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1 UNITED STATES OF AMERICA

2 NUCLEAR REGULATORY COMMISSION

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4 ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

5 + + + + +

6 TELECONFERENCE

7 + + + + +

8 TUESDAY,

9 FEBRUARY 7, 2012

10 + + + + +

11  
12 The teleconference convened at 12:00 p.m.  
13 Eastern Standard Time, LEON S. MALMUD, M.D., Chairman,  
14 presiding.

15 MEMBERS PRESENT:

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

17 BRUCE THOMADSEN, Ph.D., Vice Chair

18 DARICE BAILEY, Non-voting Member

19 MILTON GUIBERTEAU, M.D., Member

20 SUE LANGHORST, Ph.D., Member

21 STEVE MATTMULLER, Member

22 CHRISTOPHER J. PALESTRO, M.D., Member

23

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## 1 MEMBERS PRESENT (Continued):

2 JOHN SUH, M.D., Member

3 ORHAN SULEIMAN, Ph.D., Member

4 LAURA WEIL, Member

5 JAMES WELSH, Ph.D., Member

6 PAT ZANZONICO, Ph.D., Member

7 NRC STAFF PRESENT:

8 MICHAEL FULLER, Designated Federal Officer

9 ASHLEY COCKERHAM, Alternate Designated

10 Federal Officer

11 BRIAN McDERMOTT, Director, Division of Materials

12 Safety and State Agreements

13 PAM HENDERSON, Acting Deputy Division Director,

14 Division of Materials Safety and State

15 Agreements

16 MARIA ARRIBAS-COLON

17 SUSAN CHIDAKEL

18 SAID DAIBES, Ph.D.

19 DONNA BETH HOWE, Ph.D.

20 GRETCHEN RIVERA-CAPELLA

21 RONALD E. ZELAC, Ph.D.

22 SANDY GABRIEL, Region I

23 PATTY PELKE, Region III

24 LIZETTE ROLDAN-OTERO, Region IV

25 LATISCHA HANSON, Region IV

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1 ALSO PRESENT:

2 KEITH BROWN, University of Pennsylvania

3 KAREN COLUCCI, Albert Einstein Healthcare

4 ROBERT DANSEREAU, New York State Department of  
5 Health

6 WILLIAM DAVIDSON, University of Pennsylvania

7 RONALD ENNIS, American Society of Radiation  
8 Oncology

9 LYNNE FAIROBENT, American Association of  
10 Physicists in Medicine

11 PETER GOYER, Albert Einstein Healthcare Network

12 THOMAS HUSTON, Veterans Health Administration

13 DENNIS KEHOE, Jeppensen Radiation Oncology  
14 Center

15 RALPH LIETO, St. Joseph Mercy Hospital

16 JANETTE MERRILL, Society of Nuclear Medicine

17 SUBIR NAG, Kaiser Permanente

18 MICHAEL PETERS, American College of Radiology

19 BRADLEY PRESTIDGE, Society of Nuclear Medicine

20 JOSEPH RODGERS, Theragenics Corporation

21 GLORIA ROMANELLI, American College of Radiology

22 KAREN SHEEHAN, Fox Chase Cancer Center

23 MICHAEL SHEETZ, University of Pittsburgh

24 ERIC SOLTYCKI, Albert Einstein Healthcare  
25 Network

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CINDY TOMLINSON, American Society for Radiation  
Oncology

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

(12:02 p.m.)

MR. FULLER: Good afternoon. This is Mike Fuller. We'll go ahead and get started. I have some prepared remarks here for this call.

As the designated federal officer for this meeting, I am pleased to welcome you to this public meeting of the Advisory Committee for the Medical Uses of Isotopes.

My name is Mike Fuller. I am the team leader of the medical radiation safety team in the Radioactive Materials Safety Branch. And I have been designated as the federal officer for this Advisory Committee in accordance with 10 CFR Part 7.11. Present today as the alternate designated federal officer is Ashley Cockerham. She is the ACMUI Coordinator.

This is an announced meeting of the Committee. It is being held in accordance with the rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission. The meeting was announced in the February 13th, 2012 edition of the Federal Register. I'm sorry. That must be January 13th. Forgive me. That was, again, in the Federal Register, volume 77, page 2098.

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

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

14           At this point, I would like to perform a  
15 roll call of the ACMUI membership that is  
16 participating today. First, Dr. Malmud?

17           CHAIR MALMUD: Present.

18           MR. FULLER: Dr. Thomadsen?

19           VICE CHAIR THOMADSEN: Present.

20           MR. FULLER: Ms. Darice Bailey?

21           MEMBER BAILEY: Present.

22           MR. FULLER: Dr. Mickey Guiberteau?

23           MEMBER GUIBERTEAU: Present.

24           MR. FULLER: Dr. Sue Langhorst?

25           (No response.)

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1 MS. COCKERHAM: I did hear her say she was  
2 on the line earlier.

3 MR. FULLER: I thought I did, too.

4 Dr. Langhorst, are you on the line?

5 MEMBER LANGHORST: I'm sorry. I'm here.  
6 Can you hear me?

7 MR. FULLER: Yes. We can hear you now.

8 MEMBER LANGHORST: Okay.

9 MR. FULLER: Mr. Steve Mattmuller?

10 MEMBER MATTMULLER: Present.

11 MR. FULLER: Dr. Christopher Palestro?

12 MEMBER PALESTRO: Present.

13 MR. FULLER: Dr. John Suh?

14 MEMBER SUH: Present.

15 MR. FULLER: Dr. Orhan Suleiman?

16 MEMBER SULEIMAN: Present.

17 MR. FULLER: Dr. William Van Decker?

18 (No response.)

19 MR. FULLER: Ms. Laura Weil?

20 CHAIR MALMUD: I heard Laura sign on  
21 earlier.

22 MEMBER WEIL: I'm here.

23 MR. FULLER: Okay. Dr. James Welsh?

24 MEMBER WELSH: Here.

25 MR. FULLER: Dr. Pat Zanzonico?

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1 MEMBER ZANZONICO: Present.

2 MR. FULLER: Okay. I would, first of all,  
3 note that a quorum has been established and met. I  
4 would also note that Ms. Bailey does not have voting  
5 privileges at this time, but she will listen and speak  
6 on behalf of the Agreement States.

7 Now I will ask NRC staff members who are  
8 present to identify themselves. I'll start with  
9 individuals in the room here at NRC headquarters, and  
10 then I will go out to the phone to each of the NRC  
11 regions and other staff that we know are on the line.

12 Okay.

13 So, again, my name is Mike Fuller. And  
14 then?

15 DR. HOWE: Dr. Donna Beth Howe, medical  
16 team.

17 MS. CHIDAKEL: Susan Chidakel with the  
18 Office of General Counsel.

19 MS. HENDERSON: Pam Henderson, FSME.

20 MR. MCDERMOTT: Brian McDermott, FSME.

21 DR. DAIBES: Said Daibes, FSME.

22 MS. RIVERA-CAPELLA: Gretchen  
23 Rivera-Capella, medical team.

24 MR. FULLER: Okay. And then also do we have  
25 members -- I'm sorry -- NRC headquarters employees who

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1 are on the phone?

2 MS. ARRIBAS-COLON: Yes. Maria

3 Arribas-Colon.

4 DR. ZELAC: Ronald Zelac, medical team.

5 MS. COCKERHAM: Ashley Cockerham, also with  
6 the medical team.

7 MR. FULLER: Okay. We will go out to the  
8 regions, then. Region I?

9 MS. GABRIEL: Sandy Gabriel.

10 MR. FULLER: Anyone else from Region I?

11 (No response.)

12 MR. FULLER: Okay. Region III?

13 MS. PELKE: Patty Pelke.

14 MR. FULLER: Okay. Region IV?

15 MS. ROLDAN-OTERO: Lizette Roldan-Otero.

16 MS. Hanson: Latischa Hanson, DNMS

17 Inspections.

18 MR. FULLER: Okay. At this time I would  
19 like to ask Ashley Cockerham to call the roll for  
20 those individuals, members of the public, who have  
21 indicated that they plan to participate.

22 MS. COCKERHAM: Okay. First we have Dave  
23 Adler?

24 (No response.)

25 MS. COCKERHAM: Dr. Keith Brown?

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1 DR. BROWN: Here.

2 MS. COCKERHAM: Karen Colucci?

3 MS. COLUCCI: Present.

4 MS. COCKERHAM: Robert Dansereau?

5 MR. DANSEREAU: Here.

6 MS. COCKERHAM: Will Davidson?

7 MR. DAVIDSON: Here.

8 MS. COCKERHAM: Dr. Ronald Ennis?

9 DR. ENNIS: Here.

10 MS. COCKERHAM: Lynne Fairobent?

11 MS. FAIROBENT: Here.

12 MS. COCKERHAM: Joseph Goldstein?

13 (No response.)

14 MS. COCKERHAM: Peter Goyer?

15 MS. COLUCCI: He will be attending shortly.

16 MS. COCKERHAM: Okay. Thank you.

17 Dr. Michael Hagan?

18 (No response.)

19 MS. COCKERHAM: Kathi Haldeman?

20 (No response.)

21 MS. COCKERHAM: Dr. Thomas Huston?

22 DR. HUSTON: Present.

23 MS. COCKERHAM: Mary Ellen Jafari?

24 (No response.)

25 MS. COCKERHAM: Dennis Kehoe?

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1 MR. KEHOE: Here.

2 MS. COCKERHAM: Ralph Lieto?

3 MR. LIETO: Present.

4 MS. COCKERHAM: Janette Merrill?

5 MS. MERRILL: Present.

6 MS. COCKERHAM: Michael Peters?

7 MR. PETERS: Here.

8 MS. COCKERHAM: Dr. Bradley Prestidge?

9 DR. PRESTIDGE: Here.

10 MS. COCKERHAM: Joe Rodgers?

11 MR. RODGERS: Present.

12 MS. COCKERHAM: Gloria Romanelli?

13 MS. ROMANELLI: Here.

14 MS. COCKERHAM: Karen Sheehan?

15 MS. SHEEHAN: Here.

16 MS. COCKERHAM: Michael Sheetz?

17 MR. SHEETZ: Present.

18 MS. COCKERHAM: Eric Soltycki?

19 MR. SOLTYCKI: Here.

20 MS. COCKERHAM: Did I get close on that

21 one?

22 MR. SOLTYCKI: Very close.

23 MS. COCKERHAM: Cindy Tomlinson?

24 MS. TOMLINSON: I'm here.

25 MS. COCKERHAM: Boris Tsenov?

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1 (No response.)

2 MS. COCKERHAM: Is there anyone else I did  
3 not identify?

4 DR. NAG: Subir Nag.

5 MS. COCKERHAM: Oh. Hi, Dr. Nag.

6 MS. SHEEHAN: Hi. This is Karen Sheehan. I  
7 am here.

8 MS. COCKERHAM: Thanks, Karen. Okay. That's  
9 it for me, Mike.

10 MR. FULLER: Okay. Thank you, Ashley.

11 Following a discussion of the scheduled  
12 item, the ACMUI Chairman, Dr. Leon Malmud, at his  
13 option, may entertain comments or questions from  
14 members of the public who are participating with us  
15 today.

16 I would also like to add that the handouts  
17 and agenda for this meeting are available on NRC's  
18 public website.

19 At this point I would like to turn the  
20 meeting over to Brian McDermott. Brian is the Director  
21 of the Division of Material Safety and State  
22 Agreements here at NRC.

