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 Uses of Isotopes

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1 UNITED STATES OF AMERICA

2 NUCLEAR REGULATORY COMMISSION

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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,
14 M.D., 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

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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
6 NRC STAFF PRESENT:

7 MARYANN ABOGUNDE, R-1/DNMS/MB

8 MICHELLE ALBERT, OGC/GCLR/HLWFCNS

9 VALERIE BARNES, RES/DRA

10 HECTOR BERMUDEZ, R-1/DNMS/MB

11 JUNE CAI, OE

12 SUSAN CHIDAKEL, OGC/GCLR/RMR

13 ASHLEY COCKERHAM, FSME/DMSSA/LISD,

14 ACMUI Coordinator

15 JACKIE COOK, R-IV/DNMS/NMSB-B

16 SAID DAIBES, FSME/DMSSA/LISD

17 JAMES FIRTH, FSME/DILR/RB-B

18 SARA FORSTER, R-III/DNMS/MLB

19 MICHAEL FULLER, FSME/DMSSA/LISD,

20 Designated Federal Official

21 SANDY GABRIEL, R-1/DNMS/MB

22 SOPHIE HOLIDAY, FSME/DMSSA/LISD

23 DONNA BETH HOWE, FSME/DMSSA/LISD

24 JAMES LUEHMAN, Deputy Division Director,

25 FSME/DMSSA/LISD

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1 NRC STAFF PRESENT:

2 GRETCHEN RIVERA-CAPELLA, FSME/DMSSA/LISD

3 SHIRLEY XU, FSME/DMSSA/LISD

4 RONALD ZELAC, FSME/DMSSA/LISD

5
6 ALSO PRESENT:

7 SUE BUNNING, Society of Nuclear Medicine

8 CHARLES BURNS, New York State Department of
9 Health

10 ROBERT E. DANSEUREAU, New York State Department
11 of Health

12 KEITH DINGER, Government Liaison, Health
13 Physics Society

14 LYNNE FAIROBENT, American Association of
15 Physicists in Medicine

16 THOMAS HUSTON, Department of Veterans Affairs

17 SYLVIA MARTIN, State of Oregon

18 JANETTE MERRILL, Society of Nuclear Medicine

19 MARY MOORE, Philadelphia Veterans Affairs
20 Medical Center

21 DENNIS O'DOWD, New Hampshire Department of
22 Health and Human Services

23 MIKE PETERS, American College of Radiology

24 GLORIA ROMANELLI, American College of Radiology

25 GEORGE SEGALL, Society of Nuclear Medicine

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1 ALSO PRESENT: (continued)

2 MICHAEL SHEETZ, University of Pittsburgh

3 SASHA SIMPSON, ML Strategies

4 CINDY TOMLINSON, American Society for

5 Radiation Oncology

6 GARY A. WILLIAMS, Veterans Health Administration

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DRAFT

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P R O C E E D I N G S

Time: 1:04 p.m.

1
2
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
9 in 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
25 Register.

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

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

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

18 CHAIRMAN MALMUD: Here.

19 MR. FULLER: Dr. Bruce Thomadsen.

20 VICE CHAIRMAN THOMADSEN: Here.

21 MR. FULLER: Dr. Darrell Fisher.

22 MEMBER FISHER: Here.

23 MR. FULLER: Ms. Debbie Gilley.

24 MEMBER GILLEY: Here.

25 MR. FULLER: Dr. Mickey Guiberteau.

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1 Dr. Sue Langhorst.

2 MEMBER LANGHORST: Here.

3 MR. FULLER: Mr. Steve Mattmuller.

4 MEMBER MATTMULLER: Here.

5 MR. FULLER: Dr. Christopher Palestro.

6 MEMBER PALESTRO: Here.

7 MR. FULLER: Dr. John Suh.

8 MEMBER SUH: Here.

9 MR. FULLER: Dr. Orhan Suleiman.

10 MEMBER SULEIMAN: Here.

11 MR. FULLER: Dr. William Van Decker.

12 Dr. James Welsh.

13 MEMBER WELSH: Here.

14 MR. FULLER: And Dr. Pat Zanzonico.

15 MEMBER ZANZONICO: Here.

16 MR. FULLER: Okay, I will note that we
17 have a quorum, and we have at this point only two
18 members who are not in attendance.

19 I would note that Dr. Guiberteau and
20 Dr. Palestro do not have voting privileges at
21 this time, but they will listen and speak on
22 behalf of the diagnostic radiologists and nuclear
23 medicine physicians, respectively.

24 I will not introduce the NRC staff
25 members who are present here at NRC headquarters.

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1 Again, my name is Mike Fuller. I have with me
2 Mr. James Luehman. I also have June Cai, Dr.
3 Ronald Zelac, Susan Chidakel, Shirley Xu, Ed
4 Lohr, Dr. Donna Beth Howe, and --

5 MS. ALBERT: Michelle Albert.

6 MR. FULLER: Michelle Albert, and then
7 also we have some NRC Headquarters employees on
8 the phone. Could those individuals please
9 identify themselves at this time.

10 DR. DAIBES: Said Daibes.

11 MR. FULLER: Okay, Dr. Daibes. Any
12 other NRC Headquarters?

13 DR. BARNES: Valerie Barnes.

14 MS. RIVERA-CAPELLA: Gretchen Rivera-
15 Capella.

16 MS. COCKERHAM: This is Ashley
17 Cockerham.

18 MR. FULLER: I'm sorry, Ashley. Who
19 was the other person?

20 MR. BERMUDEZ: Hector.

21 MS. COCKERHAM: We will go to the
22 Regions.

23 MR. FULLER: Yes, we will get to the
24 Regions in a moment.

25 MS. HOLIDAY: Hey, Mike, this is

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1 Sophie.

2 MR. FULLER: Okay, Sophie. There was
3 one other person prior to Gretchen. Can you
4 repeat your name again?

5 MS. COCKERHAM: Mike, I think that
6 was Valerie Barnes or Michelle Albert.

7 MR. FULLER: Valerie Barnes. That is
8 who it was. Thank you.

9 MS. COCKERHAM: You are welcome.

10 MR. FULLER: Okay, next we will go to
11 the Regions. Who do we have on the call from
12 Region I?

13 DR. GABRIEL: Sandy Gabriel.

14 MR. BERMUDEZ: Hector Bermudez.

15 MR. FULLER: Anyone else from Region
16 I? Okay, we will go to Region III. Who do we
17 have on the call from Region III?

18 MS. FORSTER: Hi. This is Sara
19 Forster.

20 MR. FULLER: Anyone else from Region
21 III? Now NRC Region IV?

22 MS. COOK: Jackie Cook.

23 MR. FULLER: All right. The next thing
24 I will do is identify the members of the public
25 who notified us that they would be participating

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1 in the teleconference. So when I call your name,
2 please indicate if you are on the call.

3 Keith Brown, University of
4 Pennsylvania? Sue Bunning, Society of Nuclear
5 Medicine?

6 MS. BUNNING: Here.

7 MR. FULLER: Charles Burns, New York
8 State Department of Health?

9 MR. BURNS: Here.

10 MR. FULLER: Robert Dansereau, New
11 York State Department of Health?

12 MR. DANSEREAU: Present.

13 MR. FULLER: Keith Dinger, Health
14 Physics Society?

15 MR. DINGER: Here.

16 MR. FULLER: Lynne Fairobent, American
17 Association of Physicists in Medicine?

18 MS. FAIROBENT: Here.

19 MR. FULLER: Dr. Thomas Huston,
20 Department of Veterans Affairs?

21 DR. HUSTON: Here.

22 MR. FULLER; Jackie Kavanaugh,
23 Nordian? Sylvia Martin, Oregon?

24 MS. MARTIN: Here.

25 MR. FULLER: Andrew Mauer, Nuclear

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1 Energy Institute? Janette Merrill, Society of
2 Nuclear Medicine?

3 MS. MERRILL: Here.

4 MR. FULLER: Mary Moore, Philadelphia
5 Veterans Affairs Medical Center?

6 MS. MOORE: Here.

7 MR. FULLER: Mike Peters, American
8 College of Radiology?

9 MR. PETERS: Here.

10 MR. FULLER: Gloria Romanelli,
11 American College of Radiology?

12 MS. ROMANELLI: Here.

13 MR. FULLER: Dr. George Segall,
14 Society of Nuclear Medicine?

15 DR. SEGALL: here.

16 MR. FULLER: Michael Sheetz,
17 University of Pittsburgh?

18 MR. SHEETZ: Here.

19 MR. FULLER: Sasha Simpson, ML
20 Strategies?

21 MS. SIMPSON: Here.

22 MR. FULLER: Cindy Tomlinson, American
23 Society for Radiation Oncology?

24 MS. TOMLINSON: Here.

25 MR. FULLER: Gary Williams, Veterans

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1 Health Administration.

2 MR. WILLIAMS: Here.

3 MR. FULLER: And Stanley Wilson, Emory
4 University?

5 Okay, is there anyone else on the call
6 that I did not recognize?

7 MR. O'DOWD: A member from the public,
8 Dennis O'Dowd, representing New Hampshire
9 Department of Health and Human Services.

