

**Official Transcript of Proceedings**  
**NUCLEAR REGULATORY COMMISSION**

Title:                   Advisory Committee on the Medical  
                              Uses of Isotopes

Docket Number:       (not applicable)

Location:              Rockville, Maryland

Date:                    Wednesday, April 20, 2005

Work Order No.:       NRC-340

Pages 1-227

**NEAL R. GROSS AND CO., INC.**  
**Court Reporters and Transcribers**  
**1323 Rhode Island Avenue, N.W.**  
**Washington, D.C. 20005**  
**(202) 234-4433**

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

+ + + + +

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

(ACMUI)

+ + + + +

MEETING

+ + + + +

WEDNESDAY,

APRIL 20, 2005

+ + + + +

ROCKVILLE, MARYLAND

+ + + + +

The committee met at the Bethesda North  
Marriott Hotel and Conference Center, 5701 Marinelli  
Road, at 8:00 a.m., Leon S. Malmud, Chairman,  
presiding.

COMMITTEE MEMBERS:

LEON S. MALMUD, M.D., Chairman

DAVID A. DIAMOND, M.D., Member

DOUGLAS F. EGGLI, M.D., Member

RALPH P. LIETO, Member

SUBIR NAG, M.D., Member

ALBERT E. RAIZNER, M.D., Member

SALLY WAGNER SCHWARZ, R.Ph., Member

1        COMMITTEE MEMBERS: (cont'd)

2        ORHAN SULEIMAN, Ph.D., Member

3        WILLIAM VAN DECKER, M.D., Member

4        RICHARD J. VETTER, Ph.D., Member

5        JEFFREY F. WILLIAMSON, Ph.D., Member

6

7        NRC STAFF PRESENT:

8        THOMAS H. ESSIG, Designated Federal Official

9        ROGER W. BROSEUS, Ph.D.

10       IVELISSE CABRERA

11       DONNA-BETH HOWE

12       ANGELA McINTOSH

13       CHARLES L. MILLER

14       SAMI SHERBINI, Ph.D.

15       RONALD ZELAC, Ph.D.

16

17       ALSO PRESENT:

18       LYNNE A. FAIROBENT, AAPM

19

20

21

22

23

24

25

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

I-N-D-E-X

<u>AGENDA ITEM</u>	<u>PAGE</u>
Opening Remarks by Mr. Essig . . . . .	4
Opening Remarks by Dr. Miller . . . . .	7
Commission Briefing Preparation . . . . .	14
ACMUI Review of Medical Events Involving . . . . .	44
I-131	
Case Experience Using I-125 Seeds as . . . . .	56
Markers	
FDA Radiation Dose Limits for Human . . . . .	149
Research Subjects Using Certain Radio-	
labeled Drugs: Adults and Children	
Establishing Guidance on Exceeding Dose . . . . .	165
Limits for Members of the Public	
Status of Rulemaking, Part 35 - Training . . . . .	182
and Experience	
Public Comment . . . . .	224
Adjourn	

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

(8:13 a.m.)

MR. ESSIG: As the Designated Federal Official for this meeting, I'm pleased to welcome you to Rockville for the public meeting of the Advisory Committee on the Medical Uses of Isotopes.

My name is Thomas Essig. I'm Branch Chief of the Material Safety 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 alternate Designated Official is Cynthia Flannery.

This is an announced meeting of the committee. It is being held in accordance with the rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission. The meeting was announced in the February 28, 2005, edition of the Federal Register.

The function of the committee is to advise staff on issues and questions that arise on the medical use of byproduct material. The committee provides counsel to the staff but does not determine or direct the actual decisions of the staff or the Commission. The NRC solicits the views of the committee and values them very much.

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

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

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

19 At this point, I would like to introduce  
20 the members who are here today. Dr. Douglas Eggli,  
21 Nuclear Medicine Physician; Dr. David Diamond,  
22 Radiation Oncologist; Dr. Subir Nag, Radiation  
23 Oncologist. Would you raise your hand, Dr. Nag?

24 (Laughter.)

25 Dr. William Van Deck, Nuclear

1 Cardiologist; Ms. Sally Schwarz, Nuclear Pharmacist;  
2 Dr. Richard Vetter, Radiation Safety Officer; Dr.  
3 Jeffrey Williamson, Therapy Physicist; Dr. Albert  
4 Raizner, who is with us for the first time today, who  
5 is an Interventional Cardiologist; and Mr. Ralph  
6 Lieto, Nuclear Medicine Physicist; and Dr. Orhan  
7 Suleiman from the Center for Devices and Radiological  
8 Health from the Food and Drug Administration.

9 MEMBER SULEIMAN: Actually, that's Center  
10 for Drug Evaluation and Research.

11 MR. ESSIG: I still didn't get this right.

12 (Laughter.)

13 Okay. We'll fix it for next time. I  
14 updated some old notes.

15 Mr. Ed Bailey, who is our State  
16 Representative, and Dr. Robert Schenter, Patient  
17 Advocate Representative, were unable to attend today's  
18 meeting.

19 In accordance with the bylaws of the  
20 committee, I will chair the meeting until Dr. Malmud  
21 arrives. And then, following the discussion of each  
22 agenda item, the chair -- either myself or Dr. Malmud,  
23 at our option -- may entertain comments or questions  
24 from members of the public who are participating with  
25 us today.

1           Our first agenda item following these  
2 opening remarks, we will hear from Dr. Charles Miller,  
3 to whom this committee reports, and Charlie will share  
4 some -- some views with us.

5           Charlie?

6           DR. MILLER: Thank you, Tom. Good morning  
7 and welcome, everyone. It's going to be warm in  
8 Washington today. I think it's supposed to get up to  
9 88 degrees.

10           Angela, I don't know if we can get someone  
11 to see -- is it warm in here? Are people feeling  
12 warm? Comfortable? Warm? Maybe we could see if the  
13 building could readjust the conditioning. Absent  
14 that, I invite anyone, if you want to take your coat  
15 off, please do so. We want to be comfortable in this  
16 environment.

17           This is the first time we've had the  
18 meeting in this facility. It's a new facility, and we  
19 strive to have it in the ACRS room, but there was a  
20 conflict with the room today. I just want to let you  
21 know that I've had some meetings with John Larkins.  
22 John is the Staff Manager that really runs the ACRS.  
23 And John feels that we can -- we can get that room,  
24 but I think what we have to do is the same as the ACRS  
25 and ACNW does.



1           We're going to have to be able to schedule  
2 ahead when we want to have the meetings. And if we --  
3 if we get dates locked in that don't conflict with the  
4 ACRS and ACNW meetings, which are held on the same  
5 week every month, I think that we can do a better job  
6 of getting that room. But absent that, I think we've  
7 got a reasonable facility here today.

8           I just wanted to take a moment to also  
9 apologize on behalf of the Commission for having to  
10 move the Commission meeting until this afternoon. It  
11 was originally scheduled for this morning. That was  
12 kind of beyond our control and the Commission's  
13 control.

14           Two Commissioners were summoned down to  
15 Congress this morning and have to appear down there.  
16 And what we thought it would be best to have is that  
17 when you meet with the Commission you're able to meet  
18 with a full complement with the Commission, especially  
19 in light of the fact that the two new Commissioners  
20 were the ones that were summoned downtown.

21           So it will give you an opportunity this  
22 afternoon to -- to meet with the whole Commission, all  
23 five, and it's been a while since we've had five  
24 Commissioners. And I'm sure they're very interested  
25 in hearing your remarks.

1 I want to -- I just want to give a note of  
2 appreciation for the work that we've been doing over  
3 the past year. I think we've made some significant  
4 accomplishments, and I think you've made some  
5 significant accomplishments helping us. We'll have  
6 the opportunity to discuss some of those this  
7 afternoon with the Commission, so I look forward to  
8 that discussion.

9 Given the fact, Tom, that we're running a  
10 little bit behind, let's move on with the agenda.

11 Again, welcome.

12 MR. ESSIG: Okay. We have set aside some  
13 time this morning to -- to go over the Commission  
14 briefing preparation. We have set that -- some time  
15 aside until 9:00. The presentations that the three of  
16 you will be doing -- Jeff Williamson has two, and Dr.  
17 Eggli and Dr. Vetter each -- each have one.

18 And I believe at this point -- I mean, the  
19 slides are -- have been given to the Commission, so  
20 they're -- we really can't change what -- the content.  
21 And so I think it's -- we could probably use our time  
22 best by just quickly rolling through the slides.

23 And if anybody has any -- although we  
24 can't change the content of the slides, we can  
25 certainly, if we need to emphasize some points or --

1 or deemphasize some points, we can certainly do that.  
2 So I think it would be helpful to have the -- any  
3 members of the committee who feel that a certain  
4 emphasis or deemphasis should be made, that we can do  
5 that during the course of the presentation.

6 I would offer that three of the four areas  
7 that we'll be talking about represent works that have  
8 already been completed by the committee. They are  
9 basically in -- in the past, and, of course, that  
10 would be the -- the ICRP recommendations, which Dr.  
11 Vetter will be presenting, and the St. Joseph Mercy  
12 Hospital case that Dr. Williamson will be presenting.  
13 And then, the other one that -- the fourth one -- or  
14 the third one, I'm sorry, is the training and  
15 experience criteria that Dr. Egli will be presenting.

16 All of -- those three are -- as I  
17 mentioned, those are completed efforts of the  
18 committee, and we thought it would be appropriate that  
19 when we were asked for topics this year that we -- we  
20 share with the Commission some of the -- or that the  
21 committee felt it appropriate, through Dr. Malmud, to  
22 share with the Commission efforts that had been  
23 completed.

24 And then, one of them, the medical events  
25 criteria, is a work in progress. And the only -- the

1 only note -- well, on all of these presentations I  
2 would emphasize that if there is some -- particularly,  
3 I'll just highlight, for example, on the training and  
4 experience, the Commission has voted. The rule is  
5 final. It's been published, and the committee offered  
6 its views to the Commission.

7 The views of the agreement states were  
8 also offered on the number of hours of training and  
9 experience, and the Commission elected to choose the  
10 option for -- that the agreement states offered for  
11 the authorized user training.

12 And so as I mentioned to Dr. Eggli  
13 previously, this is not the time to -- to present to  
14 the Commission that -- I mean, you can walk through  
15 the process that was used to present -- to formulate  
16 the recommendations, and merely note that you had --  
17 you had the opportunity to present the recommendations  
18 of the Commission, but it won't serve any purpose if  
19 you attempt to tell the Commission that -- that  
20 they've made an error and it should rethink the issue.  
21 I mean, they voted on it knowing full well -- having  
22 the benefit of your -- of your views.

23 And, likewise, on the Medical Events  
24 Subcommittee, that is a work in progress. We don't  
25 have yet agreement amongst the subcommittee or the

1 full committee. But we thought enough progress had  
2 been made that it would be worth sharing with the  
3 Commission. And I notice in Dr. Williamson's slides  
4 that there are some recommendations, and we have to be  
5 careful because these are not recommendations to the  
6 Commission. They are recommendations from the  
7 subcommittee to the full committee.

8 So I think, Dr. Williamson, as part of  
9 your opening remarks, or when you -- when you come to  
10 the point in the slide when you say recommendation,  
11 make sure that the Commission understands that it's an  
12 internal committee recommendation to itself.

13 MEMBER WILLIAMSON: I will.

14 MR. ESSIG: And so, with that, maybe we  
15 should -- we should go ahead and -- what is the first  
16 one that you have up there, Ivelisse? The first one  
17 would be -- that is training and experience, I  
18 believe. No, I'm sorry. That's the --

19 MEMBER WILLIAMSON: Tom, I would recommend  
20 that --

21 MR. ESSIG: That's the medical event.

22 MEMBER WILLIAMSON: -- we not review the  
23 medical events slides at this time, but use whatever  
24 time savings we can to see if we can get our  
25 subcommittee consensus reestablished, because the

1 presentation I will make to this group is very quick,  
2 because it is essentially equivalent the one I had for  
3 the Commission staff.

4 MR. ESSIG: Okay.

5 MEMBER WILLIAMSON: Because I think a  
6 major issue for that presentation is whether we have  
7 even a subcommittee consensus at this time.

8 MR. ESSIG: Okay.

9 MEMBER EGGLI: Mr. Chairman?

10 MR. ESSIG: Yes.

11 MEMBER EGGLI: The iodine incidence will  
12 not take its allotted full hour. So if this  
13 discussion needs to roll over --

14 MR. ESSIG: Okay.

15 MEMBER EGGLI: -- the iodine incidence  
16 could easily be done in 30 minutes.

17 MR. ESSIG: That's good to know. Thank  
18 you.

19 Okay. So the first one that we have for  
20 the Commission meeting this afternoon would be the  
21 Part 35 training and experience rule, and that would  
22 be Dr. Eggli. So if we can -- if we can call up that  
23 presentation. Oh, the cap is -- oh.

24 (Pause.)

25 All right. I would suggest while we're

1 trying to -- while we're trying to work out  
2 difficulties, we may have a corrupted file.

3 MEMBER EGGLI: Okay.

4 MR. ESSIG: We have hard copy of your  
5 slides.

6 MEMBER EGGLI: Actually, they're not in  
7 everybody's binder. Apparently, somebody put them in  
8 your binder. My binder -- I have my copy, but they're  
9 not in the actual binder that was distributed.

10 MR. ESSIG: Okay.

11 MEMBER EGGLI: But I can -- we can go  
12 ahead. I mean, they were distributed in advance to  
13 all the members.

14 MR. ESSIG: Yes. Why don't we go ahead.

15 MEMBER EGGLI: Okay. The presentation to  
16 the Commission was designed to review the deliberation  
17 process. And as Tom said, even though the decision is  
18 -- has already been, you know, made, it was my  
19 intention to review the thinking process that led  
20 toward the committee's recommendations to the NRC  
21 staff.

22 And as background, as part of the revision  
23 of Part 35, ACMUI reviewed the training requirements  
24 and experience for authorized users, for authorized  
25 nuclear pharmacists, for radiation safety officer, and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 for authorized medical physicists.

2 The goal of ACMUI's recommendations for  
3 training and experience requirement was to make the  
4 requirement commensurate with the risk. And ACMUI  
5 established a subcommittee to review the training and  
6 experience requirements and make recommendations to  
7 the entire committee. The goal was to make the  
8 regulation risk-informed and performance-based rather  
9 than proscriptive.

10 With the formation of the subcommittee,  
11 the ACMUI discussion revolved around describing  
12 elements of training. Who could provide the training?  
13 Who could attest to the adequacy of that training?

14 The initial recommendations were that --  
15 of the ACMUI were that the certifying board could  
16 remain actively involved in the training and  
17 certification process. An alternate pathway was  
18 described for those individuals whose training and  
19 experience did not lead to board certification.

20 With respect that -- with respect to the  
21 training programs, ACMUI recommended that training  
22 programs would be responsible for developing a  
23 curriculum that would satisfy the broad educational  
24 and experience objectives required in the regulation.  
25 ACMUI did not recommend a specific time allocation for



1 individual curriculum components, but, rather --  
2 rather specified that content mastery should be the  
3 basis of the performance regulation.

4 In dealing with the question of who can  
5 attest to the mastery of a body of knowledge, ACMUI  
6 felt that certifying boards would not be able to  
7 actually certify competence, but could attest to  
8 mastery of a body of knowledge. And this is typical  
9 for certifying boards, is that their programs are  
10 designed to deliver a body of knowledge and to  
11 document mastery of that body of knowledge.

12 Certification has medical/legal  
13 ramifications that were unacceptable to most of the  
14 certification boards. With respect to that  
15 attestation, ACMUI recommended that the attestation be  
16 performed by training directors, since it was the  
17 training director who was responsible for similar  
18 attestations of training to the certifying boards.

19 However, the NRC subsequently determined  
20 that the public interest would be better served by  
21 requiring an authorized individual, in the case of  
22 either the authorized user, the authorized medical  
23 physicist, the authorized radiopharmacist, would be  
24 the individual who would be in the best position to  
25 provide that attestation of mastery of the body of

1 knowledge.

2           During the Part 35 rulemaking process,  
3 recommendations were offered for training requirements  
4 for all of the categories of authorized individual.  
5 And the ACMUI's recommendations were largely adopted  
6 by the Commission. A proposed rule was published  
7 based on ACMUI recommendations for a performance-based  
8 regulation.

9           Subsequently, the organization of  
10 agreement states expressed concern over authorized  
11 user training and experience for requirements of  
12 Subpart 200 and Subpart 300 uses. The concern hinged  
13 specifically on the didactic requirement and not the  
14 overall number of hours of training. The hour  
15 recommendation was 700 hours.

16           In the rulemaking process, the total hours  
17 required for training were reduced from 1,000 hours to  
18 700 hours. The distribution of training hours was a  
19 concern for ACMUI, particularly for the Subpart 200  
20 and Subpart 300 uses.

21           In clinical practice in the United States,  
22 70 percent of clinical and therapeutic nuclear  
23 medicine is practiced by diplomats of the American  
24 Board of Radiology, and it is their training  
25 requirements which most carefully are designed to meet

1 the NRC requirements. And this is because of  
2 competing training demands for diagnostic radiology  
3 residency, which is now currently one of the longest  
4 residency programs in the country at five years for  
5 baseline certification.

6 And there are 11 content areas that have  
7 to be mastered during that training period, so that  
8 most radiology residency programs will be tailored to  
9 meet the NRC's requirement to develop authorized user  
10 status within the training program, but probably not  
11 in excess of that requirement.

12 The American Board of Radiology has  
13 indicated that it intends to require training programs  
14 to train their trainees to the level of certification  
15 for Subpart 300, or therapeutic uses. The concern for  
16 ACMUI was that because approximately 20 percent of all  
17 radiology residents are not board certified  
18 immediately on completion of their training program  
19 that training directors will have to train radiology  
20 residents to the ultimate pathway requirements in  
21 Subpart 300, or the Subpart 390 requirements for the  
22 alternate pathway.

23 Some of the most talented radiologists I  
24 personally know did not make their board certification  
25 the first time around, and then there would be a

1 period of a year or more during which these diplomats  
2 would be unable to become authorized users, if they  
3 were not trained to the alternate pathway  
4 requirements. So that the American Board of Radiology  
5 will require its training programs to train its  
6 diplomats to the Subpart 390 alternate pathway  
7 requirements.

8 In its discussions, ACMUI felt that the  
9 200 hours of didactic requirement for Subpart 300 uses  
10 was excessive and recommended a didactic component,  
11 which now is defined as classroom and laboratory, of  
12 closer to 80 hours.

13 ACMUI was concerned about a negative  
14 impact of 200 hours of requirement, because, again,  
15 that would shorten the clinical time spent to  
16 approximately 500 hours. And since nuclear medicine  
17 is different than most of diagnostic radiology, where  
18 nuclear medicine is physiologic rather than anatomic  
19 imaging, and nothing else in the radiology residency  
20 reinforces that physiologic process, that the time  
21 spent in developing clinical competence would be  
22 truncated by the -- by the long didactic requirement.

23 There is also potentially a cost  
24 associated with the additional didactic training that  
25 will have to be borne by the training programs. And

1 in the current medical environment, those costs are  
2 not compensated.

3 The components of didactic and classroom  
4 training are not well defined, and that was the  
5 initial intent of ACMUI in its recommendation, that  
6 when a program was performance based that it is the  
7 responsibility of the training programs to define  
8 their programs.

9 However, as the requirement becomes more  
10 defined and less performance based, it becomes more  
11 important to define what didactic or classroom and  
12 laboratory training actually is. Dorland's Medical  
13 Dictionary defines didactic as conveying instructions  
14 by lectures and books rather than by practice.

15 As a result, there will be some potential  
16 for misunderstanding of the intent of the requirement,  
17 and training directors need to be certain that the  
18 programs they design will meet the requirement of the  
19 regulation.

20 And as a result of our further discussion  
21 with NRC staff, we would ask that -- that these  
22 requirements be defined adequately so that training  
23 directors do not have uncertainty about what elements  
24 of a training program will be accepted to meet the  
25 Subpart 200 requirements and which training components

1 will not be.

2 As a person who has to design such  
3 training programs, this is of critical importance to  
4 me. I do not want to send a preceptor statement  
5 forward to later discover that the 200-hour training  
6 program that I designed for my trainees was not  
7 adequate. This is an area I think that requires  
8 further discussion and some degree of resolution with  
9 NRC staff.

10 Thank you.

11 MR. ESSIG: Okay. Comments on Dr. Eggli's  
12 presentation?

13 DR. MILLER: I'll kick it off.

14 MR. ESSIG: Okay.

15 DR. MILLER: Dr. Eggli, you're making a  
16 recommendation that we have further dialogue on  
17 basically the guidance that's given. Do you have any  
18 -- I would be interested in the committee's thoughts  
19 on how we might go about doing it.

20 MEMBER EGGLI: For this committee, and not  
21 in front of the Commissioners, essentially what we've  
22 done is we've taken a performance-based regulation and  
23 made it proscriptive. And I think that if you're  
24 going -- if we're going to make the regulation  
25 proscriptive, we need to define the components.

1 I need to know how many hours of lecture  
2 I have to provide, and for what is called laboratory  
3 experience what elements comprise laboratory  
4 experience. You know, is it -- is it participation in  
5 surveying? Is it experience in the hot lab? Is it  
6 operation of the instrumentation? On a practical  
7 basis, what counts?

8 And I think -- truthfully, I think you  
9 need a detailed list of what counts, so that I know  
10 what I need to include, because truthfully it's going  
11 to be extremely difficult for me to get to that 200-  
12 hour mark in any kind of meaningful fashion.

13 One of the problems that I have is that  
14 radiology residents aren't very interested in nuclear  
15 medicine. And the more that I put them out into this  
16 practical laboratory experience with stuff that they  
17 perceive as busy work, the less likely they are to be  
18 fired up by many of the new and interesting things  
19 that are happening in the field of nuclear medicine.

20 So I have to try to design a training  
21 program that will hold their interest and yet comply  
22 with the letter of the regulation, because I think at  
23 this point compliance with the spirit of the  
24 regulation is inadequate.

25 MR. ESSIG: Mr. Lieto?

1                   MEMBER LIETO: I would like to echo Dr.  
2 Eggli's comments, and I think one of the things that  
3 -- and I don't know if he wants to include this as  
4 part of the presentation, if it will have value or  
5 not, is the fact, in going from this non-proscriptive  
6 performance-based requirement in the regulations that  
7 this 200 hours really had never gone out for comment.

8                   It was basically a discussion and  
9 recommendation from the ACMUI. So you really never  
10 had the opportunity for this to go out to the  
11 regulated community it's going to effect for comment.  
12 So it's something that -- that I think NRC staff and  
13 the NRC needs to be aware of.

14                   And my second comment was, to follow up  
15 how this is going to be documented, that Dr. Eggli  
16 just brought up, is will those activities that are not  
17 NRC regulated activities -- could they be included?  
18 And that's why I think now that you've gone to this  
19 very proscriptive requirement, we're going to really  
20 need to know, in these training programs, you know,  
21 what's going to be acceptable and what's not going to  
22 be challenged.

23                   MR. ESSIG: Dr. Williamson?

24                   MEMBER WILLIAMSON: And I think in the  
25 interest of quality medical education and health care,



1 you should strive to allow them to include as many  
2 meaningful things in this lecture or laboratory format  
3 as they can, and not force them to spend 200 hours on  
4 how to survey a box of equivalent things that -- you  
5 know, to -- you know, to overemphasize anyway  
6 relatively straightforward technical matters and allow  
7 them to be able to include other things such as  
8 probably case presentations and other areas -- other  
9 topics where the technical and clinical kind of blend  
10 together.

11 MR. ESSIG: Dr. Eggli?

12 MEMBER EGGLI: And, again, if we look at  
13 the -- the requirements for education and training for  
14 the more limited uses, which include radioiodine  
15 therapy by people who are only doing radioiodine  
16 therapy, the requirement for didactic and classroom  
17 training is significantly less.

18 So what we are doing, in part, the  
19 Part 300 uses, is we are making a different  
20 requirement ostensibly to cover the same material that  
21 requires a much lower requirement if all I do is that  
22 alone. And it seems if all I'm doing is that alone,  
23 you know, the risk to the public is no different if I  
24 do iodine therapy in isolation or if I do iodine  
25 therapy in conjunction with other radionuclide

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 therapies and clinical nuclear medicine.

2 So we've got a -- a double standard here  
3 in regulation that I think is a real problem.

4 MR. ESSIG: Other comments?

5 MS. SCHWARZ: Sally Schwarz.

6 MR. ESSIG: Sally?

7 MS. SCHWARZ: I would like to make one  
8 additional comment. Dr. Siegel is very concerned  
9 about the number of hours increasing from 80 to 200.  
10 And just specifically, you know, the amount of what  
11 exactly is going to be added, just as is being  
12 mentioned both by Jeff and by Doug, that it would be  
13 helpful to exactly know what can be included to  
14 increase that training to 200 hours. And cost  
15 effectively it's going to be problematic to be able to  
16 come to those hours and not take away from the  
17 clinical training, if you're adding that much into the  
18 didactic coursework.

19 MR. ESSIG: Okay. Thank you.

20 Dr. Eggli?

21 MEMBER EGGLI: One last comment. My  
22 concern is we're going to turn out physicians who are  
23 well trained in safety and inadequately trained for  
24 clinical practice.

25 MR. ESSIG: Okay. Other comments?

1 All right. We'll move on to the next  
2 topic, then. Oops. I'm sorry.

3 DR. MILLER: Before we do, I think that we  
4 -- you know, I think we need to establish some kind of  
5 path forward. The Commission has decided on the  
6 regulation. You're bringing concerns to the table  
7 that you've aired before that I assume that you will  
8 air with the Commission this afternoon.

9 MEMBER EGGLI: I won't present to the  
10 Commission anything more than I did in the formal  
11 presentation.

12 DR. MILLER: Okay. But I think, from my  
13 perspective, we need to hammer this out, you know, and  
14 I just throw this out as a thought process. I think  
15 a way to do that would be to have the committee  
16 engaged with the staff in trying to determine what  
17 regulatory guidance and what it should look like.

18 That said, what I think we also need to  
19 do, we need to get the agreement states engaged again,  
20 because they were big voices in -- in the  
21 determination and the Commission -- weighing in the  
22 Commission's decision.

23 While there's representation on the  
24 committee from the states, unfortunately Mr. Bailey  
25 couldn't be here today. But I'm just interested in

1 your thoughts on that. I mean, it would seem to me,  
2 you know, it means a spirited dialogue. It means a  
3 lot of negotiation, and it means, you know, getting  
4 the parties to the table to try to hammer it out if  
5 we're going to get there with regard to guidance,  
6 because the devil sometimes is in the details.

7 MR. ESSIG: I think Mr. Lieto was first,  
8 and then Dr. Eggli.

9 MEMBER LIETO: Well, I agree that I think  
10 the guidance is going to be the next battleground, if  
11 you will, on implementation of this training and  
12 education.

13 One thing that I'm a little bothered by is  
14 that when we had the discussion, both in the  
15 teleconference and I think in a subsequent meeting, my  
16 impression -- and it was, again, my opinion -- is that  
17 the 200 hours was not a problem with the agreement --  
18 was really an issue with only a couple agreement  
19 states that wanted this, and that generally from Mr.  
20 Bailey my impression was that the agreement states did  
21 not have a problem with our recommendation.

22 So there has been I think some dynamics  
23 that have gone on that this committee is not aware of  
24 to get an understanding of why we're at this -- you  
25 know, this difficulty that we're at right now.

1           So I think I agree that we have to have  
2 the agreement states, but I -- involved, but I think  
3 there also needs to be some understanding that when  
4 the agreement states are having input it needs to be  
5 understood that the input that we're getting is going  
6 to reflect what the actual overall opinion is of the  
7 agreement states, because I don't think that was the  
8 case.

9           MR. ESSIG: Well, I would offer that  
10 whenever we have an issue that goes to 33 agreement  
11 states, we never have unanimity of views. And we try  
12 as we can to -- to work through the OAS Executive  
13 Committee, Organizational Agreement States Executive  
14 Committee, and they present to us a view which is  
15 reasonably a consensus view. But I completely agree  
16 that there are a number of states that may have not  
17 had a problem with the 80 hours.

18           And then, there were a number of rather  
19 vocal ones that -- that preferred the 200 hours and  
20 had a -- and had a basis -- they articulated a basis  
21 for it. So I understand how we got where we are, and  
22 we'll just have to work on the guidance. As we've  
23 said, the devil is in the details, and we'll have to  
24 talk about that.

25           Dr. Eggli, you had comment?

1           MEMBER EGGLI: I was going to comment  
2 something similar to what Ralph had just said, but  
3 that, again, it was our understanding from Mr. Bailey  
4 that it was specifically two of the 33 agreement  
5 states who had a serious problem with this, and that's  
6 a very small subset of the total. And it's kind of  
7 the tail wagging the dog, in a sense.

8           And I don't -- you know, there is a  
9 serious economic impact here, and there is a serious  
10 medical education impact here. And, again, I think  
11 that a lot of this discussion happened almost out of  
12 sight, and this committee certainly didn't have an  
13 opportunity to discuss the recommendation or have any  
14 dialogue with the OAS.

15           And I think maybe a format would be to set  
16 up some kind of a -- some kind of an opportunity to  
17 have discussion between the ACMUI and the members of  
18 the agreement statement organization, so that, one, we  
19 can share our concerns with them, they can better  
20 understand the impact of the recommendation they have  
21 made.

22           And I'm not sure they fully understand the  
23 impact of the recommendation they made on a downstream  
24 basis, both economically and educationally. And to  
25 see if in the regulatory space, in the guidance space,

1 then, if we can come up with a reasonable agreement  
2 between ACMUI and the agreement states.

3 I'm certainly willing to have that kind of  
4 discussion with the agreement states, and have a good  
5 give and take as to what we're really trying to  
6 accomplish here, because I know that our goals are the  
7 same. I know that we and the agreement states want to  
8 achieve the same thing.

9 We come at it from very different  
10 perspectives, and I think it would be very useful for  
11 us to fully understand their perspective. And I think  
12 it would be very useful for the organization of  
13 agreement states to fully understand our perspective  
14 and our perceptions of the impact.