23 MR. McDERMOTT: Thanks, Mike.

24 I would like to welcome the ACMUI to this  
25 teleconference. At today's conference, we will be

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1 discussing the ACMUI's Subcommittee report on  
2 permanent implant brachytherapy medical reporting.

3 This is an important topic to the NRC as  
4 well as to the medical community. And I would like to  
5 thank the Committee for their continued hard work in  
6 this area. The staff is looking forward to the ACMUI  
7 finalizing its recommendations.

8 I would also like to take this opportunity  
9 to welcome Ms. Darice Bailey to the Committee. Ms.  
10 Bailey was selected as the State Government  
11 Representative in December. She is currently a health  
12 physicist for Texas' Department of State Health  
13 Services, where she is Manager of the Radioactive  
14 Materials Group.

15 Finally, I would like to just note that  
16 the staff is looking forward to meeting with the ACMUI  
17 members in person at our headquarters here in  
18 Rockville, Maryland on April 16th and 17th.

19 At this point I would like to turn the  
20 meeting back over to Dr. Malmud.

21 CHAIR MALMUD: Thank you.

22 This is Leon Malmud. In the interest of  
23 time, I would like to turn the meeting over  
24 immediately to the Chairman of the Subcommittee: Dr.  
25 Welsh.

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1 MEMBER WELSH: Good morning, everyone. The  
2 purpose of today's call is to discuss yet another  
3 revision of the Permanent Implant Brachytherapy  
4 Subcommittee so-called final report.

5 As most of you are aware, the --

6 THE REPORTER: I'm sorry to interrupt.  
7 This is the Court Reporter. Dr. Welsh here is sort of  
8 fading in and out.

9 MEMBER WELSH: Okay. Is that any better?

10 MS. COCKERHAM: This is Ashley. If everyone  
11 else could press \*6 to mute their lines who is not  
12 speaking? Thank you.

13 MEMBER WELSH: Okay. Can you hear me?

14 THE REPORTER: I can. Please continue.

15 MEMBER WELSH: The Subcommittee has had a  
16 number of revisions to the reports that date back  
17 several years. For example, there was one in 2008 that  
18 contained much of what is going to be discussed today.  
19 There was another one in 2010. Most recently there was  
20 one in late 2011, which was a significant change from  
21 previous suggestions contained in the previous  
22 reports.

23 In the interim between that  
24 October-December Subcommittee report and the report  
25 that is being discussed today, there were a number of

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1 communications from experienced practitioners,  
2 professional organizations, and others regarding the  
3 content within our 2011 report. And some have voiced  
4 the opinion that there would be some practical  
5 challenges to implementation of the 2011 suggestions.

6 Having said that, I believe that the 2011  
7 suggested definition for medical event was quite good.  
8 I think that the one that we have now that was  
9 modified in January 2012 is also quite good. I do  
10 think that when it comes to practical challenges and  
11 some specific content of the report; for example, use  
12 or not use of D-90, that in my opinion, the 2012  
13 version is slightly superior.

14 But before I go any further, I should  
15 mention that the Subcommittee, although it was only a  
16 handful of people, four people, there was not a  
17 unanimous decision. There was not a consensus in our  
18 recommendation. And there is a very strong opposition  
19 to some of the content contained within. And it is  
20 added as an addendum to this Subcommittee report and  
21 titled "Minority Report." And I would ask the  
22 Subcommittee member who led that particular section to  
23 speak up when there are controversies that we need to  
24 be reminded of.

25 Basically, there are a couple of

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1 significant differences between the late 2011 versus  
2 the 2012 report. And the principal difference is that  
3 in the latest rendition, the 2012 Subcommittee  
4 recommendations, we do not advocate use of D-90 in any  
5 form or fashion when it comes to medical event  
6 definition.

7 And I will say that this is because after  
8 many years of arguing against using D-90 or dose or  
9 for prostate brachytherapy as a specific example, I  
10 and many others have come to the conclusion that dose  
11 is not an appropriate parameter to use when it comes  
12 to the definition of the medical event, even if it is  
13 being used, as in the 2011 version, to basically  
14 screen out possible medical events and because of the  
15 Boolean algebra prevent something being called a  
16 medical event. I personally and others on the  
17 Subcommittee were not in favor of the use of D-90.

18 Another change to the Subcommittee report  
19 is the omission of the octant concept. The octant  
20 concept was introduced in the late 2011 version. And  
21 it's an elegant concept, which logically makes a lot  
22 of sense, but some members felt that this could be  
23 very difficult to implement on a daily basis for  
24 regulatory purposes.

25 And the third difference between the late

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1 2011 and the 2012 version is the inclusion of the  
2 attestation by the authorized user in the written  
3 directive completion.

4 Both versions include the written  
5 directive completion. The latest version includes an  
6 attestation by the authorized user in this written  
7 directive completion that specifically mentions that  
8 the seed distribution is in accordance with the plan.

9 That is a key point that it is in accordance with the  
10 plan and, therefore, can't be objectively compared to  
11 that plan.

12 So, with that introduction, I will bring  
13 it back to Dr. Malmud.

14 CHAIR MALMUD: Thank you.

15 Are you able to hear me? Are you able to  
16 hear me?

17 DR. NAG: We are muted. I have to unmute  
18 before we can say, "Yes, we can hear you."

19 CHAIR MALMUD: Thank you.

20 We have heard the report of the Chairman  
21 and the background for the recommendations. The item  
22 is now open for discussion.

23 I believe you all have received or have  
24 access to the material that was sent out, which is  
25 entitled "The Advisory Committee on Medical Isotopes

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1 Permanent Implant Brachytherapy Final Report, Modified  
2 January 2012." And the item is open for discussion.

3 Is there a --

4 MEMBER ZANZONICO: Yes. This is Pat  
5 Zanzonico.

6 I have a question with respect to the  
7 attestation required. As it's stated in the draft  
8 report, the authorized user is attesting to the fact  
9 that the actual seed placement and so forth was done  
10 according to the pre-op plan. But shouldn't there be a  
11 provision where the physician can state that they  
12 purposely deviated from the pre-op plan because of  
13 unforeseen circumstances interoperatively or is there  
14 some other provision that I overlooked in the draft  
15 report to account for that?

16 CHAIR MALMUD: Dr. Zanzonico's question is  
17 to Dr. Welsh or any member of the Committee. Dr.  
18 Welsh?

19 MEMBER WELSH: This is Jim Welsh. I could  
20 attempt to answer that for Dr. Zanzonico.

21 The wording in the current draft states  
22 that "The authorized user should provide a statement  
23 in this written directive completion attesting that  
24 the permanently implanted sources had been placed in  
25 accordance with the planned distribution."

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1           So it does not specifically say that we  
2 must be using a pre-plan or that we're using a plan  
3 that was generated before the procedure or whether it  
4 was an intraoperatively, actively modified, on-the-fly  
5 kind of plan. It just says "planned distribution" to  
6 keep it general.

7           So that it does, in essence, attempt to  
8 answer your question or anticipate your question so  
9 that it is not specifically a pre-plan that we are  
10 talking about. We are talking about the final planned  
11 distribution. And I suppose if there is objection to  
12 the way it is worded, we should say, "in accordance  
13 with the final planned distribution."

14           DR. NAG: This is Dr. Nag. I heartily agree  
15 with your revised statement. And I think your revised  
16 statement would make it much more clear.

17           CHAIR MALMUD: Thank you, Dr. Welsh and Dr.  
18 Nag.

19           Dr. Welsh, are you recognizing that the  
20 word "final" be placed in there as a modifier?

21           MEMBER WELSH: I suppose if others were as  
22 concerned as Dr. Zanzonico is, that putting the word  
23 "final" planned distribution would be acceptable and  
24 is appropriate.

25           CHAIR MALMUD: This is --

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1 MEMBER WELSH: I'll ask others on the  
2 Subcommittee if they have any objections or feelings  
3 on this, but I think that it does clarify things, as  
4 Dr. Zanzonico has pointed out.

5 CHAIR MALMUD: This is Malmud. Dr.  
6 Langhorst, Dr. Suh, Dr. Thomadsen, do you agree?

7 VICE CHAIR THOMADSEN: This is Thomadsen.  
8 I would abstain.

9 CHAIR MALMUD: Dr. Thomadsen abstains. Dr.  
10 Langhorst, Dr. Suh?

11 MEMBER SUH: This is Dr. John Suh. I am  
12 okay with the addition of the word "final."

13 CHAIR MALMUD: Thank you.

14 Dr. Langhorst?

15 MEMBER LANGHORST: This is Sue Langhorst. I  
16 think the question that Pat was asking was whether the  
17 authorized user could also document any changes that  
18 he or she had to make during this surgical implant.

19 And I agree that the authorized user  
20 should be able to make those changes as if there is a  
21 -- surgical implant in medical and other bits of  
22 challenges make it important that that authorized user  
23 be able to make changes during that procedure.

24 I am not sure if adding the word "final"  
25 right there is the right way to do that, but I do

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1 agree with the point that Pat was making.

2 One thing implicit with all of this is  
3 that the authorized user is either doing this  
4 procedure or is right there in the operating room  
5 helping to direct this procedure. And that is probably  
6 something that is subtle in this statement, but I  
7 wanted to make sure people understood the intent that  
8 the authorized user needed to be present.

9 MEMBER WELSH: This is Dr. Welsh again. If  
10 I might speak, Dr. Malmud?

11 CHAIR MALMUD: Indeed.

12 MEMBER WELSH: I would slightly disagree  
13 with Dr. Langhorst here and disagree with her  
14 interpretation of what Dr. Zanzonico is asking. I  
15 guess ultimately we have an easy way of answering this  
16 question.

17 But if you are arguing that we're saying  
18 that Dr. Zanzonico's question was regarding  
19 documentation changes that need to be made during the  
20 operative procedure, I would say that the sentence  
21 right before that addresses that specific point.

22 What happens there, it says, "Unusual  
23 aspects of the procedure, including patient-related  
24 limitations, should be documented in this written  
25 directive completion."

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1           So if there were any changes I believe  
2 that could be made on the fly, any slight adjustments,  
3 any challenges because of patient anatomy, they would  
4 be documented within this written directive  
5 completion. And then there would probably be something  
6 saying that because of these anatomical changes, the  
7 plan had to be adjusted slightly.

8           And so the final plan is that the  
9 authorized user should be attesting to. So I don't  
10 think that adding the word "final" is going to affect  
11 this concept in any way. And, for that reason, I would  
12 remain in favor of inserting it.

13           MEMBER SULEIMAN: This is Orhan Suleiman.  
14 Can I ask a question?

15           CHAIR MALMUD: Yes, please, Dr. Suleiman.

16           MEMBER SULEIMAN: Okay. Is that last  
17 sentence there really necessary? You have already  
18 stated -- I'm using the last phase of the procedure,  
19 including patients -- that patients should be  
20 documented in this written directive completion. What  
21 value does the last sentence add?

22           MEMBER WELSH: May I ask which sentence  
23 specifically?

24           MEMBER SULEIMAN: The sentence that says,  
25 "The authorized user should provide a statement in

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1 this written directive completion attesting that the  
2 permanently implanted sources had been placed in  
3 accordance with the planned distribution."

4 MEMBER WELSH: I can take a stab at that.  
5 This is Jim Welsh. I think that it is absolutely  
6 imperative that such a statement be included because  
7 this is the line that holds the authorized user  
8 responsible for the final seed distribution. And this  
9 is one way that we are attempting to deal with the  
10 seed distribution problem that has been argued for the  
11 past several years.

