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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 MEETING

7 + + + + +

8 MONDAY,

9 APRIL 11, 2011

10 + + + + +

11 The meeting was convened in room T2-B3 of  
12 Two White Flint North, 11545 Rockville Pike,  
13 Rockville, Maryland, at 9:00 a.m., Leon S. Malmud,  
14 M.D., ACMUI Chairman, presiding.

15 MEMBERS PRESENT:

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

17 BRUCE THOMADSEN, Ph.D., Vice Chairman

18 DARRELL FISHER, Ph.D, Member

19 DEBBIE GILLEY, Member

20 MILTON GUIBERTEAU, M.D., Member

21 SUE LANGHORST, Ph.D., Member

22 STEVE MATTMULLER, Member

23 JOHN SUH, M.D., Member

24 ORHAN SULEIMAN, Ph.D., Member

25 WILLIAM VAN DECKER, M.D., Member

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1 MEMBER PRESENT (cont'd):

2 JAMES WELSH, Ph.D, Member

3 PAT ZANZONICO, Ph.D., Member

4  
5 MEMBERS ABSENT:

6 CHRISTOPHER PALESTRO, M.D., Member

7  
8 NRC STAFF PRESENT:

9 JIM LUEHMAN, Deputy Director, Division of

10 Materials Safety and State Agreements

11 MICHAEL FULLER, Alternate Designated Federal

12 Officer

13 SOPHIE HOLIDAY, Alternate ACMUI Coordinator

14 NEELAM BHALLA

15 JUNE CAI

16 SUSAN CHIDAKEL

17 SUSAN E. COOPER, Ph.D.

18 SAID DAIBES, Ph.D.

19 SARENEE HAWKINS

20 DONNA-BETH HOWE, Ph.D.

21 DEBORAH JACKSON

22 ANDREA KOCK

23 VARUGHESE KURIAN

24 ED LOHR

25 JULIE MARBLE, Ph.D.

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1 NRC STAFF PRESENT (cont'd):

2 KEVIN O'SULLIVAN

3 PATRICIA PELKE

4 JOSEPHINE PICCONE, Ph.D.

5 GRETCHEN RIVERA-CAPELLA

6 SUSAN SALTER

7 GLENDA VILLAMAR

8 SHIRLEY XU

9  
10 MEMBERS OF THE PUBLIC PRESENT:

11 KEITH BROWN, University of Pennsylvania

12 WILLIAM DAVIDSON, University of Pennsylvania

13 LYNNE FAIROBENT, American Association of

14 Physicists in Medicine

15 KAREN LANGLEY, University of Utah

16 RALPH LIETO, St. Joseph Mercy Hospital

17 CANDI MCDOWELL, Georgetown University

18 JANETTE MERILL, Society of Nuclear Medicine

19 HERBERT MOWER, Ph.D., American Association of

20 Physicists in Medicine

21 MIKE PETERS, American College of Radiology

22 AMANDA POTTER, American Association of

23 Physicists in Medicine

24 JOE RODGERS, Theragenics

25 GLORIA ROMANELLI, American College of Radiology

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1 MEMBERS OF THE PUBLIC PRESENT (cont'd):

2 CONOR SCHMERTZ, George Washington University

3 DANNY SONG, M.D., American Society for

4 Radiation Oncology

5 CINDY TOMLINSON, American Society for Radiation

6 Oncology

7 ANN WARBICK-CERONE, MDS Nordion

8 JENNA M. WILKES, American Society of Nuclear

9 Cardiology

10 GARY E. WILLIAMS, Veterans Health

11 Administration

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Adjourn

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

(9:00 a.m.)

CHAIR MALMUD: Good morning, ladies and gentlemen. If you would all be seated, we would like to begin the program promptly and try to stay on schedule.

Thank you. I will begin by introducing Mr. Luehman, who will formally open the meeting.

MR. LUEHMAN: Go ahead, Mike.

MR. FULLER: Okay. As the Alternate Designated Federal Officer for this meeting, I am pleased to welcome you to this public meeting of the ACMUI. My name is Mike Fuller, and I am the team leader of the Medical Radiation Safety Team and 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.

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 April 29, 2011, edition -- I think that should be March 29th edition of the Federal Register.

The function of the Committee is to

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

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

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

16 CHAIR MALMUD: Here.

17 MR. FULLER: Dr. Bruce Thomadsen?

18 VICE CHAIR THOMADSEN: Here.

19 MR. FULLER: Dr. Darrell Fisher?

20 MEMBER FISHER: Here.

21 MR. FULLER: Ms. Debbie Gilley?

22 MEMBER GILLEY: Here.

23 MR. FULLER: Dr. Mickey Guiberteau?

24 MEMBER GUIBERTEAU: Here.

25 MR. FULLER: Dr. Sue Langhorst?

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MEMBER LANGHORST: Here.

MR. FULLER: Mr. Steve Mattmuller?

MEMBER MATTMULLER: Here.

MR. FULLER: Dr. Christopher Palestro?

(No response.)

Dr. John Suh?

MEMBER SUH: Here.

MR. FULLER: Dr. Orhan Suleiman?

MEMBER SULEIMAN: Here.

MR. FULLER: Dr. William Van Decker?

MEMBER VAN DECKER: Here.

MR. FULLER: Dr. James Welsh?

MEMBER WELSH: Here.

MR. FULLER: And Dr. Pat Zanzonico?

MEMBER ZANZONICO: Yes.

MR. FULLER: Okay. I can see that a quorum has been met by the presence of at least seven members.

I now ask NRC staff members who are present to identify themselves. I will start with individuals in the room here. I would also like to add that this meeting is being webcast, so other individuals may be watching online.

Okay. Of course, my name again is Mike Fuller.

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1 MR. LUEHMAN: Jim Luehman.