15 MR. ESSIG: Dr. Williamson?

16 MEMBER WILLIAMSON: Well, I'm wondering if  
17 perhaps a working group with the -- the three affected  
18 stakeholders, if I might call them that -- NRC, the  
19 agreement state representatives, and I think some  
20 representatives from the nuclear medicine community  
21 who are involved in developing educational standards  
22 -- and you have the opportunity for more extensive  
23 discussions and the opportunity to provide -- develop  
24 some sort of a product or draft guidance that could  
25 then be reviewed in more detail here. Maybe that

1 would be a faster, more appropriate vehicle for this  
2 process of reeducation rather than a one-hour session  
3 before the ACMUI.

4 MR. ESSIG: Okay. Thank you.

5 The record will note that Dr. Malmud has  
6 now joined us. I can -- I may relinquish my job as  
7 Acting Chair of the ACMUI to him and would ask, Dr.  
8 Malmud, that you just reposition the microphone that's  
9 in front of Dr. Suleiman, so that you may -- you may  
10 use it.

11 Just so that you know where we are on the  
12 agenda, we are going through the Commission briefing  
13 preparation, and we've heard from only Dr. Eggli at  
14 this point. And next on the -- Dr. Williamson has  
15 asked that the medical event reporting issues be -- be  
16 done last of the -- for the purposes of this dry run,  
17 and that next we could go to Dr. Vetter on his ICRP --  
18 his review for the ICRP 2005 recommendations.

19 And we have done this at the request of  
20 the Advisory Committee on Nuclear Waste. We met,  
21 discussed the -- the draft recommendations, and then  
22 Dr. Vetter carried the views of this committee forward  
23 to a special meeting of the ACMUI.

24 So, Dr. Vetter?

25 MEMBER VETTER: Thank you very much.



1           We discussed this last fall, and then I --  
2           as Tom mentioned, I carried our views forward to a  
3           meeting of the ACNW, and what I will be sharing  
4           basically is a boiled-down version of that  
5           information.

6           So what I'll be sharing with the  
7           Commissioners is that our comments will be limited to  
8           items of greatest interest to us. The recommendations  
9           are quite extensive, and so we'll be -- we simply  
10          don't have time to talk about everything. We'll make  
11          no comments about environmental recommendations.

12          One of the things that -- one of the  
13          issues that ICRP has been emphasizing in its reports  
14          is the issue of justification -- relative to medical  
15          exposure is justification. ICRP takes the view that  
16          justification of practice lies mostly with the  
17          profession rather than government, and the  
18          justification of the procedure falls on the  
19          practitioners. And ACMUI agrees with that position.

20          Restriction -- ICRP spends considerable  
21          time talking about the concept of constraints, and in  
22          some cases constraints are a fraction of the limit.  
23          In other cases, constraints are limited to the dose  
24          that's acceptable to an individual person or the most  
25          highly exposed person, and that might actually be more

1 than a limit.

2 So the discussion of constraints tends to  
3 be a little bit confusing. They do, however, state  
4 rather clearly that they consider achieving  
5 constraints to be an obligation, and that a program  
6 that exceeds constraints fails.

7 And it's ACMUI's point of view that  
8 failure -- characterizing exceeding constraints as a  
9 failure is very negative -- creates a very negative  
10 measure. It could actually be counterproductive, and  
11 we think that the use of the word "failure" when  
12 characterizing a program should be limited to the  
13 limits and not to constraints.

14 Just an example of the use of a  
15 constraint, ICRP recommends that constraint for the  
16 fetus of a declared pregnant worker should be one  
17 millisievert. In this country currently, we have a  
18 limit. It's a limit; it's not a constraint -- a limit  
19 of five millisieverts for the fetus of a pregnant  
20 worker. That has been in place for many, many years.  
21 ACMUI considers that to be safe. It's a very small  
22 fraction of the threshold at which developmental  
23 effects occur, and the risk of cancer in childhood as  
24 a result of this sort of an exposure is very, very  
25 small, perhaps negligible or zero.

1           So we think one millisievert may be an  
2 appropriate ALARA goal for some, but it should not be  
3 used as a constraint.

4           Just to try to put this into perspective,  
5 typical doses to people working in medicine in a  
6 cardiac lab are 10 to 50 millisievert to the badge,  
7 but in nuclear medicine it's -- well, it's 10 to 50  
8 millisievert to the badge.

9           The -- it's very easy to constrain, if  
10 you will, the dose to the abdomen of someone in a  
11 cardiac lab, because the energy of the radiation is  
12 quite low, and a half-millimeter lead equivalent apron  
13 takes out 97 percent of the -- attenuates 97 percent  
14 of the scattered radiation.

15           So it's rather easy to keep the doses  
16 below five millisievert. In fact, most doses to the  
17 abdomen are closer to zero in a cardiac lab.

18           In nuclear medicine, the doses typically  
19 do not exceed five millisievert to personnel. So,  
20 consequently, keeping the dose to the abdomen is not  
21 difficult. However, in the emerging field of PET, we  
22 -- first of all, we're dealing with a very energetic  
23 radiation of 511 KEV, which is almost an order of  
24 magnitude greater in energy than the typical energy in  
25 a cardiac lab. So it's very penetrating. There is

1 nothing you can do in terms of personal protection --  
2 personal protective equipment to try to reduce the  
3 dose to the abdomen.

4 It basically would require removing the  
5 individual from that area if you wanted to reduce the  
6 dose. So with typical procedures of tens of  
7 millisievert to the badge of someone working in PET,  
8 the dose to the abdomen is going to greatly exceed  
9 five millisievert. And medical centers are going to  
10 have to work hard even now to keep doses to the  
11 abdomen less than five millisievert for pregnant  
12 workers.

13 So using a constraint of one would clearly  
14 require us to remove people from that working area.  
15 There is no accommodation that could be made, and this  
16 actually would be very disconcerting for those people  
17 who had to be removed, and it would be very difficult  
18 for employers.

19 The ICRP also uses the concept of  
20 constraint for public dose limits, and they use this  
21 in two different ways, which, again, confuses the  
22 issue a little bit. For some members of the public,  
23 they actually use a constraint that exceeds the limit.  
24 In this case, they say that a few millisievert may be  
25 reasonable for some of these cases, but that we should

1 -- but that regulators should not be rigid in applying  
2 that constraint.

3 So, for example, the NRC limits the  
4 radiation exposure to a member of the public to five  
5 millisievert when that member of the public could come  
6 in contact with a radioactive patient that's been  
7 released from a hospital, the most common case being  
8 use of radioiodine to treat thyroid cancer.

9 So the limit that the NRC uses is five  
10 millisievert. If we review the NCRP recommendations,  
11 they also recommend five millisievert to be used in  
12 general, but they also say that this in some cases  
13 could be -- up to 50 millisieverts could be allowed if  
14 those members of the public are instructed and  
15 monitored.

16 For example, if you have a child who -- or  
17 an elderly member of the family who is treated and  
18 needs considerable care at home, that those members of  
19 the public should be allowed to receive more than five  
20 millisievert -- up to 50 -- if they are instructed on  
21 how to minimize the radiation exposure and if they are  
22 monitored. And the ACMUI considers that to be good  
23 guidance.

24 In another case, the ICRP uses constraints  
25 to reduce exposures below the one millisievert limit,

1 and ACMUI considers this -- the use of the constraint  
2 in this case to be very problematic in medicine, and  
3 it could result in exorbitant costs -- for example, in  
4 the shielding of facilities.

5 NCRP's position is that a -- they don't  
6 use the word "constraint." They describe it more or  
7 less as a sublimit. They say that, in general, a  
8 sublimit of .25 millisievert should be used when  
9 making plans that result in exposure of the public,  
10 but that in some cases that should be exceeded, and  
11 you could design -- for instance, in the design of  
12 medical facilities, you could design those facilities  
13 to a limit of one millisievert, if you're using -- if  
14 you're designing those facilities in accordance with  
15 the NCRP recommendations, because there is  
16 considerable conservatism built into that formula.

17 ACMUI's position on this is that ALARA  
18 still works, and we think that programs that use ALARA  
19 seriously will keep exposures way below one  
20 millisievert to members of the public, and we do not  
21 believe that a fraction of the -- a constraint should  
22 be built into the regulations to force medical  
23 facilities to reduce exposures to individual members  
24 of the public even further.

25 NCRP has recently addressed this issue.

1 In a position statement that was published in 2004,  
2 they reiterate that the limit to members of the public  
3 should be one millisievert, that in some cases this  
4 could -- this should be increased to five -- and this  
5 is to a very small number of people in this country  
6 actually, and that would be -- for example, it would  
7 be for caregivers of radiation therapy patients,  
8 radioiodine patients, for example, and that they also  
9 reiterated that the limit could be 50 millisievert in  
10 extreme cases, such as a child who had been treated  
11 with radioiodine, if the parents or caregivers had  
12 been properly trained and monitored.

13 Now, just to summarize some of the issues  
14 relative to these limits that ICRP is recommending, we  
15 consider that the limit of one millisievert per term  
16 for a pregnant worker to be very, very problematic,  
17 especially in emerging modalities where radiation  
18 exposures could be -- will be -- are considerably  
19 higher than that -- for example, in PET.

20 We're talking about a very small number of  
21 people. We're not talking about large numbers of  
22 people where we're trying to effect a limit. So we  
23 consider the risk, number one, to be very low to the  
24 individual, and the number of individuals to be very  
25 low.

1 ICRP is also recommending a general  
2 reduction after they made this recommendation  
3 previously, and they are reiterating the  
4 recommendation that workers have a limit of 20  
5 millisievert. And we consider this to be problematic  
6 for certain areas of medicine, PET being the most  
7 notable.

8 So ACRP -- ACMUI supports the NCRP  
9 recommendation and the current NRC annual limit of 50  
10 millisievert.

11 In conclusion, we find that the proposed  
12 constraints are very confusing, and in some areas  
13 would be particularly problematic. We also consider  
14 that the proposed occupational limits are problematic  
15 for some modalities.

16 Even though the average exposure to the --  
17 or the typical exposure to the average member of the  
18 worker population of medicine is a very, very small  
19 fraction of the limit, there are a few individuals  
20 where we are -- we already crowd that limit, and it's  
21 absolutely necessary in order for us to deliver  
22 adequate medical care.

23 CHAIRMAN MALMUD: Thank you.

24 Are there any comments for Dr. Vetter?

25 MR. ESSIG: Dr. Malmud, I just had one,



1 and that is the slides that you were using are -- you  
2 have some additional slides beyond those that you had  
3 given to us earlier that we had sent to the  
4 Commission. So we'll have to have copies of those  
5 slides made.

6 MEMBER VETTER: I'm sorry, I'm confused.  
7 Relative to the Commission? The Commission report?  
8 I didn't send any additional --

9 MR. ESSIG: No, I'm sorry. To the  
10 presentation for the Commission this afternoon, there  
11 were -- you had furnished some slides previously. We  
12 had six of them at least that are in the -- that are  
13 in the -- the notebook that I have that reflects what  
14 -- what went to the Commission. And there are some  
15 additional slides, so we'll probably need to get -- we  
16 will need to get copies of those -- of those made.

17 MEMBER VETTER: I don't have -- I'm sorry,  
18 I'm way off track. I don't even know what you're  
19 talking about. I don't recall sending any additional  
20 slides for the Commission. They were edited. The  
21 ones I originally sent were edited.

22 MR. ESSIG: Okay. Well, I can -- I can  
23 show you what --

24 MEMBER VETTER: Yes, okay.

25 CHAIRMAN MALMUD: Tom, are you requesting

1 a complete set of these slides?

2 MR. ESSIG: We will need to have --  
3 because I believe what went to the Commission is what  
4 we had been given earlier, which were six slides, and  
5 --

6 CHAIRMAN MALMUD: That which would address  
7 the need now is a copy of these slides?

8 MR. ESSIG: Yes. So we'll --

9 MEMBER VETTER: My understanding was the  
10 slides that I just projected is what was sent to the  
11 Commission.

12 MR. ESSIG: Okay. Then --

13 MEMBER VETTER: That's my understanding.  
14 I could be in error.

15 MEMBER EGGLI: You're using the set that  
16 Angela sent back?

17 MEMBER VETTER: I'm sorry?

18 MEMBER EGGLI: You're using the set that  
19 Angela sent back?

20 MEMBER VETTER: I'm using the set that  
21 Angela sent to me. There was nothing in my -- our  
22 packets on what was --

23 MEMBER EGGLI: I actually printed what  
24 Angela sent you, and what you projected matches.

25 MEMBER VETTER: Okay.

1 MR. ESSIG: Then, maybe what I have in  
2 this notebook, then, is -- is not truly reflective of  
3 what went to the Commission. It was my understanding,  
4 so -- there were six of them in there, so maybe there  
5 isn't a problem.

6 CHAIRMAN MALMUD: Who would know?

7 MR. ESSIG: Angela.

8 CHAIRMAN MALMUD: Angela. So we'll wait.

9 MR. ESSIG: She'll be back.

10 CHAIRMAN MALMUD: Thank you.

11 Any other items of discussion with Dr.  
12 Vetter?

13 If not, having heard from Dr. Eggli and  
14 Dr. Vetter, may we move on to Dr. Williamson.

15 MEMBER WILLIAMSON: Okay. I guess the --  
16 what you'd like me to do is just rehearse my talk on  
17 dose reconstruction. I, first, have a question of  
18 clarification. Who was the chair of the Dose  
19 Reconstruction Subcommittee?

20 MR. ESSIG: Dr. Malmud.

21 MEMBER WILLIAMSON: Okay. So this was --  
22 is in error, then.

23 MR. ESSIG: Yes. You had asked me, and I  
24 had sent an e-mail to you, and I gave you --

25 MEMBER WILLIAMSON: I didn't get that.

1 MR. ESSIG: Okay.

2 MEMBER WILLIAMSON: I sent two versions.

3 MR. ESSIG: Give me a makeup.

4 MEMBER WILLIAMSON: All right. Okay.

5 MR. ESSIG: Yes. You were the -- you did  
6 most of the technical work for the -- for the  
7 subcommittee, but Dr. Malmud was the -- was the listed  
8 chair.

9 MEMBER WILLIAMSON: All right. Do you  
10 wish to correct this slide for them -- for the  
11 Commissioners, or what should we do?

12 MR. ESSIG: We can probably --

13 CHAIRMAN MALMUD: I don't believe that the  
14 slide needs correctly. Dr. Williamson did the vast  
15 majority of the work, and I'm more than happy for his  
16 name to appear there.

17 MR. ESSIG: Okay. Fine.

18 MEMBER WILLIAMSON: Okay. All right.  
19 Well, in this presentation, I will give a brief  
20 overview of the recommendations in ACMUI's report on  
21 dose reconstruction.

22 Contrary to the first slide, Dr. Leon  
23 Malmud was actually chairman of our group.

24 Our charges were to independently review  
25 Region III's dose evaluation for an incident that

1 occurred at St. Joseph's Hospital in Ann Arbor,  
2 Michigan. In addition, we were to review the  
3 alternate dose reconstruction methodology published in  
4 a letter to the editor by Drs. Marcus and Siegel, and,  
5 finally, we also made some general recommendations  
6 regarding dose reconstruction for our incidents.

7 Our full membership is listed here. And,  
8 again, I emphasize that Dr. Malmud was the chair.

9 To briefly review the incident under  
10 consideration, nearly 300 millicuries of I-131 was  
11 orally administered to a patient who subsequently  
12 developed impaired kidney function. The patient's  
13 daughter allegedly spent six to 21 hours per day in  
14 very close proximity to the patient over a time period  
15 of six days.

16 Region III's estimate of the dose received  
17 by the daughter was 15 rem. The Society of Nuclear  
18 Medicine report by Drs. Siegel and Marcus basically  
19 claimed that this assessment was too conservative by  
20 factors of 1.6, 7.1, or 17, depending upon which  
21 features of their arguments were invoked.

22 The next slide -- let's see here, catch  
23 up. Can you move it to -- okay. This slide  
24 illustrates our methodology. We carefully reviewed  
25 the Region III calculations, along with the article

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 published by Drs. Marcus and Siegel.

2 You know, in addition, we performed some  
3 of our own calculations, including limited Monte Carlo  
4 simulations. We interviewed the current St. Joseph's  
5 Hospital radiation safety officer, and the Region III  
6 inspectors who wrote the report. And, in addition, we  
7 reviewed additional documents provided to us by St.  
8 Joseph's Hospital.

9 This slide summarizes our findings.  
10 Basically, we felt that the 15 rem dose -- the amount  
11 calculated by Region III -- was the most conservative  
12 estimate possible that is not totally implausible. We  
13 did feel that some more sophisticated techniques,  
14 including distance reconstruction, were useful and  
15 helped us come to a more realistic interpretation of  
16 the measurements.

17 So the bottom line is is that given the  
18 dwell-time scenario -- that is, the amount of time  
19 Region III believed the daughter was in close  
20 proximity to the mother -- our estimate was nine rem.

21 I think one of the more interesting  
22 features of the cases is that St. Joseph's Hospital  
23 disputes Region III's dwell times scenario, basically  
24 claiming that portable lead shields were used by the  
25 daughter 50 percent of the time. If so, according to

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 our calculations, this would reduce the deep dose  
2 equivalent, or DDE, to four to six rem.

3 One of our recommendations is -- or  
4 conclusions is -- that the inspection report should  
5 have acknowledged and justified rejection of the St.  
6 Joseph's Hospital scenario.

7 I need to pay attention to what slide I'm  
8 on here. Okay.

9 The critique by Drs. Siegel and Marcus  
10 contains several points, many of which we agree with  
11 in general terms. One of their recommendations is is  
12 that more sophisticated dose reconstruction tools  
13 should be used, such as dose reconstruction.

14 They also recommend that effective dose  
15 equivalent, not deep dose equivalent, should be used  
16 as the regulation endpoint. The practical difference  
17 between these two measures is is that EDE represents  
18 dose average over the body core, whereas deep dose  
19 equivalent is approximated by maximum dose to the body  
20 core.

21 However, we felt that the methodologies  
22 used in the Siegel/Marcus critique were overly  
23 simplistic, so we do not accept their particular  
24 factors of 1.7 to 17. The next slide, which you can  
25 see in the notes, we list the differences between the

1 Society of Nuclear Medicine document and our factors.  
2 Rather than 4.3 for distance reconstruction, our  
3 estimate is 1.5; EDE versus DDE factors, 4 versus 6.8;  
4 various other factors, they claim 50 percent we didn't  
5 think were correct.

6 So our general recommendations are is that  
7 we agree with the general point of the Siegel/Marcus  
8 critique that more sophisticated dose reconstruction  
9 tools are indicated when doses are near their  
10 regulatory limit, when the licensee disputes the NRC  
11 dose reconstruction methodology or scenario, when the  
12 plausibility of the dose reconstruction assumptions,  
13 using more standard and simple techniques, are  
14 suspect, or data are not available to justify them.

15 Then, you know, I think more sophisticated  
16 tools to attempt to reconstruct some of the data are  
17 useful. Also, when the usual approximations, such as  
18 inverse square law, are suspect, more sophisticated  
19 tools are indicated.

20 Continuing with our recommendations, per  
21 document RIS 0304, we agree with Siegel and Marcus  
22 that EDE should be used as the dose reconstruction  
23 regulatory endpoint for Part 20 compliance in  
24 scenarios such as the St. Joseph's Hospital.

25 For disputed dose reconstructions, EDE or



1 DDE ranges should be used, and acknowledgement and --  
2 of alternative reconstruction scenarios proposed by  
3 the licensee should at least be mentioned and  
4 justification contained in the report for dismissing  
5 them.

6 Finally, ACMUI believes it is very  
7 important that NRC devise some sort of practical  
8 system for exempting caregivers from the 500 millirem  
9 limited when -- limited when warranted by humanistic  
10 or medical consideration.

11 Thank you.

12 CHAIRMAN MALMUD: Thank you, Dr.  
13 Williamson.

14 Are there any comments for Dr. Williamson?  
15 May I make one? As I recall, having read all of the  
16 documents associated with the incident, the caregiver  
17 had been warned or admonished by the then current  
18 radiation safety officer at St. Joseph's that she was  
19 exposing herself to an excessive burden of radiation,  
20 and the caregiver said that that was a risk she was  
21 willing to take because it was her mother, and she  
22 wanted to be close to her. Do I recall correctly?

23 MEMBER WILLIAMSON: I believe that is  
24 correct, yes.

25 CHAIRMAN MALMUD: May I, therefore,

1 suggest that in your very introductory slide that you  
2 discuss the issue that you comment that despite  
3 warnings and admonitions from the radiation safety  
4 officer, the caregiver decided to do that, because  
5 that's a critical issue that I believe the committee  
6 chair should be aware of, because this is an incident  
7 in which a radiation safety officer gave adequate  
8 information to the caregiver, and the caregiver made  
9 a conscious decision not to adhere to the regulations.

10 And also, we are told not to use the lead  
11 shielding that was provided for her, thereby creating  
12 a real management problem for the hospital -- namely,  
13 how does one deny a daughter access to a dying mother  
14 when the daughter says, "I don't care what the rules  
15 are. I'm going to do it anyway"?

16 MEMBER WILLIAMSON: Yes.

17 CHAIRMAN MALMUD: So it just might be  
18 worthwhile inserting "despite" at --

19 MEMBER WILLIAMSON: So I will say,  
20 "Despite admonitions from the RSO regarding radiation  
21 burden and the need to use shields, the daughter  
22 consciously rejected these instructions." And I'm on  
23 firm ground saying that, Ralph? Okay.

24 CHAIRMAN MALMUD: Does the rest of the  
25 committee agree with the insertion of that comment?

1 MEMBER WILLIAMSON: I think that that's a  
2 very good idea.

3 CHAIRMAN MALMUD: Thank you.

4 Any other comments for Dr. Williamson?

5 MEMBER NAG: I think we should make a  
6 comment that the -- we should give a dose guideline.  
7 However, is there real harm done to a person if you  
8 are exceeding the guideline? Like, for example, when  
9 you have a chest X-ray or a barium enema, you are  
10 getting a larger exposure than recommended for the  
11 general public.

12 So I think we may want to make that clear  
13 -- that if they make this decision, and it is -- a  
14 barium enema for health reasons, and here it's for the  
15 humanistic reason, we should make that apparent.

16 CHAIRMAN MALMUD: Yes, Dr. Suleiman?

17 MEMBER SULEIMAN: I've expressed my  
18 opinion I think previously, and I'll reiterate it  
19 here. Medical patients are exempt, because the  
20 benefit -- and if you go through the drill -- always  
21 exceed the nominal radiation risk. Occupational  
22 workers, the general public, clearly outside the  
23 direct -- they're not direct beneficiaries.

24 I believe that a caregiver is a member of  
25 the family or a very close individual. It really is

1 a unique category. They shouldn't be lumped together  
2 with one group nor the other, and I think the NCRP has  
3 guidance that addresses this, the current ICRP has  
4 guidance, and so my professional opinion is that doses  
5 can be kept reasonable, but you have to be  
6 compassionate and make a decision.

7 So I would be careful about using the term  
8 "exempt caregivers." Exempt them from what?  
9 Unlimited dose? I think a facility could be negligent  
10 if they allowed somebody to receive an extraordinarily  
11 high radiation dose, but I think the way the practice  
12 is it's not a case, should there be a limit, the  
13 question is what should the limit be.

14 MEMBER WILLIAMSON: Well, I will make a  
15 reference to Dr. Vetter's presentation which will tie  
16 this recommendation to his presentation. I don't  
17 think we should, you know, expend huge time on this  
18 presentation, which is past business and now I hope  
19 relatively uncontroversial, because we have more  
20 controversial matters to discuss. I think we should  
21 -- well, I'll put in my last slide and make a  
22 reference to Dick's position.

23 CHAIRMAN MALMUD: Any other comments with  
24 reference to this presentation? Then, we'll move on  
25 to the next one. Dr. Williamson?

1                   MEMBER WILLIAMSON: The next one. Well,  
2                   what I would recommend, rather than rehearsing my  
3                   mission talk, is that we basically proceed to discuss  
4                   the medical event issue in general. And I can give  
5                   the presentation I have designed for this group, which  
6                   is very similar, to -- to start with.

7                   The reason for suggesting that, I think  
8                   that, you know, it has turned out in recent days what  
9                   we thought was a subcommittee consensus appears no  
10                  longer to be a subcommittee consensus. So, you know,  
11                  I think it just would be more productive for us to  
12                  spend time figuring out to what extent we do have a  
13                  consensus, so that I know how to temporize my  
14                  presentation to the Commission this afternoon.

15                 CHAIRMAN MALMUD: Please present it as you  
16                 will.

17                 MEMBER WILLIAMSON: Okay. So we want to  
18                 now go to the slides that I had designed for this  
19                 group -- not that one, no. The original set of slides  
20                 that I prepared for the ACMUI. Is that a problem?

21                 MR. ESSIG: They should be on another --  
22                 because he submitted them previously.

23                 MEMBER WILLIAMSON: I have them here on  
24                 this flash drive.

25                 MR. ESSIG: Okay. We have copies of

1 those, do we not?

2 CHAIRMAN MALMUD: Dr. Nag?

3 MEMBER NAG: I have a feeling we are not  
4 going to solve the issue in the next 20 minutes or so  
5 that we have. It might be better if we go over the  
6 slides that will be presented to the Commission, so we  
7 can say no, this is not something we should represent,  
8 or we should. Otherwise, if we rehash, in 20 minutes  
9 we are not going to have any consensus.

10 CHAIRMAN MALMUD: How many minutes do you  
11 think it would take to present this first group of  
12 slides that you wish to show, Jeff?

13 MEMBER WILLIAMSON: Probably about 10 or  
14 15 minutes.

15 CHAIRMAN MALMUD: Well, perhaps we can  
16 compromise and allow Dr. Williamson to present this  
17 with a discussion not to exceed 15 minutes of the  
18 first set, so that we can move directly into the  
19 second set, which will be that which we expect to be  
20 presented to the Commission. How does that sound to  
21 you? Ralph?

22 MEMBER LIETO: I would -- I would agree  
23 with that. And I was just thinking that maybe, if  
24 Jeff is in agreement, that as he goes through the  
25 slides just point out this -- which slides would not

1 be in the Commissioners' presentation. It will give  
2 us an idea of what would be expected to be in there.

3 CHAIRMAN MALMUD: Dr. Diamond?

4 MEMBER DIAMOND: I was just saying that's  
5 an official way to address the issue. If there are  
6 certain slides being included or excluded, point those  
7 out. It will speed up the process.

8 CHAIRMAN MALMUD: Dr. Williamson is  
9 currently occupied trying to get that presented. So  
10 I'll ask him the question as soon as he's free.

11 MEMBER DIAMOND: Jeff, the suggestion was,  
12 as you're going through these -- these slides, just  
13 point out to the committee which ones are being  
14 included and which ones are not being included.

15 MEMBER WILLIAMSON: I'll be happy to do  
16 that.

17 CHAIRMAN MALMUD: All right. Dr.  
18 Williamson, it was suggested while you were occupied  
19 that it might be most efficient for you to present the  
20 longer set of slides, just indicating which ones would  
21 and would not be presented to the Commission.

22 MEMBER WILLIAMSON: Okay. I will be very  
23 pleased to do that.

24 CHAIRMAN MALMUD: That would save us the  
25 time.

1 MEMBER WILLIAMSON: Yes.

2 CHAIRMAN MALMUD: Thank you.

3 MEMBER WILLIAMSON: Okay. All right.

4 Well, this summarizes our charge, as I understand it.

5 I think this is straightforward. We were to evaluate

6 the appropriateness and justification of the 20

7 percent threshold in the medical event rule, how best

8 to communicate risk, and per this group we were to

9 focus on the permanent interstitial brachytherapy

10 modality primarily, and identify problems in the

11 current ME rule and some proposed solutions.

12 So here is the history of our

13 deliberations. We have two closed subcommittee

14 conference calls and two noticed public calls with the

15 entire ACMUI. At the last -- second-to-the-last of

16 these we had a consultant, Dr. Louis Potter, who was

17 very helpful in bringing the group to some consensus

18 at that time, and we developed a set of

19 recommendations to be presented at the ACMUI.

20 In the last week, Dr. Subir Nag, in

21 response to my request that he develop a draft report,

22 has now indicated he has significant reservations with

23 a few -- with some of the recommendations. So it's

24 not clear what the status of our consensus is anymore.

25 Okay. So what I was going to do is

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 basically three things -- review some of the -- some  
2 background information in permanent seed brachytherapy  
3 for the benefit of the whole group, review the  
4 consensus we had achieved to date, and review the  
5 issues still under discussion or to be discussed.  
6 These slides were, of course, made before receiving  
7 Dr. Nag's communication late last week.

8 Okay. So this illustrates what the  
9 procedure looks like for prostate brachytherapy. We  
10 are talking about prostate brachytherapy because it is  
11 by far and away the most commonly practiced form of  
12 permanent seed implant. Indeed, with approximately  
13 40- to 50,000 procedures a year, it now appears to be  
14 the most frequently practiced indication for all forms  
15 of brachytherapy.

16 So the basic approach is a trans-rectal  
17 ultrasound device is used to dynamically image the  
18 prostate, as you can see here in the cross-section of  
19 the patient. Rigidly attached to this rectal  
20 ultrasound probe is a big template, which is hard to  
21 see with the lights on here, has a series of holes  
22 that direct needles containing the seeds in a  
23 direction that is parallel to the probe.

24 The probe can take either transfer images  
25 as illustrated here, or in some cases longitudinal and

1 possibly three-dimensional reconstructions. So this  
2 illustrates more graphically -- no pun intended -- how  
3 the procedure looks. Here is the probe, here is the  
4 thick plate. There is a series -- matrix of holes  
5 corresponding to these dots, which, when the operator  
6 looks at the ultrasound image, illustrate the  
7 different positions in which needles can be inserted.

8 For those of you who have not seen seeds,  
9 this is what they look like, approximately a quarter  
10 of an inch long.

11 Okay. With that introduction, I thought  
12 it would be helpful to understand the procedure flow,  
13 at least the most common form of procedure used. So  
14 it's divided into three parts -- preplanning, source  
15 placement, and host procedure dose evaluation, which  
16 occur at different times.

17 The preplanning occurs generally one to  
18 two weeks or so before the actual procedure, and it  
19 consists of basically setting up the patient and  
20 performing what is called a TRUS -- trans-rectal  
21 ultrasound volume study. So the delivery device is  
22 used to obtain images with the grid points shown on  
23 them, but no seeds are placed at this time.

