

Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Advisory Committee on the Medical
 Uses of Isotopes

Docket Number: (n/a)

Location: (teleconference)

Date: Tuesday, October 18, 2011

Work Order No.: NRC-1195

Pages 1-77

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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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TELECONFERENCE

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TUESDAY,

OCTOBER 18, 2011

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The meeting was convened in room T-03C1 of
Two White Flint North, 11545 Rockville Pike,
Rockville, Maryland, at 12:00 p.m., Leon S. Malmud,
M.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

LEON S. MALMUD, M.D., Chairman

BRUCE THOMADSEN, Ph.D., Vice Chairman

MILTON GUIBERTEAU, M.D., Member

SUSAN LANGHORST, Ph.D., Member

STEVE MATTMULLER, Member

CHRISTOPHER PALESTRO, M.D., Member

JOHN SUH, M.D., Member

ORHAN SULEIMAN, Ph.D., Member

WILLIAM VAN DECKER, M.D., Member

LAURA WEIL, Member

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1 JAMES S. WELSH, M.D., Member

2 PAT ZANZONICO, Ph.D., Member

3 NRC STAFF PRESENT:

4 CYNTHIA CARPENTER, Acting Director, Office of
5 Federal and State Materials and Environmental
6 Management Programs

7 BRIAN McDERMOTT, Director, Division of
8 Materials Safety and State Agreements

9 CHRISTIAN EINBERG - Designated Federal Officer

10 MICHAEL FULLER - Alternate Designated Federal
11 Officer

12 ASHLEY COCKERHAM - Alternate Designated
13 Federal Officer/ACMUI Coordinator

14 NEELAM BALLA

15 SUSAN CHIDAKEL

16 SAID DAIBES, Ph.D.

17 DONNA BETH HOWE, Ph.D.

18 ED LOHR

19 GRETCHEN RIVER-CAPELLA

20 RONALD ZELAC, Ph.D.

21
22 ALSO PRESENT:

23 DARICE BAILEY, TX Dept of State Health Services

24 KEITH BROWN, Univ of Penn

25 JOSEPH BUCKLES, Hays Companies

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1 ROBERT DANSEREAU, New York State Dept of Health

2 WILLIAM DAVIDSON, Univ of Penn

3 LYNNE FAIROBENT, AAPM

4 MICHAEL HAGAN, Veterans Health Admin

5 THOMAS HUSTON, Veterans Health Admin

6 JOHN KENT, Indiana Univ-Purdue Univ Indianapolis

7 KAREN LANGLEY, Univ of Utah

8 RALPH LIETO, St. Joseph Mercy Hospital

9 JANETTE MERRIL, SNM

10 RAY POSTON, Kentucky Dept of Public Health

11 MACK RICHARD, Indiana Univ-Purdue Univ Indianapolis

12 JOSEPH RODGERS, Theragenics Corp

13 GLORIA ROMANELLI, ACR

14 CINDY TOMLINSON, ASTRO

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P R O C E E D I N G S

(12:06:31 p.m.)

MR. EINBERG: Okay. I think we can go ahead and get started then. Okay. I'll go ahead and open the meeting.

CHAIRMAN MALMUD: Thank you. Someone else just joined us. Would you introduce yourself, please.

MR. KENT: John Kent.

MEMBER ZANZONICO: Hello?

CHAIRMAN MALMUD: Yes?

MEMBER ZANZONICO: Yes, this is Pat Zanzonico. I just joined.

CHAIRMAN MALMUD: Dr. Zanzonico, welcome aboard.

MEMBER ZANZONICO: Thank you.

MR. EINBERG: Okay. We're going to go ahead and get started then. Good afternoon.

As the Designated Federal Officer for this meeting, I am pleased to welcome you to this public meeting of the Advisory Committee on the Medical Uses of Isotopes. My name is Chris Einberg. I am the Chief of the Radioactive Material Safety Branch, and

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1 have been designated as the Federal Officer for this
2 Advisory Committee in accordance with 10 CFR Part
3 7.11.

4 Present today as the Alternate Designated
5 Federal Officers are Mike Fuller, Team Leader for the
6 Medical Radiation Safety Team, and Ashley Cockerham,
7 who is the ACMUI Coordinator.

8 This is an announced meeting of the
9 Committee. It is being held in accordance with the
10 rules and regulations of the Federal Advisory
11 Committee Act and the Nuclear Regulatory Commission.
12 The meeting was announced in the September 30th, 2011
13 edition of the Federal Register, Volume 76, page
14 60938.

15 The function of the Committee is to advise
16 the Staff on issues and questions that arise on the
17 medical use of byproduct material. The Committee
18 provides counsel to the Staff, but does not determine
19 or direct the actual decisions of the Staff or the
20 Commission. The NRC solicits the views of the
21 Committee and values their opinions.

22 I would request that whenever possible we
23 try to reach consensus on the procedural issues that
24 we will discuss today, but I also recognize there may
25 be minority or dissenting opinions. If you have such

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1 opinions, please allow them to be read into the
2 record.

3 At this point, I would like to perform a
4 roll call of the ACMUI Members participating today.
5 Dr. Leon Malmud, ACMUI Chairman.

6 CHAIRMAN MALMUD: Present.

7 MR. EINBERG: Dr. Bruce Thomadsen, Vice
8 Chairman, Therapy Medical Physicist.

9 VICE CHAIRMAN THOMADSEN: Present.

10 MR. EINBERG: Ms. Laura Weil, Patient's
11 Rights Advocate.

12 MEMBER WEIL: Present.

13 MR. EINBERG: Dr. Mickey Guiberteau,
14 Diagnostic Radiologist.

15 MEMBER GUIBERTEAU: Present.

16 MR. EINBERG: Dr. Sue Langhorst, Radiation
17 Safety Officer.

18 MEMBER LANGHORST: Present.

19 MR. EINBERG: Mr. Steve Mattmuller, Nuclear
20 Pharmacist.

21 MEMBER MATTMULLER: Present.

22 MR. EINBERG: Dr. Christopher Palestro,
23 Nuclear Medicine Physician.

24 MEMBER PALESTRO: Present.

25 MR. EINBERG: Dr. John Suh, Radiation

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1 Oncologist.

2 MEMBER SUH: Present.

3 MR. EINBERG: Dr. Orhan Suleiman, FDA
4 Representative.

5 MEMBER SULEIMAN: Present.

6 MR. EINBERG: Dr. William Van Decker,
7 Nuclear Cardiologist. Okay. It doesn't seem like Dr.
8 Van Decker is present.

9 Dr. James Welsh, Radiation Oncologist.

10 MEMBER WELSH: Present.

11 MR. EINBERG: Dr. Pat Zanzonico, Nuclear
12 Medicine Physicist.

13 MEMBER ZANZONICO: Present.

14 MR. EINBERG: Okay. We do have a quorum of
15 at least seven members.

16 I would also like to add Ms. Darice Bailey
17 is speaking on behalf of the Agreement States for this
18 teleconference, since the Agreement State
19 Representative position is currently vacant on the
20 Committee.

21 I now ask that the NRC Staff Members who
22 are present to identify themselves. I'll start with
23 the individuals in the room here at headquarters, and
24 next we'll go to the phone for the NRC Staff and other
25 stakeholders. So, we'll go around here.

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1 PARTICIPANT: With the Medical Team.

2 MS. CHIDAKEL: Susan Chidakel, Senior
3 Attorney, OGC.

4 DR. HOWE: Donna Beth Howe, Medical Team.

5 MR. LOHR: Ed Lohr, Rulemaking.

6 MS. BALLA: Neelam Balla, Rulemaking.

7 MR. McDERMOTT: Brian McDermott, Director
8 for the Division of Materials Safety and State
9 Agreements.

10 MR. FULLER: Mike Fuller, Team Leader,
11 Medical Team.

12 MR. EINBERG: Okay. That's everybody from
13 here in headquarters in this room here. Anybody on
14 the phone from headquarters as well?

15 DR. ZELAC: Yes, Ronald Zelac, Medical
16 Team.

17 MS. COCKERHAM: Ashley Cockerham, Medical
18 Team.

19 MS. CARPENTER: Cindy Carpenter, FSME.

20 MR. EINBERG: Okay, thank you. Now, I'll
21 go to the Regions. Region I, do we have anybody on
22 the phone? Once again, Region I, is there anybody on
23 the phone call? Hearing none, we'll move to Region
24 III. Anybody on the phone? Okay. Nobody from Region
25 III. And lastly, Region IV, anybody on the phone?

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1 Okay.

2 Let me now go to members of the public who
3 had registered for the phone call. Once again, I
4 mentioned that Darice Bailey, Texas Department of
5 State Health Services is on the call. Keith Brown,
6 University of Pennsylvania, are you on the call?

7 MR. BROWN: Yes.

8 MR. EINBERG: Joseph Buckles, Hays
9 Companies.

10 MR. BUCKLES: Yes, I'm here.

11 MR. EINBERG: Robert Dansereau, New York
12 State Department of Health.

13 MR. DANSEREAU: Here.

14 MR. EINBERG: Michael Erdman, Penn State
15 Hershey Medical Center. Lynne Fairobent, American
16 Association of Physicists in Medicine.

17 MS. FAIROBENT: Yes.

18 MR. EINBERG: William Davidson, University
19 of Pennsylvania.

20 MR. DAVIDSON: Present.

21 MR. EINBERG: Michael Hagan, Veterans
22 Health Administration.

23 MR. HUSTON: Could you repeat the name?

24 MR. EINBERG: Yes. Dr. Michael Hagan.

25 MR. HUSTON: Oh, okay. I'm Tom Huston with

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1 the VHA.

2 MR. EINBERG: Okay. Next on the list was
3 Dr. Tom Huston. John Kent, Indiana University of
4 Purdue, University of Indianapolis.

5 MR. KENT: Present.

6 MR. EINBERG: Karen Langley, University of
7 Utah.

8 MS. LANGLEY: Here.

9 MR. EINBERG: Ralph Lieto, St. Joseph Mercy
10 Hospital.

11 MR. LIETO: Present.

12 MR. EINBERG: Michael Peters, American
13 College of Radiology.

14 MR. PETERS: Who was that?

15 MR. EINBERG: Michael Peters.

16 MR. PETERS: Oh, that's me. I'm here.

17 MR. EINBERG: Okay. Richard Piccolo, Varian
18 Brachytherapy. Mack Richard, Indiana University of
19 Purdue, University of Indianapolis.

20 MR. RICHARD: Present.

21 MR. EINBERG: Joseph Rodgers, Theragenics
22 Corporation.

23 MR. RODGERS: Present.

24 MR. EINBERG: Daniel Snyder, Geisinger
25 Health System. Daniel Snyder, Geisinger Health System.

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1 Cindy Tomlinson, American Society for Radiation
2 Oncology.

