

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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MEDICAL EVENT SUBCOMMITTEE (MESC)

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MEETING

+ + + + +

Tuesday, June 28, 2005

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The meeting was conducted by teleconference, pursuant to notice, at
1:00 p.m, Leon S. Malmud, M.D., Chair, presiding.

COMMITTEE MEMBERS PRESENT:

LEON S. MALMUD, M.D.	Chair
EDGAR BAILEY, Ph.D.	Member
DOUGLAS F. EGGLI, M.D.	Member
ALBERT RAIZNER, M.D.	Member
SALLY SCHWARZ, R.Ph.	Member
RICHARD J. VETTER, Ph.D.	Member

SUBCOMMITTEE MEMBERS PRESENT:

JEFFREY F. WILLIAMSON, Ph.D.	Chair
DAVID DIAMOND, M.D.	Member
RALPH P. LIETO	Member
SUBIR NAG, M.D.	Member

NRC STAFF PRESENT:

THOMAS H. ESSIG	Designated Federal Official
NEELAM BHALLA	
IVELISSE CABRERA	
CYNTHIA FLANNERY	
DONNA-BETH HOWE, Ph.D.	
ANGELA McINTOSH	
MOHAMMAD SABA	
RONALD ZELAC, Ph.D.	

ALSO PRESENT: LYNNE FAIROBENT AAPM
GLORIA ROMANELLI, ACR
ROSHUNDA DRUMMOND, ASTRO

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

1
2 MR. ESSIG: Okay. Let me begin with my opening
3 remarks, if I may. As the designated federal official for this meeting, I'm pleased
4 to welcome you to this publicly noticed conference call meeting of the ACMUI.

5 My name is Thomas Essig. I am branch chief for the
6 Material Safety Inspection Branch, and have been designated as a federal official
7 for this advisory committee in accordance with 10 CFR, Part 7.11. This is an
8 announcement meeting of the committee. It's being held in accordance with the
9 rules and regulations of the Federal Advisory Committee Act and the Nuclear
10 Regulatory Commission.

11 The meeting was announced in the June 14, 2005 edition
12 of the Federal Register. The function of the committee is to advise the staff on
13 issues and questions that arise on the medical use of by-product material. The
14 committee provides counsel to the staff, but does not determine or direct the
15 actual decisions of the staff or the Commission. The NRC solicits the views of
16 the committee and values them very much.

17 I request that whenever possible we try to reach a
18 consensus on the various issues that will be discussed during this conference
19 call, and we also value minority or dissenting opinions. If you have such
20 opinions, please allow them to be read into the record.

21 As part of the preparation for this meeting, I have reviewed
22 the agenda for members and employment interests based on the general nature
23 of the discussion we're going to have today. I've not identified any items which
24 pose a conflict of interest for the members. If, however, during the course of our
25 business, other members determine that they have a conflict of interest in
26 matters before the committee, please state it for the record and recuse yourself

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1 from that particular aspect of the discussion.

2 At this point, I would merely acknowledge the members of
3 the committee who have indicated that they are present. I will go down the list
4 of eight that I have. If somebody has joined us, a committee member, who's
5 name I don't read, please acknowledge.

6 Dr. Douglas Eggli, nuclear medicine physician.

7 DR. EGGLI: Present.

8 MR. ESSIG: Dr. David Diamond, radiation oncologist.

9 DR. DIAMOND: Present.

10 MR. ESSIG: Dr. Subir Nag, radiation oncologist.

11 DR. NAG: Yes.

12 MR. ESSIG: Ms. Sally Schwarz nuclear pharmacist.

13 MS. SCHWARZ: Present.

14 MR. ESSIG: Dr. Richard Vetter, radiation safety officer.

15 DR. VETTER: Present.

16 MR. ESSIG: Dr. Jeffrey Williamson, therapy physicist.

17 DR. WILLIAMSON: Here.

18 MR. ESSIG: Dr. Albert Raizner, interventional cardiologist.

19 DR. RAIZNER: Present.

20 MR. ESSIG: And Mr. Ralph Lieto, nuclear medicine
21 physicist.

22 MR. LIETO: Present.

23 MR. ESSIG: Are there any members of the committee who
24 have joined us in the interim?

25 DR. NAG: What about Dr. Potters? Is Dr. Potters here?

26 MR. ESSIG: Is Dr. Potters here?

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1 DR. WILLIAMSON: No. I guess nobody informed him of
2 the meeting until I did today, so he's going to try to join us, but may not be able
3 to.

4 MR. ESSIG: Okay.

5 MS. McINTOSH: I sent him an email invitation. This is
6 Angela McIntosh of the Nuclear Regulatory Commission staff. I did send him an
7 email invitation, Dr. Williamson, when I sent it to the committee. So maybe he
8 just didn't read it or whatever.

9 DR. WILLIAMSON: Could be.

10 MR. ESSIG: In the absence of the chairperson, Dr. Leon
11 Malmud, I will conduct today's meeting as designated federal official. Following
12 the discussion of the agenda, I will at my option entertain comments from the
13 members of the public who are participating with us today.

14 The purpose of today's meeting is to hear the report from
15 the Medical Events Subcommittee, chaired by Dr. Jeff Williamson, and reporting
16 to the full committee. I would just take a second and allow the members of the
17 NRC staff to introduce themselves. We'll just go around the table here because
18 there may be members of our staff speaking. We just want to do kind of a sound
19 check and make sure that the court reporter and members can hear us. As I
20 mentioned, this is Tom Essig.

21 MS. FLANNERY: Cindy Flannery, F-L-A-N-N-E-R-Y.

22 MS. McINTOSH: Angela McIntosh, M-c-I-N-T-O-S-H.

23 DR. ZELAC: Dr. Ronald Zelac, Z-E-L-A-C.

24 MS. BHALLA: Neelam Bhalla. That's B-H-A-L-L-A.

25 MR. SABA: Mohammed Saba, S-A-B-A.

26 MR. ESSIG: Okay. Dr. Donna-Beth Howe was with us.

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1 She just stepped out of the room momentarily, but she should return shortly.

2 MR. ESSIG: Okay. I believe now we are ready to begin
3 with the report of the subcommittee.

4 Jeff, I'll turn it over to you to present your report.
5 Summarize it in whatever fashion you feel appropriate for the committee as a
6 whole.

7 DR. WILLIAMSON: Okay. Well, thank you.

8 I'm very pleased that during our last non-public telephone
9 conference, the Medical Event Subcommittee was able to achieve a consensus
10 approach to the revision of the medical event rule to permanent interstitial
11 implants.

12 We adopted a different strategy than we tried in the past.
13 We made no effort to state our conclusions or recommendations in rule
14 language. Due to the technical complexity of the task, we have become mired
15 in basically legal questions of how to interpret the existing rule and what is the
16 best way to state the new consensus in rule language, so we abandoned that
17 approach, and we simply stated our recommendations in ordinary language.

18 Well, they lack maybe the precision of rule language. I
19 think taken as a totality, the recommendations represent a coherent and
20 consistent view. So it is in this form we would like to present these to the ACMUI
21 and get your feedback, and hopefully approval of the approach. Then my
22 understanding is that the staff will attempt to take this approach and create a rule
23 language draft that I would assume we would get to review at a subsequent
24 meeting. I guess we can start.

25 DR. NAG: Are you basically going to follow the memo you
26 sent out June 21 or is there any late revision to that?

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1 DR. WILLIAMSON: The most recent one I believe was
2 sent out by Angela McIntosh -- was it the 24th of June? But I believe it says up
3 in the upper right-hand margin, "Revised 21 June 2005." And the name of the
4 document is Medical Event Subcommittee Meeting Summary and Draft
5 Recommendations to the ACMUI. So that is the document we'll be referring to.
6 I thank you for bringing my neglect of mentioning it to your attention.

7 DR. NAG: Everyone has this document that we can follow.

8 DR. WILLIAMSON: Mr. Chairman, I suggest we just step
9 through it point by point, and determine whether there is a consensus on the
10 different issues or not.

11 MR. ESSIG: Please do.

12 DR. WILLIAMSON: Okay. Well, the document is divided
13 into three parts, Parts A, B and C. Part A is essentially our view of the status of
14 the current medical event rule and associated definitions. It contains some
15 critique of the existing rule and concerns that have been developed and
16 articulated both by the subcommittee and the staff. I don't think there is a motion
17 in Section A, but I will ask the ACMUI if there are any questions or concerns
18 about any of the material in Part A of this document on pages 1 and 2.

19 MR. ESSIG: Dr. Williams, there was a break in the
20 conversation. Did somebody join us?

21 DR. MALMUD: Dr. Malmud.

22 MR. ESSIG: Excellent. I will turn over the gavel to you, sir.

23 DR. MALMUD: Thank you.

24 MR. ESSIG: We just started. Dr. Williamson is running
25 down through the points in the June 21st version of the subcommittee's report.