24 The prostate volume and critical anatomy  
25 is contoured by the physician. Dosimetry data

1 prescribed dose are input into a program. Preplanning  
2 occurs, dose distributions are reviewed, and the  
3 outcome of this procedure is basically the source  
4 strength, the number of seeds, the source arrangement  
5 -- all the things you need as the basis of a written  
6 directive.

7           So this illustrates what the output of a  
8 preplan would look like. You can see that the sources  
9 are arranged in a very idealized matrix that can never  
10 be realized exactly in practice, and then there is a  
11 list of instructions indicating what the sequence of  
12 seeds and spacers are to be loaded in each of the  
13 needles.

14           Okay. So continuing on, then, with the  
15 chronology of the procedure, the patient comes to  
16 treatment. Every effort is made to reproduce the  
17 ultrasound probe in the same orientation. Imaging --  
18 under image guidance, then the needles are inserted  
19 one by one and retracted, depositing the seeds. And  
20 this is kind of an iterative process.

21           So -- let's back up three slides. There.  
22 Thank you.

23           Okay. This is followed, then, by post-  
24 procedure dose evaluation, usually performed by X-ray  
25 CT imaging. This can occur zero to five weeks after

1 the implant, depending upon the practice, patterns,  
2 and logistic constraints of the individual  
3 practitioner.

4 Its purpose -- imaging is done, prostate  
5 is contoured, and then the dose, as actually  
6 delivered, is estimated. And, you know, at this  
7 point, then, in the conventional practice the written  
8 directive could be completed.

9 So the seed insertion procedure -- a  
10 number of things can happen. It's very difficult to  
11 reproduce the anatomy of the patient. The prostate  
12 may be deformed and displaced. It may be smaller, for  
13 example. Seed needle insertion causes prostate  
14 swelling. There may be needle insertion constraints  
15 which were not appreciated during the preplan.

16 The bottom line is is that the authorized  
17 user must be forced -- must be free to adapt the  
18 preplan to the anatomy as actually imaged during the  
19 procedure, which can differ significantly from the  
20 preplanned anatomy, upon which the original written  
21 directive was based.

22 This illustrates what a post-procedure  
23 dose evaluation looks like on CT. You can see the  
24 seeds are much more irregularly placed, indicating,  
25 you know, the difficulties in literally executing the

1 preplan. And this is probably a reasonably well-done  
2 implant.

3 I'll say this -- the post-implant doses --  
4 for example, the dose covering 90 percent of the  
5 target volume -- are viewed by the community as the  
6 most definitive estimate of delivered dose, and this  
7 is the endpoint that would be entered into at multi-  
8 institutional clinical trials, for example.

9 So moving on to the medical event  
10 definition, the current medical event definition  
11 states, "A medical event equals an administration in  
12 which the delivered versus the prescribed dose differ  
13 by 50 rem and 20 percent, or dose to an extra target  
14 site that wasn't planned, exceeds the planned dose by  
15 50 rem and 50 percent." These are the two rules, and  
16 this is the -- where we started our critique.

17 So the first question is: is the 20  
18 percent level justifiable? For temporary implants,  
19 the -- let me emphasize, these are recommendations of  
20 the subcommittee to the full ACMUI. They have not yet  
21 been acted upon by the ACMUI, or transmitted to the  
22 staff in the form of a formal report. So this  
23 represents an update.

24 For temporary implants, the group felt  
25 that 20 percent is a reasonable regulatory action

1 level, only if it is understood as a QA performance  
2 indicator, not as a patient harm index. For permanent  
3 implants, the belief is is, no, this is not  
4 appropriate. In many situations, the 20 percent  
5 threshold is comparable to the variations encountered  
6 in routine clinical practice.

7 For this reason, in general, we feel that  
8 the dose-based medical event definition really is not  
9 workable for prostate implants, and I'll go into the  
10 reasons a little more.

11 The rationale is basically that the  
12 variability in post-implant CT versus written  
13 directive dose comparisons encounter several  
14 difficulties. It's based upon different imaging  
15 modalities -- preplanning and interoperative placement  
16 is based on ultrasound, whereas post-planning is based  
17 on X-ray CT.

18 The literature documents that there can be  
19 up to 50 percent differences in the volume of the  
20 structures on these two imaging modalities due to the  
21 limited soft tissue contrast of X-ray CT. There are  
22 large operator-to-operator CT contouring variations as  
23 a result of not being able to clearly see the boundary  
24 of the prostate on X-ray CT.

25 There is a long and variable interval from

1 the time the implant is made to the time a dose is  
2 calculated based on post-planning. Then, of course,  
3 there are the legitimate preplan modifications that I  
4 mentioned. So all of these add up to a significant  
5 likelihood of there being a discrepancy close to 20  
6 percent on post-planning versus the written directive,  
7 which is based upon the preplan.

8 Other permanent implant issues is the  
9 written directive definition for all other  
10 brachytherapy is -- currently allows the authorized  
11 user to specify the number of sources and dose, or,  
12 equivalently, total source strength, at any time post-  
13 implant, and this is because the rule basically  
14 defines the -- requires the authorized user to  
15 complete the written directive only after the dose is  
16 delivered, which in the case of a permanent implant is  
17 essentially forever.

18 Another problem is the wrong site medical  
19 event, which the subcommittee believes is  
20 unenforceable. The problem is is that small errors in  
21 seed position can introduce big dose changes to dose  
22 volumes. So there are always -- probably in any  
23 implant there is at least some small bit of tissue  
24 where the 50 percent and 50 rem threshold is exceeded,  
25 if you compare the preplan to the post-procedure plan.

1           And, finally, to cover the target, it is  
2           necessary to implant, on occasion, seeds in normal  
3           periprostatic tissue, which may not be reflected in  
4           the preplan. And this is not a mistake. This is a  
5           legitimate adaptation to the situation that the  
6           radiation oncologist finds at the time.

7           MEMBER NAG: And while you have that  
8           slide, I think I need to make a comment. The previous  
9           slide. yes.

10           The Rule 35.40(b)(6) -- actually, it does  
11           not allow an authorized user to make a decision. The  
12           decision is to be made before -- before the implant,  
13           and you can make an oral directive. And I think I  
14           need to make a presentation of my own on this.  
15           Otherwise, people have doubt and confusion.

16           MEMBER WILLIAMSON: Well, I think that --  
17           why don't I finish this, and then we discuss I think  
18           the remaining issues. That's the point.

19           Okay. Moving on, so the proposal, at  
20           least as of a week ago, which the subcommittee more or  
21           less unanimously agreed upon at that time, was that we  
22           would define "medical event" in terms of where the  
23           sources are implanted, rather than the dose delivered.

24           So recommendation 1 was, for permanent  
25           implants, require that the written directive specify



1 the total source strength and number of seeds, in  
2 contrast to the current definition, which -- and  
3 interpretation which allows either absorbed dose or  
4 total source strength to be the specifier.

5 The second recommendation was to replace  
6 both the wrong site and target volume medical event  
7 definitions -- this is now only for permanent implants  
8 with the following -- medical event occurs if: a) the  
9 total source strength implanted exceeds the written  
10 directive by 20 percent, or the total source strength  
11 implanted in the target volume specifically as opposed  
12 to the surrounding tissue deviates by the written  
13 directive by more than 20 percent.

14 So this was intended to cover both wrong  
15 site and primary dose delivery error pathways in the  
16 current rule. And it allows, essentially, 20 percent  
17 wiggle room on placing sources outside the specified  
18 target volume, in order to achieve a reasonable dose  
19 distribution.

20 Third recommendation was to amend 35.40(c)  
21 and (b)(6) -- I believe that should be (ii) -- to  
22 require completion and any revision of the written  
23 directive within one working day of source insertion.

24 What is the rationale for these? The  
25 major rationale is is determining the fraction of

1 seeds in the target is much less variable than  
2 comparing doses. This is something that we believe  
3 can be done interoperatively with prostate implants  
4 using ultrasound visualization that is available at  
5 the time, thereby obviating the need to compare two  
6 plans based on different imaging modalities that may  
7 be separated from one another by many weeks.

8 The third reason is is that limiting --  
9 the final rationale is is that limiting written  
10 directive revisions to a time point of 24 hours  
11 reduces the opportunity for abuses -- that is,  
12 egregious revisions of the written directive made many  
13 months later, whose sole purpose is to avoid reporting  
14 the event as a medical event.

15 The fourth recommendation is is that  
16 medical events should be treated strictly as QA  
17 performance surrogates and divorced from patient harm.

18 So the two consequences of this, we  
19 believe -- one is is that limit the patient and  
20 relatives' reporting requirement to those MEs that  
21 involve harm or potential harm to the patient, and  
22 simply are not technical errors. Second major point  
23 is is to model NRC medical event performance on  
24 industry quality assurance practices.

25 So what is the rationale for this?

1 Medical event reporting is perceived as an invitation  
2 for regulatory burden, negative public exposure, and  
3 increased liability. And the current reporting rule  
4 places the authorized user in a dilemma when he or she  
5 believes that reporting to the patient may be  
6 medically contraindicated. Then, the physician is  
7 faced by a dilemma of medical need of the patient  
8 versus preserving confidentiality of the patient's  
9 medical information.

10 The industry practice is well codified in  
11 AAPM and ACR recommendations, but it is based on three  
12 rod principles. Errors alone are not grounds for  
13 punishment. We want people to report them, so that  
14 they can come to light in the system improve.

15 Error reports are used to improve the  
16 overall process. And, thirdly, QA deliberations are  
17 not discoverable for the purposes of any form of civil  
18 litigation.

19 Unresolved issues are: should dose  
20 calculation errors affecting the source strength  
21 written directive be exempt from regulatory review?  
22 This is something that is currently covered by the  
23 medical event reporting rule and the misadministration  
24 rule before it, that essentially whatever technical  
25 activities are interposed between the physician's

1 clinical intent and the final realization or delivery  
2 of the treatment are fair game for these regulations.

3 So a proposal that has yet to be discussed  
4 is the following -- is to add to the above  
5 recommendations a new medical event pathway that would  
6 cover errors made in dose calculation that are limited  
7 to preplanning. So, therefore, a medical event could  
8 be any calculation error leading to an error in source  
9 strength specification ultimately written in the  
10 written directive that is greater than 20 percent.

11 This has the advantage of decoupling it  
12 from all of the difficulties of post-implant planning  
13 by focusing only on the intellectual process that  
14 occurs prior to source delivery.

15 So other medical event issues include: is  
16 the current wrong site medical event criterion  
17 workable and justifiable for other types of  
18 brachytherapy and external beam treatments? This  
19 issue whether it should be dealt with is -- is yet to  
20 be discussed.

21 That concludes my presentation.

22 MEMBER DIAMOND: So, Jeff, perhaps it  
23 would be helpful now to highlight the one or two key  
24 issues of potential difference for the committee as a  
25 whole?

1                   MEMBER WILLIAMSON: Yes. I -- I can try  
2 to summarize. I think that the two main ones are --  
3 is if we were to return to my slide where I had the A  
4 and B part of the proposed medical event definition.  
5 Dr. Nag rejects having the Part B. He would like  
6 medical event to read basically, "A medical event  
7 occurs if, and only if, the source strength implanted  
8 in the target deviates from the written directive by  
9 more than 20 percent."

10                   MEMBER NAG: I propose that we postpone  
11 any discussion. I think I need to present before we  
12 comment.

13                   Before I start, I would like to, you know,  
14 state that we had a subcommittee. The people who were  
15 in the subcommittee -- the only one who was working  
16 with prostate implant and permanent implant on a day-  
17 to-day basis was myself as a physician, and Dr.  
18 Williamson as a physicist. The other subcommittee  
19 members have not been doing permanent implant.

20                   I felt that I needed to get opinion of  
21 practicing radiation oncologists, so I took a copy of  
22 the American Board -- I mean, American Brachytherapy  
23 Society board meeting to present it at the board to  
24 get feedback from 12 people who are doing permanent  
25 implant every day.

1           The other thing I would like to mention is  
2           that the American Brachytherapy Society has set up  
3           standards for permanent prostate brachytherapy and  
4           permanent prostate brachytherapy dosimetry, and I am  
5           the chair of both of those committees. I'm also on  
6           the committee under ACR that sets up the performance  
7           on permanent brachytherapy now. I think -- your  
8           comments I think would be in place.

9           A few things -- although Dr. Williamson  
10          said that permanent prostate brachytherapy --  
11          permanent implant is mainly for prostate. Whatever  
12          recommendations we make should be applicable to all  
13          permanent brachytherapy, because if you make the rule  
14          for permanent brachytherapy only because of prostate,  
15          and it may not apply to others, then you'll have a  
16          major problem for people who are doing implants in  
17          other parts other than the prostate.

18          The second thing is that although Dr.  
19          Williamson mentioned only about the preplanned method,  
20          there are many methods of doing prostate implant. The  
21          majority are slowly shifting from a preplan to an  
22          interoperative planning system where all the planning  
23          is done in the operating room in real time.

24          The other significant difference I have is  
25          that I went back in the Federal Register to see the

1 actual wordings of similar things, and I'm going to  
2 put those wordings in here, because I think it depends  
3 partially on how the wordings are interpreted.

4 Can we have the next slide?

5 By the way, Dr. Williamson recommends you  
6 are also a member of the subcommittee.

7 I am going to -- now, in addition to the  
8 meeting that we had, Dr. Louis Potter came as an  
9 expert consultant, and he was present only for part of  
10 the meeting. So really the whole discussion was not  
11 held with him being there.

12 We had the input of expert radiation  
13 oncologists on March 24th, which is why many of these  
14 things are coming after the report and meeting of the  
15 13th. And I'd like to summarize combined opinion  
16 expressed in the subcommittee as well as in the expert  
17 radiation oncologist meeting.

18 Now, right now the written directive, as  
19 it states, is that before implantation at the site,  
20 the radionuclide and dose, and before completion of  
21 the procedure, the nuclei equipment site, number of  
22 sources, total source strength, exposure time, or  
23 total dose.

24 Now, this requirement I think appropriate  
25 for temporary and removable implants, so I think we

1 are all in agreement with that. The subcommittee  
2 members all agreed with that. The only extra comment  
3 that the practicing radiation oncologists want to make  
4 that -- is that even in temporary implants there are  
5 many places that are doing a source strength base that  
6 is milligram radium -- are in written directive.  
7 Therefore, we should not exclude a source strength  
8 based written directive.

9 Right now, the way the new rule is made,  
10 for all implants it has to be dose based. So this is  
11 an extra suggestion that was made by the practicing  
12 radiation oncologist.

13 Next, again, majority of the people felt  
14 that the dose-based written directive had some  
15 problems in permanent implant, because, number one,  
16 theoretically, the implant continued to radiate  
17 indefinitely. And, therefore, you cannot define when  
18 the procedure needed to be completed.

19 And the other thing that we will show you,  
20 and as Dr. Williamson had mentioned, depends on a lot  
21 of factors including the volume, the demand, and so  
22 on, and, therefore, the authorized user had less  
23 control on the final dose.

24 You have me as a practicing radiation  
25 oncologist -- not how much we are putting in, but what



1 -- but not what the resultant dose will be. And let's  
2 see what happens.

3 That represents where the prostate volume  
4 is on CAT scan. Now, in a normal prostate, even  
5 before you do an implant, is A the prostate or B the  
6 prostate? We think we know, but we don't, because, as  
7 I will show you, in brachytherapy, the top  
8 brachytherapists in the country would not agree.

9 What we had in a meeting about three years  
10 ago was to ask the top 10 brachytherapists in the  
11 country to draw out the prostate, and we had  
12 significant difference. And that difference was  
13 increased when you are doing it in a post-implant CT,  
14 because in addition to the differences in prostate  
15 volume, you have edema and hemorrhage and seed  
16 artifact.

17 So, therefore, any of these circles could  
18 be the prostate according to some people.

19 We had the panel meeting in New York, and  
20 what we did was we superimposed the prostate on top of  
21 each other. There were, I think, 10 or 12 of us  
22 there. And we were all told to draw the prostate.  
23 Number one, these are the 10 different circles that  
24 were drawn by different radiation oncologists and  
25 physicists to indicate the prostate at the base, to

1 indicate the prostate at the apex, look at the  
2 difference.

3 In the mid-plan that was the least  
4 different. In the mid-plan, we somewhat agreed on  
5 where the prostate is. And what -- how did that  
6 matter? Well, depending on which circle you are  
7 drawing, you are going to have variation in the  
8 prostate volume for each patient. Number one, let's  
9 see the numbers.

10 Case number one, one patient, the range of  
11 volume varied from 41 to 63; number two, from 27 to  
12 39. So even though on the same patient different  
13 radiation oncologists are saying that the volume is  
14 different, so what? If the volume is different,  
15 depending on which contour you are taking, you are  
16 going to say that the patient got a different dose.

17 The isotopes -- the second one is 200  
18 percent. This is 150 percent, and the most outside  
19 one is 70 percent. So, therefore, if you do a volume  
20 that was smaller, and you will see that the patient --  
21 that same patient got 150 percent dose, where if you  
22 had gone a slightly bigger circle you would have had  
23 -- it only got less than 80 percent. So, therefore,  
24 on the same patient you would have misadministration.

25 With that, the variation in the D-90 dose,

1 the target dose normally is 125. Therefore, with the  
2 20 percent deviation, if it's less than 116 or more  
3 than 174, you will consider that a medical implant.  
4 And here, on that same patient, just see the dose. So  
5 it depends on whose volume you are looking at. You  
6 are going to call many of these patients medical  
7 implant when they are not.

8 This one entered the group, and basically  
9 it said the same thing, that you are going to have  
10 variation, that they are going to be called medical  
11 implant. And why are these? Because it -- in a  
12 normal prostate, it's difficult to say what is  
13 prostate, what is the muscle, what is the venous  
14 plexus, neurovascular bundle, part of the bladder, and  
15 the urogenital diaphragm, how much is due to edema,  
16 seed artifact, and volume gain with time, because once  
17 you have edema the edema will resolve over the next  
18 one month. And depending on when you are drawing the  
19 volume, you are going to have a different result.

20 Therefore, I think we all agreed that we  
21 should specify for permanent implant the treatment  
22 site, the radionuclide, and the total source strength  
23 rather than the dose.

24 Now, in the Federal Register, 10 CFR 35,  
25 it states, "Verbal order can be used to modify written

1 directive if significant change from preplanning  
2 occurs during the brachytherapy procedure."

3 So, therefore, I think that the  
4 misunderstanding that you are allowed to change any  
5 time you would like, no, you are only allowed to make  
6 the change while you are doing the procedure. It can  
7 be a verbal order, and you have up to 48 hours to put  
8 that verbal order into writing.

9 Why? Because when we are doing this, we  
10 are scrubbed, we are in the OR, we cannot just sign  
11 during our implantation procedure. So the law allows  
12 us to revise that procedure verbally while we are  
13 doing it, but then to put it in writing within 48  
14 hours.

15 So I do not know where this 24-hour rule  
16 came from, and I do not know where the thing came from  
17 that you can revise any time you'd like. If you don't  
18 like your implant, a month later you can revise it.  
19 I don't see anywhere in the 10 CFR 35 that allows you  
20 to do that.

21 And, therefore, according to 35.40(c), the  
22 revised written directive should be signed within 48  
23 hours of the verbal order.

24 CHAIRMAN MALMUD: Excuse me, Dr. Nag. May  
25 I just ask you a question?

1 MEMBER NAG: Yes, sir.

2 CHAIRMAN MALMUD: In the treatment of the  
3 prostate with brachytherapy, there are three possible  
4 dose estimates. One is pre-treatment, one is during  
5 treatment, and one is after treatment.

6 MEMBER NAG: Yes.

7 CHAIRMAN MALMUD: How is the pre-treatment  
8 dose calculated? What's it based upon? A CT?  
9 Ultrasound?

10 MEMBER NAG: In most cases, it is based on  
11 the ultrasound. However, some people do it based on  
12 CT.

13 CHAIRMAN MALMUD: Does anyone use any  
14 other imaging modality?

15 MEMBER NAG: MRI.

16 CHAIRMAN MALMUD: MR. So that the pre-  
17 treatment dose may be based upon ultrasound, CT, or  
18 MR.

19 MEMBER NAG: Yes.

20 CHAIRMAN MALMUD: Of those three, in your  
21 opinion, which is the most specific? Accurate?

22 MEMBER NAG: The most accurate -- if you  
23 want, we can show you -- is the MRI. However, the MRI  
24 is not widely available. In fact, I know it's  
25 available in only one or two centers in the country

1 that are doing an MRI-based.

2 CHAIRMAN MALMUD: So if we were presenting  
3 this to a group of individuals, educated but not  
4 familiar with this subject, we should probably inform  
5 them that the -- there are three times at which the  
6 dose is estimated. The pre-treatment dose, which is  
7 based upon either ultrasound or CT, and in some cases  
8 MR, depending upon the imaging modalities available to  
9 the radiotherapists at the institution in which the  
10 patient is being treated.

11 Then, during -- the second set of dose  
12 estimates is during treatment, and that is measured  
13 with ultrasound, with a trans-rectal ultrasound.

14 MEMBER NAG: In most places, except some  
15 places do it with MRI, and a few places do it with CT.

16 CHAIRMAN MALMUD: During treatment?

17 MEMBER NAG: During, yes.

18 CHAIRMAN MALMUD: Let me --

19 MEMBER NAG: And the other thing is, many  
20 places, including myself, do not do a preplan, because  
21 we do everything in the OR. You know, there is now a  
22 change in implanting which obviates the preplan.

23 CHAIRMAN MALMUD: And if I may just finish  
24 my series of questions. And the third dose estimation  
25 is post-treatment, and that's done with what

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 modalities? Ultrasound again, CT, and MR, or just CT?

2 MEMBER NAG: In most places it is CT-  
3 based. But, again, in some places, they are doing it  
4 real-time immediately after on ultrasound or on MRI.  
5 So, again, it could be either, but most places CT.

6 CHAIRMAN MALMUD: So if I -- so informing  
7 a well-educated group who is not familiar with  
8 prostate brachytherapy, we could say very concisely  
9 that, apparently, in most institutions, estimates of  
10 the dose are made at three times -- prior to  
11 treatment, during treatment, and after treatment.

12 There are three modalities that can be  
13 used at any one of these three times. Most often, the  
14 techniques are CT and ultrasound, though MR is  
15 becoming used more frequently.

16 The resolution of MR is superior to that  
17 of CT and ultrasound in differentiating the prostate  
18 from the adjacent tissues.

19 MEMBER NAG: Yes.

20 CHAIRMAN MALMUD: Fair statement?

21 MEMBER NAG: Yes. Except one other thing  
22 is that in many places instead of doing it three  
23 different times they're compressing all of the three  
24 into one session interoperatively, so that you are  
25 doing it before the implant but only a few minutes

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 before the implant. And in post-plant, instead of  
2 doing it hours, you are doing it a few minutes after  
3 the implant.

4 CHAIRMAN MALMUD: So that the current  
5 state of the art in the United States is for three  
6 measurements -- pre, during, after -- in some  
7 institutions all of these are compressed to the  
8 treatment time itself. And that there are three  
9 different modalities used -- ultrasound, CT, MR -- and  
10 these have varying degrees of resolution.

11 And, therefore, depending upon which  
12 modality is used, and which technique is used, there  
13 may be significant variations in the dose estimates.

14 MEMBER NAG: Yes.

15 CHAIRMAN MALMUD: From institution to  
16 institution. And also, within the institution, if the  
17 dose estimates are based upon different imaging  
18 modalities at different times, not to mention the fact  
19 that during the procedure and after the procedure  
20 there is some anatomic distortion due to swelling and  
21 due to the implants themselves.

22 MEMBER NAG: Right.

23 CHAIRMAN MALMUD: Now, if I were sitting  
24 there as a novice listening to what I just said, I  
25 would say to myself, "Are we really ready to establish

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 criteria for what is or is not an inappropriate dose?"  
2 I mean, we have such variation in practice among  
3 outstanding practitioners at leading medical  
4 institutions in the United States. Are we ready to  
5 establish strict criteria? That is a question which  
6 I didn't mean to answer, but --

7 (Laughter.)

8 MEMBER DIAMOND: Thank you for that non-  
9 rhetorical question. I think the bottom line is that  
10 the current definition is not workable. Therefore, if  
11 the current definition is not workable, can we go and  
12 strive to find a better set of guidance and  
13 definitions, realizing how imperfect it may be?

14 With response to one of the other comments  
15 you made, Subir, your comment that we should try and  
16 strive for a set of guidelines that encompassed the  
17 entire realm of permanent implants, I would say that  
18 would be a nice goal but is not necessary in that 99  
19 point something percent of the total permanent  
20 interstitial implants performed in the United States  
21 are directed towards the prostate.

22 I think if we could go and find something  
23 workable for the prostate, I think that would be very  
24 helpful.

25 MEMBER NAG: I agree with you, except that

1 if you make a set of guidelines that is only  
2 applicable to the prostate, then you exclude people  
3 from doing implant in other sites. And what I'm  
4 saying is we can very easily make our guidelines such  
5 it is applicable to the prostate and for any other  
6 permanent implants.

7 CHAIRMAN MALMUD: Dr. Williamson?

8 MEMBER WILLIAMSON: Yes, I'd like to make  
9 a comment. The intent was, of the current proposal  
10 summarized in my slides, for it to be applicable to a  
11 broad range of permanent implant sites.

12 You know, I think all of us on the  
13 subcommittee recognize that the prostate is kind of an  
14 exception, both by virtue of its frequency, but also  
15 the fact that it is the procedure where physicians  
16 have the most experience integrating image guidance  
17 into the process.

18 And there are other procedures where this  
19 cannot happen, and what constitutes a target volume is  
20 much more fuzzy. And, therefore, you know, the  
21 enforcement criteria and review criteria have to be  
22 commensurate with the level of uncertainty in routine  
23 clinical practice and basically adjudicating these  
24 regulations.

25 I wish to make one technical correction to

1 your summary of Dr. Nag's presentation.

2 CHAIRMAN MALMUD: Yes.

3 MEMBER WILLIAMSON: He is right,  
4 certainly, that when there is interoperative planning  
5 everything is compressed into a short time period.  
6 But in the conventional paradigm, there is only two  
7 dose calculations usually. There is preplanned dose  
8 calculation and a post-planned dose calculation.

9 Generally speaking, unless you're doing  
10 the full-blown interoperative planning, there isn't  
11 dynamically updated dose calculation during the  
12 procedures. Certainly, one -- some can do that, but  
13 it's not part of the minimum standard of practice.

14 CHAIRMAN MALMUD: So, then, it would be  
15 more accurate to say that currently, in the United  
16 States, dose estimates are obtained at one of the  
17 three times -- pre-treatment, during treatment, or  
18 after treatment -- during any one to three of those  
19 periods of time. And the modalities used are CT,  
20 ultrasound, MR, all of which have different  
21 resolutions and different qualities and advantages and  
22 disadvantages.

23 MEMBER WILLIAMSON: Yes.

24 CHAIRMAN MALMUD: All right. Now, having  
25 said that, I have two questions, one coming from Dr.

1 Diamond's comment, one from Dr. Nag. What's the  
2 objection to trying to develop a standard for prostate  
3 that may eventually, not immediately, be applicable to  
4 other organs? Why must we do it for all rather than  
5 just one?

6 MEMBER NAG: If we cannot -- we are not --  
7 it doesn't apply for permanent prostate -- for  
8 permanent implants. If you do your guideline for  
9 permanent implant that is applicable only in the  
10 prostate, you will then exclude people who are trying  
11 to do implant at other sites.

12 The major difference being that in the  
13 prostate you have a specified volume, whereas if you  
14 -- if you make your guideline only targeted to the  
15 prostate you are going to exclude people who do  
16 implants on tumor bed after resection. So the tumor  
17 is gone, and you are now trying to implant the tumor  
18 bed, and you are going to exclude those. So --

19 CHAIRMAN MALMUD: Perhaps I didn't express  
20 myself well. What I meant to ask is: why couldn't a  
21 set of guidelines be established for the prostate with  
22 the existing guidelines still applicable to other  
23 organs until such time as we first resolve whether or  
24 not we can deal with the prostate issue.

25 It's almost like, well -- excuse me. Mr.

1 Lieto?

2 MEMBER LIETO: As a member of the  
3 subcommittee, I totally disagree with Dr. Nag and the  
4 point he just made, because what we're talking about  
5 are reporting requirements. There is nothing that  
6 this subcommittee is doing is going to affect the  
7 practice of putting implants into other areas.

8 What we're talking about is simply: when  
9 does this need to be reported to the NRC? In other  
10 words, so that -- how do we set these guidelines or  
11 these levels such that they are not -- such that they  
12 can't be enforced, which is the current problem -- one  
13 of the current problems that we're facing as a  
14 subcommittee right now and trying to be addressed.

15 So, again, I think we're talking apples  
16 and oranges here. There is nothing in this discussion  
17 or in the presentation that Jeff made that would  
18 affect putting implants into lung tumors or brain  
19 tumors or anything else with the --

20 MEMBER WILLIAMSON: Or tumor beds.

21 MEMBER NAG: And I would like -- I have a  
22 few more slides, and then we can continue with that.

23 Now, what I'd like -- a written directive  
24 for permanent implant would be based on prescribed  
25 dose. However, if you do that, then, in the example

1 we showed you, a dose of less than 116 or more than  
2 174 will be considered a medical implant, whereas it's  
3 just a normal variation of satisfactory implants.

4 There was also a suggestion made to place  
5 a single prescribed dose with the dose range for  
6 permanent brachytherapy procedure, that instead of  
7 saying, you know, 140, it goes from 100 to 150. That  
8 was unanimously rejected, so that's not a problem.

9 Now, appropriateness of the 20 percent  
10 criteria -- medical implant results, if the total dose  
11 deferred from prescribed dose by 20 percent or more,  
12 this 20 percent figure, where did it come from? It  
13 came from -- ordinarily from the external beam and the  
14 Cobalt-60 administration data.

15 There was really no evidence-based  
16 criteria for returning the 20 percent. It was  
17 retained because that is what it was in the prior  
18 versions. We really don't know whether the variation  
19 of more than 20 percent will cause harm to the  
20 patient, because it depends on what site, what  
21 modality, what volume was radiated, and what was the  
22 dose given to the normal tissue rather than the dose  
23 given to the tumor.

24 For example, you can give double the dose  
25 to the tumor. So long as the dose to normal tissue is

1 not exceeded, you are not going to cause any harm.

