

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

Title:                   Advisory Committee on the Medical  
                                  Uses of Isotopes

Docket Number:       (n/a)

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1 UNITED STATES OF AMERICA

2 NUCLEAR REGULATORY COMMISSION

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4 ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

5 + + + + +

6 OPEN SESSION

7 + + + + +

8 THURSDAY, JANUARY 22, 2009

9 + + + + +

10 The committee met at 1:00 p.m. via  
11 teleconference, Leon S. Malmud, Chairman, presiding.

12 COMMITTEE MEMBERS:

13 LEON S. MALMUD, M.D., Chairman

14 RICHARD J. VETTER, Ph.D., Vice Chairman

15 DOUGLAS F. EGGLI, M.D., Member

16 DARRELL R. FISHER, Ph.D., Member

17 DEBBIE B. GILLEY, Member

18 RALPH P. LIETO, Member

19 STEVEN R. MATTMULLER, Member

20 SUBIR NAG, M.D., Member

21 ORHAN H. SULEIMAN, Ph.D., Member

22 BRUCE R. THOMADSEN, Ph.D., Member

23 WILLIAM A. VAN DECKER, M.D., Member

24 JAMES S. WELSH, M.D., Member

25 MICKEY GUIBERTEAU, Diagnostic Radiologist

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1     NRC STAFF PRESENT:

2     HECTOR BERMUDEZ, Region II

3     COLLEEN CASEY, Region III

4     JACKIE COOK, Region IV

5     CHRIS EINBERG, Designated Federal Official, FSME

6     SANDY GABRIEL, Region I

7     DONNA-BETH HOWE, Ph.D., FSME

8     ROB LEWIS, Director FSME/DMSSA

9     GRETCHEN RIVERA-CAPELLA, FSME

10    ASHLEY TULL, FSME

11    DUANE WHITE, FSME

12    JACK WHITTEN, Region IV

13    ALSO PRESENT:

14    GARY BECKER, ABR

15    JENNIFER BOSMA, ABR

16    DEAN BROGA, ABMP

17    MARY BURKHART, Illinois

18    DAWN EDGERTON, CBNC

19    LYNNE FAIROBENT, AAPM

20    DONALD FREY, AAPM

21    EMILY GARDNER, ASNC

22    ANTHONY GERDEMAN, ABR

23    BRUCE HAFFTY, ABR

24    SUSAN LANGHORST, WUSTL

25    MELISSA MARTIN, AAPM/ACR

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ALSO PRESENT: (CONT.)

RICHARD MORIN, AAPM

MIKE PETERS, ACR

DOUGLAS PFEIFFER, AAPM

AMANDA POTTER, AAPM

GLORIA ROMANELLI, ACR

KAREN SHEEHAN, Fox Chase

HARRY SKENE, Geisinger

STEPHEN THOMAS, University of Cincinnati

CINDY TOMLINSON, SNM

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P R O C E E D I N G S

1:04 P.M.

1  
2  
3 MR. EINBERG: Good afternoon. As the  
4 Designated Federal Officer for this meeting, I'm  
5 pleased to welcome you to this teleconference public  
6 meeting of the ACMUI. I am the Chief of the  
7 Radioactive Materials Safety Branch and I have been  
8 designated as the Federal Officer for this Advisory  
9 Committee in accordance with 10 CFR Part 7.11.

10 This is an announced meeting of the  
11 Committee. It is being held in accordance with the  
12 rules and regulations of the Federal Advisory  
13 Committee Act and the Nuclear Regulatory Commission.

14 The meeting was announced in the December  
15 24, 2008 edition of the Federal Register, Volume 73,  
16 page 79197.

17 The function of the Committee is to advise  
18 the staff on issues and questions that arise on the  
19 medical use of byproduct material. The Committee  
20 provides counsel to the staff, but does not determine  
21 or direct the actual decisions of the staff or the  
22 Commission. The NRC solicits the view of the  
23 Committee and values their opinion.

24 I request that whenever possible we try to  
25 reach a consensus of the procedural issues that we

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1 will discuss today. I also recognize that there may  
2 be a minority or dissenting opinion. If you have such  
3 opinion, please allow them to be read into the record.

4 At this point I would like to perform a  
5 roll call of the ACMUI members that may be  
6 participating today.

7 Dr. Leon Malmud, Chairman, Health Care  
8 Administration.

9 Mr. Malmud? We know he is here. He  
10 previously responded.

11 Dr. Richard Vetter, Vice Chairman,  
12 Radiation Safety Officer.

13 DR. VETTER: Here.

14 DR. MALMUD: I'm sorry, you couldn't hear  
15 me. Malmud is here.

16 MR. EINBERG: Okay, thank you.

17 Dr. Douglas Eggli, Nuclear Medicine  
18 Physician.

19 DR. EGGLI: Here.

20 MR. EINBERG: Dr. Darrell Fisher, patient  
21 advocate.

22 DR. FISHER: Here.

23 MR. EINBERG: Ms. Debbie Gilley, State  
24 Government Representative?

25 (No response.)

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1 Mr. Ralph Lieto, Nuclear Medicine  
2 Physicist.

3 DR. LIETO: Here.

4 MR. EINBERG: Mr. Steve Mattmuller,  
5 Nuclear Pharmacist.

6 MR. MATTMULLER: Here.

7 MR. EINBERG: Dr. Subir Nag, Radiation  
8 Oncologist?

9 DR. NAG: Present.

10 MR. EINBERG: Dr. Orhan Suleiman. Food  
11 and Drug Administration Representative.

12 DR. SULEIMAN: I'm here.

13 MR. EINBERG: Thank you. Dr. Bruce  
14 Thomadsen, Medical Physicist Therapy.

15 DR. THOMADSEN: Here.

16 MR. EINBERG: Dr. William VanDecker,  
17 Nuclear Cardiologist.

18 DR. VANDECKER: Present.

19 MR. EINBERG: Dr. James Welsh, Radiation  
20 Oncologist.

21 DR. WELSH: Here.

22 MR. EINBERG: We have a quorum as there is  
23 at least seven members present.

24 Dr. Mickey Guiberteau is representing the  
25 diagnostic radiologists. Dr. Guiberteau does not have

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1 voting privileges, but he will listen and speak on  
2 behalf of the diagnostic radiologists.

3 I would like to thank Dr. Guiberteau for  
4 acting in this capacity.

5 Is Dr. Guiberteau on the phone?

6 DR. GUIBERTEAU: Yes, I am.

7 MR. EINBERG: Thank you. I now ask NRC  
8 staff members who are present to identify themselves.  
9 We'll start with the individuals in the room here and  
10 then we'll turn it to the other NRC staff members on  
11 the phone.

12 As previously mentioned, my name is Chris  
13 Einberg.

14 MS. TULL: This is Ashley Tull.

15 MR. LEWIS: Robert Lewis.

16 MR. EINBERG: That's everybody here at  
17 headquarters.

18 Are there NRC members on the phone?

19 MS. GABRIEL: From Region I, Sandy  
20 Gabriel.

21 MR. BERMUDEZ: I'm Hector Bermudez.

22 MS. CASEY: Region III, Colleen Casey.

23 MR. WHITTEN: Region IV, Jack Whitten and  
24 Jackie Cook.

25 MR. EINBERG: Okay, thank you. Two other

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1 NRC staff members who just joined us, Duane White and  
2 Gretchen Rivera-Capella.

3 Dr. Malmud, ACMUI Chairperson will conduct  
4 today's meeting. Following a discussion of each  
5 agenda item, the Chair at his option, may entertain  
6 comments or questions from members of the public who  
7 are participating with us today.

8 Before we do that, we'd like to identify  
9 members of the public who are participating on the  
10 phone. Ashley Tull will read off a list of names of  
11 people who have indicated that they will be  
12 participating.

13 MS. TULL: James Albright, Gary Becker.

14 MR. BECKER: Here.

15 MS. TULL: Jennifer Bosma.

16 MS. BOSMA: Here.

17 MS. TULL: Dean Broga.

18 MR. BROGA: Here.

19 MS. TULL: Mary Burkhart.

20 MS. BURKHART: Here.

21 MS. TULL: Will Davidson. Dawn Edgerton.

22 MS. EDGERTON: Here.

23 MS. TULL: Lynne Fairobent.

24 MS. FAIROBENT: Here.

25 MS. TULL: Donald Frey.

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MR. FREY: Here.

