

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

Title:                   Advisory Committee on the Medical  
                                  Uses of Isotopes

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1 UNITED STATES OF AMERICA  
2 NUCLEAR REGULATORY COMMISSION

3 + + + + +

4 ADVISORY COMMITTEE ON THE  
5 MEDICAL USES OF ISOTOPEs

6 + + + + +

7 TELECONFERENCE

8 + + + + +

9 MONDAY,

10 DECEMBER 13, 2010

11 + + + + +

12 The meeting was convened, at 1:00 p.m. Eastern  
13 Standard Time, Leon S. Malmud, M.D., ACMUI Chairman,  
14 presiding.

15 MEMBERS PRESENT:

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

17 BRUCE THOMADSEN, Ph.D, Vice Chairman

18 DARRELL FISHER, Ph.D, Member

19 DEBBIE GILLEY, Member

20 MILTON GUIBERTEAU, M.D., Member

21 SUE LANGHORST, Ph.D, Member

22 STEVE MATTMULLER, Member

23 CHRISTOPHER PALESTRO, M.D., Member

24 JOHN SUH, M.D., Member

25 MEMBERS PRESENT (CONT'D):

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1 ORHAN SULEIMAN, Ph.D., Member

2 WILLIAM VAN DECKER, M.D., Member

3 JAMES WELSH, M.D., Member

4 PAT ZANZONICO, Ph.D, Member

5 NRC STAFF PRESENT:

6 ROB LEWIS, Director, Division of Materials Safety and  
7 State Agreements

8 CHRISTIAN EINBERG, Designated Federal Officer

9 MICHAEL FULLER, Alternate Designated Federal Officer

10 NEELAM BHALLA

11 JAMES BIGGINS

12 ELVA BOWDEN BERRY

13 LISA DIMMICK

14 ASHLEY COCKERHAM, ACMUI Coordinator

15 JACQUELINE COOK

16 SAID DAIBES, Ph.D

17 JAMES FIRTH

18 CINDY FLANNERY

19 SARA FORSTER

20 SOPHIE HOLIDAY

21 DONNA BETH HOWE, Ph.D

22 PENNY LANZISERA

23 ED LOHR

24 GRETCHEN RIVERA-CAPELLA

25

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1 NRC STAFF PRESENT (CONT'D) :

2 MARIA SCHWARTZ

3 DIANE SIERACKI

4 DAVID SOLORIO

5 KATIE STREIT

6 CATHERINE THOMPSON, Ph.D

7 GLENDA VILLAMAR

8 DUANE WHITE

9 RONALD ZELAC, Ph.D

10 MEMBERS OF THE PUBLIC:

11 JAMES D. ALBRIGHT, NC Dept. of Environmental and  
12 Natural Resources

13 DAVID J. ALLARD, PA Dept. of Environmental Protection

14 CHRISTOFER ALSTON, Georgetown University Hospital

15 MAXWELL AMURAO, Georgetown University Hospital

16 SUE BUNNING, Society of Nuclear Medicine

17 ROBERT E. DANSEREAU, NYS Department of Health

18 WILLIAM DAVIDSON, University of Pennsylvania

19 DEIRDRE ELDER, University of Colorado Hospital

20 NANCY FARRINGTON, Iowa Department of Public Health

21 THOMAS HUSTON, Ph.D, Department of Veterans Affairs

22 KAREN LANGLEY, University of Utah

23 ANDREW MAUER, Nuclear Energy Institute

24 CANDI MCDOWELL, Georgetown University Hospital

25 HERB MOWER, Lahey

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1 MEMBERS OF THE PUBLIC (CONT'D):

2 JOSEPH OCH, Geisinger Medical Center

3 MIKE PETERS, American College of Radiology

4 MELANIE RASMUSSEN, Iowa Department of Public Health

5 GLORIA ROMANELLI, American College of Radiology

6 GEORGE SEGALL, M.D., Society of Nuclear Medicine

7 MICHAEL SHEETZ, University of Pittsburgh

8 CINDY TOMLINSON, American Society for Therapeutic  
9 Radiation and Oncology

10 RICHARD VETTER, Ph.D, Health Physics Society

11 MICHELLE WHITE, DMS Health Technologies

12 JENNA WILKES, Society of Nuclear Medicine

13 SANDY WOLFF, Sentara

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

1:36 p.m.

1  
2  
3 MR. EINBERG: As the Designated Federal  
4 Officer for this meeting, I am pleased to welcome you  
5 to this public teleconference of the meeting of the  
6 Advisory Committee on the Medical Uses of Isotopes.

7 My name is Chris Einberg. I am the chief  
8 of the radioactive materials safety branch, and I have  
9 been designated as the Federal Officer for this  
10 Advisory Committee in accordance with 10 CFR part  
11 7.11.

12 This is an announced meeting of the  
13 Committee. It is being held in accordance with the  
14 rules and regulations of the Federal Advisory  
15 Committee Act, and the Nuclear Regulatory Commission.  
16 The meeting was announced in the November 19th, 2010,  
17 edition of the Federal Register, Volume 75, Page  
18 70955.

19 The function of the Committee is to advise  
20 the staff on issues and questions that arise from the  
21 medical use of byproduct materials. The Committee  
22 provides counsel to the staff, but does not determine  
23 or direct the actual decisions of the staff or the  
24 Commission.

25 The NRC solicits the views of the

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1 Committee, and values their opinions. I request that  
2 whenever possible, we try to reach a consensus on  
3 issues that we will discuss today. But I also  
4 recognize that there may be, there may be minority or  
5 dissenting opinions.

6 If you have such opinions, please allow  
7 them to be read into the record. At this point, I  
8 would like to perform a roll call of the ACMUI  
9 participating today. Dr. Malmud, ACMUI Chairman,  
10 hospital administrator?

11 CHAIR MALMUD: Here.

12 MR. EINBERG: Dr. Bruce Thomadsen, Vice-  
13 Chairman, therapy medical physicist?

14 VICE CHAIR THOMADSEN: Here.

15 MR. EINBERG: Dr. Darrell Fisher, patients'  
16 rights advocate?

17 MEMBER FISHER: Here.

18 MR. EINBERG: Ms. Debbie Gilley, State  
19 Government representative?

20 MEMBER GILLEY: Here.

21 MR. EINBERG: Dr. Mickey Guiberteau,  
22 diagnostic radiologist?

23 MEMBER GUIBERTEAU: Here.

24 MR. EINBERG: Dr. Sue Langhorst, radiation  
25 safety officer?

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1 MEMBER LANGHORST: Here.

2 MR. EINBERG: Mr. Steve Mattmuller, nuclear  
3 pharmacist?

4 MEMBER MATTMULLER: Here.

5 MR. EINBERG: Dr. Christopher Palestro,  
6 nuclear medicine physician?

7 MEMBER PALESTRO: Here.

8 MR. EINBERG: Dr. John Suh, radiation  
9 oncologist?

10 MEMBER SUH: Here.

11 MR. EINBERG: Dr. Orhan Suleiman, FDA  
12 representative?

13 (NO RESPONSE)

14 MR. EINBERG: Okay. Dr. William Van Decker,  
15 nuclear cardiologist?

16 (NO RESPONSE)

17 MR. EINBERG: Okay. Dr. James Welsh,  
18 radiation oncologist?

19 MEMBER WELSH: Here.

20 MR. EINBERG: Dr. Pat Zanzonico, nuclear  
21 medicine physicist?

22 MEMBER ZANZONICO: Here.

23 MR. EINBERG: Okay. We have a quorum, so we  
24 can start, or, proceed. I would also like to note that  
25 Dr. Guiberteau and Dr. Palestro do not have voting

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1 privileges at this time, but they will listen and  
2 speak on behalf of the diagnostic radiologists, and  
3 the nuclear medicine physicians, respectfully.

4 I would now go around the table here, here  
5 at headquarters, and introduce the NRC staff members  
6 and, I'm Chris Einberg. I'm the Branch chief of the  
7 radioactive materials safety Branch, as I've said  
8 earlier.

9 MS. DIMMICK: Lisa Dimmick, licensing  
10 Branch.

11 MR. LOHR: Ed Lohr, rulemaking.

12 MR. BIGGINS: James Biggins, Office of  
13 general counsel, reactor and materials rulemaking.

14 MR. LEWIS: I'm Rob Lewis, Director for  
15 materials safety and state agreement.

16 MS. BHALLA: Neelam Bhalla, from  
17 rulemaking.

18 DR. HOWE: Dr. Donna Beth Howe, and I'm  
19 in the radioactive materials Branch.

20 MS. HOLIDAY: Sophie Holiday from the  
21 radioactive materials Branch.

22 MS. RIVERA-CAPELLA: Gretchen Rivera-  
23 Capella, radioactive materials safety Branch.

24 MR. EINBERG: Okay. Well, also, do we have  
25 anybody from the NRC headquarters on the phone? I know

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1 we have Ashley Cockerham, do we have anybody else?

2 DR. DAIBES: Yes, Said is here, as well.

3 Said Daibes here from headquarters.

4 MR. EINBERG: Okay.

5 DR. ZELAC: Also, Dr. Ron Zelac, medical  
6 radiation safety team.

7 MR. EINBERG: Okay, thank you.

8 MS. COCKERHAM: Guys, this is just  
9 confirming I'm on the line. This is Ashley.

10 MR. EINBERG: Thank you.

11 MS. FLANNERY: Cindy Flannery, FSME.

12 MR. EINBERG: Thank you. Anybody else from  
13 headquarters? Okay. Nobody else from headquarters.

14 Now, I'd like to go to Region 1. Can Region 1 identify  
15 who is participating, please?

16 MS. LANZISERA: Penny Lanzisera, from  
17 Region 1.

18 MR. EINBERG: Penny, are you there by  
19 yourself, or, anybody else with you?

20 MS. VILLAMAR: I am. This is Glenda. I just  
21 signed in.

22 MR. EINBERG: Okay. Thanks, Glenda. Okay,  
23 I'd like to go to Region 3 now. Region 3, do we have  
24 any, anybody on the line?

25 MS. STREIT: This is Katie Streit with

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1 Region 3.

2 MR. EINBERG: Okay. Anybody else from  
3 Region 3? Okay. Let's go to Region 4 now. Who's on the  
4 line from Region 4?

5 MS. COOK: Jackie Cook from Region 4.

6 MR. EINBERG: Thank you. Okay. Next, we, we  
7 will identify members of the public who notified us  
8 that they will be participating with the  
9 teleconference. When I call your name, please answer.  
10 Let me go through that list. James Albright?

11 MR. ALBRIGHT: I'm here, thank you very  
12 much.

13 MR. EINBERG: Very good, thank you. And  
14 Dave Allard, Pennsylvania Department of Environmental  
15 Protection?

16 MR. Allard: Yes, I'm here.

17 MR. EINBERG: Okay, thank you. Chris--  
18 Christofer Alston, Georgetown University hospital?

19 MR. Alston: Here.

20 MR. EINBERG: Okay, and Maxwell Amurao,  
21 Georgetown University hospital as well?

22 MR. AMURAO: Yes.

23 MR. EINBERG: Sue Bunning, from SNM?

24 MS. BUNNING: I'm here.

25 MR. EINBERG: Randy Dahlin, Iowa Department

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1 of Public Health?

2 (NO RESPONSE)

3 MR. EINBERG: Robert Dansereau, New York  
4 State Department of Health?

5 MR. DANSEREAU: I'm here.

6 MR. EINBERG: William Davidson, University  
7 of Pennsylvania?

8 MR. DAVIDSON: Here.

9 MR. EINBERG: Deirdre Elder, University of  
10 Colorado Hospital?

11 MS. ELDER: Here.

12 MR. EINBERG: Nancy Farrington, Iowa  
13 Department of Public Health?

14 MS. FARRINGTON: Here.

15 MR. EINBERG: Dr. Michael Hagan, Department  
16 of Veteran's Affairs?

17 (NO RESPONSE)

18 MR. EINBERG: Dr. Thomas Huston, Department  
19 of Veteran's Affairs?

20 DR. HUSTON: Here.

21 MR. EINBERG: Karen Langley, University of  
22 Utah?

23 MS. LANGLEY: Here.

24 MR. EINBERG: Dr. Edward Maher, HPS?

25 (NO RESPONSE)

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1 MR. EINBERG: Andrew Mauer, NEI?

2 MR. MAUER: Here.

3 MR. EINBERG: Candi McDowell, Georgetown  
4 University Hospital?

5 MS. MCDOWELL: Here.

6 MR. EINBERG: Janette Merrill, Society of  
7 Nuclear Medicine?

8 (NO RESPONSE)

9 MR. EINBERG: Janette Merrill, Society  
10 of Nuclear Medicine?

11 (NO RESPONSE)

12 MR. EINBERG: Herb Mower, Lahey?

13 MR. MOWER: Here.

14 MR. EINBERG: Joseph Och--Och?

15 MR. OCH: Here.

16 MR. EINBERG: Was that a yes, here?

17 MR. OCH: Here.

18 MR. EINBERG: Yes, okay. Melanie  
19 Rasmusson?

20 MS. RASMUSSON: Here.

21 MR. EINBERG: Dr. George Segall?

22 DR. SEGALL: Here.

23 MR. EINBERG: Michael Sheetz?

24 MR. SHEETZ: Here.

25 MR. EINBERG: David Switzer? Minneapolis

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1 Radiation Oncology?

2 (NO RESPONSE)

3 MR. EINBERG: Cindy Tomlinson?

4 MS. TOMLINSON: Here.

5 MR. EINBERG: Dr. Richard Vetter?

6 DR. VETTER: Here.

7 MR. EINBERG: Gerald A. White?

8 (NO RESPONSE)

9 MR. EINBERG: Michelle White?

10 MS. WHITE: Here.

11 MR. EINBERG: Jenna Wilkes?

12 MS. WILKES: Here.

13 MR. EINBERG: And, Sandy Wolff.

14 MS. WOLFF: I am here.

15 MR. EINBERG: Very good. We have another

16 person who joined us also. Can you please identify

17 yourself?

18 MS. BOWDEN BERRY: I'm Elva Bowden Berry,

19 and I'm from OGC.

20 MR. EINBERG: Okay, thank you.

21 MS. ROMANELLI: Gloria Romanelli with ACR,

22 as well.

23 MR. EINBERG: Okay. Thank you. Is there

24 anybody else who we didn't call?

25 MEMBER SULEIMAN: Yes, Orhan Suleiman, I'm

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1 with the ACMUI and FDA Center for drugs.

2 MR. EINBERG: Okay, thanks for joining us,  
3 Orhan. This is, double check--do we have Dr. Van  
4 Decker on the line? We do not. At this time, I ask  
5 that everyone on the call who is not speaking to place  
6 their phones on mute or pause. If you do not have the  
7 capability to mute your phone, press star-6 to utilize  
8 the conference line mute and unmute functions.

9 I would ask everyone to exercise extreme  
10 care to ensure that the background noise is kept to a  
11 minimum as any strange background sounds can be very  
12 disruptive on conference calls this large.

13 Following a discussion of each agenda  
14 item, the ACMUI chairperson, Dr. Leon Malmud, at his  
15 option, may entertain comments or questions from  
16 members of the public who are participating with us  
17 today.

18 And, at this point, I'd like to turn the  
19 meeting over to Rob Lewis. He has a few opening  
20 statements before he turns it over to Dr. Malmud.

21 MR. LEWIS: Thank you, Chris. Thank you  
22 everyone for participating. I will keep this very  
23 short. There's four topics on today's agenda. Our  
24 first is trying to improve our interactions with the  
25 Committee between the Committee and the NRC staff,

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1 something we always need to focus on.

2 Also, we have an extended discussion on  
3 patient release issues. Our Part 37 Rulemaking, which  
4 is our new regulation to have security requirements  
5 for sources of radioactive materials. And last we have  
6 a discussion on, ongoing discussion on our safety  
7 culture policy statement.

8 Those are four issues for which we are  
9 very eager to collect the Committee's views so we can  
10 move those forward within NRC. So, so I won't speak  
11 much longer. I just wanted to mention, since it is a  
12 phone call, please be mindful to identify yourself  
13 when you speak. It's a little more difficult  
14 to manage especially for the transcriber than the,  
15 typical meeting.

16 And also, one management change here of  
17 note. Since the Committee last met, Cindy Carpenter,  
18 who is the Deputy Office Director under Charlie  
19 Miller, has gone to do a special project for another,  
20 for the EDO within the agency, the Executive  
21 Director of Operations, and that project is focused on  
22 reducing the NRC's overhead and budget space.

23 So, she'll be gone doing that for at least  
24 six months. It's an agency wide project, and back  
25 filling for her during that time is Mr. Scott Moore,

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1 who many of you may remember came from NMSS. His  
2 current full time job is the Deputy Director for NRC's  
3 Office of International Programs, but at least for the  
4 next six months, he'll be the Deputy Office  
5 Director here in FSME.

6 So, with that, I will turn the meeting  
7 over to Dr. Malmud. And, and thank you very much.

8 CHAIR MALMUD: Thank you, Rob. This is Leon  
9 Malmud. I was introduced, first item on the agenda is  
10 that of the NRC interactions with staff for major  
11 medical policy. In plain English, it really is an  
12 opportunity to express our thoughts about how we, the  
13 ACMUI, interact with NRC.

14 In the past, there were some very  
15 constructive comments made regarding ways of improving  
16 that interaction, and currently, the, some of the  
17 problems that existed then have been resolved.  
18 However, this is an opportunity for those of us  
19 currently on the Committee to express our feelings and  
20 make recommendations regarding ways in which the  
21 communication can be improved.

22 So, rather than introducing it myself, I  
23 would invite any Member of the Committee to open the  
24 discussion, if he or she wishes to. If not, I'll open  
25 the discussion.

