applied, and is now applying, subs like  
23 they have now expired, and we really have --

24 DR. DIAMOND: But, again, they became  
25 diplomates if they passed their oral examinations. A

1 few months ago they would have become diplomates of  
2 the ABR prior to the expiration of Subpart J.

3 I guess the only issue is, and I remember  
4 it, if some condition in the oral examination has to  
5 retake it, that would be a problem.

6 DR. NAG: Right. There are people who,  
7 you know, may be taking a repeat exam later this year.  
8 So, I mean, I think we do need a temporary fix right  
9 now until all of the board certification problems have  
10 been resolved, and need a temporary fix today

11 CHAIRMAN MALMUD: Mr. Bailey.

12 MR. BAILEY: Yeah. What I wanted to do  
13 was emphasize that if I had decided to quit working  
14 for California and go be a hospital RSO, yesterday I  
15 would have been acceptable under Subpart J. Today I'm  
16 not acceptable; is that right, as a CHP?

17 DR. ZELAC: If you were going to assume  
18 your responsibilities in an agreement state --

19 MR. BAILEY: No, I'm not. I'm coming to  
20 work right here in D.C.

21 (Laughter.)

22 MR. BAILEY: So there's no question. At  
23 a VA hospital.

24 DR. ZELAC: The answer to your question is  
25 if you had on October 23rd put in an application and

1 you were using as the basis for your recognition your  
2 CHP, it would have been acceptable.

3 MR. BAILEY: Right.

4 DR. ZELAC: If you put it in today, it  
5 will not be. You'd have to come in through the  
6 alternate pathway.

7 CHAIRMAN MALMUD: We have a representative  
8 here from the AAPM who would like to make a comment.

9 MS. FAIROBENT: Yes, Lynne Fairobent with  
10 AAPM.

11 Dr. Vetter, I just wanted to follow up on  
12 something you brought up a few discussion pieces ago,  
13 which was on certification and renewal. Remember  
14 there are quite a few people that have lifetime  
15 certificates and don't recertify. That's true for  
16 medical physics. That's true for physician authorized  
17 users.

18 And the other comment that I did want to  
19 make goes back to the four states that do require  
20 licensure for a medical physicist because those four  
21 states, we have been working with them, and there is  
22 a disconnect between the state licensure laws and  
23 NRC's regs.

24 So, in fact, you could be licensed in the  
25 State of Florida to be a medical physicist practicing

1 in therapy and not be able to qualify at the moment or  
2 once Florida should adopt these regulations, and not  
3 qualify as a therapy physicist without them coming to  
4 some agreement between the materials program in  
5 Florida and the board's state licensure folks.

6 So there is a potential problem there, and  
7 in order to be licensed in one of these four states  
8 you do have to have board certification first.

9 CHAIRMAN MALMUD: Thank you.

10 So it appears that we have some current  
11 problems.

12 Dr. Miller?

13 DR. MILLER: Yes, I'd like to bring up an  
14 issue that Donna-Beth brought to my attention as a  
15 matter of protocol. Specifically with the ABR, right,  
16 Donna-Beth?

17 You know, we've recently received their  
18 response. We've reviewed it, but there are some  
19 things that we still need to discuss with them. We  
20 haven't had a chance to discuss it with them, and the  
21 question that she was raising is if we discussed it in  
22 this form, we're discussing some specifics that yet  
23 the board hasn't received from us with regard to, you  
24 know, deficiencies yet in the application.

25 And I guess the question from the



1 committee is: do you want to get into those kinds of  
2 things, recognizing that the board yet hasn't heard it  
3 from us?

4 CHAIRMAN MALMUD: Dr. Diamond.

5 DR. DIAMOND: Sure. Again, I just want to  
6 respond to that for a pragmatic fashion. What we're  
7 trying -- what I'm trying to do at least is I'm  
8 trying to think through all the different  
9 permutations that are going to be transpiring and  
10 prevent preventable problem if we can.

11 I have every reason to believe that the  
12 ABR is going to be working in good faith with the  
13 staff and that these issues will be worked out in the  
14 near future and that will be the end of that  
15 particular issue.

16 Again, I am a little concerned that there  
17 is a potential for some delay transpiring, and that we  
18 could potentially have a situation of candidates,  
19 let's say, who took, let's say, the October 2005 oral  
20 examination, radiation oncology. There's a built in  
21 fail and condition rate around what, 25, 30 percent,  
22 Subir?

23 DR. NAG: Yeah.

24 DR. DIAMOND: That means you have a lot of  
25 good people that fail. That's just what they do, I

1 guess, and they retake it in six months, I believe.

2 I just want to do everything that we can  
3 to make sure that we can work out these detail issues  
4 so that there's not a whole crop of individuals that  
5 have now become board certified, but because of the  
6 timing of their certification, are in sort of a limbo.

7 That's my specific issue on that.

8 CHAIRMAN MALMUD: Dr. Zelac.

9 DR. ZELAC: I don't know that there would  
10 be an issue even if these individuals were not able to  
11 get authorized under the board certification pathway.  
12 The requirements under the alternate pathway are no  
13 more -- well, in one respect they are, but I don't  
14 think -- sorry.

15 In one respect they are, but I don't think  
16 that individuals would have a problem, and it all  
17 really relates to the training that they've had and  
18 the preceptor statement that is supplied. A huge  
19 amount of importance is placed on the preceptor  
20 statement, and recall that by the change in the  
21 regulation, the preceptor does not have to be the  
22 individual who provided the training and experience,  
23 but simply can be an individual who verifies that all  
24 of it was provided.

25 CHAIRMAN MALMUD: Okay. Thank you.

1           Is there a motion on the table now? It  
2 has been a while since we had discussion on that.

3           DR. WILLIAMSON: Yes, I was going to  
4 remind the group that I had made a motion that  
5 basically asked the responsible staff to provide the  
6 details in any case where a board certified  
7 professional was omitted or left out from the board  
8 certification pathway and that, you know, the detailed  
9 issues, in fact, could be examined at least at some  
10 point.

11           DR. NAG: And I would like to remind that  
12 I had made the request is there any way to have a  
13 temporary fix until these result? Is there any simple  
14 solution from an administrative way to say, well,  
15 we'll continue this until these are fixed?

16           Something that you can do administratively  
17 so that we don't end up in this limbo thing.

18           CHAIRMAN MALMUD: These are two separate  
19 issues, if I may. There's Dr. Williamson's motion,  
20 and can we once again have you express it concisely  
21 without excessive adjectives and adverbs?

22           DR. WILLIAMSON: Yes. What do you call  
23 your group, the certification review group?

24           DR. HOWE: Actually it's the entire  
25 medical radiation safety team.

1 DR. WILLIAMSON: Okay. That the MRC staff  
2 reviewing applications for recognition of board  
3 certification by the U.S. NRC provide detailed  
4 explanation in any case where a board certified  
5 individual fails to be included in the certification  
6 pathway because of a change or discrepancy in  
7 requirements.

8 CHAIRMAN MALMUD: All right. Was that  
9 motion seconded?

10 MR. LEITO: Yes, I seconded it.

11 CHAIRMAN MALMUD: Your second stands?

12 MR. LEITO: Yes, it still stands.

13 CHAIRMAN MALMUD: Any further discussion  
14 on Dr. Williamson's motion? Dr. Vetter.

15 DR. VETTER: Correct me if I'm wrong, NRC  
16 staff, but I don't think they're reviewing the  
17 qualifications of individuals

18 DR. WILLIAMSON: No, they're reviewing the  
19 qualifications of the boards as a function of time,  
20 and I understand what they are doing is because of  
21 possible semantic issues, they're getting the board to  
22 prospectively change and refine their requirements  
23 which creates the potential that past diplomates of a  
24 certification process will not be recognized with the  
25 future diplomates; that, in short, they're placing

1 cutoff dates and dividing the certified population  
2 into two parts, one part that will be recognized and  
3 one part that will not.

4 And so I'm asking that whenever the second  
5 part is non-zero, that a detailed explanation be  
6 given.

7 CHAIRMAN MALMUD: that is the motion  
8 before this committee. Any further discussion of that  
9 motion?

10 (No response.)

11 CHAIRMAN MALMUD: All in favor of Dr.  
12 Williamson's motion?

13 DR. SCHWARZ: I do have one question. How  
14 would you suggest that this information is provided?

15 MR. LEITO: Do you want it to come back to  
16 us?

17 DR. WILLIAMSON: Yes, to be provided to  
18 the ACMUI for discussion.

19 CHAIRMAN MALMUD: Dr. Williamson's motion  
20 requests that the information be provided to the  
21 ACMUI.

22 Shall we call it? All in favor --

23 DR. SULEIMAN: I have another question.

24 CHAIRMAN MALMUD: Oh, excuse me, Dr.  
25 Suleiman.

1 DR. SULEIMAN: The intent of this is to  
2 identify people that are going to be disenfranchised,  
3 right?

4 DR. WILLIAMSON: I think the intent is to  
5 determine whether, you know, the reason for excluding  
6 not individuals, but groups, of individuals, is  
7 warranted or not or whether it, in fact, maybe is an  
8 overzealous or over literal interpretation of the  
9 language in the room.

10 CHAIRMAN MALMUD: Does that answer your  
11 question, Dr. Suleiman?

12 DR. SULEIMAN: Sufficiently.

13 CHAIRMAN MALMUD: All in favor of Dr.  
14 Williamson's motion?

15 (Show of hands.)

16 CHAIRMAN MALMUD: All opposed to Dr.  
17 Williamson's motion?

18 (No response.)

19 CHAIRMAN MALMUD: Any abstentions?

20 (Show of hands.)

21 CHAIRMAN MALMUD: All in favor and one  
22 abstention.

23 Now, may I ask a question as a member of  
24 the committee? Why would anyone's prior certification  
25 be removed without cause, simply for the change of a

1 regulation?

2 DR. ZELAC: It wouldn't be -- as an  
3 example, if the board simply went out of business,  
4 stopped certifying, then it's only those individuals  
5 recognized up to the date that the board disappears,  
6 or if the board decides they want to go in a different  
7 direction in terms of what they require of their  
8 candidates for whatever their reasons are and they  
9 make a change in their certification requirements for  
10 candidates and now what they require of a candidate  
11 does not satisfy what exists in the rule as a  
12 requirement, then from that point on that board's  
13 certification process will be producing diplomates  
14 whose certifications cannot be recognized as being  
15 adequate for following the certification pathway to  
16 their own individual recognition.

17 CHAIRMAN MALMUD: So may I ask why  
18 couldn't that simply be stated, that if the board  
19 changes its regulations and no longer conforms to the  
20 new standards, that that board's future individuals  
21 who are certified would not be recognized?

22 DR. ZELAC: That is there. It's not part  
23 of the regulation, but it certainly is in the  
24 procedures that we have placed on the Web as being  
25 available. So any of the boards that want to be

1 taking various actions or not have that to review as  
2 a consideration of potential consequences of the  
3 actions they are considering.

4 CHAIRMAN MALMUD: Wouldn't that statement  
5 though achieve the same goal without raising the  
6 anxiety among all certified practitioners that their  
7 current certification may become insufficient to allow  
8 them to practice?

9 DR. ZELAC: This has nothing to do with  
10 current recognized individuals. If they were  
11 recognized under a process that met the requirements  
12 of the NRC's regulations, they're good. As long as  
13 those regulations are not changed, they're good.

14 If the board changes its process, then  
15 future diplomates of the board may not be.

16 DR. HOWE: The only issue here are those  
17 individuals that are not recognized on a license or  
18 broad scope permit or a master materials license  
19 permit as authorized users, as medical physicists, as  
20 pharmacists, as RSOs. It's those certification folks  
21 that have not gotten into that stream that are the  
22 ones that come into question.

23 CHAIRMAN MALMUD: Is it the individuals  
24 who are currently not recognized as authorized users  
25 or who have never been recognized as authorized users?



1 DR. HOWE: The regulations read that they  
2 are listed on a license. So there is an "is" which is  
3 kind of a present tense. So if you're one of these  
4 individuals and you're on a current license, the  
5 concept is that you met the requirements for when you  
6 were put on the license and you're still practicing  
7 and, therefore, you're current and that is easy to  
8 transfer to the next liense.

9 CHAIRMAN MALMUD: But if you quit a week  
10 ago and you're no longer on that license, you're not  
11 on the license.

12 DR. WILLIAMSON: A good example might be  
13 someone, for example, a medical physicist who became  
14 certified, say, in the year 2000, has worked in an  
15 institution for four or five years without HDR  
16 brachytherapy, moves to an institution where there is  
17 HDR brachytherapy and seeks now to become an  
18 authorized medical physicist for that modality, but  
19 maybe because of some SNAFU over wording, the board,  
20 the ABR or ABMP has had to change its language  
21 effective 2005 to meet the NRC regulations.

22 This notch group of physicists that  
23 weren't authorized medical physicists may be  
24 disenfranchised from the process and will have to go  
25 through the alternate pathway route.

1                   CHAIRMAN MALMUD: I think what -- I'll  
2 recognize you in a second, Dr. Nag -- I think what  
3 you're hearing is the bases for the anxiety among  
4 current users and potentially new users for  
5 interpretations of the new regulations, which are  
6 highly legalistic and, therefore, perhaps precise, but  
7 which in the process will exclude current  
8 practitioners from the privileges which they currently  
9 enjoy or would otherwise enjoy, and this has had  
10 reverberations throughout the country for which  
11 reasons we are receiving phone calls from currently  
12 certified authorized users.

13                   Dr. Nag.

14                   DR. NAG: Yes. I think in addition to my  
15 previous request for a temporary fix that would allow  
16 board certification by the way in the default pathway,  
17 I would like to add to that a grandfathering clause  
18 that people who were already existing users, even  
19 though there may be tenure in their new board  
20 requirement, they would still continue to be  
21 authorized users or authorized medical physicists, et  
22 cetera.

23                   So, again, I would like to request for  
24 some type of temporary fix to allow the board  
25 certification pathway and to be a grandfathering

1 clause.

2 CHAIRMAN MALMUD: Mr. Bailey.

3 MR. BAILEY: I'm a little concerned  
4 because I got to thinking about it, and I know several  
5 institutions that have more than one certified health  
6 physicist on it, but they only have one RSO, but  
7 they've been working as an RSO, but they are not  
8 listed on the license, although they're certified.

9 So how are -- I mean, that's one example.  
10 I think you will also have with medical physicists who  
11 are not necessarily --

12 MR. LEITO: I would just as a corollary to  
13 Edgar, you only allow one RSO to be listed on the  
14 license. So even if you had three or four individuals  
15 of equal capabilities to function independently,  
16 they're only allowed to have one on the license.

17 CHAIRMAN MALMUD: In a department with  
18 multiple physicists or multiple radiation oncologists  
19 or nuclear physicians or radiologists, there's one  
20 authorized license?

21 DR. ZELAC: No, no. It only applies to  
22 radiation safety officers listed on the license. An  
23 individual license can have as many authorized users  
24 as they wish or as many authorized medical physicists  
25 or authorized nuclear pharmacists as they wish, all

1 listed on the license.

2 CHAIRMAN MALMUD: So the situation you  
3 describe applies only to the physicist.

4 PARTICIPANTS: The RSOs.

5 CHAIRMAN MALMUD: The RSOs. Excuse me.

6 MR. BAILEY: I think it can also apply to  
7 a physicist who is in training.

8 DR. WILLIAMSON: I think it can apply to  
9 a physicist who is not in training, who happens to be,  
10 you know, temporarily engaged in employment that  
11 doesn't involve use of the particular byproduct  
12 materials over which NRC has jurisdiction.

13 So I'd say there's a lot. Take myself,  
14 for example. I function for the last three years  
15 largely as an administrator and researcher. So if I  
16 chose to go back to clinical practice, maybe my board  
17 certification would not be recognized, and that would  
18 be, you know, considerable hassle and expense for me,  
19 even though I've had many years of experience doing  
20 this and have written textbooks and hundreds of  
21 articles on the subject, that I would not be able to  
22 be recognized as an authorized medical physicist for  
23 HDR.

24 So I have concerns. I only want to make  
25 sure that if a segment of the certified population is

1 being excluded from this pathway, there are very good  
2 reasons for it, and you know, not a debatable semantic  
3 issue.

4 CHAIRMAN MALMUD: So in summary, it sounds  
5 as if the current regulations as being reformatted  
6 have the unintended consequence of at least  
7 potentially, if not actually, disenfranchising some  
8 current authorized users.

9 DR. WILLIAMSON: Disenfranchising some  
10 individuals who previously would have been eligible to  
11 be authorized users or physicists or pharmacists, but  
12 who now, due to various time blocks of certificate not  
13 being recognized can no longer be so recognized.

14 DR. HOWE: I think you can exclude the  
15 pharmacists because they're recognized back to '96,  
16 and I think they have a seven-year cycle.

17 CHAIRMAN MALMUD: So we need to craft some  
18 language to make certain that we don't create an  
19 unintended consequence which will have an impact on  
20 the community which serves patients.

21 DR. ZELAC: Excuse me. Can I interrupt at  
22 this point?

23 CHAIRMAN MALMUD: Dr. Zelac.

24 DR. ZELAC: I think it's important to  
25 recognize that we look at what's submitted from a

1 particular board. We try to get from that board  
2 sufficient information to be able to approve the  
3 program that they discuss as far back as it existed,  
4 but it's really the board that needs to supply the  
5 information

6 As Dr. Howe mentioned earlier, in some  
7 cases the practice of a board doesn't necessarily  
8 agree totally with the information that it had  
9 available to their candidates or on the Web site or  
10 whatever else, but if the program itself, the process  
11 has not changed, it will go back in terms of the  
12 approval to when that particular program was  
13 established in principle, not specifically a word-by-  
14 word definition of the program.

15 So it relies very much on the board and  
16 what it says in response to the call for information.

17 CHAIRMAN MALMUD: I think we recognize  
18 that this is not a problem which is solely the  
19 responsibility of the NRC. However, the outcome may  
20 be one which will limit the marketplace and,  
21 therefore, patient care by virtue of disenfranchising  
22 some people who could have or currently are providing  
23 service.

24 DR. ZELAC: Let me just remind everyone of  
25 what Mr. Bailey said earlier on and it's correct, that

1 80 percent of the licensees are in agreement states.  
2 They have three years from April to come into  
3 conformity. So first of all, we're talking about the  
4 20 percent.

5 Secondly, any individual who wants to  
6 achieve authorized status can certainly submit their  
7 credentials and those credentials will be considered  
8 and, if necessary, an exception or an exemption from  
9 the current requirements can be granted if it's  
10 appropriate to do so based on the circumstances of  
11 what they intend to be doing, what their background  
12 is, and their credentialing.

13 So it's not as if there's a wall over  
14 which there are no possibilities for penetration or  
15 for jumping over.

16 CHAIRMAN MALMUD: Does Dr. Zelac's last  
17 assurance satisfy your concerns, Dr. Williamson and  
18 Mr. Leito?

19 MR. LEITO: Well, if you're in an  
20 agreement state, sure, but I'm not in an agreement  
21 state. So the answer is no.

22 DR. WILLIAMSON: Nor am I.

23 MR. LEITO: I have a question as a follow-  
24 up to what Ron had just talked about. These boards  
25 that are either under review or are awaiting further

1 input. Are there issues where the board is saying,  
2 "Well, we've got to change this in our certification  
3 process to meet your requirements for new diplomates.  
4 Are there any like that or are they all saying, well,  
5 the back-and-forth between NRC and these boards, that  
6 we're trying to make this sort of retroactive to our  
7 certification dates when we were first established?

8 DR. ZELAC: I think probably the answer to  
9 the question ought to be provided by each of us  
10 because we've been -- although every application is  
11 reviewed by us as a group, there is a principal person  
12 in the group that really is fostering and working it  
13 through.

14 To those that I have been reviewing or are  
15 involved with, I have not seen anything that has to be  
16 changed now which would make all previous diplomates  
17 of the boards ineligible for recognition under the  
18 certification pathway.

19 MR. LEITO: Is that true across all of the  
20 ones that you guys have reviewed? I'm raising this  
21 question to everybody that's up there because my  
22 concern gets back to the very issue that Jeff has  
23 brought up in that if there are boards that are  
24 changing their certification criteria to make NRC  
25 happy for future, I'm wondering if they are aware of



1 what they're doing to their past diplomates.

2 MR. SABA: Yeah, the American Board of  
3 Health Physics, they have to change. They have to  
4 exclude some degree things, like mathematics, from  
5 their original requirements in order to comply with  
6 the new requirements in order to comply with the new  
7 requirements.

8 CHAIRMAN MALMUD: There is a  
9 representative here from the American Board of Health  
10 Physics who would like to speak. May we?

11 MS. ST. GERMAIN: I'm sure they would  
12 appreciate that, but on the American Board of Medical  
13 Physics.

14 CHAIRMAN MALMUD: American Board of  
15 Medical Physic.

16 MS. ST. GERMAIN: Although I do have both  
17 certifications, but I'd like to say a few words.

18 First of all, with regard to the number of  
19 boards that were solicited, the Canadian College of  
20 Medical Physics is not listed, and that is certainly  
21 a board that has been approved in the past by various  
22 state agencies and a board whose diplomates function  
23 in some of our border states to the north on both  
24 sides of that border.

25 So I would suggest that perhaps they might

1 be solicited for their input on this as well, and if  
2 it doesn't happen here, will from AAPM since the many  
3 Canadians belong to the American Association of  
4 Physicists and Medicine, taking it as the North  
5 American Association. We will make sure that they are  
6 aware of this.

7 With regard to the American Board of  
8 Medical Physics, Dr. Howe and I have been having an  
9 interesting discussion both on the telephone and by E-  
10 mail and there are certain criteria which we are  
11 deciding whether or not we're going to change, and  
12 they have to do with the acceptability in our case of  
13 certain graduate degrees and also the amount of years  
14 of experience that can be substituted for graduate  
15 degrees and an understanding of what the CAMPEP  
16 certification process is.

17 Now, the problem will be that if we change  
18 our requirements going forward, what happens to the  
19 people who met those requirements previously under the  
20 old rules and are those people who are currently  
21 certified going to be accepted going forward once we  
22 change the rules, and I think that's one of the  
23 reasons that we're still awaiting further input on  
24 that.

25 And so to answer your question which was

1 raised previously, if we change our rules, are the  
2 people who were certified under the old premise going  
3 to be allowed to be recognized or is there going to be  
4 a date, meaning people certified after this date when  
5 our rules change or our criteria change, if they do,  
6 accepted whereas people who are certified previously  
7 were not accepted.

8 And I think that's one of the questions  
9 that Dr. Williams and others were referring to, and I  
10 think it's something that we are wrestling with right  
11 now.

12 DR. HOWE: Could you identify yourself,  
13 please?

14 MS. ST. GERMAIN: I'm Jean St. Germain.  
15 I am representing the American Board of Medical  
16 Physics. Sorry.

17 MR. BAILEY: Both Dr. Vetter and I, and  
18 maybe some others, have been on the American Board of  
19 Health Physics, and I remember when we changed the  
20 mathematics degree to require I think it was 20 hours  
21 of physical science if you had -- or engineering or  
22 whatever -- if you had a degree in mathematics.

23 My concern though goes back to the days  
24 when you did not have to have any degree at all to get  
25 certified, and that's going to be a very difficult

1 cutoff point, I think.

2 And I know we did discuss concerns about  
3 whether or not our exam itself covered all of the  
4 aspects that the NRC was looking for in a hospital  
5 RSO, and I don't know if they've changed those or if  
6 you have changed.

7 CHAIRMAN MALMUD: Dr. Nag.

8 DR. NAG: I have a question for Ron.

9 Is it possible -- and it's similar to what  
10 I had asked before -- is it possible for the NRC to  
11 continue under the Subpart J until some of these  
12 issues have been resolved? Is there any objection to  
13 that? I mean that will at least solve the problem  
14 temporarily until we have solved these.