MS. TULL: Emily Gardner.

MS. GARDNER: Here.

MS. TULL: Anthony Gerdeman.

MR. GERDEMAN: Here.

MS. TULL: Robert Hattery.

(No response.)

MS. TULL: Susan Langhorst.

MS. LANGHORST: Here.

MS. TULL: Melissa Martin.

MS. MARTIN: Here.

MS. TULL: Richard Martin.

(No response.)

MS. TULL: Richard Morin.

MR. MORIN: Here.

MS. TULL: Jorge Munoz.

(No response.)

MS. TULL: Mike Peters.

MR. PETERS: Here.

MS. TULL: Doug Pfeiffer.

MR. PFEIFFER: Here.

MS. TULL: Amanda Potter.

MS. POTTER: Here.

MS. TULL: Gloria Romanelli.

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1 MS. ROMANELLI: Here.

2 MS. TULL: Karen Sheehan.

3 MS. SHEEHAN: Here.

4 MS. TULL: Harry Skene.

5 MR. SKENE: Here.

6 MS. TULL: Stephen Thomas.

7 MR. THOMAS: Here.

8 MS. TULL: Cindy Tomlinson.

9 MS. TOMLINSON: Here.

10 MS. TULL: Is there anyone's name I did  
11 not call?

12 MS. GILLEY: Ashley, Debbie Gilley.

13 MS. TULL: Hi, Debbie.

14 MS. GILLEY: Thanks.

15 DR. HAFFTY: Bruce Haffty from the ABR.  
16 Also, I'm on the call.

17 MR. EINBERG: Okay, thank you very much.  
18 At this point I'd like to turn the meeting over to Dr.  
19 Malmud.

20 DR. MALMUD: Thank you. Are you able to  
21 hear me well?

22 MR. EINBERG: Yes, we are.

23 DR. MALMUD: There are two items on the  
24 agenda for today. The first item is the NRC briefing  
25 on recent meeting with the international regulators on

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1 the issue of medical isotope shortages. And then that  
2 will be followed by the ACMUI Subcommittee  
3 recommendation for authorized user status delay for  
4 the ABR candidates.

5 So if we may, we'll begin with the NRC  
6 staff briefing on the recent meeting with the  
7 international regulators.

8 MR. EINBERG: Thank you, Dr. Malmud. This  
9 is Chris Einberg and I'll be giving the presentation  
10 on the recent meeting with the international  
11 regulators and medical isotope shortages.

12 As you all are aware of the potential  
13 shortages or the current shortages of the medical  
14 isotopes. An international meeting was held in Paris,  
15 France on January 7th through the 9th and the meeting  
16 was hosted by the French Nuclear Safety Authority,  
17 ASN.

18 Representatives from other countries  
19 participated and the representatives were from  
20 Australia, Belgium, Canada, France, The Netherlands,  
21 South Africa and United Kingdom.

22 Additionally, at the meeting there were  
23 several associations represented as well. The  
24 Association of Imaging Producers and Equipment  
25 Suppliers and the European Association of Nuclear

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1 Medicine were also present as well as the Nuclear  
2 Energy Agency.

3 I participated in the meeting with Dr.  
4 Charles Miller who is the Office Director for the  
5 Federal and States Material Environmental Management  
6 Programs here at the NRC.

7 The purpose of the meeting was to  
8 coordinate the supply of radio pharmaceuticals and  
9 manage the transition period between the shut down of  
10 old reactors and commissioning of new ones.

11 There will be a subsequent meeting at the  
12 end of the month hosted by the Nuclear Energy Agency,  
13 NEA, and the findings from the meeting, the ASN  
14 meeting from January 7th through the 9th, will be  
15 provided to the NEA as a starting point for their  
16 workshop on isotope shortages.

17 Now I'd like to go through some of the  
18 highlights that were discussed, relevant to the  
19 various countries that were represented there and the  
20 status of their isotope production.

21 First, alphabetically, we'll go to  
22 Australia. Australia's OPAL reactor has recently  
23 replaced the HIFAR reactor as the only research  
24 reactor and is in the process of hot commissioning a  
25 new molybdenum-99 production process using low

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1 enriched uranium, LU targets, and fuel.

2           Next, Belgium. Belgium's representative  
3 indicated that Belgium's BR2 research reactor has been  
4 in operation since 1962 and is the only producer of  
5 molybdenum-99 in their country. It currently produces  
6 approximately 9 percent of the world's supply. On  
7 August 22, 2008, an international nuclear events scale  
8 level 3 radiological release occurred at the Institute  
9 of Radio Elements, IRE, processing facility.  
10 Production restarted on November 3rd, 2008.

11           Canada. The Canadian representative  
12 discussed that it has increased its production of  
13 molybdenum-99 during the recent outages of The  
14 Netherlands HFR reactor, high flux reactor. The  
15 National Research Universal Reactor, also known as  
16 NRU, its license expires in 2011 at which time a  
17 safety case for the life extension will need to be  
18 made.

19           France. The French situation is the  
20 OSIRIS Research Reactor will be shut down in 2015.  
21 The average capacity has been about three percent of  
22 world supply, but it has recently increased production  
23 during the shut down of the reactor in The  
24 Netherlands.

25           A new research reactor, JHR, is under

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1 construction and is anticipated to be operational in  
2 2014. JHR will have approximately twice the current  
3 capacity of the OSIRIS Research Reactor for  
4 molybdenum-99 production. However, no decision has  
5 been made to use the reactor for production of  
6 molybdenum-99.

7 The Netherlands. The Netherlands high  
8 flux reactor is currently shut down due to a small  
9 bubble stream coming from the reactor, from the  
10 reducers in the reactor outlet line. A sleeve with  
11 epoxy sleeves is now foreseen to be installed in May  
12 2009. However, the epoxy has yet to be qualified.

13 The representatives from The Netherlands  
14 expressed that there is the serious possibility that  
15 the HFR reactor will be decommissioned. When  
16 operating, it currently supplies approximately 30  
17 percent of the world's supply.

18 South Africa. The Safari Research Reactor  
19 currently uses highly enriched uranium, but is in the  
20 process of switching to low enriched uranium. It has  
21 been in operation for 43 years and supplies  
22 approximately 10 percent of the world's supply.

23 In the United States, Dr. Miller and I  
24 reported that the U.S. currently has no research  
25 reactors producing molybdenum-99. However, both the

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1 University of Missouri and Babcock & Wilcox are  
2 exploring the possibility of producing molybdenum-99.

3 Any production will be at least four to five years  
4 away.

5 In the United Kingdom, the representative  
6 indicated that they currently do not have any plans  
7 for molybdenum-99 production and currently do not have  
8 any production.

9 The meeting culminated with the  
10 participants preparing a draft report, the findings of  
11 the meeting on the safety and availability of radio  
12 pharmaceutical production facilities. The draft  
13 report stressed that there is an urgent need to act to  
14 reinforce the complete production chain leading to the  
15 essential service to society. And as I indicated,  
16 that report will be provided to NEA as a starting  
17 point for their workshop at the end of the month.

18 With that, I'm willing to take any  
19 questions.

20 DR. MALMUD: Are there any questions? I  
21 hear no questions in which case we thank you for the  
22 report.

23 MR. EINBERG: Okay, thank you.

24 MR. MATTMULLER: I'm sorry, Dr. Malmud,  
25 this is Steve Mattmuller. I do have a question.

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1           Could you clarify, I'm sorry, what is going on  
2 in The Netherlands? I thought I heard you say they're  
3 trying to fix the problem, but they may decommission  
4 it?

5           MR. EINBERG: That's correct. They are  
6 trying to fix the problem. They would like to install  
7 a sleeve to fix the problem and currently it's  
8 anticipated that it will be installed in May 2009.  
9 However, the epoxy that will be used to make the  
10 repair has yet to be qualified and the regulator has  
11 indicator that there is discussion going on whether  
12 there's a serious possibility that the reactor may not  
13 be restarted at all.

14          MS. GILLEY: Chris, can you provide the  
15 subcommittee that's looking at this for the Commission  
16 briefing your notes?

17          MR. EINBERG: I cannot. There are  
18 additional notes on this. They're foreign government  
19 controlled information.

20          MS. GILLEY: Okay. Thank you.

21          DR. WELSH: Jim Welsh here. I have a  
22 quick question. I understood the University of  
23 Missouri and Babcock Wilcox may or have they made a  
24 commitment to producing molybdenum-99 perhaps in the  
25 next four years?

