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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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1 ALSO PRESENT: (CONT.)

2 RICHARD MORIN, AAPM

3 MIKE PETERS, ACR

4 DOUGLAS PFEIFFER, AAPM

5 AMANDA POTTER, AAPM

6 GLORIA ROMANELLI, ACR

7 KAREN SHEEHAN, Fox Chase

8 HARRY SKENE, Geisinger

9 STEPHEN THOMAS, University of Cincinnati

10 CINDY TOMLINSON, SNM

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P R O C E E D I N G S

1:04 P.M.

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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. EGGLI: Leon, this is Doug Eggli 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. EGGLE: 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. EGGLE: 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. EGGLE: 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. EGGLE: 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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