12 For example, if all of the seeds are in  
13 one line or if all of the seeds are bunched in one  
14 spot, such a bizarre situation could fly under the  
15 radar of many of the previous attempts at a medical  
16 event definition. And that is why, in part, the octant  
17 concept evolved, but because the octant concept has  
18 some limitations or inherent difficulties in my  
19 personal opinion -- and Dr. Thomadsen has a different  
20 perspective -- the alternative is this statement of  
21 attestation saying that the seeds have been placed in  
22 accordance to the computerized plan. And that specific  
23 statement I believe is important.

24 MEMBER SULEIMAN: That confuses me. So what  
25 if it deviated from the plan? Then don't they explain

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1 that? And isn't that what's said in the preceding  
2 sentence?

3 MEMBER WELSH: It is. So if there is a very  
4 challenging situation, the plan would have to be  
5 modified. And sometimes anatomical considerations or  
6 technical limitations will preclude achieving a seed  
7 distribution that is in exact compliance with the  
8 called-for seed distribution on the computer. But this  
9 is where I think that the two sentences, one stating  
10 additional circumstances that were encountered,  
11 technically or anatomically; and the other attesting  
12 that the final distribution was placed as close as  
13 humanly possible to the final desired plan.

14 MEMBER SULEIMAN: Okay. So those last two  
15 sentences really mean you're going to validate or  
16 attest that, in fact, the procedure went as planned or  
17 it deviated and these are the reasons why it deviated?  
18 That's really what you want to say in those two  
19 sentences.

20 MEMBER WELSH: So you make a positive  
21 statement that everything went as planned or it didn't  
22 and this is why. And that is -- I would consider that  
23 all part of the practice of medicine.

24 DR. NAG: This is Dr. Nag. Can I say a  
25 couple of words?

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1 CHAIR MALMUD: Please?

2 DR. NAG: Okay. At the Asheville meeting,  
3 where we had lots of experienced users who were doing  
4 this, we came up with this because the subnormal  
5 distribution or distribution of seed not in accordance  
6 with a pre-plan would be used for two reasons: one,  
7 that you purposely deviated from the plan, either  
8 because there was bone or some other anatomical  
9 structure preventing you from putting it there; -- and  
10 that's the reason for the first sentence -- or that  
11 because of error or because of something that you did  
12 not foresee and there was a misplacement. So we wanted  
13 to clarify the two differences.

14 If it's a misplacement, then it could be a  
15 medical event; whereas, if it was done purposely  
16 because of certain reasons the authorized user wanted  
17 to do, then it would not be a medical event. So that  
18 was the reason for the two sentences. And if the  
19 authorized user said that this was the way he wanted  
20 to do it, then it's quite different from yes, he  
21 wanted to do it that way, but then, you know, by  
22 mistake, they put the needle in the wrong place.

23 CHAIR MALMUD: Thank you.

24 Other questions regarding addition of the  
25 word to the existing sentences in section D?

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1 DR. NAG: This is Dr. Nag. I have a couple  
2 of comments. Since I had been involved not only while  
3 I was at the ACMUI, but also in the actual committees,  
4 first of all, I wish to congratulate the Subcommittee  
5 on their revised recommendations.

6 I heartily agree that the D-90 concept  
7 cannot be used as a regulatory means. The D-90 concept  
8 is only to be used for seeing the prognosis and so on.  
9 I heartily agree with that.

10 I also agree with taking the octant  
11 concept out. The concept is very good for theoretical  
12 reasons. However, even if you use the octant concept,  
13 you could bunch up all the seed in the center, right  
14 in the urethra, and provided that all of the seeds are  
15 in the different octant until it will qualify as the  
16 octant, but it will still go up the urethra.

17 Also, there are many people who do not  
18 implant the -- or the organ homogeneously. And in that  
19 case, the octant concept would not work.

20 So one concern I still do have now in the  
21 new one is that the intra-target structures, such as  
22 the urethra, that those do at least 5 cc at seed 150  
23 percent of that structure exposed dose.

24 The words I do not like is "the expected  
25 dose made on an improved implant dose distribution."

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1 The reason I do not like that is if the expected dose  
2 was extremely low, then 150 percent of that extremely  
3 low dose is still extremely low. And it's not of any  
4 clinical concern, but would be defined as a medical  
5 event in this case.

6 In the urethra, we have come very close to  
7 the 100 percent or 150 percent of the prescribed dose.  
8 So for the urethra, it may not matter too much. But  
9 I'm thinking that this permanent implant -- this rule  
10 is really for all permanent implants. And in that  
11 case, those are low. And 150 percent of a low amount  
12 is still low.

13 I would like to have that word "expected  
14 dose" somehow reworded so that it has some context to  
15 the tolerance of that structure. A 150 percent dose is  
16 nowhere close to the following of that structure.  
17 It's basically not a problem.

18 And I would like to hear the  
19 Subcommittee's response to that.

20 MEMBER WELSH: Dr. Malmud, this is Jim  
21 Welsh. If I could attempt a response?

22 CHAIR MALMUD: Please do.

23 MEMBER WELSH: First, I would like to  
24 return briefly to our discussion at hand, which was  
25 the question of whether or not inserting the word

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1 "final" would be worthwhile. And I continue to believe  
2 that, thanks to Dr. Zanzonico's question, that  
3 introducing the word "final" may be appropriate.

4 To answer Dr. Nag's question, I think it's  
5 a legitimate point, but I would point out first that  
6 the section A.2 regarding normal tissue structures is  
7 an a, 2(a) and 2(b). And it's an "or" there, but it is  
8 divided into neighboring structures for (a), which  
9 would be things such as the bladder or rectum and  
10 prostate, which we are all familiar with. And (b) is  
11 for intra-target structure. And the only intra-target  
12 structure that comes to mind in prostate is the  
13 urethra.

14 I would agree that this section as our  
15 recommended definition perhaps could benefit from some  
16 modifications, but I don't think that we would have  
17 too much difficulty with the current wording in that  
18 it is the expected dose based on the approved  
19 pre-implant dose distribution.

20 And, as Dr. Nag has pointed out, the  
21 urethra dose is often somewhere around 100 percent of  
22 the dose to the PTV, but it would have to exceed 150  
23 percent of the expected dose. And sometimes the  
24 expected dose depending on the specifics of the plan  
25 for the urethra could be considerably higher if it is

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1 not peripherally loaded, for example, if the seed  
2 distribution is relatively uniform the dose to the  
3 urethra could be maybe 150 percent of the dose to the  
4 perimeter, to the CTV or PTV. And it would have to  
5 exceed 150 percent of the expected dose, which, as I  
6 said, might be 150 percent of the PTV.

7 So if we were talking about 200 gray to  
8 the urethra, it would have to be 150 percent above  
9 that to trigger a medical event.

10 Having said all of that, I am not strongly  
11 opposed to introduction of tolerance, which is, in  
12 reality, more important. And the challenge would be  
13 tolerance would differ organ to organ, site to site,  
14 procedure to procedure. And unless we were going to  
15 put in the term "tolerance," rather than "planned,  
16 expected dose," we would have some difficulty with  
17 this.

18 "Tolerance," I suppose, could solve the  
19 problem, but then we would have to have specific  
20 definitions of the tolerance for each individual organ  
21 in question. And this becomes a little bit of a  
22 regulatory challenge; whereas, 150 percent of the  
23 planned dose is much easier to regulate and inspect  
24 because it doesn't assume a necessary additional  
25 knowledge on the part of the inspector.

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1 DR. NAG: This is Dr. Nag. May I respond?

2 CHAIR MALMUD: Yes.

3 DR. NAG: Okay. So I agree to some extent  
4 with Dr. Welsh. However, you have to remember a couple  
5 of things. Number one, this rule is going to be not  
6 only for the prostate, but for any permanent implant.

7 I have done permanent implant, say, in the  
8 liver. In the middle of the liver, you are going to  
9 have the inferior vena cava. Now, those that I am  
10 giving are quite low, but the tolerance of the  
11 inferior vena cava is very high.

12 I could easily get 200 percent of my  
13 expected dose to the vena cava and it wouldn't be a  
14 problem. However, by this definition, it would become  
15 a problem, number one.

16 Number two, even in the urethra, -- let's  
17 say you are going to make the supply only to the  
18 urethra -- the urethra volume, the total volume, at  
19 least on the implants that I do, the total volume of  
20 the urethra, is nowhere close to five cc. Therefore,  
21 having the statement of 5 cc, of a dose to at least 5  
22 cc, is 150 percent, is basically meaningless because  
23 unless there is an unusually large or unusually wide  
24 urethra, you are not going to come to anywhere close  
25 to 5 cc. I hope that was the statement in for

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1 consideration.

2 So I would suggest that the 150 percent of  
3 the expected dose is not what the physicians want to  
4 refer to. We would consider it a misadministration of  
5 medical event if it related to the tolerance of that  
6 dose. Otherwise, I think that, you know, we have to  
7 maybe put an "and," that it says a dose exceeded 150  
8 percent of the doctor's expected dose and expected  
9 tolerance, or something like that.

10 I haven't given enough thought as to how  
11 that sentence is to be reworded, but it has to be  
12 reworded. Otherwise, you are going to have some  
13 inappropriate definitions.

14 Thank you.

15 DR. ENNIS: This is Ron Ennis. Could I  
16 talk?

17 CHAIR MALMUD: I have a question for  
18 clarification. What is the sentence to which you are  
19 referring? The proposed sentence or --

20 DR. NAG: Okay. So this is the sentence in  
21 the recommendation, A.2(b).

22 CHAIR MALMUD: Okay. So you are  
23 recommending that that sentence be somehow modified?

24 DR. NAG: Yes.

25 CHAIR MALMUD: So we now have -- before we

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1 move on to that sentence, may we first resolve the  
2 issue of the addition of the word "final" to the  
3 recommendation B, paragraph 1, the last sentence?

4 Three out of four of the Subcommittee  
5 members agreed. One abstained with the insertion of  
6 the word "final." As Chair of the Subcommittee, Dr.  
7 Welsh, is that acceptable?

8 MEMBER WELSH: This is Dr. Welsh here. To  
9 me, that is acceptable. If three out of the four are  
10 in agreement here, it is as good as I can expect on  
11 this particular subject because our abstaining member  
12 has a very, very different perspective, which I'm sure  
13 will be expounded on shortly. So yes, I am comfortable  
14 with the addition of that word.

15 CHAIR MALMUD: May we take that as a motion  
16 to this, to add to this recommendation?

17 (No response.)

18 CHAIR MALMUD: If so, since the  
19 Subcommittee is in favor of the motion three to four,  
20 three out of four, is there a second to a member of  
21 the Subcommittee?

22 MEMBER SUH: I second the motion. This is  
23 John Suh.

24 CHAIR MALMUD: Thank you.

25 And now we have a motion that has been

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1 seconded. It is now open for discussion. And this  
2 would give Dr. Thomadsen the opportunity to express  
3 the reasons for his abstention if he wishes to do so.

4 VICE CHAIR THOMADSEN: Hi. I abstained  
5 because I am against the attestation altogether.

6 CHAIR MALMUD: Thank you. Is that all you  
7 wish to say?

8 VICE CHAIR THOMADSEN: On this motion. On  
9 this motion, yes.

10 CHAIR MALMUD: Thank you.

11 So the motion has been moved and seconded.

12 Any further discussion of the motion?

13 (No response.)

14 CHAIR MALMUD: There seems to be no further  
15 discussion of the motion. May we move on the motion?  
16 All in favor of this motion, which is the addition of  
17 the word "final" to the last sentence of  
18 recommendation B, paragraph 1? All in favor?

19 (Whereupon, there was a chorus of "Ayes.")

20 CHAIR MALMUD: Any against?

21 (No response.)