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1 MR. EINBERG: They are exploring the  
2 possibility of it.

3 DR. WELSH: Thank you.

4 DR. FISHER: Darrell Fisher with one quick  
5 question. Chris, the topic of Canada's MAPLE-1 and  
6 MAPLE-2 reactors come up and could you give a quick  
7 summary of the outcome?

8 MR. EINBERG: The MAPLE-1 and MAPLE-2  
9 reactors were discussed. However, it's not foreseen  
10 that either MAPLE-1 or MAPLE-2 will be operational.

11 MS. FAIROBENT: Dr. Malmud, Lynne  
12 Fairobent from AAPM, may I ask a question?

13 DR. MALMUD: Certainly, Lynne.

14 MS. FAIROBENT: In getting ready for the  
15 NEA meeting at the end of the month, Chris, are you  
16 all looking at the National Academy of Sciences report  
17 that just came out and is any of the information from  
18 the DOE and SAC meeting last week, will that be  
19 factored in at all? And is DOE having anyone  
20 participate in the NEA meeting?

21 MR. EINBERG: First, I know DOE was  
22 invited to the NEA meeting. There were numerous  
23 representatives invited so I believe that they will be  
24 participating.

25 We have received the National Academy's

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1 report on LEU versus HEU and we're reviewing that.  
2 Regarding NRC participation, we will be -- we will  
3 have a representative there taking notes and however,  
4 we'll be in more of the observation mode.

5 MS. FAIROBENT: Thank you.

6 DR. MALMUD: Any other questions?

7 MR. MATTMULLER: This is Steve Mattmuller  
8 again.

9 DR. MALMUD: Yes.

10 MR. MATTMULLER: As The Netherlands  
11 reactor presents about 40 percent of the world's  
12 supply of molybdenum-99, the possibility that that may  
13 be shut down is devastating news. I guess I'm stunned  
14 and through the process of this teleconference I would  
15 assume that most of the other Committee members are  
16 stunned also. But that is devastating news.

17 DR. MALMUD: We would agree.

18 DR. EGGLI: This is Doug Eggli, can I ask  
19 a question?

20 DR. MALMUD: Please do, Doug.

21 DR. EGGLI: Did any of the other people  
22 representing either reactors or governments that are  
23 producing molybdenum-99 in view of that news offer any  
24 potential solution to the shortfall for medical  
25 isotopes?

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1 MR. EINBERG: Other than that there's a  
2 need for coordination amongst the operating reactors  
3 to coordinate shutdowns and maintenance schedules.  
4 The -- everybody at the meeting recognized the  
5 importance of this issue and this needs to be  
6 communicated back to the respective governments that  
7 this is a potential crisis situation and so there is a  
8 heightened awareness of this issue.

9 DR. EGGLI: Thank you.

10 DR. VANDECKER: This is Bill VanDecker.  
11 Is there a time line for the discussion that this is  
12 going to generate to looking towards potential  
13 solutions beyond just the current upcoming meeting? I  
14 mean where do we see this timeline-wise going over the  
15 next year or two?

16 MR. EINBERG: Well, in the first meeting  
17 with ASN, I believe just the start of getting the  
18 international dialogue started on this important  
19 issue, the next meeting, the NEA meeting at the end of  
20 the month. I'm sure they will have recommendation as  
21 to a process or a path forward. But as far as a  
22 timeline, that's been laid out at this time, I'm not  
23 aware of anything.

24 DR. EGGLI: This is Doug Eggli again.

25 DR. MALMUD: Yes, Doug.

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1 DR. EGGLI: Just to make sure it's clear  
2 what the current impact of the reactor shutdown in The  
3 Netherlands is, we cannot currently get generators.  
4 We get bulk tech and unit doses during the day and we  
5 can get no technetium for emergency after hours  
6 studies.

7 DR. GUIBERTEAU: This is Mickey Guiberteau  
8 in Texas, and we are having exactly the same problem  
9 down here. And when we get bulk tech, we can't get it  
10 in the amounts we need even to compound what we need  
11 on a daily basis for our patients. The problem, other  
12 than just interruption of good patient care is the  
13 fact that when we can't deliver these studies on a  
14 dependable basis, then alternative examinations, often  
15 more expensive ones are performed. And I'm afraid it  
16 becomes debilitating for the entire nuclear medicine  
17 community in terms of being able to dependably provide  
18 these services.

19 DR. MALMUD: It is a significant issue and  
20 I'm not certain how we can assist in addressing it.

21 Questions from NRC staff?

22 MR. LEWIS: One way you can assist the  
23 NRC, this is Rob Lewis, is if there are any  
24 unnecessary regulatory obstacles that you see are  
25 impeding technetium availability, please bring those

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1 to our attention. We can do everything within our  
2 walls to make sure the regulations aren't part of the  
3 problem. I mean they'll always be some part of the  
4 problem, but we can look at the unnecessary burden if  
5 there is any.

6 DR. WELSH: This is Jim Welsh here with a  
7 comment.

8 DR. MALMUD: Yes, Jim.

9 DR. WELSH: My original question about  
10 Babcock & Wilcox and the University of Missouri,  
11 whether they have made a commitment or are  
12 contemplating it was asked because of this particular  
13 problem that is even greater than we initially  
14 anticipated.

15 So I would suggest that the United States  
16 seriously look into making isotopes available within  
17 our own boundaries since we are the largest consumer  
18 of this and make sure that as the decisions are being  
19 contemplated that regulatory issues are not likely to  
20 present any insurmountable or unnecessary obstacles as  
21 we move this forward. This seems like a logical  
22 solution to the problem.

23 MR. LEWIS: I think we've talked to  
24 Babcock and Wilcox on that point. I don't know that  
25 we talked to Missouri yet.

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1 MR. EINBERG: The other point is that  
2 Babcock and Wilcox and the University of Missouri were  
3 invited to the meeting at the end of the month and I  
4 believe that they'll be participating.

5 DR. MALMUD: Any other comments?

6 MR. MATTMULLER: Yes, this is Steve  
7 Mattmuller again. I would like to say that I believe  
8 someone mentioned this is a potential crisis. For  
9 those of us who depend on a generator every week, and  
10 have been holding our breaths waiting for The  
11 Netherlands reactor to come back on line, I would say  
12 we're -- and now with this recent news we are in a  
13 crisis.

14 In terms of what the NRC can do, in  
15 looking at a preliminary version of the report on  
16 substituting LEU for targetry, the report seems to  
17 indicate it's technically feasible and there really  
18 shouldn't be any barriers to implementing this right  
19 away whereas there's a lot of us, myself included,  
20 that say there are some significant issues that  
21 weren't necessarily addressed accurately in the  
22 report.

23 So for the NRC today, I would say do not  
24 embrace this report. Do not put any pressure at all  
25 on our current fragile supply of moly-99 with the

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1 additional burden of converting their HEU targets to  
2 LEU targets. It would be the final nail in the coffin  
3 I'm afraid for our industry, if that were to happen.

4 Thank you.

5 DR. SULEIMAN: This is Orhan. I think  
6 this is clearly beyond the scope of the Committee  
7 right now, but my observation is that some of this has  
8 been generated by Homeland Security interest, the  
9 whole issue of going away from highly enriched uranium  
10 for security reasons and whatever, and the shift over  
11 to LEU has caught some of the reactors and caused  
12 them, anyway that transition has been going on.

13 The other thing is economic. I mean the  
14 way I understand the cost of the radionuclide  
15 component of radio-labeled drugs is it's really the  
16 cheaper component. You've got economic factors.  
17 You've got government regulatory policy that comes  
18 from Homeland Security, from safety, from a variety of  
19 other issues. I -- maybe this will play out all right  
20 in the end because it's going to cause a crisis in the  
21 short term, but I think the only way to do is put  
22 pressure, respectively from any possible source.

23 I mean if it's a crisis, then people need  
24 to hear about it and bring it to the attention -- this  
25 is no different than a couple of years ago when the

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1 DOE was going to cut back on the funding for the  
2 atomic bomb survivors because they thought all the  
3 data that was necessary had been -- you know, the  
4 community stood up and hollered and they came back and  
5 you know, allowed the funding to continue on this  
6 very, valuable, long-term study.