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1 VICE CHAIR THOMADSEN: I think that--this  
2 is Bruce Thomadsen. I had been involved with  
3 coordinating some work on the official policy that  
4 would guide the relation between the Committee and the  
5 NRC staff.

6 The members of the Committee have looked  
7 at the policy and have commented, I believe, that all  
8 of the communication about this have been made  
9 available and there has been a document that  
10 incorporates all of the comments from the Committee  
11 that we would propose sending to the NRC staff on  
12 formalizing the arrangement.

13 CHAIR MALMUD: Malmud again. Thank you,  
14 Bruce. That document was emailed, I believe, to all  
15 the members of the Committee. Is there anyone on the  
16 Committee who has not received it?

17 (NO RESPONSE)

18 CHAIR MALMUD: Hearing no response, I  
19 assume that everyone has received it. I would like to  
20 therefore follow up on Bruce's comments and the email  
21 with the following. I, I have met, following the last  
22 meeting, I, which I could not remain at due to a short  
23 term illness, I had the opportunity to meet with the  
24 Commissioners.

25 I met with three and one staff person. I

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1 would make the following comments. Number one, the  
2 Commissioners are very well informed about what we're  
3 discussing within ACMUI. I was quite frankly surprised  
4 that they were as knowledgeable as they are,  
5 considering the breadth of their portfolios.

6 But, they are well informed. They also  
7 appreciate the work that the ACMUI does, and feel that  
8 if we are concerned about getting the message that we  
9 wish to get to them, delivered, more promptly and  
10 perhaps more effectively, that they are, they remain  
11 available for direct meetings with me as the Chairman  
12 or any subsequent Chairmen in order to effect that.

13 The, the issues that I raised with them  
14 were several. The first, of course, was that the ACMUI  
15 has felt that when we make a recommendation, and it  
16 isn't adopted, that we would appreciate knowing why it  
17 wasn't adopted and hearing about it in a timely  
18 fashion.

19 A lot of effort goes into our  
20 recommendations. They are often discussed over the  
21 period of a year or more at our biannual meetings and  
22 therefore there is a sensitivity with respect to  
23 whether or not the advice is accepted. Clearly, we do  
24 not assume the responsibility for the final decision,  
25 the Commissioners do.

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1                   But we would like to know why  
2                   recommendations that were not accepted were rejected.  
3                   We are satisfied, I believe I spoke on behalf of the  
4                   Committee, that we are satisfied in knowing why, when  
5                   the Committee, when the Commissioners choose to accept  
6                   a recommendation from us. It's the ones where we  
7                   differ that we seem to have a need for more feedback.

8                   That was one issue. The other issues that  
9                   were raised had to do with the staffing of the ACMUI  
10                  and the feelings of some of the Committee members that  
11                  we might be better off reporting in a more direct line  
12                  than, as the Committee, we are. I discussed this  
13                  with each of the Commissioners, and they are  
14                  interested in hearing more about it from us.

15                  I think that there are some realities  
16                  which I brought up to them and which they did not deny  
17                  existed, and that is that it would be more costly,  
18                  certainly, to staff up in the way another body does.  
19                  And, it would be more costly for us to have fixed  
20                  conference rooms dedicated just for us, which was one  
21                  of the requests which had come from some of the  
22                  Committee members, who I believe have subsequently  
23                  rotated off of the Committee.

24                  And therefore, in this, in the current  
25                  budget mood of the entire country, adding expenses is

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1 probably not something that would finally be approved,  
2 but they were not negative about hearing our concerns.  
3 The turnaround time if we used a method similar to the  
4 ACRS, would not be improved.

5 I, I--perhaps I shouldn't use the term  
6 improved. It would not be very different from the  
7 turnaround time now, and that has to do with the  
8 frequency with which we meet, as well as the need to  
9 go through staff. So, that, I'm not certain that the  
10 concerns about turnaround time would be met by  
11 changing us to a reporting mechanism similar to ACRS.

12 I did say, and I think I spoke for all of  
13 us, I, I did say very strongly that we do feel that  
14 the ACMUI needs more staff, that it's been my pattern,  
15 since I've been Chair, to delegate most discussions to  
16 subcommittees, and these subcommittees do  
17 extraordinary amounts of work with most of the work  
18 being done by the members of the ACMUI, with the need  
19 for more support staff.

20 Currently, our support person, at least,  
21 the person we look to for our support, is Ashley, who  
22 seems to be omnipresent and an extraordinary  
23 individual who is, who handles perhaps more work than  
24 we've ever asked any other person in her position to  
25 handle, and she does it.

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1                   But it's quite clear to us that the  
2 subcommittees need some more staff support in  
3 producing their documents, particularly, I said that  
4 this might be addressed by even having someone to  
5 assist with email communications, since we don't have  
6 that now.

7                   The--those were the major issues. The, the  
8 feelings of the Commissioners are very supportive of  
9 us, they are very appreciated of the work that we do,  
10 and I would ask for comments from members of the  
11 Committee at this point.

12                   So, I discussed the ACMUI recommendations,  
13 and our concern about hearing back when they're not  
14 accepted. I discussed the turnaround time, the support  
15 staff, and the concern that at least one or two of the  
16 previous members of the Committee had that our  
17 recommendations were quote, filtered, end quote,  
18 before reaching the Commissioners.

19                   I must tell you that from my initial  
20 conversation which each of them--with each of them, I  
21 did not have the feeling that anything has been  
22 filtered. They seemed extraordinarily well informed.  
23 I am therefore inviting comments from members of the  
24 ACMUI.

25                   DR. ZANZONICO: Well, this is Pat

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1 Zanzonico. I was glad to hear, Dr. Malmud, about your  
2 opportunity for direct communications with the, with  
3 the Commissioners and the only suggestion I had, and  
4 I think I had communicated this previously over the  
5 draft document is if that could be incorporated  
6 formally into that document, that, that a mechanism  
7 exists or is available for direct communication  
8 between the ACMUI, whether it's through the Chair or  
9 otherwise, with the Commissioners. That kind of  
10 formal inclusion of that variability doesn't seem to  
11 be incorporated into the draft of the policy.

12 CHAIR MALMUD: Thank you. We certainly  
13 could include that, if you wish. We do have the  
14 opportunity now, already, for a, I think they call it  
15 a drop in, and I've been invited to do a drop in again  
16 whenever we feel a sense of urgency about something.  
17 From my perspective, I, I'm hesitant to drop in on a  
18 Commissioner with something that the ACMUI itself has  
19 not reached some sort of a consensus about.

20 I don't believe that we will, that the  
21 members of the ACMUI in total, because of the  
22 diversity of the Committee and our own parochial view  
23 of things- though we all agree about our mission- that  
24 we'll ever be necessarily unanimous in anything. But I  
25 am hesitant to bring to the Commissioners something

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1 that we haven't fully discussed.

2           However, if we've fully discussed it, it's  
3 quite clear to me that I, I would, I would be  
4 comfortable bringing it to them and they would be,  
5 they would be receptive to one or several of the  
6 Commissioners giving us audience. I would ask a member  
7 of the NRC staff if my interpretation of my meetings  
8 was, is pretty correct or not.

9           MS. BHALLA: Yes. Dr. Malmud, this is  
10 Neelam Bhalla from NRC.

11           CHAIR MALMUD: Yes.

12           MS. BHALLA: The, what happened was, back  
13 in July when Commission had a meeting, a briefing on  
14 the ME Rule, as part of that, that meeting, the  
15 Commission directed the staff--the Commission directed  
16 the staff to prepare internal staff guidance, actually  
17 a procedure whereby we would convey to the Commission  
18 ACMUI's views including dissenting views on major,  
19 major medical policy issues and rulemaking, including  
20 rulemaking.

21           So, we have the procedure that has been  
22 provided, actually provided to all the members is  
23 actually the procedure which, which is an attempt to  
24 do just that, where we would be, whenever we send  
25 something to the Commission, maybe a rulemaking on

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1 other policy issues where we are looking for  
2 Commission direction, that we do include ACMUI's views  
3 on that, including dissenting views, if any.

4 So, in October, we have provided the draft  
5 guidance and, at that time, the procedure was endorsed  
6 by the ACMUI. And as it moved up the chain here, after  
7 October, we were asked to put a few clarifications in  
8 there, specifically what determines or what makes a  
9 major policy issue.

10 So, in that, we made the change to the  
11 document and then we also discussed a little bit about  
12 the predecisional nature of the document and how we  
13 can make it for ACMUI for potentially make it, you  
14 know, a publically available document because there  
15 are procedural issues involved.

16 So, right now, what the Committee, what  
17 you have in front, or with you is this revised version  
18 of the draft, and we are looking for, for ACMUI to  
19 endorse it. This is precisely, you know, the, the  
20 procedure that we'll be using, where we would be  
21 conveying to the Commission ACMUI's views and how  
22 staff is going to, if we took them in, or if we  
23 didn't, then what's the reason that we didn't.

24 CHAIR MALMUD: Thank you. You're correct,  
25 of course. The term that I had used in my discussions

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1 with the Commissioners was that we would submit a  
2 minority report as well, in those instances in which  
3 the Committee was, was not unanimous in it's  
4 recommendation, so that those on the Committee who,  
5 who had a minority opinion would have the opportunity  
6 to have it seen, although it was not the majority  
7 vote.

8 The issue that, that I have on behalf of  
9 the ACMUI is this. When we do something in the  
10 Subcommittee, it is not official until it's presented  
11 to the Committee in a public meeting. And  
12 therefore, I am concerned about discussing issues that  
13 have not yet been fully discussed at ACMUI in a formal  
14 public meeting.

15 Because, the Subcommittee report, though  
16 it's where a good bit of the work is done, is still  
17 not officially presented until it's at a full meeting  
18 with the public--in a public forum. But, having said  
19 that, the document that was prepared I think covers  
20 the, the concerns that I had heard from the members of  
21 the Committee.

22 And what I am asking at this moment is, is  
23 there anyone on the Committee who feels that the  
24 document does not sufficiently incorporate the  
25 concerns that have been discussed? I'm presenting the

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1 question to the members of the Committee.

2 MEMBER LANGHORST: Dr. Malmud, this is Sue  
3 Langhorst.

4 CHAIR MALMUD: Yes?

5 MEMBER LANGHORST: I don't have a concern  
6 about that but I do have a question on how we bring  
7 our opinion that, that we would like to voice on a  
8 certain issue that maybe has not been identified or  
9 presented to us by the NRC.

10 And, and I'm thinking, it's very obvious  
11 that Part 35 rulemaking comes to us. That just has,  
12 you know, little question to it. But, if there are  
13 issues that are in Part 20, or for instance, in  
14 part--the proposed Part 37 that we're going to be  
15 discussing here soon, how do we--how's the best way  
16 for us to--to you and the NRC staff that we would like  
17 to weigh in on, on certain topics?

18 CHAIR MALMUD: Thank you for the question.  
19 The way that I would approach it, and I'll, I'll ask  
20 a parliamentarian or someone from legal to confirm  
21 this, would be for any Member of the Committee to  
22 bring it before the public meeting of the Committee  
23 and request that it be brought before the Commission  
24 in some fashion.

25 At which point, it would have been

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1 expressed publically and the Committee would make  
2 comments about it and then we would or would not take  
3 it forward according to the wishes of the Committee.

4 MR. LEWIS: Dr. Malmud, if I could. It's  
5 Rob Lewis.

6 CHAIR MALMUD: Yes, please, Rob.

7 MR. LEWIS: I would agree 100% with  
8 everything that you just said, although I'm certainly  
9 not from legal department. But, but I think that also  
10 if there's any, any issue that someone feel strongly  
11 about, please raise it immediately, especially if it's  
12 a safety concern.

13 Because, we can get working on it, the NRC  
14 staff, especially if we don't yet have a full  
15 Committee meeting to bring--bring the issue to. Well,  
16 we would bring it to the Committee eventually but we  
17 shouldn't sit out for six months, for example, on a,  
18 on a big issue.

19 So, we do look for the Committee members  
20 to bring those up to us just as we would any other  
21 licensee and, and the process is simple. Just email  
22 Ashley or, or me or any one of our staff here and  
23 we'll get it in the process.

24 The second thing I would like to raise in  
25 that regard, if it's an issue, and I want to reiterate

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1 because there's several members of the, of the  
2 Committee that are new. I want to reiterate something  
3 that I promised several times, and, and also that  
4 Charlie Miller feels very strongly about, and he  
5 promised when he had my position, is that if there is  
6 ever any issue that the Committee or even some sub-  
7 part of the Committee feels that the Commission needs  
8 to know about, we have an open door.

9 We can--you can just write up the issue  
10 and send it in, and we have several very vehicles to  
11 get that before the Commission for information very  
12 quickly. And that--and again, that's an open  
13 invitation to do that. As Dr. Malmud said, every issue  
14 doesn't need to go to the Commission, so we may  
15 certainly want to talk to you a little bit and make  
16 sure your feelings are understood, your, your views  
17 are understood.

18 And, and that it's appropriate to go to  
19 the Commission at, at a certain time. But at the end  
20 of the day, the call would be the Committee members.  
21 And, and that also, that promise also goes for any  
22 meeting. If, if a, if a Committee Member is going to  
23 be in town and, and feels the need to meet with a  
24 Commission or a Commissioner, we're very happy to set  
25 those up.

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1 NRC staff wouldn't be further involved  
2 beyond just setting them up. And the third option that  
3 the Committee always has at it's disposal, and that,  
4 and this comes up in a couple of instances in the  
5 past, is the Committee can, can certainly write a  
6 letter to the Commission, the Chairman and the  
7 Commission.

8 And, and that's come up in the past, and  
9 that is always a vehicle open. That of course has to  
10 happen in, in the letter writing session has to be  
11 part of the public ACMUI meeting to follow the FACA  
12 requirements. But, but that's very, we're very  
13 familiar with that process. The ACRS does that all the  
14 time.

15 So, so if that's ever something that  
16 someone wants to pursue, or any particular issue that  
17 anybody wants to pursue, that, the right time to  
18 interject it, as, as Dr. Malmud said, is during the  
19 agenda planning, right before each meeting. But, but  
20 certainly don't wait until then if it's a big issue.  
21 Thank you.

22 CHAIR MALMUD: Thank you, Mr. Lewis. Does  
23 that address the concern that you've raised?

24 MEMBER LANGHORST: That helps me greatly,  
25 and, and as one of those newer members, that, that

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1 helps me have the process a little bit better in my  
2 mind.

3 CHAIR MALMUD: Thank you. I think that  
4 there, there are really two parallel issues. One is,  
5 a matter of bringing a subject that's been discussed  
6 within the Committee before the Commissioners, and the  
7 other one is the recognition on the part of anyone in  
8 ACMUI of a potential risk to patients or members of  
9 the public that needs to be addressed immediately.

10 And that should, to NRC staff,  
11 immediately. It does not require a process other than  
12 bringing it to their attention if it's an issue of  
13 either patient or public safety. Or security, for that  
14 matter, since we now have other issues to be concerned  
15 about.

16 By the way, I, I neglected to mention that  
17 I also expressed our concern to the Commissioners  
18 about the issue of fingerprinting and a new security  
19 regulations which are going to be costly for  
20 institutions. However, these, these issues are  
21 governed by Homeland Security and not directly by the  
22 NRC.

23 But I did express the frustration and  
24 concerns of the members of the Committee. Is there a  
25 motion to approve the document that's been prepared

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1 and distributed to you by email?

2 VICE CHAIR THOMADSEN: Mr. Chairman, Bruce  
3 Thomadsen. I make that motion.

4 CHAIR MALMUD: Is there a second to Dr.  
5 Thomadsen's recommendation?

6 MEMBER GILLEY: Debbie Gilley. Second.

7 CHAIR MALMUD: Thank you. Is there further  
8 discussion?

9 MEMBER MATTMULLER: Yes. This is Steve  
10 Mattmuller. We're discussing, or, preparing to vote on  
11 the document that Bruce edited and circulated?

12 CHAIR MALMUD: That's correct.

13 MEMBER MATTMULLER: Okay. Great.

14 CHAIR MALMUD: Is there further discussion  
15 of the document, or the need, or a concern about  
16 appending it in any fashion? If not, all in favor?

17 MEMBER: Aye.

18 MEMBER: Aye.

19 MEMBER: Aye.

20 MEMBER: Aye.

21 MEMBER: Aye.

22 MEMBER: Aye.

23 MEMBER: Aye.

24 MEMBER: Aye.

25 MEMBER: Aye.

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1 CHAIR MALMUD: Any opposed?

2 (NO RESPONSE)

3 CHAIR MALMUD: Any abstentions?

4 (NO RESPONSE)

5 CHAIR MALMUD: It passes unanimously. Thank  
6 you. With that, we'll move onto item number two, if  
7 that's acceptable. And item number two is the patient  
8 release following I-131 therapy for thyroid doses.

9 MEMBER LANGHORST: I'll take that on. This  
10 is Sue Langhorst.

11 CHAIR MALMUD: Thank you.

12 MEMBER LANGHORST: First off, I, I do want  
13 to say that it is the report, it concerns patient  
14 release in general, and not just limited to I-131  
15 therapy. However, that was one instance that we  
16 focused upon, so the, it should be patient release  
17 report.

18 CHAIR MALMUD: Thank you.

19 MEMBER LANGHORST: First off, I want to  
20 thank all for the Subcommittee members, especially for  
21 their patience, as we did some reworking of the report  
22 following our presentation of it at the October  
23 meeting and following discussions, great discussions,  
24 in, with the Commissioners.

25 One issue that came up during the October

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1 discussion, which was somewhat surprising to me, was  
2 the confusion over whether the current 10 CFR 35.75  
3 criteria was on a per release or per year basis. As a  
4 result of that, of that identification and especially  
5 the, my understanding that there was confusion over  
6 this, we re-reviewed the final rulemaking notice for  
7 the current part 35.75 criteria.