3 MS. TOMLINSON: I'm here.

4 MR. EINBERG: And Gary Williams, Veterans
5 Health Administration.

6 Okay. Is there anybody else on the phone
7 who I have not called, if they could please identify
8 themselves.

9 MS. ROMANELLI: Gloria Romanelli, American
10 College of Radiology.

11 MS. MERRIL: Janette Merril, Society of
12 Nuclear Medicine.

13 MR. EINBERG: Thank you.

14 MR. POSTEN: Ray Poston from Frankfort,
15 Kentucky, Radiation Health Branch.

16 MR. EINBERG: Okay. Anybody else? Okay,
17 that completes the roll call.

18 Following a discussion of the item today,
19 the ACMUI Chairperson, Dr. Leon Malmud, at his option
20 may entertain comments or questions from members of
21 the public who are participating with us today.

22 At this point, I'd like to turn the
23 meeting over to Dr. Malmud.

24 CHAIRMAN MALMUD: Thank you. The other
25 suggestion I would make just preventively is that if

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1 you are not on -- if you're not speaking, to use the
2 mute, if you have a mute available. It will reduce
3 potential interference, should we have any.

4 Okay. So, the subject of today's meeting
5 is the ACMUI Permanent Implant Brachytherapy
6 Subcommittee Report. And that Committee is chaired by
7 Dr. James Welsh. And with his permission, I will turn
8 the agenda over to Dr. Welsh.

9 MEMBER WELSH: Thank you, Dr. Malmud.

10 As you can see from the handout, or the
11 attachment in the email, we have completed our first
12 draft of the Permanent Implant Brachytherapy final
13 report. And there -- in the way of background, there
14 has been some significant change in the membership of
15 this Subcommittee over the past several years, and the
16 process has taken quite a few years to evolve into its
17 present state. Since then, several members have
18 rotated off, and we do have new members joining us.

19 Having said that, we attempted to adhere
20 to some of the initial basic premises, but also tried
21 to modernize the overall report based on input from
22 stakeholders, and feedback, and participation from the
23 recent workshops.

24 This particular Subcommittee report is far
25 more prescriptive than any of our previous attempts at

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1 the prose, and we thought that this might be an
2 opportunity to spell it out as cleanly and clearly as
3 possible. Therefore, the report does not have the
4 typical narrative that you've seen from our previous
5 reports, but does start out right off the bat with a
6 proposed definition, serves as a synthesis of the
7 various -- opinions of the various members of the
8 Subcommittee, and includes a comment on the Written
9 Directive Completion concept that was missing from
10 previous reports.

11 We did come up right off the bat with a
12 proposed definition that we believe should satisfy all
13 parties involved. It is based in large part on the
14 ASTRO definition, which is activity or source-based in
15 nature, but it also includes some components which are
16 dose-based that would serve not so much as the
17 principal backbone of the definition, but serve to
18 catch outliers that might not be captured by the ASTRO
19 original definition, and be an alternative to the
20 proposed solution that has been bandied about; namely,
21 that the Authorized User simply would sign some type
22 of attestation in the Written Directive Completion.

23 So, the Written Directive Completion was
24 not something that was permitted in the first place
25 prior to this proposition. Now we are suggesting that

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1 the Written Directive Completion be something that is
2 included, and that unlike our previous proposal, that
3 in the Written Directive Completion the Authorized
4 User provide an attestation that the seeds are placed
5 according to his or her intentions, that we have
6 something that is a little bit more verifiable from a
7 regulator's perspective.

8 It should be relatively easy for a
9 regulator or an inspector to ascertain if medical
10 event has been committed, and importantly, most
11 importantly in my perspective as a clinician, this is
12 compatible with routine standard of care practice of
13 brachytherapy.

14 Importantly, although we drew very heavily
15 from prostate permanent implant brachytherapy, the
16 definitions and recommendations herein should apply to
17 all forms of permanent implant brachytherapy, and that
18 is why we included the word "macroscopic," in Section
19 A, the proposed definition for medical event for
20 macroscopic permanent implants, because we didn't want
21 to include Y-90 microsphere brachytherapy or
22 microscopic permanent implant brachytherapy in this,
23 because it would not apply.

24 So, that is my basic introduction to the
25 report.

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1 CHAIRMAN MALMUD: Thank you, Dr. Welsh.
2 Are there comments, additional comments from other
3 members of the Subcommittee? Dr. Langhorst, Dr. Suh,
4 Dr. Thomadsen?

5 VICE CHAIRMAN THOMADSEN: This is Bruce
6 Thomadsen. I think that Dr. Welsh did a very nice job
7 in summing up the report.

8 CHAIRMAN MALMUD: Thank you.

9 MEMBER LANGHORST: This is Sue Langhorst,
10 and I agree.

11 MEMBER SUH: And this is John Suh. I also
12 agree that Dr. Welsh did a nice job in summarizing the
13 recommendations of the Permanent Implant Brachytherapy
14 Subcommittee.

15 CHAIRMAN MALMUD: Thank you. Now, having
16 heard from the Chair and members of the Committee, are
17 there comments from other members of the ACMUI, or
18 NRC, or members of the public?

19 MEMBER ZANZONICO: This is Pat Zanzonico. I
20 had several comments, some of them are fairly
21 specific. Is now the time to entertain those?

22 CHAIRMAN MALMUD: I think so.

23 MEMBER ZANZONICO: Okay. Some of these are
24 just questions, others are suggested revisions. The
25 first one deals with Item 1B, so that's A-1B, where it

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1 says, "the calculated dose to 90 percent of the CTV,"
2 et cetera. Is there any -- was there any intention of
3 associating some time frame to that? In other words,
4 Dr. Welsh said this definition of medical events now
5 largely, though not exactly, parallels the ASTRO
6 recommended definition, but it also includes
7 dosimetric components, namely this one.

8 But I was wondering what the thinking of
9 the Subcommittee was in terms of a time frame, if any,
10 as to when the actual dose would be determined, or
11 dose distribution would be determined in order to
12 determine if this criteria was or was not met.

13 CHAIRMAN MALMUD: Dr. Welsh.

14 MEMBER WELSH: Yes. I think that's a very
15 valid and important question, and we did discuss this.

16 It has been discussed repeatedly in previous ACMUI
17 meetings, as well during the recent workshops.

18 One of the problems with any time frame
19 from a regulatory perspective is that there might
20 always be some challenge to specified time frame. For
21 example, if we're using cesium-131 or palladium-103,
22 we might have different recommendations compared to
23 iodine-125. So, naturally, it should be the longest
24 time frame appropriate for all isotopes if we're going
25 to impose a time frame.

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1 VICE CHAIRMAN THOMADSEN: Jim, this is
2 Bruce. Can I jump in for just a second here?

3 MEMBER WELSH: Yes, please do.

4 VICE CHAIRMAN THOMADSEN: Pat, I think that
5 the Subcommittee's thought on this is that the time
6 frame on that is what the user would normally use for
7 their own time frame for doing the dosimetry. It would
8 be up to the user.

9 It should be noted that this is joined
10 with 1A with an "and," so by itself the dosimetry
11 criterion would not cause an event.

12 MEMBER LANGHORST: Hi, this is Sue
13 Langhorst. Can I help answer, too? Pat, in looking
14 at this and going through it many times with the
15 Subcommittee, you wouldn't do that calculated dose for
16 1B unless there has been -- unless you are greater
17 than 20 percent of the seed sources fall outside the
18 intended location, or that there is this issue with
19 how it's distributed within the planning treatment
20 volume. So, you wouldn't have to even do that dose
21 calculation unless Items 1A(i) or 1A(ii) were not met.

22 MEMBER ZANZONICO: Understood. I think
23 that's all reasonable. I just wonder from a regulatory
24 point of view if some qualifier should be added to 1B
25 saying pursuant to prevailing clinical practice, or

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1 pursuant to the judgment of the Authorized User, or
2 Attending Physician, or some such thing as that in
3 terms of timing.

4 I'm just wondering if leaving a time frame
5 implicit as opposed to explicit given how prescriptive
6 this current definition of an ME is, is a potential
7 source of confusion.

8 MEMBER WELSH: This is Jim Welsh here. I
9 think I agree with you there, Dr. Zanzonico, in that
10 if we are going to ever impose any kind of medical
11 event tag to an implant, that we can't leave this open
12 ended. And that understanding that it's a Boolean
13 and, and, therefore, it doesn't always have to be
14 performed from a regulatory perspective to identify a
15 medical event because -- unless it triggers 1A(i) and
16 1A(ii). If it doesn't trigger those, we don't have to
17 go to 1B.

18 Having said that, without a time frame it
19 can be very difficult to enforce. Because like I've
20 given in the absurd example, when the inspector comes
21 two years later, the Authorized User, Clinical Team
22 could say oh, well, we do our post implant dosimetry
23 two years and one day. So, that's not likely to happen
24 in reality, but without the words here that remote
25 possibility remains possible. So, I would be in favor

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1 of including some kind of a time frame that is
2 clinically appropriate and practical to impose.

3 MEMBER ZANZONICO: Understood.

4 MR. LIETO: A follow-up?

5 CHAIRMAN MALMUD: Yes.

6 MR. LIETO: This is Ralph Lieto. I share
7 Dr. Zanzonico's concern because you do have a dose-
8 based criterion in 2. There is no activity-based
9 criteria in that, so I share his concern about when do
10 you determine this dose value, at release, 60 days.
11 If you're going to say whenever the licensee
12 determines, then I think it should be explicitly
13 stated, and I agree with his concern.

14 CHAIRMAN MALMUD: Thank you, Ralph. Is
15 there an actual recommendation? This is Malmud. Is
16 there an actual recommendation?

17 VICE CHAIRMAN THOMADSEN: This is Bruce. I
18 thought that Pat actually had some verbiage that was
19 pretty good.

20 CHAIRMAN MALMUD: Pat?

21 MEMBER ZANZONICO: Yes. Well, I think to
22 kind of formalize it, I would say within a time frame
23 to be determined by the Authorized User consistent
24 with prevailing practice.

25 CHAIRMAN MALMUD: Thank you. Is that a

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1 motion?

2 MEMBER ZANZONICO: I'll make a motion.
3 Sure.

4 CHAIRMAN MALMUD: Thank you. Is there a
5 second to Pat's motion?

6 VICE CHAIRMAN THOMADSEN: I will second
7 that. It's Bruce.

8 CHAIRMAN MALMUD: Thank you, Bruce. Any
9 further discussion of that motion?

10 MEMBER WELSH: This is Jim Welsh, who's
11 trying to scribble this down. Dr. Zanzonico, can you
12 repeat the final phrase or your sentence?

13 MEMBER ZANZONICO: Yes. Within a time
14 frame to be determined by the Authorized User
15 consistent with prevailing practice.