15 This is becoming a relatively big issue  
16 that we haven't solved, and you know, you're having a  
17 big problem.

18 CHAIRMAN MALMUD: Dr. Miller.

19 DR. MILLER: Okay. I'll speak for the NRC  
20 on this one.

21 You asked if it's possible. Of course it  
22 would be possible. The issue here that we're  
23 debating, there's a number of things I wanted to bring  
24 into it.

25 One, to continue under Subpart J would

1 require an act of the Commission. We had to go to the  
2 Commission last year to get approval to extend Subpart  
3 J for one year. The rationale for extending Subpart  
4 J for one year was to allow the T&E rule to get in  
5 place and to allow the board sufficient time to submit  
6 applications.

7 The question to my staff: did any of the  
8 boards come back and say they didn't have sufficient  
9 time to submit an application?

10 DR. HOWE: I didn't have in.

11 PARTICIPANT: Nor did I.

12 DR. MILLER: Okay. So from our  
13 perspective, I don't want to find ourselves -- as the  
14 regulator, I don't want to find ourselves here at the  
15 same time next year in the same situation. I don't  
16 think any of us want to find that. From my  
17 perspective, I want to do everything that we can to  
18 get the boards in good standing as soon as we can so  
19 that they become, you know, recertified.

20 That said, we want to make sure that the  
21 boards have met the current requirements in what  
22 they're doing, and a lot of the anxiety here is  
23 centered on people who are currently board certified  
24 who may get disenfranchised as a result of the  
25 promulgation of the new regulations. And I think

1 that's the issue that we have to work ourselves  
2 through.

3 To be quite honest with you, Dr. Nag, if  
4 we were to go up and seek extension to Subpart J, that  
5 would require the staff to craft a paper to do so. It  
6 would have to come up for Commission approval. That  
7 might take a number of months before that happens, and  
8 my question becomes if they took that long -- and  
9 simply because how fast the process can work if it  
10 took that long -- you know, I want to make sure we  
11 continue to plow forward full steam in trying to get  
12 these boards in good standing.

13 DR. NAG: Right, but the other question  
14 was: is there any other way of doing a temporary fix?  
15 I mean, is there any way of saying we will -- I mean,  
16 I don't know the hierarchy and, you know, your  
17 administrative methods. Are there any administrative  
18 methods to delay this for a few months?

19 DR. MILLER: Obviously it has been  
20 discussed. The one way is you can always go the  
21 alternate pathway. I know that that's problematic.  
22 I know that that's burdensome, but that is an  
23 alternate way.

24 CHAIRMAN MALMUD: Dr. Holahan.

25 DR. HOLAHAN: Yes, we're talking about a

1 short time span. So we want to get the boards  
2 approved quickly, and as Dr. Miller and Dr. Zelac  
3 said, we can always go the alternative pathway, and  
4 I'd like to know, you know. I think we're looking at  
5 a few applications being done. We're talking about  
6 disenfranchised, but as Dr. Howe said, if they're  
7 currently listed on the license, they're still going  
8 to be listed on the license, and it's only those few  
9 that may not be listed on a license at the moment and  
10 in this time frame they can come in under the  
11 alternative pathway, and basically we made the rules  
12 that the board certification pathway mimics the  
13 alternative pathway.

14 So I'm asking the ACMUI: how big a  
15 problem is it in this time frame?

16 DR. WILLIAMSON: As I recall, we made the  
17 alternative pathway rather more rigorous and detailed  
18 and prescriptive than the board certification pathway  
19 so that it's, indeed, quite possible that it would be  
20 a significant hardship for those who were board  
21 certified once we're AU or AMP eligible, but no longer  
22 are.

23 CHAIRMAN MALMUD: Dr. Suleiman.

24 DR. SULEIMAN: First off, I think I want  
25 to clarify. The regulation went into effect

1 yesterday, today? So it -- right, right. So it's  
2 done. So obviously thank you for the clarification,  
3 but there's been a whole long process here.

4 The other thing is I'm wondering. There's  
5 clearly a lot of anxiety, but what's the real  
6 magnitude of the problem? So, again, I would like to  
7 see the boards collect real cases of people being  
8 disenfranchised, and if, in fact, there's an epidemic,  
9 I would expect the NRC either through internal policy,  
10 discretionary enforcement or a whole multitude of  
11 things, and you've got 80 percent of the country  
12 already under. So they've got a three-year grace  
13 period in effect.

14 So what are the actual numbers of the  
15 remaining 20 percent? I want to see the numbers  
16 instead of continuing to debate the anxiety, and  
17 probably some people are going to be, but you've got  
18 alternative pathways, exemptions. There are other  
19 ways to address that. Let's see the facts before and  
20 I think give the NRC the opportunity to respond, you  
21 know, from a policy point of view.

22 CHAIRMAN MALMUD: Dr. Suleiman, I would  
23 first state that to the best of my knowledge thus far  
24 there are zero, and from the concerns that have been  
25 expressed to me via telephone, I have responded that



1 there are zero. That doesn't seem to allay the  
2 anxiety, but your statement about let's see what comes  
3 out of this is certainly a valid one to consider.

4 Dr. Williamson.

5 DR. WILLIAMSON: Yes. I think that the  
6 motion that I made, which was accepted, that the  
7 staff, in fact, carry through with this and provide,  
8 you know, a detailed report will give us the basis for  
9 determining the magnitude of the problem, and so I  
10 agree with you that I think at this point there seems  
11 to be little that can be resolved in this forum until  
12 that information is available.

13 DR. SULEIMAN: I have a question. How is  
14 the staff going to determine that? Wouldn't it be the  
15 boards that would collect? I mean who's going to  
16 enforce?

17 Are you going out right now? How is --

18 DR. WILLIAMSON: Hold on. Let me try to  
19 explain. What they will do if they follow the motion,  
20 is they will tell us exactly what the cutoffs are in  
21 terms of time periods or durations, epochs during  
22 which various board certifications are recognized for  
23 what. We will also be given the rationale and a  
24 reason for epochs that were excluded

25 We can then go to the boards and we can

1 find out, I think, how many diplomates are in those  
2 different categories and begin to address the  
3 magnitude of the problem.

4 But first we have to understand, you know,  
5 the conditions under which the various boards are  
6 accepted and the rationales for excluding certain time  
7 periods. Then we can go and find out how many  
8 individuals are affected by this and in what way.

9 CHAIRMAN MALMUD: Dr. Williamson, do you  
10 mean how many individuals are potentially affected by  
11 it?

12 DR. WILLIAMSON: Potentially affected.  
13 That's correct. Thank you for the correction.

14 CHAIRMAN MALMUD: Is that an achievable  
15 administrative task? I ask this of the NRC staff.

16 MR. ESSIG: Yes.

17 CHAIRMAN MALMUD: Mr. Essig indicates the  
18 answer is yes.

19 CHAIRMAN MALMUD: Dr. Schwarz.

20 DR. SCHWARZ: I just would like to ask a  
21 question in terms of the boards that are currently  
22 being reviewed or are awaiting input. In your  
23 estimate, how much longer will it take in terms of  
24 being able to have this information finalized from the  
25 boards?

1 I mean, do you think months or another  
2 year?

3 DR. HOWE: I don't think we can tell you  
4 an estimate of how long it will take, but I think if  
5 you look and see who came in and who's approved now,  
6 you'll see that we've gone from August to October and  
7 we've approved three boards, and we've done -- some of  
8 those boards have been fairly simple with maybe one or  
9 two interactions. Others have been more complex with  
10 a lot of interactions.

11 But we're working as quickly as we can,  
12 and we're working as closely as we can with the boards  
13 to resolve the issues. So I think that is kind of a  
14 reasonable expectation for things that have come in  
15 recently.

16 We're going to be working as closely as we  
17 can, and we're going to be working as quickly as we  
18 can with the boards.

19 CHAIRMAN MALMUD: Thank you, Dr. Howe.

20 And with that, may we recognize that it is  
21 now 12:35, and we do have a lunch hour which has been  
22 delayed a bit? So may we resume instead of at 1:15 at  
23 1:30? Does that give everyone enough time?

24 It's less than a lunch hour, but it's  
25 still time for lunch.

1 (Whereupon, at 12:39 p.m., the meeting was  
2 recessed for lunch, to reconvene at 1:34 p.m., the  
3 same day.)

4 CHAIRMAN MALMUD: We are a few minutes  
5 behind right now and we hope to catch up if there are  
6 subjects of less controversy to be covered.

7 It now being one-thirty, the next item on  
8 the agenda for this open session is a presentation by  
9 Dr. Eggli, which will be regarding the unauthorized  
10 injections of radiopharmaceuticals.

11 Dr. Eggli will present a case history of  
12 unauthorized self-injections of radiopharmaceutical by  
13 a nuclear medicine technologist for the purpose of  
14 acquiring unauthorized imaging studies on themselves.

15 Dr. Eggli?

16 DR. EGGLI: Thank you, Dr. Malmud.

17 I am here today representing the  
18 Pennsylvania State University. The Milton S. Hershey  
19 Medical Center to present a case history of an  
20 unauthorized diagnostic pharmaceutical administration.

21 In April of 2004, a staff nuclear medicine  
22 technologist at the Milton S. Hershey Medical Center  
23 asked a student technologist both to perform an  
24 unauthorized injection of radiopharmaceutical, which  
25 was Technetium-99m HMPAO. And subsequently to perform

1 a brain tomograph imaging study on herself.

2 Initially when the student technologist  
3 expressed concern, the staff tech said don't worry  
4 about it. If anything happens, I'll take the heat for  
5 this.

6 Several weeks earlier, that staff  
7 technologist had approached me and relayed a medical  
8 history that she thought justified brain imaging. At  
9 that time, after discussion, we determined that brain  
10 imaging was not justified in that we could not approve  
11 it.

12 And she was specifically warned that if  
13 she chose to do it on her own, that it would be a  
14 violation of NRC regulation. And that there would be  
15 disciplinary consequences as a result of that  
16 administration.

17 At that point, I thought the incident was  
18 probably over. However, it wasn't. And the  
19 technologist had a student inject her and the scan was  
20 performed. The self-injection was discovered when the  
21 student began to worry about having done the injection  
22 and reported it to our chief technologist.

23 The staff technologist was within minutes  
24 suspended by me after consultation with hospital  
25 administration and our radiation safety officer. That

1 suspension was confirmed in writing by the RSO and  
2 subsequently made permanent by the Radiation Safety  
3 Committee within 24 hours of the incident.

4 The incident then was self-reported by  
5 Penn State Hershey Medical Center to the NRC. And in  
6 May of 2004, Region I initiated an investigation.

7 An internal investigation was also  
8 performed and the results of the investigation that  
9 I'm going to share with you represent both the results  
10 of the internal investigation at Penn State Hershey  
11 Medical Center and the investigation performed in  
12 Region I.

13 In our internal investigation, the  
14 technologist never expressed any remorse for her  
15 action. In fact, when she came to me to speak about  
16 it at the time of the incident, she promised that if  
17 I went ahead and reported it, that she would take me  
18 down with her and as many other people as she could.

19 In defense of her action, however, to the  
20 NRC she alleged that unauthorized self-administration  
21 of diagnostic radiopharmaceuticals was common practice  
22 at the Hershey Medical Center. To our knowledge, she  
23 never addressed the specific prior warning against the  
24 planned self-administration.

25 Based on that, the NRC launched a somewhat

1 more than a year long investigation at Penn State  
2 Hershey Medical Center. Most of the incidents were  
3 discovered to be -- that she reported were discovered  
4 to be legitimate medical uses for people who had  
5 medical indications and physician requests for their  
6 studies.

7 One incident was so old that it couldn't  
8 be tracked down. And two incidents, however, looked  
9 like they may have been unauthorized self-  
10 administrations of radiopharmaceuticals, one in 2001  
11 and one in '97.

12 There are timeline issues with the event  
13 in '97 and ultimately Hershey Medical Center agreed  
14 that it may have occurred. In 2002, the incident  
15 involved a technologist who actually had a physician's  
16 order for a test but didn't go through the process of  
17 getting the approval of the authorized user before  
18 injection.

19 So he essentially had a physician's request in hand  
20 and self-injected the radiopharmaceutical.

21 The 2002 and the 1997 events were not  
22 detected by the administration of the Division of  
23 Nuclear Medicine or the Health Physics Department at  
24 the Milton S. Hershey Medical Center. And they were  
25 not detected until they were discovered as part of the

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1 NRC's investigation of the incident which we did  
2 discover and report.

3 If we look at the question of unauthorized  
4 injections, I don't know what the incidence of  
5 unauthorized injections is but in discussion with  
6 Region I staff, their feeling was that this was not an  
7 isolated occurrence. Only those incidents which are  
8 detected by the licensee actually end up being  
9 reported. And neither Penn State nor multiple regular  
10 NRC inspections after 1997 before 2004 had detected  
11 the two incidents that were detected on the Office of  
12 Investigation activity.

13 And as it turns out, it is actually easy  
14 for a technologist to make this sort of incident  
15 invisible. The two prior incidents at Hershey again  
16 would not have been detected if the incident that we  
17 did detect and report had not occurred.

18 Sort of as a bottom line, you don't know  
19 what you don't know.

20 The dilemma here is for the technologist  
21 -- nuclear medicine procedures are considered low risk  
22 even by NRC. Nuclear medicine diagnostic procedures  
23 are considered low risk procedures. That's part of  
24 the design in the Part 35 and the risk informed  
25 regulation is these are low-risk procedures.



1           No adverse outcomes medically can be  
2           expected for the technologist who self-administers an  
3           unauthorized dose of radiopharmaceutical. The rub in  
4           this is that it is nonetheless a violation of the NRC  
5           regulation, a misuse of licensed materials.

6           And effectively Milton S. Hershey Medical  
7           Center had to deal with the fact that we had probably  
8           three unauthorized misuses of licensed radioactive  
9           materials that we were responsible for as the  
10          licensee.

11          We believed that we had a rigorous  
12          radiation safety program and that we had adequate  
13          policies and procedures in place to protect such an  
14          incident.

15          In fact, each and every one of our  
16          technologists to the person when interviewed on the  
17          internal investigation stated that they were aware of  
18          that prohibition. And that was a core part of their  
19          training as a nuclear medicine technologist. And they  
20          were fully aware that these sorts of administrations  
21          were a violation of NRC regulation.

22          Again, although we thought we had an  
23          adequate radiation safety program, we were obviously  
24          wrong because we are now confronted with three  
25          incidents of self-administration of

1 radiopharmaceuticals by technologists.

2           And as we look at this, a technologist  
3 intent on violating NRC regulation for whatever reason  
4 can probably do so with a fairly small risk of  
5 discovery. And, in fact, the earlier two incidents,  
6 had the third incident not occurred, would have never  
7 been discovered.

8           The question is raised how do we prevent  
9 that. In a position of having agreed that we violated  
10 the regulation, part of the process is to determine  
11 how do you prevent recurrences in the future. The  
12 obvious statement is to create a culture of respect  
13 for NRC regulation. We, in fact, thought we had such  
14 a culture of respect but obviously didn't.

15           I think what wasn't clear to our staff is  
16 that willful violation of NRC regulation would result  
17 in swift and certain disciplinary action. We have one  
18 example of that now which did, in fact, result in  
19 swift and clear disciplinary action.

20           I think the other key point in this is  
21 complicity of other staff technologists has to somehow  
22 be avoided. All three of the cases at Penn State  
23 Hershey Medical Center involved more than one  
24 technologist, the technologist who had the  
25 administration and another technologist who performed

1 the administration.

2           You have to be a little bit more talented  
3 to self-administer radiopharmaceutical under a camera  
4 and start the camera and get the study going. In each  
5 of the three cases, it appears that the technologist  
6 who administered the radiopharmaceutical believed that  
7 they were administering an authorized injection.

8           So that appears to be a key. The second  
9 participating technologist appears to be a key to  
10 prevention. If we can have a process that prevents  
11 another technologist from participating then maybe we  
12 can prevent the episode from occurring at all.

13           We now require a written directive as part  
14 of our revised safety program for diagnostic  
15 administrations on all radiology staff members. We  
16 require the technologist who is performing the  
17 injection to actually see the written directive. And  
18 not only to see it but to discuss it with the  
19 responsible authorized user. That is the authorized  
20 user whose signature appears on the written directive.

21           We also have initiated new employee  
22 training and annual staff training which emphasized  
23 this specific incident and the consequences associated  
24 with an unauthorized injection of radioactive material  
25 which is then classed by NRC as a willful violation,

1 which then places it -- can place it as high as a  
2 Level 2 violation, which is not something that I think  
3 any institution wants to have to defend.

4 At this point, I would like to comment  
5 that in the process of the resolution with NRC, we  
6 participated in NRC's new ADR process which is the  
7 alternative dispute resolution process, which is a  
8 mediation process.

9 Although the contents of the goings on in  
10 the room that day are confidential and everyone signed  
11 a confidentiality agreement, I can tell you that it  
12 was an open and cordial dialogue with Region I  
13 administration. And that although I would not like to  
14 have to live through one of these again, that the  
15 process was a very positive one, that the ADR process  
16 allowed Hershey Medical Center to present its  
17 position, the NRC to present its position.

18 The initial investigative report was  
19 modified based on the discussion we had in the ADR  
20 process. And I would really commend the NRC senior  
21 administration in Region I for the way they handled  
22 that ADR process.

23 At this point, I've completed the case  
24 history. I'll be happy to answer any questions that  
25 the committee members may have. And then this is to

1 be open for discussion by the committee to determine  
2 if there is anything else that needs to be done.

3 CHAIRMAN MALMUD: Thank you, Dr. Eggli.  
4 I see Dr. Diamond has his hand raised.

5 MEMBER DIAMOND: Dr. Eggli, why? Why  
6 would a technologist do this?

7 DR. EGGLI: Her comment ultimately was  
8 that she felt she needed the study and she knew better  
9 than the doctors who didn't think she did.

10 CHAIRMAN MALMUD: There was another hand  
11 raised on this side?

12 MEMBER NAG: Yes, well, I had a similar  
13 question. And how it is different from a nurse or  
14 somehow who is going to be administering a drug to a  
15 patient taking it herself or himself or a doctor who  
16 having pain meds at his disposal taking the pain meds  
17 himself?

18 CHAIRMAN MALMUD: Mr. Bailey?

19 MEMBER BAILEY: One question then a couple  
20 of comments maybe.

21 Was the study evaluated?

22 DR. EGGLI: No, it was not.

23 MEMBER BAILEY: Okay. And second of all,  
24 our comment is that I think the agreement states for  
25 a long time have argued that the NRC regulations sort

1 of missed the mark because they do not address  
2 technologists. And since most of the times the  
3 technologists are the ones that are actually  
4 administering the material.

5 I know we, as a state, have taken  
6 disciplinary action against technologists who  
7 willfully or stupidly do something -- gross negligence  
8 I think is what the lawyers call it -- do something as  
9 an effective way to emphasize to the technologists the  
10 need to follow some procedures.

11 I'm a little curious as to how any  
12 facility can prevent a deliberate illegal act by an  
13 individual. And this is one of the things that we  
14 faced in industrial radiography was that we had a  
15 community where at least reportedly individuals, not  
16 companies, took an illegal action.

17 And so we addressed that by certifying  
18 radiographers. So I'm wondering how do you get to  
19 that from an NRC standpoint if someone deliberately  
20 does something?

21 CHAIRMAN MALMUD: Dr. Miller?

22 DR. MILLER: In an attempt to try to  
23 answer your question, I don't think any of us can  
24 absolutely prevent someone who deliberately wants to  
25 do something. I think the message here that Dr. Eggli

1 has so succinctly raised is I think it is important  
2 that technologists know that such activity is an  
3 unacceptable practice.

4 You know if somebody wants to go down the  
5 highway at 100 miles an hour, I don't think any laws  
6 can prevent that from happening other than enforcement  
7 of the regulations and the laws. But I think it is  
8 important that everyone understand that deliberate  
9 violation of the regulations is not acceptable.

10 And I think the concern here is that, you  
11 know, Dr. Eggli has very accurately pointed out  
12 Hershey Medical Center feeling that they had a very  
13 solid program. And we have no reason to dispute they  
14 had a solid program. Nevertheless, we find in all  
15 aspects of nuclear regulation that, you know, there  
16 are very solid programs.

17 Someone does something you could declare  
18 stupid, not intelligent, thinking that they know more  
19 than those who are authorized to administer such  
20 activities. And there's nothing you can do to  
21 absolutely prevent something like that other than  
22 making sure that people are aware of what is right and  
23 what is wrong.

24 CHAIRMAN MALMUD: Dr. Suleiman?

25 MEMBER SULEIMAN: I know there is a

1 radiation issue but this is really a medical issue.  
2 I mean it's no different than the improper  
3 administration of a medical drug. So doesn't the  
4 oversight inherent in the institution be sufficient?

5 I mean it is interesting you had to bring  
6 in the NRC. Couldn't the hospital handle that?  
7 Aren't there enough regulations to say this was  
8 improper, this was inappropriate?

9 DR. EGGLI: I can't address that question  
10 directly, Orhan, other than that the decision to  
11 report it was made by our hospital administration.  
12 And the report was to determine -- to ask NRC to  
13 determine in a sense did we need to report it. So it  
14 initially went to NRC as an inquiry. This event  
15 occurred. Do we need to officially report it? And  
16 that's how the process started.

17 MEMBER NAG: Is the question a medical  
18 event?

19 DR. EGGLI: I don't think this -- because  
20 a patient -- no patient was involved so I don't think  
21 this qualifies under a medical event rule. But there  
22 is in the regulation, and I wish I -- over in that  
23 binder over there I have the portion of the regulation  
24 that basically deals with appropriate medical use of  
25 licensed materials. And the NRC determined that this



1 was not an appropriate use of licensed radioactive  
2 materials.

3 MEMBER NAG: Right. But this was an  
4 injection without a written directive.

5 DR. EGGLI: This was injection not only  
6 without written directive but without authorization of  
7 an authorized user. In our diagnostic studies, there  
8 is an implicit authorization that goes from me to the  
9 technologist every time they inject for a medical  
10 indication.

11 CHAIRMAN MALMUD: Dr. Vetter?

12 MEMBER VETTER: This is not a medical  
13 event. Number one, it doesn't require written  
14 directive. The regulations don't require it.

15 And second, even if it is the wrong  
16 patient, in this case, the effective dose is less than  
17 five rem.

18 MEMBER DIAMOND: So really this is outside  
19 of our purview. I think it is interesting. I never  
20 knew that this type of problem occurred. But as was  
21 mentioned earlier, this is something really outside of  
22 our purview. Hopefully the frequency is very, very  
23 low. It does require basically one individual plus a  
24 second conspirator, if you will, to make this happen.  
25 So there is some oversight. I think if people

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1 understand and it is reinforced --

2 DR. EGGLI: And I think our observation  
3 was these were unintended co-conspirators if you want  
4 to use that sort of phrase.

5 MEMBER DIAMOND: Well, in this particular  
6 example, it was obviously pressure between a teacher  
7 and a student relationship, which is another issue  
8 altogether. But I think that's really all we need to  
9 do on this particular committee.

10 And obviously the person probably has a  
11 lot of other issues going on.

12 CHAIRMAN MALMUD: Dr. Williamson?

13 MEMBER WILLIAMSON: Yes. I guess I have  
14 a question for the NRC staff. In a situation like  
15 this where a radiation safety program has undertaken  
16 all reasonable steps to ensure adequate safety and  
17 oversight, if an employee willfully and illegally --  
18 you know willfully and knowingly commits an illegal  
19 act or infraction of the regulations, is NRC's how  
20 should I say -- juridical response limited to  
21 punishing the licensee or do you have an option for  
22 actually pursuing criminal litigation or fines against  
23 the individual perpetrator?

24 DR. MILLER: The NRC's responsibility is  
25 certainly with the licensee number one. And in

1 certain instances, NRC will pursue action against  
2 individuals.

