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1 UNITED STATES OF AMERICA
2 NUCLEAR REGULATORY COMMISSION
3 + + + + +
4 ADVISORY COMMITTEE ON THE MEDICAL
5 USES OF ISOTOPES
6 + + + + +
7 TELECONFERENCE
8 + + + + +
9 WEDNESDAY
10 JANUARY 5, 2011
11 + + + + +
12 The meeting was convened via
13 teleconference at 1:00 p.m., Leon S. Malmud, M.D.,
14 ACMUI Chairman, presiding.
15 MEMBERS PRESENT:
16 LEON S. MALMUD, M.D., Chairman
17 BRUCE R. THOMADSEN, Ph.D., Vice Chairman
18 DARRELL R. FISHER, Ph.D., Member
19 DEBBIE B. GILLEY, Member
20 MILTON J. GUIBERTEAU, M.D., Member
21 SUSAN M. LANGHORST, Ph.D., Member
22 STEVEN R. MATTMULLER, Member
23 CHRISTOPHER J. PELESTRO, M.D., Member
24 JOHN H. SUH, M.D., Member
25 ORHAN H. SULEIMAN, Ph.D., Member
26

1 MEMBERS PRESENT: (continued)
2 WILLIAM A. VAN DECKER, M.D., Member
3 JAMES S. WELSH, M.D., Member
4 PAT B. ZANZONICO, Ph.D., Member
5 NRC STAFF PRESENT:
6 MARYANN ABOGUNDE
7 MICHELLE ALBERT
8 VALERIE BARNES
9 HECTOR BERMUDEZ
10 JUNE CAI
11 SUSAN CHIDAKEL
12 ASHLEY COCKERHAM, ACMUI Coordinator
13 JACKIE COOK
14 SAID DAIBES
15 JAMES FIRTH
16 SARA FORSTER
17 MICHAEL FULLER, Designated Federal Official
18 SANDY GABRIEL
19 SOPHIE HOLIDAY
20 DONNA BETH HOWE
21 JAMES LUEHMAN, Deputy Division Director
22 GRETCHEN RIVERA-CAPELLA
23 SHIRLEY XU
24 RONALD ZELAC
25

1 ALSO PRESENT:

2 SUE BUNNING, Society of Nuclear Medicine

3 CHARLES BURNS, New York State Department of

4 Health

5 ROBERT E. DANSEREAU, New York State Department

6 of Health

7 KEITH DINGER, Government Liaison, Health

8 Physics Society

9 LYNNE FAIROBENT, American Association of

10 Physicists in Medicine

11 THOMAS HUSTON, Department of Veterans Affairs

12 SYLVIA MARTIN, State of Oregon

13 JANETTE MERRILL, Society of Nuclear Medicine

14 MARY MOORE, Philadelphia Veterans Affairs

15 Medical Center

16 DENNIS O'DOWD, New Hampshire Department of

17 Health and Human Services

18 MIKE PETERS, American College of Radiology

19 GLORIA ROMANELLI, American College of Radiology

20 GEORGE SEGALL, Society of Nuclear Medicine

21 MICHAEL SHEETZ, University of Pittsburgh

22 SASHA SIMPSON, ML Strategies

23 CINDY TOMLINSON, American Society for

24 Radiation Oncology

25 GARY A. WILLIAMS, Veterans Health Administration

26

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

2 Time: 1:04 p.m.

3 MR. FULLER: This is Mike Fuller. I
4 am the alternate Designated Federal Official --
5 Officer, I should say -- for this meeting. So we
6 will go ahead and get started.

7 Actually, was that you typing, by any
8 chance? Someone is typing. I will get to that in
9 just a moment.

10 We will go ahead and get started. As
11 I said, as the alternate Designated Federal
12 Officer for this meeting, I am pleased to welcome
13 you to this teleconference meeting of the ACMUI.

14 My name is Michael Fuller, and I am
15 the Team Leader for the Medical Radiation Safety
16 Team, and I have been designated as the alternate
17 Federal Officer for the Advisory Committee in
18 accordance with 10 CFR Part 7.11.

19 This is an announced meeting of the
20 committee. It is being held in accordance with
21 the rules and regulations of the Federal Advisory
22 Committee Act and the Nuclear Regulatory
23 Commission. The meeting was announced in the
24 December 21, 2010 edition of the Federal Register.

25 The function of the committee is to

1 advise the staff on issues and questions that
2 arise on the medical use of byproduct material.
3 The Committee provides counsel to the staff, but
4 does not determine or direct the actual decisions
5 of the staff or the commission. The NRC solicits
6 the views of the Committee and values their
7 opinions.

8 I request that, whenever possible, we
9 try to reach a consensus on issues that will be
10 discussed today, but I also recognize that there
11 may be minority of dissenting opinions. If you
12 have such opinions, please allow them to be read
13 into the record.

14 At this point, I would like to perform
15 a roll call of the ACMUI members participating
16 today. Dr. Leon Malmud.

17 CHAIRMAN MALMUD: Here.

18 MR. FULLER: Dr. Bruce Thomadsen.

19 VICE CHAIRMAN THOMADSEN: Here.

20 MR. FULLER: Dr. Darrell Fisher.

21 MEMBER FISHER: Here.

22 MR. FULLER: Ms. Debbie Gilley.

23 MEMBER GILLEY: Here.

24 MR. FULLER: Dr. Mickey Guiberteau.

25 Dr. Sue Langhorst.

1 MEMBER LANGHORST: Here.
2 MR. FULLER: Mr. Steve Mattmuller.
3 MEMBER MATTMULLER: Here.
4 MR. FULLER: Dr. Christopher Palestro.
5 MEMBER PALESTRO: Here.
6 MR. FULLER: Dr. John Suh.
7 MEMBER SUH: Here.
8 MR. FULLER: Dr. Orhan Suleiman.
9 MEMBER SULEIMAN: Here.
10 MR. FULLER: Dr. William Van Decker.
11 Dr. James Welsh.
12 MEMBER WELSH: Here.
13 MR. FULLER: And Dr. Pat Zanzonico.
14 MEMBER ZANZONICO: Here.
15 MR. FULLER: Okay, I will note that we
16 have a quorum, and we have at this point only two
17 members who are not in attendance.
18 I would note that Dr. Guiberteau and
19 Dr. Palestro do not have voting privileges at this
20 time, but they will listen and speak on behalf of
21 the diagnostic radiologists and nuclear medicine
22 physicians, respectively.
23 I will not introduce the NRC staff
24 members who are present here at NRC headquarters.
25 Again, my name is Mike Fuller. I have with me Mr.

1 James Luehman. I also have June Cai, Dr. Ronald
2 Zelac, Susan Chidakel, Shirley Xu, Ed Lohr, Dr.
3 Donna Beth Howe, and --
4 MS. ALBERT: Michelle Albert.
5 MR. FULLER: Michelle Albert, and then
6 also we have some NRC Headquarters employees on
7 the phone. Could those individuals please
8 identify themselves at this time?
9 DR. DAIBES: Said Daibes.
10 MR. FULLER: Okay, Dr. Daibes. Any
11 other NRC Headquarters?
12 DR. BARNES: Valerie Barnes.
13 MS. RIVERA-CAPELLA: Gretchen Rivera-
14 Capella.
15 MS. COCKERHAM: This is Ashley
16 Cockerham.
17 MR. FULLER: I'm sorry, Ashley. Who
18 was the other person?
19 MR. BERMUDEZ: Hector.
20 MS. COCKERHAM: We will go to the
21 Regions.
22 MR. FULLER: Yes, we will get to the
23 Regions in a moment.
24 MS. HOLIDAY: Hey, Mike, this is
25 Sophie.

1 MR. FULLER: Okay, Sophie. There was
2 one other person prior to Gretchen. Can you
3 repeat your name again?
4 MS. COCKERHAM: Mike, I think that
5 was Valerie Barnes or Michelle Albert.
6 MR. FULLER: Valerie Barnes. That is
7 who it was. Thank you.
8 MS. COCKERHAM: You are welcome.
9 MR. FULLER: Okay, next we will go to
10 the Regions. Who do we have on the call from
11 Region I?
12 DR. GABRIEL: Sandy Gabriel.
13 MR. BERMUDEZ: Hector Bermudez.
14 MR. FULLER: Anyone else from Region
15 I? Okay, we will go to Region III. Who do we
16 have on the call from Region III?
17 MS. FORSTER: Hi. This is Sara
18 Forster.
19 MR. FULLER: Anyone else from Region
20 III? Now NRC Region IV?
21 MS. COOK: Jackie Cook.
22 MR. FULLER: All right. The next thing
23 I will do is identify the members of the public
24 who notified us that they would be participating
25 in the teleconference. So when I call your name,

1 please indicate if you are on the call.

2 Keith Brown, University of

3 Pennsylvania? Sue Bunning, Society of Nuclear

4 Medicine?

5 MS. BUNNING: Here.

6 MR. FULLER: Charles Burns, New York

7 State Department of Health?

8 MR. BURNS: Here.

9 MR. FULLER: Robert Dansereau, New

10 York State Department of Health?

11 MR. DANSEREAU: Present.

12 MR. FULLER: Keith Dinger, Health

13 Physics Society?

14 MR. DINGER: Here.

15 MR. FULLER: Lynne Fairobent, American

16 Association of Physicists in Medicine?

17 MS. FAIROBENT: Here.

18 MR. FULLER: Dr. Thomas Huston,

19 Department of Veterans Affairs?

20 DR. HUSTON: Here.

21 MR. FULLER: Jackie Kavanaugh, Nordian?

22 Sylvia Martin, Oregon?

23 MS. MARTIN: Here.

24 MR. FULLER: Andrew Mauer, Nuclear

25 Energy Institute? Janette Merrill, Society of

1 Nuclear Medicine?

2 MS. MERRILL: Here.

3 MR. FULLER: Mary Moore, Philadelphia

4 Veterans Affairs Medical Center?

5 MS. MOORE: Here.

6 MR. FULLER: Mike Peters, American

7 College of Radiology?

8 MR. PETERS: Here.

9 MR. FULLER: Gloria Romanelli,

10 American College of Radiology?

11 MS. ROMANELLI: Here.

12 MR. FULLER: Dr. George Segall,

13 Society of Nuclear Medicine?

14 DR. SEGALL: here.

15 MR. FULLER: Michael Sheetz,

16 University of Pittsburgh?

17 MR. SHEETZ: Here.

18 MR. FULLER: Sasha Simpson, ML

19 Strategies?

20 MS. SIMPSON: Here.

21 MR. FULLER: Cindy Tomlinson, American

22 Society for Radiation Oncology?

23 MS. TOMLINSON: Here.

24 MR. FULLER: Gary Williams, Veterans

25 Health Administration.

1 MR. WILLIAMS: Here.
2 MR. FULLER: And Stanley Wilson, Emory
3 University?
4 Okay, is there anyone else on the call
5 that I did not recognize?
6 MR. O'DOWD: A member from the public,
7 Dennis O'Dowd, representing New Hampshire
8 Department of Health and Human Services.
9 MR. FULLER: Okay, anyone else?
10 MEMBER VAN DECKER: This is Bill Van
11 Decker. I just want to let you know I got on.
12 MR. FULLER: Oh, okay. All right.
13 Did Dr. Guiberteau join us, by any chance? Okay.
14 All right. At this time, I will ask
15 that everyone on the call who is not speaking to
16 please place their phones on mute. If you do not
17 have the capability to mute your phone, please
18 press 6 to utilize the conference line mute and
19 unmute functions. I would ask everyone to
20 exercise extreme care to ensure that background
21 noise is kept to minimum. Any stray background
22 sounds can be very disruptive on a conference call
23 this large.
24 Following a discussion of each agenda
25 item, the ACMUI Chairperson, Dr. Leon Malmud, at