10 MR. FULLER: Okay, anyone else?

11 MEMBER VAN DECKER: This is Bill Van
12 Decker. I just want to let you know I got on.

13 MR. FULLER: Oh, okay. All right.
14 Did Dr. Guiberteau join us, by any chance? Okay.

15 All right. At this time, I will ask
16 that everyone on the call who is not speaking to
17 please place their phones on mute. If you do not
18 have the capability to mute your phone, please
19 press 6 to utilize the conference line mute and
20 unmute functions. I would ask everyone to
21 exercise extreme care to ensure that background
22 noise is kept to minimum. Any stray background
23 sounds can be very disruptive on a conference
24 call this large.

25 Following a discussion of each agenda

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1 item, the ACMUI Chairperson, Dr. Leon Malmud, at
2 his option may entertain comments or questions
3 from members of the public who are participating
4 with us today.

5 With that, at this point I would like
6 to turn the meeting over to Dr. Malmud.

7 CHAIRMAN MALMUD: Thank you, and
8 welcome to all of you, and a Happy New Year to
9 everyone. We have rather a full agenda today and
10 a limited amount of time in which to accomplish
11 the discussion. So if I may, we will begin
12 promptly with the first item on the agenda.

13 Now that is listed as the ACMUI
14 Reporting Structure. However, we also had a new
15 item added that appear on your email today, which
16 is the Patient Release issue. So if we can, we
17 will begin with that issue. Sue, do you wish to
18 comment on that?

19 MEMBER LANGHORST: Yes, I will be glad
20 to. This is Sue Langhorst.

21 We received comments on the ACMUI
22 patient release report, and we will have a
23 handout to the comments and our draft response,
24 which Chairman Malmud and I -- We appreciate the
25 additional insights that we were given on the

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1 comments and reasoning behind the original
2 rulemaking for the patient release.

3 Nevertheless, it is clear to ACMUI
4 that NRC established per patient release limits.

5 In that handout we provide you that conclusion.

6 I won't read through those, but this is what the
7 regulated community has to go by, a new
8 rulemaking.

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

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

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

25 CHAIRMAN MALMUD: Is there a second to

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1 that motion, please?

2 MEMBER GILLEY: Second. Debbie
3 Gilley.

4 CHAIRMAN MALMUD: Thank you. It has
5 been seconded by Debbie Gilley. Is there further
6 discussion of this motion?

7 MS. CHIDAKEL: Well, I am Susan
8 Chidakel. I am the OGC Senior Attorney that was
9 involved in this matter, and I just want to tell
10 you I want to thank you for your input.

11 I do want to tell you that we have
12 looked at the statements that you have cited and
13 read in the context of what was being discussed
14 when the rule was finalized, and we do not
15 believe that they support your view.

16 We have found no basis in reviewing
17 the information you have provided or in re-
18 reviewing the entire regulatory history to change
19 our position that this was not intended to be a
20 per release release. Our position, as we said,
21 was the rule is, obviously -- It doesn't address
22 it. The regulatory language itself doesn't say
23 anything.

24 We do agree that we need a rulemaking
25 to clarify the intent, but we don't agree with

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1 you as to your saying that the intent was that it
2 was a per release basis rather than per year.

3 CHAIRMAN MALMUD: Thank you for your
4 comment. Do we have other comments in response
5 to counsel's comment?

6 MEMBER WELSH: This is Dr. Welsh here.

7 CHAIRMAN MALMUD: Dr. Welsh.

8 MEMBER WELSH: I suppose the big
9 question at hand is not whether the wording
10 really supports per year versus per event at this
11 point, but what we would advise NRC to really
12 have in clear language. From my understanding,
13 what the ACMUI is advocating is that we seek per
14 event rather than per year, and the next question
15 is do we really need to have a rulemaking to make
16 it clear to all that it should be per event or is
17 NRC going to insist or recommend that it be per
18 year, and we still need a rulemaking for that?
19 That is the question at hand, from my
20 understanding.

21 CHAIRMAN MALMUD: Thank you, Dr.
22 Welsh. I believe that that question should be
23 addressed to Susan Chidakel. Am I correct,
24 Susan?

25 MS. CHIDAKEL: I would like you to

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1 please repeat the question, if you don't mind.

2 CHAIRMAN MALMUD: If I may interpret
3 Dr. Welsh's question, it is as follows. The
4 ACMUI believes that it should be on a per release
5 -- that is, per event basis -- not an annual
6 basis, based upon our understanding of what has
7 been promulgated in the past.

8 Therefore, the question is do we need
9 to recommend that there be a change in rulemaking
10 in order to achieve agreement that it should be
11 per release or can the accumulated wisdom of the
12 NRC staff interpret this in a way which will
13 allow us to continue practicing on a per release
14 basis?

15 MS. CHIDAKEL: Our answer is that we
16 think you need a rulemaking.

17 CHAIRMAN MALMUD: Then that would
18 require that the ACMUI recommend to NRC that
19 there be a change in rulemaking. Dr. Welsh, does
20 that answer your question?

21 MEMBER WELSH: It does. Thank you.

22 CHAIRMAN MALMUD: Now if I may, having
23 discussed this with members of the Committee, our
24 concerns are as follows. Number one, there is no
25 methodology currently available to add up the per

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1 release events between and among institutions for
2 individual patients, number one.

3 Number two, there is concern that, if
4 the interpretation of NRC is that it must be per
5 year, and without the ability of the physician to
6 accumulate the data or to assure the data, will
7 there be penalties for treating patients who
8 might exceed the per year limit on the basis of
9 being treated per event until this issue is
10 clarified; because this really interferes with
11 the current practice of medicine?

12 That is a question to counsel.

13 MS. CHIDAKEL: That isn't actually a
14 question. What you have done is you have stated
15 your concern.

16 CHAIRMAN MALMUD: It is a concern. I
17 am always willing to have an expert in the law
18 clarify an issue for us.

19 MS. CHIDAKEL: Well, I think your
20 issues are perfectly valid, and I think they are
21 things that you can raise if you want to propose
22 the rule, a rule change.

23 CHAIRMAN MALMUD: All right.

24 MS. CHIDAKEL: As far as the second
25 question about penalties and so forth, that is an

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1 enforcement issue, and I can't really address
2 that. We are talking about a rule change. I am
3 not prepared to address enforcement issues, I am
4 afraid.

5 CHAIRMAN MALMUD: Who would be
6 addressing the issue of enforcement in the
7 interim?

8 MS. CHIDAKEL: I leave that to the
9 staff.

10 CHAIRMAN MALMUD: Is there someone
11 from staff who wishes to comment? It seems to me
12 -- and I speak as the Chairman, having heard the
13 input from the members of the committee -- that
14 the Committee is almost unanimously, with one
15 exception, supportive of this being continued to
16 be practice on a per release basis, not a per
17 year basis. However, now that the issue has come
18 before NRC for clarification and there is no
19 ambiguity, according to counsel from NRC, there
20 would be concern in the medical community that,
21 in the event that a patient does receive more
22 than the annual limit by virtue of the current
23 per release practice, that there not be a
24 prosecutorial effort made against physicians who,
25 number one, have no ability to add up these doses

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1 which may be given by different institutions and,
2 number two, who have been practicing this way
3 until now anyway.

4 MR. LUEHMAN: Dr. Malmud, this is Jim
5 Luehman. I think that -- I think, going back to
6 the October 20, 2010 Commission meeting when I
7 testified to the Commission, I told them that I
8 think -- I thought that this issue needed to be
9 clarified, because as Susan stated, right now the
10 regulatory language doesn't say either. It just
11 -- You know, you have to really rely on the
12 history to look at the language and make the
13 determination.

14 Given that, I think that -- At least,
15 I personally then and I am of that same mind now,
16 think that this does need to be clarified in the
17 regulations. But what I would say in the interim
18 is, while the staff has a position, and we feel
19 it is a strongly supported position, the fact is
20 that from an enforcement standpoint, since the
21 regulation right now is silent on whether it is
22 per episode or per year, I think it is very
23 unlikely that there is going to be any
24 enforcement action taken until this is clarified;
25 because the staff would have a burden to show

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1 that there was a violation of the regulation, and
2 with the language as it presently is, that is
3 probably not something that we would pursue.

4 Having said that, I do think that your
5 concerns -- that you and the Committee and the
6 medical community have some concerns, and that
7 takes me full circle back to, at least
8 personally, I support what the Committee is
9 suggesting, that we need to get into a -- we need
10 to do a rulemaking and clarify the language one
11 way or the other, because that is the only way
12 that is going to fix this problem once and for
13 all.

14 MEMBER LANGHORST: Mr. Chairman, this
15 is Sue Langhorst again. Let me speak as a
16 licensee who would not have the access to the
17 full rulemaking history documents that NRC staff
18 would have.

19 In the statement that NRC put in the
20 final rulemaking, they said NRC is establishing a
21 dose limit of 5 millisieverts total effective
22 dose equivalent to an individual from exposure to
23 the release patient for each patient release.