26 DR. MALMUD: Yes, I heard.

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1 MR. ESSIG: Okay.

2 DR. MALMUD: He's looking for a motion or approval.

3 DR. WILLIAMSON: Well, I'm not sure in Part A there's any
4 action item in it or a motion to be made. I think Part A could be considered as a
5 whereas component.

6 I was just asking if there were any questions or concerns
7 about Part A, which is really not an action item in itself.

8 DR. MALMUD: None from Malmud.

9 DR. NAG: I suggest we go on to Part B, and on this
10 portion of Part B we go ahead and have the voting and so on.

11 DR. WILLIAMSON: All right. Is the preference of the
12 ACMUI to through Part B point by point?

13 DR. NAG: At least the main point. We may not need to
14 go through all the rationales, but let's go through the main point.

15 DR. MALMUD: Okay. Which one shall we begin with?

16 DR. WILLIAMSON: Let's start with point B1, which I can
17 read. "For all permanent implants, ME should be defined in terms of total source
18 strength and planted in the treatment site, not in terms of absorbed dose." So I
19 guess this is a motion, maybe.

20 MR. LIETO: This is Ralph Lieto. I second.

21 DR. MALMUD: It's been moved and seconded. Is there
22 any discussion? If not, may we call the vote?

23 All in favor?

24 (Chorus of ayes)

25 DR. MALMUD: Any opposed?

26 DR. WILLIAMSON: All right, point 2, B2, which is entitled,

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1 Treatment site accuracy, ME pathway. "Specifically, the Medical Event
2 Subcommittee recommends that any implant in which the source strength
3 implanted in the treatment site deviates from the written directive by more than
4 20 percent, in either direction, should be classified as an ME." That is another
5 motion.

6 DR. NAG: Could we add "total source strength" rather than
7 just "source strength"?

8 DR. WILLIAMSON: That is a good correction, yes. Let's
9 amend the motion as suggested by Dr. Nag so it now will read, "Specifically,
10 MESC recommends that any implant in which the total source strength implanted
11 in the treatment site deviates from the written directive by more than 20 percent,
12 in either direction, should be classified as an ME."

13 DR. NAG: I second the motion.

14 DR. MALMUD: All in favor?

15 (Chorus of ayes)

16 DR. MALMUD: Any opposed? Carries.

17 DR. WILLIAMSON: We move on to point B3 on page 3,
18 Wrong site medical event pathway. "The Medical Event Subcommittee
19 recommends that the revised wrong-site medical event criterion distinguish
20 between two scenarios: tissue or organs immediately adjacent to the treatment
21 site and organs that are distant from the treatment site. For permanent implants,
22 tissues that are more than 2 to 4 centimeters from the treatment site boundary
23 can be considered distant as dose has fallen to subtherapeutic levels."

24 I think it's necessary for me to at least summarize the
25 sub-bullets, 3a, d and c, because they are part of the motion. So for adjacent
26 tissue wrong-site medical event -- this is bullet B3a -- we propose, implants in

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1 which more than 20 percent of the source strength -- I guess it should be total
2 source strength -- documented in the pre-implantation written directive implanted
3 in tissue or organs adjacent to the treatment site should be classified as ME.
4 That's point a.

5 Point B is entitled, Distant organ wrong treatment site ME.
6 For erroneous implantation of radioactive seeds in an organ distant from the
7 intended treatment site, the Medical Event Subcommittee recommends that such
8 implants be classified as MEs if 1) seeds are actually implanted in a distant
9 organ; 2) the dose of a distant organ exceeds 5 Rem; and 3) the excess dose to
10 the organ is at least 50 percent greater than the dose that would have been
11 delivered had the seeds been implanted in the correct tissue volume.

12 Point C states, "For both adjacent and distant wrong-site
13 MEs, it is important to exclude seeds that were correctly implanted but
14 subsequently migrated as grounds for an ME."

15 That is the end of the motion. I'm sorry it's so long.

16 DR. NAG: Again, I second that motion.

17 DR. MALMUD: The motion's been moved by Williamson;
18 seconded by NAG. Any discussion?

19 DR. RAIZNER: Just a question. The definition of the
20 distance in this motion, it states 2 to 4 centimeters. How will you decide whether
21 3 is outside the treatment site? In other words, giving a range, is there an
22 advantage to doing that or should we define a specific distance, such as
23 4 centimeters?

24 DR. NAG: The reason we left that somewhat vague is that
25 it depends on the organ we are implanting. For example, if the tissue adjacent
26 to that organ is not critical, I have no problem it being defined as 4 centimeters;

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1 whereas, if the adjacent tissue is something critical, like the rectum or bladder,
2 then we have to be a little tighter. So that's we have that range of 2 to 4.

3 DR. RAIZNER: So will there be specific distances for
4 specific organs or left as the 2 to 4?

5 DR. WILLIAMSON: Remember, there's a distinction being
6 made between adjacent and distance. Adjacent is not exactly defined, but the
7 intent of the subcommittee was an adjacent organ is organ that is in contiguity or
8 in contact with the treatment site. So the rectum would be an adjacent organ.
9 And, presumably, any part of the rectum -- whether it's 2 or 3 centimeters
10 away -- would be considered an adjacent organ.

11 What would be a good example of a tissue that's not in
12 contact with the prostate here that we could use to illustrate a distant organ?

13 DR. NAG: The penis, for example, it went down to the
14 lower part. That's not really adjacent because you have the bulb, and then if it
15 goes to the penile tissue, that would be a distant organ.

16 DR. WILLIAMSON: Yeah. I think, to be honest, we really
17 haven't crafted an exact definition. A reasonable approach would be to say that
18 a distant organ is one whose closest boundary to the treatment site perceives the
19 less than 5 percent of the dose. That would probably be a reasonable
20 characterization that we might be able to live with.

21 DR. VETTER: So who is left to interpret whether 2 or 4 is
22 appropriate in any given medical event?

23 DR. NAG: I think this is where we can leave it to the
24 discretion of the medical person who is going to be reviewing it. And that is why
25 we gave that 2 to 4 centimeter leeway. If it is a critical organ, we would take the
26 lesser number, and if it's a less critical organ, we'll take the larger number.

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1 But this gives some room for using some of the clinical judgment, rather how
2 important it is.

3 MR. LIETO: Dr. Nag and Dr. Williamson, the concern that
4 I'm getting is that if we are going to turn this over to NRC staff to craft regulations
5 from, I think they're going to need sort of a cut-off level. I don't know if we want
6 to say 4 centimeters or 2 centimeters, or we want to say less than 5 percent of
7 the absorbed dose. I would defer to the two of you and Dr. Diamond to maybe
8 come up with the right cut-off level. I can sympathize with Dr. Vetter and the
9 other that we probably are going to need to give guidance to NRC staff if we want
10 them to craft it in the regulation.

11 DR. MALMUD: Is 3 centimeters a number beyond which
12 you think you would ever normally go?

13 DR. NAG: If we have to give only one number, I'll go for
14 4 centimeters.

15 DR. WILLIAMSON: I guess this is a situation where if you
16 ask three people, we'll come up with three different criteria. I would go for a
17 dose-based criterion. Perhaps, what we need to do is accept that in the rule
18 language that the staff craft -- that we need to work on devising a single
19 definition. I think a reasonable approach would be to, off line, examine dose fall
20 off versus distances, and try to come up with something reasonable. Maybe at
21 this time, without doing a little thought and research into the question, it might be
22 difficult to come up with a really good defensible criterion.

23 DR. MALMUD: Not being a radiotherapist, I'm just asking
24 a naive question. Is there ever a situation in which you would accept going more
25 than 3 centimeters away from the target?

26 DR. WILLIAMSON: Let me explain the rationale of having

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1 to make this distinction. The reason for wanting to distinguish between adjacent
2 and distant organs is that in adjacent organs, it is frequently necessary to implant
3 some small number of seed, usually a small minority of the total number of seeds
4 implanted. The reason for doing this is the medically legitimate need to provide
5 adequate coverage of the treatment site. So we wanted to give a fairly generous
6 criterion for that compartment of tissue, which would allow implants to be
7 performed. So there the criterion's plus or minus 20 percent.

8 The distance site criterion is also needed because there
9 certainly have occurred situations where the wrong side of the patient's body has
10 been treated by an external beam field or the applicators, or needles, have been
11 erroneously inserted into the wrong part of the patient's body. So in that
12 situation, we wanted a much tighter criterion because it was felt that, giving
13 20 percent of a therapeutic dose, even to a small volume, could be potentially
14 serious. So we wanted a tight criterion there.