2 The 20 percent criteria, the subcommittee  
3 opinion was that 20 percent dose was reasonable,  
4 action level for reporting QA significance, for  
5 temporary implants, for external beam, and unsealed  
6 pharmaceutical administration, so long that the  
7 medical implant reporting is not automatically treated  
8 as an indicator of potential medical harm, which is  
9 what we all agreed upon.

10 Now, for permanent implant at 20 percent,  
11 it is not justifiable, and Dr. Williamson, the way it  
12 was stated by the subcommittee, was that to define ME  
13 excluding seed migration and patient intervention if  
14 total source strength implanted anywhere in the  
15 patient exceeds written directive by more than 20  
16 percent, or total source strength implanted in the  
17 planned target volume deviates from the written  
18 directive by more than 20 percent.

19 When I presented this to the radiation  
20 oncologists, there were significant problems. And  
21 what -- the overall feeling is that we can still use  
22 the wording that is very similar to that written in  
23 the 35 -- 10 CFR 35, and just change a couple of  
24 words, so we can say something like this. "The  
25 medical implant result, if the total source strength

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 intent of the dose -- if the total source strength  
2 implanted into the treatment site -- we felt just keep  
3 the word "at the treatment site" rather than talking  
4 about planned target volume, because that can differ  
5 between different radiation oncologists.

6 It deferred from the prescribed source  
7 strength by 20 percent or more. And it will not be  
8 considered to be a medical implant if the deviation  
9 resulted from patient intervention or due to seeds  
10 that were implanted in the treatment site but  
11 subsequently migrated outside the treatment site.

12 All locations already in the 10 CFR 35  
13 show instead of trying to make -- by trying to make  
14 major changes you make things worse. We said that if  
15 you just change those wording to the total source  
16 strength, it will apply for permanent implant, and we  
17 felt this would be a better way to go than trying to  
18 coordinate planned target volume and make the 20  
19 percent or more, because once you say that the dose  
20 strength implanted into the treatment site deferred  
21 from the prescribed source strength by 20 percent or  
22 more, it will include someone who is trying to add  
23 more seeds, because you are now adding or you are  
24 giving a prescribed -- you are giving a dose that is  
25 already 20 percent more. So we felt this would cover

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 both the implants and make it a lot simpler.

2 CHAIRMAN MALMUD: Thank you, Dr. Nag.

3 May I ask the committee a question?  
4 Having heard professional disagreement regarding the  
5 rewriting or making a recommendation to the NRC, how  
6 many of you feel that we are currently prepared to  
7 present this to the NRC as a completed document of the  
8 ACMUI?

9 MEMBER NAG: I don't.

10 MEMBER WILLIAMSON: Who believes that we  
11 are ready to make that presentation? Do you, Ralph?

12 MEMBER LIETO: Well, I -- I want to kind  
13 of -- do you want a yes/no?

14 CHAIRMAN MALMUD: Yes, because we have a  
15 meeting this afternoon with the Commission, and  
16 they're expecting to hear a report.

17 MR. ESSIG: But not a completed report.  
18 This is one of the four items that was listed as a  
19 work in progress. And it seems to me what we're  
20 trying to do here is to -- we have an hour and 45  
21 minutes on the agenda tomorrow to discuss this topic.

22 And we're trying to squeeze everything  
23 into this, which I wanted to make the point while I  
24 have the microphone, I had a phone call during the  
25 presentation that reminded me that the chairman has

1 instituted a new procedure for presentations. There  
2 will be a green, yellow, and red light on the table,  
3 and what you want to avoid, of course, is the red  
4 light. And you do that by -- we have an hour and a  
5 half total

6 The Commission reserves half of that time  
7 -- namely, 45 minutes -- for questions and answers.  
8 That leaves, for four presentations, 45 minutes. Dr.  
9 Malmud will make some opening remarks, which will  
10 maybe be a minute or so. So let's take 44 minutes,  
11 divided by four, do the math, you're talking about 10  
12 or 11 minutes.

13 I believe the only presentation that was  
14 close to that was, Dr. Williamson, your dose  
15 reconstruction ran about 10 minutes. And, Dr. Vetter,  
16 yours took about 15, and, Dr. Eggli, yours took about  
17 15. So we'll have to look at compressing those to --  
18 so we can remain within the chairman's guidelines.

19 This particular issue, it seems to me,  
20 we're going to have to -- the Medical Events  
21 Subcommittee, we can acknowledge that there are  
22 several issues that are currently still under  
23 discussion and don't present them as a -- you know, as  
24 a completed activity.

25 MEMBER WILLIAMSON: I think we have no

1 choice but to make a presentation.

2 MR. ESSIG: Yes, we do. We have to  
3 present.

4 MEMBER WILLIAMSON: And I will simply  
5 indicate -- make my -- my spoken remarks more general  
6 and indicate, you know, areas of general consensus,  
7 but that there are many disagreements over details.

8 MEMBER NAG: My suggestion is that there  
9 are a few places where I think everyone agrees. We  
10 present those, that these have been agreed by the  
11 subcommittee. And then, where there are significant  
12 differences, we say, "These areas are under  
13 discussion, and a detailed or final presentation will  
14 be made later." That's the only way we can do it.  
15 Otherwise, we cannot -- in 10 minutes we cannot, you  
16 know, discuss all of the objections and disagreement,  
17 and so forth.

18 CHAIRMAN MALMUD: Thank you.

19 Mr. Lieto?

20 MEMBER LIETO: Mr. Chairman, I think the  
21 presentation that Jeff has accurately reflected, at  
22 the time that it was submitted, the subcommittee  
23 consensus. And I think it being presented in a  
24 context this is a works in progress as stated, and at  
25 that time that it was presented to the Commission,

1 what is the consensus of the committee --  
2 subcommittee?

3 I think the meeting that Dr. Nag had after  
4 this document was submitted, and so forth, with the  
5 other agencies or societies may provide some valued  
6 input, and so forth, to the subcommittee. But we  
7 weren't privy to that. So I -- I would say that --  
8 and maybe the timing I'll leave up to the staff and  
9 Jeff to decide, but I think that the presentation, as  
10 -- as submitted in our packets, does reflect  
11 accurately -- and I'd like to hear from David if he  
12 agrees.

13 MEMBER DIAMOND: What you're saying is  
14 correct, and I think Jeff has done a fantastic job on  
15 this.

16 And I congratulate you, Jeff, and I think  
17 the way that you outlined your discussion is perfectly  
18 appropriate. You will go through the slides as  
19 previously submitted, and areas where there needs to  
20 be a verbal notation as to some areas of disagreement,  
21 I think that's perfectly reasonable.

22 CHAIRMAN MALMUD: Yes, Dr. Miller?

23 DR. MILLER: If I could just augment what  
24 Tom said, so that you're not surprised when you get  
25 there. This new protocol that the chairman has put in

1 is an attempt to try to continue to put more  
2 discipline into the Commission rules, and to allow all  
3 parties an equal opportunity.

4 So you'll see not only the lights on the  
5 table; you'll see a clock that's counting down. So  
6 you won't be surprised that suddenly a light will turn  
7 yellow or red. You'll see the clock winding down, and  
8 what will happen will be, hopefully, what the chairman  
9 has challenged the Commissioners to do is to be  
10 disciplined in letting you do your presentations  
11 during your time, and then the Commission is given --  
12 each of the Commissioners are given a certain allotted  
13 time to ask questions.

14 And you'll see the chairman pretty much  
15 control that. They'll ask a few questions. They'll  
16 go on to the next Commissioner. If time permits,  
17 they'll come around and ask more questions.

18 So with the clock there, it gives you the  
19 visual effect of doing that. This is something that  
20 the staff has been challenged to do in our  
21 presentations with them. And the EDO has challenged  
22 us to make sure you stay in the green.

23 MEMBER WILLIAMSON: So we're each going to  
24 be given 10 minutes. Is that the --

25 DR. MILLER: Well, the total presentation

1 I assume from what Tom tells me is SECY is given 45  
2 minutes. So the total presentation of all four topics  
3 --

4 MEMBER WILLIAMSON: Okay. So it's going  
5 to count from 45 to zero.

6 DR. MILLER: Yes. So it's -- whether you  
7 equally apportion it to 10 minutes or somebody takes  
8 12 and somebody takes 8 --

9 CHAIRMAN MALMUD: Given the effort that  
10 has gone into each of the four presentations, there  
11 should be 10 minutes allowed for each presentation.  
12 That would be the fairest thing to do.

13 MEMBER WILLIAMSON: Well, I think it would  
14 be helpful, then, if someone from the staff gave us a  
15 warning when we're at 10 minutes, then, because it  
16 would be very difficult to subtract 37 minutes from 45  
17 to figure out what the clock reads.

18 MEMBER LIETO: Can you electrify the  
19 seats?

20 (Laughter.)

21 CHAIRMAN MALMUD: It's kind of like  
22 testifying before Congress. It's --

23 DR. MILLER: I think that this is where  
24 this came from. I think the chairman took this from  
25 what he saw before Congress, and it's to keep the

1 Commission meetings in the time limit that was  
2 allotted and keep the presentations at a certain  
3 level.

4 CHAIRMAN MALMUD: And those of us who have  
5 done that have lived through it. It's not difficult.

6 DR. MILLER: Yes.

7 CHAIRMAN MALMUD: What do you think of the  
8 critical elements, Jeff, that you'd like to point out  
9 to the -- to the committee? Because there's so much  
10 material that was covered.

11 MEMBER WILLIAMSON: The critical elements?  
12 What do you mean the "critical elements"?

13 CHAIRMAN MALMUD: Well, the critical  
14 elements of your testimony with regard to the 20  
15 percent reporting threshold.

16 MEMBER WILLIAMSON: I think, you know,  
17 just to reiterate, that's a point of general consensus  
18 that it's reasonable. I certainly don't disagree with  
19 any of the details Dr. Nag has added. I think what I  
20 said in one slide was adequate.

21 CHAIRMAN MALMUD: Okay. Yes?

22 MEMBER LIETO: I was just going to make  
23 one recommendation for the slides. I think the last  
24 two slides are added since the committee/  
25 subcommittees met. I think you had two what I'll call

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 Dr. Williamson slides. Maybe you might want to not  
2 present those, since we have not discussed it with the  
3 full committee, or whatever, or those two that are in  
4 --

5 MEMBER WILLIAMSON: Those are two that  
6 were made specifically for this group --

7 MEMBER LIETO: Okay.

8 MEMBER WILLIAMSON: -- because the intent  
9 at the time was to -- this would be a lead into our  
10 discussion and to frame issues that we should be  
11 discussing. Instead, you know, we're returning to  
12 older issues that we thought we had consensus on.

13 You know, I actually think with a little  
14 time at least some of these issues that Dr. Nag has  
15 brought up could be dispensed with. Whether it's --  
16 everyone agrees that, you know, the written directive  
17 definition and associated regulations should not be so  
18 elastic that months and months later an authorized  
19 user can revise the written directive.

20 There is, I don't think, anyone on the  
21 subcommittee that disagrees with that. I think we  
22 could dispense with the issue of what the words mean  
23 by hearing from the appropriate member of the staff or  
24 Office of General Counsel to determine whether Dr.  
25 Nag's interpretation is correct or not. And then,



1 that would be a major point that would disappear then.

2 So I would say, you know, we could use the  
3 time we have -- if there is time before the, you know,  
4 Commission meeting to continue deliberating these  
5 issues, we could probably resolve of them.

6 CHAIRMAN MALMUD: Thank you.

7 MR. ESSIG: And, of course, I would add it  
8 doesn't have to be resolved before the Commission  
9 meeting. Are you talking about -- if you focus on the  
10 points where you do have subcommittee consensus, and  
11 merely indicate that in some areas there are --  
12 because of some recently introduced information from  
13 various sources, the subcommittee hasn't had a chance  
14 to consider it yet, and that will be done in future  
15 deliberations of the subcommittee.

16 CHAIRMAN MALMUD: Thank you. Does that  
17 complete this discussion?

18 MR. ESSIG: Yes, it does. And I would  
19 just observe, maybe stating the obvious, but we're  
20 horribly behind schedule. We had, by previous  
21 agreement -- Dr. Eggli had indicated that his  
22 presentation, rather than the allotted 60 minutes,  
23 would only require 30.

24 However, we had scheduled a break for  
25 around 10:00, and, Mr. Chairman, it's your -- it's

1 your option. We could take the break now, and then  
2 continue with Dr. Eggli after the break.

3 CHAIRMAN MALMUD: That is an excellent  
4 idea, since I think people will work more efficiently  
5 if they have a break first. So we'll break now for 15  
6 minutes.

7 (Whereupon, the proceedings in the  
8 foregoing matter went off the record at  
9 10:24 a.m. and went back on the record at  
10 10:44 a.m.)

11 CHAIRMAN MALMUD: Ladies and gentlemen, if  
12 I may, I call you back to the committee table.

13 We will resume with Dr. Eggli's  
14 presentation.

15 MEMBER EGGLI: Thank you. At the last  
16 meeting of the ACMUI, the ACMUI was asked by NRC staff  
17 to review the I-131 therapy incidents. ACMUI  
18 established a subcommittee which included Ralph Lieto,  
19 Sally Schwarz, Richard Vetter, and myself to look at  
20 the incidents that were described in our binder at the  
21 last meeting.

22 Next slide please. The charge of the  
23 subcommittee was to review the I-131 therapy incidents  
24 looking for common themes or systematic problems and  
25 to make recommendations to the full ACMUI of any

1 measures which might further reduce administration  
2 incidents.

3 The materials that we reviewed were the  
4 NMED summaries that were available. These were  
5 summary descriptions of the events, and details were  
6 limited. And the assumption that we made as a  
7 subcommittee was that all positive observations were  
8 included in the summary, and so that absence of a  
9 specific observation indicated that there wasn't a  
10 problem or it would have been described.

11 In reviewing the incidents it became  
12 readily clear that the number of therapeutic incidents  
13 in the United States every year is small compared to  
14 the total amount of radioactive iodine administered  
15 for therapeutic purposes. There were fewer than 10  
16 incidents per year, and no institution had more than  
17 a single administration error.

18 And in the positive comments in the  
19 description there was no evidence that policies or  
20 procedures were inadequate in any of those  
21 administrative incidents. As a result it was our  
22 conclusion that most of the errors were in fact human  
23 errors. They could be categorized as failure to pay  
24 attention to details, failure to follow established  
25 policies and procedures, and missed communications.

1           And most of those missed communications  
2 were verbal. And in reviewing the incidents the  
3 question was raised, did the culture in the  
4 institutions where the events occurred permit free  
5 communication? And did that allow the staff to  
6 question the authorized user?

7           So that our recommendations reflect an  
8 effort to further reduce the human error. And again,  
9 it's our impression that these were individual human  
10 errors.

11           And so our recommendations deal with  
12 verification procedures. And one of our  
13 recommendations is that what could be considered is a  
14 patient identification verification procedure and  
15 administration procedure similar to the rules required  
16 in blood banking which in general requires two people  
17 to positively identify the patient and two people to  
18 review the dose to be administered, or in the case of  
19 blood banking, the unit of blood to be administered,  
20 to verify that it's right patient, right dose.

21           Another recommendation is that verbal  
22 orders should probably not be permitted at any step of  
23 the process of therapeutic dosage administration. In  
24 some of the incidents reported there were verbal  
25 orders issued for the ordering of the dose. And once

1 the dosage appeared on site, the chain that verified  
2 those verbal orders was weak.

3 Additional recommendation to the whole  
4 ACMUI is that the dosage should be verified against  
5 the written directive prior to administration.  
6 Essentially that the individual administering the dose  
7 ought to have the written directive in their hand.  
8 They ought to verify that the dosage to be  
9 administered does match the dosage that was actually  
10 ordered.

11 It would be useful for the therapeutic  
12 dosage to be re-verified in a dose calibrator on site.  
13 We realize that that's not required by the current  
14 rule. But again, if therapeutic administration is  
15 considered higher risk, I personally cannot imagine  
16 re-verifying the dosage received from a central  
17 pharmacy on site, and one of the errors was created by  
18 a central pharmacy sending an incorrectly labeled  
19 dosage that the site did not re-verify in a dose  
20 calibrator.

21 Another problem is two dosages available  
22 on site at the same time. And again, the ability to  
23 put the iodine into a dose calibrator to measure the  
24 activity to be administered prior to administrator  
25 would have prevented that particular error as well.

1 Another key is communication between the  
2 authorized user and the individual administering the  
3 doses. And those communication chains need to be  
4 strengthened. The administering technologist should  
5 review the treatment plan with the authorized user  
6 prior to administration.

7 The combination of those sorts of steps,  
8 and the subcommittee's feeling was those steps would  
9 strengthen the administration process and reduce the  
10 likelihood of errors, because the source of error  
11 would be reduced by strengthening communication,  
12 strengthening the process, strengthening patient  
13 identification.

14 We would also like to see, when incidents  
15 are reported, some more detailed information  
16 available. We would like to know what were the causes  
17 and contributing factors in not just a description of  
18 the incident, because it was hard for us to go  
19 backwards and try to put together an analysis of  
20 causes and contributing factors.

21 We would like to know, was the authorized  
22 user present at the site? Were multiple dosages  
23 available on site that might have led to confusion?  
24 Was the dose assayed? What role did verbal orders  
25 play in the process?

1           So a more detailed description of the  
2 incidents would be helpful in retrospectively  
3 analyzing.

4           But nonetheless, again, it is the opinion  
5 of the subcommittee that human errors were largely  
6 responsible. And I think we have a number of simple  
7 steps that do not have a dramatic burden on the  
8 ability to deliver care that might reduce these  
9 incidents.

10           MEMBER NAG: When you are talking about  
11 the treatment plan and written directive, are they not  
12 the same thing? In one place you mentioned the  
13 treatment plan has to be checked?

14           MEMBER EGGLI: Right. It's essentially  
15 the written directive, yes.

16           CHAIRMAN MALMUD: Any other questions?

17           The one point that you make - it relates  
18 to the dose calibrator. Every nuclear medicine  
19 section has a dose calibrator. There may be some  
20 practicing medical specialists who do radioiodine  
21 therapy who do not have dose calibrators. I  
22 personally can't imagine giving a therapeutic dose of  
23 I-131 without checking it personally in a dose  
24 calibrator, which is our routine, and your routine as  
25 well.

1           However, we should note that this would  
2           create a bit of a program for non-nuclear physicians,  
3           non-radiologists who are administering I-131 who may  
4           not have dose calibrators currently.

5           MEMBER EGGLI: I think the feeling of the  
6           subcommittee was that the value added by a dose  
7           calibrator, and an inexpensive dose calibrator is  
8           under \$10,000, is easily to justify, given the  
9           potential risk to the patient of an incorrectly  
10          administered dose.

11          CHAIRMAN MALMUD: I give it a hearty amen.  
12          I agree fully. I think Dr. Williamson had a comment.

13          MEMBER WILLIAMSON: Yeah, I think just to  
14          comment, this is also for brachytherapy, other than  
15          high dose brachytherapy and gamma stereotactic, the  
16          current regulations for brachytherapy and for nuclear  
17          medicine no longer require the users to verify any  
18          measurement technique at all, the source strengths, so  
19          long as it is a unit dosage.

20          And you can make a case that the vendor  
21          has followed industry standards. So anything that  
22          would be a recommendation regarding, on this point,  
23          which I have great sympathy for, would require a  
24          little change.

25          CHAIRMAN MALMUD: Dr. Williamson's point



1 of course is correct, and we're aware of that. We  
2 nevertheless, as practicing nuclear physicians, I saw  
3 Dr. Schwarz also nodding her head, concerned about  
4 giving a therapeutic dose without having checked it  
5 personally in a dose calibrator.

6 I'm sorry, Sally, I spoke for you.

7 MS. SCHWARZ: That's fine. I certainly  
8 agree that the presence of a dose calibrator,  
9 certainly in therapy doses makes tremendous sense, and  
10 I realize they are not now required. So even in terms  
11 of the mistaken - dispensing from a nuclear pharmacy  
12 when the dose dispensed was incorrect, there is no way  
13 to verify that. And it obviously does occur.

14 CHAIRMAN MALMUD: Dr. Eggli.

15 MEMBER EGGLI: Just as an experience  
16 statement, in my own practice I require that the dose  
17 be measured in a dose calibrator - be less than 10  
18 percent off from the dose that I ordered.

19 Routinely, doses come from our central  
20 radio-pharmacy that do not meet that criteria, and if  
21 I did not have a dose calibrator on site I would not  
22 be able to know that.

23 CHAIRMAN MALMUD: Thank you. Any other  
24 comments for Dr. Eggli?

25 If not, we'll move on.

1                   MEMBER LIETO:  Where do we go from here?  
2                   We've got a subcommittee report with recommendations.  
3                   Does, I mean is this something that should be going on  
4                   to the Commission?  Where do we go with these  
5                   recommendations?

6                   Because as Sally has pointed out, we may  
7                   potentially be looking at an issue of rulemaking that  
8                   we may be suggesting to staff.

9                   CHAIRMAN MALMUD:  Does a member of the  
10                  committee wish to discuss this further?  Or do you  
11                  wish to make this as a motion, Dr. Eggli, from the  
12                  subcommittee to the committee?

13                  MEMBER EGGLI:  This is the subcommittee's  
14                  recommendation to the whole ACMUI.  I think it is up  
15                  to the group as a whole to determine whether or not to  
16                  endorse this subcommittee report and send it to NRC  
17                  staff.

18                  I think that would be the appropriate next  
19                  step would be for the whole ACMUI to determine whether  
20                  or not it wants to endorse this subcommittee report  
21                  and send it to staff.

22                  CHAIRMAN MALMUD:  If we accept your report  
23                  as a motion, is there a second to your motion?

24                  MEMBER LIETO:  Second.

25                  CHAIRMAN MALMUD:  It's been seconded by

1 Mr. Lieto.

2 Is there any further discussion of this  
3 motion, which you realize will have some implications,  
4 particularly if we are recommending, as most of us do,  
5 the use of dose calibrators for all therapeutic doses  
6 of I-131?

7 Dr. Vetter.

8 MEMBER VETTER: Let me just point out  
9 that's just one of the recommendations. One of the  
10 major problems the committee had was trying to  
11 determine what the real root cause was for these  
12 medical events.

13 And so I think in the spirit of the  
14 committee's report we hope that the NRC staff would  
15 take a look at NMED and see what can be done to  
16 provide more complete information. I think that's one  
17 of the major findings of the subcommittee.

18 CHAIRMAN MALMUD: Thank you for clarifying  
19 that and reiterating it.

20 Dr. Miller.

21 DR. MILLER: Yes. Dr. Vetter, could I  
22 pursue in a little bit? Would the report be specific  
23 enough as to what changes in NMED would need to take  
24 place? And to get that information, would that  
25 require a regulatory change or rulemaking?

1                   MEMBER EGGLI: I think this is information  
2                   that the staff probably has, and it was reported  
3                   probably by the state. It just wasn't included in the  
4                   summary. And the comments that we listed, like, was  
5                   the AU present? Were multiple dosages present on  
6                   site? Was the dose assayed on site? Were there  
7                   verbal orders that confused the issue as opposed to  
8                   written directives?

9                   Again, I know that - when at least  
10                  internally when we describe what we call a recordable  
11                  event, whether it's reportable or not, we maintain  
12                  that kind of detail. And I know that when we forward  
13                  any such event to our regional office, that that  
14                  detail is contained within the report.

15                  So I suspect you have all of the material  
16                  it takes to do root cause analysis, but that NMED is  
17                  more of a summary, and it is a subset of the  
18                  information that the NRC maintains at some level.

19                  So I doubt that you have to do any  
20                  additional information collecting than you already  
21                  have. It's just how you save it in your summary.

22                  DR. MILLER: I guess what I'm searching  
23                  for and following up on that is, when you say you  
24                  supply that, the question becomes - Tom, I don't know  
25                  if you know the answer to this - are we getting that

1 information routinely in the reports that are coming  
2 in, based upon the reporting requirements.

3 CHAIRMAN MALMUD: Dr. Miller, is your  
4 question, does it relate to the fact that Dr. Eggli  
5 pointed out that there were 10 errors? In no  
6 institution did more than one arise. And that each of  
7 the 10 can be traced back to human error rather than  
8 other elements.

9 And should there be a form on which these  
10 data are reported so that they could be tracked, is  
11 that your question?

12 DR. MILLER: Yeah, I think my question  
13 is, Dr. Eggli is recommending that documentation needs  
14 to be improved at NMED. But to be able to improve  
15 that documentation, we have to have that information  
16 reported in all cases.

17 And I guess what I was searching for is,  
18 is that in fact happening? That might be a question  
19 that I have to my staff.

20 CHAIRMAN MALMUD: I think Dr. Vetter might  
21 be able to address that.

22 MEMBER VETTER: I think our answer is, we  
23 don't know.

24 The user is expected to provide that  
25 information to the NRC, including root cause. NMED is

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 such a boiled-down summary that very often we couldn't  
2 figure out what the root cause was except that it  
3 attributed it to human error. So somewhere in the  
4 middle there, the answer should be there, but we  
5 really don't know if it is. Because we didn't see the  
6 original reports to the NRC.

7 CHAIRMAN MALMUD: Sally Schwarz.

8 MS. SCHWARZ: Could I make a suggestion  
9 that possibly before we would make the recommendation  
10 for a rule change that we could actually have someone  
11 from staff if they could gather that information,  
12 potentially the forms that were submitted from these  
13 institutions, and actually analyze if that information  
14 was available before we decide that we need a rule  
15 change to require a dose calibrator?

16 It may be that each of these doses was  
17 assayed and for some reason still given incorrectly.  
18 We don't really know that there was no dose calibrator  
19 on site.

20 CHAIRMAN MALMUD: Dr. Williamson.

21 MEMBER WILLIAMSON: I think maybe the  
22 issue could be simplified in general along the lines  
23 of what Sally has suggested.

24 Perhaps reconstructing your NMED database  
25 might be a rather daunting technical project. The

1 real problem is that if you expect ACMUI to  
2 meaningfully review medical events you're going to  
3 have to provide more than human error as the root  
4 cause. You're going to have to supply more complete  
5 descriptions of the events if you want meaningful  
6 feedback as to what should be done.

7 So really, an alternative. So I think  
8 that's really the way the motion should read is that  
9 to the various medical event subcommittee NRC should  
10 endeavor to supply as complete information as possible  
11 regarding these events. And since there are very few,  
12 this should not be a major burden to gather that  
13 material or provide a list of addresses and a database  
14 that people could access themselves. For those of us  
15 who don't know how to use Adams and so forth, some  
16 effort would have to be made.

17 CHAIRMAN MALMUD: Dr. Eggli, you were able  
18 to determine, your committee was able to determine  
19 that these were 10 human errors, each occurring at a  
20 different institution.

21 What was the basis for determining that  
22 they were human errors?

23 MEMBER EGGLI: By the summary descriptions  
24 in NMED. Again, the assumption that the subcommittee  
25 made was that all pertinent positives were provided in

1 the NMED summary. And that if specific information  
2 was not provided, it probably was not an issue.

3 To make any analysis that kind of  
4 assumption had to be made, was that all pertinent  
5 positives were provided in the NMED summary. And in  
6 the description of the actual event, the summary  
7 descriptions were in fact human error type  
8 descriptions.

9 And with the majority of the subcommittee  
10 recommendations, this recommends a process that  
11 tightens up the communication failures that may have  
12 partially led to the human errors and the patient  
13 identification failures that may have led to human  
14 errors.

15 And independent of the data available in  
16 NMED, those are probably recommendations that stand as  
17 reasonable in any case. The recommendation for a dose  
18 calibrator I think stands as a recommendation  
19 regardless of any more information that may be in  
20 NMED.

21 The question that Dr. Miller asks is, does  
22 NRC in fact have the information that we are asking  
23 for? The answer to that is, the only area of  
24 uncertainty I think in the subcommittee's report, and  
25 I guess what the subcommittee is asking is not



1 necessarily that the NRC acquire any more information,  
2 but to provide, when we're analyzing events, to  
3 provide all of the information that the NRC possesses  
4 to help in the analysis of the problem.

5 CHAIRMAN MALMUD: Thank you. Does that  
6 address your question, Dr. Miller?

7 DR. MILLER: Yes.

8 MR. ESSIG: Dr. Zelac has a clarification.

9 DR. ZELAC: If I could ask Dr. Eggli, do  
10 you happen to recall or know how many of the 10 events  
11 occurred in NRC jurisdiction states as compared to  
12 agreement states?

13 MEMBER EGGLI: That information was not  
14 provided in NMED as to whether it was an agreement  
15 state or an NRC state.

16 Did the numbering help us on that, Ralph?

17 MEMBER LIETO: It did reference the state,  
18 so, it didn't say it was an agreement state or NRC  
19 regulated. But it did indicate the state that the  
20 event occurred in.

21 So my recollection - again, this is just  
22 - I don't have the data with me - but I think it was  
23 about evenly split in terms of where the reported  
24 occurrences were.

25 DR. ZELAC: The reason I ask is that the

1 current medical event reporting criteria have a  
2 compatibility C level with respect to what is expected  
3 from the agreement states in terms of comparison and  
4 agreement with ours. But the event itself in terms of  
5 what the root cause was, it's clearly an element which  
6 is necessary regardless of who is responsible for  
7 completing the report.

8 CHAIRMAN MALMUD: Thank you, Dr. Zelac.  
9 Another comment?

10 DR. HOWE: Yes, this is Dr. Donna-Beth  
11 Howe with the NRC.

12 I just have two quick questions. If I  
13 remember the database correctly, we had a number of  
14 medical events that were supposed to be I-131  
15 administrations that did not require a directive, but  
16 material was given that did require a directive.

17 Did your subcommittee look into or talk  
18 about the issue of how to capture those things where  
19 there is no written directive because it wasn't  
20 supposed to be, but the material itself would trigger  
21 one?

22 MEMBER EGGLI: I think in most of those  
23 cases, essentially, a therapeutic dose was given in  
24 lieu of a diagnostic dose. And that is part of where  
25 our strong feeling that a dose calibrator needs to be

1 on site came from because had those doses been put  
2 into a dose calibrator, it would have been - it should  
3 have triggered somebody that the amount of activity  
4 being administered required a written directive.

5 DR. HOWE: My only other comment is that  
6 the NMED database at the bottom has a list of  
7 references. And many of those references are  
8 inspection reports or letters back and forth to the  
9 licensees. So those, I think, are available, although  
10 the agreement state data is generally pretty limited.