24 To me, there is no doubt that the
25 current regulations are per release and, if the

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1 NRC intended it to be per year, that is not what
2 is stated in their final rulemaking. So if NRC
3 wants to move from per release to per year, that
4 is where rulemaking needs to occur, but as you
5 stated, Mr. Chairman, the ACMUI's majority feels
6 that it should remain as a per release limit.
7 Thank you.

8 CHAIRMAN MALMUD: Thank you.

9 MS. CHIDAKEL: If I may speak, this is
10 Susan Chidakel again. As I said before, we have
11 looked at all of the statements that you have
12 presented. As a lawyer, I have looked at them
13 from a legal standpoint in the context in which
14 these statements were made.

15 You have to look at the entire
16 context, and from looking at the context in which
17 these statements were made very carefully and
18 looking at all of the supplementary information,
19 as I said, we have not changed our position.

20 Again, the regulations do not clarify
21 it, but the regulatory history indicates that the
22 intent was that it should be an annual limit.

23 CHAIRMAN MALMUD: Thank you. We have
24 heard both positions, the position of the
25 majority of the ACMUI Subcommittee and the

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1 position of NRC counsel. We recognize that there
2 is a difference.

3 Therefore, in order to move forward,
4 there is a motion from ACMUI -- I believe, from
5 Sue Langhorst -- which would indicate that the
6 ACMUI recommends that the interpretation be on a
7 per release basis, and that pending clarification
8 of this or rulemaking, that it be allowed to
9 continue as a per release basis so that
10 practitioners need not fear prosecution in the
11 care of their patients.

12 MEMBER SULEIMAN: Dr. Malmud, this is
13 Dr. Suleiman.

14 CHAIRMAN MALMUD: Yes, Dr. Suleiman?

15 MEMBER SULEIMAN: I have a question
16 that would affect how I would feel about this.
17 The per limit -- per event limit is realistic.
18 It is practical, and is really what should be
19 adhered with how the ACMUI has felt. However,
20 the overriding question: Is there or isn't there
21 an annual limit; and if, in fact, there is an
22 annual limit that happens to be the same as the
23 per event limit, the annual limit preempts the
24 per release limit, but in this case it doesn't
25 matter. It is limited to one.

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1 So is there or isn't there an annual
2 limit? The regulation doesn't say that. 3573
3 doesn't say that, but the guidance kind of
4 implies that, but I kind of find it upsetting
5 that guidance which should be clarifying, in this
6 case has actually confused the community.

7 So there either needs to be better
8 guidance or rulemaking where the annual limit
9 does not coincide with the per event limit,
10 because we are not dealing with occupational dose
11 values here. We are dealing with very low
12 amounts of radiation, and to spend this amount of
13 time on something that is essentially very safe
14 has not been fair to the community and has caused
15 a lot of confusion.

16 CHAIRMAN MALMUD: Thank you, Dr.
17 Suleiman. Does anyone care to comment?

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

20 CHAIRMAN MALMUD: Yes.

21 MEMBER LANGHORST: Let me clarify my
22 motion. My motion is that ACMUI agrees, if NRC
23 believes the patient release criteria should be
24 changed from a per release criteria to an annual
25 criteria, this change would require new

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1 rulemaking, as was noted in Regulatory Issue
2 Summary 2008-07.

3 CHAIRMAN MALMUD: Thank you. That is
4 your motion. It has been seconded, has it not?

5 MEMBER GILLEY: Yes. Debbie Gilley
6 seconded it.

7 CHAIRMAN MALMUD: Thank you. Is there
8 any further discussion of this motion? Hearing
9 no further discussion, may I ask those voting
10 members of the Committee to say Aye if you agree.

11 Are there any negative votes? Are
12 there any abstentions?

13 MEMBER SULEIMAN: I abstain.

14 CHAIRMAN MALMUD: Dr. Suleiman
15 abstains. Otherwise, it is a unanimous vote.

16 So we believe that, in having taken
17 this vote, that we have placed the issue before
18 NRC staff for resolution and, in the meantime,
19 would plead for understanding on the part of NRC
20 with regard to physicians treating patients
21 according to the manner in which they have been
22 with regard to this issue.

23 If we may, we will move on to the next
24 item on the agenda, unless there is any further
25 discussion of this. Are there any comments from

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1 members of the public? If not, thank you very
2 much, and thank you, Sue Langhorst, for your
3 effort, and thank you, Sue Chidakel, for your
4 input. We hope that we will be able to get
5 clarification for all parties involved so that
6 patients and members of the public can both be
7 safely treated and be safely cared for.

8 The next item on the agenda is the
9 ACMUI Reporting Structure. Who wishes to comment
10 on this? Did I go mute or no one wishes to
11 comment? Shall I?

12 MEMBER THOMADSEN: Dr. Malmud, this is
13 Bruce Thomadsen. I will just say that I had
14 thought that this was about the document that we
15 had been dealing with, with our interactions with
16 the NRC as a committee, but it was clarified that
17 this is not about that. It is about who we
18 report to. So I will, just with that
19 clarification, give it over to -- I am not
20 involved in that one.

21 MS. COCKERHAM: Dr. Malmud, this is
22 Ashley.

23 CHAIRMAN MALMUD: Yes, Ashley, I was
24 just about to call on you.

25 MS. COCKERHAM: Okay. So to preface

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1 this, the Commission last year directed staff to
2 provide options or to provide recommendations on
3 how the ACMUI should report within the agency.
4 Currently, the ACMUI reports to Rob Lewis as the
5 Division Director in FSME.

6 So we are just looking for feedback
7 from the Committee. I am drafting the paper that
8 we will provide to the Commission, and talking
9 about the options that we have, we could continue
10 to report -- or the ACMUI could continue to
11 report to the Division Director or there is the
12 option of them reporting directly to the
13 Commission, which would, obviously, require some
14 changes.

15 So we are looking into those options
16 and looking for feedback from the Committee, and
17 basically whatever input the Committee provides
18 today -- I will use these transcripts and this
19 information to provide that directly to the
20 Commission in my paper.

21 CHAIRMAN MALMUD: Thank you, Ashley.
22 If I may, I should fill the entire Committee in
23 on my more recent experience. I have met
24 individually with the Commissioners, those who
25 were able to meet with me on a day that I went

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1 back to Washington after having not been able to
2 attend the last meeting that you all attended.

3 I expressed to them the concerns of
4 the ACMUI with regard to the reporting mechanism.

5 It was my impression from discussion with staff
6 as well as with the Commissioners that reporting
7 directly to them versus reporting in the current
8 manner through Rob Lewis would not necessarily
9 shorten the time frame required to process
10 issues. That is number one.

11 Number two, I was reassured and, in
12 fact, experienced the availability of the
13 individual Commissioners to us. Whenever I need
14 to call upon them, I could arrange a meeting with
15 one or with several of them, assuming their
16 availability on the same day.

17 So that is an important issue, because
18 we have not always availed ourselves of that
19 opportunity, and the opportunity is both
20 available to us and, in this case, I took
21 advantage of it.

22 The frequency that our Committee meets
23 is such that issues are not resolved -- I'm
24 sorry, was someone saying? When the issues are
25 not resolved, it takes a number of months before

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1 the next committee meeting is physically
2 together. That, I don't think, would change.

3 There are two issues related to the
4 reporting. One is the need for the Committee to
5 feel that the issues that we discuss are, in
6 fact, transmitted to the Commissioners without
7 being filtered in some fashion.

8 I was astonished, quite frankly, at
9 ~~how~~ knowledgeable each of the individual
10 Commissioners was with regard to issues that we
11 have discussed. Considering the breadth of their
12 portfolios, I was pleasantly surprised that they
13 were as knowledgeable about what we are doing and
14 what we have done as they are. They also seemed
15 quite genuine in their expression of
16 availability.

17 Now the next issue was staffing. We
18 clearly feel that we need more staffing, because
19 the way in which we function is as a committee,
20 when we have staff availability to us, but our
21 work is really done by subcommittees. For
22 example, this most recent issue was dealt with by
23 Sue Langhorst, and issues in the past have been
24 dealt with by other Subcommittee chairs, whether
25 it is the Vice Chair of the Committee or Dr.

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1 Welsh or others.

2 In those areas, we could use some
3 additional staffing, and I transmitted that with
4 the additional message that we have never had --
5 Although we have very good support from NRC, we
6 certainly are enjoying the strongest support we
7 have ever had with Ashley working directly with
8 us.

9 So it was not by way of complaint, but
10 by way of need, in that we feel we need a little
11 more staff support, which may mean that we want
12 to ask for some more staff support for Ashley.
13 The other option of reporting directly would mean
14 establishing a staffing level which, I think,
15 given the current budget concerns in Washington,
16 would probably not be addressed. However, if the
17 committee feels very strongly about it, we could
18 present it, though I wouldn't be optimistic about
19 it, and I say that just from reading the
20 newspapers.

21 So I was very satisfied with both the
22 willingness and the knowledge of the
23 Commissioners regarding the issues that we are
24 dealing with, and also with their genuine
25 appreciation of the effort that the members of

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1 the Committee put forth.