22 CHAIR MALMUD: Any abstentions?

23 VICE CHAIR THOMADSEN: This is Thomadsen.  
24 I abstain.

25 CHAIR MALMUD: One abstention. So the

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1 motion carries.

2 Now, if we may, we will move on to another  
3 item which has been raised. And that is an item raised  
4 by Dr. Nag. Am I correct, Dr. Nag?

5 DR. NAG: Yes.

6 CHAIR MALMUD: Would you care to express  
7 your concern and recommendations?

8 DR. NAG: I had already expressed my  
9 concern. My recommendation is that sentence be  
10 modified or eliminated. And that was the intent of its  
11 structure, such as the urethra and the prostate  
12 implant as an example, but those 2 at least 5 cc  
13 contiguously had received 150 percent of that  
14 structure's expected doses on approved pre-implant  
15 dose distribution.

16 As I had mentioned previously, you know,  
17 just now, that sentence will not apply to the prostate  
18 because the urethra volume is not five cc less than  
19 that. And, number two, it becomes difficult or  
20 dangerous when it applies to other structures where  
21 the normal tissue tolerance may be way higher than  
22 what the expected dose to that normal tissue would be.  
23 So that sentence to me does not have -- I have great  
24 concern for that sentence,

25 DR. ENNIS: This is Ron Ennis. Could I

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1 speak?

2 CHAIR MALMUD: Please do.

3 DR. ENNIS: Thank you.

4 So I share with Dr. Nag some of the  
5 concerns and had a potential alternative suggestion.  
6 In particular, the volume issue, five cc is  
7 essentially irrelevant when it comes to the urethra,  
8 which is generally only about a cc in volume. So there  
9 would never be a medical event on that basis.

10 And also having in mind, as Dr. Nag is  
11 suggesting, that we want this to be as universal as  
12 possible, but also needed to work and not be overly  
13 cumbersome with, I think, a different dose for every  
14 possible tissue in the body would really be  
15 unworkable. Another possibility would be that the  
16 medical event be considered that if we define it by a  
17 proportion of the normal tissue that we're discussing  
18 so that the highest dose would be, let's say, a 5  
19 percent, if 5 percent of the normal tissue got a dose,  
20 more than 250 percent of its prescribed dose, that  
21 that I think would be something that could be  
22 uniformly considered a medical event, would be a  
23 simple thing to apply. I think it could apply across  
24 all normal tissues in a uniform way.

25 I think it would avoid Dr. Nag's concern

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1 about higher than prescribed doses at the low end  
2 being called a clinical event because this is so much  
3 higher than the prescribed events that it would be  
4 unlikely that it would trigger a medical event without  
5 it being of some clinical relevance as well.

6 So I would propose that as a potential  
7 alternative definition.

8 CHAIR MALMUD: Thank you, Dr. Ennis.

9 DR. NAG: This is Dr. Nag. My suggestion  
10 would be to eliminate that sentence altogether  
11 because, even with 250 percent and if you're taking to  
12 test a small, you know, five percent of that, the  
13 inhomogeneity within a structure that is to be  
14 implanted is not something that is within the  
15 jurisdiction of the NRC. It is within the jurisdiction  
16 -- it is medical, and it is not in the jurisdiction of  
17 NRC to define actually what shows in the implant.

18 And I would highly suggest that the NRC  
19 refrain from trying to dictate what should be given to  
20 every cell within the implanted tissue. Outside the  
21 implanted tissue, you do not want to harm normal  
22 tissue but not within the target volume.

23 CHAIR MALMUD: Thank you, Dr. Nag. Are you  
24 recommending, therefore, that under recommendations A,  
25 subheading 2 for normal tissue structures, that only

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1 part B remain and that part A be struck?

2 DR. NAG: No, no, no. The other way around.

3 Part A remains. Part B is struck out because if the  
4 target -- how that dose is distributed within the  
5 target is not really within NRC's jurisdiction.

6 CHAIR MALMUD: Thank you for that  
7 clarification.

8 So Dr. Nag's recommendation is that under  
9 capital A, part 2, that we leave only one section in.

10 DR. NAG: That part A remains. Part B, even  
11 if it were to remain the way it is, has absolutely no  
12 meaning because the urethra will never be five cc.

13 We have tried to think of different ways  
14 of trying to regulate something within the volume.  
15 And that is almost impossible to do and not have some  
16 other unintended consequence if you are trying to  
17 manipulate the dose within a target.

18 CHAIR MALMUD: Thank you, Dr. Nag.

19 So we have two opinions. One is Dr. Nag's  
20 that part B be struck. The other is Dr. Ennis'  
21 suggestion of the 5 percent more than 250 percent.

22 Dr. Ennis, do you wish to comment?

23 DR. ENNIS: So I think that if we are  
24 trying to define medical event as something that is,  
25 you know, egregious and a potential public harm, then

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1 the structures, even within the target, are important.  
2 And some definition of a medical event, therefore,  
3 makes sense.

4 It is always going to be a bit of a  
5 challenge, I think. And it is somewhat imperfect. I  
6 think we could quibble a little bit about the percent  
7 volume and the percent prescribed dose above  
8 thresholds. And maybe 10 percent of the volume and 300  
9 percent would make Dr. Nag a little more comfortable.  
10 I certainly don't feel strongly about the exact  
11 parameters.

12 I think the five percent is a good one  
13 that would really work across the board. A little bit  
14 of wiggle on that, as I just mentioned, I think would  
15 be acceptable. I would be less comfortable with the  
16 definition that excluded normal tissues within the  
17 target from any possibility of being a medical event.  
18 I don't think that that is logical.

19 I think the normal tissues in the middle  
20 of the target are crucial to make sure they are  
21 protected. And obviously we need, as Dr. Nag has  
22 alluded, some flexibility. And we have some  
23 flexibility with that. It can't be a rigorous  
24 definition that is at 100 percent and nothing above  
25 but within some reasonable guidelines, allowing for

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1 dose inhomogeneity of brachytherapy, I think that  
2 something like this would be reasonable.

3 DR. NAG: This is Dr. Nag.

4 CHAIR MALMUD: Okay. Dr. --

5 DR. NAG: We can only put a limitation if  
6 it is eliminated with the tolerance of that normal  
7 tissue. You cannot have a certain percentage of that  
8 expected dose to that tissue if it is not related to  
9 the tolerance of that tissue. If we make it 300  
10 percent, 400 percent, if it is nowhere close to the  
11 tolerance of that tissue, the percentage has no  
12 meaning, 300 percent or 400 percent. If that is within  
13 a target, within something you want to implant, then  
14 the tolerance -- it has to be related to the  
15 tolerance. Otherwise, a percentage of the expected  
16 dose has no meaning.

17 So my concern is about the percentage  
18 expected dose to that structure. That is my problem,  
19 not how many percent.

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

22 CHAIR MALMUD: Dr. Suleiman?

23 MEMBER SULEIMAN: I tend to agree with Dr.  
24 Nag. I think part B really is more state of the  
25 practice of medicine and the intra-organ variability.

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1 I think they change treatment fields.

2 I would really defer to the therapy  
3 physicists and the other radiation oncologists to  
4 confirm me on that, but I think that is a level of  
5 micro regulation.

6 I think A is sufficient.

7 CHAIR MALMUD: Thank you, Dr. Suleiman.

8 VICE CHAIR THOMADSEN: This is Thomadsen.  
9 May I respond?

10 CHAIR MALMUD: Yes. I was just about to ask  
11 for the opinion of the other three members of the  
12 Subcommittee. Thank you, Dr. --

13 VICE CHAIR THOMADSEN: Yes. I disagree with  
14 Dr. Orhan that this is micromanagement. It is not at  
15 all. It is dealing, as Dr. Ennis said, with a sense to  
16 structure that may be important.

17 As far as the levels, it was set at 150  
18 percent of the plan to give quite a bit of room for  
19 variability in the implant. It could be 200. I think  
20 above 200, you are getting to be quite egregious.  
21 That is, even if you start out with a very low dose to  
22 start with, implant probably should be better than  
23 that.

24 I think that adding criteria based on a  
25 structure's tolerance would be very hard to actually

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1 in practice regulate because there is an incredible  
2 amount of disagreement as to what a structure's  
3 tolerance would be. And, as was pointed out, that  
4 depends on the time course of the treatment. And there  
5 is limited data on what exactly the structure's  
6 tolerances are, which is one reason we did not go  
7 there. It was considered in our deliberations.

8 We could modify this talking -- rather  
9 than an absolute volume and dealing with a relative  
10 volume, that would necessitate that for any permanent  
11 implant, any internal structure would be completely  
12 contoured.

13 And that might not be feasible in  
14 structures such as the head and neck, where the  
15 structure itself may go quite a ways outside of the  
16 treatment volume or the inferior vena cava in the  
17 liver. If you're looking at a relative fraction of  
18 that organ, you probably are not going to be  
19 contouring the entire organ, in which case getting a  
20 proportion of the structure becomes very difficult in  
21 practice.

22 DR. NAG: This is Dr. Nag. If there is so  
23 much objection to what I said, I will withdraw my  
24 statement and leave the sentence as it is because that  
25 sentence would, therefore, by default have no meaning.

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1 Therefore, I would have achieved my purpose. So I  
2 hereby withdraw my objection to the paragraph and  
3 would leave the paragraph as it is.

4 CHAIR MALMUD: This is Malmud. Thank you,  
5 Dr. Nag.

6 Now, we have not yet heard from Dr.  
7 Langhorst or Dr. Suh or Dr. Welsh regarding this most  
8 recent interchange. May we hear from the other members  
9 of the Subcommittee?

10 MEMBER WELSH: This is Dr. Welsh. As the  
11 Chair, I'll allow other members of the Subcommittee to  
12 place their opinion before --

13 CHAIR MALMUD: Thank you, Dr. Welsh. Dr.  
14 Langhorst? Dr. Suh?

15 MEMBER SUH: So this is John Suh. You know,  
16 I'm looking at the sentence again, "For all  
17 intra-target structures, such as urethra and prostate  
18 implant, the example is dose of at least 5 cc  
19 contiguously exceeds 150 percent of that structure's  
20 expected dose based on the approved pre-implant dose  
21 distribution." And so, you know, since this is an "or"  
22 statement, I am comfortable keeping that sentence in  
23 place.

24 I think it is important that for a normal  
25 structure -- and the urethra is a normal structure

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1 within the prostate gland -- that there is some  
2 criteria that is set because one could conceive that  
3 someone could put a very hot seed into the next  
4 urethra inadvertently, which would give a dose much  
5 higher than the 150 percent, which would constitute a  
6 medical event because when I look at the proposed  
7 definitions, I don't see anything in here that would  
8 say that putting a much higher source strength within  
9 the urethra would be considered a medical event.

10 CHAIR MALMUD: Dr. Suh, so you are in favor  
11 of leaving the document as it stands?

12 MEMBER SUH: Yes.

13 CHAIR MALMUD: Thank you.

14 Dr. Langhorst?

15 MEMBER LANGHORST: Yes. This is Sue  
16 Langhorst. I know as I have gone through this process  
17 -- and I am definitely not as -- don't have the  
18 expertise that my colleagues on the Subcommittee have  
19 in regard to this. I always ask the question, is this  
20 too much regulation? Is it possible to expect upon  
21 this type of criteria?

22 And I know I always have some difficulty  
23 in knowing for sure whether this would be something  
24 that an inspector could come in and readily evaluate  
25 whether its criteria met or not met.

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1           So I will defer to my colleagues as far as  
2 whether this is an appropriate item to leave in or  
3 not.