1 his option may entertain comments or questions
2 from members of the public who are participating
3 with us today.
4 With that, at this point I would like
5 to turn the meeting over to Dr. Malmud.
6 CHAIRMAN MALMUD: Thank you, and
7 welcome to all of you, and a Happy New Year to
8 everyone. We have rather a full agenda today and
9 a limited amount of time in which to accomplish
10 the discussion. So if I may, we will begin
11 promptly with the first item on the agenda.
12 Now that is listed as the ACMUI
13 Reporting Structure. However, we also had a new
14 item added that appear on your email today, which
15 is the Patient Release issue. So if we can, we
16 will begin with that issue. Sue, do you wish to
17 comment on that?
18 MEMBER LANGHORST: Yes, I will be glad
19 to. This is Sue Langhorst.
20 We received comments on the ACMUI
21 patient release report, and we will have a handout
22 to the comments and our draft response, which
23 Chairman Malmud and I -- We appreciate the
24 additional insights that we were given on the
25 comments and reasoning behind the original

1 rulemaking for the patient release.

2 Nevertheless, it is clear to ACMUI
3 that NRC established per patient release limits.
4 In that handout we provide you that conclusion. I
5 won't read through those, but this is what the
6 regulated community has to go by, a new
7 rulemaking.

8 So I believe that we need a vote from
9 the Committee, Chairman Malmud, that whether the
10 ACMUI -- that the NRC believes the patient release
11 criteria should be changed from a per release
12 criteria, annual criteria, this change would
13 require new rulemaking, as was noted in the
14 regulatory issue summary.

15 CHAIRMAN MALMUD: Thank you. If I
16 understand your intent, it is that we, the ACMUI,
17 currently believe that it is per release, not per
18 year, and that in order to change it to per year,
19 which we do not endorse, it would require a
20 rulemaking change. Is that correct?

21 MEMBER LANGHORST: Yes, that is
22 correct, and that would be the motion I would put
23 forward.

24 CHAIRMAN MALMUD: Is there a second to
25 that motion, please?

1 MEMBER GILLEY: Second. Debbie
2 Gilley.
3 CHAIRMAN MALMUD: Thank you. It has
4 been seconded by Debbie Gilley. Is there further
5 discussion of this motion?
6 MS. CHIDAKEL: Well, I am Susan
7 Chidakel. I am the OGC Senior Attorney that was
8 involved in this matter, and I just want to tell
9 you, I want to thank you for your input.
10 I do want to tell you that we have
11 looked at the statements that you have cited and
12 read in the context of what was being discussed
13 when the rule was finalized, and we do not believe
14 that they support your view.
15 We have found no basis in reviewing
16 the information you have provided or in re-
17 reviewing the entire regulatory history to change
18 our position that this was not intended to be a
19 per release, release. Our position, as we said,
20 was the rule is, obviously -- It doesn't address
21 it. The regulatory language itself doesn't say
22 anything.
23 We do agree that we need a rulemaking
24 to clarify the intent, but we don't agree with you
25 as to your saying that the intent was that it was

1 a per release basis rather than per year.
2 CHAIRMAN MALMUD: Thank you for your
3 comment. Do we have other comments in response to
4 counsel's comment?
5 MEMBER WELSH: This is Dr. Welsh here.
6 CHAIRMAN MALMUD: Dr. Welsh.
7 MEMBER WELSH: I suppose the big
8 question at hand is not whether the wording really
9 supports per year versus per event at this point,
10 but what we would advise NRC to really have in
11 clear language. From my understanding, what the
12 ACMUI is advocating is that we seek per event
13 rather than per year, and the next question is do
14 we really need to have a rulemaking to make it
15 clear to all that it should be per event or is NRC
16 going to insist or recommend that it be per year,
17 and we still need a rulemaking for that? That is
18 the question at hand, from my understanding.
19 CHAIRMAN MALMUD: Thank you, Dr.
20 Welsh. I believe that that question should be
21 addressed to Susan Chidakel. Am I correct, Susan?
22 MS. CHIDAKEL: I would like you to
23 please repeat the question, if you don't mind.
24 CHAIRMAN MALMUD: If I may interpret
25 Dr. Welsh's question, it is as follows. The ACMUI

1 believes that it should be on a per release --
2 that is, per event basis -- not an annual basis,
3 based upon our understanding of what has been
4 promulgated in the past.
5 Therefore, the question is do we need
6 to recommend that there be a change in rulemaking
7 in order to achieve agreement that it should be
8 per release or can the accumulated wisdom of the
9 NRC staff interpret this in a way which will allow
10 us to continue practicing on a per release basis?
11 MS. CHIDAKEL: Our answer is that we
12 think you need a rulemaking.
13 CHAIRMAN MALMUD: Then that would
14 require that the ACMUI recommend to NRC that there
15 be a change in rulemaking. Dr. Welsh, does that
16 answer your question?
17 MEMBER WELSH: It does. Thank you.
18 CHAIRMAN MALMUD: Now if I may, having
19 discussed this with members of the Committee, our
20 concerns are as follows. Number one, there is no
21 methodology currently available to add up the per
22 release events between and among institutions for
23 individual patients, number one.
24 Number two, there is concern that, if
25 the interpretation of NRC is that it must be per

1 year, and without the ability of the physician to
2 accumulate the data or to assure the data, will
3 there be penalties for treating patients who might
4 exceed the per year limit on the basis of being
5 treated per event until this issue is clarified;
6 because this really interferes with the current
7 practice of medicine?

8 That is a question to counsel.

9 MS. CHIDAKEL: That isn't actually a
10 question. What you have done is you have stated
11 your concern.

12 CHAIRMAN MALMUD: It is a concern. I
13 am always willing to have an expert in the law
14 clarify an issue for us.

15 MS. CHIDAKEL: Well, I think your
16 issues are perfectly valid, and I think they are
17 things that you can raise if you want to propose
18 the rule, a rule change.

19 CHAIRMAN MALMUD: All right.

20 MS. CHIDAKEL: As far as the second
21 question about penalties and so forth, that is an
22 enforcement issue, and I can't really address
23 that. We are talking about a rule change. I am
24 not prepared to address enforcement issues, I am
25 afraid.

1 CHAIRMAN MALMUD: Who would be
2 addressing the issue of enforcement in the
3 interim?
4 MS. CHIDAKEL: I leave that to the
5 staff.
6 CHAIRMAN MALMUD: Is there someone
7 from staff who wishes to comment? It seems to me
8 -- and I speak as the Chairman, having heard the
9 input from the members of the committee -- that
10 the Committee is almost unanimously, with one
11 exception, supportive of this being continued to
12 be practice on a per release basis, not a per year
13 basis. However, now that the issue has come
14 before NRC for clarification and there is no
15 ambiguity, according to counsel from NRC, there
16 would be concern in the medical community that, in
17 the event that a patient does receive more than
18 the annual limit by virtue of the current per
19 release practice, that there not be a
20 prosecutorial effort made against physicians who,
21 number one, have no ability to add up these doses
22 which may be given by different institutions and,
23 number two, who have been practicing this way
24 until now anyway.
25 MR. LUEHMAN: Dr. Malmud, this is Jim

1 Luehman. I think that -- I think, going back to
2 the October 20, 2010 Commission meeting when I
3 testified to the Commission, I told them that I
4 think -- I thought that this issue needed to be
5 clarified, because as Susan stated, right now the
6 regulatory language doesn't say either. It just -
7 - You know, you have to really rely on the history
8 to look at the language and make the
9 determination.
10 Given that, I think that -- At least,
11 I personally then and I am of that same mind now,
12 think that this does need to be clarified in the
13 regulations. But what I would say in the interim
14 is, while the staff has a position, and we feel it
15 is a strongly supported position, the fact is that
16 from an enforcement standpoint, since the
17 regulation right now is silent on whether it is
18 per episode or per year, I think it is very
19 unlikely that there is going to be any enforcement
20 action taken until this is clarified; because the
21 staff would have a burden to show that there was a
22 violation of the regulation, and with the language
23 as it presently is, that is probably not something
24 that we would pursue.
25 Having said that, I do think that your

1 concerns -- that you and the Committee and the
2 medical community have some concerns, and that
3 takes me full circle back to, at least personally,
4 I support what the Committee is suggesting, that
5 we need to get into a -- we need to do a
6 rulemaking and clarify the language one way or the
7 other, because that is the only way that is going
8 to fix this problem once and for all.
9 MEMBER LANGHORST: Mr. Chairman, this
10 is Sue Langhorst again. Let me speak as a
11 licensee who would not have the access to the full
12 rulemaking history documents that NRC staff would
13 have.
14 In the statement that NRC put in the
15 final rulemaking, they said NRC is establishing a
16 dose limit of 5 millisieverts total effective dose
17 equivalent to an individual from exposure to the
18 release patient for each patient release.
19 To me, there is no doubt that the
20 current regulations are per release and, if the
21 NRC intended it to be per year, that is not what
22 is stated in their final rulemaking. So if NRC
23 wants to move from per release to per year, that
24 is where rulemaking needs to occur, but as you
25 stated, Mr. Chairman, the ACMUI's majority feels