2 Now having -- Are there members of the
3 Committee who wish to express some opinions
4 regarding this issue?

5 MEMBER ZANZONICO: This is Pat
6 Zanzonico. Can I -- Ashley, can you just clarify
7 again, frankly, what the issue is at hand? Based
8 on what Bruce said, I presume we are not
9 considering FSME Policy and Procedure 2-5 at this
10 time, but a separate issue specifically dealing
11 with the route of reporting.

12 MS. COCKERHAM: Yes. Okay, so last
13 year -- I am pulling up the SRM right now. Last
14 year on July 21st the Commission -- Once the
15 Commission has a public meeting, typically they
16 send staff a Staff Requirements Memorandum, and
17 that is staff's marching orders. That is what we
18 need to do following that meeting.

19 So following that meeting, on July 21,
20 2010, there was an SRM from the Commission, and
21 it had two pieces. The first piece was that
22 staff should develop internal guidance for all
23 major medical policy. That is the Policy and the
24 Procedure that you guys have been talking about
25 at past meetings, and we have feedback from ACMUI

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1 on that, and that piece is moving up the chain.
2 So that is one part of the SRM.

3 The second part of the SRM says that
4 staff should work on a Commission paper outlining
5 possible improved mechanisms for providing the
6 Commission with the ACMUI's feedback regarding
7 medical issues, including the pros and cons of
8 restructuring the ACMUI such that it reports to
9 the Commission.

10 So this paper will also include an
11 implementation plan that would be used to effect
12 such a restructuring, should the Commission
13 decide to move forward.

14 So I am working on that Commission
15 paper, and in that Commission paper I need to be
16 able to provide ACMUI's input or feedback on what
17 this structure looks like or how the current
18 structure is working, possible improved
19 mechanisms for the current structure or if the
20 Committee wants changes. Basically any feedback
21 you have I am going to include that in my paper.

22 Does that help clarify?

23 CHAIRMAN MALMUD: Yes, thank you,
24 Ashley. I'm sorry, who was speaking next?

25 MR. LUEHMAN: Sorry, Dr. Malmud. This

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1 is Jim Luehman. Just to clarify what Ashley --
2 to extend on what Ashley said, one option for the
3 Committee to consider is that the update of the
4 procedure, the first SRM item that Ashley spoke
5 about, the Committee could find that with that
6 enhanced procedure that that has gone a long way
7 to addressing many of the concerns that you said
8 about the Commissioners getting the Committee's
9 opinions in an unfiltered manner.

10 Therefore, you could find that the
11 present structure with the enhanced procedure
12 addresses your issues, or you could say -- So
13 that is one option.

14 The Commission said -- asked the staff
15 in the second item to say, but even looking
16 beyond that, even if the staff enhances the way
17 the Commission is informed of the ACMUI's issues
18 and views on issues, does the committee or does
19 the staff -- What would the options be, if you go
20 a step beyond that and actually do a
21 reorganization or re-reporting -- change the
22 reporting structure so that not only do we
23 enhance the procedures, but we change the
24 structure.

25 So I think that what I am trying to

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1 say to the committee is you have a number of
2 options. You could look at the procedure and say
3 that the procedure addresses your concerns. You
4 could say, well, the procedure doesn't quite get
5 there, because we still have these staffing
6 issues that you addressed, but we don't think --
7 you addressed, but we don't think the
8 reorganization necessarily addresses those. So,
9 therefore, we don't favor the reorganization, but
10 we do favor some additional staffing, or you
11 could say, yeah, we favor reporting to the
12 Commission.

13 I guess what I would say about that,
14 just sort of previewing where I think Ashley is
15 going with the paper, we think that the most
16 logical place that that -- way that that could be
17 accomplished would be the Committee would then,
18 if that was the recommendation and the
19 recommendation was accepted by the Commission, it
20 would most likely be a structure where the ACMUI
21 would be supported by part of the structure that
22 presently supports the ACRS.

23 You are aware of the structure for the
24 Advisory Committee on Reactor Safety. They have
25 a staff director who has staff that supports the

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1 ACRS, and then the committee itself reports
2 directly to the Commission.

3 If that structure -- If similar
4 structure was going to be recommended for the
5 ACMUI, what we as the staff envision is that that
6 Executive Director that supports the ACRS would
7 then have some number of staff under his or her
8 purview to support the ACMUI directly, but that
9 that structure would take advantage of the
10 existing resources such as in the administrative
11 area that already support the ACRS, so that we
12 wouldn't have to duplicate those to support the
13 ACMUI, if they were going to report to the
14 Commission.

15 So you have a whole -- I think that
16 what I am trying to say is there is a whole
17 number of variations that you can go from, from
18 requesting additional staff support to additional
19 staff support plus a streamlined or updated
20 procedure, to completely changing the reporting
21 requirement to have the Committee report to the
22 Commission.

23 There's pros and cons to all of those,
24 but we are trying to get -- Ashley is trying to
25 get, I think, a sense of sort of where the

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1 Committee as a whole would be in sort of that
2 spectrum of options, so we can accurately reflect
3 that in the Commission paper.

4 CHAIRMAN MALMUD: Thank you for that
5 perspective. I would like to hear from several
6 members of the ACMUI, if we may, regarding their
7 current feelings.

8 The move to ask for status similar to
9 that of the ACRS dates back a number of years,
10 and those who were the strongest proponents of it
11 are no longer members of the ACMUI. They rotated
12 off, and I wonder if the current members would
13 care to comment on their feelings at the moment.

14 MEMBER WELSH: Dr. Malmud. Dr. Welsh.

15 CHAIRMAN MALMUD: Dr. Welsh.

16 MEMBER WELSH: I have a question
17 perhaps, to start off the discussion. That is:
18 Has anybody from ACMUI, specifically you, Dr.
19 Malmud, as our Chair, been in touch with anybody
20 from the ACRS to get insight from them about
21 their feelings about the reporting scheme they
22 experience, and compare and contrast that with
23 the ACMUI reporting scheme to see if there are
24 any advantages or disadvantages that we could be
25 aware of?

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1 CHAIRMAN MALMUD: The answer to your
2 question is I have not approached a member of the
3 ACRS. I have asked staff at NRC for their
4 informal opinions with regard to the issues that
5 concerned ACMUI members, and they are timeliness
6 of response and also explanations for rejections
7 of ACMUI recommendations.

8 We are, obviously, pleased with the
9 feedback regarding recommendations that are
10 accepted. There is some dismay among members of
11 the Committee with regard to recommendations that
12 are not accepted with what is perceived to be
13 inadequate explanation of why the recommendations
14 were not accepted, and also a timely telling of
15 why they were not accepted. But if the committee
16 wishes to, I could get the names of some of the
17 members of the ACRS and asked them what they
18 feel.

19 My impression from speaking to staff
20 was that we would really not achieve one goal,
21 which was to have faster turnaround, because that
22 is really based upon the frequency with which we
23 meet. But there is consensus, I believe, among
24 ACMUI members that we do need some additional
25 staff support for some of the yeoman work that is

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1 being done by our subcommittees.

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

4 CHAIRMAN MALMUD: Yes, Sue?

5 MEMBER LANGHORST: There's many of us
6 who are new to the Committee, and I still kind of
7 count myself as that, because it has been a
8 little over a year since I have been appointed to
9 the Committee. So I don't have a strong view one
10 way or another, and really don't fully understand
11 all that maybe what Ashley is putting into this
12 paper.

13 So I don't have good sense one way or
14 the other, and probably will talk to some of my
15 predecessors to ask their opinions of what the
16 issues were then and how they perceive issues at
17 this point in time.

18 So I can't say one way or another, and
19 so, Ashley, I apologize. I can't give you a good
20 consensus from -- I mean, I just don't know the
21 issue well enough.

22 CHAIRMAN MALMUD: I appreciate your
23 position, and I understand it. As one of the
24 more senior members of the Committee in terms of
25 my tenure with the Committee, I think that I have

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1 seen a great change in the actions of the
2 Committee, the interaction with staff, and I
3 think that we are functioning at a different
4 level than we did some years ago, and there is
5 greater satisfaction on the part of ACMUI members
6 with respect to the interaction.

7 I believe the same thing is true of
8 staff at NRC. So that some of the issues that we
9 are discussing were of significant concern to
10 former members of the Committee and, since they
11 are not here, they cannot express their concern,
12 but all I can say is that I don't feel the
13 intensity of those concerns, and I didn't then.
14 I thought some of the issues were not regulatory.
15 They were a matter of style of communication.

16 So that is why I am asking current
17 members if they really feel that they want to
18 change something which, from my perspective --
19 and I have no personal investment in this, but
20 from my perspective is functioning better now
21 than it did four or five, six years ago.

22 MEMBER ZANZONICO: This is Pat
23 Zanzonico. I would have to reiterate. At the
24 risk of sounding dense, I am not entirely sure
25 what the issues we are currently considering are,

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1 but having said that, I again -- As a new member
2 of the Committee, I haven't gotten a sense at all
3 that there is an inefficient or censored or
4 however one would like to characterize it pathway
5 of communication from the Committee to the
6 Commissioners or other officials at the NRC.