7 So I think there's no organized way or  
8 somebody you're going to go to solve this, but I think  
9 it's going to take collective yelling and screaming to  
10 raise the issue to a level where people will do  
11 something.

12 DR. MALMUD: Are you suggesting a form of  
13 collective yelling and screaming to use the term that  
14 you used?

15 DR. SULEIMAN: From my vantage point, I  
16 just see that the nuclear medicine community  
17 specifically is the victim of a set of events that it  
18 really has no direct control over. And so how do you  
19 solve that? I mean you can attend meetings, have  
20 committees make recommendations. I'm just wondering  
21 you need to get recommendations made that are going to  
22 be heard by the powers that be that can do something  
23 about it. It's not being heard by other people who  
24 can't do anything about it.

25 So if the Committee -- what's the problem?

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1       Why -- it's not that the reactors are shutting down.  
2       Why are the reactors shutting down? Are there  
3       economic reasons? Are there security reasons?  
4       There's an underlying basis as to why they're shutting  
5       down. They're just a symptom of a series of other  
6       events.

7                   Is the HEU, that issue looks like it's  
8       been resolved, favorably or unfavorably. I mean  
9       you've seen all these reactors switching over to lower  
10      enriched uranium targets. So debating that to me is  
11      of questionable value, but I think the key thing is  
12      which reactors are willing to try to get on line.  
13      This Missouri thing, I'm sure they're going to look  
14      and see if it's cost effective, if they can pull it  
15      off, they'll do it. They probably are wondering is  
16      the regulatory climate going to change in the next  
17      year that will make it less feasible for them, I  
18      suspect.

19                   I'm not an economic analyst here. But I  
20      think there are other factors that are in play. I  
21      think all we can do as a professional group say this  
22      is -- this is going to wipe out a very necessary  
23      medical profession.

24                   DR. MALMUD: Thank you, Orhan. Any other  
25      comments?

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1 MR. EINBERG: This is Chris Einberg. Just  
2 to address Dr. Suleiman's comment. One of the major  
3 factors why these are shutting down are these are  
4 aging reactors. They're all over 40 years old and  
5 some are over 50 and so that's the primary reason why  
6 these research reactors are shutting down.

7 DR. MALMUD: Clearly, however, if there  
8 were a profit in reinvesting in these reactors, it  
9 would be done.

10 DR. FISHER: Dr. Malmud?

11 DR. MALMUD: Yes.

12 DR. FISHER: Darrell Fisher. To that very  
13 point, I'm following up on what Orhan Suleiman said.  
14 One of the problems is that political pressures are  
15 driving production by low enriched targets. According  
16 to Fung Sale Devalier (phonetic) of the South African  
17 research and development company, NECSA, which  
18 operates the reactor in South Africa, he said that  
19 there's although it's possible to produce moly-99  
20 using low enriched targets, the problem is higher  
21 cost. And there is no proven process for moly-99  
22 production from low enriched uranium on an industrial  
23 scale without substantial federal subsidies to make it  
24 possible, because the costs are much higher. And  
25 there are a number of other factors that come out in

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1 the recent National Academy of Sciences report.

2 DR. MALMUD: So it clearly is an economic  
3 issue. Normally, in the marketplace though if  
4 something becomes more expensive to produce, the price  
5 goes up. Are there artificial controls on the prices?

6 DR. FISHER: No, but I think the impact is  
7 that companies wanting to invest in future production  
8 are impacted by the higher costs that they face for  
9 making moly-99, that in fact, it's not competitive  
10 with production using high enriched targets.

11 DR. VANDECKER: This is Bill VanDecker.  
12 Dr. Malmud, for clarification sake, look at this from  
13 a cost basis. I would say that technetium being the  
14 most commonly used isotope and God thank the fact that  
15 it is relatively cheap right now to produce it in  
16 radio pharmaceuticals for all the uses we use it for.

17 If that pricing begins to go up, given the current  
18 reimbursement environments, both on the hospital side  
19 and the outpatient side, it could well be a useful  
20 medical field that prices itself out of existence, so  
21 we're both hurt by the fact that we have access fears  
22 and threatened access here in addition to the fact  
23 that the fix of the access problem can't take the  
24 situation to becoming nonviable in the long-term as  
25 well.

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1 DR. MALMUD: Yes, I agree with you, Bill.

2 I guess the question for us is in our role at the  
3 ACMUI, what action do we think could be taken to  
4 assist in dealing with the current crisis?

5 Is there someone here representing the  
6 SNM?

7 MS. TOMLINSON: Sorry, I was on mute.  
8 Yes, I'm here. This is Cindy Tomlinson.

9 DR. MALMUD: Cindy, what's the Society  
10 planning to do?

11 MS. TOMLINSON: We have been looking into  
12 -- we've talked to BWXT and to MIR and to a few other  
13 companies as well. Right now, we are still looking  
14 over the NAS report. We have issued a press release  
15 where we basically say it's okay, but there are other  
16 factors that have -- that we think that they have  
17 neglected to look at such as the economics and a few  
18 other things.

19 We're trying to get as much information as  
20 we can. This is the first I've heard about the  
21 meeting earlier this month, but a lot of that  
22 information was very useful and I will be taking it  
23 back to our task group. I did know about the meeting  
24 at the end of the month, and we will have a  
25 representative there. I think we're sort of because

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1 there are so many different people looking into this,  
2 we're not quite sure where we necessarily fit in.

3 DR. MALMUD: Cindy -- I'm sorry, who  
4 wanted to speak.

5 DR. VANDECKER: I'm sorry, Dr. Malmud.  
6 This is Bill Vandecker. I think this goes to my  
7 question on timeline for flushing out alternatives  
8 because I think that all the practitioner society  
9 certainly would love to engender grass roots support  
10 for letter writing campaigns and pushing a solution,  
11 but I think that the first goal here is to have a  
12 first round of what are the most viable solutions and  
13 therefore that will identify where the push should go  
14 and where the letter writing campaigns and concerns  
15 should go rather than a more diffuse fear of where we  
16 are right now. I think the NRC is going to have to  
17 help us in sorting out where those discussions are  
18 going and where we can be helpful.

19 DR. MALMUD: I think we all agree with  
20 you, Bill. In order to protest something, we really  
21 have to offer a potential solution. That doesn't mean  
22 we have to offer the money to solve the problem, but  
23 at least a path to solving the problem, hoping that  
24 either industry or government will find the resources  
25 or the profitability in doing it.

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1           Are there any other suggestions regarding  
2 this issue?

3           MR. LEWIS: Dr. Malmud, this is Rob Lewis.

4           Just a word of caution in terms of the NRC's role and  
5 the Committee's role that it can go into promotional  
6 aspects. That's really a job for, in the Federal  
7 Government, for DOE. We just have to stay on the  
8 safety side, on the security side of the equation.

9           DR. MALMUD: Thank you. And I wasn't  
10 suggesting that ACMUI take an aggressive role in it,  
11 but if we can -- if we have some individuals within  
12 the Committee who can offer potential solutions, they  
13 should feel free to make the recommendations.

14           As Dr. VanDecker pointed out, there's no  
15 point in protesting something unless you -- unless  
16 there is potential solution that we would be assisting  
17 and recommending. But it wouldn't be the function of  
18 the ACMUI. It might be a function of some of the  
19 members of the ACMUI and their other roles, but not  
20 the ACMUI. And I think we appreciate that. Thank you  
21 for reminding us of it.

22           DR. SULEIMAN: Dr. Malmud, this is Orhan  
23 again.

24           DR. MALMUD: Yes, Orhan.

25           DR. SULEIMAN: In my capacity here at FDA,

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1 we have -- we probably have somebody from the  
2 Department of Health and Services attending the  
3 meeting later on in the month and with the change in  
4 Administration and everything else, we've just been  
5 scrambling. But we're trying to do what we can from  
6 within because I think it's more of a medical care  
7 issue, but that's just one voice. So that's just an  
8 FYI.

9 DR. MALMUD: Thank you. If we may, we'll  
10 move on to the next item on the agenda, if there's  
11 agreement to do so. Thank you. I take the silence as  
12 agreement.

13 The next item on the agenda is the ACMUI  
14 Subcommittee recommendation for authorized user status  
15 delay for the American Board of Radiology candidates.

16 And we're scheduled to discuss the Subcommittee  
17 recommendation for individuals to achieve authorized  
18 user status via the Board's certification pathway with  
19 particular attention to the period when a gap exists  
20 between the completion of training and the experience  
21 and the issuing of the Board certificate.