1 that it should remain as a per release limit.
2 Thank you.
3 CHAIRMAN MALMUD: Thank you.
4 MS. CHIDAKEL: If I may speak, this is
5 Susan Chidakel again. As I said before, we have
6 looked at all of the statements that you have
7 presented. As a lawyer, I have looked at them
8 from a legal standpoint in the context in which
9 these statements were made.
10 You have to look at the entire context
11 and from looking at the context in which these
12 statements were made very carefully and looking at
13 all of the supplementary information, as I said,
14 we have not changed our position.
15 Again, the regulations do not clarify
16 it, but the regulatory history indicates that the
17 intent was that it should be an annual limit.
18 CHAIRMAN MALMUD: Thank you. We have
19 heard both positions, the position of the majority
20 of the ACMUI Subcommittee and the position of NRC
21 counsel. We recognize that there is a difference.
22 Therefore, in order to move forward,
23 there is a motion from ACMUI -- I believe, from
24 Sue Langhorst -- which would indicate that the
25 ACMUI recommends that the interpretation be on a

1 per release basis, and that pending clarification
2 of this or rulemaking, that it be allowed to
3 continue as a per release basis so that
4 practitioners need not fear prosecution in the
5 care of their patients.
6 MEMBER SULEIMAN: Dr. Malmud, this is
7 Dr. Suleiman.
8 CHAIRMAN MALMUD: Yes, Dr. Suleiman?
9 MEMBER SULEIMAN: I have a question
10 that would affect how I would feel about this.
11 The per limit -- per event limit is realistic. It
12 is practical, and is really what should be adhered
13 with how the ACMUI has felt. However, the
14 overriding question: Is there or isn't there an
15 annual limit; and if, in fact, there is an annual
16 limit that happens to be the same as the per event
17 limit, the annual limit preempts the per release
18 limit, but in this case it doesn't matter. It is
19 limited to one.
20 So is there or isn't there an annual
21 limit? The regulation doesn't say that. 35.75
22 doesn't say that, but the guidance kind of implies
23 that, but I kind of find it upsetting that
24 guidance which should be clarifying, in this case
25 has actually confused the community.

1 So there either needs to be better
2 guidance or rulemaking where the annual limit does
3 not coincide with the per event limit, because we
4 are not dealing with occupational dose values
5 here. We are dealing with very low amounts of
6 radiation, and to spend this amount of time on
7 something that is essentially very safe has not
8 been fair to the community and has caused a lot of
9 confusion.
10 CHAIRMAN MALMUD: Thank you, Dr.
11 Suleiman. Does anyone care to comment?
12 MEMBER LANGHORST: Mr. Chairman, this
13 is Sue Langhorst again.
14 CHAIRMAN MALMUD: Yes.
15 MEMBER LANGHORST: Let me clarify my
16 motion. My motion is that ACMUI agrees, if NRC
17 believes the patient release criteria should be
18 changed from a per release criteria to an annual
19 criteria, this change would require new
20 rulemaking, as was noted in Regulatory Issue
21 Summary 2008-07.
22 CHAIRMAN MALMUD: Thank you. That is
23 your motion. It has been seconded, has it not?
24 MEMBER GILLEY: Yes. Debbie Gilley
25 seconded it.

1 CHAIRMAN MALMUD: Thank you. Is there
2 any further discussion of this motion? Hearing no
3 further discussion, may I ask those voting members
4 of the Committee to say Aye if you agree.
5 Are there any negative votes? Are
6 there any abstentions?
7 MEMBER SULEIMAN: I abstain.
8 CHAIRMAN MALMUD: Dr. Suleiman
9 abstains. Otherwise, it is a unanimous vote.
10 So we believe that, in having taken
11 this vote that we have placed the issue before NRC
12 staff for resolution and, in the meantime, would
13 plead for understanding on the part of NRC with
14 regard to physicians treating patients according
15 to the manner in which they have been with regard
16 to this issue.
17 If we may, we will move on to the next
18 item on the agenda, unless there is any further
19 discussion of this. Are there any comments from
20 members of the public? If not, thank you very
21 much, and thank you, Sue Langhorst, for your
22 effort, and thank you, Sue Chidakel, for your
23 input. We hope that we will be able to get
24 clarification for all parties involved so that
25 patients and members of the public can both be

1 safely treated and be safely cared for.

2 The next item on the agenda is the

3 ACMUI Reporting Structure. Who wishes to comment

4 on this? Did I go mute or no one wishes to

5 comment? Shall I?

6 MEMBER THOMADSEN: Dr. Malmud, this is

7 Bruce Thomadsen. I will just say that I had

8 thought that this was about the document that we

9 had been dealing with, with our interactions with

10 the NRC as a committee, but it was clarified that

11 this is not about that. It is about who we report

12 to. So I will, just with that clarification, give

13 it over to -- I am not involved in that one.

14 MS. COCKERHAM: Dr. Malmud, this is

15 Ashley.

16 CHAIRMAN MALMUD: Yes, Ashley, I was

17 just about to call on you.

18 MS. COCKERHAM: Okay. So to preface

19 this, the Commission last year directed staff to

20 provide options or to provide recommendations on

21 how the ACMUI should report within the agency.

22 Currently, the ACMUI reports to Rob Lewis as the

23 Division Director in FSME.

24 So we are just looking for feedback

25 from the Committee. I am drafting the paper that

1 we will provide to the Commission, and talking
2 about the options that we have, we could continue
3 to report -- or the ACMUI could continue to report
4 to the Division Director or there is the option of
5 them reporting directly to the Commission, which
6 would, obviously, require some changes.

7 So we are looking into those options
8 and looking for feedback from the Committee and
9 basically whatever input the Committee provides
10 today -- I will use these transcripts and this
11 information to provide that directly to the
12 Commission in my paper.

13 CHAIRMAN MALMUD: Thank you, Ashley.
14 If I may, I should fill the entire Committee in on
15 my more recent experience. I have met
16 individually with the Commissioners, those who
17 were able to meet with me on a day that I went
18 back to Washington after having not been able to
19 attend the last meeting that you all attended.

20 I expressed to them the concerns of
21 the ACMUI with regard to the reporting mechanism.
22 It was my impression from discussion with staff as
23 well as with the Commissioners that reporting
24 directly to them versus reporting in the current
25 manner through Rob Lewis would not necessarily

1 shorten the time frame required to process issues.
2 That is number one.
3 Number two, I was reassured and, in
4 fact, experienced the availability of the
5 individual Commissioners to us. Whenever I need
6 to call upon them, I could arrange a meeting with
7 one or with several of them, assuming their
8 availability on the same day.
9 So that is an important issue, because
10 we have not always availed ourselves of that
11 opportunity, and the opportunity is both available
12 to us and, in this case, I took advantage of it.
13 The frequency that our Committee meets
14 is such that issues are not resolved -- I'm sorry,
15 was someone saying? When the issues are not
16 resolved, it takes a number of months before the
17 next committee meeting is physically together.
18 That, I don't think, would change.
19 There are two issues related to the
20 reporting. One is the need for the Committee to
21 feel that the issues that we discuss are, in fact,
22 transmitted to the Commissioners without being
23 filtered in some fashion.
24 I was astonished, quite frankly, at
25 how knowledgeable each of the individual

1 Commissioners was with regard to issues that we
2 have discussed. Considering the breadth of their
3 portfolios, I was pleasantly surprised that they
4 were as knowledgeable about what we are doing and
5 what we have done as they are. They also seemed
6 quite genuine in their expression of availability.
7 Now the next issue was staffing. We
8 clearly feel that we need more staffing, because
9 the way in which we function is as a committee,
10 when we have staff availability to us, but our
11 work is really done by subcommittees. For
12 example, this most recent issue was dealt with by
13 Sue Langhorst, and issues in the past have been
14 dealt with by other Subcommittee chairs, whether
15 it is the Vice Chair of the Committee or Dr. Welsh
16 or others.
17 In those areas, we could use some
18 additional staffing, and I transmitted that with
19 the additional message that we have never had --
20 Although we have very good support from NRC, we
21 certainly are enjoying the strongest support we
22 have ever had with Ashley working directly with
23 us.
24 So it was not by way of complaint, but
25 by way of need, in that we feel we need a little

1 more staff support, which may mean that we want to
2 ask for some more staff support for Ashley. The
3 other option of reporting directly would mean
4 establishing a staffing level which, I think,
5 given the current budget concerns in Washington,
6 would probably not be addressed. However, if the
7 committee feels very strongly about it, we could
8 present it, though I wouldn't be optimistic about
9 it, and I say that just from reading the
10 newspapers.
11 So I was very satisfied with both the
12 willingness and the knowledge of the Commissioners
13 regarding the issues that we are dealing with, and
14 also with their genuine appreciation of the effort
15 that the members of the Committee put forth.
16 Now having -- Are there members of the
17 Committee who wish to express some opinions
18 regarding this issue?
19 MEMBER ZANZONICO: This is Pat
20 Zanzonico. Can I -- Ashley, can you just clarify
21 again, frankly, what the issue is at hand? Based
22 on what Bruce said, I presume we are not
23 considering FSME Policy and Procedure 2-5 at this
24 time, but a separate issue specifically dealing
25 with the route of reporting.

1 MS. COCKERHAM: Yes. Okay, so last
2 year -- I am pulling up the SRM right now. Last
3 year on July 21st the Commission -- Once the
4 Commission has a public meeting, typically they
5 send staff a Staff Requirements Memorandum, and
6 that is staff's marching orders. That is what we
7 need to do following that meeting.

8 So following that meeting, on July 21,
9 2010, there was an SRM from the Commission, and it
10 had two pieces. The first piece was that staff
11 should develop internal guidance for all major
12 medical policy. That is the Policy and the
13 Procedure that you guys have been talking about at
14 past meetings, and we have feedback from ACMUI on
15 that, and that piece is moving up the chain. So
16 that is one part of the SRM.

17 The second part of the SRM says that
18 staff should work on a Commission paper outlining
19 possible improved mechanisms for providing the
20 Commission with the ACMUI's feedback regarding
21 medical issues, including the pros and cons of
22 restructuring the ACMUI such that it reports to
23 the Commission.