8 And, added much more reference to that in  
9 our report. When you read the final rulemaking in that  
10 January 29th, 1998 final rulemaking, it is clear that  
11 the current 35.75 Rule is on a per release basis.

12 Confusion I think may have come up with the release of  
13 the regulatory issue summary 2008/07 that was issued  
14 in March of 2008, that said that NRC had met that  
15 criteria to be on a per year basis.

16 And the NRC staff considered, or, or  
17 commented at the Commission hearing, that they  
18 believed the current Rule was on a per year dose  
19 limit. After that discussion and, and Dr. Thomadsen  
20 very wisely suggested that we take some of the  
21 comments that we heard in October and do some rework  
22 on our report, we determined that even in our  
23 Subcommittee's opinion at that point in time that  
24 there was a 50-50 split in really what the current  
25 Rule meant.

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1           And, our Subcommittee came to conclusion  
2 that the basis for the per release limit should not be  
3 changed from that final rulemaking document notice  
4 without further rulemaking and public discussion. We  
5 also discussed that we, what our current opinion was,  
6 and that the vast majority of us believe that the  
7 current 35.75 release criteria should remain as a per  
8 release limit.

9           We did have one dissenting vote in our  
10 Subcommittee who felt that an annual--that a dose  
11 limit without a time frame was not appropriate, but  
12 felt that if any discussion were to happen with a per  
13 year dose limit for release criteria that the amount  
14 of dose, the dose limit itself, should be discussed  
15 and perhaps, increased.

16           So, that discussion was added, and  
17 recommendation added, to the summary item two in the  
18 first bullet in that on page two. And on the second  
19 section on annual versus per release on pages 13  
20 through 15. Dr. Malmud, I'll ask if you want to  
21 discuss this point, or should I go through further  
22 changes in the report?

23           CHAIR MALMUD: Thank you, I'll ask the  
24 members of the Committee if they wish to--anyone  
25 wishes to comment at this point. If not, we'll move on

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1 to the next item.

2 MEMBER LANGHORST: Okay.

3 CHAIR MALMUD: Thank you.

4 MEMBER LANGHORST: We also, our  
5 Subcommittee also had further discussions on patient  
6 release to non-private resident locations, like  
7 hotels. And added that discussion to that section of  
8 the report, which is on page 12. We added a, a  
9 paragraph or actually clarified a paragraph and that  
10 goes on page 12 from lines 400 to 423.

11 Now, as we had this discussion, the  
12 Subcommittee did have different opinions on how best  
13 to address patient release to locations like hotels.  
14 You'll see in the report we had one of our  
15 Subcommittee members who felt it should not be  
16 allowed, another who was questioning whether it should  
17 be allowed.

18 Six of the members felt that it should be  
19 allowed and differed only in how licensees should  
20 control that release. Is there any other--any  
21 questions on that, or shall I continue?

22 CHAIR MALMUD: The items that you're  
23 referring to are on page 12 and lines 400 to  
24 approximately 417?

25 MEMBER LANGHORST: 23. 423. So, let me go

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1 ahead and finish what we have changed. As part of that  
2 added discussion, we expanded what was formerly known-  
3 -called Appendix one, and now is just called the  
4 Appendix. We added a realistic dose calculation column  
5 to tables 1 and 2.

6 And expanded that Appendix discussion to  
7 hopefully be a more standalone section for people to  
8 use in the future. And that Appendix is page, is on  
9 page 20 through 24. We, in our past draft report we  
10 presented to the Committee in October, we had an  
11 Appendix two that was a short summary responding to  
12 specific questions that were raised in what we've been  
13 calling the Markey report.

14 The Subcommittee decided to drop that  
15 short Appendix from this current report, and discussed  
16 developing a separate report with a point by point  
17 response to that Markey report. We added a few  
18 emphasis items on the negative medical impact of the  
19 past 30 millicurie Rule, and that's in several parts  
20 of the report.

21 We strengthened discussion on benefits to  
22 family members for patient release, and that is in  
23 section exposure to other individuals from patients  
24 released from licensee control. That goes from page 3  
25 to 4. There are a few edits throughout the report on

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1 just a little bit different wording.

2 I'm not sure where that comes from, but it  
3 wasn't me. If there's--that's--summary of the changes  
4 that we made in the report.

5 CHAIR MALMUD: Thank you. Are there  
6 comments regarding the report or those changes that  
7 were made?

8 MEMBER GUIBERTEAU: This is Mickey  
9 Guiberteau. I, I just would like to ask Sue, in terms  
10 of the Appendix 2 in response to the Markey letter. I  
11 think the, if I understood what you said, that it was  
12 a recommendation that this be removed and expanded  
13 separately. Is, I mean, what, what was, what was your  
14 intent in terms of separating this from the report?  
15 Did you think this was not extensive enough, or do you  
16 think it served separate emphasis?

17 MEMBER LANGHORST: There has been a  
18 parallel path going on doing, putting together a draft  
19 as far as point by point of all issues for the, for  
20 the Markey report. Quite frankly, we felt that this  
21 report needed to get out, and we weren't sure how  
22 quickly we could finish the, the full response to the  
23 Markey report, although we feel that the issues that  
24 we raise in this current patient release report  
25 addresses all of the concerns as far as release

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1 criteria goes. It doesn't necessarily deal with  
2 process, NRC process concerns that were raised in the  
3 Markey report.

4 MEMBER GUIBERTEAU: Okay. And, and, and was  
5 it also a feeling that this might separate some of the  
6 more controversial areas of I-131 as the report has  
7 essentially been refocused to address patient release  
8 in, in, you know, multi radiopharmaceutical  
9 radioisotopic settings?

10 MEMBER LANGHORST: No, I don't believe that  
11 was one of the considerations.

12 MEMBER GUIBERTEAU: Okay.

13 MEMBER LANGHORST: I'll ask my Subcommittee  
14 members if they thought it was.

15 VICE CHAIR THOMADSEN: This is, this is  
16 Bruce Thomadsen. And I do not believe that was case.  
17 I think it was, it was just a matter of space in the  
18 report available for a more extensive reply.

19 MEMBER GUIBERTEAU: Okay. Fair enough. I  
20 was just curious.

21 MEMBER MATTMULLER: Could somebody please  
22 repeat the question from Dr. Guiberteau?

23 CHAIR MALMUD: Dr. Guiberteau, would you  
24 please repeat your question?

25 MEMBER GUIBERTEAU: My, my question was the

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1 motivation for, in, you know, how, how this might be  
2 enhanced or actually presented as presenting Appendix  
3 two as a separate report, rather than separating these  
4 issues from, you know, from the present document.

5 I presume that meant not leaving the, you  
6 know, and I'm sort of clarifying my thought there, is  
7 that I presume that this would actually disappear from  
8 the report, Appendix two, and be with, with a thought  
9 of having a more extensive separate report addressing  
10 these, these points. Or, would you keep this Appendix  
11 two and just expand on it in another document?

12 MEMBER LANGHORST: Mickey, the plan was to  
13 have a, to, to drop Appendix two from this report and  
14 to have a separate report address point by point the  
15 Markey report. It would probably highly reference  
16 current patient release report.

17 MEMBER GUIBERTEAU: Okay. I just was  
18 unclear when you said just recommended that it be  
19 separated, I wasn't sure exactly what that meant as  
20 well.

21 VICE CHAIR THOMADSEN: This is, this is  
22 Bruce Thomadsen again. At the last meeting, it was, it  
23 was decided by the Committee to have the subgroup that  
24 was writing the response to the Markey report include  
25 a response to the last letter and have that be a, a

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1 full report.

2 CHAIR MALMUD: This is Malmud. Thank you,  
3 Bruce. Does that mean that the issues relating to the  
4 concerns of, of the congressman will not be included  
5 in the final recommendation for the advisory  
6 Committee?

7 VICE CHAIR THOMADSEN: Of, of this--the  
8 report that you have in front of you, that would be  
9 correct. Although, actually, all of the issues that  
10 were of concern are addressed in this report, just not  
11 in a line by line response, and that's what the other  
12 report's going to be.

13 CHAIR MALMUD: Yes, thank you. I understand  
14 that, that means though that the response to the  
15 Markey concerns will be delayed in a separate report?

16 VICE CHAIR THOMADSEN: Yes, that is  
17 correct.

18 CHAIR MALMUD: Thank you. Just wanted to  
19 understand that fully.

20 MEMBER GILLEY: Dr. Malmud, this is Debbie  
21 Gilley. I think also that Subcommittee was going to be  
22 looking at the October 16th or 17th letter also that  
23 comes from Representative Congressman Markey's Office,  
24 maybe the 19th of October, and combining those.

25 VICE CHAIR THOMADSEN: That is correct.

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1 This is Bruce again.

2 CHAIR MALMUD: So, that--this is Malmud  
3 again--so that the, what is considered the Appendix  
4 in this report will be deleted and instead submitted  
5 as a separate report incorporating with it the  
6 responses to the concerns of Chairman Markey, that are  
7 more, more recently received.

8 VICE CHAIR THOMADSEN: The only correction  
9 is, that when you say the, the Appendix to this  
10 report, that is, what was Appendix two, what is  
11 Appendix one is still in the current report.

12 CHAIR MALMUD: Thank you for that  
13 clarification, Dr. Thomadsen.

14 MEMBER GUIBERTEAU: This is Mickey  
15 Guiberteau again. I, I think this is, I understand  
16 the plan here. I just want to express a concern, that  
17 if we should get a third and a fourth letter during  
18 this process, I think we need to be certain that there  
19 is some end to, to a specific report, and it not be a  
20 never-ending report.

21 Because, I think there are some issues  
22 here that are not only specific but generic that need  
23 to be, that are of concerns, I think, to, to more than  
24 Congressman Markey, to the public. And I think we  
25 should be certain that at some point we do get this

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1 report out and that we not have, you know, a  
2 continuing response.

3 So, I'm not sure how we would do that but  
4 I do think that some consideration should be giving--  
5 should be given to that, so that we do have a timely  
6 response to the most cogent of these, of, of these  
7 concerns, with respect to, to the broader interests of  
8 the public.

9 CHAIR MALMUD: Thank you, Dr. Guiberteau,  
10 for expressing that concern. May I make the following  
11 suggestion? And that is, that we, a vote on approval  
12 or not of the current report, including Appendix one,  
13 and then we recommend, to, we recommend to the  
14 Subcommittee that Appendix two be presented for  
15 approval at the next meeting of the AC--the next  
16 public meeting of the ACMUI, incorporating in it the  
17 concerns of the Committee Chairman, Congressman  
18 Markey, and that we call closure on it at that time.

19 MR. LEWIS: Dr. Malmud, it's Rob Lewis.  
20 Could I make a comment?

21 CHAIR MALMUD: Please do.

22 MR. LEWIS: Just, that plan would be fine.  
23 I would note that the NRC's formal response to  
24 Congressman Markey will have been sent long before the  
25 next ACMUI meeting. So, I'm sure there will be

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1 subsequent communications on this issue, as Dr.  
2 Guiberteau mentioned. But, the, the current letter we  
3 have before us, I believe we have to, we've been asked  
4 by his Office to respond on a very short time frame.

5 MR. EINBERG: And, I believe--and this is  
6 Chris Einberg--and I believe the plan was to include  
7 the ACMUI's report on patient release to the  
8 Congressman Markey, as one of the attachments.

9 VICE CHAIR THOMADSEN: This is, this is  
10 Bruce Thomadsen again. Just with a question to Mr.  
11 Einberg or Mr. Lewis, do we have a, a schedule that,  
12 that we can use for the ACMUI's reply to the  
13 Commission that would keep it in line with the, with  
14 that goal of getting the, attaching the Appendix to  
15 the response?

16 MR. LEWIS: I don't have his letter before  
17 me but, but I do remember it had a, had a please reply  
18 to me by a certain date. If anybody on the phone has  
19 that letter. But I, we're trying to meet that date,  
20 and, and logically, that means this is the only  
21 opportunity of ACMUI to provide any input before that  
22 date.

23 MR. EINBERG: And, and--this is Chris  
24 Einberg, once again--and, I would just add that the  
25 two dates are in the type of congressional letters are

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1 usually very short, on the order of two weeks to a  
2 month usually to respond. In this particular case, we  
3 did ask for a, an extension from the Congressman's  
4 Office, which was granted, and I believe one of the  
5 justifications for the extension was that we will be  
6 providing this Subcommittee report, or this Committee  
7 report, to the congressman's Office.

8 CHAIR MALMUD: Thank you, this is Malmud  
9 again. Perhaps I misunderstood. I thought that  
10 additional inquiries were from the Congressman's  
11 Office. Were they not?

12 MR. EINBERG: Yes, we've, we've received  
13 numerous inquiries from the Congressman's Office, and  
14 it, just as recently as late last week we received an  
15 additional letter pertaining to the release of  
16 patients that have been treated with radioactive  
17 iodine.

18 CHAIR MALMUD: But, is it my understanding  
19 that these letters are not bringing up new issues, but  
20 simply expressing continuing concern about the old  
21 issue?

22 MR. EINBERG: That would be a fair  
23 characterization.

24 CHAIR MALMUD: If that's so, would the  
25 members of the Committee be agreeable to just leaving

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1 Appendix two in the report and submitting it, since we  
2 are facing somewhat of a deadline and we don't intend  
3 to change the content, simply the presentation, if I  
4 understood the discussion earlier?

5 VICE CHAIR THOMADSEN: Dr. Malmud, Bruce  
6 Thomadsen again.

7 CHAIR MALMUD: Yes?

8 VICE CHAIR THOMADSEN: I think that I was  
9 the most vocal Member of the Subcommittee to remove  
10 the Appendix. My feeling was that it as, it did not  
11 really address the issues that were raised, and it did  
12 very little to clarify the situation. I thought it was  
13 probably less than useful to have the one page  
14 response included in the, in the report.

15 CHAIR MALMUD: Thank you, Dr. Thomadsen.  
16 Was yours a, a single objection, or was that, the  
17 Member, or did the majority of the members of the  
18 Subcommittee feel the same way?

19 VICE CHAIR THOMADSEN: There was a vote on  
20 the, on the exclusion of that, of that Appendix, which  
21 obviously carried, and since that's in the, in the  
22 document.

23 MEMBER LANGHORST: This is Sue. Yes, that  
24 was--Sue Langhorst--this was a, a, the majority of the  
25 Subcommittee decided to remove Appendix two and

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1 discuss about doing a point, point report.

2 CHAIR MALMUD: Thank you for the  
3 clarification. So is, therefore, is there a motion to  
4 approve the advisory Committee report from the  
5 Subcommittee, for excluding Appendix two, would be the  
6 first motion.

7 VICE CHAIR THOMADSEN: Excuse me, can you  
8 clarify what the--

9 MEMBER LANGHORST: This is--

10 VICE CHAIR THOMADSEN: --can you clarify  
11 what the motion is?

12 CHAIR MALMUD: For acceptance of the report  
13 absent the Appendix two.

14 VICE CHAIR THOMADSEN: So, the, the motion  
15 is to accept the report as presented to the ACMUI?

16 CHAIR MALMUD: Correct.

17 VICE CHAIR THOMADSEN: Thank you.

18 MEMBER ZANZONICO: This is Pat Zanzonico.  
19 But, can we get some clarification from the NRC staff?  
20 I infer from what was just said, and I may be  
21 completely wrong about this, but that there might not  
22 be, if it were not included in the Subcommittee's  
23 report, the current report, there, there would or  
24 would not be another opportunity to submit a detailed  
25 response from the ACMUI? Can that be clarified,

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1 please?

2 CHAIR MALMUD: I'll, I'll try to clarify it  
3 if I can. This is Malmud again. If we approve the, the  
4 advisory Committee, Subcommittee report, it would go  
5 forward. The response of NRC staff to the congressman  
6 would also go forward without our having submitted  
7 Appendix two.

8 The recommendation would have been made by  
9 the NRC staff to, to the congressman. We would then  
10 submit our recommendation after that recommendation  
11 had been made.

12 MEMBER GILLEY: Excuse me, this is Debbie  
13 Gilley. I think the report that we have on the table  
14 before us now addresses Congressman Markey's concern.  
15 It's just not a point by point, item by item rebuttal.  
16 I think all of the information in that report is  
17 there, and therefore, NRC could reference and include  
18 an attachment to that report. Thank you.

19 CHAIR MALMUD: Thank you--

20 MEMBER SULEIMAN: This is Orhan Suleiman.  
21 I think the Committee was pretty much, had a strong  
22 consensus on our response to [sic Congressman] Markey,  
23 but I don't think  
24 we agreed on exactly how to present it in a quick way,  
25 or whether we needed more time to go into more detail.

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1 So I think we really disagreed more on process and how  
2 much detail and justification was warranted.

3 I think I agree with, with Debbie, I think  
4 if someone were to study this report, they're going to  
5 get a good sense of exactly where we're coming in on  
6 this. To me, personally, I don't think it makes any  
7 difference whether we did or didn't include it.

8 I think the intent is, is obvious. There  
9 isn't, for your purposes, Dr. Malmud, there wasn't any  
10 major controversy over to accept the level of detail  
11 and preparation and more documentation, but I don't  
12 think it's changing our conclusions any.

13 CHAIR MALMUD: No, the sub--I agree, the  
14 substance hasn't changed. What I'm trying to find out  
15 from the Committee is, given the fact that the  
16 congressman is expecting a report from the NRC, we do  
17 have a deadline, which we have not established but  
18 which is necessary in order to respond to a Member of  
19 Congress in a timely fashion.