4           CHAIR MALMUD: Thank you, Dr. Langhorst.

5           And now Dr. Welsh?

6           MEMBER WELSH: Yes. Jim Welsh here. So I  
7 would first address Dr. Langhorst that I believe, as  
8 written, these relatively simple and, as we have heard  
9 from our conversation, perhaps overly simplified  
10 suggested parameters are going to be relatively easy  
11 to inspect and regulate upon.

12           I do think that Dr. Nag's point is very  
13 well-taken that for the prostate as an intra-target  
14 using the prostate for the intra-target structure --  
15 the one that we're talking about is the urethra --  
16 and, as currently written, would essentially never  
17 have a medical event. And I think that's worth keeping  
18 in mind. It's a subtle point, but, as we know, the  
19 urethra volume is going to be significantly less than  
20 five cc in almost all cases except it's the size of a  
21 softball.

22           So it's almost a moot point when it comes  
23 to the prostate, which means that maybe we do have to  
24 modify it slightly.

25           But I do agree with Dr. Ennis that it is

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1 important to if we're going to have overdose as a  
2 criteria -- and I personally think that if we're going  
3 to use dose at all, it should not be for the target,  
4 but it should be for overdosing of normal structures.

5 And in my opinion, that is what it is all about.

6 If you are overdosing normal structures,  
7 whether they are internal or adjacent, that is where  
8 you could get into trouble. And that is where it would  
9 be appropriate to have a medical event definition.

10 So I do agree with Dr. Ennis that  
11 maintaining some semblance of 2.B is worthwhile  
12 because to exclude intra-target structures is not in  
13 my opinion the ideal solution.

14 But then the question becomes, how does  
15 one do it? Dr. Ennis has suggested maybe 5 percent  
16 getting more than 200 percent of the dose. Dr. Nag has  
17 introduced the idea of tolerance.

18 Tolerance in an ideal world would be  
19 perfect. If we could just say that X cubic centimeters  
20 exceeds the tolerance and it is going to likely cause  
21 trouble for the patient, well, that would be a perfect  
22 definition. But, unfortunately, we don't work in a  
23 perfect world. And such a definition would be very  
24 difficult to implement. And, therefore, I'm not  
25 convinced that we could use the tolerance concept, as

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1 attractive as it may be.

2 But we do need to have some semblance of a  
3 dose-volume relationship. That is important. If we  
4 just say 200 percent of the prescribed dose to the CTV  
5 or 200 percent or 150 percent of that structure's  
6 expected dose, then we can talk about points, point  
7 doses, which might exceed that and be absolutely  
8 meaningless clinically. So it is critical to have some  
9 sort of a volume assigned to it.

10 The volume for the prostate, you know,  
11 five cc, is perhaps inappropriate because it would  
12 essentially exclude the prostate from ever having a  
13 urethral overdose. On the other hand, five cc might  
14 be small if you're talking about a large liver  
15 implant. And Dr. Nag has pointed out it could be  
16 possible to overdose the IVC according to this  
17 definition.

18 I do think that it is important to  
19 maintain some form of 2.B in our definitions. It may  
20 need to be tweaked so that it's not a rigid five cc,  
21 which is too much for the prostate, maybe too little  
22 for the IVC or other structures.

23 Is 150 the correct answer, 150 of that  
24 structure's expected dose? Could we use 150 of the  
25 tolerance dose or the tolerance dose? I don't know

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1 right now. I'm skeptical that inserting tolerance is  
2 going to be something that's inspectable.

3 But I do think that, as written now, it is  
4 fairly good. And I wouldn't try to change too much  
5 right here today.

6 CHAIR MALMUD: Thank you, Dr. Welsh. What  
7 you have done is to review the pros and cons of the  
8 current recommendations and to reaffirm your support  
9 of the current recommendations. Did I summarize what  
10 you said well?

11 MEMBER WELSH: Well, much more succinctly,  
12 yes.

13 CHAIR MALMUD: That being the case, it  
14 appears that we have a recommendation from the  
15 Subcommittee, with three of the four members, yourself  
16 included, supporting it and one abstention.

17 MEMBER WELSH: Right. So that Dr. Thomadsen  
18 could revisit his abstention because this is a --

19 VICE CHAIR THOMADSEN: I did not abstain  
20 on this, on the issue of A.2(b). My abstention was on  
21 the part B, adding to the attestations. On this issue,  
22 I am for keeping A.2(b) as it is. I am not abstaining  
23 on that.

24 CHAIR MALMUD: Thank you, Dr. Thomadsen,  
25 for that clarification.

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1 Do we have a motion from the Subcommittee?

2 MEMBER GUIBERTEAU: Dr. Malmud?

3 CHAIR MALMUD: Who is that, please?

4 MEMBER GUIBERTEAU: This is Mickey  
5 Guiberteau. I just have a question, not being a  
6 radiation oncologist, with the language as written  
7 here. Could I ask a question of the Subcommittee?

8 CHAIR MALMUD: Please do, Dr. Guiberteau.

9 MEMBER GUIBERTEAU: I am a little confused  
10 when I read this with the word "contiguously" in  
11 parentheses. As an adverb, I would presume this is  
12 meant to modify "exceeds," which doesn't make much  
13 sense to me. If it is meant to apply to the volume,  
14 the five centimeters, does "contiguous" mean that it  
15 is contiguous or next to the structure that we are  
16 talking about, A and B, or does it mean that the five  
17 centimeters needs to be one volume and not contiguous  
18 volumes and not discrete volumes adding up to five  
19 centimeters?

20 MEMBER WELSH: Dr. Malmud, this is Jim  
21 Welsh. I could answer Dr. Guiberteau's question.

22 CHAIR MALMUD: Thank you, Dr. Welsh.

23 MEMBER WELSH: Dr. Guiberteau, it is  
24 intended to be continuous structure. It is contiguous  
25 anatomical structure that is one continuous piece of

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1 tissue, rather than having a piece of tissue here,  
2 spaced by some more dose, another piece of tissue here  
3 that is a higher dose, and then a few centimeters down  
4 the road have another point that has exceeded this.  
5 It must all be in one spot because chronologically  
6 that is what makes the difference.

7 MEMBER GUIBERTEAU: Then I suggest we  
8 modify this to where it says, "at least contiguous  
9 five centimeters," rather than "contiguously," because  
10 that could mean that you mean contiguous to, say, the  
11 urethra, rather than the volume itself.

12 So I would -- you know, reading a  
13 regulation, I mean, I think it should be clearer than  
14 this. So I think it is a semantic thing, but I think  
15 it could be variously interpreted. So, you know, I  
16 would just suggest that when this is written, that we  
17 not use the word "contiguously" but -- so that it  
18 doesn't refer to exceeds but refers to the five  
19 centimeters that --

20 MEMBER WELSH: So if I could ask, this  
21 would be at least five contiguous centimeters?

22 MEMBER GUIBERTEAU: Well, that would make  
23 more sense to me because I didn't know whether it  
24 meant that the five centimeters need to be contiguous  
25 volume adding up to that or whether it's contiguous to

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1 the structure itself, such as the urethra. So what you  
2 have said makes more sense to me and makes it clearer.

3 MEMBER WELSH: Okay.

4 VICE CHAIR THOMADSEN: This is Thomadsen.

5 I would support that change. I think it would be a  
6 good change in both A and B.

7 CHAIR MALMUD: Thank you.

8 Dr. Langhorst? Dr. Suh, do you agree  
9 changing the "contiguously" adverb to an adjective,  
10 "contiguous," preceding the "centimeters"?

11 MEMBER SUH: This is John Suh. I agree with  
12 the suggested change.

13 MEMBER LANGHORST: This is Sue Langhorst.  
14 I agree, too.

15 CHAIR MALMUD: So the recommendation is  
16 changed, dropping the "(contiguously)" and, instead,  
17 using it as an adjective with the word "contiguous,"  
18 preceding the "centimeters" in both subheadings 2(a)  
19 and 2(b).

20 Is there any objection to that from  
21 anyone?

22 (No response.)

23 CHAIR MALMUD: Hearing none, we will accept  
24 that as a change in the recommendations.

25 Is there any further discussion of this

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1 recommendation?

2 VICE CHAIR THOMADSEN: Yes. This is  
3 Thomadsen. And I was the author of the minority  
4 report. And I should explain my issues to the  
5 Committee, if I may.

6 CHAIR MALMUD: Please do.

7 VICE CHAIR THOMADSEN: There were several  
8 changes compared to the previous report. The first one  
9 that I find a bit of a problem is the change to the  
10 treatment site, as opposed to the use, the explicit  
11 use, of the planning target volume or the clinical  
12 target volume. And that would be the treatment site as  
13 used in this report would mean where the sources are  
14 to be placed. And that would be exclusively the  
15 planning target volume; whereas, in the prescription,  
16 the clinician, the authorized user, is going to be  
17 defining the dose to be delivered to the clinical  
18 target volume.

19 And so we have a situation where the term  
20 "target site" would now be differently used in the  
21 written directive and in the prescription. And I think  
22 that this is potentially leading to confusion and  
23 misunderstanding.

24 The second issue is the dropping of the  
25 octant criteria. And this was to catch those implants

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1 that would have all the sources bunched not where they  
2 were supposed to be, but all in one location, which  
3 would not be crossed with the 20 percent criterion.

4 The octant, unlike it is being  
5 characterized in discussions here, is not that  
6 complicated of an issue since it is just riding the  
7 target in half along each of the axes. And it could be  
8 along any axes that would give you the distribution  
9 that would pass or, as I point out in the report, you  
10 could even just say that if you divide along any axis  
11 the targets in half, 20 percent of the sources should  
12 be in either side of that dividing.

13 So it really is not difficult. And, as far  
14 as causing discussions between regulators and users,  
15 if you can find axes that work, then it is fine. You  
16 don't have to argue anymore.

17 Would it be extra work for people?  
18 Absolutely not because most of the time as long as in  
19 the previous report, the D-90 was greater than 60  
20 percent, you wouldn't ever have to do the calculation  
21 of these distributions, which that brought us back to  
22 the discussion of the dropping of the D-90.

23 In the previous report, the use of the  
24 D-90 as being less than 60 percent was exclusionary  
25 criterion. If the implant had 20 percent or more of

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1 the sources outside of the PTV, it could still be a  
2 good implant and deliver perfectly fine therapy. We  
3 have seen examples of that.

4 If the seeds were bunched, they're bunched  
5 in a way that still treated the target. That also  
6 should be excluded as a medical event. And the D-90  
7 was the exclusionary criterion, saying that if there  
8 was going to be no harm to the patient due to either  
9 of these failures to just what you had planned, then  
10 it's not a medical event because the patient was  
11 treated just fine. And, as always, with any of these,  
12 if you plan a de-escalation of dose or an escalation  
13 of dose in one place or another or it's during the  
14 implants, you find anatomically that you cannot do the  
15 implant that you had planned, those, of course, trump  
16 any of these situations.

17 And, finally, the issue that I objected to  
18 probably the most was the attestation. And, as I point  
19 out, I do not think it is a good regulation at all,  
20 nor good medicine approach.

21 If putting the practitioner in the  
22 position of attesting to that what they did is what  
23 they were supposed to have done, if things don't go  
24 exactly how they wanted to do, they may be persuaded  
25 to attest that, well, that is what they wanted to do,

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1 it's perfectly fine.

2 Also, you are putting the authorized users  
3 in a position where the regulators and the users may  
4 disagree with how close to the intended implants the  
5 practitioner actually executed.