24 So this paper will also include an
25 implementation plan that would be used to affect

1 such a restructuring, should the Commission decide
2 to move forward.
3 So I am working on that Commission
4 paper, and in that Commission paper I need to be
5 able to provide ACMUI's input or feedback on what
6 this structure looks like or how the current
7 structure is working, possible improved mechanisms
8 for the current structure or if the Committee
9 wants changes. Basically any feedback you have I
10 am going to include that in my paper. Does that
11 help clarify?
12 CHAIRMAN MALMUD: Yes, thank you,
13 Ashley. I'm sorry, who was speaking next?
14 MR. LUEHMAN: Sorry, Dr. Malmud. This
15 is Jim Luehman. Just to clarify what Ashley -- to
16 extend on what Ashley said, one option for the
17 Committee to consider is that the update of the
18 procedure, the first SRM item that Ashley spoke
19 about, the Committee could find that with that
20 enhanced procedure that that has gone a long way
21 to addressing many of the concerns that you said
22 about the Commissioners getting the Committee's
23 opinions in an unfiltered manner.
24 Therefore, you could find that the
25 present structure with the enhanced procedure

1 addresses your issues, or you could say -- So that
2 is one option.
3 The Commission said -- asked the staff
4 in the second item to say, but even looking beyond
5 that, even if the staff enhances the way the
6 Commission is informed of the ACMUI's issues and
7 views on issues, does the committee or does the
8 staff -- What would the options be, if you go a
9 step beyond that and actually do a reorganization
10 or re-reporting -- change the reporting structure
11 so that not only do we enhance the procedures, but
12 we change the structure.
13 So I think that what I am trying to
14 say to the committee is you have a number of
15 options. You could look at the procedure and say
16 that the procedure addresses your concerns. You
17 could say, well, the procedure doesn't quite get
18 there, because we still have these staffing issues
19 that you addressed, but we don't think -- you
20 addressed, but we don't think the reorganization
21 necessarily addresses those. So, therefore, we
22 don't favor the reorganization, but we do favor
23 some additional staffing, or you could say, yeah,
24 we favor reporting to the Commission.
25 I guess what I would say about that,

1 just sort of previewing where I think Ashley is
2 going with the paper, we think that the most
3 logical place that -- way that that could be
4 accomplished would be the Committee would then, if
5 that was the recommendation and the recommendation
6 was accepted by the Commission, it would most
7 likely be a structure where the ACMUI would be
8 supported by part of the structure that presently
9 supports the ACRS.

10 You are aware of the structure for the
11 Advisory Committee on Reactor Safety. They have a
12 staff director who has staff that supports the
13 ACRS, and then the committee itself reports
14 directly to the Commission.

15 If that structure -- If similar
16 structure was going to be recommended for the
17 ACMUI, what we as the staff envision is that that
18 Executive Director that supports the ACRS would
19 then have some number of staff under his or her
20 purview to support the ACMUI directly, but that
21 that structure would take advantage of the
22 existing resources such as in the administrative
23 area that already support the ACRS, so that we
24 wouldn't have to duplicate those to support the
25 ACMUI, if they were going to report to the

1 Commission.

2 So you have a whole -- I think that

3 what I am trying to say is there is a whole number

4 of variations that you can go from, from

5 requesting additional staff support to additional

6 staff support plus a streamlined or updated

7 procedure, to completely changing the reporting

8 requirement to have the Committee report to the

9 Commission.

10 There's pros and cons to all of those,

11 but we are trying to get -- Ashley is trying to

12 get, I think, a sense of sort of where the

13 Committee as a whole would be in sort of that

14 spectrum of options, so we can accurately reflect

15 that in the Commission paper.

16 CHAIRMAN MALMUD: Thank you for that

17 perspective. I would like to hear from several

18 members of the ACMUI, if we may, regarding their

19 current feelings.

20 The move to ask for status similar to

21 that of the ACRS dates back a number of years, and

22 those who were the strongest proponents of it are

23 no longer members of the ACMUI. They rotated off,

24 and I wonder if the current members would care to

25 comment on their feelings at the moment.

1 MEMBER WELSH: Dr. Malmud. Dr. Welsh.
2 CHAIRMAN MALMUD: Dr. Welsh.
3 MEMBER WELSH: I have a question
4 perhaps, to start off the discussion. That is:
5 Has anybody from ACMUI, specifically you, Dr.
6 Malmud, as our Chair, been in touch with anybody
7 from the ACRS to get insight from them about their
8 feelings about the reporting scheme they
9 experience, and compare and contrast that with the
10 ACMUI reporting scheme to see if there are any
11 advantages or disadvantages that we could be aware
12 of?
13 CHAIRMAN MALMUD: The answer to your
14 question is I have not approached a member of the
15 ACRS. I have asked staff at NRC for their
16 informal opinions with regard to the issues that
17 concerned ACMUI members, and they are timeliness
18 of response and also explanations for rejections
19 of ACMUI recommendations.
20 We are, obviously, pleased with the
21 feedback regarding recommendations that are
22 accepted. There is some dismay among members of
23 the Committee with regard to recommendations that
24 are not accepted with what is perceived to be
25 inadequate explanation of why the recommendations

1 were not accepted, and also a timely telling of
2 why they were not accepted. But if the committee
3 wishes to, I could get the names of some of the
4 members of the ACRS and ask them what they feel.
5 My impression from speaking to staff
6 was that we would really not achieve one goal,
7 which was to have faster turnaround, because that
8 is really based upon the frequency with which we
9 meet. But there is consensus, I believe, among
10 ACMUI members that we do need some additional
11 staff support for some of the yeoman work that is
12 being done by our subcommittees.
13 MEMBER LANGHORST: Mr. Chairman, this
14 is Sue Langhorst.
15 CHAIRMAN MALMUD: Yes, Sue?
16 MEMBER LANGHORST: There's many of us
17 who are new to the Committee, and I still kind of
18 count myself as that, because it has been a little
19 over a year since I have been appointed to the
20 Committee. So I don't have a strong view one way
21 or another, and really don't fully understand all
22 that maybe what Ashley is putting into this paper.
23 So I don't have good sense one way or
24 the other, and probably will talk to some of my
25 predecessors to ask their opinions of what the

1 issues were then and how they perceive issues at
2 this point in time.
3 So I can't say one way or another, and
4 so, Ashley, I apologize. I can't give you a good
5 consensus from -- I mean, I just don't know the
6 issue well enough.
7 CHAIRMAN MALMUD: I appreciate your
8 position, and I understand it. As one of the more
9 senior members of the Committee in terms of my
10 tenure with the Committee, I think that I have
11 seen a great change in the actions of the
12 Committee, the interaction with staff, and I think
13 that we are functioning at a different level than
14 we did some years ago, and there is greater
15 satisfaction on the part of ACMUI members with
16 respect to the interaction.
17 I believe the same thing is true of
18 staff at NRC. So that some of the issues that we
19 are discussing were of significant concern to
20 former members of the Committee and, since they
21 are not here, they cannot express their concern,
22 but all I can say is that I don't feel the
23 intensity of those concerns, and I didn't then. I
24 thought some of the issues were not regulatory.
25 They were a matter of style of communication.

1 So that is why I am asking current
2 members if they really feel that they want to
3 change something which, from my perspective -- and
4 I have no personal investment in this, but from my
5 perspective is functioning better now than it did
6 four or five, six years ago.
7 MEMBER ZANZONICO: This is Pat
8 Zanzonico. I would have to reiterate. At the
9 risk of sounding dense, I am not entirely sure
10 what the issues we are currently considering are,
11 but having said that, I again -- As a new member
12 of the Committee, I haven't gotten a sense at all
13 that there is an inefficient or censored or
14 however one would like to characterize it pathway
15 of communication from the Committee to the
16 Commissioners or other officials at the NRC.
17 So perhaps, as you are alluding to,
18 Dr. Malmud, things have improved to the point
19 where something that may have been a problem of
20 style or otherwise in the past has largely been
21 resolved.
22 CHAIRMAN MALMUD: Thank you. Are
23 there any --
24 MEMBER THOMADSEN: Dr. Malmud, Bruce
25 Thomadsen.

1 CHAIRMAN MALMUD: Yes, Bruce?
2 MEMBER THOMADSEN: From discussions
3 with some of the previous members of this
4 Committee and descriptions of how things were,
5 both interacting with the staff at the time and
6 with the Commissioners, I think the situation has
7 changed remarkably.
8 I don't personally see this as a big
9 issue at this time. As the Commission changes
10 with time, it may again be. As the staff with
11 whom we work changes, it again may be. I would
12 assume that this Committee could bring up the
13 issue at that time.
14 CHAIRMAN MALMUD: Thank you, Dr.
15 Thomadsen, and that is my feeling and, in addition
16 to that, you know, I am based in Philadelphia. If
17 there is an issue which is hot and burning, I am
18 more than willing to hop on the train and make an
19 appointment to see one or several of the
20 Commissioners directly, express our concerns, and
21 then take the train back again. It is not a major
22 issue for me, and I am willing -- more than
23 willing to do that. However, I will not always be
24 the Chair, and in addition, Ashley will not always
25 be our main point person.

1 Therefore, the concern may arise again
2 in the future. I don't think it exists at the
3 moment, but I don't want to make that decision
4 since I am the one who, in a sense, engaged in the
5 self-congratulation.
6 MEMBER SULEIMAN: Dr. Malmud, this is
7 Orhan Suleiman.
8 CHAIRMAN MALMUD: Yes, Dr. Suleiman?
9 MEMBER SULEIMAN: I have always sensed
10 I think the Committee is operating pretty well
11 right now. There is a history going way back
12 where the committee -- and there was quite a bit
13 of tension between, among a number of individuals,
14 and I think Ashley really needs to be commended,
15 because I think she has improved the communication
16 and the effectiveness to a large degree, and I
17 don't know whether her superiors are actually
18 aware of this, but I think she has contributed in
19 a major way.
20 Having said that, I find both the NRC
21 at times and the Advisory Committee at times, not
22 really sure of what they are asking each other
23 for. I think sometimes the charges are not
24 clarified to the Committee, and I think sometimes
25 the Committee goes off on a slight tangent.