3 MEMBER NAG: But this --

4 DR. MILLER: But it depends upon the  
5 position that the individuals occupy. I see Susan,  
6 you're here from the Office of General Counsel.

7 PARTICIPANT: (Speaking from unmiked  
8 location.)

9 DR. MILLER: Could you come to the  
10 microphone? From a legal perspective.

11 PARTICIPANT: Sorry. Yes, we have our  
12 deliberate misconduct rule in all the regulations.  
13 That gives us the authority to take action or to, you  
14 know, take enforcement action against an individual  
15 who deliberately violates NRC requirements. Does that  
16 answer the question?

17 MEMBER NAG: Yes but this is not the  
18 problem of the licensee. It's the problem of one  
19 individual. So why would or why should the licensee  
20 be penalized? Let it happen at my institution. I or  
21 none of our people it is a problem, it's one  
22 particular individual. So why would my institution be  
23 penalized?

24 DR. MILLER: Let me answer that from a  
25 regulator's perspective, okay? If it happened to you,

1 it's you, the licensee, that hired that individual,  
2 okay? And you hold an NRC license. And those that  
3 work under that NRC license are culpable under that  
4 license.

5 I recognize that in the case that somebody  
6 decides to do something deliberately that there is  
7 sometimes nothing you, as the licensee, can do about  
8 that.

9 But I think it comes back to, you know, it  
10 is left up to you to determine the people that you  
11 hire and what the credentials, the honesty, the  
12 integrity of those people that you hire are. And that  
13 those people clearly, as does the licensee, you are  
14 responsible for the regulations that you are bound  
15 under.

16 DR. EGGLI: Subir, if I can comment. We  
17 asked sort of the same question. It's kind of the  
18 captain of the ship. We hold the license. And,  
19 therefore, we are, in fact, responsible.

20 But we decided to sort of give up that  
21 question as non-productive. And to try to ask -- the  
22 other question is is there anything we can do to  
23 further mitigate the risk?

24 And in our program, we thought there were  
25 a couple of things that we could do to further

1 mitigate the risk. Again, one of them is a self-  
2 preservation issue. These are not fun processes. And  
3 although it was a perfectly fair process, it wasn't  
4 fun. And I would just as soon not have to do it  
5 again. And if we can mitigate the risk further as the  
6 license holder, I think it is incumbent upon us to  
7 construct a safety program that to the best of our  
8 ability does mitigate risk.

9           You know we can't, you know, who is to say  
10 a technologist won't take a vial of radioactivity and  
11 go up to the cafeteria and throw it on the floor?  
12 But, you know, what can we do to mitigate that kind of  
13 risk?

14           And I think if we make sure the  
15 technologists understand that certain classes of  
16 activity which, in our case, occurred more than once  
17 over a period of about ten years, will not be  
18 tolerated. One, if they know there are consequences  
19 and two, if we introduce whatever safeguards we can to  
20 attempt to mitigate which is, in our case, dealing  
21 with the unintended accomplice by making sure that we  
22 have a process that asks the second technologist to  
23 verify the legitimacy of the administration, then I  
24 think that we are taking the next step as licensee.

25           And I think a point will come where we

1 have done everything we can. But as we looked back on  
2 our program, even thinking we had an outstanding  
3 safety program, there was clearly more we could have  
4 done. But again, you don't know what you don't know.  
5 And you learn from these events.

6 And part of the reason that I'm here  
7 sharing this is to share this experience so somebody  
8 else doesn't have to learn the hard way the way we  
9 did.

10 MEMBER NAG: Now this was a diagnostic  
11 procedure using radioactive material. Now similar to  
12 that, if a technologist has an x-ray, it fell down and  
13 without having a doctor's prescription just took the  
14 x-ray himself or herself, where would that place that  
15 situation?

16 DR. EGGLI: That actually violates Part  
17 210 of the Pennsylvania Code.

18 (Laughter.)

19 DR. MILLER: NRC has no jurisdiction on  
20 that. But it's a similar kind of thing, yes.

21 CHAIRMAN MALMUD: Ralph?

22 MEMBER LEITO: Question for Doug. Has the  
23 NRC indicated anything to the effect that they are  
24 taking any action against the technologist in terms of  
25 willful, you know, disregard for the licensee's

1 direction?

2 DR. EGGLI: The NRC has not indicated to  
3 us as the licensee what their intentions are with  
4 respect to the individual technologist involved. I  
5 don't know if that's a privacy issue. I assume that  
6 once the NRC makes a decision one way or another, like  
7 our notice of violation, I assume that turn up on the  
8 website as well once it becomes -- if there is  
9 something that happens.

10 But certainly nothing has been shared with  
11 us as licensee.

12 CHAIRMAN MALMUD: Mr. Bailey?

13 MEMBER BAILEY: Yes, one of the things  
14 that is sort of disturbing is that tech can now go to  
15 New Jersey and go to work in a hospital whereas we've  
16 seen in some of the other activities under the NRC  
17 where they actually issue an order to an individual  
18 who intentionally violates regulations.

19 And that order then goes out to all of us  
20 as sort of a hey, by the way, you ought to look at  
21 this person.

22 DR. EGGLI: Again, I don't know that NRC  
23 doesn't have other action planned. It's just that I  
24 have no personal knowledge of what the regulatory plan  
25 is.

1 CHAIRMAN MALMUD: Is there a question  
2 before this group?

3 DR. MILLER: I think the question that the  
4 staff would ask the committee is based upon Dr.  
5 Eggli's presentation and the discussion, is there  
6 anything that the ACMUI would recommend needs to be  
7 done on the part of the NRC to help, you know, try to  
8 minimize or prevent the occurrence of such activities?

9 CHAIRMAN MALMUD: Dr. Vetter?

10 MEMBER VETTER: There was an information  
11 notice wasn't there? I'm trying to recall. It seems  
12 to me I read an information notice on this. Maybe I'm  
13 wrong about that. But a reminder somewhere about --  
14 relative to our own programs reminding technologists  
15 what their responsibilities are. Does anyone else  
16 remember that?

17 MEMBER LEITO: Yes.

18 MEMBER VETTER: You do?

19 MEMBER LEITO: There is an information  
20 notice dated July 16th, 2002, unauthorized  
21 administration of byproduct material for medical use.  
22 That might be it.

23 MEMBER VETTER: Okay.

24 CHAIRMAN MALMUD: Well, if you're looking  
25 for a response, I'll give you a personal response not



1 on behalf of the committee. I don't know what else  
2 you could have done. And I don't know what else any  
3 of us can do.

4 If an employee is intent upon harming  
5 himself or herself, there's little that we can do  
6 outside of making certain that all the rules and  
7 regulations are adhered to.

8 I would have difficulty personally finding  
9 you, as a licensee, the least bit guilty for what  
10 happened since any individual can at any time do  
11 something like that despite all the rules,  
12 regulations, and understanding about the risk of  
13 radioactive material.

14 MEMBER NAG: I would like to be on record  
15 as saying that I support the institution's handling of  
16 the case. And I would like to be on the record as an  
17 ACMUI member and perhaps making an ACMUI resolution  
18 that we support the handling of the case that has been  
19 presented.

20 DR. EGGLI: If I might make one final  
21 comment, an e-mail circulated in the nuclear medicine  
22 community critical of Penn State's handling of this  
23 incident, describing me as the lilly-livered licensee  
24 without the courage to stand up to NRC for this  
25 incident.

1           So there is some feeling in some of the  
2 nuclear medicine community that Penn State  
3 overreacted. I personally disagree with that. I mean  
4 we clearly violated the regulation. We accept the  
5 fact that we violated the regulation. And we've tried  
6 to modify our program to prevent recurrence.

7           But there is an opinion out there in the  
8 nuclear medicine community that we overreacted.

9           CHAIRMAN MALMUD: Well, I must say I  
10 haven't seen that. And I don't agree with that. But  
11 I think that Dr. Nag, you have a motion on the floor,  
12 don't you? Was that a motion Dr. Nag?

13           MEMBER NAG: Yes, I was going to present  
14 it as a motion that, you know, as the ACMUI, we  
15 support the institution's reporting of the case and  
16 also taking action to prevent potential incidents in  
17 the future. And commend them for that. And we  
18 support them for that.

19           CHAIRMAN MALMUD: Is there a second to  
20 that motion?

21           MEMBER VETTER: Second.

22           CHAIRMAN MALMUD: Dr. Vetter seconds it.  
23 Any further discussion?

24           (No response.)

25           CHAIRMAN MALMUD: All in favor?

1 (Chorus of ayes.)

2 CHAIRMAN MALMUD: Any abstentions or  
3 opposition?

4 (No response.)

5 CHAIRMAN MALMUD: It's unanimous.

6 Thank you very much.

7 DR. EGGLI: Thank you.

8 MEMBER BAILEY: I just want a  
9 clarification. You said there was an information  
10 notice that went out in 2002. Has there been one that  
11 has gone out since then? Like since this incident  
12 came to light?

13 PARTICIPANT: No, not to my knowledge, on.

14 CHAIRMAN MALMUD: Sally?

15 MEMBER SCHWARZ: There was -- at the  
16 bottom of this e-mail, which actually was distributed,  
17 that went out from one of the members of the  
18 community, I think there is a publication coming out  
19 in February of '06 that's talking about unauthorized  
20 injections, technologists -- I mean there is a  
21 publication that is actually mentioned that is  
22 addressing this.

23 Probably just the fact that it is out in  
24 the community, that people are aware that this has  
25 happened.

1 DR. EGGLI: We actually have submitted a  
2 publication --

3 MEMBER SCHWARZ: Right.

4 DR. EGGLI: -- in one of the Radiation  
5 Safety Journals --

6 MEMBER SCHWARZ: Correct.

7 DR. EGGLI: -- that will be published.  
8 We're submitting another article in the Journal --  
9 probably more importantly -- in the Journal of Nuclear  
10 Medicine Technology to get this out to the nuclear  
11 medicine techs as well.

12 MEMBER SCHWARZ: And I think that is  
13 excellent in terms of just raising the level of  
14 awareness that this has occurred. And that often can  
15 at least help to stop considerations, you know, to  
16 alter behavior.

17 CHAIRMAN MALMUD: Dr. Williamson?

18 MEMBER WILLIAMSON: Well, I guess I would  
19 like to say that it would be unwise to take the moral  
20 of the story too much to heart you know in the sense  
21 that I think this is a very low probability event.  
22 And if one, you know, considers I suppose risk and  
23 view it as somehow the product of frequency and  
24 severity of effect, it is quite small of this  
25 happening. Both the probability and the consequences.

1           So, you know, recommending even that all  
2           licensees move to a very strict protocol for treatment  
3           of employees of a hospital, you know, because of such  
4           an incident would seem to me not to be a good societal  
5           use of resources for quality assurance that could be  
6           better expended in the higher risk categories of  
7           clinical care.

8           So I guess I would say there is a negative  
9           consequence regulatory -- or negative consequence to  
10          health and safety for reacting too strongly in terms  
11          of, you know, insisting or encouraging widespread and  
12          expensive practices for low probability, low severity  
13          events.

14          DR. MILLER: You lost me on that.

15          MEMBER WILLIAMSON: Oh, sorry.

16          CHAIRMAN MALMUD: Dr. Eggli?

17          DR. EGGLI: My purpose in presenting today  
18          was to do with the fact that you don't know what you  
19          don't know. Before April 29th, 2004, I would have  
20          told you there was a zero percent probability that  
21          this would happen at Penn State Hershey Medical  
22          Center.

23          My primary goal in making this  
24          presentation today is to try to create some vehicle  
25          for raising awareness in the nuclear medicine

1 community so you don't live through what I lived  
2 through. Because the answer still is you don't know  
3 what you don't know.

4 And I would never in my life have believed  
5 that this could have occurred three times in ten years  
6 at Penn State Hershey Medical Center. I just would  
7 have never believed that until I have to deal with in  
8 my face.

9 So again one of my main purposes is to  
10 share the information that it does happen. And you  
11 don't know what you don't know. And it is easy to  
12 bury it until some really serious digging around  
13 happens.

14 CHAIRMAN MALMUD: Well, Dr. Eggli, we  
15 thank you for sharing that with us. It seems to me  
16 the simplest thing to do is for every licensee to go  
17 back to his employees and say if you ever give  
18 yourself radiopharmaceutical without a physician's  
19 order, you're fired. Period. End of discussion.

20 I don't think it requires the intervention  
21 of a federal agency. I saw that only on behalf of our  
22 income tax bill. So the people will do things that  
23 are very strange that we can't anticipate.

24 Your participation in this was quite  
25 honorable and we respect that.

1 DR. EGGLI: Thank you, sir.

2 CHAIRMAN MALMUD: And with that, if we  
3 may, we'll move on to the next subject. And that is  
4 the revision of NRC Form 313A. This is an open  
5 session. We thank Sandra Gabriel from the NRC for  
6 giving us her time.

7 MS. GABRIEL: Thank you, Dr. Malmud. I've  
8 invited Dr. Howe to join me as she has worked closely  
9 on this project with me.

10 As you know, Form 313A is an available  
11 method for licensees to use to submit the training  
12 experience and preceptor statements for proposed  
13 authorized individuals. The form was revised in 2002  
14 with the Part 35 revision and also with the initial  
15 publication of NUREG-1556, Vol. 9.

16 Again, earlier this year when the Part 35  
17 training experience requirements were revised, and  
18 NUREG-1556, Vol. 9 was revised, the form was revised  
19 again.

20 The initial version of Form 313A was made  
21 to deal with relatively simple Part 35 training  
22 experience requirements. The form was relatively easy  
23 to use. And it addressed authorized users and  
24 radiation safety officers only.

25 The 2002 version was intended to deal with

1 the somewhat more complex training and experience  
2 requirements in the new portion of Part 35. The form  
3 was, therefore, more complex. Authorized medical  
4 physicists and authorized nuclear pharmacists were  
5 added so one form was intended to address four  
6 different types of authorized individuals.

7 And our experience in the region reviewing  
8 applications was that licensees had difficulty  
9 determining which sections of the form to complete for  
10 each type of authorized individual and the correct way  
11 to complete the applicable sections.

12 We also found that Form 313A was used  
13 relatively infrequently at that time because Subpart  
14 J was still able to be used. So most licensees  
15 submitted applications in accordance with Subpart J.

16 In the new 2005 version of Form 313A, the  
17 instructions on the form provided more direction about  
18 which sections to complete but we found that licensees  
19 still found the form to be confusing as did the  
20 regional license reviewers.

21 We also noted that the need for a user  
22 friendly form, user friendly to both licensees and  
23 license reviewers becomes more urgent today with the  
24 expiration of Subpart J and also with the limited  
25 number of approved specialty boards, meaning that at



1 least for a period of time, we'll be evaluating more  
2 applicants based on training and experience rather  
3 than on certification.

4 The regional participants in the Part 35  
5 working group, which consists of representatives of  
6 both headquarters and each of the regions, proposed  
7 revision of the 313A into separate forms for each type  
8 of authorized individual to try to simplify things.

9 Region I was assigned to coordinate the  
10 project. And the team working on this revision  
11 includes representatives from Regions I, III, IV, and  
12 from INMS and headquarters. We've been working by e-  
13 mail and telephone to expedite the process of updating  
14 the form.

15 Current proposal is for there to be six  
16 different versions of the form to reflect six  
17 different sets of requirements. One for radiation  
18 safety officer, one for authorized medical physicist,  
19 one for authorized nuclear pharmacist, and one for the  
20 diagnostic authorized user categories, 35100, 200,  
21 500, one for unsealed therapies 35300, and then one  
22 for authorized user for the sealed source therapies  
23 35400 and 600.

24 And the project also includes an update of  
25 the guidance in Appendix D of NUREG-1556, Vol. 9,

1 which instructs applicants how to use the forms.

2 Copies of the latest draft were  
3 distributed to you to review in advance of the  
4 meeting. And we would like to open this up to  
5 discussion now if you have any comments.

6 CHAIRMAN MALMUD: The subject is now open  
7 for discussion. Ralph?

8 MEMBER LEITO: I'd like to commend staff  
9 because I think it is a big improvement separating out  
10 the different groups. And just also for the  
11 committee's information, the 300 applies to all 300  
12 uses, not just .300 but the 390s also which is good.

13 I've asked some people to, you know, look  
14 at this also and get their feedback. And the only  
15 comment that I got back, which I think was a good  
16 comment, has to do with the authorized user training  
17 and experience for the diagnostic uses, the 100, 200,  
18 and 500s, that the different parts have sign offs  
19 because authorized users for like say the diagnostic  
20 uses, they may get their training -- the training and  
21 experience -- this would be for the non-Board  
22 certification route. I should clarify that.

23 They may get the physics and the didactic  
24 portion in one area and the clinical at a different  
25 institution altogether. And if there could be maybe

1 -- the suggestion was that authorized users are  
2 willing to sign off for those portions they provide  
3 but they're not willing to necessarily be the  
4 preceptor that everything is there.

5 So in other words, they may go through for  
6 like cardiologists, they may go down to nuclear  
7 medicine and get a certain portion of their training  
8 in nuclear medicine. And the nuclear medicine  
9 authorized user is willing to sign off for what they  
10 did. But they're not necessarily willing to be the  
11 preceptor that attests to the whole ball of training,  
12 okay?

13 And if there could be -- like on -- if you  
14 look at authorized user under the diagnostic -- under  
15 number three where they attest to the total hours of  
16 experience, if there could maybe be a sign off line  
17 that that portion was done under the, you know, for  
18 the authorized user for that portion.

19 Then I had one question. When you have  
20 that the supervisor meets the requirements below, it  
21 says check one. Would there be an objection to check  
22 all that apply? I mean if they had more training --

23 MS. GABRIEL: That's a good suggestion.

24 MEMBER LEITO: -- experience rather than  
25 just the one piece, in other words, they might be able

1 to address a larger range of training experience.  
2 It's like well, I've got diagnostic and I've got  
3 therapeutic. And why can't I check them all off that  
4 apply in terms of the users' training. Because  
5 basically you want some record of what the user's  
6 training and experience is that is providing this.  
7 And I would just suggest rather than saying check one,  
8 check all.

9 MS. GABRIEL: We will update that. Thank  
10 you.

11 MEMBER LEITO: Those are the comments that  
12 I had gotten back.

13 CHAIRMAN MALMUD: Dr. Nag?

14 MEMBER NAG: Is there a way to easily  
15 address the situation where a trainee has trained in  
16 more than one center. They did the first year in a  
17 separate center, second year or third year in a  
18 separate center. And no one preceptor can certify for  
19 the whole thing. But, you know, it may have been 80  
20 hours in one place and another 100 hours in the other  
21 place. Is that possible?

22 MS. GABRIEL: I believe our intention is  
23 that multiple copies of that page could be submitted,  
24 each one completed by one supervising individual to  
25 reflect the portion of the training that involved

1 them.

2 DR. HOWE: And you need to remember that  
3 the preceptor now is essentially verifying the  
4 training and is not the one that was responsible for  
5 giving the training. So we would still expect one  
6 preceptor statement at the end for the whole batch of  
7 things. But there can be many different supervising  
8 sheets to add up to one.

9 MEMBER LEITO: I would suggest that when  
10 you put together the instructions that go with these  
11 that maybe you indicate that so that people know that  
12 this is what they can do? Because I think there is  
13 maybe the impression it's all got to be on one form.

14 MEMBER VETTER: If I could just underscore  
15 that. It's really common in training programs,  
16 especially radiation oncology, where a training  
17 program might not have HDR, for example, or Gamma  
18 Knife stereotactic radiosurgery in their institution  
19 so the resident goes to the university medical center  
20 to get that portion of the training.

21 And in order to avoid confusion, some  
22 instructions need to address. All of that needs to be  
23 incorporated somehow into one submission and signed by  
24 the authorized user where the resident is trained.

25 CHAIRMAN MALMUD: Mr. Bailey?

1 MEMBER BAILEY: I notice that Table C, if  
2 I'm not mistaken, is --

3 DR. HOWE: Which form are you talking  
4 about? There should be a designation at the top.

5 MEMBER BAILEY: RSO.

6 DR. HOWE: Okay.

7 MEMBER BAILEY: Table C, the instructions  
8 in Part 1 are choose one of the four methods below.  
9 But then Table C, which is included in Method One, in  
10 each of the other three methods, you have to go back  
11 and complete that part of Part 1. So I would suggest  
12 that it be brought out right on top and not included  
13 in the choice.

14 DR. HOWE: We included it in number one.  
15 And then to avoid having to repeat it, we refer people  
16 back to it in number one.

17 MEMBER BAILEY: Well --

18 DR. HOWE: Do you want to see the table in  
19 all sections?

20 MEMBER BAILEY: No, no. What I'm saying  
21 is that table should be before number one because  
22 you're going to make everybody fill it out so you  
23 should fill it out right up front and then go to  
24 choice one or two or three or four.

25 Right now you've got a yo-yo going. I

1 choose two but I've got to go back to one and fill it  
2 out.

3 DR. HOWE: Okay. We take your point.

4 MEMBER WILLIAMSON: Or put it at the end  
5 as a common appendix.

6 MEMBER BAILEY: Yes, something.

7 DR. HOWE: I think we're concerned if we  
8 put it at the end then the Board certification folks  
9 may not realize they need to fill it out also. So  
10 we'll try to do something that makes it obvious.

11 CHAIRMAN MALMUD: Sally?

12 MEMBER SCHWARZ: This is under authorized  
13 user training and experience and preceptor  
14 attestation.

15 DR. HOWE: Which form? We have six.

16 MEMBER SCHWARZ: AUT.

17 DR. HOWE: AUT? Okay.

18 MEMBER SCHWARZ: Now I know we have kind  
19 of draft changes. This is what we had gotten sent  
20 out. The first part there are typos where it says  
21 35300, 300, 300, 300.

22 DR. HOWE: We'll take care of the typos.

23 MEMBER SCHWARZ: Then under Board  
24 certification on one, the question was raised why is  
25 documentation needed in C and D below if the Board is

1 recognized as meeting the NRC training and experience?

2 DR. HOWE: In the regulations, the Board  
3 certification has been separated from the specific  
4 training on devices. And so that's why one thing is  
5 separated. And also your attestation. Let me make  
6 sure where you are addressing.

7 MEMBER SCHWARZ: I think this is something  
8 different.

9 DR. HOWE: Okay. Where are you?

10 MEMBER SCHWARZ: AUT.

11 DR. HOWE: I'm on AUT.

12 MEMBER SCHWARZ: Part One, Training and  
13 Experience.

14 DR. HOWE: Yes.

15 MEMBER SCHWARZ: Board Certification.

16 DR. HOWE: Yes.

17 MEMBER SCHWARZ: That was why is the  
18 documentation needed in C and D below, which is Board  
19 Certification C and D where they refer to the tables  
20 for completion for the -- if the Board is recognized  
21 as meeting the training and experience? It has to be  
22 reiterated?

23 DR. HOWE: If the particular -- well,  
24 we'll be looking at this once we have our -- all of  
25 our Board certifications up. But if the Board



1 certification meets either for 490 -- oh no, this is  
2 a 390 one. Okay. Oh, C is because the clinical  
3 experience has been separated out from the Board  
4 certification process. And so there needs to be the  
5 clinical experience plus the preceptor statement for  
6 those individuals coming under 390.

7 The Board did ask that the clinical  
8 experience be separated from the Boards. And so it  
9 was. And so that has to be provided under C as a  
10 separate part.

11 And D is for those individuals coming  
12 under a different Board, the 490 Boards or the 690  
13 Boards. And they have to provide the additional  
14 documentation for 396. Does that help?

15 CHAIRMAN MALMUD: Dr. Vetter?

16 MEMBER VETTER: Relative to that  
17 particular section, it is elsewhere, too. For  
18 instance under RSO. But under Board certification A,  
19 provide a copy of Board certification if Board  
20 certification is older than seven years. Now is that  
21 the renewal or is that the original?