20 Therefore, we can either approve the  
21 current report with Appendix--with a second Appendix  
22 or without it. It seems to me that the members of the  
23 Committee are moving forward to approve the report  
24 without Appendix two, and if, and then Appendix two  
25 will not go forward in a timely fashion.

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1           It will go forward after NRC has already  
2 responded to the Member of Congress. Those are the  
3 realities. So, we really have a choice, of either  
4 approving it with Appendix two or without, agreeing  
5 that there's no substantive change, it's only the  
6 issue of line by line addressing the concerns.

7           With that background, the Chair would  
8 still seek a motion for approval of this report, with  
9 or without Appendix two, from a Member of the  
10 Committee.

11           VICE CHAIR THOMADSEN: Mr. Chairman, a  
12 point of question here. If we decide, if we decide  
13 today to have another meeting of the ACMUI, a tele, a  
14 teleconference, how far ahead, or how far from now  
15 would that have to be?

16           CHAIR MALMUD: Well, of course, public  
17 meetings need to be announced in advance. Then, there  
18 would be the discussion and, it, we haven't gotten a  
19 clear deadline date from NRC staff as to when the  
20 congressman expects the report from NRC. But, from my  
21 last meeting with the Commissioners, I had the feeling  
22 that the deadline was coming close. Does anyone on the  
23 NRC staff know when the response was promised to  
24 Chairman Markey?

25           MR. LEWIS: No, sir. We're, we're trying to

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1 find that. We're not at our desks, so.

2 MR. EINBERG: And, and--this is Chris  
3 Einberg--if I'm not mistaken, the due date actually  
4 probably passed already, and it's, it's at the highest  
5 levels right now being reviewed. And I think the thing  
6 was that we were waiting for this report to be  
7 finalized, so I don't think there's much time left  
8 here before it's going to go out.

9 MEMBER LANGHORST: Mr. Chairman, this is  
10 Sue Langhorst.

11 CHAIR MALMUD: Yes, Sue?

12 MEMBER LANGHORST: I believe in, and Mr.  
13 Lewis and Mr. Einberg can correct me if I'm wrong,  
14 that the NRC did a point by point response to the  
15 Markey Report earlier last spring, and I believe Dr.  
16 Guiberteau, if, if you could point out if there's any  
17 issues other than NRC process that we have not  
18 addressed in this Subcommittee report, those should,  
19 that should be included.

20 But, we believe we, we touched on all of  
21 the scientific merit of the issues raised by the  
22 Markey Report in our current patient release report.

23 MEMBER GUIBERTEAU: This is Mickey  
24 Guiberteau. I would certainly concur with that, and it  
25 wasn't my intent to imply that it had not. It is just

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1 that, you know, from a non-subcommittee member point  
2 of view, and in fact from a non-voting Committee ACMUI  
3 Member, I, I like Appendix two even though I think  
4 that, you know, a separate document expanding on this  
5 and including some of the other items would be, and,  
6 and the latest letter, would be excellent.

7 I'm just not certain what the advantage is  
8 of removing this and, and, and, as, as opposed to just  
9 expanding in another, these same issues in another  
10 document unless you feel that these might be accepted  
11 as, you know, the answers rather than the expanded  
12 answers. It, it seems to me that they're concise  
13 and very clear.

14 VICE CHAIR THOMADSEN: Can I, can I address  
15 that point? This is Bruce Thomadsen again. And the  
16 feeling was, at least, my feeling on that was that  
17 they are concise. They are not very persuasive at all,  
18 whereas the complete document response was much more  
19 persuasive. And that if somebody looks at the Appendix  
20 two as it was an earlier version, they would get the  
21 feeling that there was not very strong arguments  
22 against the points that they're being addressed.

23 MEMBER GUIBERTEAU: Well, then, then, if,  
24 again, I'm a bit confused. Is it your intent to write  
25 a, an expanded Appendix or a separate document?

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1 VICE CHAIR THOMADSEN: It would be a  
2 separate document, that's what was approved by the  
3 Committee at the last meeting. Mr. Mattmuller may be  
4 able to tell us what the status of that document is.

5 MEMBER MATTMULLER: At this point--

6 CHAIR MALMUD: Is this Mr. Mattmuller?

7 MEMBER MATTMULLER: I'm sorry, this is  
8 Steve Mattmuller.

9 CHAIR MALMUD: Thank you.

10 MEMBER MATTMULLER: I mean several drafts  
11 of the point by point have been worked on, although  
12 additional comments in regards to the most recent  
13 letter from October, Congressman Markey have not been  
14 included into it.

15 CHAIR MALMUD: Thank you. May I make the  
16 following suggestion? That we approve of the document  
17 without Appendix two, and that the Subcommittee  
18 continue working on the material in Appendix two into  
19 a separate document in anticipation of questions from  
20 the Congressman's staff for further clarification,  
21 should those questions arise.

22 MEMBER WELSH: So moved.

23 MEMBER FISHER: Darrell Fisher, second the  
24 motion.

25 CHAIR MALMUD: It's been moved and

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1 seconded. Any further discussion?

2 VICE CHAIR THOMADSEN: One more question.  
3 I did not, this is Bruce Thomadsen again. I did not  
4 get a reply from the NRC staff as far as what the,  
5 what delay has to be for notification of another  
6 meeting of the ACMUI.

7 MR. LEWIS: The, the meeting of the ACMUI  
8 I believe would require a minimum of 14 days posting  
9 and, and the other main schedule driver is  
10 availability of everyone that we need to be involved.

11 VICE CHAIR THOMADSEN: Yes.

12 MR. LEWIS: So, so that's the, the response  
13 to that.

14 PARTICIPANT: I do think we need to know  
15 who was the seconder of that motion. Who made the  
16 motion and who seconded it.

17 MS. HOLIDAY: James Welsh proposed the  
18 motion.

19 CHAIR MALMUD: And it was seconded by?

20 MEMBER FISHER: Darrell Fisher.

21 PARTICIPANT: Darrell Fisher?

22 CHAIR MALMUD: Fisher. Thank you.

23 MR. LEWIS: If we're in the point of  
24 discussion, Dr. Malmud, I did have a question for the  
25 Committee.

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1 CHAIR MALMUD: Yes, please.

2 MR. LEWIS: And, and, I think the  
3 Committee, this motion would endorse this report, as  
4 I understand, so within the report, are several  
5 suggestions or recommendations to NRC and I think we  
6 would need maybe, at a, at a future meeting, to have  
7 Committee discussion of whether any of those are  
8 intended by the Committee as actions for NRC.

9 Because, I think that the summary  
10 statement and recommendation section doesn't always  
11 have the recommendations that are in the full text,  
12 behind it. For example, the one on hotels, there are,  
13 in line 423, there's a comment that we should hold  
14 broader community discussions on this topic, but that  
15 doesn't appear in the summary statement and  
16 recommendations.

17 So, so if there are actions embodied for  
18 the NRC staff, I think we, we should, I would suggest  
19 the Committee should have further discussions so we  
20 can put them on our action item list that Ashley has,  
21 but endorsing this report will give us the basis to  
22 send it along with the NRC response, as a separate  
23 matter.

24 MEMBER LANGHORST: This is, this is Sue  
25 Langhorst.

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1 CHAIR MALMUD: Yes?

2 MEMBER LANGHORST: Rob, let me ask you how  
3 best to, I mean, we need to specifically say action  
4 items, is that right?

5 MR. LEWIS: Yes.

6 CHAIR MALMUD: Yes.

7 MEMBER LANGHORST: Okay, I, and that is my  
8 fault, as being a first time Chairman of one of these  
9 Subcommittees.

10 MR. LEWIS: It's not a fault, I think it's  
11 still a good report, and there's a lot of good  
12 recommendations in there. But, may, maybe a point by  
13 point, if you will, when speaking of point by points,  
14 to know which ones of these the full Committee says  
15 the NRC should take as an action item.

16 MEMBER LANGHORST: This is Sue. I  
17 understand now, thank you.

18 CHAIR MALMUD: There is a motion which has  
19 been seconded. Is there further discussion of the  
20 motion?

21 MEMBER WELSH: This is Jim Welsh.

22 CHAIR MALMUD: Yes, Jim.

23 MEMBER WELSH: I'd just like to point out  
24 that Dr. Guiberteau's point about this being a  
25 potentially, ongoing, never-ending process is well

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1 taken, and that's part of the reason why I make the  
2 motion of this, this particular issue, to, to move it  
3 along.

4 As an example, we just discussed last week  
5 the difference, the discrepancies, perhaps, between  
6 veterinary patients and human patients. And, it opens  
7 up a whole new chapter, but if we were to try to stop  
8 and address that inconsistency in this report, it  
9 would delay it further, and then there could be  
10 another letter from a congressman or another issue in  
11 a newspaper that would slow us down further and  
12 further, so I think that we do have to heed Dr.  
13 Guiberteau's advice and, and move, move things along,  
14 and we have something that we can move along right  
15 now.

16 CHAIR MALMUD: Thank you for that comment.

17 MEMBER SULEIMAN: This is Orhan Suleiman.

18 And, and I've been a Member of the Subcommittee and my  
19 biggest frustration with the entire process all the  
20 way from the NRC Directive of what we need to do to  
21 the Committee to the Subcommittee I think our roles  
22 haven't been clearly defined.

23 And, I've been concerned that the  
24 Subcommittee has spent an, an awful lot of extra time  
25 on a report that could have gone to full Committee for

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1 further discussion. And I too agree that we have a lot  
2 of other things to do, and I think our intent is  
3 obvious. I'd like to see this closed, and move onto  
4 some of the other issues, because I, the Subcommittee  
5 charge I think is just a subset of the overall  
6 Committee's responsibilities, and I think the other  
7 Committee members need to partake in some of the  
8 discussion and bring closure to this. We can't afford  
9 to really discuss this issue for another year.

10 CHAIR MALMUD: Thank you, Dr. Suleiman. So  
11 you are speaking in favor of approving the motion?

12 MEMBER SULEIMAN: That's what I would,  
13 what--the motion is to include both--

14 PARTICIPANT: No--

15 MEMBER SULEIMAN: --Appendix two--

16 CHAIR MALMUD: No, the motion is to  
17 include--exclude Appendix two. And, if I am, if the  
18 items which are clarified in Appendix two in kind of  
19 a line by line way, require a response, it will have  
20 been prepared and readied when those questions arrive.

21 MEMBER SULEIMAN: Okay. My concern is,  
22 frankly, to get this over sooner rather than later. I,  
23 I, I agree that if we delay, you know, we're going to,  
24 the NRC is going to respond to [sic Congressman]  
25 Markey and you'll have this other report and what's to

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1 prevent other questions or other letters to the NRC  
2 and, you can continue this for a long time without  
3 bringing closure, and--

4 CHAIR MALMUD: Well--

5 MEMBER SULEIMAN: --report what--

6 CHAIR MALMUD: --Dr. Suleiman, I agree with  
7 you and with your concern about the time being spent.  
8 However, if a Member of Congress and a Committee  
9 Chairman remains concerned about the issue, we will  
10 continue to receive inquiries and the NRC will be  
11 obligated to respond, and we will be asked to comment.  
12 So, that, perhaps the way that you're goal  
13 could be best achieved is to approve the document with  
14 Appendix one, but not Appendix two, and then continue,  
15 have the Subcommittee continue on with it's effort to  
16 expand Appendix two into a separate document in  
17 anticipation of questions which we are rather certain  
18 will continue to come in. We serve, we don't, we don't  
19 dictate process.

20 MR. EINBERG: Dr. Malmud, this is Chris  
21 Einberg. I, going to say this point is up for  
22 discussion. I have a couple things I wanted to bring  
23 to your attention. First, email here on my BlackBerry  
24 to find out what the due date for the latest letter  
25 is.

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1 We have an internal due date of January  
2 3rd for the latest letter from Congressman Markey. So,  
3 we'll be working on that. Then, this is the one that  
4 deals with the release of pets that have been treated  
5 with radioactive iodine.

6 Secondly, I also have a letter from two  
7 members of the public that has to be read into the  
8 record, and I will put it in when the appropriate time  
9 in your opinion would be, to do that, before the vote  
10 or after the vote.

11 CHAIR MALMUD: If they relate directly to  
12 the content of that which we are voting on, it might  
13 be in the best interest of the public to have them  
14 read before we vote.

15 MR. EINBERG: Okay, and with your  
16 permission, then, I'll go ahead and read that into the  
17 record now, then.

18 CHAIR MALMUD: Please do.

19 MR. EINBERG: Okay. This letter is dated  
20 November--it's actually an email. It's an email dated  
21 November 30th, 2010, to the Advisory Committee on  
22 Medical Uses of Isotopes, from David Switzer, M.S.,  
23 and Walter Roberts, M.D. The subject is, written  
24 statement regarding patient release following iodine  
25 131 therapy.

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1 Thank you for the opportunity to provide  
2 a written statement with regard to patient release  
3 following the administration of therapeutic quantities  
4 of iodine 131. We have provided services for many  
5 years for thyroid cancer patients using iodine 131.

6 We have observed that a large number of  
7 these patients have been young mothers who, if  
8 released, would have had to contend with maintaining  
9 separation from their children. A few patients have  
10 been incontinent. A few patients have been confined to  
11 psychiatric institutions, and not compliant with the  
12 usual requirements for release, had it been feasible.

13 Other instances could be enumerated. Under  
14 good practice, there are patients who do indeed  
15 qualify for release during their post administration  
16 period. At the same time, there are many patients whom  
17 we may better serve by confinement in minimal care  
18 circumstances.

19 Certainly, many studies have been  
20 undertaken that confirm the low risk involved for  
21 appropriate release of patients and the information  
22 generated by these studies should be taken into  
23 consideration. The bottom line is, the authorized  
24 users with competent medical physics support when  
25 needed should be independently determine when and if

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1 it is appropriate to confine a patient and there  
2 should be appropriate reimbursement for any and all  
3 such instances where confinement is indicated.

4 Guidance provided by the NRC guide on  
5 radionuclide therapy has been very useful in  
6 determining length and need of confinement. And that  
7 concludes the statement.

8 CHAIR MALMUD: Thank you for reading that  
9 statement to the Committee. Is there a second one?

10 MR. EINBERG: No. It's, it's signed by both  
11 David Switzer and Walter Roberts, MD.

12 CHAIR MALMUD: Thank you. It's, having  
13 heard what you just read, it seems to me that what  
14 they're saying is the judgment should be that of the  
15 physician who is treating the patient and I think  
16 they're also suggesting there should be reimbursement  
17 for the inpatient stay.

18 That seems to be something that's  
19 determined by hospital, individual hospital policy and  
20 by individual insurers willingness to pay for that.  
21 That's my only comment in response to hearing it. Do  
22 other members of the Committee have comments regarding  
23 the communication from these two professionals?

24 MEMBER ZANZONICO: This is Pat Zanzonico.  
25 I think it's, it sounds perfectly consistent with what

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1 the, the Subcommittee and the Committee are  
2 recommending and it's consistent with best practice  
3 based on a case by case evaluation there will be some  
4 patients who are suitable for releasability and others  
5 who are not, and, and this letter seems to simply  
6 reinforce that, that position.

7 CHAIR MALMUD: Thank you. Any other  
8 comments from members of the Committee?

9 MEMBER MATTMULLER: This is Steve  
10 Mattmuller. I, I concur with Pat. I mean, that was my  
11 take on the letter also, that it's very consistent  
12 with, with our report. Thank you.

13 CHAIR MALMUD: Thank you. Any other  
14 comments? If not, may we call the vote? All in favor  
15 of the report?

16 MEMBER: Aye.

17 MEMBER: Aye.

18 MEMBER: Aye.

19 MEMBER: Aye.

20 MEMBER: Aye.

21 MEMBER: Aye.

22 MEMBER: Aye.

23 MEMBER: Aye.

24 MEMBER: Aye.

25 MEMBER: Aye.

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1 CHAIR MALMUD: Any members of the Committee  
2 opposed to the report?

3 (NO RESPONSE)

4 CHAIR MALMUD: Are there any abstentions?

5 (NO RESPONSE)

6 CHAIR MALMUD: Having heard the vote, the  
7 vote is unanimous in favor of submitting the report.  
8 Thank you. If we may, we'll move onto the next item on  
9 the agenda.

10 MEMBER MATTMULLER: Excuse me, Dr. Malmud,  
11 this is Steve Mattmuller.

12 CHAIR MALMUD: Yes, Steve?

13 MEMBER MATTMULLER: First, I'd like to  
14 thank Sue Langhorst. She did an incredible job in  
15 putting this report together, and I daresay she's  
16 probably working harder than an NRC Commissioner right  
17 now in trying to balance her normal job and the work  
18 she did on this report.

19 So, she did a terrific job. The second  
20 question would be, and I suppose this would be to the  
21 NRC staff. Since it appears that we are out of time to  
22 get an official ACMUI response on a line by line basis  
23 to the Markey report, do, what other options do we  
24 have, if any?

25 CHAIR MALMUD: Oh. If I may, may I first

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1 interject that it's my assumption that, that we will  
2 continue refining what was Appendix two into more of  
3 a line by line response in anticipation of further  
4 communications from the Chairman, meaning--  
5 Congressman, because I, I'm not certain that this will  
6 be the last that we'll hear of this issue.

7 And, an enormous amount of work has gone  
8 into the document as well as in the refinement in the  
9 Appendix and it's, I believe it's a worthwhile item to  
10 address in anticipation of further questions. From the  
11 rate of correspondence that the NRC has been  
12 receiving, I don't think it's going to end with this  
13 recommendation.

14 And, I would second what you've said with  
15 respect to thanking Sue Langhorst, but I, I would, as,  
16 as Chairman of the ACMUI, wish to thank not only Dr.  
17 Langhorst, but Dr. Fisher, Debbie Gilley, Mr.  
18 Mattmuller, Dr. Suleiman, Dr. Thomadsen, Dr. Welsh,  
19 and Dr. Zanzonico, all of whom have participated in  
20 this process.