2 DR. HOWE: Dr. Donna-Beth Howe.

3 DR. DAIBES: Said Daibes.

4 MS. BHALLA: Neelam Bhalla.

5 MR. LOHR: Ed Lohr.

6 MR. O'SULLIVAN: Kevin O'Sullivan.

7 MS. RIVERA-CAPELLA: Gretchen Rivera-  
8 Capella.

9 MS. HOLIDAY: Sophie Holiday.

10 Ms. CAI: June Cai.

11 MR. FULLER: Okay. Do we have other  
12 members of the NRC staff?

13 DR. COOPER: Dr. Susan Cooper.

14 DR. MARBLE: Dr. Julie Marble.

15 MS. SALTER: Susan Salter.

16 MR. FULLER: Okay. Thank you.

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

22 Okay. At this point, I would like to  
23 turn it over to Mr. Luehman, who has some opening  
24 remarks.

25 MR. LUEHMAN: Good morning. I just would

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1 like to welcome the members of the Committee. I  
2 spoke briefly in the closed session to I think most  
3 of you, but I will reiterate what I said then. Rob  
4 Lewis, who is our normal Division Director, Rob has  
5 -- is acting as the Deputy Office Director for the  
6 Office of FSME.

7 After Charlie Miller -- Dr. Charlie  
8 Miller announced his retirement as the Office  
9 Director, he was requested by the Executive Director  
10 for Operations to head up the NRC effort to do a  
11 review of the events in Japan. And so effective last  
12 week Dr. Miller left FSME. Scott Moore, who was  
13 acting as the Deputy Director, is now the Acting  
14 Director, and Robb is the acting Deputy Director  
15 presently.

16 So he is normally here, but I will be  
17 taking his place. All the "actings" will probably go  
18 on for some period of time, but appreciate all of the  
19 members being here. I appreciate that this -- I  
20 think Mike is going to get into it a little bit more,  
21 but this meeting I think is going to be a little bit  
22 different than previous meetings in that we hope to  
23 solicit the Committee's input on a range of subjects  
24 that the Commission has directed us to have some  
25 public meetings on.

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1                   And so to the extent that we can get the  
2 public -- I mean, excuse me, the Committee's insights  
3 on those to help shape the workshops that we intend  
4 to have on these issues, that would be much  
5 appreciated. And so with that, I will turn it back  
6 over to Mike.

7                   MR. FULLER: Okay. Dr. Malmud?

8                   CHAIR MALMUD: Thank you. The next item  
9 on the agenda is Old Business, which Sophie Holiday  
10 will introduce for us.

11                   MS. HOLIDAY: Okay. I included these  
12 charts inside of your binders, and I color-coded them  
13 so you can know what changed from last meeting to  
14 now. As you can see, for 2007, we don't have any  
15 changes. Okay? For 2007, you can see that we don't  
16 have any changes from any time since the last  
17 meeting, and the same applies for 2008.

18                   So we move to 2009. Item Number 1, the  
19 only change to this is that we actually closed this  
20 item. Guidance was revised in April of 2010 and was  
21 proposed to the ACMUI and provided via e-mail on  
22 January 26, 2011. And we consider this item closed.

23                   Are there any questions?

24                   (No response.)

25                   No? Okay. Moving along, we are at Item

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1 Number 5. This is actually a very old item where the  
2 ACMUI said they would create a Subcommittee that  
3 would include three members to review ICRP Report 103  
4 and get back to Dr. Don Cool.

5 I have just been informed that the  
6 Subcommittee provided this information to Dr. Cool,  
7 which morphed into the ongoing interactions with the  
8 ACMUI and the ACRS on the staff's recommendations of  
9 how to proceed to examine the NRC radiation  
10 protection regulations. We will open a new action  
11 item if and when this action should arise from the  
12 Commission's direction.

13 Are there any questions?

14 CHAIR MALMUD: Are there any questions  
15 for Ms. Holiday?

16 (No response.)

17 MS. HOLIDAY: No?

18 CHAIR MALMUD: No. No questions.

19 MS. HOLIDAY: Okay. We will move on to  
20 2010. Item Number 2, the Permanent Implant  
21 Brachytherapy Subcommittee will revise the draft  
22 Subcommittee report and resubmit it to the full ACMUI  
23 for an e-mail vote. The ACMUI will submit a full  
24 Subcommittee report to the NRC.

25 So the Subcommittee reported to the full

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1 Committee, and the full Committee endorsed the report  
2 at the October 20, 2010, meeting, with the caveat  
3 that this is an interim report that may be revised in  
4 the future to consider additional input such as that  
5 that will be received from stakeholders at the public  
6 workshops that we will be holding in the summer.

7 NRC staff posted this report to the ACMUI  
8 public website on December 22nd of 2010.

9 Do we have any questions?

10 (No response.)

11 CHAIR MALMUD: If there are no questions,  
12 I understand that ASTRO will make a presentation  
13 today.

14 MS. HOLIDAY: They will. Thank you.

15 CHAIR MALMUD: And the memo has been  
16 distributed to members of the Committee.

17 MS. HOLIDAY: Yes.

18 CHAIR MALMUD: Thank you.

19 MS. HOLIDAY: Thank you. Moving to  
20 Item 13, Steve Mattmuller, Dr. Bruce Thomadsen, and  
21 Dr. Susan Langhorst offered to provide support to  
22 respond to the letter dated October 20, 2010, to  
23 Chairman Jaczko from Congressman Markey regarding  
24 patient release. ACMUI is currently still working on  
25 this.

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1 VICE CHAIR THOMADSEN: This is Bruce  
2 Thomadsen. I don't know if we are still working on  
3 it. Since the Chair has responded already, I think  
4 that makes this Subcommittee completely moot.