16 MEMBER WELSH: Thank you.

17 CHAIRMAN MALMUD: So, we have a motion
18 that's been moved and seconded. Any further questions
19 or discussion of that motion?

20 MEMBER WELSH: This is Jim Welsh here. I
21 would like to ask NRC Staff if we put this in in our
22 efforts to have language that is reminiscent of 10
23 CFR, is this kind of language going to be rejected, or
24 would this suffice? Is there any reason for us to
25 think about this right now before we go ahead and pen

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1 it in?

2 MS. BALLA: Yes. Dr. Malmud, this is
3 Neelam Balla from headquarters.

4 CHAIRMAN MALMUD: Yes?

5 MS. BALLA: We have our OGC Staff sitting
6 here for the regulations. Wording like that leaves
7 --- makes it a little bit ambiguous, so we would like
8 to have -- I suppose previously proposed was 60 days.
9 Would that work, or 90 days? I think we would like to
10 have a more specific time frame than -- it just leaves
11 -- for regulatory purposes, it's rather ambiguous.

12 CHAIRMAN MALMUD: Thank you. So, you would
13 like to amend that to say but not to exceed 60 or 90
14 days, whichever number is chosen?

15 MS. BALLA: Yes.

16 CHAIRMAN MALMUD: How does that sit with
17 Dr. Zanzonico's recommendation? Dr. Zanzonico?

18 MEMBER ZANZONICO: Well, I'm completely
19 ambivalent on the exact time frames, because I just
20 don't have enough insight into the clinical issues in
21 brachy to offer a time frame. And I was trying to
22 defer to folks like Dr. Welsh, who actually perform
23 this procedure on a regular basis. So, I would defer
24 to his judgment.

25 CHAIRMAN MALMUD: Dr. Welsh, Dr. Suh?

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1 MEMBER WELSH: This is Dr. Welsh here. And
2 I agree with the sentiments of NRC Staff that it can
3 be -- it does seem a little bit ambiguous with the
4 wording that Dr. Zanzonico offered, even though as a
5 clinician I'm very comfortable with that. But I have
6 to think also from the regulatory perspective, it
7 might not be as clear to somebody who is not fluent in
8 prostate brachytherapy. Therefore, adding another
9 phrase "not to exceed X number of days."

10 Now, I have stated publicly that although
11 our national guidelines, National Committee Guidelines
12 have come up with some recommendations which are
13 clinically appropriate and may be appropriate for
14 clinical trials, that from a regulatory perspective we
15 have to be far more lenient, and 30 days or 60 days
16 which might be appropriate for nine out of ten
17 prostate brachytherapy implants or maybe 99 out of 100
18 from a clinical trial perspective might still be too
19 strict from a regulatory perspective. And, therefore,
20 I wouldn't want to impose or have NRC impose
21 restrictions that -- on a community oncology center
22 brachytherapy practice that pushes them to meet or
23 exceed the National Guideline Standards for
24 prospective clinical trials, for example.

25 And, therefore, I would be in favor of

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1 having something more on the order of 90 days, or even
2 six months. And it would like, if possible, the
3 opinion of some of the experts who do a lot of
4 prostate brachytherapy that might be on this call,
5 such as Dr. Hagan, to see if six months might be
6 acceptable for this.

7 In my opinion, 30 days, 60 days would be a
8 little bit too short. Ninety days might be
9 appropriate but, again, from regulatory perspective
10 six months might be sufficient.

11 CHAIRMAN MALMUD: I think that Dr. Welsh
12 has directed a question to Dr. Hagan. Do you care to
13 respond, Dr. Hagan?

14 MS. COCKERHAM: I don't believe he's on the
15 call. This is Ashley.

16 DR. HAGAN: Yes, I'm here. Actually, I was
17 looking at another aspect of your last comment, so
18 you'd need to repeat that for me to be able to respond
19 to you.

20 CHAIRMAN MALMUD: Dr. Welsh felt that
21 putting a fixed deadline of 60 or 90 days might be too
22 strict in all circumstances, though it might be valid
23 in 90 percent of cases and, therefore, cause a
24 regulatory problem for those who had to exceed it.
25 And the question that he was posing to you is, what do

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1 you think as someone who practices prostate
2 brachytherapy, do you think that 60, 90, or 180 days
3 is the right number not to exceed?

4 DR. HAGAN: I think there are two
5 considerations here, and I think that the first, that
6 is to try to have a time that would include all
7 possibilities; that is, if we required that the
8 medical event criteria was susceptible to the impact
9 of edema so we had to have a time frame based on
10 edema, then probably neither 60 nor 90 days will catch
11 every patient. It will catch the majority of patients,
12 but not every patient.

13 But the second point is that this medical
14 event -- this ensemble of criteria that delineate
15 medical event, as I look at it, is insensitive to
16 edema. That's no longer an issue with regard to the 60
17 day, or 90 day criteria. So, our typical practice is
18 30 days, so the initial interest in the FSME Staff to
19 use 60 days was to say 60 days is long compared to 30
20 days, if 30 days is routine practice. Well, 30 days
21 is based on being able to evaluate dose separate from
22 the impact of edema, so that's the reason for the 30
23 days.

24 When there's a medical event criterion
25 that has eliminated the impact of edema, then the only

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1 issue is when we have a defined date are we going to
2 create medical events because it is unreasonable to
3 meet that date? That's what Dr. Welsh is pointing
4 out, the difficulty with having any date.

5 Well, that same criteria will apply to any
6 date you choose, so I think -- any date past 60 days
7 you choose. So, I think 60 days is fine. I think that
8 the practice can easily accommodate 60 days. I think
9 there is no one who will be requiring that a patient
10 be imaged after 60 days for the resolution of edema
11 because that's no longer an issue.

12 I think the practice that doesn't fit with
13 that in the past has been those that do day zero and
14 day one CTs because they can't get their patients back
15 in 30 days, or 60 days. Patients come from outside
16 the country. So, now since you've removed edema as a
17 major impact, then day zero, day one is a perfectly
18 good time to do this evaluation.

19 I think cobbling together the criteria you
20 have, I think you've eliminated the sensitivity to the
21 issue of date. I think 60 days would work just as well
22 as 90 days.

23 CHAIRMAN MALMUD: This is --

24 MEMBER WELSH: I believe that -- I'm sorry,
25 this is Jim Welsh.

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1 CHAIRMAN MALMUD: Go ahead, Dr. Welsh.

2 MEMBER WELSH: I agree that we have done
3 the best we can to eliminate the concerns of edema,
4 and that in practice 30 days, 60 days might work.
5 Frankly, I would be in favor of 90 days, simply
6 because we're not talking so much about clinical
7 matters here, not medical matters, but we're talking
8 about regulatory issues here. And, therefore, if
9 we're going to label something as a medical event, 30
10 days, 60 days, which would be relevant from a
11 perspective of whether or not this implant was managed
12 well, performed well, assessed well from a medical
13 perspective might still be a little bit too short,
14 from my perspective. And, therefore, I would
15 personally favor a more lenient 90 days for labeling
16 something as a medical event. And I would like some
17 feedback from others on the Subcommittee, and anyone
18 about whether 90 days is just too long, is that
19 impractical, is that ridiculous, or is that
20 appropriate for this regulatory question of when to
21 impose a medical event.

22 CHAIRMAN MALMUD: This is Malmud. This area
23 is not my area of expertise, but in my interactions
24 with the NRC, I have found that when there are
25 exceptions, if they are documented by the provider,

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1 the physician, or the physicist in a timely fashion,
2 that the NRC tends not to challenge them. It's when
3 there's no explanation, or when there's a delay in
4 communication that concern arises.

5 What does the NRC Staff feel about putting
6 in a fixed time frame, or with written justification
7 if it's to be exceeded? Dr. Howe, Dr. Zelac?

8 MS. BHALLA: Yes. Dr. Malmud, this is
9 Neelam Bhalla here, again.

10 CHAIRMAN MALMUD: Yes, I'm sorry, this is
11 your turf. I'm sorry. Go ahead.

12 MS. BALLA: We are the rule makers so we
13 need --

14 CHAIRMAN MALMUD: Yes.

15 MS. BALLA: -- to make sure things will be
16 comfortable. Certainly, when we go out on our
17 inspections, the Staff is -- the Inspectors always
18 look at the scene circumstances, or maybe one case out
19 of say 20 did not meet this, but if something is going
20 on, if a patient or patients are not imaged, or
21 there's no assessment done for all of them, or that
22 process is not in place, then we do question it. So,
23 going back to that case in hand here, I would think it
24 seems like --

25 (Background noise.)

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1 CHAIRMAN MALMUD: Please go ahead.

2 MS. BALLA: Yes, what I said was that 60
3 days does seem to be making sense. And in any case, a
4 specific case, if an assessment has not been done in
5 60 days, then the Inspectors do bring that information
6 back and exceptions are made. So, we could go with a
7 certain time frame.

8 MEMBER WELSH: This is Dr. Welsh. May I
9 then suggest an amendment to Dr. Zanzonico's original
10 proposed verbiage?

11 CHAIRMAN MALMUD: Please do.

12 MEMBER WELSH: Within a time frame to be
13 determined by the Authorized User consistent with
14 prevailing practice, not to exceed 60 days except --
15 I'm sorry -- unless accompanied by written
16 justification.

17 CHAIRMAN MALMUD: Thank you. How does that
18 sit with the individual who seconded your motion --
19 seconded Dr. Zanzonico's motion?

20 VICE CHAIRMAN THOMADSEN: That was me,
21 Bruce, and that's fine.

22 CHAIRMAN MALMUD: So, the motion has been
23 amended and seconded. Any further discussion?

24 DR. HOWE: Dr. Malmud, this is Dr. Howe at
25 NRC.

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1 CHAIRMAN MALMUD: Yes, Dr. Howe?

2 DR. HOWE: One of the things that strikes
3 me is that you don't have to put a time period in the
4 definition of a medical event. 35-41 is the program
5 that you use to assure that you've administered your
6 treatment in accordance with Written Directive. You
7 could put your time frame in 35-41 that says that you
8 make your dose assessment, if necessary, within the 60
9 days. That would take it out of being a medical
10 event, but would still make it a violation. So, the
11 medical event would be that you exceeded this dose
12 limit, or any other dose limit that you have here.
13 The violation would be if you hadn't made that
14 determination prior to the 60 days would be in 35-41.
15 I throw that out for your consideration.

16 CHAIRMAN MALMUD: Thank you. Dr. Welsh, do
17 you have a response to that?

18 MEMBER WELSH: I --

19 MEMBER LANGHORST: This is Sue Langhorst.
20 I'd like to take a crack at that, if you don't mind,
21 Jim.

22 CHAIRMAN MALMUD: Thank you, Dr. Langhorst.

23 MEMBER WELSH: Please do.

24 MEMBER LANGHORST: The dosimetry part of
25 that criterion is not needed if the first part is met.

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1 So, I don't think it would be appropriate to have it
2 in the part that Dr. Howe is suggesting, because it's
3 not necessary all the time. But the imaging would
4 need to be done in a certain amount of time.