15 It's kind of a balancing act. We could make, for example,
16 the distance very large, then there would be no problem with physicians having
17 the flexibility to implant target volume using the hairy target tissue as legitimate
18 places. But then if some wrong or critical organ lies 3 to 5 centimeters away and
19 there were an erroneous implantation, that kind of medical event would escape
20 this rule. So it's a bit of a compromise, I guess. So if we make it too
21 far away, we undercount events. If we make it too close, we would limit the
22 flexibility of the practitioner to perform good implants.

23 DR. MALMUD: I recognize that, but I'm simply asking a
24 follow-up question to the question that stimulated this aspect of the discussion.
25 And that is, if the range and the recommendation is 2 to 4 centimeters, which is
26 vague, does anyone think that 3 centimeters is a number beyond which we would

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1 consider something to be of this administration?

2 DR. NAG: Well, in the medical setting we have to make
3 this applicable to both the prostate implant as well as permanent implant. But in
4 other organs where you don't have a boundary, and you may have to
5 over-implant, I prefer the 4 cm. I think 4 cm I can live with.

6 DR. MALMUD: Looking again to try to simplify this so that
7 those who interpret regulations will not be dealing with ambiguous numbers, is
8 4 centimeters a better number, rather than 2 to 4, stating 4?

9 Q I'm not a clinician, obviously, but it seems to me,
10 considering the two sets of cases, 3 might be a good compromise. I think 4 is a
11 bit big for prostate, and being the situation where you have a reasonably,
12 well-encapsulated target that can be radiographically visualized.

13 In the post-operative setting, where you're doing some
14 implants without a tissue boundary, already I think there's a warning in the bullet
15 B2, I guess, which says you're going to have to really exercise some clinical
16 discretion in imposing this rule because there are some cases where there simply
17 isn't a well-defined boundary. So there's already, I think, enough give and take
18 in the system that 3 cm would work.

19 DR. DIAMOND: I concur with Dr. Williamson. I think
20 3 centimeters would strike a reasonable balance, particularly since we're primarily
21 dealing with prostate brachytherapy. Furthermore, I agree with Dr. Raizner that
22 by leaving it nebulous, set between 2 cm, it's going to make it very difficult for the
23 NRC staff or the agreement state staff to have guidance on this issue. So I think
24 simply compromising the 3 centimeters would yield a useful balance between
25 clarity of the rule and ability of staff to enforce.

26 DR. MALMUD: Thank you, Dr. Diamond. Is that a

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1 recommendation to amend the motion to be 3 centimeters instead of 2 to 4?

2 DR. WILLIAMSON: I would accept that as a friendly
3 amendment to what I just read.

4 DR. MALMUD: So Dr. Diamond's amendment, as a
5 friendly amendment, is seconded by Dr. Williamson. Any further discussion?

6 DR. ZELAC: Dr. Malmud?

7 DR. MALMUD: Yes, sir? Who's speaking?

8 DR. ZELAC: This is Dr. Zelac.

9 DR. MALMUD: Dr. Zelac?

10 DR. ZELAC: One suggestion for a word, which I believe
11 has been omitted from the text in B(ii). It reads currently, "The dose of the distant
12 organ exceeds 50 REM." In parallel with B(iii), it should read, "The excess dose
13 of a distant organ exceeds 50 REM."

14 DR. MALMUD: Dr. Zelac, thank you for bringing that to our
15 attention.

16 DR. WILLIAMSON: I think that's very good, yes. So the
17 excess dose. I will accept that as a second friendly amendment.

18 DR. MALMUD: Dr. Williamson is in a friendly mood. Are
19 they both seconded by Dr. Diamond and Dr. Nag?

20 DR. NAG: Yes.

21 DR. MALMUD: Thank you. Any other discussion? All in
22 favor?

23 (Chorus of ayes)

24 DR. MALMUD: Any opposed? The motion carries
25 unanimously again.

26 Thank you, Dr. Williamson. Will you continue?

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1 DR. WILLIAMSON: Yes. We now move on to motion B4,
2 located on the top of page 4.

3 "Given a source-strength-based ME criterion, it is
4 reasonable to require that the AU complete the written directive for a permanent
5 implant before the patient is released from licensee control."

6 MR. LIETO: This is Ralph Lieto. I second.

7 DR. NAG: This is Dr. Nag. Again, I know what we are
8 trying to say, but we have already written the directive before we started the
9 implant. So basically what we want to convey to the people I think is that if
10 anyone wants to revise the written directive, the revision has to be done before
11 the patient is released from the licensee controls. I don't know if that is made
12 clear in what we have written here.

13 DR. DIAMOND: Perhaps if we said something like, given
14 a source-strength-based medical event criteria of 20 percent, it is reasonable to
15 require that the AU complete any revision to the written directive for permanent
16 implant for the patient is released from licensee control.

17 DR. NAG: Right, right. I mean, that I will agree to.

18 DR. WILLIAMSON: That was certainly one of the intents.
19 I think perhaps in phrasing it, or in our original discussion, we were guilty of
20 thinking in terms of rule language rather than ordinary language because the way
21 the current rule is written, it really doesn't talk about revisions. It talks about
22 completing the written directive -- I've lost my train of thought.

23 Would you repeat what your amendment was to this?

24 DR. NAG: What we suggested was, is it reasonable to
25 require that the authorized user completes any revisions to the written directives
26 before the implant, et cetera. Just add the word "complete any revisions to the

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1 written directive."

2 DR. WILLIAMSON: Yeah, I've got that here.

3 Dr. Zelac, is that clear to you, what the meaning is?

4 DR. ZELAC: Yes, it is.

5 DR. WILLIAMSON: Okay. Well, then I think that I'll read
6 the amended motion.

7 "Given a source strength-based ME criterion of 20 percent,
8 it is reasonable to require that the AU complete any revisions to the written
9 directive for permanent implants before the patient is released from licensee
10 control."

11 UNIDENTIFIED SPEAKER: I would second that revision.

12 DR. MALMUD: The motion's been moved and seconded.

13 The revision, all in favor?

14 (Chorus of ayes)

15 DR. MALMUD: Any opposed? All right. Unanimously
16 again, Dr. Williamson.

17 DR. WILLIAMSON: Okay. Item number 5 on page 4.
18 Dose-based medical event pathway for permanent implants. "In addition to
19 incorporating the activity-based, medical event pathway, described above into
20 Part 35, the Medical Event Subcommittee recommends retaining a limited dose-
21 based medical event criterion. An implant is a medical event if the dose
22 calculations used to determine these total source strength documented in the
23 written directive are in error by more than 20 percent."

24 DR. MALMUD: Are you seeking comments,
25 Dr. Williamson?

26 DR. WILLIAMSON: Yes, this is a motion. I guess I first

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1 seek a second.

2 DR. MALMUD: Is there a second to Dr. Williamson's
3 motion?

4 DR. NAG: Dr. Nag seconds the motion.

5 DR. MALMUD: Thank you.

6 DR. WILLIAMSON: Okay. And now comments and
7 discussion.

8 MS. FAIROBENT: Dr. Malmud, this is Lynne Fairobent.

9 DR. MALMUD: Yes?

10 MS. FAIROBENT: I have a question on this, and also I
11 guess on the one above it. When you're saying by more than 20 percent, I'm
12 assuming in all these cases you're talking 20 percent in either direction.

13 DR. NAG: Yes.

14 DR. WILLIAMSON: Yes.

15 DR. MALMUD: That is correct.

16 DR. NAG: We can add that in by more than 20 percent in
17 either direction.

18 DR. WILLIAMSON: I think that is a good idea. The last
19 sentence of the amended motion now reads, "An implant is a medical event if the
20 dose calculations used to determine the source strength documented in the
21 written directive are in error by more than 20 percent in either direction."

22 DR. MALMUD: Thank you.

23 DR. NAG: I think the examples that Dr. Williamson has
24 given serve to clarify exactly what we mean.

25 DR. MALMUD: Thank you, Dr. Nag.

26 MS. SCHWARZ: I have a question also in regard to what

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1 Lynne Fairbent suggested. Is number 4 also being modified to account for
2 20 percent in either direction?

3 DR. WILLIAMSON: Point number 4 makes reference to
4 point G2, where it is clearly specified. This is on page 2 that it's in either
5 direction. So number 4 is not meant to be a stand-alone statement of the
6 source-strength-based ME criteria. It's merely saying that the source strength;
7 that the ME criterion of B2, given that criterion, it is reasonable to require that the
8 AU complete any revisions to the written directive.

9 DR. NAG: Actually, for number 4, even if you are given a
10 source strength-based medical event criteria, you don't even need to put the
11 20 percent. The sentence would still be very appropriate.