22 For instance, ABHP requires you to renew  
23 every four years or you are no longer an active  
24 certified health physicist. So if I was re-certified  
25 three years ago, does that satisfy that requirement?

1 Or are you going to go back to my original certificate  
2 from the `70s?

3 DR. HOWE: This is an area we haven't  
4 really discussed among ourselves. But my personal  
5 view is that if you are re-certified, you have  
6 provided evidence of continued training and  
7 experience. So I think we would take your re-  
8 certification date as an indication that you are.

9 MEMBER VETTER: Thank you. I think that's  
10 -- I personally would do the same thing.

11 MS. GABRIEL: And the requirement for  
12 training and experience within seven years is not a  
13 new one.

14 MEMBER VETTER: No, I know that, right.

15 MS. GABRIEL: And that's been part of the  
16 regulation for some time.

17 MEMBER VETTER: That is the recentness of  
18 training -- that's the recentness of training issue.

19 CHAIRMAN MALMUD: Bill?

20 MEMBER DIAMOND: Before I start on my  
21 question, I was going to say I thought Dr. Vetter you  
22 trained in 2002, not the 1970s.

23 (Laughter.)

24 MEMBER DIAMOND: I'm going to get confused  
25 here. Can I ask three questions if I could on Form

1 AUD, Authorized Training and Experience for .200? I  
2 guess my question revolves around .3, which is the  
3 outlining of the training and experience, both  
4 classroom and laboratories A, and then supervised work  
5 experience for B, noting the detail in the preceptor  
6 form as far as this -- what I would consider the old  
7 Subpart J breakdown for didactics. Asking whether  
8 that is still a breakdown that we want since the  
9 current regulation reads 80 hours and doesn't read  
10 that breakdown.

11 The only reason why I ask -- and I don't  
12 particularly mind except we don't have a standard for  
13 what goes -- in Subpart J, we had a fairly good  
14 standard for what went into each of those parts for  
15 the total of 200. We don't have a current standard  
16 right now.

17 And I'm not sure that across programs --  
18 I'm not sure whether we want that standard, don't want  
19 that standard. We haven't set it up so far but you  
20 have a chart in there and somebody is going to put  
21 numbers into it. What does that really mean to us I  
22 guess is the question at this point in time. Other  
23 than, you know, the total.

24 DR. HOWE: I guess I'm a little confused  
25 because if you look at 290 in the regulations, you'll

1 find that you have to have classroom and laboratory  
2 training and they indicate a minimum of 80 hours. And  
3 they list these subjects. These are the subjects that  
4 are under the first part. And then they say you have  
5 to have work experience.

6 MEMBER DIAMOND: Right. That's correct.

7 DR. HOWE: And then these are the topics  
8 under the work experience. And then the total adds up  
9 to 700.

10 MEMBER DIAMOND: That's correct. But my  
11 question is is this 20, 20, 20, 20? Are you going to  
12 get things from different ones with different numbers  
13 in there?

14 DR. HOWE: Absolutely.

15 MEMBER DIAMOND: Do those numbers mean  
16 differences to you? Or you just want to know that  
17 there were numbers in each one?

18 DR. HOWE: We want to know the numbers  
19 that are in each one. And it's a performance base.  
20 And so if you end up with a total of 80, we are  
21 satisfied. If you end up with -- then you add up to  
22 a total of 700, we're satisfied.

23 There is no set divide by the number of  
24 blocks and that's the number of hours or any other  
25 algorithm to give you specific numbers.

1 MEMBER DIAMOND: Right. But in Subpart J,  
2 there used to be a breakdown and it was not equal  
3 across these parts as far as what most people did for  
4 that training for that 200 hours.

5 And that's the only reason why I asked,  
6 you know, it doesn't -- we didn't proscribe how those  
7 80 hours got broken down. So I'm just trying to  
8 figure out when you go out to explain it to the  
9 community, what we consider as a reasonable curriculum  
10 we'll have to re-talk about and re-deal with.

11 You may see different numbers. I'm just  
12 trying to figure out what that means.

13 MS. GABRIEL: There are times in the  
14 region when we may receive applications that just show  
15 a bracket and the total number of hours confirming  
16 that all topics were covered.

17 MEMBER DIAMOND: That all topics were  
18 covered. Right.

19 MS. GABRIEL: And we generally find that  
20 acceptable.

21 MEMBER DIAMOND: Okay.

22 CHAIRMAN MALMUD: Mr. Bailey?

23 MEMBER BAILEY: On the AMP page 3 --

24 DR. HOWE: He had three questions. Were  
25 those your three questions?

1 MEMBER DIAMOND: No, my second --

2 (Laughter.)

3 CHAIRMAN MALMUD: Oh, I'm sorry. I  
4 apologize.

5 DR. HOWE: Are we still in the AUD?

6 MEMBER DIAMOND: We're still on the same  
7 one. That was question one.

8 Question two is just a subpart of that  
9 which had to do with the clinical experience  
10 documentation which I guess you just answered which is  
11 it is a block of 700 hours. And now we have all these  
12 subtypes here as far as how we add them up. And is it  
13 just good enough to say that we've done 700 and  
14 covered all the subject areas which is, you know,  
15 obviously the gestalt of what we're trying to get to.

16 So I guess those two answers to together.

17 And I guess the third question had to do  
18 with the statement that these forms are available but  
19 not required. So I guess my question to that means is  
20 when a Board on the other pathway takes a statement  
21 from a preceptor that that preceptor has fulfilled all  
22 of the categories to be considered for authorized  
23 usership status, that they can do that in a letter  
24 format that outlines all of these categories without  
25 using these forms?

1 Or are these forms something that need to  
2 be in place somewhere? In somebody's pocket.

3 MS. GABRIEL: Let me answer again as a  
4 regional license reviewer. We would accept the  
5 information required by the regulation in whatever  
6 format you wish to submit it.

7 DR. HOWE: Provided it is all there.

8 CHAIRMAN MALMUD: Does that complete your  
9 three questions Dr. Van Decker?

10 MEMBER DIAMOND: Sounds like three to me.  
11 Thank you.

12 CHAIRMAN MALMUD: Thank you. I apologize  
13 for having interrupted you after the first.

14 Mr. Bailey?

15 MEMBER BAILEY: And me, too, I apologize.

16 AMP, page three, the footnote I found  
17 interesting. It says training and work experience  
18 must be conducted in clinical radiation facilities  
19 that provide high energy external beam therapy  
20 (photons and electrons with energies greater than or  
21 equal to 1 mev) and brachytherapy sources.

22 Why? Why do they have to have external  
23 beam electron therapy before they can do -- it has  
24 nothing to do with leak tests or decay calculations or  
25 calibration or anything else.

1 MS. GABRIEL: It is taken directly from  
2 the regulation. 3551 --

3 DR. HOWE: B1.

4 MEMBER BAILEY: You mean so if I don't  
5 have an accelerator, I can't get an NRC license -- I  
6 can't be named on an NRC license?

7 DR. HOWE: Okay, the -- no -- well, okay.  
8 The requirement is that -- in B1, which is the  
9 alternate pathway, to hold a masters or doctor's  
10 degree in physics, medical physics, other physical  
11 science, engineering, applied mathematics, and  
12 completed one year of full-time training in medical  
13 physics which an additional year, or full-time work  
14 experience under the supervision of an individual who  
15 meets the requirements of authorized medical physicist  
16 for the types of use for which the individual is  
17 seeking authorization.

18 So if you're not seeking authorization for  
19 some of these things, then it doesn't have to be  
20 there. The training and work experience must be  
21 conducted in clinical radiation facilities that  
22 provide high energy external beam, energies with  
23 greater than one mev, or brachytherapy must include.

24 I think if you're not applying for an  
25 external beam, then --



1           MEMBER BAILEY:  What if I was applying for  
2 any of the isotope external beams?  Why do I need to  
3 have worked at an accelerator facility?

4           CHAIRMAN MALMUD:  Are you going to answer  
5 that question Dr. Williamson?

6           MEMBER WILLIAMSON:  Well, I think just to  
7 underscore, there is a problem.  The fact that it  
8 mentions electron beam seems to be irrelevant.  Had it  
9 just been limited to photons, then I think -- because  
10 I think the intent was to say there is megavoltage  
11 beam therapy of some form or another so as not to  
12 limit the practice to just cobalt-60 because so few  
13 training programs have cobalt-60 nowadays.

14           But it does seem that putting in the  
15 qualification -- electrons seems unnecessary though I  
16 would imagine there are very few training facilities  
17 that wouldn't have electrons.

18           DR. HOWE:  Is it sufficient to want it  
19 removed?

20           MEMBER WILLIAMSON:  No.

21           DR. HOWE:  No?

22           MEMBER WILLIAMSON:  I think it certainly  
23 is an additional requirement that doesn't really make  
24 sense.

25           MEMBER LEITO:  I think what Ed's point is

1 that it is not under the purview of the NRC whether  
2 there is electron beam therapy or not. I think for  
3 the purposes of this form, I think striking out and  
4 electrons still would achieve the NRC's intent on  
5 revision of this form.

6 CHAIRMAN MALMUD: All right? Oh, Sally?

7 MEMBER SCHWARZ: Sorry. One more question  
8 on AUT.

9 DR. HOWE: AUT? It takes us a while to  
10 get forms.

11 MEMBER SCHWARZ: That's all right. And  
12 this is that question that was raised was for 3B  
13 calculating, measuring, and safely preparing patient  
14 or human research subject doses. The question was  
15 diplomats of ABNM shouldn't have to fill out this  
16 section. Or comment as it was. Is that correct?

17 DR. HOWE: Okay. You're in --

18 MEMBER SCHWARZ: This is AUT -- Authorized  
19 User Training and Experience and Preceptor  
20 Attestation.

21 DR. HOWE: We -- and you're talking about  
22 the American Board of Nuclear Medicine? Okay. The  
23 American Board of Nuclear Medicine is recognized. The  
24 clinical case experience has to be provided because  
25 that's been separated out from the Board

1 certification.

2 They would need to fill out 3C, which is  
3 the clinical case experience.

4 MEMBER SCHWARZ: Right. This is 3B.

5 DR. HOWE: But 3B does not have to be  
6 filled out because --

7 MEMBER SCHWARZ: Does not have to be  
8 filled out, okay.

9 DR. HOWE: -- because that's part of the  
10 supervised work experience that comes -- that the  
11 Board certification takes the place of.

12 MEMBER SCHWARZ: Okay. Good.

13 DR. HOWE: Okay? And if you look up the  
14 Board certification, we do not send you to there.

15 MEMBER SCHWARZ: Okay.

16 CHAIRMAN MALMUD: Thank you. Do we have  
17 a question?

18 MS. FAIROBENT: Yes, Lynne Fairobent,  
19 AAPM. On AMP, page 5 of 6 under the preceptor  
20 attestation, I'm curious to know why you're asking for  
21 the preceptor to attest the individual is Board  
22 certified. When you look at the regulation, we  
23 decoupled that.

24 And under 3551(b)(2), it says obtain  
25 written certification that he has completed (B)(1).

1 It doesn't tie to the Board certification.

2 I'd just like clarification. We had had  
3 discussions that the preceptor may or may not know if  
4 they have been certified.

5 DR. HOWE: Excuse me. Give us a chance to  
6 find the right place. So you're talking about the  
7 preceptor attestation.

8 MS. FAIROBENT: Right.

9 DR. HOWE: And which section are you on?

10 MS. FAIROBENT: Part 2, check one of the  
11 following Board certification or 2 education and  
12 training. And you're asking I think that the  
13 preceptor attest to the individual being Board  
14 certified.

15 And if I remember correctly and in looking  
16 at the regulation, we only ask that the preceptor  
17 attested to the alternative pathway training and  
18 experience and any of the other -- the specific  
19 modality training. Not that they were certified.

20 DR. HOWE: They do not have to attest that  
21 they are certified. But they do have to attest that  
22 they have satisfactorily completed the requirements in  
23 -- I've got the right one -- A1 and A2. And what they  
24 wrote was that A1 and A2 are that you are under --  
25 that you have the full-time practical training and --

1 you have the right degree. And you have the right  
2 experience. But we do not make the authorized user  
3 attest that they passed the examinations.

4 They do not attest that they pass the  
5 examination. They have to attest that they hold the  
6 right degree and that they have completed the  
7 practical training and supervised experience.

8 MS. FAIROBENT: Isn't A1 coming in under  
9 the Board certification pathway?

10 DR. HOWE: Yes. A1 does.

11 MS. FAIROBENT: I'm confused if it is. So  
12 you are attesting that they are certified? Because  
13 they're coming in under the certification pathway?

14 DR. HOWE: No.

15 MS. GABRIEL: The header is labeled Board  
16 certification to direct you to the statement to  
17 complete.

18 MS. FAIROBENT: I think it needs  
19 clarification then.

20 DR. HOWE: You're coming in under the  
21 Board certification pathway. And if you're coming in  
22 under the Board certification pathway, then the  
23 preceptor must attest that you have completed A1 and  
24 A2. They do not have to attest that you have  
25 satisfactorily passed the examination. Only that you

1 have the prerequisites to be a candidate.

2 MEMBER LEITO: I see what you're saying.

3 CHAIRMAN MALMUD: Ralph?

4 MEMBER LEITO: I see what they're saying  
5 but it is very, very confusing. I think if you look  
6 at it from the standpoint that the preceptor is in and  
7 of itself its own entity, instead of this -- because  
8 it does -- first reading this, I was getting the same  
9 impression, that you are wanting the preceptor to  
10 attest to the Board certification.

11 And really what you want is them to attest  
12 that the whole package is there. And that's the way  
13 that I would put this together. Not all the ors and  
14 ands. Just -- because this has to be filled out  
15 regardless if you are Board certified or the alternate  
16 pathway. So I think these headings are making it look  
17 like you can, like, pick and choose. And really the  
18 whole thing has got to be done. They've got to just  
19 make one attestation to the whole piece.

20 DR. HOWE: There is a different  
21 attestation if you're coming the Board certification  
22 pathway than if you are coming the alternate pathway.  
23 Because you are attesting to something different in  
24 many of these. And that's why there is a difference  
25 on the attestation for Board certification and for the

1 alternate pathway.

2 And then you'll find other sections that  
3 are the same for both. And you'll see instructions  
4 that say complete all of the following. And then you  
5 have those things that are common to both pathways.

6 But there are different attestations  
7 depending on which pathway you're coming through. And  
8 it's in the regulation.

9 MEMBER LEITO: What this looks like is  
10 that the preceptor is making four separate  
11 attestations.

12 DR. HOWE: They are. They are attesting  
13 whether they met the training and experience, either  
14 under the Board certification pathway or under the  
15 alternate pathway. So there's a choice there for one  
16 or the other. They are attesting that they have  
17 training for the types of use that are being sought.  
18 That's paragraph C.

19 MEMBER LEITO: So what this looks like is  
20 that four different people can make attestations.

21 DR. HOWE: Part of the -- the fourth  
22 attestation is -- he's essentially attesting that he  
23 meets the requirements to be a preceptor. That's the  
24 fourth block down there. The other three are the ones  
25 in the regulation.

1 MEMBER LEITO: Now I'm more confused than  
2 when I started talking.

3 DR. HOWE: A preceptor has to meet certain  
4 requirements. And so that's the fourth block.

5 MEMBER LEITO: Well, I understand that.  
6 But it's the attestation piece here that is extremely  
7 confusing. Because the preceptor is making the  
8 attestation that all these training and experience  
9 components have been achieved.

10 So why not just have that -- the pieces  
11 that they're attesting to and then there's one  
12 signature? It's like you're making them repeat the  
13 same thing four times -- five -- four times and then  
14 signing off. And I just don't understand what is it  
15 that we're trying to achieve by making them attest  
16 four times?

17 MEMBER WILLIAMSON: I think if you read  
18 the section two in the strikeout language, which is  
19 the only clear -- the strikeout version of the T&E, it  
20 indicates that there are four different things  
21 effectively -- well, actually about three different  
22 things in any give case that preceptor must attest to.  
23 That A1 and A2 or B1 and C were done -- one or the  
24 other.

25 Then has achieved a level of competency to



1 function independently as an authorized medical  
2 physicist for each type of therapeutic medical unit  
3 for which the individual is requesting authorized  
4 physicist status. So is that right? That's sort of  
5 three things.

6 CHAIRMAN MALMUD: Mr. Bailey?

7 MEMBER BAILEY: This is confusing to say  
8 the least. And I don't see why you can't simply have  
9 a statement that the information on this form is true  
10 and accurate. And get away from all of this other  
11 stuff.

12 If you've already had to put down the  
13 hours and everything, which they probably can't attest  
14 to, I'd like to see somebody attest to when I got  
15 training in radiation physics and instrumentation. No  
16 one alive today can remember that.

17 So I mean --

18 DR. HOWE: But as a preceptor, your  
19 preceptor can verify versus being the one providing  
20 you with the training back in the Dark Ages.

21 MEMBER BAILEY: but the records are on  
22 rocks.

23 (Laughter.)

24 DR. HOWE: So he can check the rocks out.

25 MEMBER BAILEY: I mean -- there are some

1 things that ought to -- it seems to me ought to stand  
2 for themselves. Board certification, which is  
3 current, should be able to stand for some of these  
4 things. You know if I went down and said where did I  
5 get my training on 35100, do I put down ACMUI  
6 meetings? And would that be a legitimate place to  
7 have learned it?

8 I mean I have to tell you, I have not gone  
9 through a course on any of these topics here. But  
10 somebody here would attest that I stayed awake, you  
11 know?

12 (Laughter.)

13 MEMBER BAILEY: So I'm not sure how these  
14 really relate to fundamentally knowing how to do a  
15 program. They relate to -- that somebody has put the  
16 regs in front of you? Or have you sat through a  
17 session on it? And it doesn't guarantee you anything.

18 DR. HOWE: That's a different question.

19 MEMBER WILLIAMSON: It is in the  
20 regulation though. There's an attestation for the  
21 device-specific training, an attestation for the  
22 modality-specific training, kind of a general  
23 attestation to competence -- level of competence to  
24 function as an AMP, and then attestation that the A1  
25 and A2 or B1 has been completed.

1 CHAIRMAN MALMUD: All right. Ralph and  
2 then I have a question.

3 MEMBER LEITO: Jeff, if you look at the  
4 form, okay, they have --

5 CHAIRMAN MALMUD: Which form?

6 MEMBER LEITO: The form AMP, the last  
7 page, the attestation on Part 2, okay? You've got to  
8 complete all of the following. There's I attest and  
9 then you fill in the blanks and check the boxes.

10 Then you go I attest again and you go like  
11 that. Why isn't there just I attest to each of these  
12 just as a bolded item and there's one signature. I  
13 mean the signature is there but it seems like we've  
14 made this whole page on something that could just fit  
15 into a matter of five lines. And why make it so  
16 difficult?

17 MEMBER WILLIAMSON: It's worse than that  
18 because, you know, it is quite possible that this  
19 might have to be filled in by three different people  
20 -- three different forms, partially filled out forms  
21 may have to be signed by different individuals. It  
22 might have been better to create one form with several  
23 signature blocks.

24 MEMBER LEITO: You can only have one  
25 preceptor. There is one preceptor form.

1 DR. HOWE: No. You can have more than  
2 one preceptor. But you have to have a form for each  
3 preceptor. And if you look at the top of the  
4 preceptor attestation, it says if more than one  
5 preceptor is necessary to document experience then,  
6 obtain a separate preceptor statement from each.

7 So there is a possibility that there is  
8 more than one preceptor. And that's why the form is  
9 the way that it is. And the preceptor has to attest  
10 to what the preceptor can attest to.

11 MEMBER LEITO: Then you need a signature  
12 for each piece then?

13 DR. HOWE: And so -- yes -- and so you  
14 put a check in the block and then the blocks that are  
15 checked, the signature is at the bottom.

16 MEMBER LEITO: But you only have one  
17 signature box. What I'm saying is if that's what  
18 you're saying, that you could have potentially four  
19 different preceptors --

20 DR. HOWE: But that's what the check is.  
21 The check is I attest that -- and you've checked that  
22 I attest block. Or say got the hands on device  
23 operation safety procedures clinical use and then the  
24 next one is you attest that the individual has gotten  
25 a level of competency. And then you fill out what

1 your requirements are and you sign.

2 You are signing for all the blocks you've  
3 checked. And someone else may have to sign for other  
4 blocks. Or for the same blocks for a different piece  
5 of device.

6 DR. MILLER: So if I understand you,  
7 Donna-Beth, what you're saying is then if there are  
8 multiple preceptors, then there would be multiple  
9 forms signed for those portions that the preceptor --

10 DR. HOWE: Could sign for.

11 DR. MILLER: -- did.

12 DR. HOWE: That's correct.

13 DR. MILLER: And in the end, you have to  
14 have a collection of signatures and attestations that  
15 cover all four.

16 DR. HOWE: That's correct.

17 CHAIRMAN MALMUD: Okay. I have a long  
18 question.

19 DR. HOWE: Tell us which form.

20 (Laughter.)

21 CHAIRMAN MALMUD: That's why I've been so  
22 patient with everybody.

23 DR. MILLER: Can you divide it into three  
24 parts?

25 (Laughter.)

1 CHAIRMAN MALMUD: It's actually more than  
2 three parts. Let's say that I had not attended this  
3 meeting, did not have the advantage of all the  
4 questions that were asked and answered. And I now  
5 take a look at Form AUD, 313 AUD. It's four pages  
6 long.

7 DR. HOWE: Yes.

8 CHAIRMAN MALMUD: I have just completed  
9 training. I'm young again. I just completed  
10 training in nuclear radiology in a Department of  
11 Radiology. And I know that I'm going to have to get  
12 Form 313 AUD and AUT and one more form signed, right?  
13 In order for me to fulfill Sections 190, 290, 390,  
14 392, 394, and 590, I'll have to have about three  
15 forms filled out.

16 DR. HOWE: You could fill out one --  
17 well, you might need multiple copies yes for 190, 290  
18 --

19 (Laughter.)

20 DR. HOWE: -- but 390 should suffice.  
21 You would not -- if you're going for the full 390,  
22 you would not need 392, 394.

23 CHAIRMAN MALMUD: But I would need 590.

24 DR. HOWE: If you wanted to do 590, yes.

25 CHAIRMAN MALMUD: Sure. And what about

1 190 and 290?

2 DR. HOWE: 190 and 290 you probably need  
3 separate forms. But there is also a provision that  
4 if you are authorized for 290, you could be an  
5 authorized user for 190. So you could select to just  
6 go for 290.

7 MS. GABRIEL: Speaking as a reviewer, I  
8 think we would accept one form to cover the 190, 290,  
9 590.

10 CHAIRMAN MALMUD: So actually you would  
11 accept one for 190, 290, and 590. But 390 would be  
12 separate?

13 MS. GABRIEL: Correct. When we tried to  
14 construct one form to cover all of those together, it  
15 became yet more complex.

16 CHAIRMAN MALMUD: So I will not need to  
17 fill out 392 and 394 if I do 190, 290, 390, and 590.  
18 If I do those four --

19 MS. GABRIEL: Correct.

20 CHAIRMAN MALMUD: -- I'm okay. And I  
21 don't have to do 392 and 394 separately.

22 MS. GABRIEL: Correct.

23 CHAIRMAN MALMUD: Okay. So here I am,  
24 I'm young again, just coming out of training as a  
25 nuclear radiologist. And I need to have these forms

1 filled out. So I take a look at Form 313AUD, page 1.  
2 Name of the proposed authorized user. That's me.  
3 I'm requesting 100, 200, and 500.

4 I'm just finishing training. I may or  
5 may not have Board certification yet. But let's say  
6 that I have Board certification. I'm okay.

7 And then -- so I check off Board  
8 certification. I'm certified.

9 Now I go to the next question. Question  
10 No. 2, current authorized user seeking additional --  
11 that doesn't apply to me because I'm not a current  
12 authorized user yet. Is that correct?