5 MEMBER WELSH: Sue -- if I could respond,
6 Dr. Malmud, to Dr. Langhorst.

7 CHAIRMAN MALMUD: Please do.

8 MEMBER WELSH: That is not entirely correct
9 in that we have A1 or 2, and for 2 you do have to do
10 some quantitative calculations.

11 MEMBER LANGHORST: Yes, you're absolutely
12 correct. I stand corrected.

13 MEMBER WELSH: So, my response to Dr. Howe
14 at this point, that I proposed is that although this
15 language that we have written down is in the framework
16 of the regulations, none of us fool ourselves into
17 believing that we are capable of writing the actual
18 rules. And, therefore, I think that it is appropriate
19 for us to put it here explicitly, and put a little
20 asterisk afterwards saying that the real rule makers
21 could put this in 35-41 or wherever it needs to be so
22 that when final verbiage comes out it's consistent
23 with what 10 CFR is supposed to say. But if we don't
24 put it in anywhere -- or we could put it in the
25 discussion, but if we put it right here understanding

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1 that we're not expecting that this rule is going to be
2 published verbatim in the regulations, that the
3 concept will be illustrated abundantly clearly right
4 from the start if we include it right here. And
5 that's why I would favor putting something right here
6 right now.

7 CHAIRMAN MALMUD: Thank you. What do we
8 hear from the rule makers?

9 MS. BALLA: This is Neelam Balla again.
10 For these rule makers it's fine, so long as we have a
11 date, a time frame in there, and then in the proposed
12 rules you'll all get to see how we have, and where we
13 have put it, and how we have put it. And it will be
14 such that it will be easy to implement.

15 CHAIRMAN MALMUD: Thank you. So, we have a
16 motion amended and may we now vote on it?

17 VICE CHAIRMAN THOMADSEN: This is Bruce.
18 Could we hear what it says one more time?

19 CHAIRMAN MALMUD: Yes, Dr. Thomadsen. Who
20 has it written down?

21 MS. COCKERHAM: This is Ashley. I believe I
22 do, if Dr. Welsh does not.

23 CHAIRMAN MALMUD: Ashley?

24 MEMBER WELSH: Ashley, please go ahead.

25 MS. COCKERHAM: Okay. I have, "Within a

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1 time frame to be determined by the Authorized User
2 consistent with prevailing practice but not to exceed
3 60 days unless accompanied by written justification."

4 CHAIRMAN MALMUD: How does that sound?

5 VICE CHAIRMAN THOMADSEN: Sounds right.

6 But --

7 CHAIRMAN MALMUD: Did I hear a but?

8 MR. LIETO: This is Ralph Lieto. It sounds
9 like what Dr. Zanzonico originally proposed without
10 the time frame, because that last phraseology
11 basically makes it whatever they want to determine it
12 to be, just as long as they document it. And I would
13 think that would be actually document -- whatever the
14 standard practice is is going to be documented to
15 begin with. I guess it just sounds to me like it's
16 sort of waffling back and forth, and still gives
17 really an open ended time frame.

18 VICE CHAIRMAN THOMADSEN: This is Bruce
19 again. I think that the out at the ends would have to
20 be there to accommodate if you do have a patient that
21 you do, is maybe going to be out of the country for
22 the next four months, so you have to write in the
23 chart at the time why you aren't going to be doing it
24 at the normal time.

25 MR. LIETO: Would that be consistent with

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1 the clinical practice of the Authorized User?

2 VICE CHAIRMAN THOMADSEN: Hard to tell.

3 CHAIRMAN MALMUD: Ralph --

4 VICE CHAIRMAN THOMADSEN: They might always
5 do --

6 MR. LIETO: You know, I just think that
7 it's very ambiguous. I think I just would suggest
8 keeping it the way Dr. Zanzonico had suggested
9 originally. I think that's really the best way, and
10 leaves it up to the Authorized User to document in his
11 Written Directive program, which he has to have
12 anyhow.

13 CHAIRMAN MALMUD: This is Malmud. I think,
14 Ralph, that the reason for the 60 days is to establish
15 a number so that those who read it can understand that
16 that really is the goal. There obviously will be
17 exceptions. There are practices which have a large
18 number of non-compliant patients for one reason or
19 another. We're concerned about non-compliant
20 providers. And I believe that the motion as made with
21 its amendment establishes more clearly guidelines for
22 the provider to protect both the patient and the
23 provider. But that's only one man's opinion. We're
24 relying on the wisdom of the Subcommittee.

25 MEMBER WELSH: This is Jim Welsh here

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1 replying to Ralph Lieto's comment. Yes, I agree that
2 Pat Zanzonico's original words are very satisfying and
3 would be appropriate from my medical perspective, but
4 we heard from NRC Staff, the rulemaking section, that
5 they would like a number. And I proposed 90 days, but
6 I like the concept of 60 days except by written
7 justification even better because, as we've heard from
8 a member of the public, Dr. Hagan, who's an expert in
9 prostate brachytherapy and does a lot, that 60 days
10 probably is an appropriate figure. And if exceeded,
11 it would have to be accompanied by written
12 justification. And examples do abound where a patient
13 simply declines to come in, or the patient is
14 hospitalized for another medical problem, or is out of
15 the country on vacation and forgets to show up. We
16 call those so called patient specific or patient
17 related factors. And in other versions of our
18 proposed definitions or discussion we've said things
19 such that -- such as patient specific factors should
20 not be allowed to qualify as medical events. And we
21 included things like the patient just doesn't show up
22 for whatever reason.

23 So, here we're reincarnating that concept
24 but putting in slightly different words here, and
25 saying except if accompanied by written justification.

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1 And yes, although I think Pat's original words are
2 sufficient in my perspective, I understand the need
3 for a specific number, and I like the way that this
4 rolls off the tongue, not to exceed 60 days except if
5 accompanied by written justification.

6 MS. FAIROBENT: Dr. Malmud, it's Lynne
7 Fairobent. May I ask a question?

8 CHAIRMAN MALMUD: Yes, Lynne.

9 MS. FAIROBENT: I'm struggling with -- I
10 don't know how one would enforce, or who would make
11 the determination that the written justification
12 provided is valid and acceptable. My problem with
13 this that I'm struggling with the "unless accompanied
14 by written justification," is that I can't envision a
15 situation then that could occur that would result in a
16 medical event, because I think an Authorized User
17 could develop a written justification so that a
18 medical event was not noted.

19 MEMBER WELSH: This is Jim Welsh, if I
20 could reply or attempt to.

21 CHAIRMAN MALMUD: Please do.

22 MEMBER WELSH: I think that the written
23 justification could be put in at the 60 day mark by an
24 Authorized User saying that the patient was scheduled
25 to have shown up by this date and was scheduled, but

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1 failed to show for the following reasons. That should
2 be justification that would suffice for regulatory
3 purposes.

4 However, if there is no statement of the
5 sort, and there is a policy scheduling post implant
6 dosimetry and the patient was never told to come in
7 this time, and nothing was ever scheduled, and doesn't
8 show up, well, then that would be an example of --
9 that is falling below standards and might qualify as
10 the medical event according to --

11 CHAIRMAN MALMUD: Does that satisfy your
12 concern, Lynne?

13 MS. FAIROBENT: Perhaps from Dr. Welsh's
14 viewpoint. I'm not sure it would satisfy me if I was
15 still an inspector. And I guess I would like to hear
16 from not only NRC Staff, but from Darice Bailey from
17 the Agreement State viewpoint.

18 MS. BAILEY: I can speak. This is Darice.
19 Any time in regulating and enforcing, the clearer the
20 better. Practicing medicine is not black and white,
21 so it's going to be difficult. Saying with an
22 explanation, quantifying what that explanation is
23 supposed to kind of entail just leaves it open so that
24 anyone could say hey, we provided you an explanation.
25 The explanation may have been we forgot, but your

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1 rule just said provide an explanation.

2 So, while the majority of people are
3 compliant and desire to do the best, rules are written
4 for those that aren't. So, if you're going to rely on
5 providing an explanation, now you go down the bunny
6 trail of what justifies a valid explanation.

7 What I just heard, if it's patient
8 intervention, that's a given. That's easy, but I
9 think what we're going for, not necessarily patient
10 intervention because that's sort of taken care of
11 already. So, it's got to point out that this is a
12 very unusual situation for the facility, that the
13 facility's procedures were followed, and here is why
14 this was an exception. It can't just be because -- it
15 can't be a simplistic answer. And that's going to be
16 very hard to write into rule.

17 MS. FAIROBENT: Dr. Malmud, that was
18 exactly my concern.

19 CHAIRMAN MALMUD: Thank you. Are there
20 comments from the members of the Subcommittee
21 regarding this concern?

22 MEMBER WELSH: This is Jim Welsh, and I
23 suppose that my initial suggestion not to exceed 90
24 days, or maybe now even 120 days should be
25 reconsidered because if the rule makers want something

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1 very concrete and don't want something that could be
2 misinterpreted, or misused, or open ended such as
3 accompanied by written justification for any date,
4 then maybe it is best for us to put a very specific
5 date there. But, again, my sentiment is that this
6 should not be for regulatory purposes anything that is
7 at all restrictive. And I would think 90 to 120 days,
8 if you haven't done your implant -- post-implant
9 dosimetry by then, something has gone wrong, and maybe
10 it should be tagged as a medical event. And that's
11 --- I guess I would bounce it back to other members
12 of the Subcommittee and others on the call for
13 feedback on that concept.

14 MEMBER WEIL: Dr. Malmud, this is Laura
15 Weil. May I ask something?

16 CHAIRMAN MALMUD: Yes, Laura.

17 MEMBER WEIL: Would it be
18 appropriate instead of saying with written
19 justification to state with detail of attempts made to
20 bring the patient back in for imaging or dosimetry, or
21 something to that effect, so that it's clear that it's
22 not that someone forgot, or that it's been ignored,
23 but rather that there's been no response from the
24 patient to come back for this recommended part of the
25 process.

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1 CHAIRMAN MALMUD: Well, would the term
2 "written explanation" be better than the term "written
3 justification"?

4 MEMBER WEIL: I think it should be written
5 documentation of efforts made.

6 VICE CHAIRMAN THOMADSEN: This is Bruce.
7 From what we just heard from our state regulator, it
8 sounds like, as she said, it was a given if the
9 patient -- if you try to get the patient back and the
10 patient doesn't come, that we don't really have to
11 address that issue here. In which case, I'm wondering
12 if we're trying to address something that doesn't need
13 to be addressed. I'm also beginning to think maybe
14 Dr. Howe had a point, and maybe we shouldn't worry
15 about the timing at all.