12 DR. WILLIAMSON: Well, with a criterion of 5 percent, it
13 might actually be very difficult. But given the criterion in point 2, it is a reasonable
14 additional requirement.

15 MR. LIETO: Just a point of clarification. To answer Sally's
16 question that the intent was that the 20 percent applies in either direction, I think
17 that's correct.

18 DR. WILLIAMSON: Yes, that is the intent that's clearly
19 stated in bullet 2.

20 DR. NAG: Can we go into a vote?

21 DR. MALMUD: Yes. Jeff Williamson?

22 DR. WILLIAMSON: Yes?

23 DR. MALMUD: That is a motion for a vote, right?

24 DR. WILLIAMSON: Correct. It's been seconded.

25 DR. MALMUD: And it's been seconded. All in favor?

26 (Chorus of ayes)

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1

DR. MALMUD: Any opposed? Carries. Next?

2

3

DR. WILLIAMSON: Okay. We have now completed,

4

basically, the approval of the Medical Event Subcommittee proposed revised

5

approach to medical events. We now go to Part C, which is risk communication,

6

which, I'll remind everybody, was one of the charges that the Commission gave

7

us in pursuing this activity in their staff requirements memorandum following our

8

briefing with them in 2004.

9

It starts out with a problem definition, which is point 1. I

10

don't know if I need to repeat this. I'll just ask if there are any concerns, if anyone

11

on the ACMUI feels that we have not properly characterized the problem of risk

12

communication.

13

DR. NAG: Jeff, would you just summarize in one sentence

14

what you are trying to sell in that paragraph? I think that's all we need.

15

DR. WILLIAMSON: You've really put a challenge in front

16

of me. Okay. Well, I think the major point of this paragraph is that the process

17

of investigating an enforcement that follows the report of a medical event is

18

viewed by the regulated community as being very punitive in itself because of the

19

way the reporting rule is written and the associated procedures. This is the

20

essential concern. The concept being pushed is that NRC ought to look at the

21

way medical events are defined and the enforcement procedures that are

22

associated with their investigation, and try within their framework to make it as

23

much like the industry standard as possible. That's my summary of problem

24

definitions.

25

Does anyone feel it's inaccurate or requires further

26

clarification?

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1 DR. NAG: I think it's okay the way it reads now.

2 DR. MALMUD: With the approval of Dr. Nag, does
3 anybody else have an opinion?

4 MR. ESSIG: Dr. Malmud, this is Tom Essig. I just have
5 a clarifying question.

6 DR. MALMUD: Yes?

7 MR. ESSIG: Under problem definition, item c, where it
8 talks about reactive IT inspections, I'm not sure what reactive IT inspections are.

9 DR. WILLIAMSON: I thought IT was when you send a
10 team of investigators the next day after someone revokes --

11 MR. ESSIG: Okay. That's incident investigation team,
12 which is the highest level of investigation the agency does. For example, in
13 1992, when we had the Indiana-Pennsylvania medical event, where the patient
14 died due to radiation exposure, that was an IT. Those are very rare occurrences.
15 We are not proposing handling medical events in all cases. Only a very small
16 subset of them would ever become an IT.

17 DR. WILLIAMSON: Well, I believe that Washington
18 University, one that gave 50 milli REM to a thigh of a patient, where I was
19 involved, was handled in that way. Yes, that's right.

20 Would you recommend that I just delete the word, the
21 qualifier, IT? Tom, would you recommend I just delete IT?

22 MR. ESSIG: Yes.

23 DR. WILLIAMSON: I think that's fine.

24 MR. ESSIG: Because, in general, we do say reactive
25 inspections, which can be reactive to anything, not only medical events, but other
26 types of items that the licensees report.

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1 DR. WILLIAMSON: Okay.

2 Any more questions, or should we move on?

3 MR. ESSIG: One further comment. On that same line,
4 "in the same way as potential nuclear reactor disasters," it's probably --

5 DR. WILLIAMSON: Hyperbole.

6 MR. ESSIG: Yeah.

7 DR. WILLIAMSON: All right. I have no problem deleting
8 the phrase, "in the same way as potential nuclear reactor disasters."

9 MR. ESSIG: Okay, thank you.

10 DR. WILLIAMSON: Does anyone on the subcommittee
11 have an objection to deleting that hyperbolic phrase?

12 MR. LIETO: I don't mind replacing the word "disaster"
13 maybe with "problems," but I think we do need to keep the comparison, in terms
14 of reporting mechanism, between medical scenarios and reactor concerns being
15 handled in the same way. That needs to be I think referenced in the document.

16 DR. WILLIAMSON: Okay. Well, I think, Tom, there was
17 a valid intent trying to be expressed here. What this is, is a piece of feedback
18 from the community more or less. Often we tend to, in our experience, find that
19 the NRC reaction is way out of proportion sometimes to the significance of the
20 event. And that, in a sense, if part of the regulated community's perception of
21 medical event enforcement and management being punitive.

22 MR. ESSIG: What I would suggest here is rather than
23 make the linkage to a nuclear power plant, there are numerous other analogies
24 one could draw from what I would call the materials license arena, where many
25 times we have reported to our operations center events involving a sealed
26 source, mismanagement of seal source, loss seal source, exposure of an

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1 individual, that sort of thing, outside of the medical community. These are
2 industrial radiography and numerous other sealed sources that are used by
3 materials licensees. So I think a comparison with that would be fair, would be a
4 better comparison.

5 MR. LIETO: Tom, I think the issue is not so much the
6 comparison as to the reporting, where this gets reported to and how this gets into
7 the public venue.

8 MR. ESSIG: Well, no, I'm talking about the same thing.
9 The radiography events that are reported to the operation center end up in the
10 public domain just like medical events do. That's why I thought that was an
11 appropriate comparison.

12 DR. WILLIAMSON: I tend to agree with Ralph. We're
13 trying to bring something to your attention that is a subjective reaction on the part
14 of a community. This is really how it seems.

15 MR. ESSIG: Okay. If that's your perception, I can't argue
16 with perception.

17 DR. WILLIAMSON: I think disasters is hyperbolizing a bit.

18 DR. NAG: I would say as eventual nuclear reactor
19 accidents.

20 DR. WILLIAMSON: Yeah, maybe that's a better way.

21 DR. BAILEY: This is Ed Bailey. I just got on the line.

22 DR. MALMUD: There are two things. Number one, would
23 you please use your name before you speak since the stenographer is having
24 difficulty keeping up. The second one is that someone has some papers that are
25 rattling near a microphone that are causing a bit of interference. Thank you.
26 Please go on.

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1 DR. WILLIAMSON: Maybe this is a reasonable middle
2 ground in the same way as nuclear reactor accidents.

3 MR. ESSIG: Would you settle for event, nuclear reactor
4 events? I mean, an accident is pretty serious. That implies we've had a potential
5 core damage event, major releases to the environment, like a Three Mile Island.
6 That was an accident. So I think event might be a better perspective.

7 DR. MALMUD: Mr. Essig, I am in favor of accepting your
8 recommendation, since you have much more day-to-day interaction with the
9 terminology than we do.

10 MR. ESSIG: I mean, I'm suggesting that, but yet it's being
11 presented as a view from the user community. I'm not trying to direct what that
12 perception ought to be.

13 DR. MALMUD: Oh, I understand.

14 DR. WILLIAMSON: I propose we rephrase it as this:
15 "Reactive inspections are perceived by the regulated community," or "Reactive
16 inspections, following medical events, are perceived by the community to be
17 handled in the same way as potential nuclear reactor events, which jeopardize
18 the health of large numbers of individuals." Maybe that gets the point across.

19 What do you think, Ralph?

20 MR. LIETO: I think just simply saying nuclear reactor
21 events, period, would be good, Jeff.

22 DR. WILLIAMSON: All right. Well, if everyone agrees on
23 that, that's fine with me.

24 MR. ESSIG: Fine with me.

25 DR. WILLIAMSON: Okay. Any more concerns with this
26 paragraph?

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1 DR. MALMUD: Apparently none, Dr. Williamson.

2 DR. WILLIAMSON: We will move on, then, to point C2,
3 which is a recommendation. I'll read it.

4 "The role of the 10 CFR 35.3045 medical event reporting
5 rule as a technical quality performance indicator should be decoupled from its
6 use as a patient harm index. To this end, the patient reporting requirement
7 35.3045(e) should be amended to require informing the patient and/or friends
8 and relatives only if the licensee determines that the medical event may have
9 harmed the patient, could potentially harm the patient, or is materially relevant to
10 the patient's future medical treatment decision."