13 DR. HOWE: Yes, you're not an authorized  
14 user yet.

15 CHAIRMAN MALMUD: So I don't have to do  
16 that?

17 DR. HOWE: No.

18 CHAIRMAN MALMUD: Now I said this is  
19 going to be a long question. Now what if I'm Leon  
20 Malmud who is here physically today, older, do I need  
21 to go through this process again?

22 DR. HOWE: If you are currently listed on  
23 a license --

24 CHAIRMAN MALMUD: Yes.

25 DR. HOWE: -- you do not need to go



1 through this process. If you are --

2 CHAIRMAN MALMUD: So I'm Board --

3 DR. HOWE: -- if you are asking for the  
4 ability to be an authorized user for the same  
5 materials that you are authorized for use on a  
6 current license, you can go to another facility, use  
7 the fact you are an authorized user on an existing  
8 license to show that you meet the training and  
9 experience criteria. And you do not fill out the  
10 313A.

11 The 313A is for new people that are not  
12 listed as authorized users, medical physicists,  
13 pharmacists, RSOs, and that's who it is for.

14 CHAIRMAN MALMUD: So if I were to leave  
15 my current institution after 33 years and move to  
16 another institution down the street, I would not have  
17 to do anything except say I've been an authorized  
18 user at Temple where I am now and that's sufficient  
19 to get me authorized user status at the new  
20 institution?

21 DR. HOWE: For the uses that you had  
22 before and then we would probably ask for maybe the  
23 permit at the broad scope that indicated --

24 CHAIRMAN MALMUD: I'm sorry. I didn't  
25 hear the last -- you would ask for what?

1 DR. HOWE: The permit at the broad scope  
2 licensee that said you were an authorized user.

3 CHAIRMAN MALMUD: Okay. So that -- all  
4 right. Now we'll get back to this young fellow. I'm  
5 now back to my youth again.

6 DR. HOWE: Oh, but you could ask for --  
7 you could already be an authorized user and under the  
8 new rules, it wouldn't apply to you because  
9 diagnostic nuclear medicine included I-131 under --  
10 over 30 micro curies but under 33 in the old part.

11 But if you were a brand new person, then  
12 200 does not include whole body I-131 scans for  
13 patients that have already had thyroid carcinoma or  
14 other treatment. So you would come in under this  
15 Part 2.

16 CHAIRMAN MALMUD: Right.

17 DR. HOWE: You might.

18 CHAIRMAN MALMUD: But if I were to move  
19 to another institution, all I would need is evidence  
20 that I was already an authorized user and just move  
21 my authorized use permission to the new institution.

22 DR. HOWE: And the new institution would  
23 review it and approve it, if it is a broad scope. If  
24 it is a limited specific, they would then forward  
25 that information to the NRC and we would then list

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1 you on a license.

2 CHAIRMAN MALMUD: Okay. So now we're  
3 back to this young man whose just finishing training.  
4 He could be a young woman, but I don't want to go  
5 through a sex change right now. So at any rate,  
6 they've now checked off Box 1 Board certification.

7 Now we go -- no need to check off Box 2  
8 because he's currently not an authorized user. He's  
9 just finishing training.

10 He now turns the page and goes to  
11 training experience. And these boxes will be filled  
12 in by his training supervisor? His authorized user?

13 DR. HOWE: No, if he's Board certified  
14 then he provides his Board -- it says you have to  
15 select one of the three methods.

16 CHAIRMAN MALMUD: Yes.

17 DR. HOWE: And you have selected Box 1.

18 CHAIRMAN MALMUD: Right.

19 DR. HOWE: So once you have selected Box  
20 1, you do not select Box 2 or Box 3. But -- no --  
21 and this is a 200 user so there's no clinical  
22 experience there. That's already incorporated under  
23 your Board certification. But you do have to go to  
24 Part 2, the preceptor attestation.

25 CHAIRMAN MALMUD: And where does that

1 appear?

2 DR. HOWE: That's the very last page.

3 CHAIRMAN MALMUD: All right. So it seems  
4 to me that if I select Board certification, there  
5 should be a parenthesis there which says if you have  
6 selected Box 1, skip Box 2, skip Box 3 -- the same  
7 way it does on our 1040 forms where it tells you what  
8 to skip.

9 DR. HOWE: Well, we thought select one of  
10 the three methods below would do that but --

11 CHAIRMAN MALMUD: I don't think it's  
12 optimal.

13 DR. HOWE: -- it's not doing the trick.

14 CHAIRMAN MALMUD: It's not optimal.

15 DR. HOWE: And we just said A and B.

16 CHAIRMAN MALMUD: No one has had more  
17 experience in dealing with the public than the IRS.  
18 I think they're a good role model for this.

19 (Laughter.)

20 DR. HOWE: Okay, your point is taken.

21 CHAIRMAN MALMUD: So I would do that.

22 And now, naive as I am, have skipped  
23 Boxes 2 and 3 and gone to --

24 DR. HOWE: Part 2.

25 CHAIRMAN MALMUD: -- Part 2. Now you'll

1 notice at the top of page 2 of 4 has Box 3. And then  
2 it has under it an A and a B. And then we go to page  
3 3 of 4 and there's a 3 again. Does that mean 3  
4 continued?

5 DR. HOWE: Three continued, yes, it does.  
6 And the table, supervised work experience, is  
7 continued on to page 3 of 4.

8 CHAIRMAN MALMUD: Okay. So I can still  
9 skip that because I'm skipping 2 and 3. I've  
10 followed your directions on page 1.

11 DR. HOWE: Yes.

12 CHAIRMAN MALMUD: And now I'm on the  
13 preceptor attestation statement.

14 DR. HOWE: Yes.

15 CHAIRMAN MALMUD: And here it says Board  
16 certification. So my supervisor has certified that  
17 I have satisfactorily completed requirements.

18 DR. HOWE: Yes.

19 CHAIRMAN MALMUD: That doesn't mean that  
20 I'm certified does it?

21 DR. HOWE: No. He does not have to --  
22 you can get the preceptor statement. This was --  
23 goes back to her question. You can get the preceptor  
24 statement that you have completed the training  
25 requirements for the certification before you pass

1 the examination. So you could get the preceptor  
2 statement before you take the test.

3 Now when it comes to the NRC, we're going  
4 to look to see that at least when it comes to us,  
5 you've already got your certification which indicates  
6 you passed the exam.

7 CHAIRMAN MALMUD: Yes.

8 DR. HOWE: and then we'll look at this  
9 attestation that says that the person attests that  
10 you had the training --

11 CHAIRMAN MALMUD: Okay.

12 DR. HOWE: -- and the work experience.

13 CHAIRMAN MALMUD: So my preceptor has  
14 attested to my Board certification. Or he has  
15 attested or she has attested to my training and  
16 experience.

17 DR. HOWE: You're Board certified so he's  
18 just going to attest to your Board certification.

19 CHAIRMAN MALMUD: Okay. But let's say I  
20 haven't passed Part 2 of the boards yet. I've only  
21 taken the written but not the orals yet. Or I  
22 haven't passed a section or it, God forbid. So now  
23 he has to attest to my training and experience.

24 DR. HOWE: He could. He doesn't have to.

25 CHAIRMAN MALMUD: He doesn't have to

1 obviously. He's not obligated.

2 DR. HOWE: You may hold this form in  
3 abeyance until you've got your certification. And  
4 that's what would happen. You would provide this  
5 form once you got your certification.

6 CHAIRMAN MALMUD: Okay. Now I am also  
7 applying for 290. So we go through the same thing  
8 there.

9 DR. HOWE: Yes, that's correct.

10 CHAIRMAN MALMUD: And that completes that  
11 form.

12 DR. HOWE: The preceptor has to complete  
13 the bottom that says that the preceptor meets certain  
14 requirements. And then he signs it and provides the  
15 information. The form is complete.

16 CHAIRMAN MALMUD: That's not very  
17 difficult at all. That's pretty straightforward.

18 DR. HOWE: We thought so.

19 CHAIRMAN MALMUD: Now we go to 313AUT.

20 DR. HOWE: Okay. Wait a minute. AUT.

21 CHAIRMAN MALMUD: It's the next page.

22 Page 1 of 8. Now do I need to do that having done  
23 313AUD? Must I now do 313AUT?

24 DR. HOWE: 313AUD only authorizes you for  
25 those unsealed materials that require no written

1 directive. If you want to administer greater than 30  
2 micro curies of I-131, then you will need to fill out  
3 AUT.

4 CHAIRMAN MALMUD: And I certainly do wish  
5 to.

6 DR. HOWE: So you're now working on AUT.

7 CHAIRMAN MALMUD: I want to work with as  
8 little as one millicurie up to 300 millicurie, 300 if  
9 necessary.

10 DR. HOWE: Okay.

11 CHAIRMAN MALMUD: So I'm now going to  
12 fill out --

13 DR. HOWE: Do you only want to use iodine  
14 or you want permission to use other materials?

15 CHAIRMAN MALMUD: Other materials as  
16 well.

17 DR. HOWE: So then we would -- you would  
18 come under the full 390. Okay?

19 CHAIRMAN MALMUD: Okay. So --

20 DR. HOWE: So you would check 35300, use  
21 of materials for which a written directive is  
22 required.

23 CHAIRMAN MALMUD: And now we go down to  
24 the next -- Part 1 T & E, we check off Board  
25 certification because we all assume that I'm Board

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1 certified.

2 DR. HOWE: Okay. And your certification  
3 is recognized under this, yes.

4 CHAIRMAN MALMUD: Now it says current  
5 authorized user seeking additional authorization.  
6 Now we go back to the older man. And I may be  
7 seeking additional authorization for something that  
8 I haven't done before.

9 DR. HOWE: Yes.

10 CHAIRMAN MALMUD: So I would then fill  
11 out this form --

12 DR. HOWE: Yes.

13 CHAIRMAN MALMUD: -- but who will have --  
14 who will attest to that for me?

15 DR. HOWE: The person that is providing  
16 you the new -- the person that is verifying that you  
17 had this new training and experience.

18 CHAIRMAN MALMUD: Just the new training  
19 and experience?

20 DR. HOWE: Yes.

21 CHAIRMAN MALMUD: Great. Okay. So that  
22 is easily accomplished.

23 Now we move to the next page, page 3 of  
24 8. Supervised work experience. That relates only to  
25 those who are not Board certified? Or do those who

1 are Board certified require that to be filled out as  
2 well?

3 DR. HOWE: The Board certification people  
4 do not require the supervised work experience or the  
5 classroom and laboratory training.

6 CHAIRMAN MALMUD: Therefore -- oh, excuse  
7 me.

8 DR. HOWE: Yes?

9 CHAIRMAN MALMUD: Therefore, if we go  
10 back to page 1 of 8, it should say if you've checked  
11 off Board certification, skip Section so and so and  
12 so and so.

13 DR. HOWE: We could certainly put that  
14 in.

15 CHAIRMAN MALMUD: The same way --

16 MEMBER NAG: Except in 396.

17 DR. HOWE: But you do have to come down  
18 to -- well, the 396 part. You do have to provide C,  
19 supervised clinical case experience because the Board  
20 certification has been decoupled from the clinical  
21 cases. So you would have to provide the information  
22 and clinical case experience.

23 CHAIRMAN MALMUD: So it would say if you  
24 are checking off Board certification, skip Section 2A  
25 and B but complete Section 2C?

1 DR. HOWE: Right. And under C, we say  
2 for 390 provide documentation of supervised clinical  
3 experience. So that's C.

4 CHAIRMAN MALMUD: Okay. So we're now up  
5 to page 5 of 8.

6 DR. HOWE: Yes.

7 CHAIRMAN MALMUD: Now we turn to page 6  
8 of 8. Now comes the preceptor attestation.

9 DR. HOWE: Correct.

10 CHAIRMAN MALMUD: And this is just the  
11 attestation for 390, which is unsealed byproducts,  
12 392, which is oral administration of I-131 --

13 DR. HOWE: But you've indicated that you  
14 are coming in for the full 390 authorization.

15 CHAIRMAN MALMUD: Right.

16 DR. HOWE: So once you check 390, you do  
17 not have to check 392 or 394 or 396.

18 CHAIRMAN MALMUD: Okay. Then I would  
19 suggest with --

20 DR. HOWE: And we told you to check one  
21 of the following for each requested authorization.

22 CHAIRMAN MALMUD: I would suggest that  
23 where it says on page 6 of 8, if you're checking 390,  
24 you need not fill out 392, 394, or 396.

25 DR. HOWE: Okay. We can do that.

1 CHAIRMAN MALMUD: All right. Then we go  
2 to page 8 of 8. And that's just a part that requires  
3 some signatures.

4 DR. HOWE: That's correct.

5 CHAIRMAN MALMUD: All right. Now that  
6 completes it really.

7 DR. HOWE: Yes, that completes it for  
8 you.

9 CHAIRMAN MALMUD: I beg your pardon?

10 DR. HOWE: That completes it for you.

11 CHAIRMAN MALMUD: So having gone through  
12 this as a naive individual who did not attend this  
13 meeting and did not hear any of the intelligent  
14 questions asked or responded to, this is not very  
15 challenging.

16 (Laughter.)

17 DR. HOWE: We hope that's true, yes.  
18 That's our objective.

19 CHAIRMAN MALMUD: I had you to lead me  
20 through it but you have now recommended that there be  
21 some parenthesis next to some of these Board  
22 certifications to indicate which sections can be  
23 skipped. And you've created forms which I think are  
24 not very demanding of a program director.

25 Now we have already told our residents a

1 long -- well, some time ago, you better keep track of  
2 every therapy patient by some method so that you can  
3 prove to us that you really had that experience since  
4 we're not going to track those patients for you. And  
5 they're doing that. Meaning the I-131 therapy  
6 patients and so on.

7 So I think this is not a burdensome role  
8 for a training director. Now I'm no longer a  
9 training director. So I can't speak for them. I did  
10 it in the past but not now. But it doesn't seem to  
11 me that it is onerous.

12 Does anyone on the committee feel that  
13 this is onerous with this explanation having been  
14 offered to us?

15 DR. HOWE: I think I'd also like to  
16 mention that we are planning on providing guidance in  
17 NUREG-1556, Vol. 9, so that you will have a little  
18 bit more to help you through the forms than just the  
19 forms.

20 But we do think Sandy has created forms  
21 that you can pretty much go through without a lot of  
22 additional --

23 CHAIRMAN MALMUD: Well, even I could work  
24 through them with your help in the space of a few  
25 minutes. So I'm certain that they are efficient.

1 And my hat is off to both Sandy and to you for having  
2 created these forms which with a couple of little  
3 tweaks are understandable even by me.

4 So I thank you. And since the committee  
5 agreed with me -- I didn't see any opposition --

6 MEMBER SCHWARZ: I'm sorry. I'm not  
7 opposing. I'm asking. In this AUT form where you  
8 are doing training and experience for 396, where it  
9 says fill out Tables 3B and 3C, should it just be 3C?

10 CHAIRMAN MALMUD: Yes.

11 MEMBER SCHWARZ: So there is listing a  
12 direction of 3B on there as well.

13 DR. HOWE: For 396, you have to provide  
14 evidence that you have -- you are Board certified  
15 through the brachytherapy certification pathway or  
16 the therapy device pathway. And so you have to  
17 provide documentation of your 80 hours of training  
18 and experience in unsealed materials. And so you  
19 would have to fill out these forms, yes.

20 And if you go to 396, I think you'll find  
21 out that you've got 80 hours and you've got to do the  
22 A part, which is the classroom laboratory, because  
23 those subjects, radiation, physics, instrumentation  
24 is what you have to fill out.

25 And then you have to have work experience

1 under somebody. And then you have to fill out the B  
2 one for the work -- because of that work experience.  
3 And involved is also your three cases. And your  
4 three cases are over in C I believe.

5 So you do have to go and fill out the  
6 tables for the alternate pathway for 396 because your  
7 Board certification is coming from 35400 and 35600  
8 uses.

9 CHAIRMAN MALMUD: Mr. Leito?

10 MEMBER LEITO: I'd like to go back over  
11 this form that you just went over.

12 CHAIRMAN MALMUD: Yes? Which form?

13 DR. HOWE: The AUT?

14 CHAIRMAN MALMUD: Which form? Which  
15 page?

16 MEMBER LEITO: AUT.

17 CHAIRMAN MALMUD: AUT?

18 MEMBER LEITO: It says at the top okay  
19 request authorization, check all that apply. All  
20 right? So is that supposed to be 390? You told me  
21 these were typos here but is it supposed to be --

22 DR. HOWE: Oh, no, I'm sorry. These are  
23 not typos. This is 35300. And the first one is if  
24 you're going for all uses under 35300, you check that  
25 box.

1           If you're going for just oral  
2 administration or oral administration greater than a  
3 certain activity, you're going for the parental  
4 administrations of the betas and the gammas, then you  
5 check that block. And if it is the others, then you  
6 check that one. So those are not typos. I'm sorry.  
7 I hadn't seen the form quite quickly enough. Those  
8 are not typos. And --

9           MEMBER LEITO: That's, I think -- because  
10 I think this is supposed to be training and  
11 experience. And I think it indicated here the  
12 training experience that you are supplying, which  
13 identifies the use, wouldn't it be 35390, 392, 394,  
14 396? Right there --

15           DR. HOWE: The actual uses are up in 300.

16           MEMBER LEITO: Okay.

17           DR. HOWE: And the training and  
18 experience with those uses is in 390, 392, 394, 396.  
19 We could --

20           MEMBER LEITO: Well, then I guess I'm --

21           DR. HOWE: -- we could put something in  
22 here that maybe more clearer explains which training  
23 route you're coming through.

24           MEMBER LEITO: Because I think under the  
25 Board certification route, okay, it's like, okay,



1 what Board certification satisfies 394?

2 DR. HOWE: Right now? None. The  
3 American Board of Nuclear Medicine is authorized  
4 under 390 because they get the whole ball of wax.

5 MEMBER LEITO: Okay.

6 DR. HOWE: So they come under 390. You  
7 don't have to provide anything additional.

8 MEMBER LEITO: All right. So -- and then  
9 490 therapy would be --

10 DR. HOWE: To use unsealed materials  
11 would then come under 396. Or we might have some 400  
12 or 600 physicians that may also want to deliver  
13 therapeutic I-131. So they may come under 394.

14 MEMBER LEITO: Okay. Under Board  
15 certification 1A, if Board certification is older  
16 than seven years. I mean you could have a Board  
17 certification longer than that. Don't you mean  
18 recentness of training? Or I mean it's not the Board  
19 certification that's the seven year requirement.  
20 It's recentness of training. Am I making my point?

21 DR. HOWE: It is the recentness of  
22 training. And I think we put it in there and we may  
23 have to write it a better way.

24 MEMBER LEITO: Yes, it's just that it  
25 makes it a Board certification from the Dr. Malmud

1 from the 70s, I mean you're still going to meet that  
2 as long as you demonstrate --

3 MEMBER NAG: Recentness of training.

4 MEMBER LEITO: -- recentness of training  
5 and continued use. And I think that's what the  
6 intent is here. But it's not what it states.

7 MEMBER NAG: Right.

8 MEMBER WILLIAMSON: Yes, I guess to add  
9 to what Ralph just said, in this case where the Board  
10 certification there was gap or interruption and you  
11 had the Board certification. It was older than seven  
12 years, what exactly do you have to provide? Which  
13 parts of this form do you have to fill out to  
14 document recentness of training?

15 DR. HOWE: We get a few cases every few  
16 years of people that were Board certified. And this  
17 is not under the new rule but under the old rule,  
18 that are Board certified 26 years ago, never listed  
19 as an authorized user, went into the administrative  
20 area of medicine and stayed there. And now they're  
21 ready to retire and they want to get more into the  
22 clinical side of things.

23 And we treat those on a case-by-cases  
24 basis. And that we pretty much consider the  
25 alternate type of pathway. We don't require them to

1 fill out these forms. But we do require them to  
2 provide information on their training and experience  
3 in the last seven years.

4 MEMBER WILLIAMSON: Okay. So maybe you  
5 might want to put a line here that -- instructing  
6 them perhaps to prepare a separate letter or  
7 somewhere in the instructions to these forms  
8 indicating that that class of authorized user  
9 applicants should not fill out these forms.

10 MEMBER NAG: Donna?

11 DR. HOWE: Well, we do have guidance that  
12 we'll be developing in the NUREG and we can go into  
13 more detail there.

14 MEMBER NAG: Donna, do you mean that the  
15 interruption is for more than several years. And we  
16 can go into more detail there.

17 MEMBER NAG: Donna, do you mean that the  
18 interruption is for more than seven years? Or the --

19 DR. HOWE: Even if the interruption is  
20 less than seven years, then we look to see what your  
21 experience was in the last seven years. And if your  
22 experience in the last seven years was you weren't on  
23 a license for one of those seven years, we don't  
24 expect you to do much more. And we'll go ahead and  
25 put you on a license.

1           But we do have to look to see how long  
2           you've been away. Most of the ones that we really  
3           get into are those that have been out of field for  
4           significant periods of time.

5           CHAIRMAN MALMUD: With that, may we take  
6           a break because we have the public session that is  
7           supposed to be getting -- at 3:15?

8           I want to thank you both, Dr. Gabriel,  
9           Dr. Howe.

10          Dr. Suleiman?

11          MEMBER SULEIMAN: Yes, one question.  
12          These haven't been OMB cleared yet?

13          DR. HOWE: No, they have not.

14          MEMBER SULEIMAN: So that will take  
15          another --

16          DR. HOWE: We are distributing them to  
17          the Advisory Committee for your comments. We'll be  
18          developing the guidance. And then we'll be putting  
19          both the guidance and the forms out for public  
20          comment during the OMB clearance process. So the  
21          forms cannot be used until they have OMB clearance.

22          MEMBER SULEIMAN: So these may not see  
23          the light of day for at least six to twelve months if  
24          not longer unless you get through --

25          DR. HOWE: Six months is what we're

1 hoping.

2 MEMBER SULEIMAN: You don't bet do you?

3 (Laughter.)

4 DR. HOWE: Well, we have revised -- we  
5 did revise the 313A that was up on the web that's the  
6 official document. We just got a new OMB clearance  
7 for the last 313A.

8 We took out all the Subpart J  
9 requirements because that went on the web today.  
10 Subpart J is no longer in effect for us. That's the  
11 only change we made to that 313A form. But these  
12 will have to go through OMB clearance.

13 MEMBER BAILEY: Could we get a copy of  
14 what became official today?

15 DR. HOWE: Yes. I can print it out for  
16 you. It's up on our website.

17 MEMBER BAILEY: I don't have a computer.

18 DR. HOWE: That's okay. I'll print it  
19 out for you.

20 CHAIRMAN MALMUD: Thank you. We'll  
21 resume at 3:25. Thank you.

22 (Whereupon, the foregoing matter went off  
23 the record at 3:14 p.m. and went back on the record  
24 at 3:29 p.m.)

25 CHAIRMAN MALMUD: The next session will be

1 - the presenter for the next session will be Dr. Sami  
2 Sherbini, and the topic is the status of guidance on  
3 reducing doses to members of the public.

4 Thank you.

5 DR. SHERBINI: Thank you.

6 We had discussed at a previous meeting  
7 the guidance is now finished. It's just about to be  
8 issued. It's probably in a couple of days in fact.

9 We have put the guidance out for  
10 comments, and we received a lot of comments, most of  
11 them favorable comments. And we've incorporated most  
12 of them in one way or the other.

13 Some of them we were unable to  
14 incorporate either fully or in some cases maybe  
15 partially. Just to give you some idea on why we did  
16 not incorporate some of the comments, the reasons why  
17 we did not do so.

18 So this is one of the comments that we  
19 did not incorporate fully. Several commenters  
20 objected to the fact that we refer to using such  
21 treating facility as a cheap easy-to-use alternative  
22 for monitoring visitors.