16 MR. FULLER: This is Mike Fuller with the
17 NRC, maybe I can help a little bit. Dr. Howe's point
18 wasn't that we shouldn't worry about it. It's just we
19 were getting into where in the rule. Not necessarily
20 part of a medical event as opposed to a requirement
21 that they be done within a certain time frame.

22 As we look around the room here with the
23 various folks, we really think at this point in time
24 we probably have enough information. Now, maybe you
25 don't have all the feedback you need to write a

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1 motion, but the failure of the patient to show up
2 within the time frame should not be a violation.
3 That's really all we need from a rulemaking
4 perspective. As long as you guys as part of your
5 motion agree in a particular time frame, and as long
6 as there is a way for us to caveat that, and we can
7 figure out what the words are, that a patient's
8 failure to show up is not a violation. I think that's
9 all we need in the motion, again. And whether or not
10 it goes into -- and, again, it wouldn't be part of a
11 medical event definition. You want to put it as a
12 part of the motion, that's fine. We'll figure that
13 part out.

14 But what we were talking about early on is
15 the need for a time frame so that we would have what
16 we needed with regard to post-implant imaging, to make
17 the rest of the rule work. So, I hope that helps.

18 CHAIRMAN MALMUD: Yes, it does. Thank you.

19 We're back to Dr. Welsh, and the motion, which was
20 Dr. Zanzonico's motion. It has been made and amended.

21 We've heard comments from NRC with regard to their
22 understanding that this is the feeling of the
23 Subcommittee. May we vote on that motion now?

24 MEMBER MATTMULLER: Dr. Malmud, this is
25 Steve Mattmuller. Before we vote, I'm sorry. I've

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1 been struggling with this whole discussion in that
2 ASTRO's recommendation was that the medical event
3 definition should be based on source activity. And
4 from my recollection from the stakeholder meetings,
5 everyone said source activity. But now it seems the
6 Subcommittee has added the dose perspective to how we
7 define a medical event. And in past meetings and
8 discussions, and like what we've had so far today
9 there's -- it's a very, very tricky, difficult aspect
10 of dose to define in a medical event. And it seems
11 like we're rehashing a lot of what we've said in the
12 past to justify not including it in a medical event
13 definition.

14 So, I'm curious if I could ask the
15 Subcommittee why they think this is important to add
16 to the medical event definition now, as opposed to
17 just leaving it based on activity?

18 VICE CHAIRMAN THOMADSEN: Can I address
19 that?

20 CHAIRMAN MALMUD: Please do.

21 VICE CHAIRMAN THOMADSEN: This is Bruce
22 Thomadsen again. There are -- what we've seen in
23 several of prostate implants, there are implants where
24 more than 20 percent of the sources are not in the
25 target, but are around the target, and still deliver

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1 an appropriate dose to the target even though they
2 would fall outside of the criteria in 1A-1.

3 The purpose of 1A-2 -- or is that the
4 number? The purpose of the dose criteria is that even
5 if the sources aren't where they were supposed to be,
6 if the dose to the target was within a range that
7 could be considered therapeutic, then that still
8 doesn't need to be considered a medical event. It's
9 not that this criterion is there to cause a medical
10 event to be reported if the dose doesn't match that
11 criteria, but it's to screen out those cases where you
12 would trigger a medical event with 1A(i), but it
13 wasn't a significant incident; that is, the doses were
14 still adequate.

15 MEMBER WELSH: This is Jim Welsh; if I
16 might add to Dr. Thomadsen's comment.

17 CHAIRMAN MALMUD: Please do.

18 MEMBER WELSH: As evident from a
19 conversation about whether or not we could add the
20 phrase "not to exceed 90 days," not to exceed 60 days
21 except if accompanied by written justification,
22 changing that to "explanation," changing that to
23 "documentation," and whether or not this would fly
24 with regulators, is this something that's enforceable?
25 The same challenge -- we face the same challenge with

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1 the original ASTRO definition, where there was a
2 section saying that the seeds were placed in
3 accordance to the Authorized User's intention.

4 As a physician, I'm very comfortable with
5 that, but I've heard back many times from those in
6 rulemaking and others that this open ended conceptual
7 verbiage is not going to be deemed satisfactory in the
8 ultimate rulemaking. So, "in accordance with the
9 Authorized User's intention" is very analogous to what
10 we're talking about here, "60 days except if
11 accompanied by written justification".

12 And you could see that we're going back
13 and forth with just this little concept of the 60 days
14 except, we would be going back and forth ad nauseam
15 with in accordance to the Authorized User's intention.

16 How are you going to verify that? How is it -- how
17 can it be proved objectively? And, therefore, we came
18 up with this alternative proposal that as Bruce said,
19 does not trigger medical events at a low threshold,
20 but actually raises the bar for making something meet
21 the criteria of a medical event further than the
22 original ASTRO definition. So, yes it is some dose-
23 based addition, which is something that NRC expressed
24 on numerous occasions, something they like, but it
25 raises the threshold rather than lowering the

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1 threshold, and does provide something that is
2 objective and has some -- therefore, something that
3 regulators can sink their teeth into.

4 CHAIRMAN MALMUD: Thank you, Dr. Welsh.
5 Other comments?

6 DR. HAGAN: This is Mike Hagan. In response
7 to this last pair of comments, if I read this
8 correctly, as long as 1A criteria have not been met;
9 that is, as long as there is no question about medical
10 event vis-a-vis activity, placement under 1A(i) and
11 (ii).

12 One doesn't need to do a D-90 calculation.
13 The only purpose of a D-90 calculation is if either of
14 those two upper criteria may have been met, then there
15 is a need to demonstrate that it also corrupted the
16 dose, as well. As long as your implant doesn't violate
17 the two criteria conjoined by the "or", you don't need
18 to do a D-90. Is that not correct?

19 MR. LIETO: That's not correct.

20 CHAIRMAN MALMUD: Is that Mr. Lieto?

21 MR. LIETO: Yes, this is -- again, I think
22 it was pointed out in number 2, for the normal --
23 that's a whole separate criteria. You have one --

24 DR. HAGAN: I'm not talking about number 2.
25 I'm not talking about number 2.

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1 MR. LIETO: With number 2, you have to do a
2 dose calculation.

3 DR. HAGAN: I understand that, but I'm
4 talking about for the target site, not normal tissue,
5 but vis-a-vis the target site, and the calculation of
6 C-90 to the CTV. There's no need to do a D-90 if the
7 -- if neither of the upper two criteria have been met.

8 MEMBER WELSH: This is Jim Welsh. I would
9 say that Dr. Hagan is correct, that D-90 does not have
10 to be calculated, and is not incorporated for medical
11 event criteria unless we're dealing with a situation
12 of 1A(i), but Dr. Lieto is also correct in that yes,
13 we do have to do post-implant dosimetry to calculate
14 the normal tissue dose to see if you've exceeded them.

15 But D-90 does not factor in very heavily at all in
16 our current definition. And that's why we separate A1
17 versus A2, because we are talking about the target,
18 and we're talking about the normal tissues very
19 separately.

20 CHAIRMAN MALMUD: Thank you. I'm sorry, who
21 was going to say something?

22 MR. LIETO: Just a clarification on this
23 150 percent in number 2.

24 CHAIRMAN MALMUD: Is that Mr. Lieto?

25 MR. LIETO: Yes. I'm sorry, yes, Ralph

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1 Lieto. In number 2, this 150 percent, Dr. Welsh, or
2 members of the Committee, Subcommittee, that is a
3 separate prescribed dose to those organs or tissues.

4 MEMBER WELSH: That's correct.

5 MR. LIETO: See, I have a similar concern
6 that Lynne was expressing, is that if you're an RSO
7 and you're going in to audit your area on how you're
8 going to determine whether an event occurred or not,
9 because this really -- because it's so overly
10 prescriptive and detailed, it almost makes it
11 impossible for someone outside of the department to
12 identify a medical event. It's really going to have to
13 be self-identified. I think an expectation that a
14 regulator is going to come in and determine these
15 things is not realistic.

16 DR. HAGAN: This is Michael Hagan. I think
17 that's absolutely correct.

18 CHAIRMAN MALMUD: May we hear comment about
19 that from the NRC Staff?

20 MR. FULLER: At this point in time, we
21 really don't have a comment.

22 CHAIRMAN MALMUD: Thank you.

23 MEMBER WELSH: Dr. Malmud, this is Steve
24 Mattmuller again. And I would like to concur with
25 Ralph -- well, that reading through this, my

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1 impression was the Subcommittee was trying to make a
2 good definition even better, but I think the folly is,
3 is that we've -- it's now wandered into a territory
4 where it would be very difficult to regulate, or to
5 inspect against.

6 CHAIRMAN MALMUD: I heard another comment?

7 VICE CHAIRMAN THOMADSEN: May I speak up to
8 that? This is Bruce. And I would disagree with the
9 difficulty to evaluate this by a regulator, although
10 qualifications of regulators vary greatly from state
11 to state, of course. But if the regulator is at all
12 familiar with prostate dosimetry, it is not hard to
13 look at a case and evaluate the criteria. If they are
14 not, then they will be hopeless, but then again it
15 would be hopeless for them to make a reasonable
16 evaluation in any case.

17 We have to assume that, first, the
18 regulators are educated into how to do the
19 evaluations. And, secondly, we also have to recognize
20 that these implants are actually very complex, and
21 evaluating the implants are very complex. And trying
22 to make a simplistic rule is not going to work in this
23 case. It is too complex, and it requires specific
24 specialized knowledge.

25 CHAIRMAN MALMUD: Thank you, Dr. Thomadsen.

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1 Other comments?

2 MEMBER WELSH: This is Jim Welsh. Can I
3 comment further?

4 CHAIRMAN MALMUD: Yes, Dr. Welsh.

5 MEMBER WELSH: I would say I disagree with
6 the previous few comments that assert that this is
7 going to be more of a problem for regulators. I think
8 that our efforts have been specifically designed to be
9 a compromise between what is medically appropriate and
10 what is relatively easy for a regulator or an
11 inspector. And, therefore, the inclusion of dose,
12 which was very strongly opposed by many of us in the
13 Subcommittee over the past few years has been
14 introduced, in part, for exactly this reason, so that
15 there are some concrete numerical figures that can be
16 used by regulators to make things simpler. And I think
17 that everyone would agree that these concrete
18 numerical figures have to be considered more concrete
19 than the phrase "in accordance with the Authorized
20 User's intention." And although I like "in accordance
21 with the Authorized User's intention", you can only
22 imagine the debate and the arguments that would be
23 going on about whether that is enforceable, and
24 whether -- how an inspector would handle that in
25 comparison to these hinted, suggested rules here that

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1 give you objective figures.