11 DR. NAG: Seconded.

12 DR. MALMUD: It's been moved and seconded. Any
13 discussion?

14 DR. ZELAC: Dr. Malmud?

15 DR. MALMUD: Yes?

16 DR. ZELAC: This is Dr. Zelac. I simply wanted to point out
17 that in earlier considerations of this issue by the Commission, it says here in the
18 Federal Register as parts of statements of consideration, "The Commission's
19 position has been, and perhaps still continues to be, that if individuals are
20 identified in records of agencies, that those individuals know of it." This is a
21 mechanism for being sure that an occurrence involving a person who was being
22 written up in an agency record, that that individual was aware of that fact, and
23 that fact alone. If there was potential for harm or actual harm, that would, of
24 course, be part of it, but that wasn't the underlying reason.

25 DR. MALMUD: Thank you for that clarification.

26 Dr. Williamson?

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1 DR. WILLIAMSON: I think our response would be that the
2 identity of the individual is not supposed to be contained in any agency record.

3 DR. MALMUD: Dr. Zelac, does that assist you?

4 DR. ZELAC: I'm simply bringing the Commission's
5 perspective to your attention.

6 DR. MALMUD: Thank you, Dr. Zelac.

7 DR. WILLIAMSON: I would comment that I think that the
8 subcommittee members are aware of the Commission's basis for rejecting this
9 the last time around, which was about three or four years ago. But the dilemma
10 that the reporting rule places the physician in is one of the aspects of the medical
11 event reporting system that is viewed as punitive, namely the dilemma being a
12 contradiction between what is medically best for the patient and maintaining
13 privacy of the patient, the medical information. The rule can place you in a bind
14 where you have to violate one or the other.

15 DR. MALMUD: Thank you, Dr. Williamson.

16 With the history given by Dr. Zelac, can we move forward?

17 DR. WILLIAMSON: Yes.

18 DR. MALMUD: I think the ball is in your court,
19 Dr. Williamson.

20 DR. WILLIAMSON: Okay. Well, I think we have a second
21 for the motion, so we need to call for a vote.

22 DR. MALMUD: All right. All in favor of the motion?

23 (Chorus of ayes)

24 DR. MALMUD: Any opposed? Motion carries
25 unanimously.

26 DR. WILLIAMSON: Point 3. This is a general

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1 recommendation; it's not very specific. "The subcommittee recommends that
2 NRC staff tries to make the ME reporting and subsequent enforcement
3 processing more like that of the regulated community's own QA practice of follow
4 up and QA process review that occurs following detection of a delivery error or
5 potential error."

6 We further comment, "Comprehensive institutional QA
7 programs are based upon three broad principles: simply making an error is not
8 grounds for disciplinary action; institutional QA findings and deliberations are not
9 discoverable and cannot be used to increase its liability; error reports are inputs
10 through a systematic effort for improving planning, delivery, safety, QA, and
11 documentation processing."

12 This is recommended as a general, philosophical guidance
13 statement that should be used to fine tune policy operating procedures, NRC
14 operating procedures.

15 DR. NAG: Again, I second the motion.

16 DR. BAILEY: I have some concerns about whether or not
17 this can simply make this information non-discoverable, and I can also state that
18 during an investigation someone might use it and say it's not discoverable.

19 DR. MALMUD: Who's speaking, please?

20 DR. BAILEY: Ed Bailey.

21 DR. MALMUD: Thank you. Would you repeat your
22 concerns?

23 DR. BAILEY: Yes. I don't know whether simply saying it's
24 non-discoverable, number one, makes it not discoverable. Number two, having
25 a statement like that could lead an institution to say that they would not provide
26 that information to an investigator.

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1 DR. WILLIAMSON: Well, I think the implication of this
2 principle, the rationale of stating this is that QA procedures work effectively with
3 any institution because they're not punished for having them. If you create a
4 situation where every time you make an error, you're going to be severely
5 punished as an institution, you erode the incentive for institutions to go to lengths
6 to detect these errors and correct them. We believe that this is the position that
7 NRC has placed institutions in with respect to ME reporting.

8 DR. DIAMOND: Jeff, I understand what you're saying, but
9 I also just want to agree with Dr. Bailey that with respect to C3(b), unfortunately,
10 in many states, institutional QA findings and deliberations are discoverable. So
11 even though that may be your intent and the spirit, that carries no legal weight.

12 DR. WILLIAMSON: Yeah, I understand. It isn't the
13 specific recommendation that NRC do anything, but it's kind of a guiding
14 principle.

15 DR. DIAMOND: Yes, and I concur with that spirit. Again,
16 I'm not a lawyer, but I can just tell you that with several states, including the state
17 of Florida, indeed, with institutional QA committees, that is now all discoverable,
18 and it's basically causing hospitals across the state to do away with quality
19 assurance committees.

20 DR. WILLIAMSON: I understand what you're saying. I
21 think the implication is not that these procedures in the private sector are
22 absolutely not discoverable, but to the extent that they are shielded from
23 discovery, QA functions more effectively.

24 MR. LIETO: I think from the subcommittee's perspective,
25 I think our intent was that we wanted to separate what was being reported versus
26 what would be available upon review by inspectors in the course of a normal

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1 audit or follow through of a medical event report. So by putting something into
2 an urgent 24-hour reporting mechanism that immediately goes out into a web site
3 and so forth, as opposed to conducting an investigation and a "QA follow-up
4 mechanism," that would be available for inspection. We wanted to distinguish
5 between the two.

6 DR. WILLIAMSON: We're going to cover all of the points
7 Ralph just made when we come to item 4. I'll just point that out. I would suggest
8 deferring some of the points until then.

9 I have a proposal of how to clarify 3a, b, and c. I think that
10 maybe what I should do is restate them as principles rather than as absolute
11 statements of fact. In fact, if an employee makes lots and lots of errors, they
12 may be subject, eventually, to disciplinary action. So it's not meant to be a
13 statement of fact that says a hundred percent of the time when an error is made
14 by some employee, the employee is never disciplined. The point here is to
15 articulate a principle that you avoid punishing employees and staff for reporting
16 errors because you want to encourage the process. I could go through a, b, and
17 c and convert them to principles language rather than statement of fact language,
18 and I think that would address the issue that Mr. Bailey has raised.

19 DR. MALMUD: Any further comments?

20 DR. WILLIAMSON: But I don't think I could do that on line
21 in 30 seconds.

22 DR. MALMUD: Okay. Dr. Williamson?

23 DR. WILLIAMSON: Yes?

24 DR. MALMUD: Where are we now?

25 DR. WILLIAMSON: So I guess we have an amended
26 proposal point 3 -- there are three points, a, b, and c -- so as to make the

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1 subpoint a, b, and c read as principles rather than as statements of facts.

2 DR. MALMUD: Does the committee agree with that?

3 MR. LIETO: Mr. Chair? This is Ralph Lieto.

4 DR. MALMUD: Yes, Ralph?

5 MR. LIETO: Jeff, would you accept if we made the part of
6 3, starting with comprehensive institution of QA programs a, b, and c as a
7 rationale, and the recommendation would be the first sentence? Does that make
8 sense?

9 DR. WILLIAMSON: Yeah, the recommendation is the first
10 sentence, in fact, and the sort of body of what's being recommended is contained
11 in the last sentence of the full paragraph 3, plus the points a, b, c. But I do
12 understand Mr. Bailey's point that it sounds like a, b, and c are factual claims
13 rather than principles, so I have no problem rewriting them to be more clear in
14 that regard.

15 DR. MALMUD: Once again, Ralph Lieto and Jeff
16 Williamson, what is your recommendation to the committee?

17 MR. LIETO: I would maybe amend the motion to just
18 reflect that our action item, if you will, is just the first sentence of item 3.

19 DR. MALMUD: Is that agreeable with you, Dr. Williamson?

20 DR. WILLIAMSON: Yeah, that's fine.

21 DR. MALMUD: So that's an amended motion.

22 DR. WILLIAMSON: I won't delete the material; I'll just
23 rephrase the material.

24 DR. MALMUD: Any further discussion of that motion? And
25 it's second by Mr. Lieto? If not, all in favor?

26 (Chorus of ayes)

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1 DR. MALMUD: Any opposed? No opposition. Okay, it
2 carries.

3 DR. WILLIAMSON: All right. Now we come to point 4a.
4 As we get deeper and deeper into this document, the proposals are less and less
5 defined, so it may be appropriate for the ACMUI actually to have some
6 substantive discussion on these issues. I'll just point that out. But I will read
7 point 4a as a motion.

8 "To the extent possible, NRC's ME reporting and follow-up
9 procedures should be designed so as to minimize licensee liability. Keeping ME
10 reports, or at least the licensee's identity out of the public record is probably the
11 most single useful improvement NRC could make in this regard."