21 We are truly appreciative of it. It is, it  
22 is a lengthy, complete, and well thought out document.  
23 Thank you. May we move on, or does, do you wish to  
24 discuss anything relevant to this, and--

25 MEMBER MATTMULLER: I'm sorry. This is

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1 Steve Mattmuller.

2 CHAIR MALMUD: Steve.

3 MEMBER MATTMULLER: I guess this would be  
4 to Chris and Rob. Do you concur with Dr. Malmud's  
5 analysis, of, that, we can still--I, I guess--one  
6 would, maybe I should phrase it this way. When would  
7 it be most helpful to you to have the line by line  
8 response to the Markey report into the NRC?

9 CHAIR MALMUD: Is that--you're asking a  
10 Member of the NRC that question, am I correct?

11 MEMBER MATTMULLER: Yes, either Rob, or, or  
12 to Chris.

13 MR. LEWIS: This is--I'm going to, I'm  
14 going to dodge the question.

15 CHAIR MALMUD: I, I think that they have to  
16 dodge the question because they haven't been asked for  
17 information yet.

18 MR. LEWIS: Right.

19 CHAIR MALMUD: What I'm saying, as Chairman  
20 of the ACMUI, not a Member of the NRC staff is that I  
21 think we should anticipate further questions. That,  
22 I'm just saying that from, from the correspondence  
23 that's occurred up until now. And, and I think that  
24 the Committee has thought it out, Subcommittee, excuse  
25 me. The Subcommittee has thought it out in detail, and

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1 it's worth putting that document together in  
2 anticipation of what I believe is most certain to be  
3 presented to us as further questions.

4 MR. LEWIS: Yes, and I, and I would agree.  
5 This is Rob Lewis. I think that the timeline of  
6 getting a, a document, I think we can wait until the  
7 next full meeting, is my personal opinion, because it  
8 will be very useful as these discussions continue.

9 It will be a useful tool. The timeline,  
10 if, if the Committee were to request or, or expect the  
11 NRC would include this document in, in whatever the  
12 NRC response to the congressman, I think that the  
13 timeline is, is very short, even, even, you know,  
14 basically, it would have to be voted on today.

15 So, so I think that, in a, in a, in a  
16 future correspondence with a, with the congressman, we  
17 may be able to, to work this in. But in any event it  
18 would be a very useful tool for the NRC staff to have  
19 in preparing any response to any congressman on, on  
20 this issue that keeps coming up. So--

21 CHAIR MALMUD: Thank you.

22 MR. LEWIS: Thank you.

23 CHAIR MALMUD: Does that address your  
24 concern?

25 MEMBER MATTMULLER: Yes. This is Steve.

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1 Yes, it does. Thank you.

2 CHAIR MALMUD: Thanks again, Steve. If we  
3 may, then, we'll move onto the third item on the  
4 agenda, which is the rulemaking and implementation  
5 guidance for physical protection of byproduct  
6 material, that's the 10 CFR part 37.

7 VICE CHAIR THOMADSEN: Mr.--Mr. Chairman?  
8 Mr. Chairman?

9 CHAIR MALMUD: Essentially, security  
10 requirements.

11 VICE CHAIR THOMADSEN: Mr. Chairman?

12 CHAIR MALMUD: Dr. Thomadsen?

13 VICE CHAIR THOMADSEN: Yes. Well, one last  
14 thing before we get off that. If, if we would be able  
15 to get the, the ACMUI, to get on a call at the end of  
16 December, that would give us time for a, a notice of  
17 the meeting and it could give some time for the NRC  
18 staff to include our recommendations to, in their  
19 response. Would you like to, to see if the ACMUI could  
20 make such a call? Could attend?

21 MS. COCKERHAM: Dr. Thomadsen, this is  
22 Ashley. Just to kind of give you an idea on time  
23 lines, it takes three days to publish something in the  
24 Federal register, and it has to be published 15 days  
25 before the meeting. So if it was published today the

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1 meeting could be on December 29th at the very  
2 earliest. And it does take time, you know, at least a  
3 day or so, to coordinate when the Committee's  
4 available, what time, draft the notice, get that  
5 through the paperwork process.

6 VICE CHAIR THOMADSEN: Okay, so that's in  
7 addition to the, to the time that we were given  
8 earlier, as far as how much lead time we need?

9 MS. COCKERHAM: Yes.

10 VICE CHAIR THOMADSEN: Okay. I retract  
11 that.

12 CHAIR MALMUD: Thank you. And, and we will  
13 therefore move onto the next item on the agenda, which  
14 is 10 CFR part 37, which is the security requirements.  
15 Who's going to lead off on that discussion?

16 DEBBIE GILLEY: This is Debbie Gilley, and  
17 I brought this up for the Commissioner's briefing in  
18 October on behalf of the ACMUI. And we're very busy  
19 with patient release criteria and this kept getting  
20 pushed further back and further back.

21 And so, when I spoke at the Commissioner's  
22 briefing, I always spoke on items that may be of  
23 interest to the medical community from the Part 35--37  
24 security proposed regulations. I have a, a, started a  
25 report. I've had help from Sue Langhorst and Darrell

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1 Fisher to help start the process.

2 Part 37 is a rather expansive piece of  
3 regulation out there, and based on the comments that  
4 were made at the Commissioners briefing, the report is  
5 at a, a higher level, maybe, not as detailed as the  
6 patient release criteria report is, and it really  
7 focuses on the security regulations and the impact  
8 they may have on the access to medical care.

9 In the briefing that was done, there were  
10 four topics that were discussed, that was the  
11 expansion of the background checks that would be  
12 required with the regulations over the orders. The  
13 expansion of security requirements based on possession  
14 limits versus the exact activity that was on hand, and  
15 then the third one was the coordination with law  
16 enforcement and how much regulatory oversight a  
17 licensee might have in getting compliance with local  
18 law enforcement.

19 The report is in, still in a draft stage.  
20 I would appreciate it if I could get a little feedback  
21 from the ACMUI Committee if there are, this is the  
22 route they wish to go, and then I'll be glad to send  
23 the draft report out.

24 The recommendations of this report, it's  
25 not very long. It's only four pages long, is that

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1 ACMUI would be interested in having the orders that  
2 are currently enforced be codified into Rule and not  
3 expanded, and that any additional requirements from  
4 the proposed regulations would have an accumulative,  
5 negative impact on the access to medical care,  
6 basically because of cost.

7 And that licensees have stepped up to the  
8 plate on these orders and have expended already lots  
9 of limited resources to meet the compliance of the  
10 orders. And the other component was the National  
11 Source Tracking and the licenses--the licensees  
12 activities with that.

13 And, considering that most of the medical  
14 community only has to deal with annual inventory,  
15 because only the sources that of, that are of, are the  
16 major sources of concern are cobalt 60 and gamma  
17 stereotactic units and blood irradiators, then maybe  
18 they should be allowed to have the most efficient  
19 licensee notification process and maybe not  
20 necessarily the notification process of choice by NRC.  
21 I would like feedback of any of you that  
22 have had or read those proposed regulations or other  
23 things that need to be included in that report.

24 CHAIR MALMUD: I thank you for the  
25 request. Is there any feedback at this time from a

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1 member of the ACMUI?

2 MEMBER LANGHORST: Mr. Chairman, this is  
3 Sue Langhorst.

4 Debbie has tried her best to get our  
5 attention, and bless her heart, we've had a few other  
6 things on our plate with the patient release report.  
7 But with regard to NRC's justification of the new  
8 proposed Part 37, they give very good explanation of  
9 why it's not ideal to have this kind of regulatory  
10 authority reside in license orders. And I am fully  
11 supportive of the move to regulatory space, as I call  
12 it, of those requirements that are in license orders.  
13 But there's not been a good justification of why there  
14 is the expansion of requirements being proposed here.

15 One of the issues that I did not fully  
16 grasp until I went to -- I think it was the September  
17 20th workshop at Headquarters, NRC Headquarters, was  
18 that this rule expands this security requirement to  
19 licensees who have not had to address it in the past.

20 If a licensee has radioactive material  
21 possession limits that are in excess of the quantities  
22 of concern, even though they don't have that excess in  
23 one space, they will still have to be able to develop  
24 an authorization program and do background checks, as  
25 Debbie was explaining. And that is a license that may

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1 not even realize that they will be coming under this  
2 rule as it's being discussed.

3 The idea of licensees doing credit checks  
4 on all individuals who request unescorted access is  
5 quite a substantial requirement. And it is not clear  
6 why or what that gains for licensee in being able to  
7 evaluate security issues.

8 I understand if people are under a  
9 financial pressure that may lead to being coerced to  
10 do something. But if a licensee has to do all these  
11 various credit checks, it may negatively impact their  
12 security program because of the resources they're  
13 having to apply to areas of personal information that  
14 licensees don't get into at all.

15 Debbie has made clear to several of us  
16 that this is a big impact to the Agreement States that  
17 may not be able to even do credit checks or evaluate  
18 these things on a reviewing officer.

19 So, there's a lot to take in with this  
20 proposed rule that it is just yet another upheaval to  
21 us licensees with these types of materials that impact  
22 our security program just once more. And it is a big  
23 effort in a medical environment to keep much needed  
24 medical devices that come under this rule. Thank you.

25 CHAIR MALMUD: Thank you.

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1                   Are there other members of the Committee  
2 who wish to comment about this issue? No one?

3                   MEMBER GILLEY: Dr. Malmud, would you take  
4 any comments from the public? I know there are  
5 several medical institutions RSOs that are on the  
6 call?

7                   CHAIR MALMUD: We are always inviting  
8 comments from the public. Are there comments from  
9 members of the public?

10                  All right. If there's anyone on this call  
11 who is a member of the public wish to make a comment  
12 with regard to this issue?

13                  MS. LANGLEY: This is Karen Langley from  
14 the University of Utah. And I would second what was  
15 just said.

16                  CHAIR MALMUD: Thank you. You're seconding  
17 the concern about the cost of doing credit checks on  
18 individuals seeking authorized user status for  
19 radioactive material?

20                  MS. LANGLEY: That is correct. It creates  
21 quite an additional burden.

22                  CHAIR MALMUD: Thank you. Are there other  
23 members of the public who wish to comment?

24                  MR. OCH: This is Joe Och from Geisinger.

25                  CHAIR MALMUD: Yes.

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1 MR. OCH: I second what has just been said  
2 considering that a credit check, well you just said  
3 that, about an authorized user. I don't think this  
4 same level of scrutiny applies to people that are  
5 actually going to be doing surgery or medicine.

6 We'll allow them into the OR with no  
7 problem. I think we can allow them access here.

8 CHAIR MALMUD: Thank you for that comment.

9 Other comments from members of the public?

10 MR. ALLARD: Mr. Chairman, this is Dave  
11 Allard, Pennsylvania. We're going to be submitting  
12 some formal comments. But on the credit check aspect,  
13 I would think you know in these economic times it's  
14 probably fairly common for people to have bad credit.  
15 That doesn't really apply to whether their trustworthy  
16 and reliable. So, I'd just take that under  
17 consideration. Thank you.

18 CHAIR MALMUD: Thank you for the comment.

19 MEMBER LANGHORST: Mr. Chairman, this is  
20 Sue Langhorst again.

21 CHAIR MALMUD: Yes, Sue?

22 MEMBER LANGHORST: I've had just a little  
23 opportunity to look at the transcript from the cesium  
24 chloride workshop that occurred at the beginning of  
25 November. And I would just encourage the other ACMUI

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1 members to maybe take a look at that at some of the  
2 public discussions that's going on with regard to even  
3 Part 37. Thank you.

4 CHAIR MALMUD: May I ask you what  
5 conclusions you drew from your experience?

6 MEMBER LANGHORST: I can't say that I've  
7 drawn any conclusions yet, because I've only just  
8 looked at them briefly and have not had time to study  
9 them. I don't know if any of our members of the  
10 Committee went to that workshop in November

11 CHAIR MALMUD: Are there any other members  
12 of the Committee who attended that workshop.

13 MR. LEWIS: Dr. Malmud, it's Rob Lewis.

14 I don't believe any ACMUI members were  
15 there. But I could offer a point of view. I was  
16 there.

17 CHAIR MALMUD: Please do.

18 MR. LEWIS: We had two medical licensees  
19 there, there were several but two gave presentations  
20 in some of the sessions. And I believe a gentleman  
21 from Harvard and a gentleman from the Mayo Clinic in  
22 Jacksonville, Florida.

23 And many of the same issues that we have  
24 just heard were raised, particularly credit checks was  
25 a big issue. But I will say that those people also

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1 made some positive comments about some of the things  
2 in Part 37. In particular the new requirement to have  
3 a security plan. In their case, at least, that's  
4 something that they have anyway, so they don't see  
5 that as an additional burden to do even though the  
6 increased controls orders did not require a security  
7 plan in writing.

8 Other aspects of the regulation. The  
9 possession limits, I think that it was the -- the  
10 possession limits were always the key factor, not what  
11 was actually possessed. At least the way the NRC did  
12 the increased control orders. We issued them to  
13 anybody who had a possession limit who could possess  
14 that material, whether they possessed it or not. And  
15 the question in the orders was whether you needed to  
16 implement. And all people were ordered based on  
17 possession, and only a subset of those had to  
18 implement based on actual possession.

19 And I think it is true there is some  
20 different language in the new rule, although I think  
21 the rule was never that different. That possession  
22 limit defines certain things to do, but actual  
23 possession defines many more things to do.

24 And the transcript for the cesium chloride  
25 workshop is available on the NRC website. If you just

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1 go to -- and I think click key issues and cesium  
2 chloride, you'll find the transcript. There's a page  
3 dedicated to the cesium chloride policy statement.

4 The other aspect of that meeting, of  
5 course, it was very narrowly focused on cesium  
6 chloride, but the take home message that we got from  
7 the entire workshop was the policy statement on cesium  
8 chloride, which is a little different issues than Part  
9 37. Most people think the draft policy statement hit  
10 the mark very well.

11 So, and that's a summary of some of the  
12 Part 37 things that were said at the cesium chloride  
13 workshop.

14 When the time is right, I do have a  
15 logistical problem to bring up before the Committee  
16 about the Part 37 comments. Thank you.

17 CHAIR MALMUD: Are there any other comments  
18 from members of the public or from members of the  
19 Committee? I have a question for NRC Staff. Does this  
20 item on the agenda require action on our part?

21 MR. LEWIS: No, I don't believe it does.

22 CHAIR MALMUD: For information only?

23 MR. LEWIS: Well --

24 MEMBER GILLEY: Not exactly. This is  
25 Debbie Gilley. I think the NRC wants a report from

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1 ACMUI on Part 37, am I correct?

2 MR. LEWIS: I don't recall that we've  
3 asked for a report on Part 37. But the Committee, of  
4 course, is very welcome to submit public comments.  
5 And that was my logistical problem. Maybe the time is  
6 right now, Mr. Chairman.

7 CHAIR MALMUD: The time is now. Please  
8 present your logical problem or the logistical problem  
9 has already been presented.

10 MR. LEWIS: Yes. I think the comment  
11 period for this rule, which has already been extended  
12 post January 18th, and I think that if the Committee  
13 as a group were looking to submit a public comment  
14 letter on the rule, this may be the last opportunity  
15 today to do something. But if the Committee as  
16 individual Committee members were to submit comments,  
17 of course, then that issue is solved. But we do have  
18 a January 18th deadline for comments, public comments,  
19 on this proposed rule.

20 CHAIR MALMUD: If I may, I'll ask a  
21 question then. Who bears the economic expense of  
22 doing the credit check on an individual at a  
23 particular institution? Is this going to be borne by  
24 a federal agency or by the mother institution?

25 MR. LEWIS: Yes, the licensee.

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1 CHAIR MALMUD: The licensee? So this is  
2 an additional expense for the licensee?

3 MR. LEWIS: Yes.

4 MEMBER LANGHORST: Mr. Chairman, this is  
5 Sue Langhorst.

6 CHAIR MALMUD: Yes, Sue?

7 MEMBER LANGHORST: We have estimated that  
8 we currently for our need-to-know access, people spend  
9 about \$1100 per person on the current review under  
10 increased controls and about \$1200 per person on  
11 unescorted access.

12 We estimate because of the time involved  
13 in the discussions with individuals about credit  
14 reports and other background checks that those costs  
15 will about double per person. And so effectively  
16 diminish the number of people that we will have who  
17 can have access to these much needed research  
18 instruments and medical equipment.

19 CHAIR MALMUD: Those are the kinds of data  
20 that I was hoping you would present. And how many  
21 individuals currently would you have to document?

22 MEMBER LANGHORST: We believe of the order  
23 of around a couple of hundred.

24 CHAIR MALMUD: So if it were several  
25 hundred and it's about another \$200,000, give or take,

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1 from what you said, it's a substantial expense?

2 MEMBER LANGHORST: As with any research  
3 university, medical use university, we have people  
4 coming and going all the time. And so it is we  
5 estimate about a 100 or so that go through both those  
6 different levels in any one year. And the new  
7 regulations will require us to redo background checks  
8 every ten years, although that should be a little  
9 easier because people will have tended to stay here  
10 for ten years and have fewer local law enforcement  
11 checks required on them.

12 CHAIR MALMUD: So for your institution it  
13 would be about \$200,000 per year?

14 MEMBER LANGHORST: At least.

15 CHAIR MALMUD: And one could extrapolate  
16 that to other larger research institutions as well.

17 So the answer to the question from NRC  
18 Staff is that the ACMUI Committee members and the  
19 public is concerned about the expense entailed in  
20 meeting these requirements. It's essentially a mandate  
21 without funding. Does that answer your question, Rob?