1 So I don't know whether new protocols
2 need to be addressed or whatever, but I think
3 that, clearly, a little bit more clarification in
4 what the committee is being asked to do would
5 help, and sometimes the rules of how the Committee
6 should operate. If, in fact, we are in violation
7 of something, we need to be aware of that rather
8 than go ahead and expending a lot of effort and
9 then finding out that we went into an area that we
10 really didn't need to.
11 Aside from that, I think the -- I
12 would give everybody a passing grade, but I think
13 there needs to be -- There is more room for
14 improvement in terms of clarification of what we
15 need to do and how we go about it.
16 CHAIRMAN MALMUD: Thank you, Dr.
17 Suleiman. You are also one of the more senior
18 members of the committee in terms of tenure, and I
19 appreciate your opinion.
20 MEMBER SULEIMAN: Don't let me -- I am
21 sorry for interrupting, but also under your
22 leadership -- I really don't want to take that for
23 granted. I think you help the committee
24 tremendously as well. I don't want to omit that.
25 CHAIRMAN MALMUD: Well, thank you. We

1 have had really, I think, superior interaction
2 with staff members of NRC, and I am appreciative
3 of their efforts which has made things easy for me
4 and, of course, we have had -- Both the current
5 members of the Committee and the previous members
6 of the Committee, the intellect and the experience
7 of all of you is extraordinary, and the public is
8 well served by this Committee's intellect and
9 knowledge, and I think NRC is well served, as we
10 are well served by NRC.
11 Now having accomplished the
12 congratulations, I would ask the Committee whether
13 they feel that we should go through the process of
14 requesting a status similar to the ACRS or whether
15 we should maintain the current structure, asking
16 for some additional staff.
17 MEMBER WELSH: Dr. Malmud, I am Dr.
18 Welsh. I would like to --
19 CHAIRMAN MALMUD: Yes, Dr. Welsh.
20 MEMBER WELSH: -- ask one additional
21 question here before we proceed. As a semi-senior
22 for the ACMUI, I, too, have witnessed some
23 dramatic improvement in the past few years, and
24 therefore, the question in my mind might be one of
25 the old adages; should we attempt to fix something

1 that is not broken anymore.
2 I can appreciate and understand the
3 previous members' concern, but I generally agree
4 with you that maybe some of those concerns have
5 already been addressed and rectified.
6 Having said that, I am aware of the
7 former Advisory Committee on Nuclear Waste and
8 Material, and they have merged with the -- They
9 are now part of the ACRS, leaving -- just correct
10 me if I am wrong -- only two Advisory Committees,
11 us, the ACMUI, and the ACRS, and there seems to be
12 a little bit of a -- There is a disconnect in the
13 fact that one Advisory Committee has a different
14 reporting scheme than the other Advisory
15 Committee.
16 Would it help NRC in any form or
17 fashion if all Advisory committees, if there are
18 only two now -- would it be better to have the
19 uniform reporting status for all Advisory
20 Committees? So this is a question, I suppose, for
21 NRC staff.
22 CHAIRMAN MALMUD: Well, we can ask
23 Ashley to inquire of more senior NRC staff if they
24 are looking for a change, and then get that
25 feedback to us.

1 MR. LUEHMAN: Dr. Malmud, this is Jim
2 Luehman. I just -- I will attempt to answer that
3 right now. A couple of things.
4 One is, you know, I know that the new
5 members are at somewhat of a disadvantage, but
6 basically -- and I don't want to oversimplify
7 this, but the way the ACRS operates is they meet
8 about -- formally, about once a month, and that is
9 their meeting frequency, and they have a lot of
10 subcommittees in the interim, and for each issue
11 that they review, what they do -- and this is the
12 way that they get formal visibility with the
13 commission -- is they issue a formal letter to the
14 Commission on their position on significant
15 licensing action or approval of a reactor design
16 or whatever it is that they are looking at, and
17 the staff is required to formally respond to that
18 letter.
19 That is really the methodology that
20 they -- that is, by regulation and by statute, is
21 that that is how they get -- that their views are
22 directly transmitted to the Commission.
23 There is -- Obviously, it gives the
24 ACRS direct access to the Commission, but I would
25 say that that comes with a cost to the Committee.

1 Their structure is -- they are very structured in
2 the way -- in the regularity of their meetings.
3 They have definite deadlines for the production of
4 these letters.
5 So they are on pretty tight schedules
6 as they review those things. Given the make-up of
7 that committee, that there are many emeritus and
8 retired individuals, not all the full ACRS but
9 many, they are able to do a lot of their work in
10 that regard.
11 All I would offer is that, if the
12 ACMUI, being for the most part practicing
13 physicians, I would say that such a structure may
14 not be the best, given that it is a little bit
15 less flexible. But that is for your
16 consideration.
17 As far as your question about what the
18 staff recommends or sees, our view is, again, we
19 think that you should -- We think that the
20 structure can be significantly enhanced by the
21 Policy and Procedure that has been discussed, that
22 if that is done right and lays out clear guidance
23 as to how the staff is going to engage the ACMUI
24 and what the staff's responsibility for
25 transmitting the ACMUI's views to the Commission

1 and when that has to be done, in what
2 circumstances, we think -- this is just my
3 personal opinion, and I think many of the staff --
4 that that will address much of your concern that
5 you brought up where you said that you are happy
6 when they adopt ACMUI positions. You are somewhat
7 a little bit disappointed or dismayed or, in fact,
8 uninformed as to when or why certain positions
9 weren't adopted that the ACMUI recommends, that
10 you don't always get that feedback when there is
11 not adoption.

12 Again, we think that the procedure --
13 updating the Policy and Procedure and making those
14 feedback loops clear would probably be the best
15 option, but the Commission asks -- again, in Part
16 2 of the SRM, as I said, they ask for an
17 exploration of all the options.

18 The other one would be a more formal
19 reporting. Now as to Dr. Welsh's concern or
20 comment about there being two committees and would
21 it make sense for both Committees to report along
22 the same chain, I think that the staff's view on
23 that is that the ACRS affects -- The Policies and
24 Procedures that they deal with reach across a
25 number of -- many offices at the NRC, now that

1 they include the ACNW. It includes the Office of
2 Nuclear Reactor Regulations, the Office of New
3 Reactors, the Office of Nuclear Materials Safety
4 and Safeguards, as well as a portion of our office
5 here in FSME.
6 The issues that they deal with span
7 all of those offices, and that is why I think the
8 Commission level reporting exists there. For the
9 ACMUI, while the very important issues that you
10 deal with, they only report in -- There is only
11 one office that has regulatory responsibility for
12 the medical issues, and that is the office -- this
13 office.
14 I think that is originally why, and I
15 think it is my view, personal view, why I think
16 that a more tailored reporting for the ACMUI was
17 originally structured, and again my personal view
18 why it is still apropos today. But again, that is
19 just my opinion and why I think that it makes
20 sense that, if it stays this way, if the Committee
21 felt strongly that they would want to be part of
22 the larger structure, then that is fine, too.
23 That can be considered.
24 MS. COCKERHAM: Dr. Malmud, this is
25 Ashley.

1 CHAIRMAN MALMUD: Yes, Ashley?

2 MS. COCKERHAM: Just to add one thing

3 to what Jim said as well, as far as structuring of

4 ACRS versus ACMUI, just a little bit of history.

5 ACRS is mandated by law. It is

6 something that Congress came up with. They said

7 there will be an ACRS, and they will advise the

8 NRC. Then the way the ACMUI came about, it goes

9 all the way back to the Manhattan Project, but

10 long story short, the Commission, not Congress,

11 created ACMUI to advise staff.

12 So just -- It is not like we just

13 magically came up with this and said, oh, we are

14 going to have two different reporting structures.

15 It goes way, way back from how they were created

16 from the very beginning, and ACMUI is not mandated

17 by a law, but they are created by the Commission.

18 So we operate at the level that we do. I don't

19 know if that helps.

20 CHAIRMAN MALMUD: Yes, it does. It is

21 historical perspective on it.

22 MS. COCKERHAM: Yes.

23 CHAIRMAN MALMUD: Are there other

24 comments?

25 MEMBER GILLEY: Dr. Malmud, this is

1 Debbie Gilley. Can I just ask Ashley a question?
2 If the ACMUI were to report directly to the
3 Commission, would that require statutory changes
4 or is that something that the Commission can do
5 internally?
6 MS. COCKERHAM: The Commission would
7 be able to do that internally.
8 MEMBER GILLEY: Thank you.
9 CHAIRMAN MALMUD: I will comment by
10 saying that I am more than willing to take the
11 time and meet with members -- with the
12 Commissioners at the request of the Committee, and
13 they have expressed a willingness to meet with me,
14 and it needn't be on a restricted basis. It can
15 be on the basis of need.
16 So having been in administration for a
17 while, I am always concerned about unintended
18 consequences and, therefore, my own inclination
19 would be to keep the reporting lines as they are
20 with the enhancements that were discussed earlier.
21 MEMBER WELSH: Dr. Malmud.
22 CHAIRMAN MALMUD: Yes, Dr. Welsh.
23 MEMBER WELSH: Dr. Welsh again. Given
24 what I have just heard in response to my comments
25 and questions, I think that I as a member of the

1 ACMUI feel very fortunate that we don't have the
2 horrible circumstances that the ACRS is subjected
3 to. So perhaps I would just like to count my
4 blessings and, for all it is worth, I think that
5 maybe it is best to keep things the way they are
6 and not try to fix them if they are not broken
7 anymore.
8 CHAIRMAN MALMUD: Will that be a
9 motion from you?
10 MEMBER WELSH: I can phrase it in the
11 form of a motion, which is: I propose that we
12 maintain the status quo in terms of our ACMUI
13 reporting scheme.
14 CHAIRMAN MALMUD: With the
15 enhancements that were suggested?
16 MEMBER WELSH: Thank you.
17 CHAIRMAN MALMUD: Is there a second to
18 Dr. Welsh's motion?
19 MEMBER ZANZONICO: Seconded by
20 Zanzonico.
21 CHAIRMAN MALMUD: Thank you. Any
22 further discussion?
23 MEMBER VAN DECKER: Dr. Malmud, this
24 is Bill Van Decker.
25 CHAIRMAN MALMUD: Yes, Bill?