12 DR. NAG: When we have our QA meetings, we bring out
13 all the possible problems because they are not discoverable, and our QA
14 meetings, we are shielded, and, therefore, we bring out not only the problem but
15 how they can be solved, and that leads to improvement in the treatment of the
16 patient. If the report can be seen by everybody, that causes embarrassment, and
17 you are less likely to self-report. One of the premier points about self-reporting
18 is that by self-reporting you should not be discriminated.

19 DR. WILLIAMSON: Can you rephrase that, please,
20 Dr. Nag?

21 DR. NAG: Oh. One of the principles of self-reporting is
22 that by self-reporting, you should not be penalized. Therefore, having the identity
23 out is going to be really important. And we want to convey that to the NRC.

24 DR. WILLIAMSON: Are you agreeing?

25 DR. NAG: Yes. I'm agreeing with this, but I'm explaining
26 why we wrote that sentence.

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1 DR. RAIZNER: Can I make a suggestion on that
2 sentence? The way it reads, "designed so as to minimize licensee liability,"
3 sounds somewhat self-serving and maybe inappropriately so. But if it were
4 phrased, "designed so as not to increase licensee liability," that would convey the
5 point that I think you're trying to make, without making it look self-serving.

6 DR. WILLIAMSON: I agree.

7 DR. BAILEY: Would you mind rephrasing that? You were
8 breaking up when you were saying that.

9 DR. WILLIAMSON: Okay. Here is the proposed revision
10 by Dr. Raizner, of 4a. "To the extent possible, NRC's ME
11 reporting and follow-up procedures should be designed so as not to increase
12 licensee's liability."

13 DR. MALMUD: Good. Is that clear?

14 DR. BAILEY: It's clear to me.

15 DR. MALMUD: Is that acceptable?

16 DR. BAILEY: Yes.

17 DR. MALMUD: All in favor?

18 (Chorus of ayes)

19 DR. MALMUD: Any opposed? It carries.

20 Dr. Williamson?

21 DR. WILLIAMSON: Okay. Proposal 4b.

22 "NRC should develop a more nuanced and graded
23 enforcement response process that ties the intensity and immediacy of its
24 enforcement response to the risk to the individual patient and the public health
25 implications of the event. For example, for relatively minor MEs, where public
26 health and safety is not in question, NRC could hold off on reactive inspections

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1 of the licensee, pending a satisfactory investigation and quality improvement
2 response on the part of the licensee. Thus, MESAC recommends that NRC
3 manage minor MEs much like reportable events in the old Part 35."

4 So the basic idea is if you do a good job investigating, and
5 following up, and introducing corrective action in the wake of a medical event,
6 you won't necessarily have the wrath of the regulatory agency visited upon you.

7 DR. BAILEY: I would ask NRC, if they don't already, in
8 fact, do that. I don't think they go out on every ME that's reported.

9 MR. ESSIG: Yeah, you're correct, Ed, because it's a
10 question of resources. We don't have unlimited resources to go out on every
11 medical event, so we minimize the number of reactive inspections that we need
12 to go on to those that I would call more significant and more egregious.

13 DR. WILLIAMSON: Well, that's good. Then this is a very
14 easy recommendation to carry out. And it was the intent that this be dealt with
15 at the level of enforcement policy rather than creating a more complex reporting
16 rule, like the old rule, which had recordable events and mis-administrations. We
17 didn't mean to imply that should be done.

18 DR. MALMUD: Okay. Do we still need 4b?

19 DR. WILLIAMSON: I think it's useful.

20 DR. NAG: I think we ought to agree on it. We can vote
21 upon it.

22 MS. SCHWARZ? Jeff, can I make a suggestion? Instead
23 of saying "hold off on reactive inspections," could you just say "minimize"?

24 DR. WILLIAMSON: Yes, I think so.

25 DR. MALMUD: All right. We have 4b.

26 MR. ESSIG: Dr. Malmud?

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1 DR. MALMUD: Yes?

2 MR. ESSIG: We are talking off line, and what I just said
3 regarding our reaction to medical events may not be totally correct. We need to
4 check the inspection manual. It might be that there is a requirement that we, in
5 fact, have a reactive inspection to each medical event. I think the
6 recommendation, though, is one that we could certainly accept as a
7 recommendation. But I just wanted to clarify for the record that my statement
8 that I made earlier, in response to Mr. Bailey's comment, may not have been
9 totally correct.

10 DR. MALMUD: Thank you, Mr. Essig.

11 So the motion for 4b has been moved by Williamson,
12 seconded, and is now open for discussion, if there is any more discussion.

13 DR. WILLIAMSON: Yes. It's been amended by Sally
14 Schwarz to replace the word "hold off" by "minimize".

15 DR. MALMUD: Yes.

16 MR. ESSIG: I must tell you, as a matter of usage, I would
17 be more enthusiastic about this if we said that "the NRC is encouraged to
18 develop a graded ME enforcement response process" rather than the wording
19 that we've used.

20 MR. LIETO: Mr. Chair, I was just going to make the same
21 comment. I think the term "more nuanced" might not be very clear to us
22 non-Readers Digest aficionados. If we could maybe just use your terminology,
23 I would accept that.

24 DR. MALMUD: If I may, I'll make a motion to amend, which
25 would say that "the NRC is encouraged to develop a graded ME enforcement
26 response," et cetera.

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1 MR. ESSIG: Dr. Malmud, just one clarification. The
2 current enforcement process is already graded in the very real sense. What may
3 not be graded, and I think the point that's being made here, is the reactive
4 inspection.

5 DR. WILLIAMSON: Okay. Then the phrase, "more
6 graded" actually makes sense in relation to current policy.

7 DR. WILLIAMSON: So if it reads, "NRC is encouraged to
8 develop a more graded ME enforcement process that ties the intensity and
9 immediacy of the enforcement response to" --

10 MR. ESSIG: It's not the enforcement response, though.
11 The enforcement action is considered separately as part of the inspection, and
12 the enforcement is already tied to the intensity, and the immediacy, and so on.
13 What isn't tied to that is the inspection itself and whether or not to go on a
14 reactive inspection.

15 DR. WILLIAMSON: Okay. Should I replace the word
16 "enforcement" with "inspection response"?

17 MR. ESSIG: Yes.

18 DR. MALMUD: So Williamson asked the question, and
19 Essig gave the answer, which was yes.

20 DR. WILLIAMSON: All right. So now let me read the first
21 sentence of the amended motion.

22 "NRC is encouraged to develop a more graded ME
23 enforcement response that ties the intensity and immediacy of the inspection
24 response to the risk to the individual patient and public health implications of the
25 event."

26 DR. MALMUD: Okay. Mr. Essig, does that sound more

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1 in line with what you would hope for?

2 DR. HOWE: This is Dr. Howe. You needed to replace
3 "enforcement" at the beginning of the sentence with "inspection", "the immediacy
4 of its inspection response."

5 DR. MALMUD: Thank you, Dr. Howe.

6 DR. HOWE: And then, "the graded ME inspection
7 response." So every time you have "enforcement," say "inspection."

8 DR. WILLIAMSON: All right. What I'll do is I'll delete the
9 first occurrence of "enforcement," since I think it's redundant. We already have
10 "inspection response." So I'll say, "NRC is encouraged to develop a more
11 graded ME response process that ties the intensity and immediacy of its
12 inspection response to the risk of," et cetera.

13 DR. MALMUD: Dr. Howe?

14 DR. HOWE: Much better.

15 DR. MALMUD: Thank you, Dr. Howe. Thank you,
16 Dr. Williamson.

17 We now have a multiply-amended statement, which has
18 been read to us by Dr. Williamson, and I assume it's been seconded. Any further
19 discussion of it? If not, all in favor?

20 (Chorus of ayes)

21 DR. MALMUD: Any opposed? It carries unanimously
22 again. Thank you. That's item 4b on page 6.

23 We are now left with item 4c on page 7. Dr. Williamson?

24 DR. WILLIAMSON: Yes. I will read the proposed motion.

25 "Change the 24-hour operation center reporting procedure.
26 Minor medical events having little potential for harm, to either the patient involved

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1 or the general public, seem to be equated with nuclear reactor events which have
2 the potential to harm entire populations." This is one that maybe needs to be a
3 little more specific, so I entertain the ACMUI's suggestions, once it's seconded.

4 DR. MALMUD: Is there a second? Do we have a second?

5 DR. NAG: Yes, Dr. Nag seconds.

6 DR. MALMUD: Dr. Nag seconds. Now, is there any
7 further discussion?

8 DR. WILLIAMSON: Ralph, this was your proposal.

9 MR. ESSIG: The point I wanted to make is that there's a
10 very broad spectrum of events that are reported to our operations center, ranging
11 from those that have very little dose to consequence. For example, moisture
12 density gauge that is used during construction of highways gets run over by a
13 bulldozer. The gauge is not even particularly damaged. I mean, the source is
14 still in tact, but the gauge is unusable. That gets reported to our operations
15 center quite often. So it's events like that that we need to be aware of that could
16 possibly impact source integrity, source misuse, loss sources; a broad
17 spectrum of events that are associated with that.