11 So I think the access to the data is there  
12 in NMED, we just have to pull it out.

13 MEMBER EGGLI: Probably, and some of this  
14 has to do with the limited ability of some of the  
15 subcommittee members, myself specifically, to navigate  
16 the NRC's website.

17 CHAIRMAN MALMUD: Are the incidents to  
18 which Dr. Howe is referring incidents in which perhaps  
19 a dose of I-123 without a written directive was  
20 ordered but instead I-131 was given, which does  
21 require a written directive and given incorrectly  
22 because there was no dose calibrated or checked that  
23 it was I-131 rather than I-123?

24 MEMBER EGGLI: I believe that most of the  
25 incidents were the intention to deliver less than 30

1 microcuries of I-131 rather than an I-123.

2 CHAIRMAN MALMUD: Thank you.

3 MEMBER EGGLI: And again, what that had to  
4 do with the fact, though, is that a higher dose of  
5 iodine was physically present on the site and  
6 available to be confused with the lower dose.

7 CHAIRMAN MALMUD: That clearly would be an  
8 instance in which a written directive was not required  
9 but a dose of I-131 was given in error. And that  
10 would be an incident in which the use of a dose  
11 calibrator with documentation of the dose immediately  
12 before administration would have detected the problem.

13 Thank you. Yes?

14 MEMBER RAIZNER: Really just a question.  
15 Does anybody have an idea of what the denominator  
16 would be of these 10 events? In other words, it's 10  
17 of what number and what percent?

18 MEMBER EGGLI: The bottom number is huge,  
19 probably well in excess of 10,000.

20 MEMBER RAIZNER: So 10 in 10,000 --

21 MEMBER EGGLI: It is small.

22 MEMBER RAIZNER: Would we be improving -  
23 that seems like a very good outcome, rather than a  
24 very bad outcome. Not that we shouldn't strive to  
25 reduce it. But would requiring calibration, do you

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 believe we would ever eliminate human error entirely?

2 CHAIRMAN MALMUD: We have a comment from  
3 Dr. Suleiman.

4 MEMBER SULEIMAN: My experience, and I  
5 know FDA's experience, is that medical events are  
6 grossly underreported, so when it even surfaces, you  
7 can assume that it's probably greater than it is.

8 We see problems all the time with drugs  
9 that have similar sounding names, and they're  
10 prescribed just because their names are similar. And  
11 they're prescribed incorrectly.

12 So I think if this sounds logically  
13 correct, you know, we shouldn't - I always ask that  
14 question, what's the denominator. That came up with  
15 the recent Vioxx thing. I said, how many people  
16 received this drug? And so you were projecting these  
17 deaths.

18 The point is, they probably happen more  
19 frequently than you'd care to admit. So I'm impressed  
20 with the committee conclusions.

21 But I think generally the whole medical  
22 event reporting science is extremely soft. The  
23 databases are frustratingly not complete, at least  
24 that's been my experience.

25 And so the fact that you've been able to

1 get some information out of this in a credible  
2 consistent way I think is commendable.

3 CHAIRMAN MALMUD: I think the statistical  
4 argument in medicine doesn't really carry much weight.  
5 Our real goal is zero tolerance for errors. We  
6 recognize we'll never achieve it, but it still is the  
7 goal.

8 The issue of a dose calibrator, for  
9 example, is just a one-time capital expenditure. It's  
10 not an ongoing investment in personnel, because it's  
11 the same personnel just taking one more step. So it's  
12 not an extraordinary expense.

13 And considering the damage that could be  
14 done from a large dose of a beta emitter as opposed to  
15 a small dose of a gamma emitter or even a trivial dose  
16 of a beta emitter, it's a worthwhile expense. It only  
17 would affect very few departments that currently don't  
18 have such a device on hand.

19 But I think the basic issue is that we try  
20 to achieve zero tolerance for medical errors,  
21 recognizing that we're all human and errors will  
22 occur.

23 Thank you, Dr. Eggli.

24 MEMBER EGGLE: Actually, there is a  
25 motion.

1 CHAIRMAN MALMUD: Your motion, which was  
2 seconded by Mr. Lieto.

3 Any further discussion of the motion? All  
4 in favor?

5 MEMBER WILLIAMSON: I have a question.

6 CHAIRMAN MALMUD: Oh, you do?

7 MEMBER WILLIAMSON: It's a very broad  
8 amorphous motion with about six motions all wrapped up  
9 in one. I mean does everybody feel comfortable voting  
10 en bloc?

11 CHAIRMAN MALMUD: Well, I think the motion  
12 includes - if I may dare to summarize for you, the  
13 motion includes the fact that the 10 errors found all  
14 seem to have been human; that one of the  
15 recommendations for correction of these is better  
16 communication systems and better documentation; two  
17 witnesses to administer doses; and the recommendation  
18 that departments that are dispensing I-131 in  
19 therapeutic doses have a dose calibrator on site.

20 Is that a good summary?

21 MEMBER EGGLI: Yes, the specific  
22 recommendations are contained on slides 7, 8, 9 and  
23 10. It's a limited number of recommendations.

24 With the exception of the dose calibrator,  
25 we did not think that any of the recommendations

1 imposed a significant personnel or economic burden on  
2 any department, and had a good chance of reducing  
3 incidents further.

4 So since the impact was small, it seemed  
5 that these were reasonable steps to take. Admittedly  
6 the dose calibrator has an economic impact less than  
7 \$10,000. I can buy a lot of dose calibrators for one  
8 malpractice settlement.

9 CHAIRMAN MALMUD: Dr. Williamson?

10 MEMBER WILLIAMSON: Well, perhaps my  
11 juridical instincts have been sharpened too much by  
12 thinking so much about medical events lately. But I  
13 frankly feel uncomfortable voting for this and saying  
14 all these things should be made in regulations.

15 I think to make patient verification  
16 procedures similar to blood administrations, that's a  
17 recommendation for a rule change. It's both too  
18 imprecise and too prescriptive in my mind.

19 So I actually think, rather than take  
20 thoughtless action on this package which isn't well  
21 specified enough and implies all sorts of potentially  
22 complicated rule changes, I think it needs to be split  
23 out in little bits or perhaps rescheduled for more  
24 extensive discussion and a more detailed proposal made  
25 before I'd feel comfortable supporting all of these en



1 bloc.

2 Not that I don't have sympathy, or believe  
3 there is not value to the recommendations. But  
4 essentially what the meaning of making a  
5 recommendation is needs to be spelled out, I think, on  
6 a bit by bit basis, and we have to determine what  
7 recommendations are supported by existing regulations,  
8 which would be best handled by guidance, and so forth.

9 There are just many practical issues that  
10 need to be considered before I think this would be  
11 meaningful to the staff.

12 CHAIRMAN MALMUD: I think you've clearly  
13 stated your position.

14 Dr. Eggli?

15 MEMBER EGGLI: I would like to agree with  
16 the concept of Dr. Williamson, with the exception that  
17 this is simply a recommendation for possible action,  
18 and that everything that Dr. Williamson describes  
19 would be part of the process going forward.

20 We're making a recommendation that this be  
21 considered. And again, part of that process would be  
22 determining whether this could be done as guidance, as  
23 part of existing regulation, whether new regulation is  
24 required.

25 That's downstream. I think the first step

1 in this process is this series of recommendations to  
2 be considered by staff. We're not recommending  
3 regulation. We're recommending that a process be  
4 considered.

5 And I think then that everything that Dr.  
6 Williamson correctly states will be part of the  
7 downstream effort, once the process starts.

8 MEMBER WILLIAMSON: Well, I think if you  
9 could amend your recommendation to more precisely say  
10 we should engage in a future process of considering  
11 this in more detail, I could support it.

12 CHAIRMAN MALMUD: I believe Dr. Van Decker  
13 wanted to say something.

14 MEMBER VAN DECKER: I would agree with Dr.  
15 Williamson's last statement.

16 I guess the point I was going to make is,  
17 I don't think that anyone wants to jump the gun by  
18 saying we want to reopen rulemaking again, even in  
19 pieces, after the experiences we've had going through  
20 this, and the whole goal of doing the rulemaking  
21 process was to put us in a position where we were  
22 flexible enough to do other things, and guidance in  
23 other ways, so that that becomes a living document.

24 I think it's very reasonable to say we've  
25 had a thoughtful subcommittee that's thought about

1 this, has a few recommendations, and we can put this  
2 on the table for some further discussions as to how  
3 this can happen down the line and leave it at that for  
4 now.

5 CHAIRMAN MALMUD: Thank you.

6 Dr. Lieto, you had another comment.

7 MEMBER LIETO: Well, I think actually I'm  
8 just going to paraphrase what Dr. Eggli and Dr. Van  
9 Decker have said, is that I thought the motion was for  
10 the committee to accept the recommendations and  
11 proceed further. It's not to recommend regulatory  
12 changes as part of the motion.

13 CHAIRMAN MALMUD: Is that your motion, Dr.  
14 Eggli, that the committee accept the report and then  
15 take the next step within the committee?

16 MEMBER EGGLI: It is.

17 CHAIRMAN MALMUD: With that caveat, will  
18 you support the motion as amended, Mr. Lieto?

19 MEMBER LIETO: So seconded.

20 CHAIRMAN MALMUD: You second it, and does  
21 it now gain your approval, Dr. Williamson?

22 MEMBER WILLIAMSON: Yes.

23 CHAIRMAN MALMUD: Good. Dr. Miller.

24 DR. MILLER: At the risk of negating the  
25 approvals here, one of the things that the staff needs

1 from the committee is the committee's advice. And a  
2 recommendation of a subcommittee and a report endorsed  
3 by the full committee is certainly something of a step  
4 in the right direction.

5 But ultimately what the staff needs is  
6 advice from the committee as to what should be done as  
7 a regulator. And I think that's what we're struggling  
8 with.

9 So in framing the motion, in framing what  
10 the committee decides from the motion, I think we need  
11 to think about that aspect of it crisply.

12 CHAIRMAN MALMUD: Thank you. I believe  
13 that those of us who practice nuclear medicine, Dr.  
14 Eggli, Dr. Van Decker, myself, could supply the forms  
15 that we're currently using as a working document to  
16 see how we actually engage in each of these activities  
17 that the committee has recommended.

18 Because actually we do those things as  
19 does Dr. Eggli, as does Dr. Van Decker in the practice  
20 of cardiology. So we could supply the actual form.

21 But I don't believe that it's our  
22 responsibility to actually draft the final  
23 documentation. So we could prepare that, and I think  
24 that the motion on the table as amended by Dr. Eggli  
25 in support of Dr. Williamson will bring us to the next

1 step, which is to prepare such a form, which would  
2 certainly take care of the issues of misadministration  
3 at the time that the patient receives the dose.

4 Each of the elements that was presented to  
5 us would be covered in this form.

6 That which would not be covered would be  
7 if the I-131 did not come as sodium iodide. If it  
8 came as I-131 labeled something else, it would still  
9 be a mistake in the central pharmacy, which we  
10 wouldn't detect in the dose calibrator, because the  
11 dose calibrator is testing the activity not the  
12 pharmaceutical.

13 But the point is that the errors that have  
14 been described could be largely dealt with with the  
15 forms that are currently on hand.

16 We'd be happy to engage in that process as  
17 a committee, I assume, Dr. Eggli?

18 MEMBER EGGLI: My other comment is, I  
19 don't think anything other than the dose calibrator  
20 recommendation requires anything other than guidance  
21 for what makes a good safety program to implement.  
22 Because I think the rest of it is covered broadly in  
23 existing regulation, and guidance helps the end user  
24 understand how the Agency will interpret the existing  
25 regulation.

1           And again, with the exception of the dose  
2           calibrator, I don't think there is anything in the  
3           recommendations that requires new regulation. It may  
4           require clearer guidance, but I don't believe that  
5           anything other than the dose calibrator would require  
6           regulations.

7           DR. MILLER: I agree with Dr. Malmud's  
8           statement that it's not the role of the committee to  
9           have to craft regulatory tools, whether it's a  
10          regulation, guidance, or some other action.

11          But I think what the staff needs is the  
12          conclusions from the committee with regard to your  
13          findings. And I think you're close.

14          I'm thinking of a lot of things, and I  
15          don't know how it would play out, so I'm talking off  
16          the top of my head here.

17          With regard to the dose calibrator, I  
18          think the staff would have - if the committee feels  
19          strongly about that as a body, then the staff has to  
20          take that on and say, well, what form do we do this  
21          in?

22          In other words, you don't necessarily go  
23          off and write a regulation to address that. It may be  
24          that we provide guidance to the industry through some  
25          kind of generic communication or something to say,

1 this is a good practice. Is that enough?

2 Doing this will help prevent human error  
3 and help prevent you getting in a situation where  
4 you're in violation of the regulations.

5 That's kind of where I'm coming from, and  
6 just saying, conclusions of the committee, making a  
7 recommendation to the staff. If as a result of  
8 endorsing the report from the subcommittee, it means  
9 that the committee needs to do a little bit of further  
10 work to do that, whether that's to supply forms or  
11 whatever to staff, that's fine.

12 CHAIRMAN MALMUD: The skills and talents  
13 of the members of this committee can prepare such a  
14 document. And I think we could volunteer to do that,  
15 from which the Agency could then decide what it wants  
16 to do.

17 DR. MILLER: What would be the appropriate  
18 action, and then having the staff frame what that  
19 appropriate action is, it seems to me that at that  
20 time we could come back to the committee for a  
21 discussion and endorsement or committee views on what  
22 the proposal is as we go from there.

23 CHAIRMAN MALMUD: Mr. Essig.

24 MR. ESSIG: I would ask one question.  
25 That is, is there additional documentation, to which

1 I think Dr. Eggli alluded to, that was not in the NMED  
2 summary, that the committee or the subcommittee could  
3 use in formulating its recommendation to the staff?

4 And if so we could certainly furnish that  
5 if it's available.

6 CHAIRMAN MALMUD: Dr. Eggli?

7 MEMBER EGGLI: If there is more detailed  
8 information, it would be useful to look at that to  
9 make sure that our assumptions were not in error. If  
10 our assumptions were not in error, then our  
11 recommendations, I think, as a subcommittee stand.

12 So I would, I guess, as a personal note,  
13 I think that the recommendations of the subcommittee  
14 for me, as a practicing nuclear medicine physician,  
15 who dispenses literally thousands of doses of  
16 treatment doses a year - well, maybe not thousands,  
17 hundreds of treatment doses a year - I think these are  
18 good practice regardless of what other data turns up  
19 in NMED.

20 But I think it would be useful to know,  
21 nonetheless, that the assumptions that we based our  
22 recommendation on were valid, and that we did not miss  
23 some root cause information where we might have made  
24 a better recommendation.

25 CHAIRMAN MALMUD: Thank you. So the



1 motion has been moved, seconded, and discussed.

2 Is there any further discussion? If not,  
3 I wish to call the motion. All in favor?

4 Any opposed?

5 Any abstentions?

6 Let the record indicate it carries  
7 unanimously. Thank you.

8 We'll move on to the next agenda item.  
9 Dr. Vetter. We're up to the case experience using I-  
10 125 seeds as markers.

11 MR. ESSIG: If I could offer one --

12 CHAIRMAN MALMUD: Please, Mr. Essig.

13 MR. ESSIG: -- sort of a preliminary  
14 thought before Dr. Vetter starts.

15 This item, as the committee may recall, we  
16 had a presentation during the last meeting of the  
17 committee by Mr. Gallagher from Massachusetts, who is  
18 the chair of a workgroup that is implementing pilot  
19 project number four from the National Materials  
20 Program, which the focus of that pilot four group is  
21 to develop guidance for us by NRC and agreement state  
22 licensees for using these seeds as markers.

23 And the purpose of today's briefing, I  
24 believe, is for Dr. Vetter to share the experience at  
25 the Mayo Clinic. But the one thing I would caution

1 us to do is to not get out ahead - that this committee  
2 should not be getting out ahead of the working of this  
3 pilot group number four.

4 This would be certainly useful information  
5 for that committee, and I believe that the next  
6 meeting of this committee we will have Mr. Gallagher  
7 back. Unfortunately he couldn't be here at this  
8 meeting. But we'll have him back either during the  
9 next intervening noticed - publicly noticed conference  
10 call or at the next face-to-face meeting of the  
11 committee, where we'll dialogue further on this issue,  
12 using Dr. Vetter's material as input to that  
13 committee.

14 CHAIRMAN MALMUD: Thank you for bringing  
15 that fact forward. We were prepared to move the next  
16 step except for the absence of Mr. Gallagher, and  
17 therefore, Dr. Vetter's presentation will be the  
18 discussion today, and the next meeting that we have  
19 Mr. Gallagher will be able to make his presentation.  
20 And then we'll take it the next step along.

21 I know that there is external interest in  
22 this issue. And we do not wish to be a party to  
23 delaying it. However, we must give it a fair hearing.

24 MEMBER VETTER: Thank you. And thank you,  
25 Mr. Essig, for that introduction. After Mr.

1 Gallagher's report at our last meeting I volunteered  
2 to provide some case experience simply because we  
3 didn't have much knowledge of this practice.

4 And so the only purpose of this  
5 presentation is to provide some case experience. It's  
6 not to make any recommendations.

7 First of all I'd like to acknowledge a  
8 number of colleagues who actually did all this work.  
9 This includes physicists, surgeons, radiologists, and  
10 technicians. I won't go through who each of them is.

11 Now the current standard of practice uses  
12 a wire to localize the tumor in breast tissue. The  
13 radiologist places that wire in the tumor. And one of  
14 the disadvantages of that wire approach is that the  
15 radiologist's approach to the tumor, implanting the  
16 wire, may be different than the surgeon's preference  
17 because the surgeon has to basically follow that wire.  
18 And it may not necessarily be the best pathway to  
19 conserve breast tissue. So there is that disadvantage.

20 Another is scheduling conflicts. With the  
21 wire localization procedure, the surgery generally has  
22 to occur the same day because of the risk of the wire  
23 being dislocated. Wire does provide some limits for  
24 post-localization mammograms. That is, the wire can  
25 sort of get in the way.

1           There is this worry about wire migration.  
2           It's not a huge problem, but it is a risk.

3           And then there is the risk of infection,  
4           although that's pretty low. So the alternative that's  
5           being explored by a number of medical centers  
6           including Mayo being done in research protocols  
7           because it's an off-label use of the I-125 seed, is  
8           this use of radioactive seeds, that is Iodine-125  
9           seeds, placing them in the tumor in the place of the  
10          wire.

11          The seed that's used is the standard  
12          Iodine-125 seed that's used in therapy, although the  
13          amount of activity is very, very low compared to  
14          what's implanted in a tumor.

15          Some advantages are that the radioactive  
16          seed localization technique can allow surgery to take  
17          place up to five days later, and this minimizes  
18          scheduling conflicts between the radiologist and the  
19          surgeon.

20          The radiologist can approach the tumor  
21          from any direction, because when he or she finishes,  
22          they will simply leave the seed in the tumor, as  
23          opposed to a wire, which might be sticking out from  
24          any particular direction.

25          It also facilitates bracketing of the

1 lesions if you need to use more than one seed, and  
2 that does not interfere with any of the post-  
3 localization mammograms.

4 Some other advantages. Cost is a wash,  
5 and in surgery to remove - for lumpectomies, they  
6 commonly will inject some technetium near the tumor  
7 and allow that to be drained by the lymph node so that  
8 the surgeon then during surgery can find the first  
9 lymph node that's draining the breast and remove that  
10 lymph node and determine whether or not the tumor is  
11 spreading.

12 The same equipment can be used to do the  
13 sentinel lymph node biopsy as is used for the  
14 radioactive seed localization procedure.

15 This shows that the antoges (phonetic) are  
16 very similar, but they are distinct enough that simply  
17 changing the discriminators on the instrument allows  
18 you to usually detect the seed as opposed to the  
19 technetium which, there still would be some residual  
20 technetium in the breast.

21 In this particular case experience, some  
22 colleagues studied 200 consecutive patients, they did  
23 wire localization on half of them, they did that the  
24 same day as surgery, and for the radioactive seed  
25 localization technique, 68 percent of them were done

1 at least one day prior to surgery. So in other words  
2 this allowed them to delay surgery at least until the  
3 next day.

4 Then the radiologists were asked to rate  
5 the preference of using the radioactive seed  
6 localization technique versus the wire localization.  
7 Patients were asked to rank comfort and convenience.

8 This shows the box. You can't see the  
9 liner very well, but there is a little red liner in  
10 there to shield the seed.

11 Angela, could I get you to click on that  
12 box? There is supposed to be a video here. It's not  
13 working. We're going to miss the video.

14 The video is a short video to show how the  
15 needle is actually loaded with the seed. A little bit  
16 of bone wax is used to seal the end of the needle.  
17 The seed is then emplaced - no, that's all right - the  
18 seed is then placed inside the needle. It's followed  
19 by the stylat (phonetic), which will later be used to  
20 push the seed into the tumor tissue. And this is all  
21 done under sterile technique. So we're going to miss  
22 that.

23 This shows an ultrasound of the needle and  
24 the seed right on the end of it. Here the seed has  
25 been pushed out. And in the next view the needle has

1       been withdrawn and the seed remains in the tissue.

2                   This shows some radiographs of the same  
3       sort of thing.

4                   Post-localization mammogram, a little bit  
5       hard to see here - if you look real closely you can  
6       see the seed right there in that tumor.

7                   So when the patient gets to surgery, the  
8       surgeon uses the probe to locate the seed, and then  
9       the tumor is dissected and the specimen is - oops, I'm  
10      sorry. Here the surgeon is using the probe to confirm  
11      that the seed is in the specimen, so that's done  
12      immediately after surgery, right there on the drape.  
13      Here is a radiograph of the specimen showing the seed  
14      in place, and if you look really carefully here, you  
15      can see the seed in this specimen. It's located right  
16      there.

17                  So it's a fairly straightforward  
18      technique.

19                  So the results of this particular study,  
20      there were six radiologists who conducted this study.  
21      All six preferred the radioactive seed localization  
22      technique. Five of them thought the technique was  
23      actually technically easier than placing the wire.

24                  When patients were asked to rank comfort  
25      and convenience of the seed they considered the

1 discomfort to be about the same between the two.  
2 After all you're sticking a foreign object into the  
3 breast. It can't be very comfortable.

4 Patients rated the convenience, however,  
5 of the radioactive seed localization technique  
6 considerably more convenient than the wire  
7 localization because they don't have to necessarily  
8 come when both the radiologist and the surgeon are  
9 available on the same day, and they can allow some  
10 flexibility both in their schedule, and in the  
11 schedule of the radiologist and the surgeon.

12 During this study one seed migrated from  
13 the site due to a hematoma. It actually migrated into  
14 the hematoma. But there was no spontaneous migration  
15 of the seeds outside the tumor except in that one  
16 case. There were no infections reported.

17 I'll kind of skip over that. The main  
18 thing on the results is, other than convenience and so  
19 forth, is looking at the actual results, what  
20 advantages does that do for the patient?

21 Relative to margins being negative on the  
22 surgery, with the radioactive seed localization  
23 technique, 74 percent of the margins were negative,  
24 compared to wire localization where 54 percent were  
25 negative. And margins that required re-operation, 90



1 percent of the seed technique did not require re-  
2 operation, 90 of them - whereas 76 on the wire  
3 localization. So there were more re-operations for  
4 wire localization than there were for the radioactive  
5 seed, which is obviously an advantage for everyone.

6 And I don't know what I did here, but my  
7 numbers are missing. But basically, if you take the  
8 worst case, which is about 300 microcuries of iodine  
9 in a seed and leave that in the breast tumor for five  
10 days, you'll deliver a dose to the one centimeter  
11 margin of about 20 rads, and of course that decreases  
12 as you go out.

13 Typically they're going to take two or  
14 three centimeters, so the dose to the breast is in the  
15 neighborhood of a few rads.

16 With 100 microcuries leaving it for one  
17 day, this is 1.2 rads. And this is about .3 rads.

18 That is in the neighborhood of a  
19 mammogram. So if you use a low activity seed, and you  
20 do surgery within 24 hours, the dose to the breast  
21 tissue is about the same as a mammogram. So we're not  
22 talking very large doses here, even though that seed  
23 is used normally for therapeutic purposes.

24 So the conclusions were that the  
25 technique, the radioactive seed localization technique

1 was considered to be easy, it's accurate, it's  
2 preferred by radiologists. The seeds can be deployed  
3 up to five days prior to surgery, and it's  
4 significantly more convenient for the patients.

5 The technique increased the frequency of  
6 negative margins in the first specimen, and decreased  
7 the frequency of re-operation - a very significant  
8 advantage.

9 Now we're only talking - this is 200  
10 patients. Mayo has done the seed technique on several  
11 hundred patients by now, and nothing has changed that  
12 conclusion. But still, several hundred patients is  
13 not a large number.

14 But so far that technique is working out  
15 very well for us.

16 Now a question came up at our meeting last  
17 time about the integrity of the seed relative to  
18 surgeons and their cutting around the seed. What  
19 could happen if they struck that seed with the  
20 scalpel?

21 So I asked one of my assistants, Kelly  
22 Classic (phonetic), to do a little experiment and see  
23 how difficult it would be to compromise the integrity  
24 of one of these seeds if we were cutting in some  
25 tissue.

1           So the objective of the study was to  
2 determine the vulnerability of the seed by both  
3 scalpel and cautery.

4           So a little experiment was done studying  
5 seeds in various configurations. One was a control.  
6 One was an attempt to cut the seed with a scalpel.  
7 Another one was to rupture the seed with cautery. And  
8 they used typical surgery technique of 15 kilowatts,  
9 if that's important to this discussion.

10           So they did that in pig tissue, and then  
11 another experiment they actually put the seeds on the  
12 stainless steel plate of the electrocautery, so that  
13 if someone was trying to cut the specimen on a hard  
14 object, what would that do to the seed?

15           Now they don't do that, but this was sort  
16 of what's the extreme of what might be contemplated,  
17 that would be it.

18           So again, a control, attempt to cut the  
19 seed with a scalpel, and attempt to rupture it with  
20 cautery.

21           This shows a dummy seed on a stainless  
22 steel plate and cutting it with a scalpel. In  
23 addition , live seeds, we took some very old seeds  
24 that had been in storage for decay, at a fraction of  
25 a microcurie, put them on a stainless steel plate, and

1 attempted to rupture the seed with electrocautery, and  
2 then did leak tests on that.

3 Results. The scalpel did cut through a  
4 dummy seed on stainless steel grounding plate, but it  
5 required significant pressure. The technologist who  
6 was doing this said he had to push down real hard in  
7 order to cut that seed with the scalpel.

8 With cautery he pushed with similar force.  
9 And this is a scanning electron micrograph of that  
10 seed. And you can see a little bit of a dent there.  
11 Cautery was not able to break the seed, and this was  
12 pushing down on a hard surface.

13 MEMBER WILLIAMSON: Which model seed was  
14 it?

15 MEMBER VETTER: This is the ampo  
16 (phonetic) seed.

17 MEMBER WILLIAMSON: 67 11?

18 MEMBER VETTER: Or 13? Let's see. 67 11,  
19 is that it?

20 MEMBER NAG: Ampo seed, is that the lymph  
21 node one, lymph node seed?

22 MEMBER VETTER: 67 11. So let's see, so  
23 yes, in this case we saw the cautery dented the seed.

24 And in pig tissue neither the scalpel nor the cautery  
25 was able to damage the seed. The seed simply moved

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 around. When you tried to push against it with  
2 cautery or push against it with the scalpel, it just  
3 moved. And this shows no damage to those seeds.

4 And then the one study using  
5 electrocautery to try to break the seed on a stainless  
6 steel plate - this was with a live seed, low activity  
7 live seed. First they did a wipe test on it to try to  
8 detect any radioactivity on the outside of the seed  
9 before and after that study.

10 And then when they finished they soaked  
11 the seed in betadine to try to determine if any  
12 activity was leaching out of the surface of that seed.  
13 And that also was some background radiation. So there  
14 was no activity on the outside of that seed.

15 So basically the purpose of the  
16 presentation was to simply give us some case  
17 experience and to address that issue of concern, if a  
18 surgeon is cutting and strikes that seed, what does  
19 that do to the integrity of the seed? And our  
20 conclusions were it did nothing, it did not damage the  
21 seed at all.

22 CHAIRMAN MALMUD: Thank you, Dr. Vetter.

23 Dr. Nag.

24 MEMBER NAG: One question and some  
25 comments.

1                   How many seeds do you typically put in,  
2 one or more than one?

3                   MEMBER VETTER:           Typically one,  
4 occasionally two, to define the margins. Sometimes if  
5 you want to define the margins they'll use two.

6                   MEMBER NAG:   If you use more than one,  
7 then using the gamma probe would not be particularly  
8 helpful unless you are using a gamma probe both on the  
9 specimen and on the breast because you may have taken  
10 one seed out and not the other.

11                   MEMBER VETTER:   Oh, true, they do it in  
12 both. They use them both.

13                   MEMBER NAG:   Now the comments, we have  
14 used radioimmuno-guided brachytherapy techniques,  
15 where we used to inject radioactive material -  
16 radioactive I-125 before the procedure, and in the OR  
17 used the gamma probe to define the margins for  
18 implants. This is something I see very useful, that  
19 can be very useful.

20                   But you made the comment that the wire  
21 localization you can have migration but not with the  
22 seed. I'm sorry, I think you are going to have equal  
23 migration problems. If you had equal sized wire and  
24 equal size seed, both of them can migrate.

25                   So I don't think using the seed can

1 obviate or can improve on the migration problem. It  
2 will improve on the reaction problem, because it's  
3 radioactive. You can find out where it is.

4 MEMBER VETTER: The experience of the  
5 radiologists of this study showed that there was no  
6 migration of the seed.

7 MEMBER NAG: Right. But what I'm saying  
8 is, if there is no migration of the seed, there should  
9 be no migration of the wire. They are both equal in  
10 size.

11 MEMBER VETTER: Let's ask a radiologist.

12 MEMBER EGGLI: Actually they're not. The  
13 wire is a very tiny thin wire. It sticks out of the  
14 skin, and most wire migration problems come from  
15 inadvertent external manipulation of the wire. And  
16 where the seed is completely internalized and the wire  
17 is a very fine gauge wire. It is like a 23-gauge  
18 wire, so that the size of the seed and the size of the  
19 wire are in no way, shape or form comparable.

20 MEMBER NAG: Okay, then in that case I  
21 take it back. Because the way I do my localization in  
22 other tumors is to use inactive seed, which is about  
23 the same size as the I-125 seed. So the migration  
24 problem is the same.