23 We modified the risks and softened that  
24 statement somewhat by saying that in some cases it  
25 might be an expense that is not justified, but some

1 other way could be found to provide real-time control  
2 of the doses.

3 So that was just partially adopted.

4 Please be consistent with use of  
5 radiation terminology. Use SI units. And so forth.  
6 And do not interject TEDEs.

7 We incorporated this partially. The NRC  
8 policy is to use both the old and the new units. The  
9 new units followed by the old ones in parens.

10 Unfortunately we have to use TEDEs  
11 because that is the quantity licensees are required  
12 to show compliance to, which is the sum of both  
13 internal and external. So since there is always a  
14 potential for external dose, then it is necessary to  
15 show that the TEDE does not exceed this.

16 TEDE is the name that currently being  
17 used in the industry for the sum of the external and  
18 internal doses. Unfortunately ICRP did not define  
19 this or give it a name, so each agency essentially  
20 names its own quantities using TEDE.

21 And so the use of TEDE is inescapable.

22 We also used Rankin in that guidance.  
23 And the reason we used Rankin is that a lot of the  
24 survey instruments and the subtreating dosimeters, et  
25 cetera, are still calibrated to Rankin. So this

1 being the practical guidance, we thought it would be  
2 appropriate to discuss this in terms of units that  
3 are normally seen on the instruments.

4 The use of the rakin is also still  
5 allowed by the ICLU, so it's not such a big issue  
6 from the SI system.

7 It was suggested that measuring excreta  
8 should be deleted from the guidance. We had  
9 something that the intention was not to actually do  
10 bioassays or anything like this. The intention was  
11 that if there is any data on excreta that sometimes  
12 urine is collected in shielded bottles and surveyed.

13 This is the kind of data we have in mind.  
14 It would help us if we had to do those  
15 reconstructions if we had this kind of data  
16 available.

17 And so we modified the write-up slightly  
18 to indicate this.

19 It was suggested that the retrospective  
20 dose reconstruction be removed from the document.  
21 The intent wasn't to discuss how to do dose  
22 reconstruction, but merely to indicate what kind of  
23 data should be collected if such a reconstruction was  
24 to be done. So we clarified this point. Just tell  
25 us what kind of data we should have in hand. It does



1 not tell how to do the reconstruction.

2 The suggestion was made to change from  
3 the first to the second. Although the proposed  
4 rheolite is good, it changes the meaning of the  
5 sentence. The first sentence intended to highlight  
6 the fact that control is paramount. And that is why  
7 we say they were inadvertently permitted to exceed  
8 the dose, indicating that control was not as good as  
9 it should have been.

10 The second sentence does not have that  
11 thought in it, and so we decided to leave the first  
12 sentence as is.

13 MEMBER VETTER: Doesn't the first  
14 sentence imply that the licensee knew, a priori, that  
15 the member of the public would receive a dose in  
16 excess of the limits?

17 DR. SHERBINI: Well, either knew or  
18 should have known, either way it was permitted. In  
19 other words, the licensee is in control. The failure  
20 of control could be because the licensee didn't know,  
21 or because the visitor did not cooperate.

22 But in either case, the licensee should  
23 be control in the sense of knowing what is going on.  
24 And that was the thought we wanted to highlight by  
25 putting "permitted" in there. Because whatever

1 happens at the licensee's facility is either  
2 permitted by the licensee, or at least it is done  
3 with the knowledge of the licensee at the very least.

4 We realize sometimes the licensee can't  
5 do anything about it, but at least we know about it.  
6 So that is the point here.

7 CHAIRMAN MALMUD: Dr. Sherbini?

8 DR. SHERBINI: Yes, sir.

9 CHAIRMAN MALMUD: Even with the wisdom of  
10 hindsight, how would you have prevented that  
11 individual from receiving doses in excess of the  
12 regulatory permit?

13 DR. SHERBINI: You probably couldn't  
14 help, in the risk that if this situation is seen to  
15 be approaching, then the NRC should be notified. And  
16 the notification implies two things, that something  
17 might be done by the NRC about it, or at least that  
18 the licensee is in control and knows what is going to  
19 happen imminently. So that's basically it.

20 CHAIRMAN MALMUD: The committee certainly  
21 agreed, and in fact, discussed the fact that had NRC  
22 been notified in a contemporaneous fashion that  
23 perhaps this incident would not have escalated to the  
24 level.

25 However, those two sentences don't relate

1 to that. They relate to how the member of the public  
2 received the doses. And I prefer your second  
3 sentence to the first one, your second introduction  
4 to the first one, quite frankly.

5 DR. SHERBINI: I see your point.

6 There was an item that had to do with  
7 internal contamination. We did not delete preference  
8 in front of contamination, but we softened it and  
9 clarified it a bit.

10 The point is, there is always a  
11 potential. And if there is a potential the licensee  
12 is required to do a survey.

13 By survey we mean that at the very least  
14 to be aware or to state that there is no protection.  
15 That is all that is intended here.

16 Of course if there is a potential, then  
17 appropriate measurements would have to be taken.

18 Another suggested change was - I  
19 personally didn't like the second, because it puts  
20 the onus on the visitor, whereas really the onus is  
21 on the licensee. The visitor doesn't comply with  
22 anything except maybe directions of the licensee if  
23 they had to comply with them.

24 But the idea of compliance does not  
25 really apply to a visitor.

1 Yes, sir.

2 MEMBER VETTER: Excuse me, but yes,  
3 certainly the licensee is in the final analysis  
4 responsible, but we as licensees don't have the  
5 authority to throw a visitor out of a room. If a  
6 patient walks out of a hospital, regardless of  
7 whether they have radioactivity in them, if they  
8 simply walk away that's in violation of a joint  
9 commission regulation.

10 There are some things that are beyond the  
11 control of a hospital, and so to say we lack  
12 sufficient control of visitor activities, I'm just  
13 thinking that is a little strong.

14 DR. SHERBINI: We're not implying control  
15 in the sense of physically restricting the activities  
16 of a visitor. By control we mean, as I said earlier,  
17 the very lowest level of control is awareness, and we  
18 can take it to that level. We recognize that the  
19 visitor can say, no, I'm not going to do what you're  
20 telling me, and you can't do anything about it.

21 MEMBER LEITO: That's not what you're  
22 saying. You are saying that even though the  
23 awareness was there, okay, the physical barriers,  
24 physical signs, instruction, that lack of compliance  
25 by the visitor with all those requirements, or those

1 guidelines, that that's not what's here. You're  
2 basically throwing that out again. You're just  
3 saying that lack of sufficient control of visitor  
4 activities.

5 DR. SHERBINI: No.

6 MEMBER LEITO: The controls were there.  
7 The instructions were there. The visitor  
8 consciously, that is sort of analogous to what Dr.  
9 Eggli's example was about you have all these - you  
10 have all these proper instruction and everything is  
11 in place, and if someone willfully decides not to  
12 comply, you can't necessarily say that the licensee  
13 didn't have control of the problem.

14 DR. SHERBINI: But we can in the sense  
15 of, at least in the case we had in mind, that the  
16 licensee did not really know that the dose was going  
17 to be exceeded by quite a few of the visitors, and  
18 that is from our regulatory perspective, that is lack  
19 of control.

20 Control may be an unfortunate word, but  
21 implies physical restriction or something of the  
22 sort. Control in this sense means that the situation  
23 doesn't run away from the licensee, meaning that  
24 people don't get doses when they don't know about it.  
25 They can get doses when they know about it, call the

1 NRC, get exemptions, et cetera.

2 But you need to know what is going on.

3 DR. WILLIAMSON: That may be a good point  
4 to make, but I think you should then expand that  
5 sentence into a paragraph that makes the different  
6 subtle distinctions between different forms of  
7 control, rather than assume everybody understands  
8 that. Because what you're hearing is that that is  
9 not the common ordinary language and interpretation  
10 of the word, control.

11 MEMBER NAG: At our previous meeting with  
12 the commissioners, I think the commissioners were  
13 very much aware, and they were very much sympathetic,  
14 to the fact that there may be a loved one who, even  
15 though the licensee is under control, the licensee  
16 has told the person. That person consciously decided  
17 to - I would do something - but decided to go above  
18 the limit, and I think the commissioners were very  
19 sympathetic that this is something that we should  
20 find a way to permit the visitor to do without  
21 violating some rules.

22 DR. SHERBINI: Yes, we are working on  
23 that. As I would indicate in a few minutes. But  
24 even under this provision, even if there was a  
25 provision, the provision will require the licensee

1 to request from the NRC some kind of exemption from  
2 the default limits, which means call the NRC and say,  
3 we have this person who is about to exceed the  
4 default limits. We need to increase to another  
5 limit.

6 It still doesn't get away from the  
7 control issue, which is, in order to do that, you  
8 need to know what is going on. You need to know that  
9 this person is about to go over 100, and therefore  
10 call the NRC before you do.

11 MEMBER NAG: But many times we may not  
12 know what those limits are going to be. We know that  
13 it may be potentially a problem. For example, I  
14 treat children all the time. And the mother of the  
15 child may say, I want to be with that child. I  
16 wouldn't know beforehand what that dosage would be,  
17 but I would know potentially it will be over the  
18 limit. So we will ask potentially - we see the  
19 potential problem. We want to be allowed to exceed  
20 the limit.

21 DR. SHERBINI: That would be acceptable.  
22 That would be what we are looking for basically.

23 CHAIRMAN MALMUD: Dr. Sherbini, we have  
24 a visitor from the University of Pennsylvania who  
25 wishes to make a comment if he may.

1 DR. SHERBINI: Oh, sure.

2 MR. FORREST: Hi, Rob Forrest, University  
3 of Pennsylvania.

4 When the outpatient guidance came out,  
5 the NRC issued something to the effect that, I don't  
6 know if it was in a RIS (phonetic) or something else,  
7 that the licensee would not be held responsible if  
8 the patient did not follow their instructions, which  
9 would potentially lead to the same situation you're  
10 discussing.

11 So I'm a little concerned that the same  
12 principle doesn't apply to an in-patient, if a  
13 visitor, you give them instructions, you give them  
14 training, you give them whatever, they choose  
15 purposefully not to follow those instructions, why  
16 the same principle doesn't apply.

17 DR. SHERBINI: Because it's not the same  
18 situation. The example you give would be analogous  
19 to a situation where the licensee did not realize  
20 that the patient needed to be given instructions, and  
21 just was let go basically, because the licensee was  
22 not aware that the dose did not meet the criteria, or  
23 did not require provision of instructions or  
24 something.

25 This would be the analogous situation.



1 In other words, if the licensee knows what is  
2 required of them, provide instructions. The patient  
3 goes out, doesn't follow the instructions; that is  
4 one situation. If the licensee releases the patient  
5 when instructions should be given, but the licensee  
6 fails to give that instruction, that is a wholly  
7 different situation. That is a loss of control.

8 That is what we are talking about here.  
9 We are talking about the visitor who is in the room.  
10 The licensee has the responsibility to recognize at  
11 least there is a potential there. The doses are  
12 high, there is a potential based on the behavior of  
13 the visitor, that this dose is going to be exceeded.  
14 But there is not going to be a way to keep it within,  
15 say, 100, and therefore action is called for. Call  
16 NRC, get the higher dose limit, get an exemption,  
17 whatever.

18 And that is what we mean by control.

19 MEMBER FORREST: I think I would have to  
20 agree with Dr. Vetter. You are asking us to do  
21 things we can't do. There are positions where we can  
22 say, you sit in this chair, and if we come in the  
23 next morning and they are on the other side of the  
24 shield, how could we possibly have known without  
25 doing some psychoanalysis on the person that they

1 weren't going to follow our instructions? It's  
2 impossible.

3 DR. SHERBINI: That is your  
4 responsibility as a licensee.

5 MEMBER NAG: No, I'm telling you, I don't  
6 agree with that. Our responsibility is to instruct  
7 the patient and the visitor. We have to instruct  
8 them. We have to let them know potential problems.  
9 And if they willfully desire to exceed that, that is  
10 not under our control.

11 We can tell them and advise them. And  
12 that is all.

13 DR. SHERBINI: There is a factor that we  
14 are not mentioning here. And that is the dose rate.  
15 And this example is really important. The dose rate  
16 is important, because it will tell you what is likely  
17 to happen.

18 We have somebody sitting in the room  
19 overnight, and the dose rate is two millirem per  
20 hour, it is unlikely by the morning it will have  
21 exceeded 100 millirem. But if the dose is 50 or more  
22 per hour, then I would think the licensee would have  
23 to do something about it, even put somebody up all  
24 night to make sure that this person doesn't go behind  
25 - because the dose rate controls how quickly the

1 situation can run away from you.

2 MEMBER NAG: Right, but the dose rate  
3 depends whether you are sitting on the other side of  
4 the lead shield, or whether the placing of the  
5 visitor had gone on their own away from the shield.  
6 That's not up to the control of the licensee. The  
7 licensee can instruct and say, you do not go around  
8 the other side of the shield. But if the visitor  
9 decides to go on the other side of the shield, there  
10 is really nothing I or my safety officer can do other  
11 than physically pulling the visitor out.

12 DR. SHERBINI: Okay. I guess we are  
13 going around here in circles. Basically the  
14 situation that elicited all of this was that the  
15 visitor was actually going behind the shields, and  
16 was actually approaching the patient, and the dose  
17 rates were notably quite high.

18 So even back of the envelope  
19 multiplication would have quickly alerted anybody  
20 that this patient is no way going to stay within the  
21 dose limit; no way. It doesn't take much to do even  
22 in your head.

23 But despite all of that, despite the  
24 existence of those rates of a couple of hundred per  
25 hour, nobody could know.

1 Now, we can't say --

2 MEMBER FORREST: It's not true.

3 DR. SHERBINI: Well, the overexposures  
4 were discovered several days or weeks afterwards, at  
5 least the records indicate that that is what  
6 happened. But that was our concern.

7 CHAIRMAN MALMUD: Mr. Bailey.

8 MEMBER BAILEY: Earlier we talked a  
9 licensee being responsible for an employee who  
10 violated, directly violated procedures and everything  
11 else.

12 And now it seems as though we're taking  
13 it a step beyond even the employee; we're taking it  
14 to a member - to someone that the hospital or the  
15 licensee does not employ, does not have police power  
16 or anything else, and making nit a violation of the  
17 licensee.

18 And to me that is going at least one step  
19 too far.

20 DR. SHERBINI: No, I think there is a  
21 step which you left out, which is that if the  
22 licensee notifies the NRC before this happens that  
23 there is not going to be a violation.

24 MEMBER BAILEY: But how would you know  
25 that the person was going to go around the shield?

1 DR. SHERBINI: The person is in the  
2 hospital. There is stuff there. And if the dose  
3 rates are high, and if the visitor shows that they  
4 are not about to obey instructions, then you know  
5 that the dose is going to be high.

6 MEMBER BAILEY: Well, I would pose a  
7 hypothetical situation. The person is there in the  
8 room, outside the shield. They perceive something is  
9 going on with their loved one, and they say the heck  
10 with the instructions you gave them, and they run  
11 around the shield.

12 DR. SHERBINI: And many of them do it.

13 MEMBER BAILEY: Would that be something  
14 that the licensee could logically assume is going to  
15 happen and therefore they should ask permission in  
16 case it did?

17 This seems to me to be a medical event;  
18 not a violation.

19 CHAIRMAN MALMUD: Dr. Williamson

20 MEMBER WILLIAMSON: I think I have to  
21 agree with Dr. Sherbini on part of this. I think  
22 that it is reasonable to make a distinction between  
23 being responsible for a visitor's behavior versus  
24 being responsible for making a reasonable effort to  
25 ensure that the visitor is following instructions

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1 while in the licensee's facility.

2 And I think that it is a reasonable  
3 injunction to make in an RIS to say that licensees  
4 should be aware, and make an effort to be aware of  
5 whether visitors are complying with the procedures or  
6 not.

7 And if they are not, and it looks like  
8 there is a significant chance of exceeding limits,  
9 then the user has some recourse to ameliorate the  
10 regulatory fall out from that event. I think that is  
11 reasonable.

12 I think part of the problem we have is  
13 that the specific incident at the hospital that we  
14 keep returning to, there is a lot of - there was sort  
15 of a nasty incident in the sense that there were very  
16 different stories told by different people, by the  
17 people in the hospital, by the inspectors who  
18 inspected the facility.

19 And I don't think we should be arguing  
20 too much over the particulars of that incident. But  
21 what is reasonable guidance in a situation like this,  
22 in general, quite apart from that incident.

23 DR. SHERBINI: I think we are - Dr.  
24 Williamson is well taken, that maybe we should take  
25 away the control word, and explain what we mean.

1                   MEMBER WILLIAMSON: I think that would be  
2 very wise. Because you do have to make a distinction  
3 between somebody that is an agent of the licensee, an  
4 employee, who is responsible, whose behavior and  
5 performance the licensee is legally responsible for,  
6 and a patient or a visitor over whom no such  
7 corporate control exists.

8                   DR. SHERBINI: We'll make a change.

9                   Yes, it was suggested that we move a  
10 substantial - we weren't sure what to put in its  
11 place, so we ended up leaving "substantially," hoping  
12 that most people will understand that substantially  
13 means you are getting close to where you shouldn't  
14 be.

15                   Substantial also will change depending on  
16 the dosage. If the dose rate is high, then a  
17 substantial fraction might be 20 percent of the  
18 limit. If the dose rate is very low, then it might  
19 be 80 percent of the limit.

20                   So it is open to interpretation by the  
21 individual licensees. That is probably appropriate.

22                   We left the discussion of nonuniformity  
23 and variation with time of dose fields -- only  
24 because we thought this was useful information. The  
25 licensee take it or leave it, depending on whether

1 they think it would be useful for them. And that is  
2 certainly something that does happen, so it should be  
3 considered at least.

4 We did not change dose assessment to dose  
5 estimates primarily because for the NRC dose  
6 assessment is a much broader term, and it is not  
7 necessarily mean cascading numbers. It could mean  
8 reviewing what happened, deciding whether you should  
9 calculate numbers or not, deciding whether to use  
10 sophisticated models or not, and so on.

11 So it's a much broader term that  
12 encompasses a lot more activities than to estimate  
13 the dose. And so we decided to leave it as  
14 assessments. It doesn't really matter one way or the  
15 other.

16 But it also fits in with a lot of our  
17 other documentation which uses assessments rather  
18 than estimated dose.

19 Delete the section on biological  
20 dosimetry. We weakened that section considerably,  
21 but left something in there, because it is sometimes  
22 useful, if for nothing else, put some people's minds  
23 at rest if they think they got a high dose. We have  
24 run into that situation many times where people don't  
25 believe our sophisticated models and calculations.

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1 They want to see a test, and so in situations like  
2 this we found that doing biological dosimetry  
3 cytogenetics analysis puts their minds at rest when  
4 the result comes out negative, below detected limits.  
5 So that helps a lot in many situations.

6 And so it is certainly an option.  
7 Licensees don't have to take that option if they  
8 don't want to, but it's there.

9 MEMBER VETTER: Excuse me, just a point  
10 of clarification. You are talking about biological  
11 dosimetry on the visitor.

12 DR. SHERBINI: Yes.

13 MEMBER VETTER: I'm just wondering in my  
14 mind how am I going to capture this visitor and get  
15 a urine sample.

16 DR. SHERBINI: Well, the chances are that  
17 the visitor will express concern to somebody saying,  
18 I got a high dose and I don't believe your numbers.  
19 We have run into that situation many, many times,  
20 even for people whose dose estimate was just a few  
21 hundred millirem, and they insisted that they got a  
22 big dose. And so the only way to settle that was  
23 just to draw a blood sample and send it for  
24 cytogenetic analysis. And the test comes back that  
25 whatever dose they received was below detectable

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1 limits. And so it kind of settles the issue.

2 CHAIRMAN MALMUD: Mr. Leito.

3 MEMBER LEITO: I have a general question  
4 for Dr. Miller. The RIS doc itself. That stands  
5 for regulatory issues summary?

6 DR. MILLER: Yes, issue summary, correct.

7 MEMBER LEITO: Could you just for the  
8 education of the group here, what is the purpose of  
9 an RIS? It might help in the context of some of  
10 these things, and also my next comment.

11 DR. MILLER: A regulatory issue summary  
12 can involve a number of things. The one thing it  
13 cannot do, it cannot set new requirements.

14 What it's intended to do is to provide  
15 information that will allow licensees to be able to  
16 meet their requirements, and sometimes it's helpful  
17 hints. Sometimes we give information with regard to  
18 events that have taken place, so that people can be  
19 aware of them and prevent them themselves. Sometimes  
20 it gives helpful hints on things you may do to  
21 prevent violation of the regulations.

22 Did I miss anything?

23 MEMBER ESSIG: I was just going to add to  
24 it that it's one of four types of generic  
25 communications we have. The top tier is the bulletin

1 in which we can actually request information from the  
2 licensee because of the severe safety significance of  
3 the issue.

4 The next step down is a generic letter,  
5 which conveys a strongly worded message and may or  
6 may not request information.

7 And then a RIS is third, and then an  
8 information notice is the bottom of the tier.

9 The information notice merely conveys  
10 information, maybe on an event. It might be a lesson  
11 learned from an event that we had.

12 And so those are the four. So this is  
13 the next one up from the bottom if you will.

14 MEMBER LEITO: When we had the  
15 teleconference over this RIS, there were a number of  
16 things that I think were pretty well consensus of the  
17 ACMUI members that participated of things that were  
18 bothersome.

19 Were there any of those issues that you  
20 did take and adopt in totality into this RIS?  
21 Because in looking at these here, it seems like  
22 almost everything that was objected to or we had  
23 problems with has been either kept in or modified  
24 slightly.

25 That's kind of --

1 DR. SHERBINI: I don't really have a  
2 tally of what fraction was adopted whole, and what  
3 fraction was partially or not adopted.

4 The hope and objective of this  
5 presentation was to try and show you, and give  
6 reasons why we did not adopt certain accommodations  
7 that you provided.

8 And hopefully the reasons that I  
9 presented were convincing.

10 MEMBER LEITO: From this member's  
11 standpoint, I think keeping in biological dosimetry  
12 as, well, you want to do it, you don't, in a document  
13 like this basically is saying, you know, if you are  
14 going to put it in this document, then what you are  
15 doing is you are telling a licensee this is something  
16 that you should be considering doing. And I really  
17 can't find any need to do biological dosimetry on a  
18 visitor.

19 I mean there is no way that they are  
20 going to get a dose, even in a situation that  
21 precipitated this whole event, that would warrant  
22 anything like this type of dosimetry.

23 So to even keep it in there, because it  
24 is not a standard of practice, it is not a  
25 consideration in any of these events. And I don't

1 know of any case to date involving a medical exposure  
2 of a visitor or a worker where they have done this.

3 DR. SHERBINI: Well, no, that's true,  
4 they haven't. But there are some cases where they  
5 could have, that could have settled a lot of  
6 questions without --

7 MEMBER WILLIAMSON: What is the lower  
8 threshold for biological dosimetry to be able to  
9 detect with any certainty?

10 DR. SHERBINI: You can go down to five  
11 rads with sufficient number of cells.

12  
13 MEMBER SULEIMAN: Well, it depends on  
14 what you're looking for. A bioassay, if you are  
15 looking for a radionuclide in the blood --

16 MEMBER WILLIAMSON: That's if you have a  
17 background.

18 DR. SHERBINI: Yeah, if the - some of the  
19 labs will analyze up to 2,000 metaphases. And if  
20 they do that, you can go down to about five rem. So  
21 in some cases there have been cases where the dose  
22 was above this.

23 MEMBER VETTER: I think if you are going  
24 to make the suggestion of biological dosimetry, you  
25 should either by reference or by a little paragraph

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1 maybe indicate what some of the limitations and  
2 strengths of this tool are, such as where it breaks  
3 down and where it's not applicable; at least give  
4 references.