7 So perhaps, as you are alluding to,
8 Dr. Malmud, things have improved to the point
9 where something that may have been a problem of
10 style or otherwise in the past has largely been
11 resolved.

12 CHAIRMAN MALMUD: Thank you. Are
13 there any --

14 MEMBER THOMADSEN: Dr. Malmud, Bruce
15 Thomadsen.

16 CHAIRMAN MALMUD: Yes, Bruce?

17 MEMBER THOMADSEN: From discussions
18 with some of the previous members of this
19 Committee and descriptions of how things were,
20 both interacting with the staff at the time and
21 with the Commissioners, I think the situation has
22 changed markedly.

23 I don't personally see this as a big
24 issue at this time. As the Commission changes
25 with time, it may again be. As the staff with

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1 whom we work changes, it again may be. I would
2 assume that this Committee could bring up the
3 issue at that time.

4 CHAIRMAN MALMUD: Thank you, Dr.
5 Thomadsen, and that is my feeling and, in
6 addition to that, you know, I am based in
7 Philadelphia. If there is an issue which is hot
8 and burning, I am more than willing to hop on the
9 train and make an appointment to see one or
10 several of the Commissioners directly, express
11 our concerns, and then take the train back again.

12 It is not a major issue for me, and I am willing
13 -- more than willing to do that. However, I will
14 not always be the Chair, and in addition, Ashley
15 will not always be our main point person.

16 Therefore, the concern may arise again
17 in the future. I don't think it exists at the
18 moment, but I don't want to make that decision
19 since I am the one who, in a sense, engaged in
20 the self-congratulation.

21 MEMBER SULEIMAN: Dr. Malmud, this is
22 Orhan Suleiman.

23 CHAIRMAN MALMUD: Yes, Dr. Suleiman?

24 MEMBER SULEIMAN: I have always sensed
25 I think the Committee is operating pretty well

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1 right now. There is a history going way back
2 where the committee -- and there was quite a bit
3 of tension between among a number of individuals,
4 and I think Ashley really needs to be commended,
5 because I think she has improved the
6 communication and the effectiveness to a large
7 degree, and I don't know whether her superiors
8 are actually aware of this, but I think she has
9 contributed in a major way.

10 Having said that, I find both the NRC
11 at times and the Advisory Committee at times not
12 really sure of what they are asking each other
13 for. I think sometimes the charges are not
14 clarified to the Committee, and I think sometimes
15 the Committee goes off on a slight tangent.

16 So I don't know whether new protocols
17 need to be addressed or whatever, but I think
18 that, clearly, a little bit more clarification in
19 what the committee is being asked to do would
20 help, and sometimes the rules of how the
21 Committee should operate. If, in fact, we are in
22 violation of something, we need to be aware of
23 that rather than go ahead and expending a lot of
24 effort and then finding out that we went into an
25 area that we really didn't need to.

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1 Aside from that, I think the -- I
2 would give everybody a passing grade, but I think
3 there needs to be -- There is more room for
4 improvement in terms of clarification of what we
5 need to do and how we go about it.

6 CHAIRMAN MALMUD: Thank you, Dr.
7 Suleiman. You are also one of the more senior
8 members of the committee in terms of tenure, and
9 I appreciate your opinion.

10 MEMBER SULEIMAN: Don't let me -- I am
11 sorry for interrupting, but also under your
12 leadership -- I really don't want to take that
13 for granted. I think you help the committee
14 tremendously as well. I don't want to omit that.

15 CHAIRMAN MALMUD: Well, thank you. We
16 have had really, I think, superior interaction
17 with staff members of NRC, and I am appreciative
18 of their efforts which has made things easy for
19 me and, of course, we have had -- Both the
20 current members of the Committee and the previous
21 members of the Committee, the intellect and the
22 experience of all of you is extraordinary, and
23 the public is well served by this Committee's
24 intellect and knowledge, and I think NRC is well
25 served, as we are well served by NRC.

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1 Now having accomplished the
2 congratulations, I would ask the Committee
3 whether they feel that we should go through the
4 process of requesting a status similar to the
5 ACRS or whether we should maintain the current
6 structure, asking for some additional staff.

7 MEMBER WELSH: Dr. Malmud, I am Dr.
8 Welsh. I would like to --

9 CHAIRMAN MALMUD: Yes, Dr. Welsh.

10 MEMBER WELSH: -- ask one additional
11 question here before we proceed. As a semi-
12 senior for the ACMUI, I, too, have witnessed some
13 dramatic improvement in the past few years, and
14 therefore, the question in my mind might be one
15 of the old adage, should we attempt to fix
16 something that is not broken anymore.

17 I can appreciate and understand the
18 previous members' concern, but I generally agree
19 with you that maybe some of those concerns have
20 already been addressed and rectified.

21 Having said that, I am aware of the
22 former Advisory Committee on Nuclear Waste and
23 Material, and they have merged with the -- They
24 are now part of the ACRS, leaving -- just correct
25 me if I am wrong -- only two Advisory Committees,

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1 us, the ACMUI, and the ACRS, and there seems to
2 be a little bit of a -- There is a disconnect in
3 the fact that one Advisory Committee has a
4 different reporting scheme than the other
5 Advisory Committee.

6 Would it help NRC in any form or
7 fashion if all Advisory committees, if there are
8 only two now -- would it be better to have the
9 uniform reporting status for all Advisory
10 Committees? So this is a question, I suppose,
11 for NRC staff.

12 CHAIRMAN MALMUD: Well, we can ask
13 Ashley to inquire of more senior NRC staff if
14 they are looking for a change, and then get that
15 feedback to us.

16 MR. LUEHMAN: Dr. Malmud, this is Jim
17 Luehman. I just -- I will attempt to answer that
18 right now. A couple of things.

19 One is, you know, I know that the new
20 members are at somewhat of a disadvantage, but
21 basically -- and I don't want to oversimplify
22 this, but the way the ACRS operates is they meet
23 about -- formally, about once a month, and that
24 is their meeting frequency, and they have a lot
25 of subcommittees in the interim, and for each

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1 issue that they review, what they do -- and this
2 is the way that they get formal visibility with
3 the commission -- is they issue a formal letter
4 to the Commission on their position on
5 significant licensing action or approval of a
6 reactor design or whatever it is that they are
7 looking at, and the staff is required to formally
8 respond to that letter.

9 That is really the methodology that
10 they -- that is, by regulation and by statute, is
11 that that is how they get -- that their views are
12 directly transmitted to the Commission.

13 There is -- Obviously, it gives the
14 ACRS direct access to the Commission, but I would
15 say that that comes with a cost to the Committee.

16 Their structure is -- they are very structured
17 in the way -- in the regularity of their
18 meetings. They have definite deadlines for the
19 production of these letters.

20 So they are on pretty tight schedules
21 as they review those things. Given the make-up
22 of that committee, that there are many emeritus
23 and retired individuals, not all the full ACRS
24 but many, they are able to do a lot of their work
25 in that regard.

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1 All I would offer is that, if the
2 ACMUI, being for the most part practicing
3 physicians, I would say that such a structure may
4 not be the best, given that it is a little bit
5 less flexible. But that is for your
6 consideration.

7 As far as your question about what the
8 staff recommends or sees, our view is, again, we
9 think that you should -- We think that the
10 structure can be significantly enhanced by the
11 Policy and Procedure that has been discussed,
12 that if that is done right and lays out clear
13 guidance as to how the staff is going to engage
14 the ACMUI and what the staff's responsibility for
15 transmitting the ACMUI's views to the Commission
16 and when that has to be done, in what
17 circumstances, we think -- this is just my
18 personal opinion, and I think many of the staff -
19 - that that will address much of your concern
20 that you brought up where you said that you are
21 happy when they adopt ACMUI positions. You are
22 somewhat a little bit disappointed or dismayed
23 or, in fact, uninformed as to when or why certain
24 positions weren't adopted that the ACMUI
25 recommends, that you don't always get that

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1 feedback when there is not adoption.

2 Again, we think that the procedure --
3 updating the Policy and Procedure and making
4 those feedback loops clear would probably be the
5 best option, but the Commission asks -- again, in
6 Part 2 of the SRM, as I said, they ask for an
7 exploration of all the options.

8 The other one would be a more formal
9 reporting. Now as to Dr. Welsh's concern or
10 comment about there being two committees and
11 would it make sense for both Committees to report
12 along the same chain, I think that the staff's
13 view on that is that the ACRS affects -- The
14 Policies and Procedures that they deal with reach
15 across a number of -- many offices at the NRC,
16 now that they include the ACNW. It includes the
17 Office of Nuclear Reactor Regulations, the Office
18 of New Reactors, the Office of Nuclear Materials
19 Safety and Safeguards, as well as a portion of
20 our office here in FSME.

21 The issues that they deal with span
22 all of those offices, and that is why I think the
23 Commission level reporting exists there. For the
24 ACMUI, while the very important issues that you
25 deal with, they only report in -- There is only

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1 one office that has regulatory responsibility for
2 the medical issues, and that is the office --
3 this office.