25 We have done a lot of implants using I-125

1 active seeds, full activity seeds, in the liver and  
2 other organs where we are doing surgery at the same  
3 time. And so far we have not noticed any rupture of  
4 the seeds. And we have used cautery nearby, although  
5 I have told the surgeons not to cauterize directly on  
6 the seeds. We haven't noticed any loss of integrity  
7 on actual patients with full strength iodine seeds.

8 CHAIRMAN MALMUD: Dr. Williamson.

9 MEMBER WILLIAMSON: I have a comment,  
10 question, comment. I think as a general comment, it  
11 seems like a very intriguing and useful application of  
12 the product.

13 The question is, are these seeds freshly  
14 manufactured to have this activity, or are they seeds  
15 that the vendor has had for nine months and have  
16 decayed in storage?

17 MEMBER VETTER: They are seeds that are  
18 ordered from the manufacturer specifically for this  
19 purpose and approved for one-time use. How the  
20 manufacturer manufactured them, I don't know. Whether  
21 he stored them --

22 MEMBER WILLIAMSON: Well, I think one  
23 issue to think about a little bit, I suspect it might  
24 not be a problem with I-125, is that - my guess is the  
25 manufacturers are taking all their leftover seeds that



1 they haven't sold, that have decayed away. And so  
2 they're very old from the time of reactor activation.

3 And I think some thought should be given  
4 kind of model by model to the presence of high energy  
5 contaminant lines in the spectrum.

6 I think if the iodine is manufactured in  
7 the reactor driven way, probably the primary  
8 contaminant is I-126, which would decay away quickly.  
9 But palladium seeds, if you were to ever contemplate  
10 using those, there is a variety of manufacturing  
11 techniques, including both accelerator and reactor  
12 produced palladium-103, so there is the potential of  
13 higher energy lines.

14 And this of course would not be a problem  
15 for seeds which are relatively quickly used after  
16 activation, because overwhelmingly the short-lived  
17 palladium would outweigh those.

18 But when you keep a seed for nine months,  
19 what started out as .1 percent contamination level  
20 would grow proportionately to the low energy. So I  
21 think it's one manufacturing issue that should at  
22 least be looked at.

23 CHAIRMAN MALMUD: Dr. Nag.

24 MEMBER NAG: Maybe I can address that.

25 The manufacturer of the iodine seed had approached me

1 about five or six years ago to ask me whether seeds  
2 that were made for prostate implant were used for  
3 permanent implant only, we use usually slightly higher  
4 for external. Breast implant, we use slightly lower  
5 activity.

6 But after that those seeds were being  
7 thrown away, and they were asking us whether we could  
8 use those seeds for any other activity, like using  
9 them as a detector.

10 And so as far as I know, all of these  
11 seeds are seeds that were manufactured for prostate  
12 implant, permanent implants.

13 CHAIRMAN MALMUD: Thank you. May I just  
14 ask a question? What's the fate of the seeds, Dr.  
15 Vetter, after they are removed? I understand the  
16 implantation and the surgical removal. Now the  
17 specimen goes to pathology. Do the pathologists  
18 dissect out the seed, and is there some tracking of  
19 the radioactive seed so that they are disposed of in  
20 a fashion which is satisfactory to you?

21 MEMBER VETTER: Well, recognizing that  
22 this is all being done on protocols at this point in  
23 time, it's not a standard practice yet.

24 What we require is that a nuclear medicine  
25 technologist deliver the seed to the radiologist, and

1 that a nuclear medicine technologist be called to  
2 surgery to collect the seed. It is actually removed  
3 in surgery by the surgeon. So it doesn't go to  
4 pathology.

5 We have, however, educated our pathology  
6 lab in the event -- they actually have a detector and  
7 they check the specimen as well, in the event somehow  
8 it got there.

9 But for the purposes of this protocol, we  
10 do track that seed very carefully. It gets delivered  
11 directly to the radiologist. It's picked up from  
12 surgery by the nuclear medicine technologist. It's  
13 then delivered to radiation safety for storage and  
14 decay.

15 It could be - if it becomes a matter of  
16 standard practice it could be delivered back to the  
17 manufacturer.

18 CHAIRMAN MALMUD: The loop is closed. The  
19 seed is not lost.

20 MEMBER DIAMOND: Richard, what is the  
21 protocol if the patient for some reason cannot proceed  
22 with the planned surgery?

23 MEMBER VETTER: You would ask that.

24 No, that's a very good question. And the  
25 patients are instructed to stay locally, if they are

1 from a long distance away. They are instructed to  
2 stay in a hotel locally until the day of surgery, and  
3 to report on that day.

4 They are called 24 hours in advance to  
5 remind them that they have to come to surgery on the  
6 next day. So if a patient decided to leave town, so  
7 they would leave town with one seed in their breast.  
8 It would be a permanent implant at that point, and I'm  
9 not sure what the final dose would be.

10 We've never had that problem.

11 MEMBER DIAMOND: My comment was really not  
12 towards the patient that absconds, but is really  
13 towards the patient that has some inter-current  
14 illness and is not medically fit to proceed with  
15 surgery. The person has some bleeding disorder, has  
16 a cardiac issue, so forth.

17 MEMBER VETTER: Just to respond quickly,  
18 I didn't review the exclusion criteria for these  
19 patients on the protocol, but I'm sure they screen  
20 them very carefully to be sure they're healthy  
21 otherwise.

22 MEMBER NAG: I think very relevant to this  
23 would be permanent implants in the prostate, where the  
24 seeds migrate to the lungs, we have done sufficient  
25 study. We have published our data, which shows that

1 one or two seeds, and those are full activity seeds,  
2 have not had any detrimental effect on the lung or any  
3 other organ they may have migrated to.

4 So my suspicion is that if it is one seed  
5 with such a low activity it would not produce any  
6 detrimental effect on the tissue.

7 CHAIRMAN MALMUD: Thank you, in the  
8 interests of time, if there are no more questions  
9 we'll move on to Dr. Suleiman's presentation. Is that  
10 agreeable?

11 Mr. Essig.

12 MR. ESSIG: I would just offer if - we had  
13 an hour scheduled for Dr. Suleiman's presentation. We  
14 need to allow the committee to have lunch as well. So  
15 if we want to go ahead with that, is it possible to  
16 condense Dr. Suleiman's presentation?

17 CHAIRMAN MALMUD: Dr. Suleiman  
18 spontaneously offered to reduce his presentation to 30  
19 minutes earlier this morning. So he's ahead of us on  
20 that subject.

21 But I will ask him whether he'd prefer to  
22 give his presentation before or after lunch?

23 MEMBER SULEIMAN: Either way. It doesn't  
24 bother me at all.

25 CHAIRMAN MALMUD: All those in favor of

1 hearing it now, raise your hand.

2 All those in favor of having lunch first,  
3 raise your hand?

4 Lunch wins.

5 (Laughter.)

6 MEMBER NAG: By one vote.

7 CHAIRMAN MALMUD: We are adjourned for  
8 lunch. Can we reduce it to 45 minutes? Would that be  
9 acceptable to everyone? Thank you.

10 So we will re-congregate here at 12:45.

11 (Whereupon, the above-entitled matter went  
12 off the record.)

13 CHAIRMAN MALMUD: Good afternoon,  
14 everybody. We'll get started with the afternoon  
15 session. And it will begin with Dr. Suleiman, whose  
16 introductory slide is up on the screen right now.

17 MEMBER SULEIMAN: Thank you, Dr. Malmud.

18 FDA had a public meeting on November 16,  
19 2004 to discuss some issues associated with human use  
20 using certain types of radiolabeled drugs. And I gave  
21 a presentation there regarding the radiation dose  
22 issues. And so I thought in the spirit of better  
23 communication, I'd give that same presentation here.

24 I'll discuss it later, but I might as well  
25 mention it now. The comment period for the public

1 meeting ended in January, but we are going to extend  
2 it to sometime in July. Because at the same time  
3 there was another guidance that was being proposed by  
4 FDA that was raised at the advisory committee called  
5 an Exploratory IND. And that FAR notice hit the  
6 streets either late last week or early this week. So  
7 their formal closing period is July 13th. So since  
8 the Exploratory IND will have some impact on the  
9 Radioactive Drug Research Committee program, we  
10 decided to keep the comment period open. So if you  
11 have any comments, the comment period is in fact open.

12 FDA allows research without an  
13 investigation on a new drug uncertain situations. Most  
14 human research in the United States involving drugs  
15 requires application of investigation of a new drug,  
16 unless the drug's already been improved. And if there  
17 are certain criteria that are met, FDA allows human  
18 research to be done to be performed with unapproved  
19 drugs, again if certain criteria are met, under this  
20 Radioactive Drug Research Committee. And I'll review  
21 that briefly. So I'd better get going.

22 In 1975 when the Nuclear Regulatory was  
23 established from the old Atomic Energy Commission, FDA  
24 promulgated 21 CFR 361.1, which basically authorized  
25 such research. These regulations have been on the

1 books for 30 years. And the November 16th meeting sort  
2 of addressed -- actually, it was called Radioactive  
3 Drugs for Certain Research Uses. And so we were sort  
4 of looking at all the issues associated with that  
5 Committee.

6 Transcripts of the meeting, all of the  
7 presentations are all available on the FDA website. So  
8 if you want to see what else was discussed, I would  
9 direct you there.

10 As a brief review without going into  
11 detail, provisions of 21 CFR 361.1 allowed research to  
12 be done without an IND for research drugs if there are  
13 certain pharmacological dose limits met. Specifically  
14 we say there shall be do clinically detectable  
15 pharmacological effect. There are certain radiation  
16 dose limits that have to be met.

17 The qualifications of the investigator,  
18 proper licensing and NRC agreement states to your  
19 license, informed consent for subjects, the quality of  
20 the drug, protocol, reporting of adverse events and  
21 separate approval of the institutional review board  
22 associated with the institute.

23 The only hook here is that the committee  
24 has to be approved by FDA and consist of at least five  
25 members, one of whom is a nuclear medicine physician,



1 an expert on drug formulation and a radiation  
2 dosimetry expert.

3 So that's sort of the RDRC program in 30  
4 seconds or less. What I'm going to be discussing  
5 right now really are the radiation dose limits.

6 Why do we need to revisit the dose limits?  
7 First off in 1975 when we adopted these, we basically  
8 used the NRC's occupational dose limits. Since that  
9 period of time there have been constantly changing  
10 radiation metrics that are more current. A new  
11 concept effective dose has been introduced in the  
12 scientific community. There's more scientific data  
13 regarding radiation risk. And there are also new human  
14 research regulations for institutional review boards,  
15 which also have some impact on such research.

16 Does that bother anybody it's off the  
17 screen? But anyway, these are the current dose  
18 limits. And these were the then occupational dose  
19 limits used by the Nuclear Regulatory Commission

20 If you look at the slide, you can see that  
21 in fact it's a two-tier set of standards. We have a  
22 whole body limit and we also have organ specific  
23 limits. At the time the feeling was that leukemia or  
24 active blood forming organs were a major risk. So we  
25 had limits for that.

1           Lens of the eye basically was a derivative  
2 of the occupational dose concept. It was felt that if  
3 a worker received the maximum dose on a yearly basis,  
4 they'd eventually get a deterministic cataract.

5           At that time also there was quite a bit of  
6 concern regarding hereditary effects with the gonads.  
7 We've seen since then that the hereditary issues are  
8 much, much less than was felt at that time. And then  
9 the other organs were sort of thrown in under a catch-  
10 all category.

11           We also made a differentiation between  
12 adults and pediatric research where we said subjects  
13 under 18 would receive 10 percent of the adult dose.

14           Also, since the body doesn't differentiate  
15 between the source of radiation, we required that the  
16 radiation dose that the human research subject  
17 received from associated x-ray procedures associated  
18 with the research study would also be included in this  
19 dose calculation.

20           As I said, the rationale for adopting the  
21 occupational limits were that an adult is able to make  
22 a decision, and we assumed that a risk also applies  
23 the same way for an informed subject.

24           And the other critical thing that  
25 sometimes seems to be overlooked but it's clearly

1 there is that the concept of ALARA -- as low as  
2 reasonably achievable -- is specified in the  
3 regulation. And that even though some of the people  
4 felt that the dose limits were too high at the time,  
5 the dose limits were intended as that, as a maximum.  
6 But it was felt that medical doses could be kept lower  
7 to be consistent with the study.

8 A review of our files basically showed  
9 that organ doses are the limiting constraint, not  
10 whole body limits. And in general, though the  
11 committees must report to FDA on an annual basis so  
12 you would expect that when you self-report and list  
13 all your doses, we require that all the doses be  
14 calculated, you'd expect general compliance. And I  
15 use the word "general," because we still do get some  
16 examples of doses that have exceeded the organ limits  
17 and they're reported to us. But the Committee didn't  
18 apparently review all the doses that were there.

19 Another reason for the change, and I  
20 initially wanted to label this slide as just why  
21 there's so much confusion, but this is an extremely  
22 brief synopsis of what's transpired over the last 30  
23 years. But when the dose limits for the Radioactive  
24 Dose Committee were promulgated, the biological  
25 absorbed dose equivalent was rem. In '77 the

1 International Commission on Radiological Protection  
2 promulgated effective dose equivalent. And during  
3 this period of time until now we still have the  
4 international system of units, SI, sort of looming  
5 like an 800 pound gorilla and people still use the old  
6 units. We're all guilty of it. But the rads to gray,  
7 the rems to sieverts, the curies to becquerels.

8 In 1991 the NRC to their credit got around  
9 to adopting the effective dose equivalent about the  
10 same time that the ICRP replaced effective dose  
11 equivalent with effective dose. Conceptually these  
12 are two very similar concepts. There's less  
13 difference between them than there was between the  
14 introduction of effective dose equivalent. Effective  
15 dose equivalent was based more so on mortality risk,  
16 whereas effective dose included more morbidity. But  
17 probably when you consider the uncertainty associated  
18 with the risk estimates, they're scientifically  
19 statistically probably very equivalent.

20 In '93 the U.S. National Council on  
21 Radiologic Protection adopted an effective dose. And  
22 last year in 2004 ICRP proposed some modification of  
23 effective dose. And here's FDA sitting there with a  
24 30 year old set of doses.

25 Brief review for effective dose. It's

1 basically what I call a homogenized metric for  
2 radiation risk. And it allows, the real value of it,  
3 partial body irradiations like a chest x-ray to be  
4 equated to a uniform whole body irradiation. So it  
5 allows you to compare doses from a variety of sources.

6 A caveat is that this was designed as a  
7 unit of radiation protection and it really was not  
8 intended for scientific studies or epidemiological  
9 studies where the specific organ doses really need to  
10 be known along with the age and the sex of the  
11 individuals. But in order to derive effective dose you  
12 really need to know the organ doses. And for research  
13 you should know the age and the sex.

14 To calculate effective dose each  
15 individual dose is essentially multiplied by its  
16 respective tissue-weighting factor. And the sum of  
17 all these is the equivalent to effective dose.

18 Here, just to show you one of the problems  
19 with guidances or regulations, is things change over  
20 time and sometimes it takes as long to change the regs  
21 to keep up with the science. But you can see back in  
22 1977 the tissue-weighting factors have changed  
23 somewhat for the gonads. They've been downgraded.  
24 The breast has undergone a dramatic change. And that's  
25 because like congressional redistricting, the tissue-

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 weighting factors have to add to 1.0. So if you give,  
2 you have to take away from somebody else. So it's a  
3 quasi-political, you know, scientific set of numbers.  
4 So that's why you've had some anomalous changes there.

5 And, in fact, at the public meeting Eric  
6 Hall from Columbia actually proposed why doesn't FDA  
7 just go ahead with a single, assign a tissue weighting  
8 factor of .1. He says these aren't too significant  
9 figures anyway, so why not just simplify. So we're  
10 going to note that comment.

11 I also went to an awful lot of effort  
12 because the value, the value of effective dose is that  
13 you can compare doses from a variety of sources.  
14 Using effective, though, for standardize from the  
15 second column you can compare the dose in  
16 millisieverts for relative risk with other metrics for  
17 relative risk with other metrics, such as the standard  
18 chest x-ray. I spent most of my career doing studies  
19 where we measured the dose patients received from  
20 chest x-rays. So anytime somebody compares the  
21 standard chest x-ray it would always bother me because  
22 I knew they didn't understand what the standard chest  
23 examine was. But, in discussing this with individuals  
24 and with lay people and lay professionals I said which  
25 relative metric do you feel more comfortable with. I

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 was surprised that the chest x-ray seemed to be more--  
2 even though they didn't know what the dose was from a  
3 x-ray, they knew that better than background, which  
4 somehow confused people which is what I call  
5 equivalent time. And I thought as scientists the fifth  
6 column was really my piece of cake. I said here,  
7 here's the actual risk. Cancer mortality using the  
8 ICRP dose coefficients, you know. One in 10,000, one  
9 in a 100,000 or so on. And that seemed to be looked at  
10 that least. I mean, people were more concerned about  
11 the relative issues.

12 And I do want to make a point here that  
13 these are average doses. Inherent in these numbers is  
14 a certain amount of very real variability. Background  
15 environmental levels may vary by a factor of two,  
16 depending on whether you live in Denver or sea level  
17 or whatever. Radiopharmaceutical doses may vary by  
18 several factors depending on how much activity is  
19 delivered to image the patient faster or  
20 inefficiencies in the imaging system.

21 X-ray doses can also vary as much as an  
22 order of magnitude. And some exams, like fluoroscopy  
23 can vary by as much as two orders of magnitude, a  
24 factor of a 100. But these are relatively credible  
25 numbers and gives you a feel here.

1                   The bottom two lines, which was really my  
2 bottom line was well where do the RDRC dose limits fit  
3 in in this. And here you have the whole body dose  
4 limit of 5 rem or 50 millisieverts. And also, as I  
5 said, the organ doses are constraining. And so here's  
6 the red bone marrow dose as an example. And that was  
7 much, much less of a dose.

8                   MEMBER VETTER: Excuse me, Orhan, what was  
9 your equivalent time again? What is that?

10                  MEMBER SULEIMAN: Oh, equivalent time is  
11 just natural background environmental radiation. So  
12 three millisieverts which is 300 millirem from the  
13 U.S.. And so I've seen slightly different numbers  
14 depending on which report people talk about. But the  
15 variability is greater than the reported numbers.

16                  So we formally asked at the meeting are  
17 current dose limits for adults for research conducted  
18 under 361.1. And if not, what should we use? And  
19 should there be different dose limits for different  
20 adult age groups?

21                  We then continued the discussion to  
22 pediatrics, because there has been some recent  
23 legislation encouraging pediatric research. There have  
24 been recent regulations addressing pediatric research.  
25 So we wanted to address this. And we generated a



1 similar table here.

2 And I point out here, because we had some  
3 nice examples of the dose of 5, a 10 year old and an  
4 adult would receive. Because patient size also has a  
5 significant impact on how much dose an individual may  
6 receive.

7 The pediatric issue was multifaceted,  
8 because I think it was in 2001 there were new  
9 regulations by HHS regarding protection of human  
10 subjects and Subpart D for additional safeguards for  
11 children in clinical investigations. I will not go  
12 into detail here, but there has been quite a bit  
13 controversy. Part of it is because these regulations  
14 define minimal risk, define greater than minimal risk,  
15 define indirect benefit to the subject, but they don't  
16 give any numbers. So a minimal risk is defined as the  
17 risk associated with daily living. And so what does  
18 that mean? And so until -- I understand there's some  
19 guidance that may come out, but until they actually  
20 come up with some guidance, that's really left up to  
21 the interpretation of different people.

22 Also basically from the life span study  
23 we're seeing -- back that up. Can you back up the  
24 slide?

25 From the life span study we also see --

1 we're validating what we suspected that the atomic  
2 bomb survivors, they're living longer. Just like the  
3 healthy worker syndrome, it's now called the healthy  
4 survivor syndrome. They are living longer, but they  
5 do have higher levels of cancer, albeit very low  
6 levels. You know, they are showing up with that.  
7 There's also a non-cancer risk. And this is still a  
8 work in progress. Most of the survivors will probably  
9 die in the next 10, 20 years in which we will get more  
10 of this information. And so we'll have some science.  
11 So it's not zero risk, but it's extremely low risk.

12 And here I want to thank Dale Preston for  
13 sharing, allowing me to use this slide. But you can  
14 see, this red line here, the zero to 9 at time of  
15 exposure survivors. And they have about two and a  
16 half relative risk. And if you come down here to the  
17 much older population, it's like one fourth. So  
18 you've got about ten to 12 fold difference in  
19 sensitivity, you know, for these different age groups.

20 So if you're doing research and you want  
21 to keep the risks the same, should we make an effort  
22 to adjust for age. So we asked the same questions for  
23 pediatric. It's consistent with the human research  
24 regulations; do current dose limits appropriate for  
25 pediatrics studies, if not what do you think would be

1 appropriate? And should we have different pediatric  
2 age groups?

3 So this concludes my formal presentation,  
4 which I gave at our November 16th meeting. But during  
5 that meeting the public was also made aware that FDA  
6 was preparing a parallel guidance called Exploratory  
7 IND, which would allow microdose quantities of a drug  
8 to be tested first in humans and would potentially  
9 eliminate the prohibition of first in humans research  
10 under RDR. We do not allow first in humans to be  
11 conducted under this research program.

12 And so there was concern to extend the  
13 comment period for the RDR public meeting to coincide  
14 with the Exploratory IND guidance. So that FR notice  
15 which was had published it in January, just got  
16 published either early this week or very late last  
17 week. And the closing date on that is July 13th. And  
18 yesterday I found out our closing date is going to be  
19 very close to July 13th, but we don't know what date  
20 the lawyers are going to put in. But it's going to be  
21 sometime in mid-July, so that people will have the  
22 opportunity to read both sets, both the public meeting  
23 and the Exploratory IND comment.

24 And, again, if you go to our FDA website,  
25 or an easier way is just to go [fda.gov](http://fda.gov) and search

1 rather than try to the long URL link.

2 Thank you

3 CHAIRMAN MALMUD: Thank you. Thank you  
4 for the update and the presentation.

5 Any questions for Dr. Suleiman? Dr.  
6 Vetter?

7 MEMBER VETTER: Correct me if I'm wrong,  
8 but I think the RDRC regs already take into account  
9 pediatrics. Isn't the limit 500 millirem.

10 MEMBER SULEIMAN: Yes.

11 MEMBER VETTER: Okay. So it's 5 rem for  
12 adults, 500 for --

13 MEMBER SULEIMAN: It's ten percent of the  
14 adult limit.

15 MEMBER VETTER: Right.

16 MEMBER SULEIMAN: Correct.

17 MEMBER VETTER: Now that actually turns  
18 out to be consistent with some very recent guidance  
19 from EPA which has stated that they believe that the  
20 risk to children is anywhere from three to ten times  
21 that of an adult, depending on age category. The risk  
22 is higher.

23 MEMBER SULEIMAN: Yes.

24 MEMBER VETTER: So in fact it's consistent  
25 with EPA's recent findings?

1                   MEMBER SULEIMAN: Well, if we're looking  
2 at the same science data, we should be drawing the  
3 same conclusions.

4                   MEMBER VETTER: Right. Exactly. Yes. So  
5 then the question that comes to my mind is why would  
6 we want to change that?

7                   MEMBER SULEIMAN: My concern  
8 professionally is that there's no differentiation  
9 right now between a neonate and a 17 year old. And  
10 the difference between a 17 and 18 year old is tenfold  
11 in terms of how much they're allowed to receive.

12                  MEMBER VETTER: Okay. Now you look at the  
13 EPA guidance, I think it's from puberty up to 18 it's  
14 a factor of three. And below that it's a factor ten.  
15 So you actually more conservative in protecting the 17  
16 year old than what the data would suggest you need to  
17 be?

18                  MEMBER SULEIMAN: Okay.

19                  MEMBER VETTER: So consequently then, I  
20 mean my own personal reaction to that would be that,  
21 again, we have adequate protection for the entire  
22 pediatric range by being a factor ten lower in the  
23 limit.

24                  MEMBER SULEIMAN: I mean, I don't want to  
25 comment too much, because we're in an open comment

1 period. But the pediatric issue, as we debated within  
2 FDA, was everybody was lumped together whether they're  
3 neonate or 17 year old. And even with adults you have  
4 a drop off as people get older

5 CHAIRMAN MALMUD: So you are suggesting  
6 that we may wish to consider a weight-based or age-  
7 based sliding scale?

8 MEMBER SULEIMAN: We wouldn't have asked  
9 the question if we weren't considering it. And I think  
10 we want to hear what the community has to say and then  
11 we'll take those comments into consideration and make  
12 a decision

13 CHAIRMAN MALMUD: Thank you again, Dr.  
14 Suleiman.

15 If we may, we'll move on to the next item  
16 on the agenda, which is Dr. Sherbini's presentation on  
17 establishing guidance on exceeding dose limits for  
18 members of the public.

19 Dr. Sherbini.

20 DR. SHERBINI: Thank you. Good afternoon.

21 This subject came up in last year's  
22 meeting. And the discussion was we need to do  
23 something to allow some people, members of the public  
24 who are taking care of patients in the hospital, to  
25 exceed the currently allowable dose limits. And we've

1 done some work on this, and this is what we have come  
2 up with.

3 Okay. The issue is that the dose limit is  
4 100 millirem under normal conditions. And this can be  
5 raised to 500 under certain specified conditions. They  
6 can be raised by the authorized user, basically. And  
7 on some occasions this limit, even the 500 millirem,  
8 for caregivers situation.

9 Where are the high limits needed?  
10 Obviously in hospital settings where radioactive  
11 materials are being used and where a member of the  
12 public is taking care of a patient or participating in  
13 patient care, and the dose required for such care is  
14 estimated to be much higher than the allowable dose.

15 We looked at several options, and one of  
16 the options which is the one also recommended by NCRP,  
17 is to go up to 5 rem. We didn't like this option  
18 partly because the underlying considerations for  
19 arriving at the 50 millisievert. does not really  
20 conform to the caregiver situation in the hospital.

21 First of all, the annual dose limit of 5  
22 rem represents an apportioned risk, which is the  
23 underlying risk is a lifetime risk and were just  
24 simply divided over 50 years. And that represents one  
25 of the 50 years. So even that doesn't really represent

1 a meaningful risk level for a caregiver situation.  
2 And also, we felt that the 5 rem would not be needed  
3 in a lot of situations, in fact in most situations it  
4 would not be needed. The needed dose would probably  
5 be less than 5 rem, and we felt that allowing a limit  
6 that is much higher than is needed may encourage  
7 people to use what is allowed, basically, and there is  
8 less care in minimizing the dose.

9 So for all these reasons we felt this was  
10 not a viable option.

11 We then looked at the guides and also the  
12 emergency dose situation limits. And these  
13 philosophically correspond much more closely to the  
14 caregiver situation. But the down side that the dose  
15 is way too high. It's inconceivable or very unlikely  
16 that anyone would need 25 rem for a caregiver  
17 situation. So we felt this was not an option.

18 Having eliminated these two options, all  
19 that we were left with was to basically let the  
20 licensee determine what dose is need, and then tell  
21 the NRC is what they need. And the NRC would basically  
22 approve it. And that is the option we like best, and  
23 that is the option we're recommending to the  
24 Commission.

25 Yes, sir?



1 MEMBER DIAMOND: Just for clarification,  
2 could I ask you to define what a patient caregiver is?  
3 Are you talking about a family member taking care of  
4 an ill relative? Are you talking about a nurse who is  
5 providing specific comfort to a patient? I'm just  
6 curious about your definition.

7 DR. SHERBINI: No. This is basically a  
8 special case of a member of the public. This is not an  
9 occupational situation. So the --

10 MEMBER DIAMOND: So a family member, for  
11 example?

12 DR. SHERBINI: Yes, a family member,  
13 somebody, a friend; somebody like this who would  
14 normally under normal circumstances be considered a  
15 member of the public.

16 MEMBER DIAMOND: And therefore by that  
17 definition be considered a one time exposure as  
18 opposed to an ongoing thing?

19 DR. SHERBINI: Yes. Absolutely.

20 So that's what we're recommending to the  
21 Commission.

22 How would this system work? Somebody at  
23 the licensee's facility or some authorized person  
24 would decide that they have what we might call a  
25 caregiver situation. In other words, they have a

1 family member who needs to take care of a patient. So  
2 this is the condition would be recognized and  
3 acknowledged.

4 The user then would estimate how much dose  
5 is needed and the regional office would be contacted  
6 to obtain a license amendment for that case.

7 These things might change a little. For  
8 example, the authorization from the regional office  
9 may not be for a specific patient or a case-by-case  
10 basis, it could be for a license which has been done  
11 before. So these things still need to be worked out.

12 MEMBER DIAMOND: Could you move your  
13 microphone just a little?

14 DR. SHERBINI: Pardon?

15 MEMBER DIAMOND: Can you move your  
16 microphone a little?

17 DR. SHERBINI: Oh, okay. I'm sorry.

18 All right. Basically there will be  
19 certain, you know, procedures that has to be followed  
20 to ensure that the approach is not misused or  
21 mishandled. And so the caregiver would be provided  
22 instructions, they would sign a consent acknowledging  
23 the risk that they are undertaking. They would provide  
24 it to dosimetry to measure the dose more accurately  
25 than just estimating it from survey data.

1           The dose, the running dose would be  
2           tabulated and the radiation protection staff would  
3           keep track of it. If the dose is going to be exceeded  
4           from what is authorized, then actually it would have  
5           to be taken to raise the limit and the new limit would  
6           be established.

7           What we plan to do is if the Commission  
8           approves this approach, we would plan to issue  
9           guidance. And the purpose of the guidance would be to  
10          make implementing this program, more or less, uniform  
11          across regions and also by the agreements.

12          Yes, sir?

13          MEMBER DIAMOND: If I may, the way I think  
14          of this is sort of analogous to what Dr. Williamson  
15          was talking about earlier today where this is a very,  
16          very rare situation where for humanistic reasons  
17          exemptions are granted to current guidelines. So by  
18          definition, to go and ask a licensee to request a  
19          specific amendment or to go through the amendment  
20          process for an eventuality that may never occur to me  
21          is not useful. Instead what I would say is probably  
22          within the guidance space would be a discussion that  
23          in extraordinary circumstances provided certain key  
24          step are met such as the clear cut informed consent  
25          documentation by the authorized user, use of formal

1 dosimetry, attempts to minimize the radiation exposure  
2 as much as possible. I think that probably would be  
3 sufficient. In my career, I've never had one of these  
4 instances, for example, and except for the example  
5 that we heard earlier I really can't think of an  
6 example of this happening.