5 DR. SHERBINI: Yes, I think we have done  
6 that to some extent. We haven't given references,  
7 but we have weakened to the point where it's sort of  
8 an oh-by-the-way kind of thing.

9 CHAIRMAN MALMUD: Dr. Vetter.

10 MEMBER VETTER: This is kind of on the  
11 edge of my knowledge of IRBs, but I don't think that  
12 we have the authority to get a blood sample from a  
13 visitor without going through our institutional  
14 review board.

15 DR. SHERBINI: No, that is true.

16 MEMBER WILLIAMSON: It's assault and  
17 battery.

18 MEMBER VETTER: So I'm just really having  
19 a lot of difficulty with this, how we would ever  
20 implement this.

21 DR. SHERBINI: This is the situation  
22 where this is used, it's almost always initiated by  
23 the exposed person. Because the exposed person is  
24 generally the person who is concerned with the  
25 accuracy or the reliability of the dose estimates

1 based on analytical methods.

2 MEMBER VETTER: I think that is a  
3 different matter. If the visitor came to us saying  
4 I'm concerned, that is a different matter. I don't  
5 think we would be arguing about this.

6 This implies that we should have in our  
7 program some prospective thought about biological  
8 dosimetry on visitors.

9 DR. SHERBINI: No, I will make sure that  
10 this is not written this way. I'm sure it isn't, but  
11 I'll make sure it isn't. It does not imply that you  
12 should do anything of the sort.

13 DR. MILLER: Sami, let's see if I can  
14 help or hinder this discussion.

15 The concern here would be that if a  
16 visitor felt that they got a higher dose of radiation  
17 than they really received; is that correct? And  
18 therefore the biological - if you took a sample and  
19 did a biological analysis on it, then that could show  
20 that it didn't reach a threshold, which means it is  
21 something below that.

22 As a regulator how would we use that?

23 DR. SHERBINI: The way it usually comes  
24 - first of all, the exposed person generally does not  
25 know about biological dosimetry. So if the person

1 has doubts about the licensee or whoever does the  
2 assessment of dose, then this could be offered as an  
3 option, okay, do you want to do biological dosimetry?  
4 Here is what is involved, and here is what it can do  
5 for you, and here is what it can't do for you.

6 It's an option that the licensee or the  
7 exposed person can use if he or she decides to do so.  
8 That's all it is.

9 DR. MILLER: But from a regulatory  
10 perspective, for we as regulators, okay, we would  
11 only use that if a member of the public voluntarily  
12 submitted to such a test for lack of a better word.

13 DR. SHERBINI: Yes.

14 DR. MILLER: And then the licensee  
15 presented the results of that test as evidence that  
16 the licensee - that the individual did not get a dose  
17 of radiation.

18 Other than that, we wouldn't have a stake  
19 in it as regulators.

20 DR. SHERBINI: Well, there are situations  
21 where this is your only option. In other words there  
22 are situations where there is no data, and we have  
23 had such situations. And the only option you have  
24 left is biological dosimetry, since there are no  
25 numbers, there is no measurement, there is nothing.



1 MEMBER VETTER: Well, another IRB issue  
2 is that the information - if the visitor is coming  
3 for simply their own edification that the dose is  
4 okay, that is going to be privileged information, and  
5 we would not be - we wouldn't have the authority to  
6 share that with anyone.

7 We probably wouldn't even know. I mean  
8 that is going to be - that is a visitor issue. They  
9 essentially become a patient at that point, and that  
10 is privileged information.

11 Perhaps they'd be satisfied, well, you  
12 couldn't detect it, I'm okay with that, and that will  
13 be the end of the issue.

14 But suppose they do get a number, suppose  
15 it does say 10 rem, the patient has to be - that  
16 visitor has to want to share that information with  
17 us.

18 DR. SHERBINI: There is always a release  
19 form.

20 MEMBER VETTER: I'm sorry?

21 DR. SHERBINI: There is always a release  
22 form. And the form says that the results will be  
23 shared with the licensee, and often with the NRC.

24 DR. MILLER: But he would have to consent  
25 to that.

1 DR. SHERBINI: Oh, yes. That's standard.  
2 That's standard like anything else.

3 CHAIRMAN MALMUD: We have a comment from  
4 a member of the public.

5 MS. FAIROBENT: Lynne Fairobent, AAPM.  
6 Actually I have a question. Because of other  
7 meetings I've been in recently, how many facilities  
8 are there even in the U.S. that can do this type of  
9 biological dosimetry that you are looking for, and at  
10 what cost to the licensees?

11 DR. SHERBINI: Right now, there is one.  
12 It is very expensive. But very soon we will have  
13 another one that is not as expensive.

14 MS. FAIROBENT: It's still relatively  
15 expensive?

16 DR. SHERBINI: Yes. \$500 typically.

17 MEMBER NAG: On a similar issue, if you  
18 have let's say a nurse or someone who has to take  
19 care of that patient, has a badge, but complains that  
20 I'm feeling faint. I may have gotten too much  
21 radiation, what are the avenues that the licensee has  
22 to, A, either confirm or deny that that worker did or  
23 did not get an excessive dose of radiation? That  
24 itself shows no radiation?

25 DR. SHERBINI: There are several ways.

1 You can calculate the dose and ensure that it was  
2 small, or there it is, biological dosimetry.

3 There are situations where the reading of  
4 the dosimeter is suspect. It could be defective, the  
5 dosimeter could read high because somebody spiked it,  
6 or whatever.

7 So there is something about the reading  
8 of the dosimeter that makes me believe that it might  
9 not be as reliable as you would like it to be. So  
10 you do calculations --

11 MEMBER NAG: But you know calculations  
12 can vary by a huge fraction depending on the  
13 assumptions you make. Where is your hand? Is your  
14 hand close to the implant area? Is your body 10  
15 centimeters away or 100 centimeters away? I mean  
16 those things are very difficult.

17 DR. SHERBINI: That's why we left this in  
18 here, because this gives an additional option. You  
19 don't have to take it. You don't have to use it.  
20 But it's an option; it's there, in addition to  
21 calculations and measurements and everything else.  
22 It's the whole slew of options that you have when you  
23 are faced with this situation.

24 Most situations won't need such things,  
25 but some situations do.

1           It's a piece of information. I'm not  
2 understanding why providing more information to the  
3 licensee is viewed negatively. We are not suggesting  
4 that they should do it, or that they should be  
5 prepared to do that analysis themselves.

6           We're suggesting that here is another  
7 option by which you can assess where the dose lies.

8           MEMBER WILLIAMSON: I guess from having  
9 heard everything, it sounds like it's so far out of  
10 the mainstream, and because it's a medical procedure  
11 done on a visitor, its use is so restricted that it  
12 seems to me to hardly be useful enough to include in  
13 a mainstream report of this nature.

14           DR. SHERBINI: We can revisit this. We  
15 can revisit it to see if maybe it might be  
16 appropriate to just remove it if it's causing such  
17 difficulty.

18           CHAIRMAN MALMUD: Are there any other  
19 c o m m e n t s ?           D r .       S u l e i m a n .

20  
21           MEMBER SULEIMAN: Yes, I'll just repeat  
22 this, because I've repeated several times previously.  
23 Again, I don't understand why the NCRP - I think it  
24 was commentary report #11 which addresses this very  
25 issue of caretakers - is only a few pages long and

1 very clear and simple. And I think this entire  
2 exercise is really taken a lot of extra effort.

3 And I also - I noticed in your journal  
4 article that you used SI units consistently, so the  
5 journal apparently required that. I don't understand  
6 why as a minimum the NRC can't use SI units along  
7 with the TEDEs and the Rankin and whatever.

8 DR. SHERBINI: We have to do that. It's  
9 required.

10 CHAIRMAN MALMUD: Dr. Nag?

11 MEMBER NAG: From the ACMU side, I would  
12 like in your report to make sure that an emphasis  
13 that you do emphasize that the licensee has a  
14 responsibility to explain and warn the visitors, but  
15 that the licensee itself cannot be held responsible  
16 for making sure that the visitors comply with that.  
17 Because that is really not up to the licensee's  
18 control. I would like to emphasize that.

19 CHAIRMAN MALMUD: Any other questions or  
20 comments for Dr. Sherbini on this issue?

21 MEMBER SCHWARZ: My comment is on this  
22 biological dosimetry. Since it really is such a - I  
23 mean it's a test that is certainly not routinely  
24 performed. And as far as data that would be  
25 available once a visitor might have such a test

1 performed, there is not really a lot of correlate  
2 information that is going to reassure them that  
3 something bad hasn't happened to them.

4 I think this is probably not the best  
5 route to go to assure a person that essentially they  
6 have not sustained damaging effects.

7 DR. SHERBINI: It hasn't been a  
8 situation, especially when people do not have much  
9 confidence in complex computer programs and things  
10 like this. People don't feel that these programs are  
11 really producing good numbers that they can believe  
12 in. But a test is stronger. A test is - I'll  
13 rethink this and maybe remove the whole thing since  
14 it is taking such --

15 CHAIRMAN MALMUD: Mr. Bailey.

16 MEMBER BAILEY: I would have to agree  
17 with some of the people who have been talking about  
18 the biological testing.

19 Number one, we have historically years  
20 and years and years of bioassay performed on nuclear  
21 med techs, and about the only time we got anything  
22 measurable is when somebody was really messing up.

23 As far as going to cytogenetics, we too  
24 had a case recently where basically it was 150 whole  
25 body equivalent dose. We sent it to two different

1 centers. We got widely varying results. And the one  
2 in the United States was the most unbelievable,  
3 because it didn't correlate with either the film  
4 badges or the clinical symptoms of the patient.

5 To me that is one of the most disturbing  
6 things that can happen to an individual is to have  
7 two results, and they are different, and so they say,  
8 you don't know anything.

9 To me it is not reassuring to necessarily  
10 have bioassay data of any kind.

11 DR. SHERBINI: Well, we learned that the  
12 hard way. We had some bad experiences.

13 But that does not really - this is not a  
14 critique of the method; it's a critique of the lab.  
15 It's a fine distinction, but it's important to keep  
16 in mind that this would apply to any kind of medical  
17 test you do.

18 Yes, some labs will give you wrong test  
19 results, but that doesn't mean the tests shouldn't be  
20 done or that they are bad.

21 MEMBER BAILEY: Well, I guess I would  
22 argue, if you can't trust the test results, you are  
23 worse off with bad results.

24 DR. SHERBINI: I agree.

25 MEMBER WILLIAMSON: So maybe you

1 shouldn't take a position advocating its use in this  
2 instance.

3 MEMBER SULEIMAN: Well, last I knew there  
4 were no commercial labs who did this sort of thing.  
5 Are these commercial labs or are they private labs?

6 MEMBER BAILEY: They are governmental.

7  
8 MEMBER SULEIMAN: Okay. But the cost of  
9 a personal dosimeter would be how much compared to  
10 one of these tests?

11 DR. SHERBINI: Much less. Okay, I will  
12 remove it.

13 CHAIRMAN MALMUD: May I summarize what I  
14 suspect the feelings of the committee are, since  
15 we've discussed this for a long time, Dr. Sherbini.

16 I think that the committee feels that the  
17 licensee in this case, was unduly punished for  
18 something that was not under the licensee's control  
19 at the time.

20 We recognize that the regulations require  
21 the licensee be held responsible. Once having said  
22 that, the next question is not how we measure the  
23 dose to the unauthorized member of the public who is  
24 receiving more than he or she should have, but how do  
25 we prevent this from happening again.



1           And I've thought about it. Other members  
2 of the committee have thought about it. There are  
3 some things we simply can't control.

4           Calling the police would not have  
5 resulted in a response either, and it's unlikely that  
6 a police officer is going to drag a daughter away  
7 from her dying mother in a room which is known to be  
8 radioactive by virtue of the mother's presence. He  
9 himself would be anxious about entering the room.

10           Nor would hospital security be able to do  
11 it, nor would the radiation safety officer.

12           We agree, I think you and we agree, that  
13 the way this should be handled should such an  
14 incident, which is extremely rare, occur in the  
15 future, is for a timely notification of the NRC that  
16 the problem exists.

17           Now how would we know that the problem  
18 existed? Probably the only way that is practical  
19 would be for the nursing directive, the order to be  
20 written that someone monitor the room every two  
21 hours, let's say, to make sure that the visitor is  
22 behind the lead shield. And if the visitor is not on  
23 the right side of the lead shield to notify the  
24 radiation safety office who would then notify the  
25 local NRC office, that would constitute a prompt

1 notification.

2 And then the NRC office with the licensee  
3 could scratch their heads and try and find out a way  
4 of convincing this noncompliant visitor of the merits  
5 of not being noncompliant.

6 Other than that I think there is little  
7 that we as human beings, who are concerned for one  
8 another both in terms of radiation safety and  
9 humanity, could do about a situation such as this.

10 Now clearly there is an exception. The  
11 exception is, if the behavior of the individual puts  
12 someone else at risk, someone other than the  
13 individual himself or herself, then we have every  
14 right and every responsibility in the world to  
15 protect others.

16 This was a sad situation for all  
17 individuals concerned - the patient, the daughter,  
18 the radiation safety officer, the hospital  
19 administrator - for all. And it's been a very time  
20 consuming on the part of many skilled people who  
21 devoted many hours to this.

22 I would hope that what we have learned  
23 from this is that should such a rare situation occur  
24 in the future that it be dealt with with closer  
25 monitoring, visual monitoring, and that could be done

1 from the door of the room, just looking through the  
2 door to see if the visitor is compliant. And then  
3 prompt notification of the RSO and the NRC.

4 From there on in it becomes a conjoint  
5 issue, and probably would not generate the kind of  
6 response that was forthcoming in this case.

7 And I would hope once again, on behalf of  
8 the public, and on behalf of the taxpayer, that this  
9 kind of effort would not be necessary in the future  
10 for an incident such as this.

11 And lastly, I think that we sitting here  
12 would wish that you would be a little more  
13 understanding of the clinical issue involved, and  
14 soften the language, as you have shown examples on  
15 the slides, but use the softer language.

16 Because being a clinician and having the  
17 responsibility for the patient, and indirectly, the  
18 responsibility for the visitor, is very different  
19 from being a scientist, and looking at this as an  
20 issue of dosimetry and physics.

21 We very much respect your scientific  
22 skill, and would hope you similarly recognize that  
23 physicians and individuals taking care of patients  
24 have other things to take into consideration as well.

25 And perhaps with that we could close the

1 subject for this committee, which has been  
2 extraordinarily time consuming on our behalf. And I  
3 think we've learned something from it. We've learned  
4 many things from it. And we thank you.

5 MEMBER ESSIG: Dr. Malmud, there is a  
6 small part two, which is a fast forward.

7 CHAIRMAN MALMUD: That's the next 15  
8 minutes, and we've consumed a few minutes of it. But  
9 Dr. Sherbini, you're on again.

10 DR. SHERBINI: This is very short, just  
11 two slides. Basically we are working on the  
12 caregiver dose limit, which was the first opportunity  
13 for discussion.

14 These are just steps we are pursuing.  
15 The first step has been completed with us the regions  
16 for input basically. But they are going to be the  
17 ones who will implement this policy.

18 So they are going to tell us what they  
19 think the policy should look like. And two of the  
20 regions have already done that. We're waiting for  
21 the third region to do this.

22 Once we get these, we are going to  
23 develop these thoughts and put them into the form of  
24 a RIS. We'll give it back to the regions to review.  
25 And once we've taken care of all the comments, we

1 will put it out for general comment including ACMI  
2 members, state licensees and so forth.

3 And once these comments are resolved,  
4 then the RIS can be issued, hopefully by the end of  
5 next year. And that should take care of that.

6 CHAIRMAN MALMUD: Thank you very much.

7 That was one of the most succinct  
8 presentations, and we thank you for that.

9 MEMBER WILLIAMSON: This is a very  
10 factual question. Are there two RISs now?

11 DR. SHERBINI: Yes.

12 MEMBER WILLIAMSON: So there is an RIS  
13 that in general goes over - it's more focused on this  
14 one case and the lessons learned. Then there is this  
15 RIS which is actually going to be a load of  
16 propagating policy?

17 DR. SHERBINI: Yes.

18 MEMBER WILLIAMSON: I think it's very  
19 good you've separated them. That I think was one of  
20 our recommendations at the telephone meeting we had.

21 CHAIRMAN MALMUD: Thank you again.

22 Oh, Dr. Vetter.

23 MEMBER VETTER: I've got a question which  
24 is sort of post-RIS. I assume that this second RIS  
25 talks about the - what licensees would need to do is

1 we saw a visitor in the room and couldn't control  
2 them, and we know they are going to go over the  
3 limit.

4 And it would mean calling our region or  
5 headquarters to get permission for that visitor to go  
6 over the limit, it becomes a license amendment, as I  
7 understand it.

8 And the question I have is, is the NRC  
9 prepared to issue that license amendment immediately  
10 without sending someone out to confirm what we're  
11 seeing? That is a little cloudy in my mind. As a  
12 licensee I'm going to call you and say, I've got a  
13 visitor in the room. The patient is dying. I cannot  
14 control that visitor. He or she wants to be next to  
15 their parent or child who is dying, and I know they  
16 are going to get five rem. You are going to give me  
17 that license?

18 DR. SHERBINI: Yes.

19 MEMBER VETTER: Just like that?

20 DR. SHERBINI: The way it's structured is  
21 that everything will be prepositioned, the kind of  
22 information that the licensee needs to provide to the  
23 region would be given; the kind of information that  
24 the region would be expecting would be established;  
25 the procedure they have to go through, the form of

1 the exemption, the kinds of controls that we would  
2 expect the licensee to have in place; everything  
3 would be known and documented.

4 MEMBER VETTER: And now what happens when  
5 that visitor gets 10 REM?

6 DR. SHERBINI: Well it's a progressive  
7 thing. The approach is that there is no limit.

8 MEMBER VETTER: Okay, all right.

9 MEMBER VETTER: As long as we are doing  
10 whatever we can, there basically is no limit?

11 DR. SHERBINI: That's right.

12 MEMBER NAG: Now maybe a hypothetical  
13 question, what if the NRC or the agreements they have  
14 imposed say, "No we are not prepared to increase your  
15 limit?"

16 DR. SHERBINI: No, that is the whole  
17 purpose of this thing.

18 CHAIRMAN MALMUD: If I may, the NRC would  
19 have been notified, and would be a participant in  
20 attempting to help you find a mechanism for reducing  
21 the dose to that individual, and would share in the  
22 problem.

23 It's different from letting the NRC know  
24 retrospectively that this occurred, and that no  
25 attempt that the NRC recognizes as having been

1 substitute was made, whether or not it was made.

2 So I think there is a difference. And  
3 the contemporaneous notification of the NRC is  
4 probably the lesson that we've learned from this.

5 Mr. Bailey.

6 MEMBER BAILEY: I have to respond to  
7 that. To me this whole issue is form over substance,  
8 and I find it very unlikely that an agreement state  
9 program, particularly those based in a health  
10 department, would be able to do anything to that  
11 hospital. When we took it to our lawyers, they would  
12 just laugh at us, and I think that that would not be  
13 an uncommon finding in most of the agreement states.

14 You would call up and say, yes, we  
15 understand the problem, or if you told us the next  
16 day. I mean there is an implication that if this  
17 occurs at midnight, you're going to phone NRC and  
18 tell them this is occurring.

19 So again, I think, and I hope, that my  
20 colleagues in the agreement states would have an  
21 appreciation for the problems that are being  
22 confronted by the patient and caregiver and the  
23 hospital and the physician and everybody involved in  
24 it.

25 DR. SHERBINI: I think it's important to



1 point out that what the RIS is going to do is nothing  
2 that is not already happening. The whole process of  
3 exemption is already in place; it's just going to  
4 streamline it. That is all the RIS is trying to do  
5 anyway.

6 MEMBER DIAMOND: Again, excuse me, let's  
7 just keep the context straight. As Dr. Malmud said,  
8 these are extraordinarily rare events. In fact they  
9 should never, ever happen.

10 But the practice of medicine is outside  
11 our purview. However I can tell you if I ever found  
12 the physician who gave this ministrations to his dying  
13 patient, I would speak to that person privately and  
14 say, what is wrong with you? Because this makes no  
15 medical sense at all.

16 It is time for this issue to be put at  
17 rest, and let's be done with it. It's really not a  
18 useful expenditure of your time or our time, because  
19 the frequency of the event is so rare.

20 MEMBER BAILEY: I have to disagree. It's  
21 - I would say that once every two to three months we  
22 get a case where a patient dies with radioactive  
23 material in them. And the family wants to cremate  
24 the body. And we end up with cases where essentially  
25 they've either got to be buried before sundown, or

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1 they have got to be cremated, and we have to give  
2 exemptions. Because if we look at the dose level  
3 coming off the urn, or whatever, there are some  
4 pretty heavy doses that can come off.

5 But the patient dying with a radioactive  
6 source or pharmaceutical in them is not infrequent.

7 MEMBER NAG: The other problem that I  
8 sometimes face is that when you start the radioactive  
9 implant doses, the patient is in fairly good shape.  
10 But sometimes during that three, four or five days  
11 that the implant is in place, because of medical  
12 problems, the patient deteriorates suddenly in the  
13 middle.

14 And that is a problem that you do face,  
15 if you do enough implants.

16 CHAIRMAN MALMUD: If we may, we'll move  
17 on with the agenda, to the next item. And it looks  
18 as though Dr. Howe is back on. We'll take a short  
19 break.

20 (Whereupon at 4:29 p.m. the proceeding in  
21 the above-entitled matter went off the record, to  
22 return on the record at 4:40 p.m.)

23 CHAIRMAN MALMUD: Dr. Howe has been  
24 ready, and I think the audio-visuals have caught up  
25 with her.

1 MS. HOWE: They have indeed.

2 CHAIRMAN MALMUD: Okay, Dr. Howe, you're  
3 on.

4 MS. HOWE: Okay. Recently - well maybe  
5 not so recently, about a year ago, we did an  
6 inspection at one of our medical licensee facilities.  
7 And it is essentially the first time that we have run  
8 into a licensee in which they had electronic written  
9 directives.

10 What we are used to seeing is that there  
11 are electronic records; there are electronic  
12 treatment planning systems; but people print out the  
13 directive, and then they sign it, and then they put  
14 the piece of paper in the patient's folder.

15 In this case they said they are  
16 electronic, and they are keeping all the patient  
17 records electronically, and the written directive is  
18 electronic. And they also print a paper copy of the  
19 electronic written directive and put that in the  
20 folder.

21 And the issue is, this is kind of the  
22 first time. So where are we in our regulations, and  
23 what is it we're going to be looking for, and what is  
24 it we're going to be accepting?

25 And if you look in 35-5, it says that you

1 can maintain records stored in an electronic media if  
2 you have the capability of producing a legible,  
3 accurate and complete record during the retention  
4 period. For a written directive that's three years.

5 And then other records such as letters  
6 drawings, specifications, must include all pertinent  
7 information such as stamps, initials and signatures.

8 So those are our general performance  
9 criteria that we will be evaluating different  
10 licensees against. And as we bring this issue up to  
11 our IT folks, they are looking for very prescriptive  
12 things, and we don't have prescriptive regulations.  
13 We have general guidelines. And so we will be  
14 comparing them against these general guidelines.

15 And then the licensee also has to  
16 maintain adequate safeguards against tampering or  
17 loss of records.

18 So that's our general baseline for  
19 keeping electronic documents.

20 Let's look and see what you have to have  
21 in a written directive. It has to be dated and  
22 signed by the authorized user, before the  
23 administration, and it must include specific  
24 information.

25 When we develop written directives and

1 put them in the regulations a few years ago, we made  
2 it clear that it's not - it doesn't have to be in a  
3 prescription. It can be in any kind of document, as  
4 long as it has somewhere in it the minimum  
5 information we need for a written directive, and the  
6 authorized user has dated and signed it.