6 The discussion of this could go on in many  
7 different implants where the attestation would be  
8 questioned. If the attestation isn't being questioned  
9 at all, it certainly could be used to assess that the  
10 sources went where they should have gone, regardless  
11 of there being more than 20 percent outside of the  
12 target. You can do away with both criteria for the  
13 implant and just have the attestation left over. And  
14 this is a very strange process on the regulatory side.

15 By having any criteria, are we impinging  
16 on the practice of medicine? Well, this has come up  
17 many times at the ACMUI when we talk about possible  
18 medical events. And for the protection of the public,  
19 including the patients, it has always been decided  
20 that there is a responsibility on the part of the NRC  
21 to hold the practitioners responsible for what they  
22 do. And this should be something that could be  
23 quantitative, as opposed to just taking the  
24 practitioners' word that they did exactly what they  
25 felt they should have done.

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1 Without addressing the four items that I  
2 list in the minority report, I think the medical  
3 events criteria that we have come up with fails to be  
4 robust, as far as dealing with a quantitative and  
5 practically applicable definition for medical event.  
6 I think it would cause more confusion and more  
7 distention between regulators and authorized users. I  
8 think it will potentially result in the reporting of  
9 medical events that should not be seen as medical  
10 events.

11 CHAIR MALMUD: Thank you, Dr. Thomadsen.

12 Well, the items are in the minority  
13 report, which are found on pages 8 through 12 of the  
14 report. There are differences in your minority report  
15 from that given to us by the majority of the  
16 Committee. What are you recommending instead or are  
17 you not recommending?

18 VICE CHAIR THOMADSEN: I would recommend  
19 going back to the recommendations in the previous  
20 report, the 2011 November report. I think that they  
21 were well-thought-out and addressed the concerns that  
22 have been expressed in the meeting. They do not follow  
23 the recommendations of many of the people who are in  
24 the meetings, but they don't really run contrary to  
25 the goals of what has been expressed. I think that it

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1 would clarify the situation much better than the  
2 current proposed draft.

3 CHAIR MALMUD: Thank you, Dr. Thomadsen.

4 Dr. Welsh, do you wish to respond?

5 MEMBER WELSH: I do. Thank you.

6 So I will reply first that I think that  
7 the October 2011 version that Dr. Thomadsen is in  
8 favor of is actually a very good definition. It was  
9 well-thought-out. And it has certainly got a lot of  
10 merit.

11 But it is worth remembering that a large  
12 professional organization, namely ASTRO, of which we  
13 have representation on the phone today, actually wrote  
14 a letter to NRC and ACMUI expressing opposition. So  
15 this I think indicates that if the largest body of  
16 radiation oncologists is expressing concern with the  
17 definition, it certainly merits further consideration.

18 After that consideration, I, personally,  
19 as a member of this Subcommittee, not speaking for  
20 everybody -- I can reply to Dr. Thomadsen's concerns  
21 point by point. Number one, the term "treatment site,"  
22 we have argued at ACMUI meetings since -- well, I  
23 don't even remember when. It goes probably back to  
24 2005 or so.

25 VICE CHAIR THOMADSEN: Two thousand six.

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1 MEMBER WELSH: Okay.

2 -- that we should perhaps be using  
3 terminology like "CTV," "PTV," "gross tumor volume,"  
4 et cetera. But at that time, the terminology was  
5 relatively new to NRC and new to some practitioners as  
6 well. But now, fast forwarding to 2012, this is not  
7 terminology that is new or unfamiliar to anybody.

8 And, therefore, if we are too restrictive  
9 in any form or fashion with our definitions about  
10 volumes, we are potentially causing some conflict.

11 And, therefore, I personally favored use  
12 of the term "treatment site," which gave a little bit  
13 more latitude to the authorized user to be talking  
14 about a GTV in this case or CTV or prescribing to a  
15 PTV depending on the individual authorized users and  
16 the institution's preference.

17 Some institutions always prescribe to a  
18 GTV. Others prescribe to a CTV. Others include the  
19 expansion and prescribe to a PTV. "Treatment site" is  
20 a generic term that would encompass all of them. So  
21 that's why I remained in favor of "treatment site."

22 As to the octet concept, yes, it is  
23 relatively simple, any three orthogonal axes. But I  
24 anticipate that, in actual practice, the three  
25 orthogonal axes could be challenging. What if somebody

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1 says, "Here is the middle. We're going to put a line  
2 down"? Well, no, no. Here's the middle. It's two  
3 millimeters to the left. No. Here's the middle. It's a  
4 millimeter to the right of what you are saying the  
5 middle is. You get one of those axes off. The whole  
6 concept of the octants becomes challenging.

7           What about that situation where you come  
8 up with, say, orthogonal axes that are perfectly set  
9 up but then it's not a medical event but then if you  
10 rotate it five degrees, you find that the seeds are  
11 not perfectly distributed. Well, in principle, it  
12 might be possible to have a medical event triggered in  
13 one set of orthogonal axes and not another.

14           And I know Dr. Thomadsen has thought about  
15 this and has a response. But to me, it would seem like  
16 it is going to be a challenge from the regulatory  
17 perspective.

18           Then, going on to the D-90 greater than 60  
19 percent, I think it is worth emphasizing what Dr.  
20 Thomadsen has said over and over again, that this is  
21 not to trigger a medical event but to prevent a  
22 medical event. In essence, D-90 greater than 60  
23 percent means you don't have to even look at the  
24 octants, everything is okay.

25           So superficially I would say, man, that is

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1 great. That is just what we want. But then I start  
2 thinking that they're using the D-90, the D-90, which  
3 we have opposed so, so vigorously for the past six  
4 years, that, even though it's being resurrected here  
5 not to trigger an event but to prevent the event,  
6 conceptually I remain opposed to it. That doesn't mean  
7 that I can't be swayed by logical argument, but use of  
8 D-90 just is anathema to the ACMUI conceptually over  
9 the past six years.

10 But I think that Dr. Thomadsen's point  
11 that the D-90 is being used here not to trigger but to  
12 prevent a medical event is worth emphasizing because  
13 that is an important point.

14 Finally, the argument that Dr. Thomadsen  
15 uses opposing the attestation, I would submit that it  
16 is not entirely subjective, but there is an objective  
17 component to it. And we discussed that at the  
18 beginning of this teleconference.

19 By putting the word "final" there, the  
20 "final" plan, we have something that is objective, is  
21 on the computer, and can be compared to the seed  
22 distribution so that if somebody puts all of the seeds  
23 in one bunch and then you look at the seed  
24 distribution on the computer according to plan and go  
25 all around the perimeter, you know that there is

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1 something wrong. The authorized user cannot attest  
2 that the seeds are in the right place. And if they do,  
3 they are going to be caught because this is fraud and  
4 they would be exposed. But now they must attest or  
5 sign something that says that they put the seeds in  
6 accordance with the plan or, else, if they don't sign  
7 it, well, then it's going to be a red flag that will  
8 trigger an investigation.

9 So those are the main points that I have  
10 in response to Dr. Thomadsen.

11 CHAIR MALMUD: Thank you, Dr. Welsh. I  
12 assume you are speaking on behalf of yourself, Dr.  
13 Langhorst, and Dr. Suh as the three members of the  
14 Committee who supported this recommendation.

15 MEMBER WELSH: I believe that I am, but I  
16 think that given that ASTRO was an organization that  
17 opposed our 2011 version -- and if there are ASTRO  
18 representatives on the line, they should perhaps speak  
19 up now, too. But I believe and I hope that I am  
20 speaking for the rest of the Subcommittee.

21 DR. ENNIS: This is Ron Ennis. I would be  
22 happy to address Dr. Welsh's comments. I am on the  
23 call representing ASTRO. I think he summarized ASTRO's  
24 position and most of the issues well, but I will  
25 elaborate a little bit.

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1           Using a D-anything, D-x, while used as a  
2 tool for clinicians to assess their implant, it is  
3 fundamentally flawed and really can never really be  
4 fully overcome. And, therefore, we have been unhappy  
5 with it as a regulatory criterion because of the  
6 implications thereof.

7           The fundamental flaws are two. A) it is  
8 largely affected or tremendously affected by the  
9 amount of prostate swelling or edema that will occur  
10 after the procedure, which is out of any clinician's  
11 control. And that can easily create a quality implant  
12 or a quality execution, at least, into a medical event  
13 if we use a D-90 criteria.

14           And b) it is highly dependent on prostate  
15 imaging quality. And there is a lot of variation in  
16 the different imaging modalities and their ability to  
17 define the borders of the prostate, which, of course,  
18 is the volume on which the D is calculated. And,  
19 therefore, if you use one imaging modality, you can  
20 easily get a very different D-x than you will with  
21 another imaging modality, MR, CT, and ultrasound being  
22 the three main modalities.

23           So it is such a fundamentally flawed  
24 measurement. While a good tool for the clinician to  
25 use, it doesn't seem to be logical as a regulatory

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1 criterion. Twenty percent of seeds outside of the area  
2 that is to be implanted, what's called treatment site  
3 in the current document, is something that is not  
4 affected by any of these fundamental flaws. It is  
5 objective. And we, therefore, think that that is  
6 really the best way to define a medical event.

7 In terms of the other specific things that  
8 were brought up, we agree with Dr. Thomadsen that  
9 treatment site is a little vague and could potentially  
10 allow practitioner to say, "Well, that was my  
11 treatment site."

12 And PTV would seem to be a good definition  
13 in that that is the largest of the volumes that we are  
14 trying to treat. And generally you would want, you  
15 know, certainly all of your seeds to be within that  
16 structure.

17 An alternative could be to say treatment  
18 site as defined by the practitioner on the plan or  
19 something along those lines to allow them to say PTV  
20 or PTV plus another centimeter or something along  
21 those lines. But just saying treatment site to us, we  
22 agree with Dr. Thomadsen. That's a little vague.

23 Just backing up to octant concept, I think  
24 it has already been well-spoken, its limitations.  
25 Just another to me likely-scenario with a lot of

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1 implants would be, as one was dividing the prostate  
2 along these different axes, seeds would cross those  
3 axes or be aligned along those axes. There are many  
4 seeds within the prostate, and it's highly likely that  
5 many would be -- and then which octant do they get  
6 counted in? And they got double counted in each of the  
7 two octants on which they border. And, again, this  
8 could be just, you know, a quagmire that wouldn't get  
9 anyone anywhere.

10 I do think the attestation at the end of  
11 the procedure is key to allow the flexibility but also  
12 allow the regulator to come in and say, "Well, you  
13 know, this is nothing like your plan" and allow the  
14 practitioner to be held to a standard saying, "You  
15 said you implanted as your plan" or you were specific  
16 in what you did differently and why. We do think that  
17 it ought to say, you know, a justification for why.

18 And, to get to Dr. Thomadsen's point about  
19 the regulator and practitioner fighting, I think a  
20 provision that the case be reviewed by an independent  
21 radiation oncologist could be put in as a message for  
22 evaluating.

23 And that independent reviewer would assess  
24 the written directive, final written directive, to  
25 say, "Okay. What was the reason in the attestation for

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1 why the plan was changed? Is that reasonable? Is that  
2 what happens? And was this modification done in a  
3 reasonable fashion?"

4 CHAIR MALMUD: Thank you, Dr. Ennis, for  
5 your explanation of ASTRO's opinion.

6 VICE CHAIR THOMADSEN: This is Thomadsen.  
7 May I make a comment?

8 CHAIR MALMUD: Yes, Dr. Thomadsen?

9 VICE CHAIR THOMADSEN: Discussing some of  
10 the points made, particularly with regard to the use  
11 of D-90 and its sensitivity to imaging, many of the  
12 same arguments would apply to evaluation of whether 20  
13 percent of the sources or more lie outside of the  
14 treatment volume if the imaging is that dependent. So  
15 that argument itself does not go against D-90 for 20  
16 percent of the seeds.