2 So, that's where these objective figures
3 come from, and that's where the concept of limited use
4 of dose, not D-90 for the target mind you, but dose in
5 the specific context may be reasonable for these
6 particular definitions in that they provide some
7 objectivity that is very difficult to otherwise
8 incorporate into rulemaking. And this is the best
9 we've got so far, and I think most of us like it.

10 CHAIRMAN MALMUD: Thank you, Dr. Welsh. May
11 I ask a question of NRC Staff; and that is, if this
12 recommendation had been in place at the time of the
13 issues that arose in Philadelphia at the VA, would
14 these interpretations and recommendations have aborted
15 the number of incidents that occurred in Philadelphia?
16 Would this have been helpful in preventing some of
17 those?

18 DR. HOWE: We would have to go back and
19 look. I believe this would take out most of the
20 medical events, because you're saying with written
21 justification and what the intent was. In that
22 particular case, the Authorized User made statements
23 like well, I intended to give two fractions, and
24 because I took 35 out of the bladder the first time,
25 I'm just going to have him come back for a second

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1 fraction which didn't happen. So, we would not have
2 been able to pick up our index patient.

3 CHAIRMAN MALMUD: So, this would not have
4 been helpful in reducing the number of incidents at
5 the Philadelphia VA, for example.

6 DR. HAGAN: This is Michael Hagan. That's
7 not -- I can give you exactly the answer to that
8 question.

9 CHAIRMAN MALMUD: Thank you, Dr. Hagan.

10 DR. HAGAN: Out of the 116 implants, 10
11 would represent medical events under these
12 definitions. There are none that would fall under
13 Rubric 2 for normal tissues. There are 11 that would
14 fall under 1A with greater than 20 percent of the
15 activity outside of the PTV, and one of those, the D-
16 90 was greater than 80 percent, actually. So, would
17 not be a medical event because of the boolean and for
18 calculated dose to D-90. That would leave 10 that
19 would have been medical events out of Philadelphia.

20 CHAIRMAN MALMUD: And does that mean that
21 if they would have been medical events, that the NRC
22 would have been alerted to a problem occurring there
23 and would, therefore, have given much closer oversight
24 to what was occurring, and prevented the others from
25 occurring?

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1 DR. HAGAN: Yes, that would be correct.
2 Out of those 10, there were a number that occurred
3 early in the course of this implants; that is, in the
4 2003 time frame. So, had Quality Assurance Evaluations
5 been done and a regulatory evaluation been done under
6 this set of rubrics, and done accurately, they would
7 have been identified and would have pointed out that
8 there was a problem with this program.

9 Although 10 sounds like a low number
10 compared to the previous number, 10 medical events in
11 any program is not only unacceptable, but highly
12 unacceptable, so this would have -- the application
13 --- the correct application of this definition would
14 have identified early on the implant problem in
15 Philadelphia.

16 CHAIRMAN MALMUD: So, that if I were a
17 member of the public and I were to ask if this new
18 Permanent Implant Brachytherapy Subcommittee report
19 would have prevented the number of incidents at the
20 Philadelphia VA, the answer would be affirmative, it
21 would have helped to prevent the number.

22 DR. HAGAN: Yes, and my only caveat is that
23 it would be the accurate application of this medical
24 event definition. And the issue that I shared with
25 the other caller about the need for self-

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1 identification comes from the use of CTVs and PTVs,
2 and the rendering of octants in order to be able to
3 use a portion of medical event definition. Those are
4 not trivial in terms of being able to in a rigorous
5 and objective way to identify what the Authorized User
6 is absolutely calling PTV and CTV, and how he renders
7 his octants, because in today's treatment planning
8 system where you can generate octants automatically,
9 there's more than one choice, there's more than one
10 way of rendering those octants. And I can choose ways
11 that eliminate medical event criteria.

12 CHAIRMAN MALMUD: Thank you, Dr. Hagan.
13 So, I'll just ask the question again rather simply;
14 and that is, as a member of the public would I be
15 reassured that if this Permanent Implant Brachytherapy
16 Subcommittee report were advanced that the scale of
17 problems at the Philadelphia VA would not recur?

18 DR. HAGAN: Correct.

19 CHAIRMAN MALMUD: Thank you. Any other
20 further discussion of the motion with the amendment?
21 May we --

22 MEMBER WEIL: This is Laura Weil. May I say
23 something?

24 CHAIRMAN MALMUD: Yes. I'm sorry, I didn't
25 hear the name.

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1 MEMBER WEIL: Laura Weil.

2 CHAIRMAN MALMUD: Yes, please.

3 MEMBER WEIL: In terms of the time frame
4 that we're discussing for A1-B, and given Dr. Hagan's
5 comments, I wonder if it makes sense to include the
6 shorter time frame, 60 days rather than 90 days, in
7 the interest of identifying problems in a more timely
8 way so that further difficulties can be avoided?

9 CHAIRMAN MALMUD: That's a question to the
10 members of the Subcommittee. Dr. Welsh, you chair it.

11 MEMBER WELSH: This is Dr. Welsh, and I
12 have to apologize that I dropped the call for a second
13 when Dr. Hagan was probably saying the most important
14 point.

15 CHAIRMAN MALMUD: Actually, Dr. Welsh, a
16 question came in afterwards from Laura Weil; and that
17 is: Is the 90-day too broad? And would 60 days be a
18 better date beyond which there should be the written
19 statement?

20 MEMBER WEIL: For the purpose of
21 identifying problematic situations sooner in order to
22 prevent future problems.

23 MEMBER WELSH: Okay. And I can answer
24 personally that I'm comfortable with 60 days with the
25 addition of the phrase "except if accompanied by

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1 written justification", "explanation",
2 "documentation", whichever word we'd like to add. Some
3 members of the rulemaking group have questioned
4 whether or not we can really use "except if
5 accompanied by written whatever." I proposed an
6 alternative of just saying flat out this number of
7 days, and I suggested the number 90. But if others are
8 more comfortable with the concept of 60, I guess I
9 could go along with that. I still like the phrase "if
10 accompanied by written justification," but if that's
11 not going to fly with rulemaking--

12 CHAIRMAN MALMUD: No, I don't think it was
13 dropped. It's still the amendment to your motion. And
14 I think we agreed to allow the NRC to polish this up
15 according to the way that they saw fit. I think they
16 volunteered to do that. Am I correct?

17 MR. FULLER: Yes, you're correct, Dr.
18 Malmud. This is Mike Fuller with the NRC.

19 CHAIRMAN MALMUD: Thank you, Mike. So, I
20 would ask now, Dr. Langhorst, Dr. Suh, and Dr.
21 Thomadsen if they agree with Dr. Welsh that 60 days
22 would be acceptable as an alternative?

23 VICE CHAIRMAN THOMADSEN: This is Bruce.
24 Affirmative.

25 MEMBER SUH: This is John Suh. So, I'm

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1 okay with the 60 days, as well, as long as there's a
2 comment saying it's accompanied by some written
3 explanation beyond 60 days, because there are some
4 circumstances where patients do not show up within
5 that 60-day period.

6 CHAIRMAN MALMUD: Thank you, Dr. Suh. Dr.
7 Langhorst.

8 MEMBER LANGHORST: And I agree with my
9 esteemed colleagues, and with Dr. Hagan on if they
10 feel that 60 days is a workable time frame, I support
11 that.

12 CHAIRMAN MALMUD: Thank you. So, we have
13 another amendment to the motion, and that just changes
14 the 90 days to 60 days with the other amendment still
15 standing. May we move on that motion? I'll call for
16 the vote of the Subcommittee. That's Dr. Welsh,
17 Thomadsen, Suh, and Langhorst, affirmative on it?

18 MEMBER SUH: Affirmative.

19 VICE CHAIRMAN THOMADSEN: Affirmative.

20 CHAIRMAN MALMUD: Thank you. Is there any
21 other action required on this Advisory Committee of
22 Medical Uses of Isotopes Subcommittee? I think that
23 otherwise it appears to be met with approval, and it
24 represents an enormous amount of effort and discussion
25 on the part of the Subcommittee, for which we are very

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1 appreciative. Dr. Welsh, Dr. Langhorst, Dr. Suh, Dr.
2 Thomadsen, thank you all very much, and for the input
3 of the comments of those who participated in this
4 conversation, in this discussion today, including
5 members of the public and the NRC Staff.

6 Is there any other business that you wish
7 us to engage in for this meeting? I'm asking that
8 question --

9 VICE CHAIRMAN THOMADSEN: Dr. Malmud, this
10 is Bruce Thomadsen.

11 CHAIRMAN MALMUD: Yes, Dr. Thomadsen.

12 VICE CHAIRMAN THOMADSEN: Would it be
13 appropriate to have the ACMUI endorse the
14 Subcommittee's report?

15 CHAIRMAN MALMUD: Yes, it has to be moved
16 forward to the ACMUI before it goes to the NRC. Do we
17 have a quorum of ACMUI?

18 MR. EINBERG: Dr. Malmud, Chris Einberg
19 here. We have a couple of questions from the NRC Staff
20 here before we move to take a vote on this. Dr. Howe?

21 DR. HOWE: Yes. I have a very basic
22 question and comment. This particular definition for
23 medical event is supposed to be activity-based. I see
24 no mention of activity in this definition. And I've
25 got three different kinds of medical events that we've

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1 had in the past that I'm interested in whether you
2 considered those and decided that they're not
3 important any more. One would be the -- you order air
4 kerma, you get millicuries, or you order millicuries
5 and you get air kerma, so you get a different activity
6 than what you ordered. So, I'm looking at the activity
7 of the sources.

8 The second one would be whether you had
9 decayed sources. And we had a particular case this
10 past year where there were palladium sources that were
11 ordered for a May procedure, the patient couldn't come
12 in. They came in in June and the May seeds were
13 inadvertently picked up instead of the June seeds and
14 given. So, all the sources were where they were
15 supposed to be, but they were nowhere near the
16 activity they were supposed to be.

17 And the third one would be, if there's a
18 mistake in filling the order, and we had that a number
19 of years ago where the group filling the order mistook
20 what was written and they sent in a much higher
21 activity source than was ordered. But I see no
22 discussion of whether there is a problem if the
23 activity is not what was ordered. And I wondered if
24 that should go into Item 3 of the definition.

25 CHAIRMAN MALMUD: Thank you for bringing

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1 that to our attention, Dr. Howe. Dr. Welsh, do you
2 care to deal with that?

3 MEMBER WELSH: Yes, I'd be happy to. Thank
4 you. I would say that Dr. Howe brings up some very
5 important points that we may have inadvertently
6 omitted in Section 3 where we tried to incorporate
7 everything by saying the wrong radionuclide. Maybe we
8 should have specifically said wrong radionuclide, or
9 wrong activity. We have wrong patient, wrong site,
10 wrong body part, wrong modality or leaking sources,
11 but if we also add somewhere wrong activity, then that
12 would probably capture the events that you discussed,
13 and complete Section 3 a little bit more than it is
14 presently.