7 It doesn't have to be generated by the  
8 authorized user; it just has to be dated and signed  
9 by the authorized user.

10 So if we have an electronic written  
11 directive, we are going to be looking to see if it  
12 has been dated and signed by the authorized user, and  
13 if it has the minimum specific information that is  
14 required in a written directive.

15 You can also have an oral directive,  
16 provided a written directive is prepared within 48  
17 hours.

18 You can also have a revision, as long as  
19 the revision is dated and signed by an authorized  
20 user, and it is before the administration with unseen  
21 material, gamma, sterotactic, teletherapy, et cetera.

22 So when you go to an electronic record of  
23 this, if there is a revision to a written directive,  
24 then we need to be able to see both the revision and  
25 the original electronic record.

1           And one of the things that we found out  
2           is that an electronic written directive has to be  
3           audited in the electronic mode.

4           If you print out a copy of an electronic  
5           written directive, it's now a piece of paper. It's  
6           no longer in electronic mode, and you can't use that  
7           for auditing purposes.

8           If you are using a treatment planning  
9           system, and you print it out and then sign names on  
10          it, that's fine. That is now a paper written  
11          directive, and it's got a real signature on it.

12          If you were keeping this totally  
13          electronically, you would have some kind of  
14          electronic signature process. And we would have to  
15          inspect the electronic written directive in the  
16          electronic mode.

17          If you printed that piece of paper out,  
18          it would no longer be an electronic written  
19          directive.

20          MEMBER DIAMOND: I'm a little confused.  
21          So let's say you were inspecting my office, and I had  
22          an electronic medical record. And you were  
23          inspecting online, and you wanted to review the  
24          electronic written directive, can't - I would assume  
25          that in each of these systems there is a methodology

1 to print out a true copy of the electronic record as  
2 it existed at that time that you could go and put it  
3 in your folder and take back with you.

4 In other words, don't these records  
5 indicate any annotation to show that a record has  
6 been changed? I mean that is the whole purpose of  
7 it. If they were changeable, then they would not be  
8 true medical records. There would be no way for them  
9 to be valid as recordkeeping instruments for medical  
10 purposes.

11 MS. HOWE: I think we have to verify on  
12 the electronic system that it was the written  
13 directive. And then once we printed it - but you  
14 have to be in the electronic system. Otherwise you  
15 could have - you could have almost anybody create  
16 something that looks very much like what you had, but  
17 it wouldn't really be your electronic written  
18 directive. That is the guidance we're getting.

19 MEMBER DIAMOND: Are you talking about a  
20 forgery? Is that what you are referring to?

21 MS. HOWE: Forgery, or generation in  
22 some other manner.

23 MEMBER DIAMOND: Well, I mean the same  
24 could be said for a paper record. Of course if  
25 someone wanted to make a false copy, the statement

1 could be true.

2 So I'm just not really understanding what  
3 you are getting at.

4 MS. HOWE: The issue is that when you  
5 are reviewing electronic written directives, you need  
6 to review the electronic version of it. So you need  
7 to do an electronic audit in order to ensure that it  
8 is there in the system.

9 CHAIRMAN MALMUD: If I may, what you are  
10 saying is that in reviewing the electronic record,  
11 the reviewer wants to look at the electronic record  
12 in the computer if you will, in the same way that the  
13 reviewer will want to have seen the original hand  
14 signature, not a Xerox copy of it, when reviewing the  
15 written record.

16 Does that help you?

17 MS. HOWE: Yes.

18 MEMBER DIAMOND: That's understandable.

19 CHAIRMAN MALMUD: Then you can print a  
20 copy of it if you wish for a hard copy, or you can  
21 Xerox a copy of the original handwritten. But you  
22 want to see it in its original form.

23 MS. HOWE: Yes.

24 CHAIRMAN MALMUD: Is that a fair analogy?

25 MS. HOWE: Yes, it is.



1 MEMBER SULEIMAN: So you can look at it  
2 on the screen.

3 MS. HOWE: Yes.

4 MEMBER SULEIMAN: You have to look at it  
5 on the screen is what she is saying. But once you  
6 print out a paper copy it doesn't void the electronic  
7 version.

8 MS. HOWE: No, it doesn't void the  
9 electronic. It's just that is not the official  
10 record that you are looking at.

11

12 MEMBER SULEIMAN: Now let me ask a third  
13 way to look at this. What if you have a paper copy  
14 with a signature, and you want to scan it in and get  
15 rid of the paper copy?

16 MS. HOWE: If you have a paper copy with  
17 a signature and you want to scan it in --

18

19 MEMBER SULEIMAN: And throw away the  
20 papers and have an electronic copy of that, an  
21 electronic image of it.

22 MS. HOWE: I think the electronic image  
23 of the paper copy is fine. Because then it is not  
24 really an electronic written directive; it's a  
25 facsimile of the paper written directive. We do that

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1 in audits all the time.

2 CHAIRMAN MALMUD: If I may, the reason  
3 that that would be valid is that your handwritten  
4 sheet which is then read into the computer will be  
5 timed by the computer as to when the computer  
6 received it.

7 So if there was a desire on the part of  
8 someone who had less than honorable motives to alter  
9 the original record, they could not do that beyond  
10 the point that it was entered into the computer as  
11 the original record.

12 Dr. Nag?

13 MEMBER NAG: Do you have any methodology  
14 for the electronic signature? For example there are  
15 some where the electronic signature, you type in your  
16 password, and some where you type in your password  
17 and the computer will almost hand sign it as if it  
18 were your signature.

19 Do you have some way of documenting that  
20 this was that person's electronic signature?

21 MS. HOWE: To do that, it's part of our  
22 inspection audit process. We're in the process - you  
23 know this is the first time we've run into electronic  
24 signatures for documents that are generated  
25 internally, but NRC has a requirement for you to

1 keep. So they are not documents that you send to the  
2 NRC.

3 And so we're new in this, and we're  
4 feeling our way through as to what we're going to be  
5 looking for, and what is going to be acceptable.

6 And we're coming to the ACMUI in a very,  
7 very early part, and one of the things we're going to  
8 be looking at is, what is the function of your normal  
9 written signature? Your normal written signature  
10 actually is a biometric. The way you sign, even if  
11 it's a straight line, can be tied back to you.

12 So we may in some cases have to find out  
13 more about the software to see how that signature is  
14 generated.

15 The signature does authentication. It  
16 does nonrepudiation, where you can't repudiate you  
17 signed the document. And it also - there is a  
18 function of data integrity.

19 And electronic signature we would expect  
20 to do many of the same things that you have in a  
21 written signature. We expect it to perform the  
22 functions of a written signature. We think the  
23 individual ought to know that they are signing. We  
24 think the document has to be unchangeable; that is  
25 kind of a function of an electronic signature.

1           Now electronic signature is a big  
2 umbrella. It is a huge umbrella. There can be many  
3 many ways of doing an electronic signature.

4           One of those is a digital signature. If  
5 you are submitting information to the NRC for NRC to  
6 review, we have a digital signature system that you  
7 have to use. And there is encryption, and there are  
8 certificates, and it's a very elaborate system.

9           That is one form an electronic signature.  
10 When we look at the requirements in 35-5, it doesn't  
11 say you have to have a digital signature. It just  
12 says you have to keep things in a complete and  
13 accurate method.

14           And if you look at 35-40, it says you  
15 have to date it and sign it.

16           So we are not holding people to a digital  
17 signature. And what you were describing is kind of  
18 part of what --

19           MEMBER NAG: In most radiation oncology  
20 specialties, they have a data verification system,  
21 and therefore, that electronic record is part of  
22 that. And usually what they will do is, you have the  
23 dictation, and then when we put in our password, the  
24 dictation becomes official, and you can not change  
25 any dictation after you put in your electronic

1 password.

2 So those are things that are involved in  
3 electronic signatures that I know of.

4 MS. HOWE: And we looked at related  
5 documents to try to understand more about electronic  
6 signatures and what was happening. Most of the  
7 documents we find have to do with commerce, because  
8 commerce is really the big elephant in the middle of  
9 the room.

10 MEMBER NAG: The what?

11 MS. HOWE: Commerce is the big elephant  
12 in the middle of the room. It is how do you transact  
13 business electronically. And health care is just one  
14 small part of it.

15 But there seems to be an ASTM standard  
16 for electronic authentication of health care  
17 information that most of the health care systems seem  
18 to be subscribing to, and it seems to be the standard  
19 that they are trying to meet.

20 And that is one that we're looking to for  
21 a lot of guidance. We are in an interesting  
22 situation. We can't enforce other people's  
23 regulations or standards unless we adopt them in  
24 rulemaking, and we haven't done rulemaking yet.

25 But we can look to the ASTM to see the

1 standard the health care community seems to be  
2 adopting, and seeing what its asking of its people.  
3 And then try to compare what we see with our  
4 performance-based regulations, looking to see what  
5 we're requiring in 35-40, what we were requiring for  
6 the recordkeeping part, and what in 35-5.

7 Right now, we're still in a data  
8 collection mode, for this particular licensee that  
9 we're looking at. We have had information technology  
10 people get in touch with the software manufacturer to  
11 see what the capabilities of the software, because  
12 there may be things that are just transparent to the  
13 users but are important for understanding the  
14 electronic signature.

15 And then we're also, one of our  
16 inspectors went out to visit this facility after our  
17 initial inspection, and got to see more of a real-  
18 life demonstration or real-life electronic audit of  
19 what they were capable of doing, and how they could  
20 safeguard different information.

21 So we are pulling all that information  
22 in, and we are going to be coming up with a  
23 determination of whether this particular licensee's  
24 electronic signature was an electronic signature, and  
25 the way they are keeping their electronic records is

1 acceptable to us.

2 But we have not reached a conclusion on  
3 that. We're still in a data collection mode.

4 And I think what we're coming to the  
5 ACMUI for is to see your experience in your  
6 facilities with electronic recordkeeping, how you are  
7 handling electronic signatures and things.

8 Trip, do you want to say something? The  
9 microphone is over there, but right now we're not in  
10 rulemaking space.

11 MR. ROTHCHILD: I'm Trip Rothchild,  
12 assistant general counsel at the NRC.

13 The question that really comes up is when  
14 you don't have an electronic signature and you have  
15 an electronic system, and you go to your computer,  
16 and you have a password, and so you put your password  
17 in, your initials whatever it is, and you log in and  
18 you then type in your instructions, and then you  
19 electronically transmit it to someone, you have no  
20 signature on the page at all.

21 The system has no signature, because  
22 there is no requirement that you then make a paper  
23 copy of it, and you sign it.

24 And I guess the real question as I  
25 understand that you want to present to the ACMUI is,

1 is that acceptable to us? Do we have enough  
2 certainty that someone didn't give the password,  
3 these systems are secure enough to where the nurse  
4 didn't get into it, or someone else didn't know your  
5 password that wasn't authorized to do so, and could  
6 just go in and tamper with the system, or someone  
7 goes down the hallway and the computer is sitting  
8 there, and someone then starts typing stuff up and  
9 sends it, because all we know is that someone had  
10 access to that computer, and we have no real  
11 signature that says, this was me.

12 When you go to some of the digital  
13 signatures and everything you're talking about, you  
14 do have that kind of assurance. And I think the real  
15 question the staff is raising is, we get in this  
16 electronic world, and more and more people move into  
17 that kind of system, is that going to be acceptable  
18 to the NRC? Should it be acceptable to the NRC?  
19 What are the medical community's standards when you  
20 don't really ever have a physical signature that you  
21 can go look at, and you're not using digital  
22 technology.

23 MS. HOWE: Not using a digital  
24 signature, you are using a broader electronic  
25 signature instead of a digital signature.



1                   MEMBER WILLIAMSON: Could you define the  
2 difference just as a point of information. What is  
3 the difference between an electronic signature, and  
4 using the password?

5                   MS. HOWE: Password could be a method of  
6 electronic signature, but the - if you go to - if you  
7 go to the ASTM standard for health care, then the  
8 electronic signature is an act of attaching a  
9 signature by electronic means.

10                   After the electronic signature process.  
11 It is a sequence of bits associated with the  
12 electronic document which binds it to a particular  
13 entity.

14                   And supposedly when you add an electronic  
15 signature, the information that you are adding the  
16 electronic signature to now becomes frozen in time.

17                   MEMBER WILLIAMSON: Okay, so it's the act  
18 of freezing it and rendering it uneditable; that's  
19 the difference between the password-protected system  
20 and the electronic signature of a document.

21                   MS. HOWE: Now there are password  
22 systems --

23                   MEMBER WILLIAMSON: That's different than  
24 the situation Mr. Rothchild raised, the situation  
25 where someone else could happen to know the password,

1 which I guess is the biometric link between an  
2 individual and the electronic signature.

3 MS. HOWE: And if you go further into  
4 the ASTM, you will see user authentication with  
5 passwords. Passwords have proven to be a very  
6 effective means of providing identity when used  
7 properly, and used properly means, the password is  
8 not shared with anybody else, and you keep it.

9 But they have severe limitations in the  
10 realm of electronic signatures, because they are not  
11 the top level, but they certainly are one of the  
12 levels.

13 CHAIRMAN MALMUD: Dr. Howe, you made the  
14 point early in your presentation that the place to  
15 look is in commerce. And in fact most banks today  
16 encourage their members to use electronic signatures,  
17 and to bank over the Internet. And this has proven  
18 to be not terribly much more subject to forgery than  
19 handwritten signatures.

20 Our hospital, and I don't propose to be  
21 an IT expert, but our hospital is using electronic  
22 signatures. About every three months, they require  
23 that we change our signature. I'm looking over to  
24 Dr. Van Decker, because he is in a different  
25 department, and I assume he has the same problem.

1 So they require us to enter our --

2 MEMBER VAN DECKER: You mean I can't  
3 remember my password when they change it every month?

4 CHAIRMAN MALMUD: Exactly. That is the  
5 problem I'm referring to. They surprise us one day,  
6 and it says it rejects our password, and we have to  
7 enter a new password.

8 But the point is that it's very  
9 effective. The hand signature is irrelevant, because  
10 in order for me to enter a facsimile of my signature,  
11 I'd have to type in an electronic signature to  
12 generate the hand signature.

13 It's an irrelevancy. It's no longer  
14 important on a document if it says electronically  
15 signed.

16 So that is the method we're using for  
17 signing our reports. We have not gotten far enough  
18 long in that transition for me to electronically sign  
19 my orders, so when I order a dose of I-131 for a  
20 hyperthyroidism it's a hand signature. In fact it's  
21 three signatures, and one set of initials, all for  
22 the same dose.

23 MS. HOWE: And that's typical of what  
24 we're finding. We're finding that facilities have  
25 electronic patient records, but they haven't

1 necessarily gone to electronic written directives.

2 CHAIRMAN MALMUD: At our institution we  
3 haven't because we have not been budgeted to go that  
4 far yet. But that will be on the horizon.

5 And with respect to leaving the computer  
6 open, the signature on an order has to be an  
7 individual order. So if I were to write an order for  
8 Patient X, I sign it then.

9 The computer is still on. It's still on  
10 my page. But another order cannot be written without  
11 my signing it. My signing it means I have to enter  
12 my password. So I'll enter MalmudLS which was my  
13 identification, then I'll put in my password, let's  
14 say my password is magic - it isn't, but let's say  
15 that it is.

16 So they'd have to - and then every three  
17 months to have to change it, to magic1, magic 2, or  
18 tragic, or whatever I can remember.

19 MS. HOWE: Well, the session that we  
20 looked, the physician initially enters their log in  
21 and their password, and then there are certain  
22 screens that just the physician has access to. And  
23 so he gets access to that screen, he inputs his  
24 information, and then he has an A or an E button to  
25 push.

1 CHAIRMAN MALMUD: Exactly.

2 MS. HOWE: And he either accepts or he  
3 edits.

4 CHAIRMAN MALMUD: In the example that Mr.  
5 Rothchild cited, if I were to enter my computer to do  
6 a report, I'd have to enter my name and then my  
7 password. I know have access to the screen that  
8 allows me to dictate or type in my report.

9 But the report can't go out until it's  
10 signed, so the password has to be reentered as the  
11 electronic signature.

12 So if I left it open and unsigned, no one  
13 else could sign it for me unless they knew my  
14 password.

15 MS. HOWE: In the facility we're looking  
16 at, you do not reenter your password.

17 CHAIRMAN MALMUD: That could be  
18 troublesome.

19 MS. HOWE: You just push an A or an E.

20 CHAIRMAN MALMUD: That can be  
21 troublesome, because that leaves the opportunity that  
22 Mr. Rothchild alluded to of my having been called out  
23 to an emergency, leaving my screen on with orders  
24 partially written, and someone else could complete  
25 the order for me, or complete the dictation and it

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1 would not be a valid document.

2 So we do require that the signature be  
3 reentered for each entry.

4 Now if I am dictating a series of 20  
5 cases, I can dictate all 20, sign none of them until  
6 the very end. Then it will show me a list and I can  
7 sign them all at one time. I don't have to sign each  
8 one individually. But no one else can sign them;  
9 only I can sign them with my password.

10 Now I don't know that that is the best  
11 system in the world, but it works very well at our  
12 institution, and it has worked very well for us.

13 MS. HOWE: And I think it's easier for  
14 us to accept the second password entry as kind of,  
15 you understand you have to take another step that  
16 includes your specific password and ID, but that we  
17 have to look at the other ones too. And we don't  
18 know exactly where this line is, and that's one of  
19 our difficulties right now.

20 So we're in the beginning of it. I was  
21 out on a site visit at a very big facility. And I  
22 thought, okay, while we're at this sophisticated high  
23 therapy device thing, I'll ask about their electronic  
24 written directives. And I said, do you have  
25 electronic written directives? No.

1                   It's not broken yet, so we're not going  
2 there.

3                   And what they do is, they use the  
4 treatment planning system to develop a written  
5 directive, and then they sign and date it, and it's  
6 a paper written directive.

7                   So I didn't get a chance to see one at  
8 the facilities.

9                   Anybody else have experience?

10                  CHAIRMAN MALMUD: Dr. Vetter.

11                  MEMBER VETTER: We are using, we are  
12 generating written directives electronically, but as  
13 Dr. Malamud mentioned, it does require the physician  
14 to go back in and reenter the password as a  
15 signature.

16                  And we've had a couple of times when that  
17 was missed, and the technologist said, it's not a  
18 completed written directive, and called the  
19 physician. The physician had to go back in, reopen  
20 it up, and sign it.

21                  MS. HOWE: So both of you are using  
22 password entry twice.

23                  MEMBER VETTER: Password entry twice.

24                  CHAIRMAN MALMUD: And the other element  
25 of this is, with a computer at home, and the ability

1 to access the computer at the hospital from home, if  
2 we did forget to sign it, we could even sign it - we  
3 can review it at home and sign it at home, in the  
4 example you cite.

5 MEMBER VETTER: I just wanted to mention  
6 one other thing, the reason we caught - we were aware  
7 of this is because the computer system keeps track of  
8 when the written directive was written, and when the  
9 signatures were placed.

10 So we caught the fact that the signature  
11 was a different time than the written directive. So  
12 we asked why are they different? We wanted to ask  
13 that before the NRC inspector saw it.

14 MEMBER NAG: Also it allows any  
15 authorized user to sign using his or her name. So  
16 let's say with my patient, for whatever reason, we  
17 wouldn't do it, so we can call up and tell them, and  
18 they can enter the system using their password, using  
19 their name, the signature will come under that  
20 authorized user's name. So that also is possible.

21 But you will be able to keep track of who  
22 exactly signed it.

23 MS. HOWE: Right.

24 MEMBER VAN DECKER: I was just going to  
25 make a comment. I don't envy you your task right now



1 of trying to delve into this from a smaller piece of  
2 it.

3 Obviously looking at the large global  
4 health care electronic medical record issue, there  
5 are lots of different ways things are being done.  
6 There are arguments for going to proprietary  
7 mechanisms versus nonproprietary electronic records,  
8 and cost issues and a variety of other things that go  
9 on.

10 So I think you are going to see a variety  
11 of electronic options out there, and trying to decide  
12 what may be useful for your issues as opposed to  
13 general health care is obviously not going to be an  
14 easy line to put in the sand. Because as usual, I  
15 would probably suggest that if you look at all the  
16 different models out there, looking at the physician  
17 order entry systems for the hospitals, where  
18 physicians are doing physician order entry, that  
19 whatever mechanisms they have in place would be the  
20 same type of mechanism you want for a written  
21 directive, which I suspect is, you want an  
22 identifiable order, separated from all other kinds of  
23 medical information with an attached identifier timed  
24 and can't be changed without an annotation modifier  
25 put to it at the same time.

1           And I think that is kind of what you want  
2           to be looking at. Most of those are double password  
3           protected.

4           MEMBER LEITO: Is the NRC looking just at  
5           electronic signatures for written directives? Or  
6           also electronic records for other nonwritten  
7           directive purposes? In other words, there are a lot  
8           of records, QC records, survey records, things like  
9           that, that require names of individuals that are -  
10          you can buy commercial packages that has - provides  
11          the NRC record of compliance.

12          MS. HOWE: There are other documents  
13          that require signatures. A fair number of our  
14          documents now only require initials of who did the  
15          check. An initial in this case, it doesn't quite  
16          carry the weight of a signature.

17          MEMBER LEITO: Well, you are kind of  
18          alluding to my next questions, because Part 35 says  
19          that the records have the name of the individual  
20          performing it. But a lot of the commercial packages,  
21          like Rio (phonetic) pharmacy packages and so forth,  
22          they only allow initials.

23                 So there has been a question amongst a  
24                 lot of RSO types that the fact that you can only by  
25                 the fact of the software itself, only put I think a

1 three-letter initial in there, does that still meet  
2 the recordkeeping requirements of the name of the  
3 individual?

4 And we've gone back to these commercial  
5 vendors, and they aren't going to change it, because  
6 they say they have to go back to the FDA - no  
7 offense, Orhan - go back to the FDA to make these  
8 changes in their software.

9 So we're kind of in this quandary where  
10 one way we've done it, and we haven't been challenged  
11 on it, but we don't necessarily wave it in front of  
12 the inspectors, is the fact that we have this sort of  
13 cheat sheet where we have - each person has a unique  
14 mnemonic that belongs to them, has their signature,  
15 and so any record or signature is identified by this,  
16 you know, this shall I say this standard if you will  
17 that can be referenced.

18 But it still doesn't meet the literal  
19 part of the record in terms of the name of the  
20 individual.

21 MS. HOWE: I think in the past we have  
22 accepted a system that is similar to what you  
23 describe. There is a difference between naming who  
24 did it, putting initials of who did it, and having to  
25 have something signed and dated.

1           So right now we think the written  
2 directive is probably our most important document  
3 where you really have to - and it has to be a  
4 specific person that signs and dates it and it has  
5 to be signed and dated before the administration.

6           So that's why we're looking at this one  
7 very closely right now. But we have accepted I think  
8 in the past a cheat sheet that says, DBH is Donna-  
9 Beth Howe, and you can't have anybody else use those  
10 initials.

11           Sandy, is that your experience as an  
12 inspector? And Sandy is nodding yes, that is her  
13 experience as an inspector.

14           CHAIRMAN MALMUD: Does that complete the  
15 presentation, Dr. Howe?

16           MS. HOWE: He seems to have a question.

17           Oh.

18           Yes, that completes my presentation.

19           CHAIRMAN MALMUD: Thank you very much.  
20 It's 10 after 5:00. We agreed to adjourn at 5:00.  
21 We're only 10 minutes late.

22           Is there a motion for adjournment of  
23 today's session?

24           MALE VOICE: So move.

25           CHAIRMAN MALMUD: Second?

1 MALE VOICE: Second.

2 CHAIRMAN MALMUD: All in favor? It's  
3 unanimous, thank you.

4 (Whereupon at 5:12 p.m. the proceeding in  
5 the above-entitled matter was adjourned)

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