17 The fact that the D-90 may be sensitive to  
18 all of these things -- and it is. As I point out in my  
19 minority report, all of the reasons that we objected  
20 to the use of D-90 for defining an event still hold.  
21 And they are all valid.

22 The use of D-90 as an exclusionary tool,  
23 on the other hand, simply means that if you had edema  
24 and the D-90 were somewhat low and you had -- and  
25 implants were 20 percent or more of the sources were

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1 outside of the treatment site, if the D-90 were fine,  
2 then you would not have a medical event. And you  
3 wouldn't think about this case further.

4 If, for any of those reasons, the D-90 was  
5 less than 60 percent, then you still would have the  
6 medical event, just like you would if you had no D-90  
7 criterion, because the 20 percent of the sources were  
8 outside of the treatment site.

9 So, even though the D-90 might be affected  
10 by all of the things that we say that it is, it could  
11 prevent the unnecessary reporting as medical events  
12 perfectly fine implants, where 20 percent of the seeds  
13 might be out of the treatment volume. And it might not  
14 work if you exclude others. But in its absence, none  
15 of those, none of those would be excluded.

16 So far the argument on the octant and  
17 trying to find axes that will or will not pass, do  
18 remember that in a normal distribution, you would have  
19 12 and a half percent of the sources in each octant.

20 The criteria was having five percent in  
21 each octant. If you're just making small changes in  
22 the axes, you aren't going to have that type of  
23 sensitivity to bring a lot of discussion into this.  
24 And if we saw, as I point out in the minority report,  
25 that if you find axes that work and you don't have a

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1 problem, that eliminates the discussion between the  
2 user and the regulator, who would say, "Well, it  
3 worked in your axes but not in mine." The ties goes in  
4 favor of the authorized user.

5 So I don't think that those objections  
6 really hold.

7 DR. NAG: Hello. This is Dr. Nag. Can I add  
8 a couple of comments?

9 CHAIR MALMUD: You may, but I want to make  
10 certain that Dr. Thomadsen had completed his --

11 DR. NAG: Oh. I thought he had finished.

12 VICE CHAIR THOMADSEN: Yes, I had.

13 CHAIR MALMUD: Thank you.

14 Dr. Nag?

15 VICE CHAIR THOMADSEN: All yours.

16 DR. NAG: Okay. So this is Dr. Nag. A  
17 couple of comments on some of these points. First of  
18 all, let's start with the octant concept.

19 The octant concept is a beautiful  
20 function, works very well on a theoretical basis from  
21 a physics standpoint. However, the problems in that  
22 particular thing is that, number one, when we are  
23 doing our implants, we are not putting offsets when I  
24 am putting my thing.

25 Number two, more important than that,

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1 let's say all of the things were put in one place. If  
2 octant concept works, if you are trying to  
3 homogeneously implant a certain organ, at this time  
4 clinically we do not want to implant homogeneously. We  
5 want to implant more in one area, less in another area  
6 because certain areas have either normal tissue that  
7 we want to avoid or certain areas have high risk of  
8 tumor that we want to get higher results.

9 And, therefore, doing an offset will not  
10 work because just an octant will have higher dose.  
11 And just an octant will have a much lower number of  
12 seeds because that is our intention. And it may be  
13 even lower than the five percent that was trying to  
14 obtain.

15 It also cannot work, even if you have  
16 bunched all the seeds. You wanted to try and get the  
17 unusual situation where all the seeds may be bunched  
18 into one area. I can bunch all the seeds in the middle  
19 of the prostate. And you have a reaction. And I'll  
20 have 12 and a half percent in each of the octants. And  
21 I am going to the urethras. So even of the octant  
22 concept is not the same.

23 So, because of all of these reasons, I  
24 would not want the octant concept in a regulatory  
25 sense. You can use it in research to do some research

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1 parameters and diagnosis and so forth but not for  
2 regulation.

3 Secondly, let's talk about the treatment  
4 site. I think I agree with Dr. Thomadsen that there is  
5 some ambiguity about treatment site. We had mentioned  
6 about this in the ASTRO report that came out in  
7 Practical Radiation Oncology dealing with medical  
8 event destination from permanent brachytherapy in  
9 November or October through December 2001, Practical  
10 Radiation Oncology I think still deserves another  
11 reading.

12 The site that we are talking about is  
13 somewhat ambiguous. When we are talking about the  
14 prescription, we are talking about we are prescribing  
15 through the CTV. And when we are talking about  
16 analysis and how many percent is outside the treatment  
17 site, we are really talking about the PTV.

18 So I think I agree with Dr. Thomadsen if  
19 we revise these two that the treatment site for the  
20 prescription would be CTV, outside the treatment site  
21 20 percent and that would be the PTV. I think that  
22 would help to clarify the method to some extent.

23 The third one is the octant concept.  
24 Again, I agree with Dr. Ennis that the octant concept  
25 has to be removed from the plan for many reasons,

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1 including the plan that authorized user has no control  
2 of the distribution of the seeds after it has been  
3 released. And we talked about the edema and so on and  
4 so forth. Those are outside the control of the  
5 authorized user.

6 Well, these are just some of my comments.

7 Thank you.

8 CHAIR MALMUD: Thank you, Dr. Nag.

9 Are there comments from other members of  
10 the Subcommittee or from other members of the ACMUI?

11 VICE CHAIR THOMADSEN: This is Thomadsen.  
12 May I reply to a couple of his comments?

13 CHAIR MALMUD: Please do.

14 VICE CHAIR THOMADSEN: The first issue is  
15 looking at the octant and whether it only works for  
16 homogenous distribution and there are problems  
17 otherwise.

18 In the proposal, it was assumed that many  
19 of the times, the authorized user would want to have  
20 differential distribution of the sources. That worked  
21 into the written directive. That would not then cause  
22 a -- that would not trigger an event based on the  
23 octant, that the authorized user said that they aren't  
24 going to be using a homogeneous distribution.

25 The question that they don't rely on the

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1 distribution to get the sources in the octant, that's  
2 perfectly fine. They don't have to find it to have it  
3 evaluated that way. Most implants do work out with the  
4 distribution working pretty much into the octant, even  
5 with some escalation and de-escalation. So the fact  
6 that the authorized user has control over the  
7 evaluation of this eliminates that as a problem.

8 The question of whether or not all of the  
9 seeds clustered around the axis would be caught, it  
10 may not be caught. Particularly it wouldn't be of  
11 interest if the D-90 still was 60 percent according to  
12 the previous version of this report.

13 Also, if that happened, how many cases  
14 could that possibly be where the sources would all be  
15 congregated around the ASTRO? And if we don't catch  
16 that one, fine. It got to be a very few, if any, cases  
17 that could ever happen. Once again, the discussion  
18 turns to D-90 and its problems, as I said last time,  
19 the D-90 as a trigger for a medical event has been  
20 completely argued. And we all know that that is not a  
21 good tool, but that is an exclusionary device.

22 None of the arguments about it hold. It's  
23 still a good exclusionary device if it eliminates a  
24 good proportion of unnecessary medical events.

25 I'm done.

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1 CHAIR MALMUD: Thank you, Dr. Thomadsen.

2 MEMBER WELSH: This is Dr. Welsh. If there  
3 are no immediate replies to Dr. Thomadsen?

4 CHAIR MALMUD: Please, Dr. Welsh.

5 MEMBER WELSH: I would start off by saying  
6 I agree with Dr. Thomadsen that D-90, as bad as it is  
7 for the target, if it was going to be used at all in  
8 regulation, it would be reasonable to resurrect it as  
9 an exclusionary criterion, rather than a defining  
10 perspective, defining parameter, for medical event.

11 I still stand by my initial statement that  
12 I am opposed to D-90 in all forms and fashions. It is  
13 very arbitrary. That's where I am today.

14 Regarding the point about the treatment  
15 site, we have heard Dr. Thomadsen's perspective as  
16 well as Dr. Nag and Dr. Ennis representing ASTRO. My  
17 reply is that the reason why I favor treatment site in  
18 general, the defined term "treatment site," is because  
19 I was fearful that NRC now that they understand CTV,  
20 GTV, PTV might arbitrarily pick one of those three for  
21 us and not give us the latitude to say in this case I  
22 am talking about the PTV or I am accustomed to using  
23 the GTV for this list. And now NRC is intruding into  
24 the process of medicine by picking one of those three  
25 volumes and saying, "You must use CTV here."

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1           And that is why I thought treatment site,  
2 being generic and giving us latitude to decide which  
3 one of those is being alluded to here, was preferable  
4 than allowing NRC to tell us "You must be talking  
5 about the CTV in your written directive," no ifs,  
6 ands, or buts. And that is the reason why I favored  
7 the treatment site.

8           If NRC rulemaking is going to allow us to  
9 make the decision, are we talking about GTV here, PTV,  
10 CTV? That would be fine, but I was fearful that NRC  
11 rulemaking might pick one of those and say, "Here is  
12 how it is. Here is how you have to comply from now  
13 on." And that is something I didn't want to run the  
14 risk of.

15           As far as Dr. Thomadsen's point about the  
16 octants, possibly there being a discrepancy between an  
17 unusual case where if the authorized user says, "Well,  
18 look at these octants. All is fine" but now the  
19 inspector said, "Well, I rotated at three degrees.  
20 And look at these octants. All is not fine," the tie  
21 goes to the authorized user.

22           I'm not so convinced that NRC would say  
23 that the tie goes to the authorized user. They might  
24 say that the tie goes to the inspector.

25           If we can find any example where the

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1 octant concept is violated, that's a medical event.  
2 And, therefore, rather than decreasing the number of  
3 medical events, it might, surprisingly, increase them.

4 Finally, regarding the effect of edema on  
5 D-90, yes, we know that edema causes changes in D-90  
6 that would be unfavorable for the authorized users  
7 with the current definition.

8 But I'm not so sure that volume changes  
9 due to edema affect the 20 percent outside the  
10 treatment site concept as much as they affect D-90.

11 So yes, there would be subtle impact on  
12 the 20 percent, but major impact on the D-90. And,  
13 therefore, I don't know that that argument really  
14 holds about the edema.

15 Those are my comments.

16 CHAIR MALMUD: Thank you, Dr. Welsh.

17 I think we have heard the arguments  
18 expressed eloquently of the majority of the  
19 Subcommittee as well as the minority Subcommittee. Do  
20 we have any additional comments from members of the  
21 public?

22 MR. LIETO: Yes.

23 CHAIR MALMUD: May I ask who is speaking?

24 MR. LIETO: This is Ralph Lieto.

25 CHAIR MALMUD: Yes, Ralph?

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1 MR. LIETO: I have a couple of comments. I  
2 would agree with the comments regarding the proposed  
3 definition A.1 regarding treatment site. This has been  
4 argued in previous ACMUIs. And the overwhelming  
5 agreement by the various ACMUIs as well as the general  
6 public was that plan target volume was the way to go,  
7 instead of the treatment site.

8 My second comment has to do with A.2  
9 regarding the dose-based criteria that are being  
10 proposed by the Advisory Subcommittee. In listening to  
11 the discussions by the various members from ASTRO and  
12 the practitioners and Dr. Thomadsen, there is  
13 obviously a great inconsistency and disagreement on  
14 some of these aspects.