5 MS. HOLIDAY: Okay.

6 VICE CHAIR THOMADSEN: Would the other  
7 members of that Subcommittee agree that we aren't  
8 still working on it, that it is closed as far as  
9 we're concerned?

10 (Several responses in the affirmative.)

11 MS. HOLIDAY: Okay. That will work for  
12 me.

13 Alright. Moving on, Item 17, ACMUI will  
14 provide a list of action items for NRC staff based on  
15 the recommendations provided in the Patient Release  
16 Subcommittee report. I also have this listed as an  
17 open item that the ACMUI is still working on.

18 MEMBER LANGHORST: This is Sue Langhorst.  
19 Yes, we -- I had offered to clarify action items. I  
20 think that Rob Lewis had asked for that, but have not  
21 done so yet, because I thought it would be helpful to  
22 have this discussion on that topic for this meeting,  
23 and also the workshops to include those in that  
24 consideration. So I consider that as still open and  
25 am willing to work on that.

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1 CHAIR MALMUD: Thank you.

2 MS. HOLIDAY: Okay. We will on to 2011.  
3 Item Number 4, the ACMUI endorsed the Draft Final  
4 Safety Culture Policy Statement. The change here is  
5 that staff provided the proposal final policy  
6 statement for Commission consideration. The  
7 Commission held a meeting to discuss the policy  
8 statement on January 24th where Dr. Thomadsen  
9 presented ACMUI views on this policy statement.

10 The Commission approved the publication  
11 of the final policy statement on March 7th. Staff  
12 will make necessary changes, and then it has to  
13 undergo congressional review before it is published  
14 in the Federal Register.

15 Any questions?

16 CHAIR MALMUD: Any questions regarding  
17 that? There are none. Oh, there are. Mickey?

18 MEMBER GUIBERTEAU: When do you  
19 anticipate this will be published?

20 MS. HOLIDAY: I'm not completely sure. I  
21 have just been told that it is still undergoing  
22 review. But as soon as I know, I will let the  
23 Committee know.

24 MS. FAIROBENT: Dr. Malmud?

25 CHAIR MALMUD: Yes.

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1 MS. FAIROBENT: May I ask a question?

2 CHAIR MALMUD: Please do.

3 MS. FAIROBENT: Lynne Fairobent, American  
4 Association of Physicists in Medicine. Sophie, you  
5 said that this is pending congressional review before  
6 being released? Did you mean Congress, or did you  
7 mean Commission review?

8 MS. HOLIDAY: I guess it would be  
9 Commission. I just -- my notes say the Congressional  
10 Review Act.

11 MS. FAIROBENT: Okay.

12 MS. HOLIDAY: Yes.

13 MS. FAIROBENT: Review against the Act,  
14 not that Congress is --

15 CHAIR MALMUD: Right.

16 MS. FAIROBENT: -- going to review it.

17 MS. HOLIDAY: Yes.

18 MS. FAIROBENT: Okay. Thank you for  
19 clarifying.

20 MS. HOLIDAY: You're welcome.

21 Okay. I think that's all I have.

22 CHAIR MALMUD: Thank you.

23 MS. HOLIDAY: Thank you.

24 CHAIR MALMUD: Are there any questions  
25 for Ms. Holiday?

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1 (No response.)

2 There are no questions. Thank you.

3 MS. HOLIDAY: Thank you.

4 CHAIR MALMUD: We'll move on to the next  
5 item on the agenda, which is the Medical Events  
6 Subcommittee Report. Dr. Welsh?

7 MEMBER WELSH: Thank you, Dr. Malmud.  
8 Thank you to the members of the Subcommittee for  
9 assistance in preparing this report. It will differ  
10 from prior reports presented here at the ACMUI in  
11 that a request for some denominators, which allow us  
12 make more sense of this information, that request has  
13 been granted, and we are grateful to the NRC for  
14 providing this information through IMV.

15 So I'll go through these initial slides  
16 relatively quickly. The top number just shows you  
17 how many procedures there are in this country per  
18 year, so it's over a million. And among  
19 brachytherapy procedures, low dose rate prostate  
20 implants represent a large fraction, as do HDR, high  
21 dose rate afterloading procedures.

22 And one of the challenges that I will  
23 talk about again later is that the data provided is  
24 not categorized in the fashion that we would like it  
25 to be -- namely, according to 10 CFR 35 sections. So

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1 you have to tease out the various components and then  
2 categorize them yourself. But, nonetheless, it was  
3 quite valuable to have this information.

4 We found that only in the 35.400 category  
5 there were about 25,000 of these brachytherapy  
6 procedures, the majority being prostate implant  
7 brachytherapy, and a smaller proportion being  
8 temporary implants.

9 As far as the 35.600 series goes, there  
10 are about 42,000 of these, the vast majority being  
11 HDR brachytherapy procedures, followed by about 8,500  
12 Gamma Knife procedures, a huge number of diagnostic  
13 imaging procedures using radionuclides under 35.200.

14 And this slide is a little bit confusing.  
15 I'm talking here about 35.300 series, radionuclides  
16 with written directives. You can see on the bottom  
17 two lines, I-131 thyroid imaging is nearly half a  
18 million, thyroid therapy approximately 56,000, and  
19 then other iodine-131-based therapies, samarium,  
20 strontium, and others with written directives are the  
21 rest.

22 Out of all of those, there were four  
23 medical events last year, or in the fiscal year that  
24 we are referring to here. Three of them were I-131  
25 thyroid patients. One was a neuroblastoma patient

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1 treated with I-131 MIBG.

2 So out of 92,400, this represents an  
3 error rate that is quite minuscule. So it appears  
4 that we are doing relatively well in this regard as  
5 far as avoiding medical events.

6 Keep in mind that this is -- this  
7 denominator was provided through IMV, and it's 2007  
8 and we're talking about 2010. So it's not perfect,  
9 but it does give us a good ballpark figure, a very  
10 good ballpark figure.