22 Who wishes to speak first to this issue?

23 DR. EGGLI: Leon, this is Doug Eggli, the  
24 Subcommittee chair.

25 DR. MALMUD: Yes, Dr. Eggli.

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1 DR. EGGLI: Hopefully, most of the  
2 Committee members have seen the draft report  
3 distributed by Ashley. The first three quarters of  
4 that report sort of lays out the problem and the last  
5 one quarter of the report finds the solution. To be  
6 succinct, the Board certification pathway is probably  
7 the preferred pathway for obtaining authorized user  
8 status for trainees who are trained, whose training  
9 leads to certification by a Board that the NRC  
10 recognizes.

11 The alternative pathway exists to provide  
12 a pathway to achieve authorized user status for those  
13 for individuals who are qualified, but do not train  
14 under the auspices of a training program that leads to  
15 Board certification that NRC recognizes or for a rare  
16 individual who trains on the Board certification  
17 pathway, but for some reason doesn't quite get there.

18 With the change in the training paradigm  
19 which is coming down the road for particularly the  
20 American Board of Radiology, 100 percent of the people  
21 completing the initial training period for the  
22 American Board of Radiology will have about a 15-month  
23 gap before they could achieve authorized user status.

24 And so we were trying to develop a way of essentially  
25 maintaining relevance of the Board, relevance of

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1 primacy of the Board certification pathway for  
2 achieving authorized user status.

3 The solution, we thought, should be  
4 designed such that it wasn't a tailored solution for  
5 American Board of Radiology, but could be applied by  
6 -- could be used by any certification board that  
7 perceived a problem with a time gap between when their  
8 trainees completed training and when they finally  
9 achieved Board certification.

10 But on the other hand, no Board would be  
11 required to implement a solution that they did not  
12 need, if they were not experiencing a problem with a  
13 time gap and in no way would a solution to the time  
14 gap require a change in the training paradigm for any  
15 of the Board.

16 It was the intent of the Committee to  
17 provide essentially a way to maintain this Board  
18 certification pathway and the proposed solution is  
19 basically that the certification boards would provide  
20 a certification of completion of all the training and  
21 experience requirements for AU eligibility by that  
22 certification board and that AU eligible certificate  
23 would fulfill the requirements of the Board  
24 certification pathway. And it was intended again to  
25 then -- what this means -- preserve the primacy of the

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1 Board certification pathway.

2 DR. MALMUD: Therefore, if I understood  
3 what you just said and what is proposed in the  
4 document that I've looked at, it is that the Boards  
5 themselves would adhere to the alternate pathway  
6 requirements within the Board training program.

7 DR. EGGLI: No, that's actually not the  
8 case.

9 DR. MALMUD: Would you please explain it  
10 again.

11 DR. EGGLI: Okay, that basically the  
12 Boards would train residents or trainees as they  
13 currently do as their programs -- as their programs  
14 are certified to do, maintaining the same kind of  
15 record keeping requirements and I think the primary  
16 difference between the alternate pathway and the Board  
17 certification pathway is the burden of the record  
18 keeping requirements as to exactly what goes on during  
19 the period of training, but that the Boards would  
20 train their residents as they do now, examine their  
21 residents as they do now, but provide a separate  
22 certification that these individuals have met all of  
23 the training and experience requirements for Board  
24 certification and with respect to NRC requirements  
25 would issue a separate AU eligible certificate that

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1 would be issued prior to the final Board certification  
2 certificate.

3 DR. MALMUD: Thank you for clarifying  
4 that. Is there discussion of that proposed solution  
5 that Dr. Eggli's Subcommittee has brought forth?

6 DR. VETTER: This is Dick Vetter. A  
7 question for Dr. Eggli, how does that differ -- I  
8 assume that a candidate would need to complete some  
9 paperwork for the Board to evaluate and how does that  
10 differ from the paperwork for the alternative pathway?

11 DR. EGGLI: The record keeping requirement  
12 for the alternative pathway is fairly rigorous on the  
13 distribution of the training components and I don't  
14 believe the Boards are required to maintain  
15 documentation at that level of detail. The Boards  
16 have told the NRC that their training program complies  
17 with all the requirements of 10 CFR 190, 10 CFR 290,  
18 10 CFR 390 as relevant, but they are not required to  
19 document exactly how they achieve that training to  
20 meet those requirements. So the program directors  
21 document to the American Board of Radiology that the  
22 residents have met the training requirement. But  
23 documentation -- the detailed documentation that's  
24 required by the alternate pathway is not required in  
25 the Board certification pathway.

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1 DR. MALMUD: Thank you, Dr. Eggli. Has  
2 NRC staff agreed with that observation?

3 MR. EINBERG: Dr. Malmud, we're still  
4 evaluating the report and we haven't had a chance to  
5 take a position on it yet.

6 DR. MALMUD: Okay, so this is a  
7 recommendation from Dr. Eggli's Subcommittee, but it  
8 has not yet been totally evaluated by NRC staff.

9 MR. EINBERG: That's correct.

10 DR. THOMADSEN: Dr. Malmud?

11 DR. MALMUD: Yes, who is speaking, please?

12 DR. THOMADSEN: Bruce Thomadsen.

13 DR. MALMUD: Yes, Bruce.

14 DR. THOMADSEN: Does the ADR have  
15 clarification on the documentation requirement  
16 compared to the alternate pathway?

17 DR. MALMUD: May we address that question  
18 to someone from the ABR?

19 MR. BECKER: Is Mickey on? Did we lose  
20 Mickey Guiberteau?

21 DR. MALMUD: Dr. Guiberteau? I think we  
22 might have lost him.

23 DR. GUIBERTEAU: Who's that? I'm sorry, I  
24 punched the wrong button. I was punching the mute  
25 button to speak and --

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1 DR. MALMUD: Mickey?

2 DR. GUIBERTEAU: Yes.

3 DR. MALMUD: There's a question as to  
4 whether or not the ABR has had a chance to review the  
5 recommendation of Doug Eggli's Subcommittee.

6 DR. GUIBERTEAU: Yes, we've basically been  
7 moving in this direction in terms of supporting this  
8 proposal by actively changing some of our policies in  
9 terms of when to provide a certificate, our  
10 willingness to provide a certificate stating that one,  
11 we have received assurance, as we now do from the  
12 training programs that the candidates have completed  
13 their training and experience; and two, they have  
14 finished the exam related to radiation safety as per  
15 the NRC curriculum as expanded by the radiological  
16 experience, in providing that certificate at the time  
17 they actually finish their training, rather than  
18 waiting until they finish their additional post-  
19 residency experience for another 15 months.

20 Essentially nothing has changed in terms  
21 of the record keeping would change in terms of the  
22 record keeping of the Boards. It would simply be an  
23 opportunity because the reason this pathway has been -  
24 - for residency has changed, in terms of the Board  
25 examination is to come in line with many other medical

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1 specialties who require an additional year of  
2 experience before they take their final clinical  
3 boards. But in actuality, all we're really doing is  
4 decoupling the certificate that we now give with AU  
5 eligibility, dividing that into two parts.

6 We would give the AU eligible part when it  
7 is -- everything has been complied with like we now do  
8 and the clinical part of that, 15 months later.

9 So essentially, it's just dividing our current  
10 certificate into two parts.

11 DR. MALMUD: Thank you for that  
12 explanation.

13 Doug?

14 MR. PFEIFFER: Dr. Malmud, this is Doug  
15 Pfeiffer with AAPM, may I ask a question?

16 DR. MALMUD: Please do.

17 MR. PFEIFFER: Would these AU certificates  
18 have some sort of time limitation on them? If an  
19 individual should complete the training portion, but  
20 then is unable to make it through the certification  
21 process then, is there some method for revoking that  
22 AU status?

23 DR. GUIBERTEAU: This is Mickey  
24 Guiberteau. We haven't discussed that in terms of how  
25 that would come about. We actually are open to

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1 suggestions, but principally are interested in taking  
2 this one step at a time. But I do understand your  
3 question.

4 DR. EGGLI: Leon, this is Doug Eggli to  
5 respond to that?

6 DR. MALMUD: Yes, Doug.

7 DR. EGGLI: Again, come back to the  
8 primary difference between the alternate pathway and  
9 the Board certification pathway is the burden of  
10 record keeping. What the NRC has said is that based  
11 on the -- my interpretation of what the NRC is saying  
12 to the Boards is that based on their submission they  
13 believe that the Boards' mandated training program  
14 meets all the requirements for AU status.