4 I think that is originally why, and I
5 think it is my view, personal view, why I think
6 that a more tailored reporting for the ACMUI was
7 originally structured, and again my personal view
8 why it is still apropos today. But again, that
9 is just my opinion and why I think that it makes
10 sense that, if it stays this way, if the
11 Committee felt strongly that they would want to
12 be part of the larger structure, then that is
13 fine, too. That can be considered.

14 MS. COCKERHAM: Dr. Malmud, this is
15 Ashley.

16 CHAIRMAN MALMUD: Yes, Ashley?

17 MS. COCKERHAM: Just to add one thing
18 to what Jim said as well, as far as structuring
19 of ACRS versus ACMUI, just a little bit of
20 history.

21 ACRS is mandated by law. It is
22 something that Congress came up with. They said
23 there will be an ACRS, and they will advise the
24 NRC. Then the way the ACMUI came about, it goes
25 all the way back to the Manhattan Project, but

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1 long story short, the Commission, not Congress,
2 created ACMUI to advise staff.

3 So just -- It is not like we just
4 magically came up with this and said, oh, we are
5 going to have two different reporting structures.

6 It goes way, way back from how they were created
7 from the very beginning, and ACMUI is not
8 mandated by a law, but they are created by the
9 Commission. So we operate at the level that we
10 do. I don't know if that helps.

11 CHAIRMAN MALMUD: Yes, it does. It is
12 historical perspective on it.

13 MS. COCKERHAM: Yes.

14 CHAIRMAN MALMUD: Are there other
15 comments?

16 MEMBER GILLEY: Dr. Malmud, this is
17 Debbie Gilley. Can I just ask Ashley a question?

18 If the ACMUI were to report directly to the
19 Commission, would that require statutory changes
20 or is that something that the Commission can do
21 internally?

22 MS. COCKERHAM: The Commission would
23 be able to do that internally.

24 MEMBER GILLEY: Thank you.

25 CHAIRMAN MALMUD: I will comment by

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1 saying that I am more than willing to take the
2 time and ~~meet~~ meet with members -- with the
3 Commissioners at the request of the Committee,
4 and they have expressed a willingness to meet
5 with me, and it needn't be on a restricted basis.

6 It can be on the basis of need.

7 So having been in administration for a
8 while, I am always concerned about unintended
9 consequences and, therefore, my own inclination
10 would be to keep the reporting lines as they are
11 with the enhancements that were discussed
12 earlier.

13 MEMBER WELSH: Dr. Malmud.

14 CHAIRMAN MALMUD: Yes, Dr. Welsh.

15 MEMBER WELSH: Dr. Welsh again. Given
16 what I have just heard in response to my comments
17 and questions, I think that I as a member of the
18 ACMUI feel very fortunate that we don't have the
19 horrible circumstances that the ACRS is subjected
20 to. So perhaps I would just like to count my
21 blessings and, for all it is worth, I think that
22 maybe it is best to keep things the way they are
23 and not try to fix them if they are not broken
24 anymore.

25 CHAIRMAN MALMUD: Will that be a

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1 motion from you?

2 MEMBER WELSH: I can phrase it in the
3 form of a motion, which is: I propose that we
4 maintain the status quo in terms of our ACMUI
5 reporting scheme.

6 CHAIRMAN MALMUD: With the
7 enhancements that were suggested?

8 MEMBER WELSH: Thank you.

9 CHAIRMAN MALMUD: Is there a second to
10 Dr. Welsh's motion?

11 MEMBER ZANZONICO: Seconded by
12 Zanzonico.

13 CHAIRMAN MALMUD: Thank you. Any
14 further discussion?

15 MEMBER VAN DECKER: Dr. Malmud, this
16 is Bill Van Decker.

17 CHAIRMAN MALMUD: Yes, Bill?

18 MEMBER VAN DECKER: Recognizing that I
19 am probably one of the now senior members of this
20 group -- that scares me -- let me just make a
21 couple of comments, and you personally probably
22 recognize my inability to really recognize
23 regulatory structure or internal structures at
24 all usually in life. So I don't know what models
25 work, but I would point out that one of the

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1 issues that, I think, has been very helpful in
2 the last few years is that the Commission has met
3 personally with ACMUI once a year, and actually
4 had an open forum that actually sometimes has
5 even included other stakeholders.

6 I would point out that there was a
7 period of time where that did not occur, and I
8 think that that actually is a very, very useful
9 process for making everyone feel comfortable,
10 that there has been some personal discourse for
11 the filtering issue, whatever people may believe,
12 and I think that we should really believe that
13 that should happen every year.

14 I think that the staff has done an
15 incredibly good job, and I have been very pleased
16 with their give and take and their knowledge base
17 and helping ACMUI work right now.

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

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

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

17 Having said that, there is no reason
18 in my mind to expect that, you know, as some of
19 this stuff starts to come to fruition in the next
20 year or two, that we won't have anything but
21 fairly transparent and clear-cut back and forth
22 and that type of stuff. But I do think when it
23 becomes very clear rulemaking stuff that the
24 concerns heighten, and the communication,
25 obviously, needs to be fairly clear. But I do

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1 thank the Commissioners themselves for meeting
2 with us on a yearly basis over the last couple of
3 years, and I think that that is very, very
4 helpful, and I think that the model itself
5 depends on the good faith of everybody involved
6 and what they are trying to accomplish, and I
7 think that that is the most important thing.

8 So I am personally comfortable where
9 we currently are, but I think that some
10 enhancements and making sure that some things are
11 happening, especially in the rulemaking process
12 for discussions of decisions and especially a
13 yearly personal meeting to express the body
14 language and concerns is important.

15 CHAIRMAN MALMUD: Thank you, Dr. Van
16 Decker. Any other comments or discussion? There
17 is a motion which has been seconded.

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

20 CHAIRMAN MALMUD: Yes, Sue?

21 MEMBER LANGHORST: I still feel at a
22 real disadvantage on this, and if we do vote on
23 this today, I would have to vote no, because I
24 just -- I would like the draft of the report that
25 Ashley is putting together so I can have a more

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1 full understanding personally.

2 CHAIRMAN MALMUD: So would you like to
3 table the motion or are you objecting to the
4 motion?

5 MEMBER LANGHORST: Well, I think we
6 need some time, especially given that we didn't
7 even know what this item covered. I think it
8 would be nice to table the motion and have some
9 time to review what Ashley is putting together.

10 CHAIRMAN MALMUD: Thank you.

11 MEMBER GUIBERTEAU: Chairman Malmud,
12 hi, this is Mickey Guiberteau. I have joined the
13 call sometime ago, but I was waiting for a chance
14 to speak.

15 I would support tabling this motion
16 for the reasons that Sue said, and although I
17 have heard most of the conversation, it was not
18 clear to me that on this call that this would be
19 something that we would be putting on the table,
20 either to reject or to put forward as a model.

21 So I think further discussion among
22 the Committee would be a good thing, further
23 thought and, as you have suggested, perhaps some
24 further consultation with the Commissioners.

25 CHAIRMAN MALMUD: All right. Thank

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1 you, Dr. Guiberteau. There have been two
2 recommendations for tabling this. It could be
3 brought up at our spring meeting, at which time I
4 would ask if Ashley could have her comments
5 prepared. Would that be a reasonable time limit,
6 Ashley?

7 MS. COCKERHAM: Yes. Did you say
8 before the next phone call?

9 CHAIRMAN MALMUD: The next meeting.

10 MS. COCKERHAM: Yes.

11 CHAIRMAN MALMUD: Which is in April, I
12 believe.

13 MS. COCKERHAM: Oh, actually, my paper
14 is due to the Commission before.

15 CHAIRMAN MALMUD: It would be even
16 before that? That is even better.

17 MS. COCKERHAM: Yes, and actually,
18 this is why we set up the January 12th
19 teleconference, and there is one topic on the
20 agenda, and it is the ACMUI reporting structure.

21 I actually need feedback from the Committee for
22 sure before the end of this month, because my
23 paper is due to the Commission April 1st, and I
24 will not be here for that next meeting anyway.

25 CHAIRMAN MALMUD: So then we will have

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1 this discussion on January 12th, if we table it
2 today. Is that correct?

3 MS. COCKERHAM; Yes.

4 CHAIRMAN MALMUD: All right. Is that
5 acceptable to those who made the motion?

6 MEMBER WELSH: This is Dr. Welsh, and
7 I agree fully with what Dr. Langhorst has brought
8 up, that perhaps it would be wise to table this
9 until this presentation concludes before we
10 proceed.

11 CHAIRMAN MALMUD: Thank you. If the
12 Committee is in agreement, we will table it for
13 the Committee phone meeting January 12th. Is
14 that acceptable? Any opposed to it? Sounds like
15 it is acceptable. Okay, thank you.

16 We now move on to the next item on the
17 agenda, which is the rulemaking and
18 implementation guidance for physical protection
19 of byproduct material. Who is going to tackle
20 that for us?

21 MEMBER GILLEY: This is Debbie Gilley.
22 I kind of started the ball rolling. Sue
23 Langhorst and Darrell Fisher also serve on our
24 Subcommittee.