7 DR. SHERBINI: Yes. In answer to your  
8 question, first of all, the licensee would not request  
9 such an amendment unless they feel they need it. So  
10 most licensees would not request such an amendment.

11 And the other thing is that because it is  
12 done outside of the regulations, the amendment is  
13 necessary otherwise the licensee would be in  
14 violation. Because the regulations still apply. I  
15 mean, the limit is still 100 millirem or 500 millirem  
16 per year. Even if the circumstances are extraordinary,  
17 if the licensee allows a member of the public to  
18 exceed that, they're in violation and they would have  
19 to be cited. And that's what an amendment is supposed  
20 to take care of; to put in the license the fact that  
21 the licensee is allowed to do this.

22 We explored the possibility of changing  
23 the regulations so that they would do exactly what you  
24 just said. But the people who reviewed this proposal  
25 almost unanimously agreed that rulemaking is not

1 warranted. It's very expensive and the number of  
2 cases is very small, and therefore it is not  
3 warranted, at least at this time.

4 Yes, sir?

5 MEMBER EGGLI: I can foresee this  
6 happening in my pediatric thyroid cancer population.

7 DR. SHERBINI: Yes.

8 MEMBER EGGLI: Where a parent needs to  
9 provide care for the child because the child can't  
10 manage an isolation environment and maintain the  
11 conditions. But although we have some lead time, we  
12 don't have massive lead time. How nimble do you  
13 anticipate this system to be to respond to these  
14 special situations as they arise?

15 Sometimes our lead times are a week or  
16 two, sometimes they're shorter than that. But they're  
17 not months. So how nimble will this kind of system  
18 be?

19 DR. SHERBINI: We are hoping, if we do  
20 this right, we are talking days. Not more than days.  
21 And if a department, a pediatric department has a need  
22 for this kind of thing on a regular basis, it might be  
23 possible to put this into license so you don't have to  
24 get an amendment for each patient. But that would be  
25 a broader --

1 MEMBER EGGLI: You mean that would be to  
2 describe the general case of a parent caring for a  
3 child?

4 DR. SHERBINI: Yes. Absolutely.

5 Yes, sir

6 CHAIRMAN MALMUD: I think Dr. Williamson  
7 had an earlier question.

8 DR. SHERBINI: Oh, Dr. Williamson?

9 MEMBER WILLIAMSON: No. Dr. Eggli  
10 essentially asked. My question was I was concerned  
11 that the license amendment process could respond in a  
12 timely enough fashion to preclude, for example, like  
13 the St. Joseph's Hospital event from escalating.

14 DR. SHERBINI: Yes.

15 MEMBER WILLIAMSON: Because perhaps  
16 sometimes the level of cooperativeness of a relative  
17 can't be predicted, and the event might be ongoing.  
18 So I should think very nimble.

19 DR. SHERBINI: Yes. I think the purpose  
20 of the guidance is to have everything in place in such  
21 a way that once a phone call is received from a  
22 licensee, everything would be more or less automatic.  
23 It's been worked out before, all the details are  
24 worked out before. So it would be a matter of just  
25 quick approval. And so it shouldn't take much time at

1 all.

2 Yes, sir?

3 MEMBER VETTER: My question as along the  
4 same line. The only experience we've had that is  
5 similar to this was with an iridium implant where I  
6 received a phone call at 10:00 at night and the  
7 patient was going downhill was very fast.

8 DR. SHERBINI: Yes.

9 MEMBER VETTER: The family wanted to spend  
10 time with the patient. And the patient had to be  
11 moved to ICU. And so we were able to provide portable  
12 shielding and so forth to accommodate that.

13 DR. SHERBINI: Right.

14 MEMBER VETTER: But with widely dispersed  
15 radioiodine, it wouldn't be nearly that easy. And so  
16 at 10:00 at night I'm going to have to call someone at  
17 NRC and say -- I mean, in terms of the response time,  
18 that's what we would be looking for.

19 CHAIRMAN MALMUD: It would be rare  
20 occurrence, though, would it not?

21 MEMBER VETTER: Oh, yes. These are very  
22 rare.

23 DR. SHERBINI: Yes. We would have to work  
24 this out. I'm not sure how to answer this question at  
25 this point because we haven't worked out the details

1 yet.

2 CHAIRMAN MALMUD: Dr. Nag?

3 MEMBER NAG: We are not frequently, like  
4 on and off, in this situation with low dose rate  
5 brachytherapy in the pediatric population. We solve  
6 it most of the time by using high dose rate so that we  
7 don't expose the parents. But I think that we'll be  
8 able to solve it a lot of time, we work on a case-by-  
9 case basis. Can we not have in the guidance that in  
10 a situation where a similar condition exists, you  
11 would be able to exceed if it is in a medically --  
12 with all these provisions that you have made that, you  
13 know, that the relative be informed and informed of  
14 the risk and so on?

15 DR. SHERBINI: Yes. This can be arranged  
16 by simply making the amendment broader than patient-  
17 by-patient as I said earlier. Every time you have a  
18 patient you call, then it will be your department is  
19 authorized to do this for any patients in a similar  
20 situation. So that's possible.

21 CHAIRMAN MALMUD: Yes?

22 MEMBER RAIZNER: A question. You focused  
23 on the caregiver but you mention in the slide higher  
24 level may be needed in some hospital settings. Are you  
25 referring there to hospital personnel? And that might



1 be the more common scenario. And would you anticipate  
2 a similar system of notification for that one specific  
3 individual and that specific situation? That might be  
4 a more --

5 DR. SHERBINI: Well, if we're talking  
6 hospital personnel, I would interpret as somebody who  
7 is occupationally exposed. And they don't fall into  
8 this population.

9 MEMBER RAIZNER: So they would not need  
10 special provision for --

11 DR. SHERBINI: No, they're already limited  
12 to 5 rem per year, so that really isn't a problem.

13 Yes, sir?

14 MR. ESSIG: We do have the plan special  
15 exposure that is occupational that they can implement.

16 DR. SHERBINI: I understand that, too.  
17 Yes. Right

18 CHAIRMAN MALMUD: So, Dr. Sherbini -- or,  
19 excuse me. Dr. Schwarz?

20 MEMBER SCHWARZ: I just was asking if like  
21 Dick Vetter has suggested, that there's ever been an  
22 opportunity in their facility to have an occasion that  
23 might be warranted at 10:00 at night, would it be  
24 reasonable for these institutions to then  
25 automatically -- I mean, at the point the guidance is

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 written, to go ahead and submit an amendment that  
2 would cover at least an initial starting point that  
3 would allow that licensee to have a higher limit for  
4 these particular cases. Though they're isolated, at  
5 least it would avoid that 10:00 at night call if they  
6 could anticipate a situation. And then possibly as the  
7 case would progress, they might have to then revisit  
8 the NRC and ask for another increase in the exposure  
9 for that particular person.

10 DR. SHERBINI: That would seem reasonable.  
11 But I don't know if it would be legal. We would have  
12 to check with our lawyers to see if we can do that.

13 Yes, sir

14 CHAIRMAN MALMUD: Dr. Sherbini, it sounds  
15 as if what the Committee is suggesting is that the  
16 first element of this be the requirement for  
17 contemporaneous notification to the NRC district  
18 office that this is a need, allowing the practice of  
19 medicine to move forward and giving the NRC office  
20 adequate time to respond. Because, in general, if the  
21 exposure is going to be significant, it's going to be  
22 over a matter of days anyway. So the NRC regional  
23 office would have time to respond.

24 It'll be interesting to review that, as  
25 you will do with NRC legal staff, to determine if

1 that's acceptable currently in the event that another  
2 event situation should arise similar to one that  
3 occurred in the hospital Michigan.

4 DR. SHERBINI: Yes. I think for  
5 occurrences that transpire during the day, that should  
6 not be a problem. And that's the whole purpose of  
7 preworking out all the details. But the situation that  
8 was raised as to late at night, I'm not sure how this  
9 could be handled. We can probably work out something,  
10 but I'm not sure how.

11 CHAIRMAN MALMUD: Dr. Zelac?

12 DR. ZELAC: It's probably worth noting  
13 that if a particular licensee is going to implement a  
14 specific procedure where they anticipate that the  
15 doses to the caregivers will exceed the current  
16 limits, they can apply in advance, as Dr. Sherbini has  
17 said, to get an amendment to their license to cover  
18 that circumstance.

19 We have at least one broad scope licensee  
20 who has done exactly that and has described both the  
21 dose limit that they feel is appropriate for the  
22 parents of the children, as well as the training that  
23 the parents will receive, as well as the safeguards  
24 that they will implement for all the parents. And they  
25 have an amendment and can on a routine basis treat

1 patients following that protocol.

2 CHAIRMAN MALMUD: Thank you, Dr. Zelac.  
3 Dr. Suleiman was next.

4 MEMBER SULEIMAN: I had a similar comment.  
5 First off, to have to file an amendment to allow this  
6 seems to me absurd and very difficult. Okay. I would  
7 think that any license that's going to administer  
8 therapeutic quantities of a drug probably would have  
9 in it an inherent -- you know, something to address  
10 this sort of situation. And I don't mean particularly  
11 anything from Ralph Lieto's presentation, but I was  
12 looking at it and I think -- it shouldn't have to be  
13 done on a case-by-case basis. I think this has the  
14 potential of being done more frequently and maybe just  
15 isn't reported as often. But I think making it just  
16 part of a license application would be appropriate.

17 DR. SHERBINI: Well, you know, taking this  
18 route involves a lot of work and preparation. And I  
19 would imagine that generalizing it to most licensees  
20 would be cumbersome for most licensees, because most  
21 of the things that need to be done under this method  
22 would not be done by most licensees. For example,  
23 monitoring, instructions to people who are about to  
24 exposed, the caregivers, et cetera. There are a lot  
25 of things that you need to do if you're going to do

1 this, which you wouldn't otherwise. And so  
2 generalizing it would really not be beneficial for  
3 most people. It would be cumbersome.

4 CHAIRMAN MALMUD: We're looking forward to  
5 the next step in the process as it evolves.

6 DR. SHERBINI: Thank you. Thank you.

7 CHAIRMAN MALMUD: Oh, Dr. Miller?

8 DR. MILLER: Yes. If I may just  
9 supplement. It seems to me there's two aspects of  
10 this proposal that Dr. Sherbini has made on behalf of  
11 the staff. One is the technical merits of what he's  
12 proposed. And I think, you know, as we move forward,  
13 part of the reason for his presentation today I think  
14 is so that the Committee understands where the staff  
15 has come out with regard to the technical merits of  
16 it. That meaning, should there be an absolute dose  
17 limit or not. And I think we've concluded that there  
18 shouldn't be. It's a case-by-case basis.

19 We don't know how the Commission will  
20 react to that proposal. But I guess what's beneficial  
21 is to know how that strikes the Committee. And I  
22 think Sami's had some preliminary discussion with the  
23 Committee on this already.

24 The other side of is is what we'll call  
25 the legalistic aspect; how do you implement it? And

1 the license amendment is the vehicle, but in practice  
2 what you're asking for is an exemption to the  
3 regulations as they're currently written. And if it's  
4 rare that this takes place, our lawyers will entertain  
5 exemptions. If we find that it becomes more routine,  
6 then what our lawyers instruct us is we can't regulate  
7 by exemption; that we have to change the regulations.

8 And so I think what Sami's proposed I  
9 think he feels is something that will happen in a more  
10 rare case, if I understand it, so therefore the  
11 exemption process would be more appropriate for that.

12 I recognize what we're also looking for  
13 here is your insights, and some of it has already been  
14 put on the table concerning the timing of it. Is this  
15 something that you're only going to know a few hours  
16 in advance? Can it be predicted? Is it something  
17 that gives enough time? We have mechanisms in place  
18 to move fairly rapidly on emergency actions if the  
19 merits of the case meet the action. But if those  
20 emergency actions, as I said, become more routine than  
21 not, we're pushed by our lawyers to get a permanent  
22 regulatory fix to the problem.

23 So there are the issues that we're going  
24 to face as we move forward on this.

25 CHAIRMAN MALMUD: Thank you, Dr. Miller.

1           Is there another comment? If not, we'll  
2 move on to the next item on the agenda, thanking Dr.  
3 Sherbini for -- did I hear who?

4           MEMBER LIETO: I think I have a  
5 presentation on this.

6           CHAIRMAN MALMUD: Dr. Lieto? You are the  
7 next item on the agenda

8           MEMBER LIETO: Just as background note, I  
9 know that these slides are not in the packet, although  
10 they were sent out individually to staff and to ACMUI  
11 members. But there are also copies, I believe, of the  
12 slides on the desk if people have not gotten them yet.

13           In putting together my presentation, I did  
14 not, unfortunately, have the benefit of Dr. Sherbini's  
15 slides, so I did though use as some input the draft  
16 staff document that ACMUI commented on I think in  
17 January that addressed sort of a draft position that  
18 NRC staff was looking at regarding this specific  
19 subject.

20           Just as some background as to what the  
21 purpose is, the impetus for this, the discussion of  
22 the dose reconstruction and the incident that involved  
23 that St. Joseph's Hospital in Ann Arbor, which was  
24 addressed at the Commissioner's meeting in April of  
25 last year. It was further affirmed as a secondary

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 goal of the dose reconstruction and specifically a  
2 goal of the ACMUI at its meeting following that in  
3 April.

4 That should say 2004, not 2002. Sorry  
5 about that.

6 And most of this has been specified in a  
7 SECY document 04-0107, which I'll refer to just as  
8 SECY 107 in the future.

9 The issue, as I see it, is that we have  
10 dose limits for members of the general public which  
11 are either family members or external caregivers that  
12 may exceed the 100 millirem annual limit for members  
13 of the general public.

14 We are specifically looking at situations  
15 where the hospitalized patient contains a therapeutic  
16 amount of radioactive materials. Now, as I understand  
17 it, the limit for members of the general public in  
18 terms of the documentation for allowing them to get  
19 the 500 millirem applies to released patients. Okay.  
20 What we're talking about is still hospitalized  
21 patients. So it's the 100 millirem limit that is  
22 applicable here.

23 And just to sort of underscore that, that  
24 was one of the major violation citations to St.  
25 Joseph's Hospital, was exceeding the 100 millirem



1 limit. Not the 500 millirem.

2 And what I'm going to present here are a  
3 couple of assumptions that I think we've already  
4 addressed. These are rare occurrences for any  
5 individual licensee. The initiating event can and  
6 could occur and did occur in an extremely short period  
7 of time, within a matter of 24 hours. And to  
8 underscore this point, it occurred over a holiday.

9 So I think requiring even regional  
10 emergent approval of a license amendment would not  
11 have satisfied or benefitted this situation that  
12 occurred at St. Joseph's.

13 The licensee has resources available  
14 because of existing authorization for hospitalized  
15 patients.

16 Now, the guidelines that I'm going to  
17 present here are basically what should that dose limit  
18 be on that be members of the public that would be  
19 allowed. Who these guidelines should apply to  
20 specifically. And a process for that should be  
21 incorporated into this or could be incorporated into  
22 these guidelines? And where should reference for these  
23 guidelines occur in?

24 I'll take the latter one first. There are  
25 different types of references where the guidelines

1 could be established. One would be in regulation. I  
2 think we're all in pretty much agreement, this is  
3 really undesirable to have this in a very prescriptive  
4 regulatory space as well as the fact just the time to  
5 achieve coming to some resolutions on guidelines, we  
6 could be looking at years.

7 A license amendment is still a regulation.  
8 It's a de facto commitment. It is a prescriptive  
9 requirement. And it is something that the licensee  
10 would have to stay on top of as they go about changing  
11 this. So that if a license amendment was submitted,  
12 say now and was approved and yet this event that might  
13 occur years down the road, did occur, heaven forbid,  
14 the situation may be such that they may need to make  
15 some changes to that. They would have to go back into  
16 amendment space, if you will, with the NRC to get  
17 changes to that.

18 The preferences, again from my  
19 perspective, would be either as a regulatory guide  
20 which is a well established mechanism, or the  
21 regulatory issue summary which is a relatively new  
22 thing with the NRC. But in reading what is the  
23 purpose of a regulatory issue summary, a couple of the  
24 objectives for that is to solicit voluntary licensee  
25 participation and staff sponsored programs. Another

1 purpose of this is to announce staff technical or  
2 policy positions not previously communicated to  
3 licensees or broadly understood. So that might be a  
4 more positive mechanism, plus giving us some latitude  
5 in changing things as we go along.

6 Now, there may be another guideline that  
7 NRC staff may be familiar with that they might want to  
8 present that these guidelines should be in. But I  
9 think definitely the former two there, or the first  
10 two regulations or license amendments are definitely  
11 undesirable.

12 The next point that I wanted to make a  
13 recommendation for discussion is the allowable dose  
14 limit. In the draft staff statement or document they  
15 basically said let's leave it up to the licensee. The  
16 first thing a licensee is going to ask is what limit  
17 do you want. Okay. They're going to need some  
18 boundaries by which they can act upon in terms of  
19 communicating risks and implementing procedures.

20 I'm recommending a two tiered approach in  
21 that there would be the 100 millirem to 500 millirem or  
22 one to five millisievert which would simply require  
23 notification of the NRC regional office and/or the  
24 agreement state.

25 Now I'm kind of questioning this because

1 I don't know if the agreement states are empowered  
2 under their compatibility rules to allow these higher  
3 values, if you will, or these differences in the dose  
4 limits. Again, I would defer to NRC staff to clarify  
5 that. But simply it would require an immediate  
6 notification of the situation to the NRC regional  
7 office and if appropriately, in the case of an  
8 agreement state, to the appropriate agency in the  
9 state.

10 The second tier would be up to 5 rem or 50  
11 millsieverts. Again, same type of notification in  
12 addition to fulfilling certain criteria and  
13 commitments.

14 Now, the 5 rem justification is that the  
15 5 rem has been addressed in NCRP Commentary 11, which  
16 specifically addressed dose limits to individuals who  
17 receive exposure from radionuclide or  
18 radiopharmaceutical therapy -- or radionuclide therapy  
19 patients.

20 I do disagree that with Dr. Sherbini that  
21 I think in terms of a risk limit, an equivalent risk  
22 limit that the fact that 5 rems is being allowed for  
23 occupational radiation workers does provide a  
24 justification for allowing exposures up to that level.  
25 It's again, just simply not from an apportion

1 standpoint, but just simply the risk to an individual  
2 from radiation. And also that 5 rems, even though as  
3 Dr. Suleiman has pointed out, this is a fairly old,  
4 the FDA still does allow up to 5 rem dose limit for  
5 research subjects of agents that are "generally  
6 recognized as safe."

7 So I think the 5 rem is a reasonable  
8 justification. And when you look at it as being a  
9 factor of 50 larger than what is allowed right now, I  
10 think it still allows a very large increase in  
11 exposure to a member of the general public. And I  
12 think by establishing also a limit, it does provide a  
13 justification in trying to maintain an ALARA concept  
14 to how much you're going to allow the individual.

15 Now, who would be the patients that would  
16 be involved in this? Obviously, if there was a life-  
17 threatening situation where the patient is going to  
18 pass away in a matter of hours or days, there's a  
19 compassionate implication or reasoning here. As Dr.  
20 Eggli brought up in the case of pediatric patients  
21 where the medical care might be adversely effected  
22 without the family caregivers being present, but it  
23 would require determination by the patient's physician  
24 and possibly the authorized user. In other words,  
25 there would need to be a documentation that both the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 referring physician and the authorized user were  
2 involved in this situation of allowing for this  
3 situation to be occurring.

4 The family caregivers, I seem to recollect  
5 that in NCRP Commentary 11 they actually define what  
6 they mean by the caregivers in these types of  
7 situations. And it would be essentially, as was  
8 discussed earlier, a relative or an extended family  
9 member who has been involved with that individual's  
10 care.

11 A suggestion is not including minors or  
12 allowing minors to be present. I think there's,  
13 obviously, there probably is going to be some  
14 discussion on maybe that point. But it's just, again,  
15 a suggestion in terms of recommendation of who these  
16 caregivers, family caregivers are.

17 And that it has to be willingly accepted.  
18 It can't be something where these individuals are  
19 saying they need some additional care, you need to be  
20 there. It's got to be something that's willingly  
21 accepted by the family caregiver member that's  
22 present.

23 Now, one category of family caregivers  
24 that I think needs to be discussed in the future has  
25 to do with what happens if it's a mother who is

1 pregnant. Okay. And can we say or should we say that  
2 they might be excluded or they should be excluded with  
3 the understanding that if they're willing to accept  
4 the additional risk, it's the choice of the mother? In  
5 other words, it should be a should rather than a must  
6 type of scenario. But I think it's something that  
7 would require further discussion.

8           The process for allowing the 5 rem dose,  
9 I have allowable up there in quotation marks, requires  
10 again immediate notification of the following  
11 individuals or groups. Hospital management, the  
12 licensee's RSO. As I pointed out earlier, the NRC's  
13 regional office and if appropriate the agreement state  
14 agency. And the hospital risk management. These are  
15 individuals and groups that deal with risk scenarios  
16 involving workers, patients, visitors. Not just in  
17 terms of radiation events, but you know infectious  
18 diseases, other types of scenarios. And are well-  
19 versed individuals. And there is, at least in my  
20 investigation on this, is that every hospital has an  
21 individual who is designated as a risk manager. Now  
22 they may share other duties, but in larger hospitals  
23 especially in multi-modality hospitals, this is a sole  
24 designated individual that's involved in this. So it  
25 would reflect, I think, a non -- shall we say

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 radiation perspective of looking at risk to the family  
2 member, the caregiver as well as the institution in  
3 looking at various aspects of allowing a higher dose  
4 level.

5 In terms of the family caregiver, this  
6 individual would get a dose monitor. Now, this might  
7 be the only suggested additional expense that might be  
8 incurred by the licensee. Some licensees might have  
9 electronic dosimeters that are used. But what I'm  
10 seeing is that it would be something as simple as just  
11 maintaining an extra set of occupational dosimeters  
12 that are available for being assigned for this  
13 individual, which would be a relatively inexpensive  
14 means of providing these monitors.

15 The electronic types are somewhat  
16 expensive, involving several hundred dollars each, but  
17 you know leave it up to the licensee on how they want  
18 to accomplish that.

19 They will need to get radiation  
20 precautions and risk instruction as to what these  
21 radiation risks are involved. And it would involve as  
22 a documentation a radiation risk management, risk  
23 management consult with the risk manager.

24 Now, it was mentioned earlier that means  
25 of documenting this and providing this instruction



1 would be very timely or would be time consuming and be  
2 difficult to achieve. This is essentially is sort of  
3 a glorified informed consent process. Okay. Which is  
4 done on a daily basis, hundreds of times in a  
5 hospital. And I think it would be, again, a sort of a  
6 specialized means but it would be a means of providing  
7 this radiation risk information to the patient. It's  
8 a means of documentation. I think in this case the  
9 caregiver would get a copy of this, all right. And it  
10 would be done between the authorized user and the  
11 caregiver at a minimum.

12 So that all these processes of dose  
13 monitoring and the dose result, the precautions, the  
14 risk management consult, the informed consent would be  
15 all documentation that would be done and available for  
16 regulatory review.

17 So where do we go from here? Probably a  
18 suggestion is reviewing also NRC information on any  
19 previous events that are authorized to date. Dr.  
20 Zelac, and I think also in the NRC document before,  
21 there have been incidents evidently that either the  
22 region or headquarters have been involved with in  
23 authorizing levels above 500 millirems. It would be  
24 very interesting to see what was included in that  
25 process, what was documented, what was the

1 requirements of the licensee and use that maybe as a  
2 template to proceed as we go along. But not having  
3 privy to any of that information, it would be  
4 interesting to see what the differences are between  
5 what's proposed here and what has been done in the  
6 past.

7 I think guidelines with the NRC staff and  
8 the ACMUI will need to be drafted to address the  
9 various components proposed here and just simply as a  
10 means of trying to achieve a final result on this  
11 would suggest a final ACMUI review and approval of a  
12 proposed draft line by the fall meeting.

13 CHAIRMAN MALMUD: Thank you. Yes?

14 MR. ESSIG: I want to offer one problem.  
15 And that is we cannot allow dose limits to be exceeded  
16 without proper authorization. We cannot do that by  
17 guidance. It either has to be by rule or by exemption  
18 via license amendment. And unfortunately, I think  
19 that's a significant problem with what you've  
20 proposed.

21 There's a lot of good ideas there. Don't  
22 get me wrong. But I think to hinge it on a guidance  
23 document that we could issue; you mentioned a RIS and  
24 Reg. Guide, that sort of thing. We just cannot  
25 authorize licensees to exceed the 100 millirem dose

1 limit for members of the public with a guidance  
2 document.

3 MEMBER LIETO: Well, I appreciate that. I  
4 think you would even run into bigger problems just  
5 saying you want in regulatory space that you want to  
6 provide or allow members of the public to get some  
7 unnamed limit. I think you'd really run into some  
8 real difficulties with that.

9 If it does require it, it could be simply  
10 something as simple as your -- what is it -- the PSEs,  
11 the --

12 MR. ESSIG: Planned special exposures.

13 MEMBER LIETO: The special exposures. It  
14 could be someplace as simple as simple as that, just  
15 saying that this could be allowed and then it would --  
16 and then in guidance that -- or the RIS mechanism  
17 would specify how you would implement that. But, I  
18 mean, if it has to a regulation as far as exceeding  
19 that, then fine.

20 MR. ESSIG: We had looked at the option of  
21 rulemaking. But then we also looked at the number of  
22 such cases that we would expected to see. And I think  
23 Dr. Sherbini pointed out that we only have the St.  
24 Joseph Mercy case and the one licensee in Pennsylvania  
25 that we had approved a priori exceeding the public

1 dose limit because of a series of children that were  
2 going to be treated and the necessity for the parents  
3 to provide care. And that case, it was 2 rem, as I  
4 mentioned was the limit that we authorized in the  
5 exemption.

6 And so that was the way that we have  
7 approached it. But the volume is so small that it  
8 wouldn't justify on a cost benefit basis undertaking  
9 a rulemaking because it would just -- that's what we  
10 have to look at. How many exemptions might we  
11 process? And if it's only a handful, literally, over  
12 a several year period, it wouldn't justify the cost of  
13 a rulemaking. That's the balance that we have to  
14 make.

15 MEMBER LIETO: From what I'm hearing is  
16 that to exceed this, to allow higher than this,  
17 requires rulemaking.

18 MR. ESSIG: No. But requires an exemption.  
19 Well, either a rulemaking that provides for a higher  
20 limit or an exemption to the existing regulation. And  
21 we can do that through a license amendment process.

22 MEMBER NAG: One of the thing is that  
23 because you have this rule, many people do not want to  
24 go through this exemption or ask the Commission and  
25 this kind of implant cannot be done on children. So if

1 it was an easy mechanism and it didn't require any  
2 special formalities, then more people would be willing  
3 to do implant in children. For example I know for  
4 sure I avoid low dose rate implant in children because  
5 of this reason. You know, this was -- although you  
6 are saying relative people have asked for an  
7 exemption, that too, but if it was available without  
8 meeting an exemption, more people may have attempted  
9 to do -- procedures.

10 MR. ESSIG: And I think as we noted, we're  
11 trying to work out the protocols of how this would be  
12 handled. I think they're very real problems of what  
13 Dr. Vetter mentioned, the 10:00 in the evening issue.  
14 Well, we don't have people on 24/7 duty to amend  
15 licenses. We fully realize that. But we do have an  
16 operations center and then we have a series of duty  
17 officers that are on call. I mean, that could at  
18 least constitute prior agency notice. They wouldn't  
19 get approval, but at least it would be notice.

20 And so some of the details are what we're  
21 trying to work out. But we would set up a process  
22 which would make for a more simplified and  
23 straightforward approval. That's the goal. And,  
24 Sami, correct me if I'm wrong, but I think that was  
25 the path you're heading.

1 DR. SHERBINI: Yes, that was basically  
2 what I was going to say.

3 There's just one other comment I want to  
4 make, and that is the 500 millirem limit, although  
5 it's true in Part 35, it's for patient release, there  
6 is a similar provision in Part 20 for members of the  
7 public that don't have to do with patient. So Part 20  
8 does contain this provision. You can raise the dose to  
9 500 without prior NRC notification or -- it's already  
10 in the regulations.

11 CHAIRMAN MALMUD: One thing seems clear,  
12 and that is that we're working toward a solution to  
13 what had been a problem in the instance in the  
14 hospital in Michigan. And that whatever mechanism we  
15 use must have either a rule or an exemption as part of  
16 the process.

17 DR. SHERBINI: Yes.

18 CHAIRMAN MALMUD: So Dr. Williamson?

19 MEMBER WILLIAMSON: Well, I think in the  
20 interests of having some mechanism in place soon, even  
21 though it may be the number of incidents is low, I  
22 think it's prudent to proceed with the development of  
23 a process for granting timely and rapidly license  
24 amendments. You know, I think the caution may be  
25 heard from several people, is they might to be really,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 really more timely than your current administrative  
2 infrastructure allows for it to really be useful.

3 MR. ESSIG: We fully understand that, yes.

4 MEMBER WILLIAMSON: Yes. And I guess you  
5 can always look at the accumulated experience over a  
6 year and decide whether a rulemaking is warranted.

7 MR. ESSIG: Yes. Yes.

8 MEMBER WILLIAMSON: You're deluged by  
9 these amendments.

10 CHAIRMAN MALMUD: Dr. Suleiman?

11 MEMBER SULEIMAN: Yes. I understand your  
12 regulatory strategy, and I think I agree with it. But  
13 I think if you make the users aware of this amendment  
14 or exemption process ahead of time and lay out the  
15 guidelines or criteria, and I think, Ralph, you've  
16 laid it out real well, I professionally don't think  
17 that most any situation will exceed the 500 millirem.  
18 But it's nice to have that two-tier thing. It's going  
19 to force them to think. But I think if you allow them  
20 that option, I think you're going to be surprised.  
21 For the record, I predict that you'll get a lot more  
22 applications for exemptions than you think you would.  
23 And if that in fact plays out as you said, then it  
24 would be a justification for rulemaking.