15 It is the intent of the Subcommittee that  
16 this decoupled certificate would serve permanently as  
17 having met all the training and experience  
18 requirements to be an authorized user and in fact, the  
19 final Board certification is a clinical statement and  
20 not necessarily relevant, so that the AU eligible  
21 certification stands on its own as the certification  
22 document that fulfills the requirements of the Board  
23 certification pathway.

24 DR. MALMUD: Thank you for that  
25 clarification.

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1 DR. LIETO: Dr. Malmud?

2 DR. MALMUD: Yes, who is speaking?

3 DR. LIETO: This is Ralph Lieto. I would  
4 also like to support Dr. Eggli's statement in that I  
5 would not be in favor of having this training and  
6 experience if the candidate has met those  
7 requirements, just by failure maybe to complete the  
8 Board certification requirements, they've already  
9 demonstrated that they've met the radiation safety  
10 aspects which is basically what this first part would  
11 address before they completed that 15 months' clinical  
12 requirement.

13 So if they've met the requirements for  
14 that radiation safety aspect, it should not be  
15 rescinded just because they didn't pass the Board  
16 certification aspects of it that come later on.

17 DR. MALMUD: Thank you for that supportive  
18 statement, Ralph.

19 Other comments?

20 DR. GUIBERTEAU: This is Mickey Guiberteau  
21 again. I think what Ralph is saying and what the  
22 Committee's intent was as Doug has said is that  
23 currently the NRC has said that competence in clinical  
24 practice is not its concern, that it is with the  
25 safety aspects and that's what the original

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1 certificate, the initial certificate the NRC eligible,  
2 AU eligible certificate would be. And the clinical  
3 certificate would come after.

4 So in that sense, any expiration of that  
5 certificate would be whatever the expiration, would be  
6 under the current portion of the rule that deals with  
7 obtaining AU status within a specific time period.

8 DR. MALMUD: Thank you. Other comments?

9 MS. CASEY: This is Colleen in Region III.

10 DR. MALMUD: Yes.

11 MS. CASEY: I've been listening carefully  
12 to what you're saying and I'm just offering some  
13 observations and thoughts. I'm a Materials Licensing  
14 Reviewer here.

15 Would it be possible for the -- let's say  
16 the first level certificate that is granted after the  
17 physician's training and experience is completed,  
18 could there be a time-limited provisional certificate  
19 that would have a built-in expiration of say a certain  
20 number of years, dependent upon the completion of the  
21 exam. And say if the exam is not completed  
22 successfully within a time frame of say three to five  
23 years, then that certificate expires.

24 DR. EGGLE: Leon, this is Doug Eggle to  
25 respond.

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1 DR. MALMUD: Please do.

2 DR. EGGLI: Again, the final half of that  
3 certification is purely clinical. What essentially we  
4 are asking the Board to do is to divide their  
5 certification process, to earlier on issue a final  
6 certification on the training and experience related  
7 to radiation safety and that is a final certification  
8 for that component of their training.

9 The other component is clinical and not  
10 related and so the training and experience certificate  
11 expires as all training and experience certificates  
12 expire currently, seven years after the date of the  
13 awarding of the certificate. I don't think any other  
14 pulling back is required because clinical competence  
15 is not required to achieve authorized user status.  
16 Ability to safely handle radioactive materials is  
17 required. And that's what, again, the alternate  
18 pathway does not require demonstration of clinical  
19 competence.

20 The Board certification pathway, again,  
21 the training and experience requirements are  
22 functionally, except for the record keeping identical  
23 to the alternate pathway and if you can achieve  
24 authorized user status in the alternate pathway  
25 without Board certification you should be able to

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1 achieve authorized user status effectively in the  
2 Board's certification pathway if the Board certifies  
3 the training and experience without completion of the  
4 final clinical component of that Board certification.

5 So again, what we're talking about is  
6 splitting the Board certification in two and offering  
7 effectively two separate certifications: one  
8 certification applying to the NRC authorized user  
9 status and the second certification applying to  
10 completion of the clinical part of the training.

11 DR. MALMUD: Thank you. Colleen, does  
12 that clarify anything for you?

13 MS. CASEY: Yes, I suppose it does. I  
14 guess what concerns me a little bit is we're deviating  
15 from what we do with other Board certifications and so  
16 that just naturally gives me a little pause, but I  
17 certainly don't want to see us impact patient care,  
18 none of us do.

19 DR. EGGLI: Leon, can I respond again?

20 DR. MALMUD: Please do.

21 DR. EGGLI: And I apologize that this  
22 didn't get out in time for all of the NRC people to  
23 review it in detail, but this is a solution designed  
24 to address the immediate problem of the American Board  
25 of Radiology.

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1 I see it as portable to any certification  
2 board that sees any problem between the time gaps is  
3 to split their certification process.

4 Other Boards may not have a similar time  
5 gap problem, but if they do this solution isn't  
6 designed for the American Board of Radiology. This  
7 solution is designed for any recognized Board where  
8 there is a time gap between completion of training and  
9 obtaining the final clinical certification status.

10 So this is not just American Board of  
11 Radiology and I don't think it's been splitting the  
12 Board recognition process. It's essentially  
13 redefining the Board recognition process to allow  
14 Boards to split the clinical and the safety  
15 certifications.

16 DR. MALMUD: Thank you, Dr. Eggli. So  
17 what you're saying is that the proposal is immediately  
18 applicable to the American Board of Radiology, but  
19 will be similarly applicable to other Boards?

20 DR. EGGLI: Yes, sir.

21 DR. MALMUD: Thank you. I'm going to put  
22 you on mute for a second because I can't stop my other  
23 phone from ringing. Okay, we're okay now.

24 I'm back with you. Sorry.

25 DR. EGGLI: Okay, yes, so that's exactly

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1 correct, Leon. The process is extendable to any Board  
2 who might have me to employ it.

3 DR. MALMUD: Thank you. Other comments or  
4 questions?

5 MS. CASEY: This is Colleen Casey again.  
6 So how are we proposing to do this if you meet the  
7 recommendation? Is this a rule making thing?

8 DR. MALMUD: It's a recommendation from  
9 the ACMUI.

10 DR. EGGLI: But to answer, this is Doug  
11 Eggli, to answer Colleen's question directly, yes.  
12 And the reason that we pushed ahead on this was so  
13 that if appropriate, it could make the next rulemaking  
14 cycle. But I think again, Headquarters staff could  
15 speak to this more effectively than I could, but I  
16 believe this could potentially require rulemaking.

17 DR. HOWE: This is Dr. Howe at  
18 Headquarters. I think we have to look at it more  
19 carefully. If you're proposing that there are two  
20 Board certifications, one is a Board certification of  
21 radiation safety and the clinical work that has to go  
22 with the radiation safety component because clinical  
23 experience is part of the supervised work experience,  
24 then -- and you're asking us only to recognize that  
25 certification, we would not look at the certification

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1 that tested the clinical -- that focused more on the  
2 clinical side of it.

3 So I don't know whether we have to do  
4 rulemaking or we would just have to reevaluate  
5 submissions.

6 DR. MALMUD: Dr. Howe, would you be  
7 evaluating that in the near future?

8 DR. HOWE: It depends on what we receive.  
9 I mean we have certain criteria now that are in place  
10 in the regulation. If what is submitted can fit the  
11 regulations as they are currently written, then we  
12 would not need rulemaking, but we would not  
13 necessarily recognize the Board certification document  
14 as it currently exists if the Board changed that  
15 document to fit the radiation safety only part.

16 DR. LIETO: Dr. Malmud, this is Ralph  
17 Lieto.

18 DR. MALMUD: Yes.

19 DR. LIETO: I'm not quite sure if I  
20 understood what Donna-Beth was saying. Are you  
21 saying, it's not two separate Board certificates, I  
22 mean two different certifications. It's just that the  
23 process is split into two. They would complete that  
24 radiation safety piece which is required to document  
25 the training and experience requirements for the

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1 authorized user earlier than they would receive the  
2 final certificate of Board certification which  
3 documents the completion of the clinical aspect.