25 We took a high level approach to

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1 coming up with comments over the overall
2 regulations, just detailed comments, and they
3 were provided for you in a draft report for your
4 review.

5 The recommendations from the report
6 from the Subcommittee: Encourage NRC to
7 implement the existing orders into regulations
8 and not to enhance them, and also to begin
9 looking at developing strategic rulemaking that
10 can be based on risk informed.

11 I will answer questions to the report,
12 if you have had a chance to read it.

13 CHAIRMAN MALMUD: Has anyone not had a
14 chance to read it?

15 MEMBER GILLEY: I would ask also that
16 Dr. Fisher and Dr. Langhorst please weigh in on
17 this. It has been a real tight timeline for us.

18 CHAIRMAN MALMUD: Thank you. Do we
19 have additional comments from either Dr. Fisher
20 or Dr. Langhorst?

21 MEMBER FISHER: Yes. Dr. Malmud, this
22 is Darrell Fisher. I have got a little
23 laryngitis. So I hope you can bear with me.

24 The Subcommittee supports the general
25 concepts that this proposed Part 37 works toward,

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1 but in many cases a lot of new requirements have
2 been added that are not currently part of the
3 orders to which licensees must comply; and in a
4 lot of cases, the extra burden of complying with
5 the new requirements may be so burdensome to the
6 licensee that it will have two distinct impacts
7 on the practice of medicine.

8 The first distinct impact would be to
9 greatly increase the cost of providing certain
10 services that require use of Category I and
11 Category II materials.

12 The second ultimate impact of these
13 new regulations appears to be such that, with the
14 requirements for safety and security being so
15 burdensome, that medicine will abandon the use of
16 these procedures outright, and that they will not
17 be available to benefit patients.

18 So we believe that there is a -- that
19 a reasonable balance between availability of
20 Category I and Category II sources for patient
21 therapy and research and counterbalanced with a
22 need for safety and security, but that excessive
23 requirements for safety and security would
24 neither make these sources safer nor make them
25 available to patients who need them.

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1 So I would agree with what Debbie
2 Gilley has summarized, that there is a reasonable
3 balance that can be achieved, that can be
4 successful in securing these materials so that
5 they are not available for illegal activities.

6 CHAIRMAN MALMUD: Thank you.

7 MEMBER LANGHORST: Dr. Malmud, this is
8 Sue Langhorst.

9 CHAIRMAN MALMUD: Yes, Sue?

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

20 So we feel that there was much
21 upheaval for licensees, and speaking as a medical
22 licensee, a lot of upheaval in my office, when
23 we implemented the increased controls, license
24 orders, and added the FBI fingerprint/background
25 check, and we currently have those in line.

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1 I think a lot of licensees are doing
2 well in that, and have enhanced security for
3 these sources. So I think this is an opportunity
4 to move from orders to regulatory space, as I
5 call it, or to codify these current requirements,
6 and then work in a very strategic manner on what
7 is going to be effective security enhancements.

8 One of the things that I personally
9 would like to see is that there be more
10 performance base in between what you do for
11 determining individuals' trustworthiness or
12 reliability versus what the actual situation is
13 for a given source, either by what isotope it is,
14 what form it is in, what device it is in.

15 So I would like that performance based
16 opportunity to be able to let up a little bit on
17 the trustworthiness and reliability requirements,
18 if you have really strong physical protection.

19 Thank you very much.

20 CHAIRMAN MALMUD: Thank you. For
21 those of you who might wonder what Sue was
22 referring to, page 4 of her document -- her
23 Subcommittee's document -- lists the ACMUI
24 recommendation, and she was referring in the
25 second part of this discussion to the second

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1 bullet point, which had to do with working with
2 developing a strategic rulemaking.

3 You have all had a chance to review
4 the document from the Subcommittee. This is now
5 a meeting of the actual Committee itself and,
6 therefore, the Subcommittee report would be
7 considered a motion to the Committee. Is that
8 fair, Debbie?

9 MEMBER GILLEY: Yes, sir.

10 CHAIRMAN MALMUD: So this is a motion
11 to the Committee. Is there a second to this
12 motion?

13 MEMBER SUH: I second the motion.

14 CHAIRMAN MALMUD: Who seconded?

15 MEMBER SUH: It is John Suh.

16 CHAIRMAN MALMUD: Thank you. Further
17 discussion?

18 MEMBER ZANZONICO: This is Pat
19 Zanzonico. Just for my personal clarification,
20 based on my reading of the proposed rulemaking
21 and the Subcommittee report, I gather that
22 perhaps the two issues that are the most onerous
23 are the background check issue and the
24 requirement of licensees to interact with local
25 law enforcement, which do strike me as the most

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1 problematic components in practice of the
2 proposed rulemaking.

3 Is that basically -- Am I reading the
4 Subcommittee report correctly in kind of
5 inferring that from the report?

6 CHAIRMAN MALMUD: This is Malmud. I
7 read it similarly, but not exactly. So,
8 therefore, I would ask the Chair of the
9 Subcommittee, Debbie Gilley, to comment. My
10 interpretation was that there are two major
11 issues. One was the cost involved, and the other
12 one was, because of the cost and the regulatory
13 delays and requirements, that some of the
14 services may be made unavailable to patients as a
15 result of the expense and time commitment.

16 Was that a summary between the two of
17 us, Debbie?

18 MEMBER GILLEY: That is correct. It
19 is really on two different levels. We took a
20 high road or a big universal approach, and the
21 cost of doing business with the additional
22 requirements is definitely at a higher level.

23 The individual activities that Dr.
24 Zanzonico brought to attention of the Committee
25 are just areas where we are demonstrating that

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1 cost and that implementation and, most
2 importantly, licensees remaining compliant with
3 the requirements are problematic.

4 CHAIRMAN MALMUD: Thank you.

5 MEMBER ZANZONICO: I will just say
6 thank you.

7 CHAIRMAN MALMUD: So I think the
8 problems are well summarized on page 4 of the
9 document that the Subcommittee presented, and the
10 recommendations are well summarized. The
11 problems are well summarized in the first three
12 pages.

13 This has been presented as a motion
14 with a second. Any other comments? It is a very
15 thoughtful and detailed document which represents
16 a lot of effort, for which we are appreciative to
17 members of the Subcommittee.

18 All in favor? Any opposed? Any
19 abstentions? It passes with unanimity.

20 MEMBER GILLEY: Thank you.

21 CHAIRMAN MALMUD: Thank you. Thank
22 you, Debbie Gilley, Sue Langhorst and Dr. Fisher.

23 If we may, we will move on to the next
24 item on the agenda, which is the impacts of the
25 Draft Safety culture Policy Statement for Medical

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1 Licensees. Who would like to tackle that one?

2 MEMBER THOMADSEN: I think I am
3 probably the one who should probably --

4 CHAIRMAN MALMUD: Bruce?

5 MEMBER THOMADSEN: -- address that.

6 Yes. I was the one who raised most of
7 the issues with that when it came before the
8 ACMUI before. Since that time, there was a
9 second version of the Policy Statement which was
10 sent to the ACMUI with two clarifications, which
11 apparently had meant to be in the Statement that
12 was sent out but got cut somehow.

13 One was pointing out that the traits
14 are not complete, that there are other traits
15 that would be important, and the other is that
16 the traits were not intended to be enforceable,
17 which basically addressed most of the points that
18 I had, worrying about this Statement.

19 On the 24th there is a meeting in
20 Washington to discuss the Culture Policy
21 Statement. I am going to be representing the
22 ACMUI at that meeting, and to that end, I would
23 like to tell the Committee what I am planning on
24 saying, and seeing how it strikes the rest of the
25 Committee.

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1 I will start by saying I now think
2 that the Policy Statement is, in general, a good
3 statement, a good policy, and as explained but
4 not necessarily in the policy, I am not as
5 worried as I was about how it might be used in
6 enforcement. But with your permission, I will
7 tell the five points that I plan on making at
8 that meeting.

9 CHAIRMAN MALMUD: Please do.

10 MEMBER THOMADSEN: And, please, if you
11 have comments about any of them or how they are
12 being stated, please let me know as we go.

13 The first is, while good, the list
14 traits is not exhaustive. There are many other
15 traits organizations with safety cultures that
16 are not included. The policy statement does
17 recognize this.

18 Two: Also while the traits are good,
19 an organization need not exhibit the traits to be
20 safe. For example, an organization without trust
21 or respect can, and likely would, establish
22 procedures with layers of redundancy, possibly
23 automatic, to prevent errors, since the leaders
24 would not have trust that the workers would
25 execute their jobs correctly.

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

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

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

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

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

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1 MEMBER THOMADSEN: Please.

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

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

14 Is that compatible with your item
15 number four?

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

24 Why that was the case, the authors of
25 the article didn't have a clue, but it is not

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1 clear that that was so effective, and in part it
2 may not be so effective, because it may be
3 something, a trait, which is forced upon
4 hospitals and may not be performed very
5 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
10 alerted had we had an incorrect limb operated on
11 or something like that.