1 MEMBER VAN DECKER: Recognizing that I
2 am probably one of the now senior members of this
3 group -- that scares me -- let me just make a
4 couple of comments, and you personally probably
5 recognize my inability to really recognize
6 regulatory structure or internal structures at all
7 usually in life. So I don't know what models
8 work, but I would point out that one of the issues
9 that, I think, has been very helpful in the last
10 few years is that the Commission has met
11 personally with ACMUI once a year, and actually
12 had an open forum that actually sometimes has even
13 included other stakeholders.
14 I would point out that there was a
15 period of time where that did not occur, and I
16 think that that actually is a very, very useful
17 process for making everyone feel comfortable, that
18 there has been some personal discourse for the
19 filtering issue, whatever people may believe, and
20 I think that we should really believe that that
21 should happen every year.
22 I think that the staff has done an
23 incredibly good job, and I have been very pleased
24 with their give and take and their knowledge base
25 and helping ACMUI work right now.

My last comment would, obviously, be that the biggest sticking point to this situation is usually when very, very personal rulemaking is going on, because that intensifies pressure of Part 35, patient release and that type of stuff where people really want their views heard, and things kind of are really clear-cut in their mind.

The role of any committee is, obviously, to hear and to be heard. So the "to hear" piece is each of us has a constituency, and a good portion of what we do is hearing things from the other side and transmitting to the constituency and getting feedback. That is kind of like work-arounds and operational stuff, not much big deal there. That needs to happen and happen smoothly.

The other piece is, obviously, being heard, and being heard in a manner that seems to carry the weight that we have, the concerns for our constituencies. So sometimes in the rulemaking process and the structure that we may find out how well the communication is going and how satisfied people are.

Having said that, there is no reason in my mind to expect that, you know, as some of

1 this stuff starts to come to fruition in the next
2 year or two, that we won't have anything but
3 fairly transparent and clear-cut back and forth
4 and that type of stuff. But I do think when it
5 becomes very clear rulemaking stuff that the
6 concerns heighten, and the communication,
7 obviously, needs to be fairly clear. But I do
8 thank the Commissioners themselves for meeting
9 with us on a yearly basis over the last couple of
10 years, and I think that that is very, very
11 helpful, and I think that the model itself depends
12 on the good faith of everybody involved and what
13 they are trying to accomplish, and I think that
14 that is the most important thing.
15 So I am personally comfortable where
16 we currently are, but I think that some
17 enhancements and making sure that some things are
18 happening, especially in the rulemaking process
19 for discussions of decisions and especially a
20 yearly personal meeting to express the body
21 language and concerns is important.
22 CHAIRMAN MALMUD: Thank you, Dr. Van
23 Decker. Any other comments or discussion? There
24 is a motion which has been seconded.
25 MEMBER LANGHORST: Mr. Chairman, this

1 is Sue Langhorst.

2 CHAIRMAN MALMUD: Yes, Sue?

3 MEMBER LANGHORST: I still feel at a
4 real disadvantage on this, and if we do vote on
5 this today, I would have to vote no, because I
6 just -- I would like the draft of the report that
7 Ashley is putting together so I can have a more
8 full understanding personally.

9 CHAIRMAN MALMUD: So would you like to
10 table the motion or are you objecting to the
11 motion?

12 MEMBER LANGHORST: Well, I think we
13 need some time, especially given that we didn't
14 even know what this item covered. I think it
15 would be nice to table the motion and have some
16 time to review what Ashley is putting together.

17 CHAIRMAN MALMUD: Thank you.

18 MEMBER GUIBERTEAU: Chairman Malmud,
19 hi, this is Mickey Guiberteau. I have joined the
20 call sometime ago, but I was waiting for a chance
21 to speak.

22 I would support tabling this motion
23 for the reasons that Sue said, and although I have
24 heard most of the conversation, it was not clear
25 to me that on this call that this would be

1 something that we would be putting on the table,
2 either to reject or to put forward as a model.
3 So I think further discussion among
4 the Committee would be a good thing, further
5 thought and, as you have suggested, perhaps some
6 further consultation with the Commissioners.
7 CHAIRMAN MALMUD: All right. Thank
8 you, Dr. Guiberteau. There have been two
9 recommendations for tabling this. It could be
10 brought up at our spring meeting, at which time I
11 would ask if Ashley could have her comments
12 prepared. Would that be a reasonable time limit,
13 Ashley?
14 MS. COCKERHAM: Yes. Did you say
15 before the next phone call?
16 CHAIRMAN MALMUD: The next meeting.
17 MS. COCKERHAM: Yes.
18 CHAIRMAN MALMUD: Which is in April, I
19 believe.
20 MS. COCKERHAM: Oh, actually, my paper
21 is due to the Commission before.
22 CHAIRMAN MALMUD: It would be even
23 before that? That is even better.
24 MS. COCKERHAM: Yes, and actually,
25 this is why we set up the January 12th

1 teleconference, and there is one topic on the
2 agenda, and it is the ACMUI reporting structure.
3 I actually need feedback from the Committee for
4 sure before the end of this month, because my
5 paper is due to the Commission April 1st, and I
6 will not be here for that next meeting anyway.
7 CHAIRMAN MALMUD: So then we will have
8 this discussion on January 12th, if we table it
9 today. Is that correct?
10 MS. COCKERHAM; Yes.
11 CHAIRMAN MALMUD: All right. Is that
12 acceptable to those who made the motion?
13 MEMBER WELSH: This is Dr. Welsh, and
14 I agree fully with what Dr. Langhorst has brought
15 up, that perhaps it would be wise to table this
16 until this presentation concludes before we
17 proceed.
18 CHAIRMAN MALMUD: Thank you. If the
19 Committee is in agreement, we will table it for
20 the Committee phone meeting January 12th. Is that
21 acceptable? Any opposed to it? Sounds like it is
22 acceptable. Okay, thank you.
23 We now move on to the next item on the
24 agenda, which is the rulemaking and implementation
25 guidance for physical protection of byproduct

1 material. Who is going to tackle that for us?
2 MEMBER GILLEY: This is Debbie Gilley.
3 I kind of started the ball rolling. Sue Langhorst
4 and Darrell Fisher also serve on our Subcommittee.
5 We took a high level approach to
6 coming up with comments over the overall
7 regulations, just detailed comments, and they were
8 provided for you in a draft report for your
9 review.
10 The recommendations from the report
11 from the Subcommittee: Encourage NRC to implement
12 the existing orders into regulations and not to
13 enhance them, and also to begin looking at
14 developing strategic rulemaking that can be based
15 on risk informed.
16 I will answer questions to the report,
17 if you have had a chance to read it.
18 CHAIRMAN MALMUD: Has anyone not had a
19 chance to read it?
20 MEMBER GILLEY: I would ask also that
21 Dr. Fisher and Dr. Langhorst please weigh in on
22 this. It has been a real tight timeline for us.
23 CHAIRMAN MALMUD: Thank you. Do we
24 have additional comments from either Dr. Fisher or
25 Dr. Langhorst?

1 MEMBER FISHER: Yes. Dr. Malmud, this
2 is Darrell Fisher. I have got a little
3 laryngitis. So I hope you can bear with me.
4 The Subcommittee supports the general
5 concepts that this proposed Part 37 works toward,
6 but in many cases a lot of new requirements have
7 been added that are not currently part of the
8 orders to which licensees must comply; and in a
9 lot of cases, the extra burden of complying with
10 the new requirements may be so burdensome to the
11 licensee that it will have two distinct impacts on
12 the practice of medicine.
13 The first distinct impact would be to
14 greatly increase the cost of providing certain
15 services that require use of Category I and
16 Category II materials.
17 The second ultimate impact of these
18 new regulations appears to be such that, with the
19 requirements for safety and security being so
20 burdensome, that medicine will abandon the use of
21 these procedures outright, and that they will not
22 be available to benefit patients.
23 So we believe that there is a -- that
24 a reasonable balance between availability of
25 Category I and Category II sources for patient

1 therapy and research and counterbalanced with a
2 need for safety and security, but that excessive
3 requirements for safety and security would neither
4 make these sources safer nor make them available
5 to patients who need them.

6 So I would agree with what Debbie
7 Gilley has summarized, that there is a reasonable
8 balance that can be achieved, that can be
9 successful in securing these materials so that
10 they are not available for illegal activities.

11 CHAIRMAN MALMUD: Thank you.

12 MEMBER LANGHORST: Dr. Malmud, this is
13 Sue Langhorst.

14 CHAIRMAN MALMUD: Yes, Sue?

15 MEMBER LANGHORST: The Subcommittee --
16 we also agree that we understand that the need to
17 implement, to develop and implement the increased
18 controls, license orders necessitated the
19 structure of a one-size-fits-all model, but we are
20 concerned that perpetuation of this one-size-fits-
21 all model into the regulations with added
22 requirements is not in line with how NRC develops
23 their performance based risk enhanced regulations.

24 So we feel that there was much
25 upheaval for licensees, and speaking as a medical

1 licensee, a lot of upheaval in my office, when we
2 implemented the increased controls, license
3 orders, and added the FBI fingerprint/background
4 check, and we currently have those in line.
5 I think a lot of licensees are doing
6 well in that, and have enhanced security for these
7 sources. So I think this is an opportunity to
8 move from orders to regulatory space, as I call
9 it, or to codify these current requirements, and
10 then work in a very strategic manner on what is
11 going to be effective security enhancements.
12 One of the things that I personally
13 would like to see is that there be more
14 performance base in between what you do for
15 determining individuals' trustworthiness or
16 reliability versus what the actual situation is
17 for a given source, either by what isotope it is,
18 what form it is in, what device it is in.
19 So I would like that performance based
20 opportunity to be able to let up a little bit on
21 the trustworthiness and reliability requirements,
22 if you have really strong physical protection.
23 Thank you very much.
24 CHAIRMAN MALMUD: Thank you. For
25 those of you who might wonder what Sue was

1 referring to, page 4 of her document -- her
2 Subcommittee's document -- lists the ACMUI
3 recommendation, and she was referring in the
4 second part of this discussion to the second
5 bullet point, which had to do with working with
6 developing a strategic rulemaking.
7 You have all had a chance to review
8 the document from the Subcommittee. This is now a
9 meeting of the actual Committee itself and,
10 therefore, the Subcommittee report would be
11 considered a motion to the Committee. Is that
12 fair, Debbie?
13 MEMBER GILLEY: Yes, sir.
14 CHAIRMAN MALMUD: So this is a motion
15 to the Committee. Is there a second to this
16 motion?
17 MEMBER SUH: I second the motion.
18 CHAIRMAN MALMUD: Who seconded?
19 MEMBER SUH: It is John Suh.
20 CHAIRMAN MALMUD: Thank you. Further
21 discussion?
22 MEMBER ZANZONICO: This is Pat
23 Zanzonico. Just for my personal clarification,
24 based on my reading of the proposed rulemaking and
25 the Subcommittee report, I gather that perhaps the

1 two issues that are the most onerous are the
2 background check issue and the requirement of
3 licensees to interact with local law enforcement,
4 which do strike me as the most problematic
5 components in practice of the proposed rulemaking.
6 Is that basically -- Am I reading the
7 Subcommittee report correctly in kind of inferring
8 that from the report?
9 CHAIRMAN MALMUD: This is Malmud. I
10 read it similarly, but not exactly. So,
11 therefore, I would ask the Chair of the
12 Subcommittee, Debbie Gilley, to comment. My
13 interpretation was that there are two major
14 issues. One was the cost involved, and the other
15 one was, because of the cost and the regulatory
16 delays and requirements, that some of the services
17 may be made unavailable to patients as a result of
18 the expense and time commitment.
19 Was that a summary between the two of
20 us, Debbie?
21 MEMBER GILLEY: That is correct. It
22 is really on two different levels. We took a high
23 road or a big universal approach, and the cost of
24 doing business with the additional requirements is
25 definitely at a higher level.