22 MR. LEWIS: Yes.

23 MR. EINBERG: Chris Einberg once again.

24 CHAIR MALMUD: Yes.

25 MR. EINBERG: If the Committee wanted to

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1 make a formal comment or discuss this further and to  
2 solidify the Committee's view on this, there may be an  
3 opportunity to have another teleconference in the  
4 January time frame. As we had discussed about a week  
5 ago, we discussed having a teleconference to discuss  
6 the reporting structure of the Committee.

7 CHAIR MALMUD: Yes.

8 MR. EINBERG: And this could be an  
9 opportunity to use that same teleconference in the  
10 January time frame to solidify the ACMUI views on this  
11 and to formally submit something to the NRC.

12 CHAIR MALMUD: So your suggestion is that  
13 our teleconference in January we discuss two issues  
14 thus far. One is the ACMUI reporting mechanism versus  
15 the ACRS reporting mechanism, that's item 1. And  
16 number two is the concern about members of the public  
17 and the Committee members themselves regarding the  
18 unfunded mandate for a census of doing credit checks  
19 on individual who will be handling radioactive  
20 material?

21 MR. EINBERG: Yes, that is correct.  
22 However, you would need to have something that the  
23 ACMUI would be voting on. So, one of your members  
24 would need to put together some type of document that  
25 you'd be voting on and endorsing.

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1 MEMBER GILLEY: Dr. Malmud, Debbie Gilley.  
2 There is a draft document that's circulating around a  
3 Subcommittee. It's just we did not have time to  
4 finalize it as a Subcommittee report to bring it  
5 before the Committee today.

6 CHAIR MALMUD: Thank you, Debbie. I don't  
7 believe I've seen it. Am I correct that I have not?  
8 It's not been sent to me yet?

9 MEMBER GILLEY: No, sir.

10 CHAIR MALMUD: So that might be a good  
11 basis for discussion. May I ask a question of a member  
12 of the public? Dr. Vetter, are you still with us from  
13 the Mayo Clinic?

14 DR. VETTER: I am still with you, but I  
15 represent the Health Physics Society.

16 CHAIR MALMUD: Oh, okay. Do you have any  
17 concerns about this additional mandate with regard to  
18 credit checks?

19 DR. VETTER: The Health Physics Society  
20 has not taken a position on that particular issue.

21 CHAIR MALMUD: Thank you. Have you any  
22 other comments?

23 DR. VETTER: The only other comment I  
24 would make is that the Health Physics Society would be  
25 in favor of expanding security to include Category 3

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1 sources, but they would not be in favor expanding  
2 increased controls.

3 CHAIR MALMUD: Could you elaborate on  
4 that, please?

5 DR. VETTER: Well the increased controls  
6 are those regulations that require the credit  
7 checks, fingerprinting and so forth. And they are  
8 currently required for Category 1 and 2 sources.

9 CHAIR MALMUD: Yes.

10 DR. VETTER: But the Health Physics  
11 Society would not be in favor or expanding increased  
12 controls to include Category 3, but they do believe  
13 that increased security would be appropriate for  
14 Category 3.

15 CHAIR MALMUD: Thank you. Has the Society  
16 sent anything by mail yet to the NRC regarding their  
17 position?

18 DR. VETTER: They have not, but they do  
19 plan to submit comments by the January 18 deadline.

20 CHAIR MALMUD: Thank you. My inquires are  
21 intended to invite you to do so.

22 DR. VETTER: Thank you for the opportunity  
23 to share our comments.

24 DR. VETTER: Thank you.

25 MEMBER FISHER: Dr. Malmud?

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1 CHAIR MALMUD: Yes.

2 MEMBER FISHER: Darrell Fisher.

3 CHAIR MALMUD: Yes.

4 MEMBER FISHER: I think of more concern in  
5 terms of cost may be the proposed requirements under  
6 subpart (b) access authorization program, which would  
7 require a background investigation on persons having  
8 access to these Category 1 and Category 2 sources.

9 My understanding is that a full background  
10 investigation could be much more expensive than a  
11 security -- then a credit check.

12 MEMBER GILLEY: That is actually kind of  
13 correct. There are nine items that are required for  
14 the background check. The credit report is just one  
15 of those.

16 CHAIR MALMUD: This is Malmud. I have a  
17 question for Debbie Gilley. When you approximated  
18 1100 dollars for one item and 1200 dollars for  
19 another, I rounded it off to 2000 dollars. Didn't  
20 that include the background, the 2000 dollars?

21 MEMBER GILLEY: Dr. Langhorst is the one  
22 who provided you those numbers based on her  
23 institution.

24 CHAIR MALMUD: Excuse me. Then I'll  
25 address my question to Sue Langhorst.

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1 MEMBER LANGHORST: Yes. That includes  
2 credit checks, background checks and so on, and the  
3 time it takes to gather all those from every state or  
4 foreign nation that the person has resided in.

5 CHAIR MALMUD: Thank you. Thank you.  
6 So the number that I rounded off very approximately to  
7 2000 dollars did include the background check. It  
8 really boils down to, other into the intrusion into  
9 one's privacy, it boils down to an expense which is  
10 not minimal in a large institution. Would that cover  
11 the spirit of your concern?

12 MEMBER LANGHORST: Yes, that's correct.  
13 And also, this is not the only security requirement  
14 that is being imposed on us. There are select agents,  
15 chemical security and so on. And anytime that the  
16 Federal Government adds these things if they can  
17 coordinate the effort so that there is a combination  
18 that if you could pass with one, you could pass with  
19 the other, that would also be helpful. But that's not  
20 currently being looked at by all these different  
21 federal agencies adding these security requirements.

22 CHAIR MALMUD: Yes, I have to agree with  
23 you. But, hopefully, these things will be coordinated  
24 at some time in the future.

25 Well, all right. Then we will have a

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1 Committee meeting in January to discuss this item as  
2 well. And if that document could be presented to the  
3 members of the Committee in advance, the draft of the  
4 document, we'll have something to work with before the  
5 Committee actually meets in January. And I thank you  
6 for that.

7 MR. EINBERG: Dr. Malmud, could we ask  
8 Ashley to coordinate the dates for this next  
9 teleconference?

10 CHAIR MALMUD: Yes, of course.

11 MR. EINBERG: Ashley, would you be so  
12 kind?

13 MS. COCKERHAM: I'm sorry. I'm just making  
14 sure it's before January 18th.

15 MR. EINBERG: Okay. Did you want to do  
16 that right now while you have all the Committee  
17 members on the line?

18 MS. COCKERHAM: I think it may be easier  
19 if I pick like three different days, three different  
20 times. I don't know, unless everyone has their  
21 calendars right now, we can do it.

22 MR. EINBERG: However you normally do, it  
23 Ashley.

24 MS. COCKERHAM: For teleconference I would  
25 typically send out options in an email and ask for a

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1 response within a couple of days as to everyone's  
2 availability to pick the date that works best for  
3 everyone.

4 MR. EINBERG: Okay. That's fine with me  
5 if it's fine with Dr. Malmud.

6 CHAIR MALMUD: Yes, it's fine with me.  
7 The best days would be probably be Wednesday  
8 afternoons. If not, we could try a Monday again, but  
9 obviously not the 3rd.

10 MS. COCKERHAM: Okay. Monday morning  
11 option.

12 CHAIR MALMUD: Afternoons I think are --  
13 my experience has been that afternoons are better for  
14 most members of the Committee.

15 MS. COCKERHAM: Okay. And we do have  
16 people on the West Coast, so I know it's still morning  
17 for them.

18 CHAIR MALMUD: All right. We'll look  
19 forward to hearing from you about that.

20 MS. COCKERHAM: Okay.

21 CHAIR MALMUD: And if we may, we'll move  
22 on to the next item.

23 MEMBER GILLEY: Thank you.

24 CHAIR MALMUD: Thank you. The next is just  
25 the impact of the draft safety culture statement for

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1 medical licensees. And who is going to lead off on  
2 that?

3 MS. SCHWARTZ: That is Maria Schwartz.  
4 I'm with the Office of Enforcement. I'm here with  
5 Kitty Thompson and Dave Solorio from the Office of  
6 Enforcement as well.

7 CHAIR MALMUD: Okay.

8 MS. SCHWARTZ: I don't know what you would  
9 like us to do. Whether you'd like us to do a little  
10 presentation of what we've done since we last met with  
11 you.

12 CHAIR MALMUD: Yes, please.

13 MS. SCHWARTZ: Okay. Well, all right. Let  
14 me do that then. What we're looking for today is a  
15 motion in support of the revised draft safety  
16 Statement of Policy. And since we last met with you we  
17 have made a few revisions to the Statement of Policy,  
18 two of which were made in response to suggestions or  
19 comments that you made at our last meeting. So,  
20 specifically I'd like to go over those.

21 First, we added language indicating that  
22 the Commission is aware that the Statement of Policy  
23 is applicable to a diverse group of organizations and  
24 that the Commission will take that what various  
25 organizations have already done during implementation

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1 so that there will be awareness that some  
2 organizations have already expended significant time  
3 and resources.

4 And then the second thing we added was a  
5 ninth trait questioning attitude. And we did that to  
6 address concerns about complacency.

7 Then based on other comments from the  
8 September 17th Federal Register notice, we added  
9 additional language regarding the use of rewards as a  
10 means for encouraging certain behaviors. We wanted to  
11 make sure that people looking at that concept of  
12 rewards would recognize that some monetary incentives  
13 or other reward programs can work against making a  
14 safe decision.

15 So, the seven items that I guess we would  
16 like to highlight in the final draft Statement of  
17 Policy is that:

18 First, the Statement of Policy adopts the  
19 definition and traits that were developed at the  
20 February 10, 2010 workshop, which have gotten  
21 consensus from stakeholders during our outreach. And  
22 that includes the preamble and addressing security  
23 since the term security has not been included in the  
24 definition or the traits.

25 The second thing is that the Statement of

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1 Policy itself includes the traits, whereas the draft  
2 Statement of Policy did not. The draft statement had  
3 a lot more description and it was more down into  
4 almost implementation space. The traits that we have  
5 now which were the ones that were developed at the  
6 2010 workshop are very high level, and they are very  
7 just descriptive of the sorts of things that people  
8 should be considering when they are developing their  
9 own implementation strategies.

10 The third thing to notice that  
11 implementation is not directly addressed in the policy  
12 statement. It just provides our overarching Statement  
13 of Policy.

14 Then as I mentioned, it recognizes the  
15 diversity of the various organizations.

16 And then in our September 17th Federal  
17 Register notice we discussed the differences between  
18 a regulation and a policy statement and why the  
19 Commission at this time believes that moving forward  
20 with a Statement of Policy is the more appropriate way  
21 to engage stakeholders. And since we are now moving  
22 forward with a Statement of Policy I think that  
23 indicates why that we are going in that path.

24 We also added vendors and suppliers,  
25 safety related components. They've been included in

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1 the Statement of Policy.

2 And finally, as I mentioned, we added the  
3 ninth trait, questioning attitude to address  
4 complacency.

5 So that's kind of a brief overview of  
6 where we are since the last time we spoke.

7 CHAIR MALMUD: Thank you. And are we asked  
8 to take any action on this?

9 MS. SCHWARTZ: We're asking you to  
10 endorse, I guess to do a motion in support of the  
11 Statement of Policy.

12 CHAIR MALMUD: Do I hear such a motion?

13 MEMBER ZANZONICO: This is Pat Zanzonico.  
14 I had a couple of issues with the draft SOP. And, you  
15 know as far as I can tell it at no point did I see any  
16 consideration of those issues. So, I'd like to re-  
17 raise them if I may.

18 CHAIR MALMUD: Please do.

19 MEMBER ZANZONICO: Okay. The first issue  
20 was I didn't see any mention of redundancy. And it  
21 seemed that in any safety culture, and again this may  
22 be getting a bit down into the weeds in terms of  
23 implementation, but I think it would be important that  
24 in an SOP to at least mention redundancy as a general  
25 approach or a general feature of safety culture.

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1 I had originally submitted that comment in  
2 September -- or October, rather, after having seen the  
3 September draft. And I still maintain that's a note  
4 worthy feature of a safety culture as included among  
5 the traits.

6 And the second issue, which I think at  
7 least needs to be acknowledged, I'm not even sure how  
8 it should be addressed, but at least acknowledged is  
9 the issue in terms of safety culture of an  
10 organization like a hospital in which in some  
11 instances there may be a conflict between safety at  
12 the admission of the entity, of the licensee. And by  
13 that I mean an instance, where for example a post-  
14 therapy patient has some acute event and needs some  
15 acute hands-on medical care.

16 Now in an instance like that safety,  
17 frankly, is taking a backseat to delivering the  
18 appropriate medical care. And I know that this  
19 document -- or I shouldn't say I know. It appears  
20 that this safety culture document widely grew out of  
21 the power industry. But it was going to be applied  
22 across all licensees.

23 And again, I don't know in what form, but  
24 there should be some acknowledgement that there are  
25 issues operated to things such as cost, and so forth

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1 and so on, where safety may in effect in conflict with  
2 other appropriate features and so forth and practices  
3 of the licensee. Again, I submitted that comment as  
4 well. So those are my two comments:

5 (1) Number one that redundancy should be  
6 incorporated into the traits of a safety culture, and;

7 (2) Some acknowledgement that in the  
8 medical setting staff's safety may in effect be in  
9 conflict with other issues.

10 So those are my comments.

11 MS. SCHWARTZ: Okay. And Dr. Zanzonico,  
12 I think that you sort of hit the nail on the head when  
13 you talked about the redundancy in terms of it being  
14 something that we would be really considering and each  
15 Program Office would be looking at during  
16 implementation.

17 I think that comes under and probably in  
18 that mind-mapping exercise that we had at the February  
19 workshop, things like that did come up because of  
20 course with power reactors redundancy is a big issue.  
21 But one of the traits that we developed or the  
22 workshop panelists developed, was work processes in  
23 which the process of planning and controlling work  
24 activities is implemented so that safety is  
25 maintained. And I would believe that that redundancy

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1 would be one of the things that would be considered  
2 under that trait.

3 I mean, the traits that we have now are  
4 very high level, and so they really have a lot of  
5 different pieces underneath them that would be part of  
6 the implementation piece of this. And it would be  
7 done during that implementation phase.

8 As far as the other discussion, I don't  
9 know if James Firth is on the line and he could pick  
10 that up. Because we have talked about that before  
11 with the patient safety versus use of materials. And  
12 my understanding would be that we wouldn't be  
13 discounting the fact that the patient had undergone  
14 some kind of treatment that involved nuclear  
15 materials, but that the patient's safety, of course,  
16 is the primary thing that a doctor is considering. But  
17 they shouldn't be in direct conflict. It would be  
18 very unusual that that would happen.

19 MR. FIRTH: Yes, this is James Firth. We  
20 have received a number of comments in terms of how the  
21 medical community addresses patient safety versus  
22 other forms of safety. And I guess as a separate  
23 example, the National Transportation Safety Board has  
24 looked at the safety of its personnel when they're  
25 going out to get to airplane crashes. That they

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1 mandated that their personnel should not be driving  
2 while on the cell phones because it's important that  
3 they get to the site safely as well as being able to  
4 get there and to look at the safety of the people that  
5 might be involved in the accident.

6 So, safety is not one-dimensional. So, in  
7 say a hospital setting there's aspects in terms of the  
8 safety of the patient, safety of the medical personnel  
9 that just couldn't be somewhat -- it's multi-  
10 dimensional. So things are going to be having to be  
11 looked at.

12 And it's not in terms of: (a) culture of  
13 the organization. If the organization is rational  
14 about how it's making its decision and how people are  
15 acting, then that's still okay. If people are  
16 grossly negligent in terms of recklessly trying to do  
17 things that they're not asking those questions as  
18 they're acting, that might be a little bit more of a  
19 concern.

20 But I guess, Dr. Zanzonico, in terms of  
21 your question we did not specifically get into the  
22 details of that interplay in the Statement of Policy.  
23 We've kept it at a very general level.

24 It looks like it would be something that  
25 as we get into things here within what we would do in

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1 terms of medical licensees, whether it's infections or  
2 guidance, or what have you, that would be something  
3 that FSME would develop further and in more detail  
4 then.

5 CHAIR MALMUD: This is Malmud, if I may,  
6 Dr. Zanzonico made a very important point, though, and  
7 that is that a good safety programs includes  
8 redundancy. And I believe that the word "redundancy"  
9 is not used in the document, is it?

10 MS. SCHWARTZ: No, it's not.

11 CHAIR MALMUD: Would the document not be  
12 improved by the use of that word since we use  
13 redundancy in patients who are being prepped for  
14 surgery and so on. It's routine. I use redundancy in  
15 treating a patient with radioiodine, everything is  
16 double checked even though it's obvious that it isn't  
17 necessary. But nevertheless, checking it off and  
18 documenting it makes a mistake less likely. It's like  
19 a "time-out" before surgery.

20 So I think Dr. Zanzonico's recommendation  
21 is one that might be worthwhile incorporating.

22 MS. SCHWARTZ: And I don't discount that  
23 at all. Because I believe redundancy, as you  
24 mentioned for yourself and probably for any number of  
25 our licensees and certificate holders, is a really

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1 important consideration.

2 The checklist that you mentioned also are  
3 ways of making sure that you've not only looked at it,  
4 but you've gone back and checked that you've looked at  
5 it. And that kind of redundancy as a surgical patient  
6 myself I can really appreciate some of the things that  
7 I've seen in operating rooms that ensure that  
8 everybody is on the same page of music before you  
9 start an operation.