12 MEMBER THOMADSEN: Yes, right, and in
13 your institution, which may be, I would assume,
14 an organization that has a good faith culture,
15 adoption of such measures might not be forced,
16 but when offered an something that appears like
17 it may be useful, may be adopted quite willingly
18 and 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
22 and 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

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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 surgeon 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?

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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
14 behaviors that have to be in place that are not -
15 - and those would not be traits but things that
16 have to be done -- enforcing that upon the
17 licensees can be very useful and productive. You
18 don't have to change their attitude toward it,
19 which would be 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
23 raising concerns. How they deal with those
24 concerns is quite another matter.

25 It is like the suggestion box in the

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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
6 are necessary for safety.

7 MEMBER ZANZONICO: Understood.

8 CHAIRMAN MALMUD: I am not a
9 philosophy expert and, therefore, I am treading
10 in dangerous ground for myself, but the
11 imposition of rules carried over a period of time
12 can alter a 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
23 before touching a patient and upon leaving the
24 patient's room. We have known for over 100 years
25 that that was necessary, but now we are imposing

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1 it, and it is being carried out, and it is second
2 nature to us now. So that the imposition of a
3 rule has made 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

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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
19 you, Bruce, for the effort, and I will present
20 this to the Committee as the motion, which has
21 been seconded, to be added on. Any further
22 discussion?

23 All in favor? Any opposed? Any
24 abstention?

25 MEMBER GILLEY: Debbie Gilley,

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1 abstaining.

2 CHAIRMAN MALMUD: Debbie Gilley
3 abstains. All right. Any further comment? If
4 not, it carries, with one abstention.

5 MEMBER THOMADSEN: Mr. Chairman, can I
6 ask, just in case it may be something we should
7 include in the presentation, what Ms. Gilley's
8 hesitation is, why she is abstaining? Is there
9 something I should include in the message we
10 send?

11 CHAIRMAN MALMUD: Debbie, that is a
12 question to you from Dr. Thomadsen.

13 MEMBER GILLEY: Well, I come from the
14 regulatory side of the house, and the Policy
15 Statement is not enforceable in regulatory world,
16 and I don't know how we can have consistent
17 safety culture requirements across agreement
18 states and NRC without it either being in
19 regulations or we won't be able to enforce it, if
20 it is just a policy statement.

21 CHAIRMAN MALMUD: Thank you for
22 clarifying that. Dr. Thomadsen?

23 MEMBER THOMADSEN: I am not sure
24 exactly how to put that in and whether it -- Is
25 that sentiment common for the Committee? Should

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1 that be included in the report?

2 CHAIRMAN MALMUD: Dr. Thomadsen is
3 asking a question of members of the Committee.

4 MEMBER THOMADSEN: Yes.

5 CHAIRMAN MALMUD: Any members have a
6 comment?

7 MEMBER ZANZONICO: This is Pat
8 Zanzonico. I am certainly sympathetic to
9 Debbie's position, but my overall feeling is that
10 not every pronouncement from a regulator such as
11 the NRC need be an enforceable regulation to have
12 some value among the entities being regulated,
13 and I think this is one example of that.

14 So I understand and sympathize with the
15 issue, but I think this statement as a
16 nonenforceable statement has value potentially
17 for users.

18 MEMBER SULEIMAN: Chairman Malmud,
19 this is Dr. Suleiman.

20 CHAIRMAN MALMUD: Yes, Dr. Suleiman?

21 MEMBER SULEIMAN: I sort of agree with
22 Pat. I think trying to establish an attitude of
23 culture -- we do it all the time in FDA for a
24 variety of things. It is not necessarily
25 enforceable. In fact, it is good that it is not

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1 enforceable. It is just an attitude where people
2 pay attention more to safety than other things.

3 You see that a lot in the airline
4 community, for example. So I have no trouble
5 supporting this.

6 CHAIRMAN MALMUD: Thank you. Any
7 other comments?

8 MEMBER GUIBERTEAU: Yes. This is
9 Mickey Guiberteau. I just wanted to ask Debbie,
10 what is -- In terms of the inability to regulate
11 the elements of this policy, instead is there not
12 a mechanism by which the states or by which the
13 organization of agreement states may endorse or
14 actually adopt this policy for states and use it
15 in the way that we have discussed in terms of
16 changing attitude and culture?

17 MEMBER GILLEY: Yes. That is not the
18 issue. The issue is it is a policy statement
19 that has no enforceability to it. It will be
20 interpreted by every agreement state, at NRC, at
21 their whim, which leaves the licensee somewhat
22 not knowing when they have a safety culture and
23 when they do not have a safety culture.

24 In other words, there is not clear
25 guidance provided for you to know when you have a

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1 safety culture.

2 MEMBER GUIBERTEAU: Well, would you
3 propose that some guidance be developed along
4 with this policy or is that -- Is there a
5 mechanism for that?

6 MEMBER GILLEY: I don't know. You
7 know, I live in the world of regulation. Policy
8 statements -- you know, if they had -- implied
9 that medical communities already had a safety
10 culture that is completely above the small subset
11 of nuclear medicine and therapy that might be
12 going on in their institution. We hope that that
13 is the way it is.

14 So in some respect, this is additional
15 safety culture policy to an organization that
16 should already have the best safety culture out
17 there, because they are dealing with human beings
18 in a medical environment.

19 CHAIRMAN MALMUD: This is Malmud. I'm
20 sorry, who was --

21 MEMBER VAN DECKER: Oh, I'm sorry, Dr.
22 Malmud. This is Bill Van Decker.

23 CHAIRMAN MALMUD: Yes, Bill?

24 MEMBER VAN DECKER: Let me ask Ms.
25 Gilley a question. The additional part of this

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1 discussion a few weeks or a month ago, whatever,
2 seemed to imply to me that there may be a second
3 step in this process that somebody described as,
4 quote, "implementation safety characteristics"
5 which to me implied that there may be a movement
6 toward regulatory space with some pieces of this
7 as it got fleshed out.

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

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

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

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

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1 Then I look at what the licensees can
2 -- we can truly expect them to be able to respond
3 to and become compliant of, and in this
4 particular case, it is a policy statement that is
5 somewhat nebulous.

6 MR. FIRTH: This is James Firth on the
7 NRC staff, if I could add a little bit, please.

8 CHAIRMAN MALMUD: Please do.

9 MR. FIRTH: The Committee has received
10 the draft Federal Register notice that is going
11 to be going to the Commission. There is also a
12 Commission paper that is going to convey that up
13 to the Commission, and there we do talk about
14 some of the next steps that we are taking.

15 The way we have been looking at the
16 policy statement and what would come afterward is
17 that we don't want the policy statement to go out
18 and that there be no further effort on education
19 or increasing awareness. Otherwise, we would
20 lose the value of the policy statement.

21 So we would be looking at continuing
22 to increase awareness among medical as well as
23 non-medical licensees. The policy statement
24 includes common terminology which includes
25 definition in the traits that have been

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1 discussed.

2 As we were developing that framework,
3 we were also looking at there may be more
4 industry specific terminology which might include
5 certain examples of good practices that might
6 then be developed and included as something that
7 would be available to licensees, whether it is in
8 guidance or whatever.

9 So there is common terminology in this
10 policy statement, trying to reach across the
11 board, but we are planning on taking steps to
12 look at what we might do for the different
13 applications of nuclear material, and that might
14 get a little bit to some of Debbie's concerns in
15 terms of that the policy statement may be a
16 little bit on the general side, and something
17 else later might be useful.

18 CHAIRMAN MALMUD: Thank you. Is that
19 helpful, Debbie?

20 MEMBER GILLEY: That is all right, but
21 I am still abstaining.

22 CHAIRMAN MALMUD: Thank you. All
23 right. So the motion carries with one
24 abstention, and I think it expresses the concern
25 of all of us, including Debbie Gilley, with

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1 regard to the nature of a safety culture and the
2 ultimate goal of achieving greater patient safety
3 and safety to the public. That is a concern of
4 all of us.

5 The issue is not concern for it, but
6 the best way in which to achieve it.

7 Are there any other items that members
8 of the Committee or the public wish to bring
9 before the Committee at this moment? Hearing
10 none, I would ask Ashley, are there any business
11 items that you wish to bring before us at this
12 time?

13 MS. COCKERHAM: No. We already have
14 the January 12th meeting scheduled for 1:00 p.m.
15 to follow up on the ACMUI reporting structure.
16 So I will try to provide some information to the
17 committee as soon as possible.

18 CHAIRMAN MALMUD: Thank you.

19 MS. COCKERHAM: They can discuss it
20 next week.

21 CHAIRMAN MALMUD: Thank you. I thank
22 the members of the committee, the members of the
23 NRC staff and members of the public for having
24 joined us, and we will meet again on January
25 12th. Thank you all.

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1 MR. FULLER: This is Mike Fuller. As
2 the alternate Designated Federal Officer for this
3 meeting, I would also like to thank everyone who
4 participated in the ACMUI for their service, and
5 at this point in time I would like to adjourn the
6 meeting.

7 CHAIRMAN MALMUD: Thank you. The
8 meeting is adjourned.

9 (Whereupon, the foregoing matter went
10 off the record at 2:52 p.m.)

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