18 If we didn't have it reported to the operations center, we
19 basically have no other place to report it other than a written report, which is our
20 other option. But reporting to the operations center enables us to keep on top of
21 events. We have a daily discussion of events with our original offices, and our
22 management is briefed here. The events are always put in perspective in terms
23 of their significance, if it involves exposure to an individual, or a loss source, or
24 whatever it may involve. So I think to consciously delete a source of information
25 on events, the committee is certainly free to make that recommendation if it
26 chooses. But I'm just suggesting that it's one that we could not use.

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1 DR. WILLIAMSON: The intent is not to suggest that the
2 events not be reported to NRC in one form or the other. If you accept that a
3 reasonable goal is to try to encourage licensees to participate in a more positive
4 way that buys in to NRC's effort to quantitate these events -- this is one of the
5 issues; that having to report it within 24 hours by telephone, before you've done
6 a full investigation and so forth, definitely seems like the message to the licensee
7 is that the event is being elevated in significance, public health significance, far
8 beyond what is usually the case.

9 MR. LIETO: I would underscore Jeff's statement with the
10 24-hour reporting. Secondly, I don't know of any non-criminal situation, any type
11 of medical situation to be reported with such urgency to such a public reporting
12 mechanism in the practice of medicine. So why are we having to be held at such
13 a high level -- that no other event, in the practice of medicine -- regarding these
14 situations. Again, we're not saying they don't have to be reported, but I think the
15 public reporting in such a short time is really uncalled for.

16 DR. NAG: I think it's the same basis as external beam.
17 We had the same level, more than 20 percent difference. The urgency is not that
18 if that patient was treated by external beam.

19 DR. MALMUD: Dr. Nag, are you concurring or
20 disagreeing?

21 DR. NAG: I'm saying that I agree with both Dr. Williamson
22 and Dr. Lieto that there should not be a 24-hour rule. There's really no need for
23 a 24-hour rule. The magnitude is not that huge.

24 DR. WILLIAMSON: Maybe we need to give some more
25 positive suggestion of what should be done in lieu of the 24-hour oral reporting
26 procedure. Perhaps we should say "a written report within seven days."

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1 DR. NAG: Yeah, within a week was what I was thinking.

2 DR. WILLIAMSON: "A written report within seven days."

3 DR. BAILEY: My only problem with that suggestion as a
4 comment is the use of the word "minor ME," without that being defined really. So
5 it's all in the eye of the beholder what a minor ME is as opposed to a major one.

6 DR. WILLIAMSON: I guess that's a good point. How
7 about deleting the word "minor," and just "MEs in general should be reported
8 within seven days"?

9 DR. NAG: I would go for that.

10 DR. MALMUD: Jeff, are you amending your statement
11 under c?

12 DR. WILLIAMSON: Well, I guess I'm suggesting that I
13 could if it's met with support from the committee.

14 MS. SCHWARZ: I have a question in regard to external
15 beam, what would be the requirement for reporting on external beam.

16 DR. WILLIAMSON: Is that Sally?

17 MS. SCHWARZ: Yes, this is Sally Schwarz.

18 DR. WILLIAMSON: At this time, unless it's Cobalt-60
19 teletherapy or gamma stereotactic, there's no requirement from NRC to report
20 external beam at all. I think the agreement states, often would have parallel
21 reporting requirements, and probably mechanisms to NRC. Maybe Mr. Bailey
22 could comment.

23 DR. BAILEY: Yes. Many states have adopted similar
24 reporting requirements for any type of therapy procedure, whether it be external
25 beam or not. In fact, I think we've had some of the more serious ones occur
26 when the machine produced external beams.

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1 DR. VETTER: As I understand the history of this, I think
2 the intent was that any medical event that causes or could cause a major health
3 effect or death in a patient needs to be reported immediately so that the NRC can
4 get a medical consultant on site rather quickly. Is that not the case?

5 DR. MALMUD: The question is addressed to a member
6 of NRC staff?

7 DR. VETTER: Correct.

8 MR. ESSIG: Dr. Vetter, this is Tom Essig. I believe that's
9 the case. What you've said is true, unless the other energy staff around the table
10 have any additional comments.

11 DR. HOWE: I think the intent certainly is to have the very
12 severe ones reported immediately so we can get a consultant out there right way.
13 But I don't think we have a limit that it's just the severe ones that have to be
14 reported immediately. I don't know if that's ever been the direction of the
15 Commission, that we just report immediately.

16 DR. RAIZNER: Can I make a suggestion on phrasing this
17 recommendation? To provide, "MEs having little potential for harm, to either the
18 patient involved or the general public, may be reported within seven days," and
19 just leave it at that. That would separate out what is being called here minor MEs
20 from the current policy. I think it would be assumed that major, catastrophic MEs
21 would be reported within 24 hours as is currently required.

22 DR. WILLIAMSON: I think that's a very reasonable
23 proposal because we have actually invoked the criterion of major and minor, and
24 defined it in the previous paragraph. I'll point out here that in paragraph C2, we
25 basically say that reporting requirement 35.3045(e) should be different,
26 depending upon whether the ME has harmed the patient, could potentially harm

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1 the patient, or is materially relevant to the future management of the patient. So
2 that's a criterion that's already been articulated in this document, so we could just
3 invoke that criterion as suggested by Dr. Raizner.

4 We could leave, perhaps, the first sentence and simply add
5 a sentence saying, "MEs that the licensee has determined have not harmed the
6 patient, could potentially harm the patient, or are materially relevant to the
7 patient's future medical treatment decisions, need not be reported orally to the
8 24-hour operation center, but may be communicated by a written report within
9 seven days."

10 DR. MALMUD: Is there a second to that? That's a revision
11 of c. Is there a second to Dr. Williamson's last statement?

12 DR. NAG: Dr. Nag seconds.

13 DR. MALMUD: Dr. Nag seconds. Any further discussion?
14 If none, all in favor?

15 (Chorus of ayes)

16 DR. MALMUD: Any opposed? None. It carries
17 unanimously.

18 Dr. Williamson, that completes the items on that list, does
19 it not?

20 DR. WILLIAMSON: It does. I would just close by asking
21 if the ACMUI members have any additional suggestions on the topic of risk
22 communication that would be reasonable to add to this list of recommendations.
23 The concept of risk communication was not to us a very well-defined charge.
24 This is how we chose to work with it, but there may be other ideas which are
25 worth exploring.

26 DR. MALMUD: Is there anyone who wishes to explore that

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1 at this time? I do not hear a response of enthusiasm for reviewing that issue at
2 this time.

3 DR. WILLIAMSON: Okay.

4 DR. MALMUD: Are you completed, Dr. Williamson?

5 DR. WILLIAMSON: I am completed, except I have one
6 follow-up question.

7 DR. MALMUD: Why don't you go ahead with your
8 follow-up question before my comment?

9 DR. WILLIAMSON: My follow-up question is what process
10 do we follow after this point?

11 DR. NAG: What do you mean? I thought we make the
12 recommendations to the committee, and this ACMUI committee
13 recommendations goes to the NRC officials for implementation, right?

14 DR. WILLIAMSON: Well, I think that's what we should
15 discuss. I guess there's one minor issue. I assume what I should, since I have
16 taken all of the notes about the minor changes to this document, go ahead and
17 make those changes and resubmit this to the ACMUI.

18 DR. NAG: Yeah, I think that you have been involved from
19 the beginning, and you know all the nuances. It would be easier if you would
20 revise it, maybe circulate, and, hopefully, there will be no additions to it.

21 DR. WILLIAMSON: Yes, I would hope so. My
22 understanding is, then, that the staff is going to take this and convert it to some
23 other format and make a set of recommendations to the Commission. Is that
24 correct?

25 DR. MALMUD: I believe, Dr. Williamson, that the next step
26 is that the subcommittee presents it to the committee.

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1 DR. NAG: I thought the subcommittee has given it to the
2 committee.

3 DR. MALMUD: Yes, and that the committee then presents
4 it to the NRC as a recommendation.

5 DR. NAG: Well, that is what we are doing now.

6 DR. MALMUD: And the NRC is then free to accept the
7 recommendation as it stands, or to make
8 changes to it, or even to ignore it if it wishes to.

9 DR. WILLIAMSON: Well, that's true in the long run, but
10 there is a detailed process that's going to be followed because this whole activity
11 was instituted by the commissioners in their staff requirements memo of spring
12 2004. So what the staff is going to do is develop a white paper, and then present
13 that to the Commission to satisfy their staff requirements memo.