11 As far as 35.400 series, there were 27  
12 events involving 27 patients. And this contrasts  
13 with 10 events in the prior period involving 114  
14 patients.

15 I included the Y-90 microspheres here,  
16 but, as you know, they are in the 1000 category and  
17 probably shouldn't be lumped with these.

18 In the current period that we are  
19 discussing, there were 26 events involving 75  
20 patients. So this is the 2010, and that means it is  
21 not very different from the year before. I included  
22 the Y-90 microspheres since we did that last year,  
23 last time, and that was a total of five -- one  
24 cesium-137 vaginal implant case in which the cylinder  
25 came out prematurely and was identified quickly. The

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1 patient had approximately 76 rem to the thigh.

2 But then there were 69 patients who were  
3 identified having misadministration medical events  
4 with permanent prostate brachytherapy. Of these 69  
5 patients, eight were categorized as overdoses, one an  
6 excess dose to normal tissue, one incorrect seed  
7 activity. And of the overdoses, one was retracted  
8 based on repeated post-implant dosimetry.

9 The rest of these were underdoses. Two  
10 of the underdoses were retracted and not felt to be  
11 true medical events. Upon repeat post-implant  
12 dosimetry, it was felt that the gland -- prostate  
13 gland swelled, and upon reevaluation at a later point  
14 when the swelling had subsided the final dose was  
15 within 20 percent of the prescription, of the written  
16 directive.

17 In one case, the D90 was less than one  
18 percent, so medically this would be a quite  
19 inadequate implant. But it was not categorized as a  
20 medical event, since 39 out of the 41 seeds were  
21 within the target and implanted within a few  
22 millimeters of the so-called isoline. The report  
23 states literally, "The seeds could have been placed  
24 in a better location." And the event was attributed  
25 to poor image quality. But upon review, it did not

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1 meet the definition of medical event.

2           The majority of the medical events in  
3 this period were based on dose, specifically the D90,  
4 and the number of seeds outside the prostate. Review  
5 of these medical events leads one to again question  
6 the same thing we asked last time, which is, would  
7 these medical events be so labeled if we used a  
8 different definition, specifically one that was  
9 source-, strength-, or activity-based.

10           An interesting but important observation  
11 is that many, many of the implants -- the medical  
12 events during this reported time period were from  
13 earlier times. This tells me that many institutions  
14 are going back and reviewing their permanent implant  
15 brachytherapy programs and identifying medical events  
16 that might have taken place a number of years back.

17           And I can tell you that many more will be  
18 expected next year, because I used an arbitrary  
19 cutoff date of October 1, as we always do, and there  
20 were at least as many between October 1 and the  
21 present as in the prior period. And it seems that  
22 this is due to institutional reviews, and I think  
23 that many states are conducting such reviews. It's  
24 not just the institutions themselves.

25           There were approximately 25,000 implants

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1 done according to the IMV data, and 26 events in  
2 2010, and that means that we have an error rate or  
3 medical event rate of 0.297 percent. For prostate  
4 specifically, it is 0.33 percent, using the available  
5 denominator.

6 When it comes to the 600 series, you can  
7 see that comparing 2009 versus 2010 there is not a  
8 very significant difference at all. The Gamma Knife,  
9 the second one from the bottom, really no --  
10 obviously no increase, and this might suggest that  
11 the Perfexion unit is not going to lead to an  
12 increase in medical events.

13 As far as the 600 events go, there were  
14 four HDR Nucletron events reported -- wrong catheter  
15 length in two cases, as well as software failure,  
16 incorrect treatment unit mode, incorrect contours  
17 entered.

18 The Varian source had four events --  
19 wrong length, patient movement, possibly this was a  
20 wrong length as well, cylinder shift, and another  
21 with no information.

22 Three events reported in Gamma Knife due  
23 to incorrect coordinates entered, moving helmet, or  
24 the frame not fastened securely enough. Two events  
25 were in the Part 100 because of the new Perfexion

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1 unit. One was wrong side treatment, and the other  
2 was a hard drive failure.

3 So as far as observations in the 600  
4 category, wrong length seems to be the most important  
5 type of error. But when you put things in  
6 perspective, overall there were nine medical events  
7 out of 33,000. The rate is quite impressive at 0.027  
8 percent.

9 Similarly, with Gamma Knife, three  
10 failures out of 20,000 procedures, 0.015 percent.  
11 And teletherapy had no problems.

12 And as the 1000 category goes, the two  
13 events in the Perfexion, with the Perfexion unit,  
14 four events with microspheres out of 1,400 treatments  
15 leads to a medical event rate of 0.3 percent, two  
16 each for the resin and glass spheres, one coronary  
17 brachytherapy event.

18 So as far as what we have learned through  
19 this exercise using the IMV surveys goes, we are very  
20 appreciative that we have the denominators now, but  
21 we have learned that there are some challenges with  
22 this. IMV focuses on a business -- with a business  
23 perspective, and it doesn't collect data by  
24 regulatory section of 10 CFR 35.300. So there is a  
25 little bit of an inconvenience in that regard.

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1           They collect data based on site rather  
2 than procedure. From the raw data, it's not exactly  
3 clear where I-131 sodium iodine might fall, or where  
4 I-131 Bexxar treatments would be listed. And the  
5 radiopharmaceutical data was a composite of two  
6 years, and led to a little bit of confusion. But,  
7 nonetheless, we consider it quite valuable in  
8 providing a denominator that is truly close enough  
9 for demonstrating where we would need to direct  
10 further attention.

11           At least one of our Subcommittee members  
12 felt that unless there was change, a significant  
13 change, further reviews might benefit from focusing  
14 only on 35.400 to 35.1000 series.