15 I would like to point out that during the  
16 workshops when this proposed rule was being addressed,  
17 which did not include a dose-based criteria, that  
18 overwhelmingly the various professional societies and  
19 workshop attendees agree that an activity-based or  
20 source strength criterion was the way to go and that  
21 it should not involve a dose-based criterion.

22 And there seems to be -- with these  
23 changes that are being added to A.2, this just seems  
24 to have taken what was thought to be a healing sore  
25 and picked the scab and raised it into an open wound

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1 again.

2 And my recommendation is that the  
3 dose-based criteria be eliminated altogether. There  
4 are inconsistencies and agreement and also would be  
5 consistent with what the workshops and various public  
6 input during the previous ACMUI meetings on this  
7 subject have supposed, which is a source  
8 strength-based criterion.

9 And one other -- and I have a question to  
10 the ACMUI Advisory Committee -- was this dose-based  
11 criteria, this would be assessed when: at 1 day or 30  
12 days when they do the post-implant assessment? Was  
13 that the implied intent here?

14 CHAIR MALMUD: Thank you, Mr. Lieto. I will  
15 direct your question to Chairman Welsh of the  
16 Subcommittee.

17 MEMBER WELSH: So first my reply to Mr.  
18 Lieto is that yes, we have, the ACMUI and the  
19 Subcommittee, in particular, have, argued against use  
20 of dose for many years, but we have been focusing  
21 primarily on dose when it comes to targets because the  
22 current definition leads to ambiguity. The one that is  
23 in practice right now and is triggering 100 medical  
24 events per year is ambiguous enough and problematic  
25 enough that we have argued for the dose to the target

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1 for this time.

2 So in the process of trying to revise the  
3 medical event definition, we went back to some very  
4 basic concepts. And the basic concept that I'm  
5 alluding to here is the overdosing of normal tissue,  
6 which can leave harm to the patient. And if we focus  
7 on that concept, it does seem to make sense that dose  
8 could be used appropriately and understandably used  
9 for overdosing of normal tissue.

10 So when we are talking about dose at this  
11 point here, I am opposed to using dose at all under  
12 any circumstance, D-90 even for the target, even if  
13 it's exclusionary.

14 So no dose to the target is my perception.  
15 Dr. Thomadsen has pointed out possible use of dose as  
16 an exclusionary measure. But I don't think we are  
17 opposed to the modern concept of using limited use of  
18 dose when it comes to normal tissue overdose because  
19 that is what we do in actual practice of medicine. If  
20 we're overdosing the structure, that is a medical  
21 problem. And it's also a radiological problem. And  
22 it's reasonable to have it incorporated into the NRC's  
23 medical event definition.

24 As far as when to evaluate this, I think  
25 that it is important to have some kind of limitation.

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1 You don't want to evaluate this years later. But you  
2 don't want to do it too soon for the reasons that have  
3 been alluded to many times about the problems with  
4 edema that give you a false picture, quite literally.

5 And so it might depend slightly on the  
6 particular isotope and the half-life chosen, but  
7 generally there are criteria or guidelines that are  
8 used for when is best to do a post-implant dosimetry.  
9 And the post-implant dosimetry that is used for  
10 judging the quality of the implant from the  
11 practitioner's perspective and being able to tell the  
12 patient what the outcome is likely to be in terms of  
13 cure and complications is also the same post-implant  
14 dosimetry study that would be used for defining  
15 whether or not there is an overdose to the normal  
16 structures.

17 And it might be approximately six to eight  
18 weeks after the implant, but it might vary.

19 CHAIR MALMUD: Thank you, Dr. Welsh. So you  
20 are replying to Mr. Lieto's question by indicating  
21 that there is no specific time for recommendation, but  
22 that you would entrust that to the medical practice,  
23 rather than the NRC?

24 MEMBER WELSH: I would because, as I  
25 mentioned earlier, if you have a cesium-131 implant

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1 with a half-life of approximately 10 days, you might  
2 choose to do your post-implant dosimetry at a very  
3 different time point from I-125 implant with a  
4 half-life. So there should be some latitude there.

5 And it would be inappropriate for a  
6 regulatory body to say, "It must be done at this time  
7 interval." I think that is something that should be up  
8 to the individual treatment team depending on the  
9 specific isotope.

10 CHAIR MALMUD: Thank you, Dr. Welsh.

11 I think that we have had a two-hour lively  
12 discussion regarding the recommendations, the minority  
13 opinion, with the input of ASTRO and interested  
14 members of the public. If we may, we can move this  
15 recommendation to the full ACMUI, which is in  
16 attendance on this Committee. Is there such a  
17 recommendation of the Subcommittee be brought forth to  
18 the ACMUI?

19 MEMBER ZANZONICO: This is Pat Zanzonico.  
20 I would make that motion.

21 CHAIR MALMUD: Is there a second to the  
22 motion?

23 MEMBER WELSH: I second it.

24 CHAIR MALMUD: Dr. Welsh seconds the  
25 motion. Can we move the motion forward, having heard

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1 the discussion?

2 (No response.)

3 CHAIR MALMUD: I hear no objection to  
4 moving the motion forward. We'll move the motion  
5 forward. All of the members of the ACMUI in favor  
6 please indicate aye.

7 (Whereupon, there was a chorus of "Ayes.")

8 CHAIR MALMUD: Are there any nays?

9 VICE CHAIR THOMADSEN: Yes, nay.

10 CHAIR MALMUD: May I ask who says, "Nay"?

11 VICE CHAIR THOMADSEN: Thomadsen.

12 CHAIR MALMUD: Dr. Thomadsen? Thank you.

13 Are there any abstentions?

14 (No response.)

15 CHAIR MALMUD: Hearing none, the motion  
16 moves forward with one negative, the rest positive  
17 votes.

18 Is it necessary -- I am asking now this of  
19 NRC staff. Is it necessary for us to indicate the  
20 names of each of those who have voted because we are  
21 now almost two hours into the Committee meeting. It's  
22 certain that we have a majority.

23 MR. FULLER: To answer your first question,  
24 no. I don't think we need -- well, we have called the  
25 roll. We have one abstention. We know who that is. So

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1 by process of elimination, we know who voted.

2 CHAIR MALMUD: Well --

3 MR. FULLER: But one question I have for  
4 clarification now, when you say "move it forward,"  
5 it's with the one change that was adopted early in the  
6 meeting, correct?

7 CHAIR MALMUD: That is correct. It was the  
8 insertion of one word.

9 MR. FULLER: Okay.

10 VICE CHAIR THOMADSEN: One question, was  
11 there not also the change of "contiguous"?

12 MS. COCKERHAM: This is Ashley. I have that  
13 change noted as well.

14 VICE CHAIR THOMADSEN: Yes. Thank you.

15 MEMBER WELSH: And this is Jim Welsh. If I  
16 could raise one last time that question about  
17 treatment site versus a specific GTV, CTV, or PTV. I  
18 think you have heard my argument that using the  
19 generic term "treatment site," which is defined in the  
20 terminology section, our glossary, allows us to select  
21 which one of those three volumes we want to use and  
22 the reason. My preference was that I don't want NRC  
23 rulemakers to say, "You must use CTV, end of story."

24 And, having stated my argument, I am  
25 wondering if those who opposed the use of "treatment

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1 site" still remain opposed or if their opinion has  
2 changed?

3 CHAIR MALMUD: If I may, Dr. Welsh, the  
4 recommendation includes the terminology "treatment  
5 site" and, therefore, was just approved by the ACMUI.

6 MEMBER WELSH: I think there was opposition  
7 from the public and from some members which I think --  
8 I remain in favor of using the generic term --

9 CHAIR MALMUD: When you say, "I," you mean  
10 the majority of the Subcommittee, which made the  
11 recommendation to the ACMUI, do you not?

12 MEMBER WELSH: Yes. Yes.

13 CHAIR MALMUD: Thank you. I just wanted to  
14 clarify that for the record, that three of the four  
15 members of the Subcommittee brought forth this  
16 recommendation, which we correctly now identified with  
17 two changes. One was the change of the adverb to the  
18 adjective. The other was the addition of one word.

19 I wanted to thank all of the members of  
20 the Committee; the diligence of the Subcommittee,  
21 including the thoughtfulness provided by the member of  
22 the Subcommittee which provided the minority report;  
23 the participation of members of the public, including  
24 ASTRO and all of those who spent the two hours with us  
25 in resolving this very difficult and challenging

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1 problem.

2 If I may in closing make a final comment,  
3 having passed the motion. That is, I think we must be  
4 very careful in the future of not attempting to make  
5 regulations that apply --

6 THE REPORTER: Mr. Chairman, I am going to  
7 have to interrupt. This is the Court Reporter. I am  
8 hearing phone interference.

9 CHAIR MALMUD: I am hearing the interference  
10 as well.

11 THE REPORTER: Yes. Participants, if you  
12 are not speaking, please mute your telephones. If you  
13 don't have a MUTE button, \*6 works.

14 CHAIR MALMUD: Thank you.

15 THE REPORTER: Thank you, sir.

16 CHAIR MALMUD: Having passed the  
17 resolution, the recommendation, what I am now saying  
18 as a final comment is it is very difficult for us to  
19 make a resolution or recommendation which is  
20 applicable across an entire specialty field by trying  
21 to apply it broadly to many different organs, for  
22 example, in this case and make it at the same time a  
23 rule which is applicable and enforceable. And we may  
24 in the future need to look at individual organs should  
25 the need arise without prejudice in an effort to make

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1 the rules easier to apply and easier to understand  
2 than those which would be applicable across all organ  
3 systems within the body, regardless of their location.

4 One of the discussants pointed out very  
5 eloquently that the issue of dealing with the prostate  
6 is very different than dealing with sites that might  
7 be in the head or neck. And, therefore, applying the  
8 same rules to each different part of the anatomy of  
9 the human body may not be practical under certain  
10 circumstances. And in the future, we should probably  
11 consider that, should the need arise.

12 It's just an editorial comment which might  
13 be applicable in the future, but was not meant to  
14 alter any of the decisions or recommendations made  
15 today.

16 Once again I want to thank all of the  
17 members who participated in this conference call.  
18 Thank you for your time, your thoughtfulness, your  
19 effort, and your attendance.

20 MR. FULLER: Dr. Malmud?

21 CHAIR MALMUD: Yes? Who is speaking,  
22 please?

23 MR. FULLER: This is Mike Fuller with the  
24 NRC.

25 CHAIR MALMUD: Yes?

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1 MR. FULLER: If you might, I mean, if you  
2 would, before you adjourn the meeting, Brian McDermott  
3 had to leave, but our Acting Deputy, Pam Henderson,  
4 has some remarks she would like to make before you  
5 adjourn the meeting if that would be okay.

6 CHAIR MALMUD: Absolutely. I was not aware  
7 that such a request existed. By all means, go ahead.

8 MR. FULLER: Thank you.

9 MS. HENDERSON: Hi. This is Pam Henderson.  
10 The NRC staff recognizes the challenge associated  
11 with reaching consensus recommendations on this  
12 important subject.

13 On behalf of FSME, I would like to thank  
14 the ACMUI members for all of their efforts on  
15 permanent implant brachytherapy guidance and, in  
16 particular, their openness and willingness to work  
17 with the input from stakeholder groups. This is really  
18 in line with NRC's values and our ways of doing  
19 business. Thank you.

20 CHAIR MALMUD: Thank you. And thank you for  
21 the comments from the NRC.

22 Is there a motion for adjournment?

23 MEMBER WELSH: So moved.

24 CHAIR MALMUD: Thank you. Our meeting is  
25 adjourned.

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(Whereupon, the foregoing matter was  
concluded at 2:06 p.m.)

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