10 But this is something that we really will  
11 be addressing at the implementation stage. And each  
12 type of organization or licensee will have different  
13 needs and different ways of addressing redundancy.  
14 And what we were doing under this work practices and  
15 procedures would be to ensure that people are starting  
16 to consider those very sorts of things as they are  
17 thinking about ways that they want to implement a  
18 safety culture or have started probably, probably and  
19 have started implementing a safety culture. So that's  
20 why it's not called out specifically in this higher  
21 level overarching safety policy statement.

22 CHAIR MALMUD: I see. But you anticipate  
23 that it will be?

24 MS. SCHWARTZ: Absolutely.

25 CHAIR MALMUD: Thank you. Does that

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1 address your concern, Dr.Zanzonico?

2 MEMBER ZANZONICO: This is Pat Zanzonico.  
3 Well, I think there's so much that we'll agree to  
4 disagree. I think it would be worthwhile to have  
5 redundancy explicitly incorporated into a general  
6 document or general SOP such as this. But certainly  
7 if subsequent documents that go out of this were  
8 included, I could live with that. But, again, we can  
9 agree to disagree. I would still recommend including  
10 it explicitly in this document, but if for other  
11 reasons that was decided not to be done, I could live  
12 with that.

13 MS. SCHWARTZ: One of the things that  
14 we've called to the Commission's attention is the fact  
15 that many of the comments that we've received from  
16 stakeholders indicate that there's a real desire to  
17 continue working with the Commission as implementation  
18 proceeds so that there'll be various workshops, like  
19 we had the workshop in February, where people will get  
20 together from various organizations and look at what  
21 they really need to do to ensure that this safety  
22 culture is implemented in their own organization most  
23 effectively. And this is where that will be coming  
24 up.

25 MR. FIRTH: This is Jim Firth. If I could,

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1 I guess, a couple of things. One is that the way the  
2 Statement of Policy is written it indicates that there  
3 may be some other examples of safety culture traits  
4 that were not listed in the Statement of Policy. I  
5 just wanted to mention that.

6 If the Committee is interested in either  
7 going on record of having redundancy included in the  
8 Statement of Policy or specifically included in other  
9 things that we would consider later, you may want to  
10 consider a motion to do that for the record. Because  
11 the next step is pretty much for the proposed  
12 Statement of Policy to be provided to the Commission  
13 for their approval. And they may be making some  
14 changes as well. So any recommendations that you have  
15 could influence a Commission decision as well as what  
16 that might do for the FSME implementation.

17 CHAIR MALMUD: Thank you. With that, would  
18 you care to make a motion Dr. Zanzonico?

19 PARTICIPANT: Can I ask something?

20 MEMBER ZANZONICO: Yes, I'd be happy to.  
21 So I would move that the trait or characteristic of  
22 redundancy be explicitly incorporated into any SOP  
23 and/or related document on safety culture.

24 CHAIR MALMUD: That's a motion. Is there  
25 a second to the motion?

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1 MEMBER WELSH: I second it.

2 CHAIR MALMUD: Who seconded it, please.

3 MEMBER WELSH: Jim Welsh.

4 CHAIR MALMUD: Oh, thank you, Dr. Welsh.

5 Now, is there any discussion of the motion?

6 VICE CHAIR THOMADSEN: Yes, this is Bruce  
7 Thomadsen.

8 CHAIR MALMUD: Yes.

9 MEMBER THOMADSEN: And I'd like to speak  
10 against that. Redundancy is great, we use it a lot.  
11 But it's one tool out of a huge toolbox. It's not the  
12 essential tool. There's a lot of other tools that  
13 could do a stellar thing.

14 I don't think it's appropriate to single  
15 out that one tool in this high level document.

16 CHAIR MALMUD: Thank you, Dr. Thomadsen.  
17 Other comments regarding this?

18 MR. SOLORIO: Dave Solorio from the NRC  
19 Staff.

20 CHAIR MALMUD: Yes.

21 MR. SOLORIO: I just wanted to add to a  
22 prior discussion before Dr. Thomadsen. I hope I  
23 pronounced his correctly.

24 The higher level traits that we have right  
25 now were really developed by a large group of

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1 individuals from varying backgrounds. So what we have  
2 here is some terminology that, hopefully, the reactor  
3 community, the materials community, the medical  
4 materials community, the medical industrial community  
5 could agree on at a high level. And that once they  
6 got to the point of actually trying to implement these  
7 higher level traits, each entity organization, you  
8 know each area for instance medical materials, would  
9 then take those high level traits and put them in  
10 language that means a lot more sense to the medical  
11 community, and the industrial materials folks would do  
12 the same, and the reactor folks would do the same.

13 So, that's what we were trying to speak to  
14 as far as implementation. And if in fact the medical  
15 community believed that diversity was important, then  
16 they would build it into their programs under the  
17 general area of work practices. And that's kind of how  
18 the high level language came about.

19 Just wanted to add that. Thank you.

20 CHAIR MALMUD: Thank you. Other comments?

21 MEMBER ZANZONICO: This is Pat Zanzonico  
22 again. Your comments are very well taken, and actually  
23 the emphasis on the higher level language in this  
24 document, in fact I'm going beginning to appreciate  
25 it, it's a bit of legalese to me. But I understand

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1 the intent.

2 My concern is, for example, if you look  
3 through the traits of a safety culture, and this is  
4 not a rhetorical question: Which of those would  
5 happen might imply or lead to redundancy, in lack of  
6 a better term, lower level language in an  
7 implementation document?

8 PARTICIPANT: The work processes in which  
9 the process of planning and controlling activities is  
10 implemented, where the safety is maintained. Also  
11 when you think about it, you could even put it under  
12 problem identification and resolution where you look  
13 at a situation and realize that adding a layer that  
14 addresses a redundancy is something that needs to be  
15 done in order to more effectively address a situation.

16 I think there's various ways. Even  
17 question attitude, which was added, when you're  
18 looking at all the various process you might say in  
19 this case we need to add another layer that addresses  
20 redundancy. But again, this is something whereas this  
21 progresses in implementation phase, each of the  
22 organization's entities that's involved would  
23 determine how to carve that out most effectively for  
24 their own organization. Because redundancy for a  
25 nuclear power plant is going to be different than

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1 redundancy for an individual in a hospital.

2 CHAIR MALMUD: Thank you. So it sounds as  
3 if you've anticipated these things.

4 Dr. Zanzonico, would you like to leave  
5 your motion on the table, table it or withdraw it?

6 MEMBER ZANZONICO: I think I'm convinced.  
7 I think I will withdraw it and based on the last  
8 series of comments.

9 I mean, of course I think it's still an  
10 essential component of a safety program. But perhaps  
11 given the language and so forth in this current draft  
12 SOP it's better left for a subsequent implementation  
13 document. So, on that basis I would withdraw it.

14 CHAIR MALMUD: Thank you. And I might add  
15 that your mere raising of the subject documents it in  
16 perpetuity. So you should feel reassured by that as  
17 well.

18 Yes? Who is speaking, please?

19 MEMBER VAN DECKER: This is Bill Van  
20 Decker. How are you?

21 CHAIR MALMUD: Dr Van Decker. Fine, thank  
22 you.

23 MEMBER VAN DECKER: Can I ask a question  
24 of our presenters here? Because my small mind is  
25 still trying to grapple with some of this.

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1           You know, and my perspective obviously,  
2           Statement of Policy is something like from "Pirates of  
3           the Caribbean," it's kind of kind guidelines. And I  
4           think that we certainly would not argue with the  
5           philosophical goodness of some of the things that are  
6           laid out here, and we'd like to say we're reaching for  
7           those types of philosophically good traits.

8           But I guess my question becomes the more  
9           pragmatic from North Jersey, you know coming out of  
10          the Enforcement Section here. Do we see citations  
11          coming out because somebody didn't follow trait 6, or  
12          somebody didn't follow trait 4? Do we see this  
13          implementation phase being the devil is in the details  
14          and that there will be specific markers of  
15          implementation for these traits that then become part  
16          of regulatory guidance or even regulatory space? I'm  
17          just trying to get a feel for it down the line. This  
18          should be something that I think we would all support  
19          philosophically and all would hope to believe we're  
20          doing?

21                 MS. SCHWARTZ: Well, the devil is in the  
22          details in the sense that at the implementation phase  
23          each one of our organizations and the entities that  
24          are involved will have to figure out what is the  
25          approach that they should be taking. And that will

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1 require a lot of brainstorming and a lot of further  
2 thought.

3 The NRC is trying very hard at this point,  
4 the Commission is specifically trying very hard to  
5 make sure that we're focusing on a safety first  
6 approach to the way that activities are conducted.  
7 And this policy statement is a way to do that without  
8 getting into regulation.

9 Right now they really want to engage  
10 stakeholders into a thought process. Our mission as  
11 an agency is to provide for adequate protection of the  
12 public health and safety. When an entity has a safety  
13 first focus, they can ask a lot more of themselves as  
14 the regulated -- I mean you're responsible for safety.  
15 We're responsible for providing for adequate safety.  
16 You're responsible for safely using your materials.

17 And whenever you engage in any activity,  
18 of course you're going to be focusing on safety. But  
19 we're not using this as a check list to go into  
20 enforcement space. We're using this as an opportunity  
21 for people to consider sort of a way of looking at the  
22 spirit of the law, so to speak. Instead of when you're  
23 faced with choices that you consider the safe use  
24 above anything else.

25 And production is a big deal. I mean, we

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1 live in a society that is very focused on money. So,  
2 you know this is a way of saying we want a regulated  
3 community to really consider the important aspects and  
4 the impacts a safety culture can have on it.

5 MR. FIRTH: This is James Firth. I could  
6 add that, I mean if you look at the safety culture  
7 traits, a lot of these are embedded either implicitly  
8 or explicitly in the existing regulations. So going  
9 forward, what I think you can foresee is that similar  
10 to what we we're doing today, which is the violations  
11 are based on the requirements that are in place, is  
12 what would happen.

13 If, in the course of doing that, the root  
14 cause is indicating that there's weaknesses in an area  
15 that's important to safety culture, that might be an  
16 element of discussion between NRC and the licensee,  
17 for example. It's not that we would be fighting  
18 against weaknesses in the trait, but to help the  
19 licensee to perform better there would be that  
20 discussion, or if something does not rise to the level  
21 of a violation, if certain things are seen by  
22 inspectors, they might use some of the language in the  
23 policy statement that might help the licensee identify  
24 things earlier so that they might make corrections  
25 before something more significant might have happened

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1 later.

2 So, a lot of it is in terms of  
3 communication, trying to address things early before  
4 violations. But it's not necessarily in terms of --  
5 it's at an informal level because the licensee are  
6 responsible for their own activities in terms of what  
7 they're doing for safety culture.

8 MEMBER VAN DECKER: Thank you.

9 CHAIR MALMUD: Dr. Van Decker, does that  
10 address your concern?

11 MEMBER VAN DECKER: Well, I believe it is  
12 adequate. There's an explanation of where we're  
13 heading, and I appreciate it.

14 CHAIR MALMUD: Thank you. Now may I ask  
15 what is sought of the Committee today with respect to  
16 the issue of this? An endorsement?

17 MS. SCHWARTZ: Yes. Some kind of a motion  
18 in support of the revised draft of the Statement of  
19 Policy.

20 CHAIR MALMUD: Is there anyone who wishes  
21 to make that motion?

22 MEMBER LANGHORST: This is Sue Langhorst.  
23 I so move.

24 CHAIR MALMUD: Is there a second to the  
25 motion?

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1 MEMBER ZANZONICO: Yes. This is Pat  
2 Zanzonico. I'll second it.

3 CHAIR MALMUD: Thank you. The motion has  
4 been made and seconded. Any further discussion?

5 VICE CHAIR THOMADSEN: Mr. Chairman?

6 CHAIR MALMUD: Yes.

7 VICE CHAIR THOMADSEN: It's Bruce  
8 Thomadsen.

9 CHAIR MALMUD: Yes.

10 VICE CHAIR THOMADSEN: And this morning I  
11 sent out my comments on this draft. It's the third  
12 draft that I have commented on.

13 And just as preparation, I would like to  
14 point out, as I did in those comments, that I have  
15 taught the Patient Safety Course at University of  
16 Wisconsin for over a decade. As part of that course  
17 I teach about safety cultures, I teach about the  
18 tools, I teach the importance of all these aspects in  
19 patient safety.

20 Looking at the document and being asked to  
21 support it, is like having your son come to you and  
22 start out by saying "Dad, don't you agree that bonding  
23 time is good in principle?" And, of course, expecting  
24 if you agree, to go on with enforcement of how that  
25 might look.

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1           It's very hard to really make an  
2 endorsement of a policy statement like this without  
3 knowing what it's going to look like in the end. And  
4 it's quite clear that that isn't known yet.

5           It's sort of like going to war without an  
6 exit strategy or just starting out for a vacation  
7 getting into the car and driving and deciding later  
8 where you'll go.

9           That being said, I think there are  
10 problems with the policy statement, many which I have  
11 pointed out in the document with almost each of the  
12 traits that are listed. But I think the big problem  
13 is trying to assess whether or not this is a  
14 reasonable policy without having any idea where its  
15 headed.

16           I think we would be remiss to the medical  
17 community to endorse these statements and not know how  
18 they're going to be used in evaluation of programs,  
19 possibly against people despite the vague assurances  
20 that we've been given at this meeting.

21           I realize that this is like trying to stop  
22 a freight train at the moment. That it's on the way,  
23 it's not going to be stopped. But I think that we at  
24 least do not have to let it go by without comment.

25           CHAIR MALMUD: Well, thank you. That's

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1 exactly what we're being asked for.

2 VICE CHAIR THOMADSEN: I realize. I'm  
3 speaking against the motion, obviously.

4 CHAIR MALMUD: Thank you. Are there any  
5 other comments for or against the motion? I think  
6 we've now heard two which I would interpret as being  
7 at least of concern if not, frankly, against the  
8 motion. Dr. Van Decker's as well as yours, Dr.  
9 Thomadsen with the same concern, and that is how will  
10 this be enforced and will the end result of this be  
11 enough anxiety to actually diminish the availability  
12 of services.

13 MR. FIRTH: This is James Firth. If I  
14 could say something either in favor or against the  
15 motion. But that is that if there are other concerns  
16 that the Committee may have that you might want to do  
17 a separate motion, that might clarify that, we'd be  
18 interested in terms of getting a feel for any of the  
19 other issues that you'd like to raise.

20 MEMBER LANGHORST: Mr. Chairman, this is  
21 Sue Langhorst.

22 CHAIR MALMUD: Yes, Sue?

23 MEMBER LANGHORST: I'm glad that Bruce  
24 made his motion and his comments. And I while making  
25 the motion, was hoping that that would then bring in

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1 that discussion.

2 I, too, am concerned about how this will  
3 ultimately be used. I think they're very clear. NRC  
4 has been very clear in their statement that the policy  
5 statements cannot be considered binding upon or  
6 enforceable against NRC or Agreement State licensees  
7 and certificate holders. And I hope that guidance  
8 that gets developed from this we can at least have  
9 some initial look at that to make sure that that is  
10 how policy statements continue to go. Thank you.

11 CHAIR MALMUD: It isn't clear to me  
12 whether you were speaking in favor of or against the  
13 motion.

14 MEMBER LANGHORST: I like the idea of  
15 bringing the ideas that this policy statement brings.  
16 But I agree with Dr. Thomadsen that I am concerned of  
17 how it will be used. And so I made the motion so that  
18 we could get to this discussion point.

19 I would say that if we want to have a  
20 separate motion of our concern about how ultimately  
21 the policy will be used, I would be in favor of  
22 supporting the current policy as it stands, but with  
23 that concern that we've voiced here about how it will  
24 be used.

25 MEMBER SULEIMAN: This is Orhan. How was

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1 the motion exactly worded again?

2 CHAIR MALMUD: Will the individual who  
3 made the motion please clarify his or her statement?

4 MEMBER LANGHORST: This is Sue Langhorst.

5 I believe I made the motion in support of  
6 the policy. And so I am just also voicing that I have  
7 the same concern that Bruce does, how it will be used.  
8 And so I am -- I can amend my motion that we support  
9 it but we are concerned of ultimately how it will be  
10 used against licensees.

11 CHAIR MALMUD: That's an amendment to a  
12 motion.

13 MEMBER LANGHORST: This is Sue Langhorst.  
14 That's correct.

15 CHAIR MALMUD: Who seconded the motion?

16 MEMBER ZANZONICO: Pat Zanzonico.

17 CHAIR MALMUD: Are you willing to second  
18 the amended motion?

19 MEMBER ZANZONICO: Yes.

20 CHAIR MALMUD: So the new motion has been  
21 moved and seconded that there is approval but concern  
22 for the manner in which it will be effected and  
23 interpreted. Is that a fair statement.

24 MEMBER LANGHORST: This is Sue Langhorst.  
25 I'll agree to that.

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1 CHAIR MALMUD: Any further discussion of  
2 this amended motion?

3 VICE CHAIR THOMADSEN: Yes. Mr. Chairman.

4 CHAIR MALMUD: Dr. Thomadsen.

5 VICE CHAIR THOMADSEN: If we were voting  
6 on that, then I would say I also have issues with the  
7 statement itself. While the principles themselves are  
8 very nice traits, if they are being used in any way,  
9 and this is separate from how its being enforced, to  
10 push organizations to try to look like this, like  
11 what's shown, it's going to have quite negative  
12 results. It can sap resources from safety  
13 applications that may not appear to follow these  
14 traits.

15 Also, you have the problem that with  
16 trying to look like the organization has these traits,  
17 they may sublimate their actual trait. You would have  
18 situations, for example, where somebody is trying to  
19 look like they are addressing concerns that are raised  
20 and set up some sort of sham mechanism by doing that  
21 but not change what the administration of that  
22 organization feels should be done.