15           So one might be able to conclude that  
16 brachytherapy in the United States is an extremely  
17 safe procedure, but one thing that we did observe is  
18 that in 2004 there were 192,000 or so prostate cancer  
19 patients treated; 41,790 were treated with permanent  
20 prostate implant brachytherapy, accounting for 22  
21 percent.

22           But then, in 2009, after the series of  
23 medical events were reported and the negative  
24 publicity surrounding these events really was  
25 emphasized, in 2009 we had an increase in the number

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1 of prostate cancer patients treated -- 219,000 -- but  
2 a significant decrease in the absolute number of  
3 prostate seed implants down to 17,490, and an even  
4 more substantial drop in the percentage.

5           Whether or not this is truly due to the  
6 negative publicity surrounding the medical events  
7 nobody will be able to say. It could be that  
8 alternative treatments have surfaced and caused  
9 prostate brachytherapy to decrease in relative and  
10 absolute numbers.

11           But one can't help but speculate, because  
12 so many people have said that this could very well  
13 happen. It did happen. Whether or not there is a  
14 direct correlation to the publicity in -- the  
15 negative publicity surrounding medical events is  
16 anyone's guess.

17           So I will conclude the presentation at  
18 this point.

19           CHAIR MALMUD: Thank you, Dr. Welsh. Are  
20 there questions for Dr. Welsh, or comments?

21           MEMBER ZANZONICO: Question?

22           CHAIR MALMUD: Dr. Zanzonico?

23           MEMBER ZANZONICO: The teletherapy, that  
24 is just for byproduct teletherapy? So that number  
25 doesn't reflect Linux and that sort of thing?

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1                   MEMBER WELSH: That's correct. I think  
2 it's only a cobalt-60-based teletherapy.

3                   CHAIR MALMUD: Dr. Fisher?

4                   MEMBER FISHER: Darrell Fisher.  
5 According to some of the physicians that I have  
6 talked to, the decrease in prostate cancer  
7 brachytherapy also may correspond to negative  
8 publicity on medical radiation.

9                   MEMBER WELSH: Like I said, nobody will  
10 ever know the truth, because the DaVinci robot  
11 robotic surgery has surfaced in testing modulated  
12 radiation therapy. External beam radiotherapy is  
13 very safe and effective.

14                   And so these things could be competed  
15 with prostate brachytherapy, but I personally -- and  
16 many others in the field -- do feel that prostate  
17 brachytherapy has experienced a decline, at least in  
18 part, because of the negative press surrounding the  
19 medical events.

20                   CHAIR MALMUD: Dr. Guiberteau?

21                   MEMBER GUIBERTEAU: Yes. As you  
22 mentioned, the IMV data is not perfect, but it is  
23 confusing even going back to the data, especially in  
24 terms of unsealed source therapies with I-131, since  
25 those requiring a written directive are not all

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1 therapies. And I see you tried to pull them out  
2 here.

3 But I am curious to know under your slide  
4 here on page 3, on the I-131 thyroid patients using  
5 -- requiring a written directive, you have three  
6 medical events. And since there are only three, I am  
7 wondering if you could elaborate, first of all,  
8 whether those were all therapy patients, and then,  
9 two, what the events were.

10 MEMBER WELSH: Return to that slide. I  
11 might ask for assistance from our Subcommittee member  
12 who might --

13 CHAIR MALMUD: It's Number 9.

14 MEMBER WELSH: -- have addressed that  
15 specific section. But as I said at the start, there  
16 were -- we acknowledged that there are some  
17 challenges with IMV data and pulling out the  
18 subcategories from this raw data.

19 CHAIR MALMUD: Number 9, Slide Number 9.

20 MEMBER GILLEY: Debbie Gilley. This was  
21 the section that I wrote on, and I do not remember  
22 what those three were. I am making the assumption  
23 they were thyroid oblations for thyroid cancer, but I  
24 can't, without looking at the raw data, tell you  
25 that. Maybe you have the raw data, Donna-Beth?

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1 CHAIR MALMUD: Would a member of NRC  
2 staff have those data? Dr. Howe?

3 DR. HOWE: I don't have the raw data with  
4 me, but I can get it. It seems to me many of the  
5 cases were two capsules and only one was given. And  
6 I believe they were the therapy. There may have also  
7 been a diagnostic that ended up getting greater than  
8 30 microcuries, so I can check on that later.

9 CHAIR MALMUD: Thank you. Dr. Thomadsen,  
10 did you say you had this?

11 VICE CHAIR THOMADSEN: I am looking.

12 CHAIR MALMUD: Oh, okay. Dr. Guiberteau?

13 MEMBER GUIBERTEAU: I have a suggestion.  
14 No one likes big, committees that are too big, but I  
15 think it might be helpful since most unsealed source  
16 therapy in the United States is performed by either  
17 diagnostic radiologists with nuclear medicine  
18 training or nuclear medicine physicians that perhaps  
19 it would be helpful to have someone with that  
20 background, a physician with that background, either  
21 as a consultant to the Committee, so that they can be  
22 understanding -- starting to understand these  
23 analyses now that we do have the IMV data, and to  
24 follow it, because it is confusing and we want to  
25 make sure that in terms of those actually using this

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1 that we can come up with some information and our  
2 rationales for any changes in our policies.

3 MEMBER WELSH: Well, if I could respond  
4 to that --

5 CHAIR MALMUD: Dr. Welsh?

6 MEMBER WELSH: -- I would certainly  
7 welcome any additional help from someone with  
8 expertise on this Subcommittee, and nobody, of  
9 course, wants the Subcommittee to get so large that  
10 it becomes unwieldy. But I don't think that the  
11 addition of an individual with such expertise would  
12 cause that.

13 This slide, however, suggests that since  
14 the number of medical events in the 200 and 300  
15 categories is just so low that one of the  
16 Subcommittee members suggested that we focus only on  
17 the section where the real action is.