1 The individual activities that Dr.
2 Zanzonico brought to attention of the Committee
3 are just areas where we are demonstrating that
4 cost and that implementation and, most
5 importantly, licensees remaining compliant with
6 the requirements are problematic.
7 CHAIRMAN MALMUD: Thank you.
8 MEMBER ZANZONICO: I will just say
9 thank you.
10 CHAIRMAN MALMUD: So I think the
11 problems are well summarized on page 4 of the
12 document that the Subcommittee presented, and the
13 recommendations are well summarized. The problems
14 are well summarized in the first three pages.
15 This has been presented as a motion
16 with a second. Any other comments? It is a very
17 thoughtful and detailed document which represents
18 a lot of effort, for which we are appreciative to
19 members of the Subcommittee.
20 All in favor? Any opposed? Any
21 abstentions? It passes with unanimity.
22 MEMBER GILLEY: Thank you.
23 CHAIRMAN MALMUD: Thank you. Thank
24 you, Debbie Gilley, Sue Langhorst and Dr. Fisher.
25 If we may, we will move on to the next

1 item on the agenda, which is the impacts of the
2 Draft Safety culture Policy Statement for Medical
3 Licensees. Who would like to tackle that one?
4 MEMBER THOMADSEN: I think I am
5 probably the one who should probably --
6 CHAIRMAN MALMUD: Bruce?
7 MEMBER THOMADSEN: -- address that.
8 Yes. I was the one who raised most of
9 the issues with that when it came before the ACMUI
10 before. Since that time, there was a second
11 version of the Policy Statement which was sent to
12 the ACMUI with two clarifications, which
13 apparently had meant to be in the Statement that
14 was sent out but got cut somehow.
15 One was pointing out that the traits
16 are not complete, that there are other traits that
17 would be important, and the other is that the
18 traits were not intended to be enforceable, which
19 basically addressed most of the points that I had,
20 worrying about this Statement.
21 On the 24th there is a meeting in
22 Washington to discuss the Safety Culture Policy
23 Statement. I am going to be representing the
24 ACMUI at that meeting, and to that end, I would
25 like to tell the Committee what I am planning on

1 saying, and seeing how it strikes the rest of the
2 Committee.
3 I will start by saying I now think
4 that the Policy Statement is, in general, a good
5 statement, a good policy, and as explained but not
6 necessarily in the policy, I am not as worried as
7 I was about how it might be used in enforcement.
8 But with your permission, I will tell the five
9 points that I plan on making at that meeting.
10 CHAIRMAN MALMUD: Please do.
11 MEMBER THOMADSEN: And, please, if you
12 have comments about any of them or how they are
13 being stated, please let me know as we go.
14 The first is, while good, the list
15 traits are not exhaustive. There are many other
16 traits organizations with safety cultures that are
17 not included. The policy statement does recognize
18 this.
19 Two: Also while the traits are good,
20 an organization need not exhibit the traits to be
21 safe. For example, an organization without trust
22 or respect can, and likely would, establish
23 procedures with layers of redundancy, possibly
24 automatic, to prevent errors, since the leaders
25 would not have trust that the workers would

1 execute their jobs correctly.

2 Three: Safety is easiest and most
3 natural in organizations that exhibit such traits
4 and that is why publishing them would be a good
5 educational enterprise.

6 Four: A positive safety culture is in
7 the nature of an organization and cannot be forced
8 upon an organization. While practices can be
9 imposed, forcing practices that appear as traits
10 in a good safety culture likely will not have the
11 same effects as if the organization developed them
12 naturally, and can be counterproductive if it uses
13 resources that could be devoted to actual safety
14 practices.

15 Five: Given point four, the statement
16 in the policy, these traits are not necessarily
17 inspectable and were not developed for that
18 purpose, should be remembered into the future.

19 That is the -- That is pretty much the
20 sum and substance of what I will be saying at the
21 meeting.

22 CHAIRMAN MALMUD: Thank you. Dr.
23 Thomadsen is inviting comments from members of the
24 Committee or others who wish to comment on his
25 five points. Hearing none, may I ask you a

1 question, Bruce?

2 MEMBER THOMADSEN: Please.

3 CHAIRMAN MALMUD: Having recently
4 experienced surgery, I was still awake when they
5 had a "time out," at which time a list of details
6 was checked, including the name of the patient,
7 date of birth of the patient, the site of the
8 surgery, and the specific procedure, etcetera,
9 etcetera.

10 This was not something which came from
11 within the world of surgery but really was
12 imposed, if you will, by a higher authority, both
13 centrally and within the institution, and it is
14 very effective.

15 Is that compatible with your item
16 number four?

17 MEMBER THOMADSEN: It actually is, in
18 that I would like to have -- I would like to see
19 more data on your point that it is very effective.
20 Statistically, it has not been shown to be very
21 effective. The number of wrong side surgeries --
22 and this is in a study that came out two years ago
23 -- had not changed since before those “time outs”
24 were instigated.

25 Why that was the case, the authors of

1 the article didn't have a clue, but it is not
2 clear that that was so effective, and in part it
3 may not be so effective, because it may be
4 something, a trait, which is forced upon hospitals
5 and may not be performed very sincerely.
6 CHAIRMAN MALMUD: All right. So that
7 my observation, which is based upon a sample of
8 one, may not hold, although I do know that at our
9 own institution I probably would have been alerted
10 had we had an incorrect limb operated on or
11 something like that.
12 MEMBER THOMADSEN: Yes, right, and in
13 your institution, which may be, I would assume, an
14 organization that has a good faith culture,
15 adoption of such measures might not be forced, but
16 when offered a "something" that appears like it
17 may be useful, may be adopted quite willingly and
18 with rigor and sincerity.
19 CHAIRMAN MALMUD: Okay. I am
20 laughing, because I am thinking back to my
21 experience when the surgeon stopped everything and
22 said time out. It reminded me of, when my
23 daughter was younger, behavior in the preschool
24 where they had a time out if something was going
25 wrong, and everyone did stop, and everyone did

1 fulfill a checklist of requirements before they
2 went on with the procedure, and I was, I guess, a
3 little amused by it, but also impressed that
4 people of such stature in terms of anesthesia,
5 nursing and, of course, the surgeons were doing
6 this.
7 All right. Well, in that case, I am
8 perfectly agreeable with what you have pointed
9 out. Anyone else have a comment?
10 MEMBER ZANZONICO: This is Pat
11 Zanzonico. I also just wanted to pursue that
12 point for all of you. I mean, it is kind of akin
13 to a statement that, you know, morality can't be
14 legislated, and the issue is then, is it a futile
15 exercise? If an organization or whatever doesn't
16 have a rigorous or any safety culture, is it
17 futile to enumerate traits to kind of codify a
18 safety culture in the way it is being proposed,
19 etcetera, etcetera?
20 I am kind of agreeing with Dr. Malmud,
21 I guess, in that sort of forcing some
22 organizations like some people to do certain
23 things for their good and the greater good is
24 worthwhile and serves the greater good, and isn't
25 that somewhat counter to your point four?

1 MEMBER THOMADSEN: No, and do not
2 confuse trying to impose a safety culture with
3 safety practices. They are entirely different,
4 and let's assume for the moment that time outs
5 actually do serve some function.
6 Imposing that particular behavior
7 could be useful, just as requiring what big tests
8 of radiation sources can be useful, even if that
9 wouldn't be something that the culture of the
10 nation wanted to do.
11 You don't have to change their culture
12 to change that behavior, and in this case the
13 point to be made is, if there are safety behaviors
14 that have to be in place that are not -- and those
15 would not be traits but things that have to be
16 done -- enforcing that upon the licensees can be
17 very useful and productive. You don't have to
18 change their attitude toward it, which would be
19 their culture.
20 If you look at the list, the list
21 isn't of behaviors so much as attitudes. You can
22 force an organization to be open to people raising
23 concerns. How they deal with those concerns is
24 quite another matter.
25 It is like the suggestion box in the

1 cartoons with the bottom cut open. You can be
2 open to suggestions being submitted, but that
3 doesn't mean you are open to the ideas.
4 You can't force something like that,
5 but you can force whatever behaviors you think are
6 necessary for safety.
7 MEMBER ZANZONICO: Understood.
8 CHAIRMAN MALMUD: I am not a
9 philosophy expert and, therefore, I am treading in
10 dangerous ground for myself, but the imposition of
11 rules carried over a period of time can alter a
12 culture, can it not?
13 MEMBER THOMADSEN: Absolutely.
14 CHAIRMAN MALMUD: And that is what we
15 are seeking. That is what you are seeking.
16 MEMBER THOMADSEN: That is what I
17 would be seeking.
18 CHAIRMAN MALMUD: Yes. That is what
19 we are hoping for.
20 MEMBER THOMADSEN: Right.
21 CHAIRMAN MALMUD: In the same manner,
22 we have seen the transition to hand washing before
23 touching a patient and upon leaving the patient's
24 room. We have known for over 100 years that that
25 was necessary, but now we are imposing it, and it

1 is being carried out, and it is second nature to
2 us now. So that the imposition of a rule has made
3 it part of our culture.
4 MEMBER THOMADSEN: That is correct.
5 MEMBER FISHER: And, Mr. Chairman,
6 this is Darrell Fisher. I would like to take the
7 position as a member of the Committee that the
8 Statement of Policy is really quite well written,
9 very carefully drafted, and very sensitive to
10 comments that have been received from the public,
11 and I think that those who have developed this
12 statement really need to be congratulated.
13 As a Committee, I think we should
14 consider endorsing this wholeheartedly so that it
15 can go forth to the Commission with our positive
16 recommendation.
17 CHAIRMAN MALMUD: Thank you. Will
18 that be the second to the motion?
19 MEMBER FISHER: Yes.
20 CHAIRMAN MALMUD: The motion coming
21 from the Subcommittee?
22 MEMBER THOMADSEN: What is the
23 Subcommittee?
24 CHAIRMAN MALMUD: I thought that was--
25 MEMBER THOMADSEN: I don't think that

1 there was a Subcommittee working.