15 CHAIRMAN MALMUD: Thank you, Dr. Welsh.
16 You just said under 3A preferring using the wrong --
17 prefer using the wording "using the wrong
18 radionuclide, or wrong activity." Is that acceptable?
19 And would that satisfy the concern that Dr. Howe
20 correctly brings to us?

21 DR. HOWE: Do you have a level at which the
22 wrong activity would be acceptable?

23 CHAIRMAN MALMUD: Dr. Welsh?

24 MEMBER WELSH: It would depend on the
25 particular isotope, of course, so we wouldn't be able

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1 to -- we would have to say plus or minus a certain
2 percentage. And I would want to be consistent with
3 previous statements and regulations in that regard.

4 CHAIRMAN MALMUD: In nuclear medicine we
5 use plus or minus 10 percent. Is that acceptable in
6 this case?

7 MEMBER WELSH: I think that plus or minus
8 10 percent would be acceptable in this case, yes. If
9 it's more than 10 percent that is clearly the wrong
10 activity, and should probably meet the definition of a
11 medical event, because it would have been the wrong
12 date, wrong activity sent, wrong order, and I think
13 that it would be caught.

14 VICE CHAIRMAN THOMADSEN: The current
15 guidelines are, I think, at 20 percent. Is that not
16 the case, Dr. Howe?

17 DR. HOWE: At the current time, I don't
18 believe we have an activity base.

19 VICE CHAIRMAN THOMADSEN: I think you do.
20 When you talk about the dose as far as sources, it's
21 actually in source strength, I think.

22 MEMBER WELSH: If the question at hand is,
23 is it 10 percent or 20 from our perspective right here
24 today, then I would vote in favor of 10 percent. If
25 it's off by 10 percent or more, there's something

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1 wrong. That's why I think it's important to discuss
2 it right now.

3 CHAIRMAN MALMUD: Dr. Welsh, I spoke from
4 the perspective of nuclear medicine. I was not
5 suggesting that it be applied to radiation oncology,
6 except if it's appropriate. So, the choice is up to
7 the members of your Committee. The recommendation is
8 that of your Committee, your Subcommittee.

9 MEMBER WELSH: So, I would ask Dr.
10 Thomadsen, irrespective of whether there's something
11 that says 20 percent now, would you concur that if the
12 activity is off by 10 percent that something is wrong
13 in terms of the activity or the date perhaps would
14 catch it, or if it's the wrong order, is 10 percent
15 strict enough to catch those kinds of situations?

16 VICE CHAIRMAN THOMADSEN: The problem with
17 that is that if you put together all the possible
18 uncertainties in source activity that you would be
19 using in a patient, you could get to 10 percent quite
20 easily. And I'll base that on the AAPM Task Group
21 138th Report, in which case that may be close to what
22 we're actually operating at.

23 And I think that the usual number that's
24 being used by most practitioners would be 20 percent
25 would be an event, or would be appropriate for an

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1 event. Plus or minus 10 percent is probably
2 relatively normal.

3 MEMBER WELSH: So, then 20 percent might be
4 a more appropriate figure if we're going to include a
5 number. Anybody else on the Subcommittee have an
6 opinion about this?

7 MEMBER LANGHORST: This is Sue Langhorst. I
8 would agree with the 20 percent.

9 CHAIRMAN MALMUD: Thank you. Dr. Suh?

10 MEMBER SUH: Yes, I would also with the 20
11 percent. I think the 10 percent is probably too low
12 of a number.

13 CHAIRMAN MALMUD: All right. So, the
14 Committee recommends 20 percent. Dr. Howe, is that an
15 acceptable recommendation to the NRC?

16 DR. HOWE: It's the Committee's
17 recommendation. It's acceptable.

18 CHAIRMAN MALMUD: Thank you.

19 VICE CHAIRMAN THOMADSEN: And for the
20 wording on that I would like to see it be either
21 activity -- that the "activity or source strength".

22 CHAIRMAN MALMUD: So, you'd like 3A to
23 read, "using the wrong radionuclides or wrong
24 activity."

25 VICE CHAIRMAN THOMADSEN: "Or source

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1 strength".

2 CHAIRMAN MALMUD: "Or source strength".

3 MEMBER WELSH: And then parentheses plus or
4 minus 20 percent.

5 CHAIRMAN MALMUD: Plus or minus 20 percent.

6 MS. FAIROBENT: Dr. Malmud, it's Lynne
7 Fairobent.

8 CHAIRMAN MALMUD: Yes?

9 MS. FAIROBENT: I would suggest that you
10 make that activity and source strength a new item
11 under 3, and not tie it to 3A.

12 VICE CHAIRMAN THOMADSEN: And I would agree
13 with Ms. Fairobent on that one. I think it should be a
14 separate item.

15 CHAIRMAN MALMUD: Which item would you like
16 it to be?

17 MEMBER WELSH: B.

18 CHAIRMAN MALMUD: B. All right. So, that
19 will be the new B, and then B through E will be moved
20 down and made into C-F. Is that it?

21 MEMBER WELSH: Maybe it would be -- yes, so
22 there be a total of F.

23 CHAIRMAN MALMUD: Yes.

24 MEMBER WELSH: A, B, C, D --

25 CHAIRMAN MALMUD: B will become C, C will

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1 become D, D will become E, E will become F, and this
2 will be the new B.

3 MEMBER WELSH: May I ask a practical
4 question here? Ashley or somebody, is somebody getting
5 all this down or is this going to be the
6 Subcommittee's responsibility to include all these
7 comments. I just want to know. I'm scribbling as fast
8 as I can, but if somebody else is doing this.

9 CHAIRMAN MALMUD: Ashley, that question is
10 to you, if you're with us.

11 MS. COCKERHAM: I'm writing it, and I can
12 talk to you, Dr. Welsh, and make sure that the
13 Subcommittee report is revised.

14 CHAIRMAN MALMUD: Thank you, Ashley.

15 MEMBER WELSH: Thank you.

16 MS. COCKERHAM: He's scribbling this, so we
17 can compare our scribbles, please.

18 MR. EINBERG: This is Chris Einberg. The
19 meeting is being transcribed, as well.

20 CHAIRMAN MALMUD: Oh, thank you. Chris
21 tells us the meeting is being transcribed, as well.

22 Now, we have a motion with several
23 changes, the last of which was to include the wrong
24 activity or source strength plus or minus 20 percent
25 as Item 3B, and making the appropriate changes below

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1 that. Having heard the recommendation, the amendments,
2 are all in favor?

3 (Chorus of ayes.)

4 CHAIRMAN MALMUD: Thank you. Now, we don't
5 have a quorum of the ACMUI on this conference call, do
6 we? Ashley?

7 MR. EINBERG: Yes, we do.

8 MS. COCKERHAM: Yes, we do.

9 MR. FULLER: You do, you have every one
10 except -- every member except for one.

11 CHAIRMAN MALMUD: Okay. And that --

12 MS. COCKERHAM: Dr. Van Decker joined us.

13 CHAIRMAN MALMUD: Oh.

14 MR. FULLER: Yes, everybody is here.

15 CHAIRMAN MALMUD: Wonderful. May we take
16 this motion from the Subcommittee to the full ACMUI
17 for its approval? Would someone care to make that
18 motion?

19 VICE CHAIRMAN THOMADSEN: I'd make it if
20 nobody else. This is Bruce.

21 CHAIRMAN MALMUD: Thank you, Dr. Thomadsen.
22 Is there a second?

23 PARTICIPANT: Seconded.

24 CHAIRMAN MALMUD: Thank you. So, the motion
25 of the -- the proposal of the Subcommittee chaired by

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1 Dr. Welsh is that we accept this as the recommendation
2 with the approval of the full ACMUI. Any further
3 discussion?

4 DR. ZELAC: Dr. Malmud?

5 CHAIRMAN MALMUD: Yes, Dr. Zelac?

6 DR. ZELAC: I have two very small items
7 that I'd like to bring to the attention of the ACMUI
8 for possible modification of the Subcommittee's
9 report.

10 CHAIRMAN MALMUD: Please do.

11 DR. ZELAC: The first is in Section A,
12 number 1(a)(i) reads currently, "greater than 20
13 percent of the sources fall out of the intended
14 locations." My suggestion would be to change that to
15 "more than 20 percent". Excuse me. That's not quite
16 what I wanted to say. Change it to "greater than" --
17 change it to "20 percent or more".

18 In other words, it currently reads --

19 CHAIRMAN MALMUD: I understand.

20 DR. ZELAC: -- "greater than 20 percent".
21 I would suggest changing it to "20 percent or more of
22 the sources" simply for consistency with all of the
23 other sections within 3045.

24 CHAIRMAN MALMUD: Thank you. Is that
25 acceptable to Dr. Welsh?

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1 MEMBER WELSH: To me, it is acceptable.
2 Initially I had a greater than sign with the unth line
3 which meant greater than or equal to, and then I
4 didn't want to start a sentence out with a symbol so I
5 put the words in, and omitted greater than or equal
6 to. So, from my perspective that is fine. I'd like
7 to be sure that others on the Subcommittee are also
8 fine.

9 CHAIRMAN MALMUD: Drs. Langhorst, Suh,
10 Thomadsen, is that agreeable with you?

11 VICE CHAIRMAN THOMADSEN: It's agreeable.

12 MEMBER SUH: Yes.

13 CHAIRMAN MALMUD: Thank you. All right.
14 Your second suggestion, Dr. Zelac?

15 DR. ZELAC: Yes, I did. This is on page 2
16 under the section called "Terminology," and
17 specifically the definition that's given of D-90.

18 CHAIRMAN MALMUD: Yes?

19 DR. ZELAC: I believe that to be correct
20 the word "minimum" should be inserted between "the"
21 and "dose." In other words, the definition would read
22 "the minimum dose to 90 percent of the CTV."

23 CHAIRMAN MALMUD: Thank you for that. Is
24 that agreeable with you, Dr. Welsh, and members of
25 your Subcommittee?

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1 MEMBER WELSH: I'm going to ask Bruce to
2 comment on that. We have some discussion about
3 minimum. I think that this would be okay. Bruce, is it
4 okay with you to amend that definition slightly?

5 VICE CHAIRMAN THOMADSEN: That is okay. It
6 doesn't really change it, because the D-90 is both the
7 minimum dose, 90 percent of the CTV, and it is the
8 dose to 90 percent of the CTV. So, I have no
9 objection to inserting that.