4 So it's -- Dr. Eggli, correct me if I'm  
5 wrong, it's not anything that has been different in  
6 the past other than the record keeping aspect of --  
7 excuse me, the documentation of the record keeping  
8 aspect.

9 DR. EGGLI: Yes, and this is Doug Eggli, I  
10 guess again, the question would come back to NRC, if  
11 NRC was willing to accept the AU certification as a  
12 legitimate document for the Board certification  
13 pathway, then I guess no rulemaking would be required.

14 But in the worst case scenario, it could require and  
15 conceivably rulemaking if you don't see it that way.

16 DR. MALMUD: This is Malmud. If I may,  
17 Donna-Beth, it seems to me that this is unique way of  
18 avoiding the terminology of Board eligibility which  
19 doesn't exist in the eyes of the NRC by producing two  
20 certificates for each candidate, potentially, from the  
21 ABR. And therefore, it might avoid the issue of  
22 rulemaking, given our concern about introducing a new  
23 term. But that will have to be reviewed by you and  
24 the NRC staff and NRC legal to see if that would be  
25 acceptable.

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1 DR. HOWE: I also think that the  
2 Subcommittee draft report needs to be clearer on what  
3 Dr. Eggli was describing. Dr. Eggli was describing  
4 two separate documents.

5 DR. EGGLI: This is Doug Eggli, that's why  
6 this document carries the label draft.

7 DR. HOWE: Yes. That's my point. You  
8 would have to really clarify what it was you were  
9 looking for and what it is you expected us to  
10 evaluate and to recognize.

11 DR. EGGLI: This is Doug Eggli again, I  
12 hope to use this discussion today to produce the final  
13 document, to have the input of the Committee and NRC  
14 staff and I do appreciate that input and the document  
15 can be made more specific, but this -- it was called a  
16 draft today so that it was a topic for discussion to  
17 be -- then to be tuned up as required to be submitted  
18 as a final recommendation.

19 DR. MALMUD: This is Malmud again. Doug,  
20 would you be seeking some input from a member of NRC  
21 staff to help you with the draft?

22 DR. EGGLI: I would be very happy to have  
23 a formal review by NRC staff to make it clear what  
24 they want to see in a final draft.

25 DR. MALMUD: Do we have some NRC staff who

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1 might be able to give Dr. Eggli some time to flesh out  
2 the document together?

3 MR. EINBERG: This is Chris Einberg.  
4 We're just discussing that here. I'm not sure that we  
5 can draft a report together like that. I think the  
6 report has to come from the ACMUI as your  
7 recommendation.

8 DR. MALMUD: Okay, so it appears then that  
9 the ball is back in Dr. Eggli's court. And he'll  
10 flesh it out, send it to you, let you make your  
11 comments and then send it back to him.

12 DR. EGGLI: This is Doug Eggli again. Is  
13 there -- Chris, is there any problem with you verbally  
14 telling me where your threshold is?

15 MR. EINBERG: We can certainly do that and  
16 we can answer any questions you have. You can work  
17 with our staff here.

18 DR. EGGLI: Who would you identify for  
19 conversation about this, a staff member that I should  
20 use as a contact point?

21 MR. EINBERG: Right now, I would say to  
22 contact Cindy Flannery and Cindy will -- if need be,  
23 she will parse it out to somebody on the team.

24 DR. EGGLI: Okay, that's very good. thank  
25 you.

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1 DR. HOWE: Dr. Eggli, I have a question.  
2 We don't have exactly the same requirements for Boards  
3 that we have for the alternate pathway in that we  
4 don't require a minimum number of hours for the  
5 classroom, laboratory, didactic training.

6 DR. EGGLI: I understand and it's -- but  
7 as I see it, what the Boards have certainly agreed to  
8 do is to meet the spirit of the regulation in their  
9 training to provide all that regulation and again,  
10 what I think we're saying is that the document that  
11 the Board will produce is a Board certification type  
12 document for that part of the training.

13 DR. HOWE: Dr. Eggli, let me finish. My  
14 -- I think we need to address what happens to those  
15 individuals that go through your training program and  
16 don't receive the certification for the radiation  
17 safety.

18 DR. EGGLI: Yes.

19 DR. HOWE: They're disenfranchised.

20 DR. EGGLI: Yes, let me tell you now how I  
21 see that and see if any of my Subcommittee members  
22 disagree with me. If a candidate in a program that  
23 leads to a certification by one of the recognized  
24 Boards fails to achieve that authorized user status  
25 eligible certificate from the Board, then they would,

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1 if they were going to become an authorized user, those  
2 individuals would have to have a higher quality of  
3 documentation to take them down the alternate pathway.

4 DR. GUIBERTEAU: This is Mickey  
5 Guiberteau. I agree with Doug.

6 Currently in the process if someone in  
7 terms of our examination process does not pass the AU  
8 eligible portions of our examination process, they get  
9 a certificate that does not have AU eligible on it.  
10 And it would essentially be simply because either one,  
11 they did not submit or their program did not submit  
12 the appropriate attestations as to completion of the  
13 training which would make them ineligible to receive  
14 AU eligible portion on their certificate or they did  
15 not pass that portion.

16 If they're eligible and didn't pass, they  
17 do have a way to remediate that by taking a special  
18 examination, but essentially what Doug is saying is  
19 it's true, that basically you have to fulfill all the  
20 requirements and pass the appropriate examinations  
21 before an AU eligible certificate would be given.

22 DR. MALMUD: Thank you, Dr. Guiberteau.  
23 So if I may try to summarize the recommendation, it  
24 would be in the best of all situations a candidate  
25 would receive the first certificate, let's call it the

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1 preliminary with having passed the AU requirements as  
2 part of the Board. And then we go on to get the  
3 Board, the full Board certification after the  
4 additional clinical experience.

5 And the second possibility, the candidate  
6 would get part one with the -- as an AU, but would for  
7 some reason either not take or fail the clinical part,  
8 but would still be an AU.

9 The third situation, the individual would  
10 not achieve AU status as part of this or her Board  
11 training program and the certificate which would make  
12 them eligible to take part two, certifying clinical  
13 competence, would also not carry AU authorization in  
14 which that candidate, in order to achieve AU  
15 authorization, would have to take the alternative  
16 pathway.

17 Is that a good summary?

18 DR. GUIBERTEAU: Yes.

19 DR. MALMUD: Thank you. Are there other  
20 comments regarding the report from Dr. Eggli's  
21 Subcommittee?

22 MS. FAIROBENT: Dr. Malmud, Lynne  
23 Fairobent.

24 DR. MALMUD: Yes, Lynne.

25 MS. FAIROBENT: Do you know when the

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1 Subcommittee report will be made available?

2 DR. MALMUD: I'm having a little  
3 difficulty hearing you. There's another conversation  
4 going on in the background. Could you repeat that,  
5 please?

6 MS. FAIROBENT: Sure. I was asking when  
7 the Subcommittee report might be available publicly  
8 for us to be able to read it?

9 DR. MALMUD: That's a good question. I  
10 don't know the answer to it. Who would know the  
11 answer? When can that Subcommittee report which was  
12 distributed to the member of the Committee be made  
13 public?

14 DR. EGGLI: Leon, this is Doug Eggli. I  
15 think within the next day or so I will try to contact  
16 Cindy Flannery and make sure I understand what  
17 potential issues NRC might have and then the  
18 Subcommittee over the next week or two will draft a  
19 final version. Then the question becomes a  
20 parliamentary one. Does the full -- since it's a  
21 Subcommittee report to the ACMUI, my assumption is the  
22 full ACMUI would have to approve the report before it  
23 could be distributed publicly.

24 DR. MALMUD: That is correct.

25 DR. EGGLI: So I think that the

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1 Subcommittee can have a final report ready within a  
2 couple of weeks and then the question is the process  
3 of getting the full ACMUI to accept the report.

4 So one of the questions I guess Leon that  
5 I would like to ask, do any of the ACMUI members have  
6 a significant problem with the proposal as made?

7 DR. MALMUD: Dr. Eggli's question is to  
8 the ACMUI members who are on this conference call.

9 I'll ask the question in this fashion. If  
10 anyone has an issue with the recommendation would he  
11 or she speak up now?

12 DR. LIETO: I have a question for  
13 clarification.

14 DR. MALMUD: This is Ralph Lieto, yes.

15 DR. LIETO: Ralph Lieto, yes. Dr. Eggli,  
16 the Subcommittee is composed of yourself and if memory  
17 serves me right, wasn't it Dr. VanDecker and Dr.  
18 Guiberteau. Was there anybody else?