23 As a matter of fact, in my response I go  
24 through several of the traits and show that they  
25 really aren't what we would want to be evaluating an

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1 organization on.

2 In the end, what's going to make a  
3 difference is the organization's behavior; whether  
4 they actually are acting in a safe manner or not. And  
5 then the staff who had looked at this a lot says you  
6 can't really change the culture. What we can change  
7 is their behavior and they can be forced to behave in  
8 a safety manner by the regulation. They may not be  
9 able to be forced to have an attitude that we would  
10 like to see, but that becomes irrelevant.

11 As such, I don't think that you can  
12 separate the value of this statement as a matter of  
13 policy from how it's going to be enforced. And just  
14 as a matter of policy, it's probably bad as far as a  
15 way to go.

16 As a matter of education, it may be good.  
17 But then it wouldn't be coming out as a policy  
18 statement.

19 CHAIR MALMUD: Therefore?

20 VICE CHAIR THOMADSEN: I'm speaking  
21 against the revised motion.

22 MEMBER ZANZONICO: This is Pat Zanzonico.  
23 Can I direct a question to Dr. Thomadsen?

24 CHAIR MALMUD: Yes, please do.

25 MEMBER ZANZONICO: Bruce, so are you

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1 opposed to an SOP in general on safety culture or just  
2 the specifics of how its formulated in the current  
3 draft?

4 VICE CHAIR THOMADSEN: I guess the  
5 question comes down to what you mean by SOP. This a  
6 policy statement. I don't know what an SOP is in the  
7 NRC.

8 CHAIR MALMUD: Are you seeking a  
9 definition of a SOP from the NRC?

10 VICE CHAIR THOMADSEN: Or from Dr.  
11 Zanzonico.

12 MEMBER ZANZONICO: No. I'm not  
13 volunteering to give a definition. But I would like to  
14 hear one from the NRC.

15 CHAIR MALMUD: Anyone on the NRC Staff  
16 have a definition of the NRC's SOP?

17 MR. FIRTH: Yes. This is James Firth.  
18 Basically the Statement of Policy allows the  
19 Commission to either direct things internally in terms  
20 of what the NRC Staff is going to be doing, but it  
21 also allows its a vehicle for the Commission to  
22 express its views on something, issues that are  
23 germane to the Commission's activities at large.

24 So this one is a Statement of Policy.  
25 Unlike the medical use policy statement that provides

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1 a very clear outline in terms of how the Commission  
2 was going to be proceeding with regulating the medical  
3 use of isotopes. This policy statement is more along  
4 the lines of expressing an expectation that does not  
5 have that similar framework as the medical use policy  
6 statement.

7 So it's expressing an expectation. It's  
8 not setting anything specifically in line for specific  
9 implementation.

10 The discussion on implementation generally  
11 arises from the Commission's interest in general of  
12 having the NRC increase the attention that it pays to  
13 safety culture. So, anything that we would do on the  
14 material side to increase the attention to say either  
15 among the NRC Staff or with licensee or certificate  
16 holders, we would want to be consistent with this  
17 policy statements. But that increased attention could  
18 happen with or without the policy statement. The  
19 policy statement is expressing its expectation on what  
20 the Commission would like to see licensees and  
21 certificate holders, and vendors and suppliers of  
22 safety-related equipment to do.

23 VICE CHAIR THOMADSEN: In that case an  
24 answer to Dr. Zanzonico, I do feel that you can't  
25 separate support for the policy from support for how

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1 it's going to be used, which we don't know yet. And  
2 that is as I call in my response, the ominous last  
3 sentence of this, the Commission will take this into  
4 consideration as the Statement of Policy is  
5 implemented, which we have no idea where that's going.

6 Do keep in mind the old Quality Management  
7 Program that was implemented by NRC years ago. It did  
8 not have the expected results. I have the feeling  
9 that something like this may not have the effected  
10 results either.

11 MEMBER SULEIMAN: This is Orhan. Wouldn't  
12 this sort of send a sense of support for the policy.  
13 The policy is not a regulation, it's not even a  
14 guidance. It's just a general statement as to what  
15 our thinking is.

16 So lacking any specifics, I appreciate Dr.  
17 Thomadsen's concerns, but I'm wondering if the NRC  
18 would get more specific, would we have a chance to  
19 comment on that if it deviated from this?

20 CHAIR MALMUD: That's a question from Dr.  
21 Suleiman to a member of the NRC Staff.

22 MS. SCHWARTZ: And I think that's  
23 absolutely correct.

24 MR. FIRTH: This is James Firth.

25 If I could clarify. The policy statement

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1 is going up to the Commission for their consideration.  
2 And if they say they want it to be more specific,  
3 depending on the direction that they give us would  
4 determination whether or what degree of public  
5 involvement there would be. So sometimes policy  
6 statements could be rewritten at the Commission level  
7 and then issued. But if it comes back to the staff,  
8 presumably, there would be another opportunity. But we  
9 have to see how things would develop.

10 MS. SCHWARTZ: That's the response time.

11 CHAIR MALMUD: So, if I can summarize. It  
12 sounds as if the members of the ACMUI are strongly  
13 supportive of a safety culture policy for medical  
14 licensees. However are concerned regarding the manner  
15 in which these will be regulated and enforced because  
16 excessive penalties or enforcement may result in a  
17 limitation of access to these technologies by  
18 patients. Is that a fair summary of what we've heard.

19 MEMBER LANGHORST: This is Sue Langhorst.  
20 I think that's good.

21 VICE CHAIR THOMADSEN: This is Bruce. I  
22 still don't think it's quite captured. I think the  
23 policy statement may result in detrimental effects to  
24 patient safety as a result of trying to at least look  
25 like you're adopting the traits.

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1 MR. SOLORIO: This is Dave Solorio from  
2 the NRC Staff. I would just like to add one thing to  
3 speak to this concern. We expect all individuals and  
4 organizations performing regulated activities to take  
5 the necessary steps to promote a positive safety  
6 culture by fostering these traits as they apply to  
7 their organizational environment.

8 We already recognize the diversity of the  
9 organizations out there and acknowledge that some  
10 organization have already spent significant time and  
11 resources in development of positive safety culture.  
12 So, we would take this into consideration as the  
13 Statement of Policy is implemented.

14 So, to speak to the concern about the  
15 medical community trying to adopt all these nine  
16 traits and then hurting themselves, the goal here  
17 would be as we're working through the implementation  
18 we try to take advantage of what the medical community  
19 is already doing. They may not have to implement all  
20 nine traits for their environment. It's going to be  
21 a very collaborative effort between the NRC and the  
22 medical community to come out to a place where there  
23 is an implementation expectation for the medical  
24 community on the policy statement.

25 Thank you.

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1 CHAIR MALMUD: Thank you. Any further  
2 discussion of this motion?

3 MEMBER MATTMULLER: Dr. Malmud, this is  
4 Steve Mattmuller?

5 CHAIR MALMUD: Yes, Steve?

6 MEMBER MATTMULLER: My concerns in regards  
7 to all this is that from the medical licensee's  
8 perspective, and I suppose this is mostly directly to  
9 the NRC Staff, is that our safety culture right now is  
10 being driven by the Joint Commission. And despite our  
11 current employment by the NRC and even with Orhan in  
12 the room, we pay the most attention to the Joint  
13 Commission when it comes to safety culture issues.

14 And so my concern would be that something  
15 developed by the NRC does not conflict or hinder, or  
16 work against what the Joint Commission has already  
17 been quite successful in establishing in medical  
18 licenses.

19 Thank you.

20 CHAIR MALMUD: Thank you. Your concern,  
21 therefore is there might be conflict between NRC  
22 policy and Joint Commission policy.

23 MEMBER MATTMULLER: Right. Right. I mean,  
24 it's somewhat addressed in the policy, and I don't  
25 have the exact words in front of me because I can't

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1 talk in my phone and read my screen at the same time.  
2 But the previous speaker from the NRC mentioned that  
3 individual or specific organizations will have the  
4 flexibility to tailor the safety culture to their  
5 environment. And what I'm trying to emphasize is that  
6 the medical community already has developed a pretty  
7 good safety culture by way of influence from the Joint  
8 Commission.

9 MR. FIRTH: This is James Firth. If I  
10 could add a little bit of elaborating information.

11 Part of the effort with the policy  
12 statement was to develop some common terminology  
13 relating to safety culture. And in the public  
14 workshops that we held to come up with the definition  
15 and the traits in February of this year, we included  
16 a number of the Joint Commission on the stakeholder  
17 panel that developed the language.

18 so, the intent is not to develop anything  
19 that would conflict with other organizations, but  
20 would to have what NRC would like to comport with or  
21 be consistent with what others are doing. So, the  
22 intent is not to be creating a new structure, but that  
23 the essence and principles behind it are there.

24 And I guess with medical licensees as well  
25 as others who do have some variability in terms of how

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1 well the organizations are functioning and whether  
2 there are problems are not.

3 CHAIR MALMUD: Thank you. Other comments?

4 MEMBER GUIBERTEAU: This is Mickey  
5 Guiberteau.

6 I think that comment begs the question did  
7 the representative from the TJC on the panel feel that  
8 there was any conflict of interest or express that?  
9 I mean, he may have felt that. But did he express  
10 that?

11 MR. FIRTH: Yes. This is James Firth.  
12 When the decision on coming up with the language of  
13 the definition as well as the specific lists of  
14 traits, and this was does not include questioning  
15 attitude per se, the basis for consensus was whether  
16 each of the organizations or individuals felt that  
17 they could live with it for their constituencies. And  
18 everyone affirmed that was the case.

19 He did not mention any problems or  
20 inconsistencies or areas of concern with what we had.

21 MS. SCHWARTZ: And, in fact, there was  
22 some discussion about the do no harm, and that all of  
23 this was wrapped into the final sort of alignment on  
24 the definition that was developed as not conflicting  
25 with any of the-- it wasn't perhaps what each would

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1 have liked if they'd individually written it, but it  
2 was one that everybody could live with because it was  
3 broad enough to encompass what all the organizations  
4 had in mind.

5 CHAIR MALMUD: Thank you.

6 MR. SOLORIO: This is Dave Solorio again.  
7 I wanted to just add that I found out today that one  
8 of your members, I believe, is going to be a speaker  
9 at the training or meeting we're having on the 24th  
10 January. Maybe it's Donald. I don't remember.

11 MS. SCHWARTZ: It's Dr. Thomadsen.

12 MR. SOLORIO: It's Dr. Thomadsen. So you  
13 have a firsthand opportunity also to express these  
14 concerns to the Commission.

15 CHAIR MALMUD: This is Malmud again. As  
16 Chair of the Committee, we do want to make a  
17 statement, I'm sure, that we wish to always support  
18 the safety culture for medical licensee. I don't  
19 think we wanted to appear that we're opposed to the  
20 concept. At the same time we want to communicate  
21 our concern regarding the issues that Dr. Thomadsen  
22 has raised, and that have been echoed by others.

23 So the question is what kind of a  
24 statement can we make that indicates both of those  
25 issues? And is that statement contained in our

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1 current motion?

2 VICE CHAIR THOMADSEN: Mr. Chairman.

3 CHAIR MALMUD: Yes, sir.

4 VICE CHAIR THOMADSEN: Bruce Thomadsen  
5 again. I think that you summarized quite well  
6 what the motion might say. It's not what we have on  
7 the table right now. But we could say that the ACMUI  
8 strongly supports medicine following cultures of  
9 safety. And that the traits in general do not stand  
10 out as contradictory to this. Or you could even be  
11 stronger about that. But the Committee has concerns  
12 for the policy statement as it is written and how it  
13 may be used in the future.

14 CHAIR MALMUD: Thank you. I'll try to  
15 make it briefer statement, if I may.

16 The members of the ACMUI strongly supports  
17 a safety culture policy for medical licensees.  
18 Period. It remains concerned about the policy not  
19 conflict with the access to care or existing standards  
20 care as they are applied in various disciplines.

21 How's that?

22 VICE CHAIR THOMADSEN: Well, I don't think  
23 that quite captured it at all, but--

24 CHAIR MALMUD: Okay. Well if you don't  
25 think it captured it at all, it's not good. Let's see

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1 if we can do something that will capture your concern.

2 I mean, the Committee's clearly in favor  
3 of a safety culture policy statement for medical  
4 licensees.

5 VICE CHAIR THOMADSEN: I don't know.  
6 That's what we were voting on, but we haven't voted  
7 yet so we don't know that that's the case.

8 CHAIR MALMUD: Well, I haven't heard  
9 anyone object to that part of it.

10 VICE CHAIR THOMADSEN: Oh, I'd object to  
11 that.

12 CHAIR MALMUD: I think what we're  
13 concerned about is -- well you raised, which is a  
14 valid concern. And how do we put the two together,  
15 that's my question.

16 MEMBER LANGHORST: Mr. Chairman, this is  
17 Sue Langhorst.

18 If it's helpful, I can withdraw my motion.

19 CHAIR MALMUD: Well, what I'm trying to do  
20 is to address Dr. Thomadsen's concerns because they're  
21 real. We've experienced circumstances in the past  
22 where the Commission's felt that regulations were  
23 intrusive and obstructive, and not necessarily in the  
24 best interest of the patient. And --

25 VICE CHAIR THOMADSEN: Dr. Malmud?

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1 CHAIR MALMUD: Yes, Dr. Thomadsen?

2 VICE CHAIR THOMADSEN: Let me try again  
3 then. The motion could be that the Committee supports  
4 a culture of safety in medicine, but short of  
5 understanding how a policy statement would be used,  
6 the Committee cannot support the current policy  
7 statement.

8 CHAIR MALMUD: That's one way of phrasing  
9 it.

10 MEMBER GUIBERTEAU: This is Mickey  
11 Guiberteau. Is there a time constraint for this  
12 endorsement?

13 CHAIR MALMUD: You have to ask NRC Staff  
14 that question. Is there a time constraint?

15 MS. SCHWARTZ: Well, we're planning to  
16 send this up to the Commission the 20th of this month.  
17 So, originally we had like a March date, but the  
18 Commission moved that up to January. So we have had  
19 to respond accordingly.

20 MR. FIRTH: This is Jim Firth. I guess I  
21 would also add that the Commission meeting is  
22 scheduled for the 24th of January. And it does sound  
23 as if there is going to be another teleconference  
24 that's going to be in the first part of January. So  
25 that might provide another opportunity for the

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1 Committee to revisit if they need to and of they  
2 wanted something to inform, say, a Commission briefing  
3 even if it's something that we would not be able to  
4 incorporate in what would go up to the Commission.

5 MEMBER GUIBERTEAU: This is Mickey  
6 Guiberteau. I think given the concerns that we all  
7 have in how this expression of support with some  
8 reservations might be expressed, I think perhaps we  
9 should work on this and do this in our January phone  
10 call.

11 I realize it wouldn't be the ideal  
12 endorsement, presuming that's what it is, in terms of  
13 timing. But I think it would be best if we express it  
14 so that we cover exactly what we're talking about.

15 CHAIR MALMUD: That's a recommendation  
16 from Dr. Guiberteau. Is there a second to that  
17 recommendation?

18 MEMBER GILLEY: I second it. I second it.  
19 Debbie Gilley.

20 CHAIR MALMUD: Any further discussion?  
21 All in favor?

22 ALL: Aye.

23 CHAIR MALMUD: Any opposed?

24 (No response.)

25 CHAIR MALMUD: Any abstentions? If not,

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1 the decision to defer it until January is unanimous.

2 And that completes the business of this  
3 official meeting.

4 Are there any comments from the public  
5 that we have not had an opportunity to entertain as  
6 yet? If not, I will --

7 MR. EINBERG: Mr. Malmud, a quick one.

8 CHAIR MALMUD: Excuse me.

9 MR. EINBERG: Mr. Malmud, can we take  
10 about two minutes to see if there's anyone else on the  
11 line who didn't identify themselves? If so, could  
12 they identify themselves now?

13 CHAIR MALMUD: Is there anyone who joined  
14 the Committee meeting who wishes to be identified for  
15 the record.

16 MR. PETERS: This is Mike Peters from the  
17 American College of Radiology.

18 CHAIR MALMUD: Thank you.

19 MEMBER VAN DECKER: And Bill Van Decker a  
20 couple of minutes late.

21 CHAIR MALMUD: Thank you.

22 MS. SIERACKI: Diane Sieracki, NRC.

23 CHAIR MALMUD: Thank you.

24 MS. FORESTER: And Sara Forester, Division  
25 of Nuclear Materials Safety, Region III.

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1 CHAIR MALMUD: Thank you.

2 MS. COCKERHAM: Dr. Malmud, this is  
3 Ashley. I just wanted to let you know I'm going to  
4 send an email to the Committee for potential dates for  
5 the next teleconference.

6 CHAIR MALMUD: Thank you.

7 MS. COCKERHAM: I'm looking at January  
8 5th, 10th, 12th and 17th. So if everyone could  
9 respond to that email, I would appreciate it.

10 CHAIR MALMUD: 5th, 10th, 12th and 17th  
11 are our choices.

12 MS. COCKERHAM: Yes. From 1:00 to 3:00  
13 p.m.

14 CHAIR MALMUD: I think we're still here.  
15 Is there a motion for adjournment?

16 PARTICIPANT: Yes, a motion.

17 CHAIR MALMUD: All right. There is a  
18 motion for adjournment. I would like to thank you all  
19 for a lengthy meeting, but a very productive one. And  
20 one in which we've heard a variety of opinions, all of  
21 which are valuable. And we look forward to our next  
22 meeting.

23 Wishing you all a happy holiday season and  
24 a happy and healthy New Year.

25 (Whereupon, at 3:57 p.m. the

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1 Teleconference was adjourned.)  
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