18 And I guess if you look at the numbers,  
19 the real action might amount to 0.01 percent or  
20 higher, and those numbers are so low that, in my  
21 opinion, the difference between 0.00001 and 0.001 is  
22 not different enough -- significant enough that we  
23 should drop a section or two.

24 So I think that we could continue to  
25 focus on the 300 series, and I would welcome

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1 additional assistance from somebody with expertise in  
2 that area.

3 CHAIR MALMUD: If I may, there is a  
4 member of the Committee who still performs I-131  
5 therapy on a regular basis, and he would be happy to  
6 review each case individually if they are brought to  
7 his attention. That would be myself. Is that  
8 permissible, for the Chair to engage in such a role?

9 MR. LUEHMAN: You can be a member of a  
10 Subcommittee.

11 CHAIR MALMUD: I'm willing to serve as a  
12 reviewer of one, which is what you are asking for.  
13 Am I correct?

14 MEMBER WELSH: Yes.

15 CHAIR MALMUD: I would be happy to serve  
16 as a reviewer of one to just screen those cases  
17 individually and give you my impression as to what  
18 happened. I'm more than happy to do that.

19 MEMBER WELSH: And if I might go back to  
20 the slide and ask the individual on the Subcommittee  
21 if he or she feels strongly about that last bullet  
22 point. I think it was Mr. Mattmuller.

23 CHAIR MALMUD: Dr. Welsh, which bullet  
24 point are you referring to?

25 MEMBER WELSH: The last bullet point here

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1 on this slide.

2 CHAIR MALMUD: Slide 27?

3 MEMBER WELSH: Which is that further  
4 reviews should really focus only on 400 to 1000. I  
5 personally don't think that we need to drop anything  
6 here, but I can understand that when we're talking  
7 about numbers that are so extremely low that it might  
8 not be worth the exercise.

9 CHAIR MALMUD: If I may, Dr. Welsh, I  
10 think that what has happened, what possibly has  
11 happened, is that a single incident consisting of  
12 perhaps as many as 90 cases with a single institution  
13 has cast a pall over brachytherapy. And it is not a  
14 matter of statistical reality, but a matter of public  
15 perception.

16 My own impression, being in Philadelphia,  
17 the city in which this occurred, is that a number of  
18 patients have chosen not to select brachytherapy as  
19 their form of therapy.

20 Therefore, we would be doing a continuing  
21 public service by monitoring these activities, and  
22 the NRC, of course, by enforcing whatever regulations  
23 are appropriate to assure that these kinds of  
24 incidents don't occur, because a single incident can  
25 result in patients not choosing a therapy which would

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1 otherwise have been very therapeutic and useful for  
2 them.

3 So that, in a sense, we are dealing with  
4 a perception rather than reality, but perception  
5 becomes reality in the minds of a public which is not  
6 highly educated to the risks and benefits of many of  
7 the procedures that we perform in medicine and  
8 surgery.

9 Therefore, it is my impression that it is  
10 a worthwhile effort to continue to track these things  
11 in the manner in which you have begun to do already  
12 on a regular basis. Regardless of the small number  
13 of incidents that occur, these are almost like  
14 airplane accidents in which a single accident will  
15 have an effect upon people's willingness to travel by  
16 air in some instances.

17 But in this case, we are dealing with  
18 patients who are not necessarily choosing an optimal  
19 therapy when it is offered to them, because of fear  
20 of what they have read about one institution and its  
21 results.

22 So I would think that that which you have  
23 presented to us is extremely useful and can serve the  
24 public best if we continue our effort and the NRC  
25 continues its effort. But, of course, we want to see

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1 and hear from ASTRO with regard to its comments with  
2 respect to what policy should be employed in the  
3 future if its opinion differs from the opinion so far  
4 expressed by the Committee as a whole. Does that  
5 resonate with you?

6 MEMBER WELSH: I fully concur with what  
7 you've said; with the addition that it is not only  
8 limited to therapeutic procedures. If a diagnostic  
9 procedure starts to get a reputation that it could in  
10 some way be risky, patients would shy away from that  
11 as well, and, therefore, I would favor including all  
12 of the items that we included in this particular  
13 year's exercise in future exercises.

14 CHAIR MALMUD: Thank you. I think there  
15 are other comments from members of the Committee.  
16 Dr. Thomadsen?

17 VICE CHAIR THOMADSEN: Just in response  
18 to Dr. Guiberteau's question, of the four iodines,  
19 three were therapeutics. One was a patient who had  
20 received iodine therapy and was supposed to have a  
21 diagnostic scan as follow-up but got, by mistake, a  
22 therapeutic dose. So, all of them were therapeutic  
23 doses. One was a peculiar one.

24 MEMBER WELSH: Thank you.

25 CHAIR MALMUD: Thank you. Was there

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1 another comment? Yes, Dr. Suleiman.

2 MEMBER SULEIMAN: I think maybe if we  
3 took a step back and look at things a little bit more  
4 globally, number one, I am not so sure the negative  
5 publicity has had the impact that we perceive. I  
6 think you've got a lot of alternative modalities,  
7 technologies, protocols, that are competing with a  
8 lot of these procedures, some of them non-  
9 radioactive.

10 The other concern that I have had for  
11 many years -- and I think I explained it to the  
12 Committee before, and I'll restate it again -- radio-  
13 labeled therapeutics or radio-labeled drugs, the  
14 dosimetry associated with them is much different than  
15 the dosimetry associated with external beam or  
16 brachytherapy where you can pretty much trust the  
17 precision and accuracy of what you are measuring and  
18 how you define a medical event.