19 DR. EGGLI: Yes, Dr. Nag.

20 DR. NAG: Subir Nag.

21 DR. LIETO: Okay, my point of  
22 clarification would be if you're going to try to have  
23 this applicable to other Boards outside the ADR, would  
24 it be of value to have either the pharmacy and/or RSO  
25 representatives involved in sort of the review of the

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1 final recommendations before it came back to see if  
2 there would be applicability of those Boards to this  
3 process.

4 DR. EGGLI: Again, Ralph, we tried to  
5 generalize this as best we could. I'd be happy to  
6 have the input of any -- essentially, I'd be happy to  
7 expand the Subcommittee to include anyone else who has  
8 an interest in seeing this final draft before it comes  
9 back to the whole ACMUI.

10 So if Subir is representing radiation  
11 oncology, if Steve would like to see this for -- or to  
12 have more input for the radio pharmacy training. I  
13 guess Dick is our RSO representative. If somebody  
14 wants to do this for medical physics, I'd be happy to  
15 have -- I think we're sort of in the home stretch on  
16 this. I don't think it would be a significant burden  
17 for additional people at this point. I'd be happy to  
18 have -- expand the Subcommittee wherever the ACMUI  
19 would like to see that Subcommittee go.

20 DR. VETTER: This is Dick Vetter. I think  
21 Ralph's suggestion is a good one. That might just  
22 take us one step closer to completion by the time we  
23 reach our meeting in May.

24 DR. EGGLI: I could then -- I will add  
25 Steve for pharmacy. I will add you, Dick, for RSO.

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1 Should I add someone from medical physics? Ralph, do  
2 you want to look for medical physics?

3 DR. LIETO: I would be glad too.

4 DR. EGGLI: Okay, is there anyone else  
5 that you think would be more appropriate?

6 MR. BROGA: Dr. Eggli?

7 DR. EGGLI: Yes.

8 MR. BROGA: Dean Broga with the ABMPI.  
9 I'd be happy to look at it and I'd also like to  
10 suggest to the floor that the bottom line question I  
11 think that's going to be addressed to the NRC starts  
12 off in all these sections with the statement "is  
13 certified by the Medical Specialty Board." What is  
14 the interpretation of that? Does that mean full  
15 certification or whether those Medical Specialty  
16 Boards can certify that the person has met the minimum  
17 requirements? I think that's what the interpretation  
18 is going to come down to, what that statement means.

19 DR. EGGLI: I think you're absolutely  
20 correct on that.

21 Leon, let me ask a question. Can I extend  
22 the Subcommittee beyond the ACMUI?

23 DR. MALMUD: Can you extend the  
24 Subcommittee beyond -- well, we can certainly get  
25 input from non-ACMUI members.

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1 DR. EGGLI: Am I allowed to share the  
2 draft report or does that have to stay internal with  
3 ACMUI or maybe that's a question to the people who  
4 keep us legal in NCR, in NRC, rather.

5 DR. MALMUD: I suspect it's a question for  
6 the NRC because my feeling is that we should be able  
7 to do that, but we need NRC's opinion.

8 May we ask someone from NRC?

9 Cindy? Chris Einberg?

10 MR. EINBERG: Cindy is not here. She's  
11 out ill. Could you please repeat the question?

12 DR. EGGLI: Okay, we are enlarging the  
13 Subcommittee to create the final draft for ACMUI to  
14 approve. Can that draft be shared with someone  
15 outside of ACMUI for input or is it because it's a  
16 Subcommittee report not yet approved by ACMUI as a  
17 whole, are we unable to share it?

18 MR. EINBERG: You're not able to share it.

19 DR. EGGLI: Okay, so we have to share only  
20 with ACMUI?

21 MR. EINBERG: If you want to share it, it  
22 has to be public. If you give it to one person, you  
23 have to give it to all the public.

24 DR. EGGLI: I think the answer is, Leon,  
25 until we come up with a final report, we can't share

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1 it.

2 MS. FAIROBENT: Dr. Malmud, it's Lynne  
3 Fairobent?

4 DR. MALMUD: Yes, Lynne?

5 MS. FAIROBENT: There have been other  
6 ACMUI Subcommittees where you have had non-member  
7 consultants participate in the drafting. I'm thinking  
8 back to the electronic brachytherapy report.

9 DR. MALMUD: Yes, we have had consultants.

10 MS. FAIROBENT: Right.

11 DR. MALMUD: That is correct, and we have  
12 had input.

13 MS. FAIROBENT: Yes.

14 DR. EGGLI: So Leon, I need your direction  
15 on this.

16 DR. MALMUD: I would feel free to ask the  
17 contributions of non-members, but they would not be  
18 official members of the Subcommittee.

19 DR. EGGLI: I understand and I'm okay to  
20 share the document if they are working as a consultant  
21 to the Committee?

22 DR. MALMUD: My understanding is that it  
23 is okay if they are an official consultant to the  
24 Committee.

25 DR. EGGLI: Okay.

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1 DR. MALMUD: But we still need to get  
2 NRC's approval.

3 DR. EGGLI: Okay.

4 MR. LEWIS: This is Rob Lewis. I do not  
5 believe we're thinking off the top of our heads here,  
6 but I do not believe the Committee can take voluntary  
7 consulting services. You have to pay. We have to pay  
8 for people to be consultants to the Committee.

9 DR. NAG: This is Dr. Nag. I have had  
10 been on Subcommittees where I have had consultants and  
11 they were not paid and basically we needed that input  
12 on certain things like the gamma knife and so forth  
13 and there was no payment and they were non-voting  
14 members. We just asked them for their opinion.

15 MR. LEWIS: Let us look into it, I guess.  
16 It's a legal question and we don't have a OGC person  
17 here.

18 DR. EGGLI: Okay, this is Doug Eggli  
19 again. If you send me an email and let me know what  
20 the resolution to that is?

21 MR. EINBERG: We certainly can.

22 MS. GILLEY: Dr. Malmud, this is Debbie  
23 Gilley, may I just make a comment?

24 DR. MALMUD: Yes, Debbie.

25 MS. GILLEY: If for some reason we do need

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1 to go through the rule promulgation process, could we  
2 please include the agreement states in that activity?

3 DR. MALMUD: Absolutely.

4 MS. GILLEY: Thank you.

5 DR. EGGLI: Debbie, this is Doug Eggli,  
6 would you like to be added to the expanded  
7 Subcommittee?

8 MS. GILLEY: Pretty soon that Subcommittee  
9 is going to be the entire ACMUI Committee.

10 DR. EGGLI: I understand that, that's  
11 another interesting point that I'll stay away from.

12 Again, I have no problem with that.

13 MS. GILLEY: I'll be glad to look at what  
14 you all are working on and see if I see any issues  
15 that might have impact for the agreement states.

16 DR. EGGLI: I think that's -- I have had  
17 conversations with particularly people from the  
18 American Board of Nuclear Medicine about the issues of  
19 NRC states versus agreement states and I think it  
20 would be desirable if we could propose a solution that  
21 the agreement states would also find acceptable,  
22 because there's going to be a lot of radiology,  
23 graduating radiology residents who are going to be  
24 working in agreement states rather than NRC states.

25 DR. MALMUD: Yes, thank you. Are there

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1 any other comments regarding the report prepared by  
2 Dr. Eggli and his Subcommittee?

3 If not, I would suggest that we have  
4 completed our agenda which was two items.

5 Is there any other comment that a member  
6 of the Committee or a member of the public and or  
7 course, if NRC staff wishes to make with respect to  
8 this issue?

9 If not, is there a motion for adjournment  
10 of this Committee?

11 DR. VETTER: This is Dick Vetter. I move  
12 to adjourn.

13 DR. MALMUD: Dr. Vetter makes a motion to  
14 adjourn.

15 DR. LIETO: Ralph Lieto seconds.

16 DR. MALMUD: Second. All in favor?

17 (Chorus of ayes.)

18 DR. MALMUD: Thank you all for a very  
19 productive session. We thank Dr. Eggli, in  
20 particular, for his contribution and the members of  
21 his Committee and also to the members of the public  
22 for their participation with us. Thank you all.

23 (Whereupon, the above-entitled matter was  
24 concluded at 2:21 p.m.)

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