10 CHAIRMAN MALMUD: Dr. Langhorst and Dr.
11 Suh, do you agree?

12 MEMBER LANGHORST: I agree.

13 MEMBER SUH: Agree.

14 CHAIRMAN MALMUD: Thank you. So, we now
15 have agreement. Do you have any other suggestions,
16 Dr. Zelac?

17 DR. ZELAC: No, that is all.

18 CHAIRMAN MALMUD: Thank you. So, we now
19 have the motion of the Subcommittee with the
20 amendments approved by the Subcommittee before the
21 full ACMUI, and any further discussion?

22 MR. FULLER: Dr. Malmud?

23 CHAIRMAN MALMUD: Yes. Who is this,
24 please?

25 MR. FULLER: This is Mike Fuller with the

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1 NRC. And I had a couple of things that I wanted to get
2 clarification on, as well.

3 CHAIRMAN MALMUD: Please.

4 MR. FULLER: First of all, with the term
5 "macroscopic," we heard Dr. Welsh say that the reason
6 that was put in there was to insure that these
7 definitions and recommendations do not apply to
8 yttrium-90 microspheres. Is that the -- so, my
9 question is, is that the only consideration or
10 concern, or is there something other? Because what
11 we're thinking of here as we try to draft a proposed
12 rule is that there might be a more clear way of
13 capturing that, or clarifying that. So, I just wanted
14 to make sure that yttrium-90 microspheres issue, if
15 that was the only thing that they were concerned
16 about. And that's why they put "macroscopic" here.

17 CHAIRMAN MALMUD: If I recall correctly,
18 our concern was that there will certainly be other
19 microspheres besides yttrium coming along, and this
20 was in anticipation of other products that will be
21 introduced in the near future.

22 MR. FULLER: Okay. All right. Well, thank
23 you for that. And, also, I had another comment; and
24 that is, if you'll recall in April of this year, the
25 ACMUI endorsed the ASTRO position. So, I want to just

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1 make it clear that if -- when you get ready to endorse
2 this -- or if, in fact, you endorse the Subcommittee
3 report, now you will be on the record of actually
4 endorsing two different positions. So, I would just
5 ask that you make sure that in your remarks or
6 whatever motion that you make that you clarify for us
7 if it's one or the other, or both, or what have you.

8 CHAIRMAN MALMUD: Thank you. Dr. Welsh, do
9 you wish to comment on that?

10 MEMBER WELSH: Yes, I'd like to comment on
11 both of Mr. Fuller's points. First, the reason why we
12 put the word "macroscopic" in was because there was
13 some discussion surrounding the original version of
14 our report that made it seem like it applied only to
15 prostate. And we admit that the original report a
16 couple of weeks ago looked an awful lot like a
17 prostate only, or prostate specific definition. So, we
18 tried to polish it to incorporate all forms of
19 Permanent Implant Brachytherapy.

20 During the teleconference we realized that
21 if we included microscopic permanent implant, such as
22 radio immuno therapy, if it could be considered that,
23 Y-90 or other isotope microsphere brachytherapy that
24 we would have to really amend this. And we didn't want
25 to go back to the drawing board once again.

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1 We felt that the edits encompassed all
2 forms of Permanent Implant Brachytherapy that are
3 visible to the naked eye, and that's why we used the
4 word "macroscopic" there. And it is intended to
5 incorporate prostate, but also other forms of
6 permanent implants with the exception of the ones that
7 we mentioned, radio immuno therapy, microsphere
8 brachytherapy.

9 The second point was regarding the ASTRO
10 definition. And, yes, the ACMUI endorsed this a
11 number of months back, but that was -- we have had a
12 number of workshops and internal conversations, and
13 meetings that have allowed us to refine the ASTRO
14 definition. And I believe that our current
15 Subcommittee report is not so much at odds with the
16 ASTRO definition, but perhaps a refinement of the
17 ASTRO definition that addresses some of the many, if
18 not all of the caveats or concerns that came up with
19 the ASTRO definition.

20 Therefore, it is reasonable for ACMUI to
21 have endorsed the ASTRO definition a number of months
22 back, but now to endorse this Subcommittee report
23 which is a final more workable version of the ASTRO
24 framework.

25 CHAIRMAN MALMUD: Thank you, Dr. Welsh.

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1 Does that answer your question, Mr. Fuller?

2 MR. FULLER: Yes, it does. And thank you
3 for that explanation.

4 CHAIRMAN MALMUD: Any other further
5 discussion of the Subcommittee's motion before the
6 full Committee? Are we willing to take a vote on it
7 now?

8 DR. HAGAN: Dr. Malmud?

9 DR. HOWE: Dr. Malmud, I have just one
10 clarification.

11 CHAIRMAN MALMUD: Who's speaking?

12 DR. HOWE: This is Dr. Howe.

13 CHAIRMAN MALMUD: Oh, Dr. Howe. Yes,
14 please.

15 DR. HOWE: As I was reading through the
16 document and the Written Directive Completion, it is
17 once the patient is released from the Authorized
18 User's control. That, to me, seems a little bit
19 ambiguous. It seems like in the proposed rule we had
20 something like the patient was released from the post
21 recovery room. I wasn't sure at what point you release
22 the patient from the Authorized User's control.

23 CHAIRMAN MALMUD: Thank you for the
24 question. I'll address it to Dr. Welsh and the
25 Committee. That's under B, Written Directive

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1 Completion, the last sentence. Am I correct? Is that
2 your concern, Dr. Howe?

3 DR. HOWE: Yes, it is.

4 CHAIRMAN MALMUD: Thank you. Dr. Welsh, Dr.
5 Howe is addressing us to Item B, Written Directive
6 Completion, the last sentence, which says, "the
7 permanent implant procedure shall be considered
8 complete once the patient is released from the
9 Authorized User's control."

10 MEMBER WELSH: Yes, this is Dr. Welsh.
11 That's a fair question. We didn't specify it right
12 there in the suggested language, but we discuss it
13 briefly in the discussion section, specifically on
14 page 4 where -- the second paragraph from the bottom,
15 beginning with, "Completion of the Written Directive
16 after implantation." We mention that this time frame
17 is consistent with other types of surgical procedures
18 allowing the physician to complete the surgical
19 documentation while the patient is in the surgical
20 recovery area.

21 So, if we -- if the concern is that the
22 present language saying that "released from Authorized
23 User's control" is too vague, perhaps we could be more
24 prescriptive and define for you what Authorized User's
25 control truly is. And surgical recovery area is

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1 something that is often recovery room, or perhaps
2 discharged from the hospital, discharged from the
3 clinic could be used.

4 MR. FULLER: Dr. Welsh, this is Mike
5 Fuller. We appreciate that clarification, and I think
6 we have what we need in the way it's written.

7 CHAIRMAN MALMUD: Thank you, Mr. Fuller.
8 And, Dr. Howe, is that satisfactory?

9 DR. HOWE: Yes. I wasn't sure whether you
10 were equating this particular type of surgery with the
11 other kinds of surgery, but if you mean the surgical
12 recovery area, that's clear.

13 CHAIRMAN MALMUD: Thank you. Thank you for
14 bringing it to our attention. All in favor of -- any
15 further discussion?

16 MR. KENT: Dr. Malmud?

17 CHAIRMAN MALMUD: Yes?

18 MR. KENT: This is John Kent. I would like
19 to ask one question, one clarification on the new Item
20 3B.

21 CHAIRMAN MALMUD: Yes?

22 MR. KENT: That it state "greater than 20
23 percent of the activity or source strength prescribed"
24 to tie it into the Written Directive.

25 CHAIRMAN MALMUD: 3B?

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1 VICE CHAIRMAN THOMADSEN: That was what we
2 added.

3 MR. KENT: That's what you added in order
4 to address the fact that there was no criteria of
5 using "incorrect" activity or source strength.

6 CHAIRMAN MALMUD: I'm sorry. Your
7 suggestion was?

8 MR. KENT: That it state "greater than 20
9 percent of the activity or source strength
10 prescribed," which ties it into the prewritten
11 directive, what was ordered, what came in, what was
12 assayed, et cetera.

13 CHAIRMAN MALMUD: Yes. Dr. Welsh, is that
14 acceptable?

15 MEMBER WELSH: It's not the word
16 "prescribed," perhaps "as called for in the pre-
17 implant written directive", or in the -- "as called
18 for in the Written Directive".

19 CHAIRMAN MALMUD: "As called for in the
20 Written Directive".

21 (Simultaneous speech.)

22 MEMBER WELSH: -- prescribed in terms of
23 source --

24 CHAIRMAN MALMUD: Yes.

25 MEMBER WELSH: But, yes, the concept is

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1 valid and the point is well taken.

2 CHAIRMAN MALMUD: Thank you.

3 DR. ZELAC: Dr. Malmud?

4 CHAIRMAN MALMUD: Yes, Dr. Zelac?

5 DR. ZELAC: Yes. Currently, the pre-
6 implantation portion of the Written Directive doesn't
7 call for anything but the treatment site, the
8 radionuclide, and the intended dose at the treatment
9 site. There's no mention there currently of the total
10 source strength to achieve that. However, the after
11 implantation portion of the Written Directive does
12 call for the total source strength, and in this case
13 exposure time is superfluous, or the total dose. So,
14 I think what we're really talking about is variance of
15 20 percent or more from the total source strength as
16 specified in the Written Directive. And, of course,
17 what portion is, in fact, the post-implant portion of
18 the Written Directive.

19 MEMBER WELSH: Dr. Zelac is right and, yes,
20 perhaps we -- I strike that phrase "pre-implant
21 Written Directive." It opens up, of course, the whole
22 other topic of should the pre-implant Written
23 Directive state the activity. I don't want to open
24 that conversation today, but to address the point at
25 hand, it probably should say "Written Directive"

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1 rather than "pre" or "post", or anything specified
2 like that.

3 CHAIRMAN MALMUD: So, the wording will be
4 just "Written Directive" without indicating pre or
5 post, or anything else. Thank you. Any further
6 comments? All in favor of the motion as amended and
7 corrected?

8 (Chorus of ayes.)

9 CHAIRMAN MALMUD: Any abstentions? Any
10 negative votes?

11 (No response.)

12 CHAIRMAN MALMUD: If not, it passes
13 unanimously. And, once again, I want to thank the
14 Subcommittee for an extraordinarily thorough job, and
15 I know how difficult it must have been. And please
16 accept our appreciation for it.

17 I believe that completes the business of -
18 - am I correct, Ashley?

19 MS. COCKERHAM: It does for my end. Anyone
20 else at headquarters?

21 MR. EINBERG: No, that completes it from
22 our end also at NRC, and I'd like to thank the
23 Subcommittee as well as the full Committee for the
24 extraordinary work here and who do the work that went
25 into this.

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1 CHAIRMAN MALMUD: Thank you, Mike Fuller
2 and Ashley, and all the other Staff from NRC. We did
3 contain the meeting to less than two hours. Thank you.

4 (Whereupon, the proceedings went off the
5 record at 1:53:34 p.m.)

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