19 We are entering an era where you are  
20 getting a lot of hybrid protocols, you are getting a  
21 lot of hybrid modalities, you are getting diagnostic,  
22 and you are getting therapeutic. There is real  
23 potential there for confusion by the community using  
24 it, and I -- so this business about a diagnostic  
25 being used as a therapeutic, or whatever, doesn't

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1 surprise me at all. I think you may see more of that  
2 in the future if the practitioners or the users of  
3 these products aren't, you know, more careful.

4 So I definitely think we should look at a  
5 broad scope, but at the same time, I'm concerned in  
6 that I'm still not very comfortable with the whole  
7 medical event definition, because what we are seeing  
8 now, a lot of the high doses are -- a lot of the  
9 imaging procedures, both radioactive and non-  
10 radioactive, radioactive material, and then you may  
11 be using X-ray and other modalities, are associated  
12 with the heart.

13 And there was a meeting -- I was at the  
14 American College of Cardiology meeting, I believe,  
15 and I think one of the papers talked about some  
16 patient receiving 15 exams. Now, this doesn't  
17 address this -- it's a little bit out of scope of the  
18 medical event, but it's an issue of public safety and  
19 concern.

20 There needs to be more emphasis on  
21 keeping track of doses, especially for therapeutic  
22 patients where they may be getting a pretty sizeable  
23 dose from one procedure, and they may get a dose from  
24 another procedure. And if they're sick, they may go  
25 into different hospitals, and so I -- we may be

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1 getting into an area where you may be seeing some  
2 toxicity issues coming.

3 But unlike SCID where you may see the  
4 damage, internally you don't. We have had -- this is  
5 public information -- we have had clinical trials  
6 where patients -- subjects have died because somebody  
7 didn't do the dosimetry right and the wrong organ  
8 received a certain amount of dose. So the level of  
9 science in the unsealed sources is nowhere near.

10 And when you talk about radiation  
11 therapy, people assume that it has a level of  
12 precision associated with people like, you know, our  
13 medical physicists in the field who are doing the  
14 therapy calculations. But in terms of the unsealed  
15 sources, most of the effort historically has been on  
16 the diagnostic side.

17 So let's not focus so much on the  
18 regulatory criteria. I mean maybe we need to look at  
19 this a little bit more carefully if we are concerned  
20 about the public

21 CHAIR MALMUD: Another comment. Dr. Van  
22 Decker?

23 MEMBER VAN DECKER: Yes, just a couple of  
24 comments. Number one, I wanted to thank Dr. Welsh  
25 for his persistence in getting some type of

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1 denominator here. I think that, you know, that is  
2 always useful in getting a sense for things, and I  
3 think the IMV data is probably the best you've got  
4 because it goes across all age groups.

5 I would also point out, obviously, that  
6 if you're looking for individual CPT codes -- and  
7 since this is, no matter how you look at it, only  
8 going to be a gross denominator, obviously, to CMS  
9 and HOP's databases by CPT code for each of these  
10 things, maybe give you a relative decision breakdown  
11 of where therapy is in the iodines versus not -- you  
12 know, something to kind of keep in mind.

13 As far as the comment on, you know,  
14 diagnostics versus, you know, high group therapies,  
15 you know, I think I would just take us back to the  
16 step of what this process is all about. I mean, all  
17 we are really looking for here is a review of things  
18 that could allow us to see systems, issues that would  
19 allow us to create safety.

20 So I think that, you know, the goal of  
21 the Committee is to just have an eye on what is  
22 safety, and so I think looking at all of the  
23 different realms from 100 on up is not unreasonable,  
24 because you never know when a system's issue might  
25 show up as a background noise.

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1           And so, you know, I think that, you know,  
2           the goal is to know what those individual things are,  
3           because even if one case shows up, as Donna-Beth Howe  
4           has proven to us over the years, if it's one case  
5           where there is a dramatic system error that could be  
6           propagated to the stakeholder community through this  
7           group, then that is something that creates a positive  
8           impact for safety down the line.

9           And so I think that we are looking for  
10          individual system safety issues, plus some sense for  
11          what is the background noise of what is going on,  
12          which is, you know, the reality of choosing one or  
13          the other. And so I would just try to put that into  
14          context in -- you know, into the context that we are  
15          all here trying to make sure that, you know, we do  
16          what's right for patients and get some good outcomes  
17          as well. And, you know, these are all useful  
18          techniques in doing that in one way or the other.

19                 CHAIR MALMUD: Thank you, Dr. Van Decker.

20                 Are there other comments regarding this  
21                 issue?

22                 (No response.)

23                 I would just add, if I may, that the  
24                 regulatory environment is critically important,  
25                 because it can govern the availability of procedures

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1 to patients, since physicians or other practitioners  
2 who are hesitant to use a modality because of  
3 ambiguous regulations will withhold it, to the  
4 detriment of the public.

5 At the same time, the adherence to  
6 regulations is critically important, because it  
7 reassures the public of the safety of that which is  
8 being provided. So that the reason for the  
9 regulations is very clear, and it affects both the  
10 providers and the patients and is something that we  
11 are entrusted with monitoring, with the NRC, and  
12 which we take very seriously.

13 I think if I caught the undercurrent of  
14 your comment it is that what we need are clear,  
15 practical regulations, for the benefit of the public  
16 as the recipients of this, and to reassure the  
17 providers that they will not be unjustly punished or  
18 criticized for therapies that are correctly applied.

19 MEMBER WELSH: I fully agree with what  
20 you have just said, Dr. Malmud. The area that still  
21 stands out in this exercise is the area that stood  
22 out last year -- namely, permanent implant  
23 brachytherapy, specifically, prostate seed implant  
24 brachytherapy.

25 And to underscore what you have just

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1 said, the definition remains a little bit confused in  
2 the opinion of many, and, therefore, institutions and  
3 states have gone back to review cases going back  
4 several years and have discovered that strict  
5 application of this definition is leading to a  
6 surprising number of implant -- medical events in  
7 implants that would seem perfectly acceptable on the  
8 surface.