25 MR. ESSIG: Yes.

1 CHAIRMAN MALMUD: Thank you.

2 If that completes the discussion of that  
3 topic, I wanted to thank Mr. Lieto again and Dr.  
4 Sherbini for their presentations. And we'll move on  
5 to the next topic.

6 That would be Dr. Broseus. Oh, there you  
7 are. I hadn't seen you, that's why I hesitated.

8 DR. BROSEUS: Good afternoon.

9 Thank you for the opportunity to review  
10 where we're at with requirements for training and  
11 experience in Part 35. I'd just like to call to your  
12 attention that in your handout material and on the  
13 table we have provided copies of these slides, a copy  
14 of the *Federal Register* notice which includes the rule  
15 language for the revisions to Part 35, as well as a  
16 redline strikeout comparison between the effected  
17 sections in the final and the rule that was current  
18 before the publication of Part 35 amendments on the  
19 30th of March.

20 The rule was published on March 30th and  
21 I've added to the material since you got your slides.  
22 The specific *Federal Register* citation was volume 30  
23 of the *Federal Register* starting on page 16335.

24 This rule will be effective 30 days after  
25 publication; that is on April 29th of this year.



1       However, licensees will have until October 24, 2005 to  
2       implement the changes to the rule. This coincides with  
3       the extension of the effective date for Subpart J to  
4       October 24, 2005.

5               And lastly, agreement states will have  
6       three years to adopt the final rule.

7               The review I'm conducting today is not  
8       intended to be an extensive review of the changes to  
9       the requirements for training and experience in the  
10      final rule. Rather, I want to review the amendments  
11      with an eye to providing an overview of the nature of  
12      the changes to the requirements for T&E, and some of  
13      the major changes.

14              You may recall that the stage was set for  
15      this rulemaking by the Advisory Committee on the  
16      Medical Use of Isotopes, which I tend to lapse into  
17      ACMUI, excuse. It's an acronym I pronounced before I  
18      came to the NRC.

19              Okay. The ACMUI briefed the Commission on  
20      February 9, 2002 and called to the attention of the  
21      Commission a problem relating to the requirements for  
22      training and experience and the inability -- I  
23      shouldn't say the inability, but the fact that many  
24      boards would not be meeting the requirements. And so  
25      we'd be left in the pickle of not having board

1 certifications recognized, save for the one board  
2 which came in and met the requirements.

3 The NRC staff presented recommendations  
4 for rulemaking to the Commission in October of 2002 in  
5 SECY 02-0194. And this included attachment 2, not to  
6 this, but that SECY paper which was based largely on  
7 the recommendations of the ACMUI and its Subcommittee  
8 on Training and Experience.

9 Just going back over a little history for  
10 some members of the Committee who weren't here at the  
11 time, and for some members of the public might benefit  
12 from this, too.

13 Well, the final rule that we published in  
14 March reflects a culmination of ACMUI recommendation,  
15 a resolution of public comments on a proposed rule  
16 published in December 2003, as well as the extensive  
17 consultations between ACMUI and agreement states over  
18 the past three years. And these requirements in terms  
19 of key changes are changes to the requirements for  
20 recognition of specialty board certifications to serve  
21 as demonstrated adequacy of training and experience  
22 for use of radioactive material that is byproduct  
23 material, and also to serve as an RSO, an authorized  
24 nuclear pharmacist, authorized nuclear physicist.  
25 That combined with a preceptor statement which I'll

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 mention again in a moment, will get one approved to  
2 serve in those capacities.

3 As I have mentioned it applies for these  
4 four different categories. There are requirements  
5 that were in the rule that also apply to the so called  
6 alternate pathway, that is the pathway that's an  
7 alternate to board certification for administrating  
8 adequate of training and experience.

9 Preceptor statements were changed,  
10 highlights now, to use the word "attest" and  
11 "attestation" in place of "certify" and  
12 "certification." Now both the ACMUI and members of the  
13 public and agreement states felt that this would be a  
14 good change.

15 Preceptor statements are required for  
16 board and alternate pathways. However, the requirement  
17 for a preceptor statement has been decoupled from the  
18 requirements. Oh, that doesn't look good on a slide,  
19 does it? This thing. Hey. De-coopled. It doesn't  
20 look like that on my material. Anyway. Decoupled was  
21 a word that we used during some of the discussions.  
22 And the requirement for a preceptor statement still  
23 applies to individuals who are board certified, but it  
24 is not required for a board certification process to  
25 be recognized by the Commission.

1 Present in the original recommendations.  
2 Here's more manglement. Excuse the spacing here. It  
3 doesn't look like it's any place except on this  
4 particular computer.

5 In the original recommendations of the  
6 Advisory Committee and the attachment to SECY 02-194  
7 there was a recommendation to add, I call it use-  
8 specific training for radiation safety officers and  
9 AMPs, and for a class of AUs in high risk uses. That  
10 is under section 600. This is gamma sterotactic  
11 radiosurgery and so on. So that requirement is also  
12 in the rule and applies to all applicants.

13 We're removed the requirement in section  
14 390 for experience with elution and et cetera. Use of  
15 generators and so on. The ACMUI argued or mentioned  
16 one of our means we had over a year ago, I guess it  
17 was, that we felt that this training was not necessary  
18 for individuals to qualify under 300 and felt that the  
19 more general term experience and training and the  
20 preparation of dosage was adequate for this particular  
21 category.

22 We also decoupled in section 390  
23 requirements for experience with oral and parenteral  
24 administrations from requirement for recognition of  
25 certifications. In this (b) (1) (ii) (G) of 390 there's

1 a requirement that individuals have experience with  
2 certain numbers of cases. That requirement is  
3 retained, but it is not required for a board  
4 certification to be recognized by the NRC or an  
5 agreement state. An individual would still have to  
6 demonstrate that they have this experience to be  
7 authorized for 300 use.

8 We added a new section 35.396, which is  
9 for the parenteral administration of unsealed  
10 byproduct material for which a written directive is  
11 required. This accommodates a group of physicians that  
12 was brought to the attention of the NRC by ACMUI and  
13 also recognized by some members of the staff. And  
14 that is a group of physicians that now qualify, for  
15 example, under Subpart J, but would not meet the  
16 requirements for section 300 uses. In particular,  
17 these are oncologists many times who have training and  
18 experience that's applicable to therapeutic use of  
19 unsealed material. The one addition the staff made  
20 here, the most important one I believe, is the  
21 requirement for 80 hours of training with unsealed  
22 sources. So that an individual who may have had  
23 experience with brachytherapy and be highly trained in  
24 radiation hazards and so on, we wanted to ensure that  
25 those individuals also had some training experience in

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 handling unsealed forms of radioactive material.

2 We have provided a pathway for medical  
3 physicists who are not named as AMPs to become  
4 radiation safety officers.

5 The final highlight I'd like to call to  
6 your attention is the petition resolves. Petition PRM  
7 35-17. This is filed on behalf of the Organization of  
8 Agreement States. Most of us are familiar with this  
9 particular petition. The agreement states recommended  
10 that there be requirements established for minimum  
11 numbers of hours classroom or laboratory training for  
12 nuclear pharmacists in section 35, as well as for  
13 authorized users in sections 35.190, 290 and 390.  
14 These are basically uses of unsealed byproduct  
15 material, in 190 and 290, for which a written  
16 directive is not required and a 390 for which a  
17 written directive is required those being the higher  
18 risk uses. And that underlies the rationale for  
19 requiring a written directive.

20 I might note parenthetically that other  
21 sections do have requirements for minimum numbers of  
22 classroom and laboratory hours for high risk uses.

23 As many are aware, this is the resolution  
24 of what we came out of the discussions with. And I  
25 might mention again that as most of you are aware, we

1 had several conversations about this. And the most  
2 recent one I recall being with you all for the better  
3 part of four hours in a meeting not too long ago and  
4 which we discussed this at some length. And I want to  
5 come back to those discussions and the efforts that  
6 you have made in this regard in my concluding remarks.

7           However, let me note that for the various  
8 sections that we have listed on the table, there were  
9 already established in regulation space a requirement  
10 for total number of hours of training and experience  
11 that included classroom and laboratory training as  
12 well as other types of supervised training. But there  
13 was no requirement in these sections for a minimum  
14 number of classroom and laboratory hours. And the  
15 resolution and the rule is to require the numbers of  
16 hours for the various sections that we have listed  
17 here in the table. I want to note that this applies  
18 only to the alternate pathway and not to the board  
19 certification pathway.

20           And we also are now using the term  
21 "classroom and laboratory hours" rather than the  
22 "didactic" to make sure that it's clear what we're  
23 talking about.

24           And let me come back to the clarity issue  
25 in a minute reflecting on comments that Dr. Eggli made

1 this morning.

2 "Classroom and laboratory" seems to be a  
3 more acceptable term to many people for describing  
4 this type of training. And we are also using now  
5 consistently throughout the rule, I'm not using  
6 "didactic" in one section and "classroom and  
7 laboratory training" in another.

8 I'd like to take note, and this is not my  
9 slides, but react to some of the comments this morning  
10 from Dr. Eggli about the 200 hour requirement and in  
11 particular the suggestion that we should be more  
12 specific about what would be acceptable for that  
13 particular area. I will emphasize that the comments  
14 I'm going to make are somewhat spontaneous in that we  
15 haven't cleared this part of my talk with managers,  
16 but I want to emphasize what I'm drawing from is  
17 material in the *Federal Register* notice.

18 In our last big meeting on this issue the  
19 ACMUI actually talked about this issue before. And  
20 that is what is classroom and laboratory training.  
21 And in the *Federal Register* notice we take note that  
22 somebody -- and one of the stakeholders suggested that  
23 we define classroom and laboratory training. You  
24 might recall in the last meeting that there was  
25 considerable discussion about this and some people



1 said, "Well, be careful. You might get you ask for."  
2 And in fact, my personal view is that if you define  
3 the stuff too closely, you're becoming more  
4 perspective. And so one needs to -- when you go  
5 forward in looking at both sides of these issues, I  
6 would recommend that that particular part of the issue  
7 be kept in mind.

8           However, let me finally point out that we  
9 do have a discussion of this issue in the *Federal*  
10 *Register* notice talking about classroom and laboratory  
11 training. And I don't want you to go leafing through  
12 the fine print now, because I'll lose you. You can go  
13 look later on page 16350. I'm sorry 16349 under Issue  
14 7, should the term laboratory training be defined.

15           And what we have said there is also  
16 reflected in draft revisions to our licensing  
17 guidance, in which we point out that the NRC feels  
18 that you have to take a broad view of what training is  
19 in terms of laboratory. There are structural  
20 educational programs, we took note in our discussions  
21 that there are other types of training programs that  
22 are more innovative. There's online training,  
23 etcetera.

24           Also we have included in the guidance that  
25 while the NRC expects that when credit is taken for

1 classroom and laboratory training for radiation safety  
2 that that's the area it truly should be in. But the  
3 NRC will broadly interpret training to include various  
4 types of instruction received by candidates for  
5 approval, including online training as long as the  
6 subject matter relates to radiation safety and  
7 handling of byproduct materials.

8 We also recognize in our discussion that  
9 some of this training may be in the clinical  
10 laboratory. And I'm using the terminology loosely,  
11 but the point is that we in the discussion in the  
12 *Federal Register* notice and reflected in our guidance,  
13 that it's broader. So I would suggest that those two  
14 points be kept in mind as we go forward.

15 After of the publication of the rule we  
16 move into the implementation phase.

17 Yes, sir?

18 MEMBER LIETO: Back on your last slide, how  
19 would those boxes be filled in in terms of total and  
20 classroom laboratory for the 396s, for 396?

21 DR. BROSEUS: 396, the requirement's for 80  
22 hours of classroom and laboratory training. And for  
23 certification by a board recognized, as I recall, for  
24 600 uses. Okay. That's one pathway. So if a person  
25 is certified by a board, recognized in 35.690 and has

1 it has 80 hours of training experience for unsealed  
2 sources, that's a pathway for --

3 MEMBER LIETO: Eighty hours.

4 DR. BROSEUS: Okay. Okay. Let's go on to  
5 the next phase.

6 When we publish a rule, we move into  
7 implementation space. And as I mentioned earlier in  
8 the slides, the licensees have until October 24th,  
9 2005 to implement the final rule. During this  
10 implementation period, the NRC, the MSIB in fact, the  
11 Material Safety and Inspection Branch, has already  
12 sent out letters to boards inviting them to apply for  
13 a recognition of their certifications. We are in the  
14 final stages of revising licensing and guidance for  
15 medical use. This is NUREG 15.56 volume 9 revision 1,  
16 and we anticipate that being released to the public  
17 and published within the next couple of weeks, I  
18 should hope.

19 In parallel with that, there's a revision  
20 to NRC Form 313A. This is the medical use, training  
21 and experience and preceptor attestation form. This  
22 is the form that applicants may use to submit  
23 information about training and experience and  
24 preceptor attestation to the NRC to document the  
25 adequacy of their training and experience.

1 I didn't realize that you had moved on.  
2 Excuse me.

3 These will be available to everybody for  
4 implementation of guidance that I just mentioned, this  
5 will be available on paper. It will be mailed to  
6 licensees as well as being available on our website.  
7 This is under the medical uses licensee tool kit on  
8 NRC's webpage. And I've included the URL for your  
9 convenience here.

10 The *Federal Register* announcement which  
11 includes the revised language as well as the redline  
12 strikeout version, the highlights, changes, is  
13 available on the rule form and the URL for our  
14 rulemaking form is listed there.

15 I'd like to close with the following  
16 comment and then open up -- I think we still have a  
17 few minutes for questions, Dr. Malmud?

18 CHAIRMAN MALMUD: Yes. Yes.

19 DR. BROSEUS: With the publication of the  
20 final rule in T&E in the *Federal Register* on March  
21 30th we collectively completed a complex multiyear  
22 effort to put into place regulations and requirements  
23 for training and experience of SROs, AMPs, ANPs and  
24 authorized users. The culmination of this effort is  
25 due in no small part to the work of the members of the

1 ACMUI, particularly the Subcommittee on Training and  
2 Experience. I offer my personal thanks for your  
3 efforts in this undertaking, especially and required  
4 to the modification requirements for recognition of  
5 especially board certifications to qualify individuals  
6 to serve as RSOs, authorized medical physicists,  
7 authorized nuclear pharmacists and authorized users.  
8 Thousands of licensees, NRC and agreement state staff,  
9 hundreds of individuals per year will benefit from  
10 these changes. This is on an annual basis there will  
11 be hundreds of individuals who will benefit from these  
12 efforts. So I am proud to have been a participant in  
13 this effort. And I am very thankful for the very  
14 considered thought and input of members of the  
15 stakeholder community, the public, agreement states  
16 and the ACMUI. Thank you.

17 Thank you.

18 CHAIRMAN MALMUD: Comments? Questions?

19 Dr. Eggli?

20 MEMBER EGGLI: Thank you, Dr. Broseus.

21 However, let me say that I have to  
22 respectfully continue to emphasize concern that's  
23 emphasized by many members of the nuclear medicine  
24 community including an email that I have here from Dr.  
25 Berry Siegel, who most of you know very well. Being

1 a little perspective is like being a little pregnant.  
2 I don't understand the concept of "a little  
3 prescriptive." Once you're perspective, you're  
4 perspective. And training directors are going to have  
5 a lot of anxiety of what's going to qualify in the  
6 preceptor statement.

7 You know, didactic was an interesting  
8 definition. I could show you definitions of didactic,  
9 once you separate it to classroom and laboratory I am  
10 much more comfortable with the concept of classroom.  
11 But I am not comfortable with the concept of  
12 laboratory. Leaving it ill-defined allows in the  
13 regions some variable interpretation. And what may  
14 pass muster in one region may not pass muster in  
15 another region. And training directors are scared to  
16 death that they will write preceptor statements that  
17 will not be accepted for licensure.

18 Finally, 20 percent of diplomats of the  
19 American Board of Radiology do not pass their board  
20 examine first time. As a result, to work we will have  
21 to train all radiology residents who do over 70  
22 percent of the clinical nuclear medicine in the United  
23 States to alternate pathway requirements. So to say  
24 that there is no prescriptive requirement for training  
25 for board certification pathway is technically true,

1 but functionally untrue. Because of that the fact  
2 that 20 percent do not pass first go around means that  
3 we are going to have to train all of our residents to  
4 alternate pathway guidelines.

5 The other question is we have a lot of  
6 people -- a follow-up question is we have a lot of  
7 people in the pipeline already. And now that we're  
8 prescribing specifically 200 hours and the preceptor  
9 statement, how are we going to get third year  
10 radiology residents who are actually fourth year post-  
11 graduate out of a five year training programs within  
12 that very short period of time up to October 2005  
13 trained to the level where they can become authorized  
14 users? We have a very short time line for the people  
15 who are already deep in the pipeline with the fact  
16 that there was no previous prescriptive requirement  
17 for a board certification pathway. Now for my  
18 purposes as a person who has to design and operate  
19 these training programs, it is now prescriptive.

20 DR. BROSEUS: I really don't have an answer  
21 for your question because we're moving into an  
22 implementation phase of how the staff will look at  
23 people who are now in the pipeline. I would imagine  
24 that people who are certified by boards recognized by  
25 the NRC who meet the requirements, those people would

1 be approved.

2 MEMBER EGGLI: But they still have to have  
3 a preceptor statement?

4 DR. BROSEUS: Yes.

5 MEMBER EGGLI: And if that preceptor  
6 statement doesn't contain all of these elements, they  
7 may not get their authorized user status, even though  
8 they're board certified.

9 DR. BROSEUS: I don't know if anybody from  
10 MSIB is here wants to address that question. Anybody  
11 else?

12 CHAIRMAN MALMUD: I can't speak from that  
13 respect, but I can speak from the perspective of  
14 having heard -- I can't speak as a member of the  
15 board, but I can speak as someone who has received the  
16 same concerns that you have via the mail and email.

17 Number one, it is true as you point out  
18 that about 20 percent of the graduates of the training  
19 program will not be board certified for yet another  
20 year beyond their completion of their training, and  
21 therefore would have to meet the criteria set for  
22 those who have not yet passed the boards. So we'll  
23 accept that as a fact.

24 The changing of the wording from  
25 "didactic" to "laboratory to classroom" really gives



1 the training program director the kind of flexibility  
2 that he or she would need in certifying the trainee's  
3 experience in that even the minimalist approach to  
4 training in nuclear medicine will require three months  
5 of training in the course of the radiology residency.  
6 We're not addressing nuclear medicine residents, it is  
7 because they are a minimum of two years dedicated full  
8 time to nuclear medicine with all the time in the  
9 world to have accomplished these goals. But in  
10 radiology it could be as little as three months, which  
11 is 480 hours. Of that 480 hours, 200 would have to be  
12 "classroom and laboratory." The laboratory clearly  
13 now, as I have interpreted the messages that I'm  
14 hearing from those who have described it, including  
15 Dr. Broseus, includes the clinical laboratory  
16 experience meaning the experience in the hot lab and  
17 in the clinical lab. A clinical lab is, as we all  
18 know, what we do everyday. So I believe that we are  
19 covered.

20 The concern remains, and I'm expressing  
21 this not from my perspective but from the emails that  
22 I've received, that an overly zealous lower level  
23 employee in one of the regions may decide to redefine  
24 laboratory and clinical and say that the -- excuse me.  
25 Laboratory and classroom and may decide that his or

1 her career depends upon etching something in stone  
2 that wasn't there to begin with.

3 But it seems to me that with all of the  
4 documentation that we have of these discussions  
5 amongst ourselves and the presentations that have been  
6 made by members of the NRC staff including Dr. Broseus  
7 that there is a printed record of what the definition  
8 of -- how the definition of "didactic" has been  
9 changed to laboratory and clinical -- excuse me.  
10 Laboratory and classroom, and that we seem to agree  
11 that we shouldn't request any more definition because  
12 this will really meet the training -- this will mesh  
13 well with the existing training requirements and the  
14 number of hours spent in nuclear medicine.

15 Parenthetically, the number of hours spent  
16 in classroom by radiology residents includes relevant  
17 radiologic physics that applies to nuclear medicine as  
18 well. So some of the physics training that our  
19 residents get during the course of their four years of  
20 residency is certainly applicable to the radiation  
21 safety issues and to nuclear medicine physics.

22 So, in a sense we're better off the way it  
23 is it seems to me. I can't address what some over  
24 zealous employee may decide to do in the advancement  
25 of his or her interest or concerns. But it seems to

1 me that this distinguished group has defined that we  
2 meet the requirements.

3 MEMBER EGGLI: I disagree.

4 CHAIRMAN MALMUD: Doug?

5 MEMBER EGGLI: I have to respectfully say  
6 that I don't agree with your analysis and the  
7 definition of "clinical laboratory" is wide open for  
8 interpretation which could be interpreted in a wide  
9 variety of ways. And, again, as I am at risk in a  
10 couple of ways.

11 One is I could be -- our programs can be  
12 sued by candidates who now say that we have damaged  
13 them in the job market because we have inadequately  
14 prepared them because the preceptor statement we wrote  
15 didn't pass muster.

16 Again, I don't think you can have a  
17 partially prescriptive rule. I think if you say that  
18 the rule is we have to provide a body of knowledge and  
19 demonstrate mastery of body of knowledge in those  
20 skills, then it is up to me to define a training  
21 program. Once you start putting broad hourly limits  
22 on that requirement, you have made it prescriptive.  
23 And what you have done is made it prescriptive with  
24 uncertainty. And I think that is the worst of all  
25 possible situations.

1 CHAIRMAN MALMUD: And Dr. Eggli's concerns  
2 are the concerns that I have been receiving from other  
3 members of the radiology community who are very  
4 anxious about the subject.

5 Dr. Diamond, were you next?

6 MEMBER DIAMOND: I just wanted to point  
7 out the comment that Roger made on page 16349 of the  
8 *Federal Register* Issue #7, which is the first column  
9 on the left hand side, there is an extensive  
10 discussion regarding the definition and connotation of  
11 these terms, which I think would serve to the point  
12 that Leon spoke to a few moments ago as far as the  
13 discussion why it was opted not to become more  
14 prescriptive to provide more definitions and so forth.

15 So, again, in the hypothetical case of an  
16 over zealous regulator I think that this commentary  
17 should serve us very well.

18 CHAIRMAN MALMUD: Dr. Williamson? Oh, I  
19 think Williamson was next and then Dr. Nag, then Mr.--

20 MEMBER WILLIAMSON: Yes. I certainly have  
21 been listening to both sets of arguments of Dr. Malmud  
22 and also thinking about it from the perspective of  
23 radiation oncology, which will also be I think  
24 effected by the outcome of this. And I do have to say  
25 I think the statements of consideration, these

1 question and answers, really do set forth a body of  
2 material for the ultimate that would be used in an  
3 adversarial situation to try to resolve what is the  
4 meaning of the specific regulations. And I guess if  
5 the Commission has spoken, they may not in the near  
6 future be willing to reconsider rulemaking initiatives  
7 on this point again. And at least for the short term,  
8 you know, I think one should think very carefully  
9 about encouraging initiatives that would make it more  
10 prescriptive than it already is. Because that, as has  
11 been pointed out, might be more injurious and perhaps  
12 a certain amount of uncertainty is better than more  
13 clarification that restricts the practice of medicine  
14 even more.

15 So I should think a major practical  
16 initiative would be to try to get a reasonable set of  
17 residency guidelines approved via the American Board  
18 of Radiology, got that on the website, and that would  
19 go a long way towards encouraging the agreement states  
20 to accept a rational curriculum in radiology, and by  
21 extension in radiation oncology as well.

22 CHAIRMAN MALMUD: All right. Next is Dr.  
23 Nag.

24 MEMBER NAG: Yes. Dr. Eggli, you were  
25 concerned that 200 hours for nuclear medicine may be

1 difficult sometimes to meet for general radiology  
2 residents because of the short time is spent in  
3 nuclear medicine. But I am aware these 200 hours  
4 includes general radiology, radiation safety which is  
5 done in a general radiology residency. So some of  
6 that will overlap, wouldn't you think?

7 MEMBER EGGLI: There is a small amount of  
8 overlap. And I think we discussed this at our last  
9 meeting. At least in the didactic arena the overlap  
10 between what we consider -- and again, we've designed  
11 the classroom portion to be a reasonable curriculum.  
12 We have about a 33 percent overlap between radiology,  
13 physics and specific nuclear medicine physics. We  
14 spend a lot of time teaching specific physics of CT  
15 specific physics, of ultrasounds, specific physics of  
16 MRI none of which are directly applicable to nuclear  
17 medicine issues. We have about a 33 percent overlap  
18 in our curriculum between general diagnostic radiology  
19 physics and physics specific to nuclear medicine and  
20 radiation safety.

21 CHAIRMAN MALMUD: Thank you. I think Mr.  
22 Lieto and then Dr. Vetter.

23 MEMBER LIETO: Roger, the commentary that's  
24 in there that defines or clarifies the terms  
25 laboratory and classroom, are those going to be to

1 some extent in the NUREG document also? Because  
2 that's probably where the regions are going to be  
3 looking in terms of guidance. You know, if the very  
4 broad description of what that includes or addresses  
5 is there, I would think it might minimize over zealous  
6 interpreters, if you will.

7 DR. BROSEUS: Appendix D has a discussion.  
8 And there's a note that has been added that talks  
9 about classroom, laboratory, didactic training and the  
10 discussion that we just had. And it reflects the  
11 language rewritten for guidance. That's in the FRN.

12 While I have the microphone, I'd just like  
13 to build a little bit on the comments made by a couple  
14 of Committee members.

15 I believe personally from my experience as  
16 well as on one side -- on the other side as well as  
17 here that some creative thinking may be required but  
18 if one looks at the content required in radiation  
19 safety training, I think one in many cases will find  
20 more overlap than one might expect. There's training  
21 in radiation physics and instruments, radiation  
22 protection, radiobiology, chemistry of byproduct  
23 materials, radiation biology, radiation dosimetry and  
24 that's quite an expansive area.

25 I'd like to also note that when the staff

1 went through this they also had to take into  
2 consideration the concerns of the agreement states and  
3 the feeling that there needed to be a minimum  
4 established to be able to judge the adequacy of  
5 training programs. And so we have somewhat of a  
6 compromise here, but I believe that if this is tackled  
7 during the implementation phase, that it's doable.

8 I think that the issue that was brought up  
9 early about the people who were in this little window  
10 here, my own personal feeling is that the staff on the  
11 implementation side and the MSIB will look at these  
12 issues and try to work with them as much as possible.  
13 I can't speak officially for that group because I'm  
14 not a member of it, but my own personal experience in  
15 working with the -- see I'm on the rule writing group,  
16 okay, and there's an implementation group. And this  
17 group has been working very closely with people in the  
18 regions. They have monthly meetings to discuss issues  
19 and licensing issues. And I think there's room to  
20 work these out.

21 CHAIRMAN MALMUD: Thank you, Dr. Broseus.

22 We have several announcements to hear from  
23 Mr. Essig and then we have to be over at the  
24 Commission briefing. So is there anything? Excuse  
25 me, Dr. Van Decker?



1                   MEMBER VAN DECKER: Can I just ask one  
2 quick question before Dr. Broseus leaves?

3                   Now with the academic year ending in a  
4 couple of months do we see revised Form 313 coming out  
5 shortly or do we see ourselves still where we are for  
6 next several months?

7                   DR. BROSEUS: The 313A?

8                   MEMBER VAN DECKER: Yes.

9                   DR. BROSEUS: Coming out shortly?

10                  MEMBER VAN DECKER: Yes.

11                  DR. BROSEUS: It should be available  
12 shortly on our website. We have a copy of it  
13 reproduced in Appendix B of the guidance document. But  
14 the form itself should be on the website by the  
15 effective date of the rule.

16                  CHAIRMAN MALMUD: We have a member of the  
17 public who has been waiting. Can we hear that comment  
18 first? Please.

19                  MS. FAIROBENT: Lynne Fairobent with AAPM.

20                  Just two quick points. One, I'd like  
21 clarification of when the three years for the  
22 agreement states is effective? Is it April 2008 or is  
23 it October 2008? I've seen nothing in any of the  
24 documentation and clarifies. And from discussion I've  
25 heard it interpreted both ways.

1           And secondly, just a quick comment and  
2 concern about the reflection of the classroom and  
3 laboratory hours being discussed in guidance.  
4 Agreement states do not have to adopt the guidance.  
5 They only have to adopt the regulation. And I do  
6 think that there may be some concern.

7           I agree with Dr. Eggli's viewpoint that  
8 there may be some very different interpretations of  
9 what that is meant in the implementation phase in some  
10 of the agreement states.

11           CHAIRMAN MALMUD: Thank you for your  
12 comments.

13           DR. BROSEUS: Regarding the question about  
14 when agreement states have to implement, I can't  
15 answer that. I would have to defer it to ODC or Office  
16 of State and Travel Programs. I'm not sure what the  
17 date would work out to be.

18           CHAIRMAN MALMUD: Thank you.

19           Dr. Essig?

20           MR. ESSIG: Just quick announcements?

21           CHAIRMAN MALMUD: Please.

22           MR. ESSIG: We need to be over in our main  
23 building at 3:15 promptly. We actually need to be  
24 there before that because the Commission will actually  
25 start. It's the Commission Conference Room on the

1 first level. The tall building, Building One. If you  
2 walk past the guard, they'll direct you to where the  
3 Commission Conference Room is.

4 I would invite members of the public who  
5 are here to certainly attend that meeting.

6 Also remind members of the public that the  
7 Committee meeting tomorrow morning from 8:00 to 10:00  
8 is closed to the public. So if you wish to participate  
9 tomorrow, come at 10:00.

10 CHAIRMAN MALMUD: Any other announcements?

11 MR. ESSIG: No.

12 CHAIRMAN MALMUD: All right. So we are  
13 adjourned to head over to the Commission meeting.  
14 Thank you.

15 MR. ESSIG: Yes. There is one other  
16 announcement for members of the Committee. That is  
17 for members of the Committee those presenters along  
18 with you will sit at the table opposite the  
19 Commission. The rest of the Committee will sit in a  
20 row down in what we call the well or the pit. You'll  
21 sit right behind the Committee members who are the  
22 table.

23 CHAIRMAN MALMUD: Mr. Essig reminds us  
24 that those who are presenting will be in the front row  
25 and everyone else in the amphitheater arrangement.

1 The pit. Thank you.

2 MR. ESSIG: The pit. Yes.

3 (Whereupon, the meeting was adjourned at  
4 2:49 p.m.)

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25