14 DR. MALMUD: Yes, but we will have fulfilled our task, I
15 believe, by having had the subcommittee and the committee meet and make the
16 recommendation, will we not?

17 DR. WILLIAMSON: Well, my concern is that I don't know
18 what will happen to these recommendations after they leave our hands and what
19 kind of paper will go forward to the Commission. What I would like to make a
20 plea for is that the subcommittee, or if not the full ACMUI, get an opportunity to
21 review the white paper that NRC prepares, especially any rule language that they
22 adopt to express these recommendations. I think it would be very useful to both
23 the NRC and to the regulating community if we could have the possibility of some
24 feedback at that time.

25 DR. MALMUD: So you are requesting that once we will
26 have submitted this material to the NRC, that it give us the courtesy of the

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1 opportunity to review the document as they have prepared it?

2 DR. WILLIAMSON: That's correct.

3 DR. NAG: I wish to be a little stronger than that. I think we
4 could demand it because we have made the recommendation. When you
5 convert those into legal terms, some of the sense may be totally lost or totally
6 distorted. And you want to make sure that what we said in principle is what is
7 written in the legal document.

8 DR. WILLIAMSON: I would concur with Dr. Nag and
9 suggest we rephrase my slight request to a demand.

10 MR. ESSIG: May I comment?

11 DR. MALMUD: Please do, Tom.

12 MR. ESSIG: The process -- I've believed we've touched
13 on it from this point -- is now that the committee has accepted all of the parts of
14 the subcommittee's recommendations, Dr. Williamson, then, will incorporate all
15 the comments, and then he will provide this to you, Dr. Malmud. A way of doing
16 it would be to attach a cover memo on ACMUI letterhead, and attach the
17 subcommittee's report, a memo from yourself to Dr. Miller, saying attached is the
18 ACMUI report, which was discussed in a conference call of June 28, 2005, so on
19 and so on. We are submitting it to you as a recommendation. And if you want
20 to tie in to the SRM, you certainly can.

21 The process from that point, then, is Dr. Miller will get it.
22 He'll provide copies to his staff, and we will engage with the rulemaking and
23 guidance branch, who also reports to Dr. Miller, and they will commence
24 prioritizing this activity amongst the other rules that they have in front of them.

25 When we actually start putting pen to paper in terms of
26 crafting the rulemaking language, ACMUI will be intimately involved in that. We

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1 will certainly circulate any proposed rule language to you well ahead of the time
2 that we will present it to the Commission. So you will have several bites at the
3 apple, so to speak. We'll have your recommendations, and then we'll incorporate
4 those into rule language.

5 DR. WILLIAMSON: I have a question for you, Tom.

6 MR. ESSIG: Yes?

7 DR. WILLIAMSON: What gets submitted to the
8 Commission on July 28th, by that deadline that Angela has referred to in the
9 past?

10 MR. ESSIG: I'll ask either Dr. Zelac or Angela to speak to
11 that.

12 DR. ZELAC: This is Ron Zelac. The deadline of July 28th
13 had been predicated upon having final recommendations from the Advisory
14 Committee at the end of April, so we could, May, June and July, prepare a paper
15 which would present staff's recommendations to the Commission with respect to
16 the acceptability of the current medical event definitions and criteria.

17 Prior to this discussion and prior to all of this dealing with
18 the Medical Event Subcommittee on Prostate for Permanent Brachytherapy, you
19 may recall that the entire committee considered the broader questions of, for
20 example, the 20 percent criteria as it applied to other modalities for treatment.
21 Recommendations were made, and they are in the record, of the ACMUI's
22 meeting with respect to all of the other modalities except this one, permanent
23 implant brachytherapy. This has been the missing piece.

24 By today's activity, the entire gamut of recommendations
25 needed from the Advisory Committee to staff have now been at least finalized if
26 not formally conveyed, and we are now in a position to move forward with those

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1 recommendations to craft a commission paper in response to its direction, its
2 staff requirements memorandum, to simply bring to the attention of the
3 Commission what staff's opinion is, with input from the Advisory Committee, on
4 the question of the suitability of the current definitions of medical event.

5 Now, as I was saying, the July 28th deadline had been
6 crafted, based upon the assumption that we would have recommendations from
7 the Advisory Committee by the end of April. Since that did not occur and we are
8 now two months later, we are probably talking of at least a two-month extension
9 before we will be submitting two the Commission that paper.

10 DR. WILLIAMSON: Okay. Then I guess the
11 request/demand would be, can we have an opportunity to review your draft of the
12 white paper before it's sent on to the Commission? Can we at least be able to
13 offer our feedback on it?

14 MR. ESSIG: You certainly can. I mean, you have to
15 handle it as a pre-decisional document, which means it cannot be shared outside
16 the committee.

17 DR. WILLIAMSON: Well, all of this has been handled as
18 pre-decisional anyhow.

19 MR. ESSIG: Yeah, but I just wanted to make that special
20 emphasis on a paper that's going directly to the Commission.

21 DR. WILLIAMSON: Well, yeah. I guess I would suggest
22 a motion, Dr. Malmud, in that we ask that the NRC give the ACMUI an
23 opportunity to review and offer feedback on the proposed commission white
24 paper before its submission to the Commission.

25 DR. MALMUD: Is there a second to that motion, which is
26 a request?

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1 DR. NAG: Dr. Nag seconds.

2 DR. MALMUD: It's seconded by Nag. All in favor?

3 (Chorus of ayes)

4 DR. MALMUD: Any opposed? So it is a unanimous
5 recommendation of this committee that we be given that courtesy.

6 MR. ESSIG: Dr. Malmud, this is Tom Essig again. I would
7 just add that we cannot build into the schedule a large amount of review time for
8 the ACMUI. We might be talking on the order of two weeks or so.

9 DR. MALMUD: That would be two weeks more than we've
10 had in the past in some cases, and, therefore, would be welcomed by the
11 committee.

12 MR. ESSIG: Okay.

13 DR. MALMUD: Is there any more business that you wish
14 to present, Dr. Williamson?

15 DR. WILLIAMSON: No, we are very pleased to have
16 completed out task as a subcommittee.

17 DR. MALMUD: Thank you. I have one item I wanted to
18 add, and that is an extremely grateful statement on the part of the chairman to
19 Dr. Williamson for a yeoman's job in husbanding this through the process, and,
20 of course, the other members of the committee who participated, and whose
21 emails I have seen flying back and forth with their comments. It's been a lot of
22 effort, and we are all very appreciative of the time and talent that you've put into
23 this.

24 Is there a motion for adjournment of this meeting?

25 MR. ESSIG: Dr. Malmud?

26 DR. MALMUD: Yes?

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1 MR. ESSIG: You might at this juncture -- since the
2 subcommittee has completed its business and the full committee has probably
3 completed most of its business -- offer the floor to any members of the public
4 who haven't already spoken and wish to make comments at this time. We have
5 just a few minutes remaining in the call.

6 DR. MALMUD: Thank you, Mr. Essig, for reminding me of
7 that. I've been hearing these little beeps over the phone, which I assume are the
8 timers telling us that we're running out of time.

9 MR. ESSIG: Yeah, we're down to 10 minutes.

10 DR. MALMUD: By all means. Are there any comments
11 from members of the public or other participants in this conference call? I hear
12 none. Thank you.

13 Mr. Essig, any other items?

14 MR. ESSIG: No.

15 DR. MALMUD: Not having heard any comments from the
16 members of the public or others who are on this call with us, I do want to thank
17 you for your participation in the call, and your willingness to stay with us for the
18 period. I also apologize for having been late for the committee meeting. My
19 colleague is out of town and I am running both departments, and actually treating
20 a patient with radio-iodine while you were waiting for me. I'm sorry.

21 MR. ESSIG: That happens.

22 DR. MALMUD: It is our policy to do that personally. We
23 don't allow technologists to administer the dose, so you have to excuse me.

24 At any rate, we should not be meeting on a regular basis
25 over the course of the summer. I wish you all a healthy, happy, and enjoyable
26 summer, and if needed, we will contact you by email. Once again, thank you all

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1 for your participation, and especially you, Dr. Williamson, and the others who
2 worked with you so diligently on crafting this document.

3 DR. WILLIAMSON: I would like to thank my subcommittee
4 members, all of whom contributed substantially and intellectually in terms of their
5 ideas to this proposal, and also to our consultant, Dr. Potters.

6 DR. MALMUD: Thank you all.

7 Is there a motion for adjournment?

8 UNIDENTIFIED SPEAKER: So moved.

9 DR. MALMUD: Seconded? Than you all. Good bye.

10 (Whereupon, the foregoing matter went off the record at
11 2:53 p.m.)

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