2 CHAIRMAN MALMUD: Oh, it was a

3 subcommittee of one. Thank you, Dr. Thomadsen.

4 MEMBER FISHER: This is Fisher again.

5 CHAIRMAN MALMUD: We will accept this

6 as Dr. Thomadsen's recommendation, seconded, and

7 open for further discussion, if any.

8 MEMBER THOMADSEN: I think that I

9 would be delighted to take this motion as another

10 bullet point to put into the presentation.

11 Actually, I would put it as the first bullet

12 point, saying all those things that Dr. Fisher

13 said, and would ask him to send me an email with

14 the exact wording that he just said, along with

15 just noting the concerns that the Committee has

16 about the Policy Statement.

17 CHAIRMAN MALMUD: All right. This is

18 Malmud again. I want, first of all, to thank you,

19 Bruce, for the effort, and I will present this to

20 the Committee as the motion, which has been

21 seconded, to be added on. Any further discussion?

22 All in favor? Any opposed? Any

23 abstention?

24 MEMBER GILLEY: Debbie Gilley,

25 abstaining.

1 CHAIRMAN MALMUD: Debbie Gilley
2 abstains. All right. Any further comment? If
3 not, it carries, with one abstention.
4 MEMBER THOMADSEN: Mr. Chairman, can I
5 ask, just in case it may be something we should
6 include in the presentation, what Ms. Gilley's
7 hesitation is, why she is abstaining? Is there
8 something I should include in the message we send?
9 CHAIRMAN MALMUD: Debbie that is a
10 question to you from Dr. Thomadsen.
11 MEMBER GILLEY: Well, I come from the
12 regulatory side of the house, and the Policy
13 Statement is not enforceable in regulatory world,
14 and I don't know how we can have consistent safety
15 culture requirements across agreement states and
16 NRC without it either being in regulations or we
17 won't be able to enforce it, if it is just a
18 policy statement.
19 CHAIRMAN MALMUD: Thank you for
20 clarifying that. Dr. Thomadsen?
21 MEMBER THOMADSEN: I am not sure
22 exactly how to put that in and whether it -- Is
23 that sentiment common for the Committee? Should
24 that be included in the report?
25 CHAIRMAN MALMUD: Dr. Thomadsen is

1 asking a question of members of the Committee.
2 MEMBER THOMADSEN: Yes.
3 CHAIRMAN MALMUD: Any members have a
4 comment?
5 MEMBER ZANZONICO: This is Pat
6 Zanzonico. I am certainly sympathetic to Debbie's
7 position, but my overall feeling is that not every
8 pronouncement from a regulator such as the NRC
9 need be an enforceable regulation to have some
10 value among the entities being regulated, and I
11 think this is one example of that.
12 So I understand and sympathize with
13 the issue, but I think this statement as a
14 nonenforceable statement has value potentially for
15 users.
16 MEMBER SULEIMAN: Chairman Malmud,
17 this is Dr. Suleiman.
18 CHAIRMAN MALMUD: Yes, Dr. Suleiman?
19 MEMBER SULEIMAN: I sort of agree with
20 Pat. I think trying to establish an attitude of
21 culture -- we do it all the time in FDA for a
22 variety of things. It is not necessarily
23 enforceable. In fact, it is good that it is not
24 enforceable. It is just an attitude where people
25 pay attention more to safety than other things.

1 You see that a lot in the airline
2 community, for example. So I have no trouble
3 supporting this.
4 CHAIRMAN MALMUD: Thank you. Any
5 other comments?
6 MEMBER GUIBERTEAU: Yes. This is
7 Mickey Guiberteau. I just wanted to ask Debbie,
8 what is -- In terms of the inability to regulate
9 the elements of this policy, instead, is there not
10 a mechanism by which the states or by which the
11 organization of agreement states may endorse or
12 actually adopt this policy for states and use it
13 in the way that we have discussed in terms of
14 changing attitude and culture?
15 MEMBER GILLEY: Yes. That is not the
16 issue. The issue is it is a policy statement that
17 has no enforceability to it. It will be
18 interpreted by every agreement state, at NRC, at
19 their whim, which leaves the licensee somewhat not
20 knowing when they have a safety culture and when
21 they do not have a safety culture.
22 In other words, there is not clear
23 guidance provided for you to know when you have a
24 safety culture.
25 MEMBER GUIBERTEAU: Well, would you

1 propose that some guidance be developed along with
2 this policy or is that -- Is there a mechanism for
3 that?
4 MEMBER GILLEY: I don't know. You
5 know, I live in the world of regulation. Policy
6 statements -- you know, if they had -- implied
7 that medical communities already had a safety
8 culture that is completely above the small subset
9 of nuclear medicine and therapy that might be
10 going on in their institution. We hope that that
11 is the way it is.
12 So in some respect, this is additional
13 safety culture policy to an organization that
14 should already have the best safety culture out
15 there, because they are dealing with human beings
16 in a medical environment.
17 CHAIRMAN MALMUD: This is Malmud. I'm
18 sorry, who was --
19 MEMBER VAN DECKER: Oh, I'm sorry, Dr.
20 Malmud. This is Bill Van Decker.
21 CHAIRMAN MALMUD: Yes, Bill?
22 MEMBER VAN DECKER: Let me ask Ms.
23 Gilley a question. The additional part of this
24 discussion a few weeks or a month ago, whatever,
25 seemed to imply to me that there may be a second

1 step in this process that somebody described as,
2 quote, "implementation safety characteristics"
3 which to me implied that there may be a movement
4 toward regulatory space with some pieces of this
5 as it got fleshed out.

6 I assume that Debbie would be willing
7 to be giving us her vote and her opinion on that
8 stuff as it develops down the line.

9 MEMBER GILLEY: If that were the
10 direction that it was going, but right now it is
11 on the table as a policy statement, and I assume
12 that if the policy statement works as is, there
13 will be no reason to go the next step as far as
14 implementation for regulatory noncompliant issues.

15 MEMBER VAN DECKER: It comes under the
16 heading of be careful what you ask for in life.

17 MEMBER GILLEY: You know, I kind of
18 sit on this committee and look at what we can, as
19 the agreement states, regulate, and this one is a
20 hard one, because I think we are going to see
21 safety culture be interpreted across the board in
22 many different directions.

23 Then I look at what the licensees can
24 -- we can truly expect them to be able to respond
25 to and become compliant of, and in this particular

1 case, it is a policy statement that is somewhat
2 nebulous.
3 MR. FIRTH: This is James Firth on the
4 NRC staff, if I could add a little bit, please.
5 CHAIRMAN MALMUD: Please do.
6 MR. FIRTH: The Committee has received
7 the draft Federal Register notice that is going to
8 be going to the Commission. There is also a
9 Commission paper that is going to convey that up
10 to the Commission, and there we do talk about some
11 of the next steps that we are taking.
12 The way we have been looking at the
13 policy statement and what would come afterward is
14 that we don't want the policy statement to go out
15 and that there be no further effort on education
16 or increasing awareness. Otherwise, we would lose
17 the value of the policy statement.
18 So we would be looking at continuing
19 to increase awareness among medical as well as
20 non-medical licensees. The policy statement
21 includes common terminology which includes
22 definition in the traits that have been discussed.
23 As we were developing that framework,
24 we were also looking at there may be more industry
25 specific terminology which might include certain

1 examples of good practices that might then be
2 developed and included as something that would be
3 available to licensees, whether it is in guidance
4 or whatever.
5 So there is common terminology in this
6 policy statement, trying to reach across the
7 board, but we are planning on taking steps to look
8 at what we might do for the different applications
9 of nuclear material, and that might get a little
10 bit to some of Debbie's concerns in terms of that
11 the policy statement may be a little bit on the
12 general side, and something else later might be
13 useful.
14 CHAIRMAN MALMUD: Thank you. Is that
15 helpful, Debbie?
16 MEMBER GILLEY: That is all right, but
17 I am still abstaining.
18 CHAIRMAN MALMUD: Thank you. All
19 right. So the motion carries with one abstention,
20 and I think it expresses the concern of all of us,
21 including Debbie Gilley, with regard to the nature
22 of a safety culture and the ultimate goal of
23 achieving greater patient safety and safety to the
24 public. That is a concern of all of us.
25 The issue is not concern for it, but

1 the best way in which to achieve it.
2 Are there any other items that members
3 of the Committee or the public wish to bring
4 before the Committee at this moment? Hearing
5 none, I would ask Ashley; are there any business
6 items that you wish to bring before us at this
7 time?
8 MS. COCKERHAM: No. We already have
9 the January 12th meeting scheduled for 1:00 p.m.
10 to follow up on the ACMUI reporting structure. So
11 I will try to provide some information to the
12 committee as soon as possible.
13 CHAIRMAN MALMUD: Thank you.
14 MS. COCKERHAM: They can discuss it
15 next week.
16 CHAIRMAN MALMUD: Thank you. I thank
17 the members of the committee, the members of the
18 NRC staff and members of the public for having
19 joined us, and we will meet again on January 12th.
20 Thank you all.
21 MR. FULLER: This is Mike Fuller. As
22 the alternate Designated Federal Officer for this
23 meeting, I would also like to thank everyone who
24 participated in the ACMUI for their service, and
25 at this point in time I would like to adjourn the

1 meeting.

2 CHAIRMAN MALMUD: Thank you. The

3 meeting is adjourned.

4 (Whereupon, the foregoing matter went

5 off the record at 2:52 p.m.)

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