9 But when you adhere strictly to this  
10 current definition, many implants that appear  
11 medically acceptable and maybe even effective,  
12 certainly safe, are labeled as medical events.

13 And that's why I said that next year we  
14 could be in for a disappointingly large number of  
15 these, simply because this review process is going on  
16 at many institutions in many states using the current  
17 definition, which I know is the subject of great  
18 discussion and debate, and I think we will continue  
19 that discussion right after my presentation.

20 CHAIR MALMUD: Thank you again, Dr.  
21 Welsh.

22 MEMBER MATTMULLER: Dr. Malmud?

23 CHAIR MALMUD: Yes, excuse me.

24 MEMBER MATTMULLER: Steve Mattmuller.

25 Again, I really appreciate your comments on

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1 perception versus reality, because that often trips  
2 us up -- so often. And I had planned to make this  
3 comment later, but I think it might be appropriate  
4 for now in dipping through the backgrounds on medical  
5 events, especially in regards to brachytherapy.

6 And this comes from a SECY document of  
7 10-0062. In regards to what a medical event is --  
8 and to read from this -- they are designed to detect  
9 events that have the potential to harm -- I've lost  
10 my place, sorry -- to harm the involved patients.  
11 And the goal is to identify possible problems before  
12 they rise to that level.

13 So in dealing with perception versus  
14 reality, some of these get identified as medical  
15 events, and I'm sure the public perceives that as  
16 this is bad, something awful has happened to these  
17 patients, where in fact especially in the prostate we  
18 know that's not the case.

19 So I think through all of our discussions  
20 I think that is an important aspect to how the NRC  
21 looks at a medical event. It has the potential.  
22 It's not that something bad has happened potentially  
23 -- or I should say something unusual during the  
24 administration occurred. Potentially there is harm,  
25 but we're not saying there is harm; we're just

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1 looking at it to make sure things remain as safe as  
2 possible.

3 Thank you.

4 CHAIR MALMUD: Thank you, Mr. Mattmuller.

5 Other comments regarding Dr. Welsh's  
6 presentation?

7 (No response.)

8 Thank you.

9 We'll move on to the next item on the  
10 agenda, if we may, and that is the Purpose of  
11 Rulemaking Meeting, which Mr. Fuller will provide for  
12 us.

13 MR. FULLER: Thank you, Dr. Malmud.

14 Again, my name is Mike Fuller, and I am the Team  
15 Leader for the Medical Radiation Safety Team. I want  
16 to take just a few minutes and talk about this  
17 particular meeting, and take just a moment to talk  
18 about how this meeting is just a little bit different  
19 than some of the other meetings at the ACMUI.

20 In Staff Requirements Memo SECY 10-0062,  
21 the one that Steve Mattmuller just referred to, the  
22 Commission directed the staff to hold a series of  
23 stakeholder workshops. And so we are complying with  
24 that in a certain way, and also in accordance with  
25 our SECY paper 11-0035. We informed -- the staff

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1 informed the Commission that it planned to devote  
2 this meeting to 10 CFR Part 35 rulemaking activities.

3 So, and our direction from the Commission  
4 to hold a series of workshops, we are dedicating this  
5 particular meeting to 10 CFR Part 35 rulemaking  
6 activities. And in addition to that, we will have  
7 two more workshops, currently scheduled -- I should  
8 say tentatively scheduled for the middle of June and  
9 more developments on that, more discussion on that  
10 later.

11 We have been working very diligently and  
12 very hard recently to try to get these dates and  
13 locations nailed down, and we should have some very  
14 good news on that shortly. So that's what we were  
15 trying to do.

16 Also -- go to the next. Okay. So over  
17 the course of the next two days -- today and tomorrow  
18 -- the ACMUI members and members of the public will  
19 have the opportunity to provide the staff with their  
20 comments, concerns, and insights on the key topics  
21 that we will be discussing.

22 Now, in my earlier, more formal remarks  
23 when we opened the meeting, I mentioned the fact that  
24 we would like to have consensus whenever possible.  
25 And that is still the case. However, for purposes of

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1 this particular meeting, we are very interested in  
2 the comments, concerns, and issues that individual  
3 members of the ACMUI would like to provide us with.  
4 But if, in fact, the Committee would like to provide  
5 us with a consensus position, then we would very much  
6 welcome that as well. It's just not, you know,  
7 absolutely the focus for this particular meeting.

8           And so our primary position, the staff's  
9 primary objective, is -- for this particular meeting  
10 is for us to listen. So over the course of today and  
11 tomorrow, we will be having various members of our  
12 staff come and provide you with a brief summary of  
13 the issue that we would like to hear about, or hear  
14 from you about, and provide you with whatever status  
15 we might have on that, where we are in the rulemaking  
16 process, if we are actually in the rulemaking process  
17 yet on that.

18           But, again, our focus is to listen  
19 primarily to what your comments are. And, of course,  
20 at Dr. Malmud's discretion, if you want to open it up  
21 to members of the public, we would very much welcome  
22 those comments and concerns as well.

23           After me, Neelam Bhalla and Ed Lohr from  
24 our Division of Intergovernmental Liaison and  
25 Rulemaking will be providing sort of a brief overview

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1 of all of the expanded -- of all the issues and  
2 topics that are being considered currently under the  
3 expanded Part 35 rulemaking activities.

4 And then, after that, for the balance of  
5 the meeting, we will discuss four topics in  
6 particular. They are permanent implant  
7 brachytherapy, the extending of grandfathering to  
8 certain certified individuals, and some rulemaking  
9 activities related to preceptor attestation  
10 requirements, and then also we will have a discussion  
11 on the public dose limits and the need -- potential  
12 need for rulemaking on public dose limits for  
13 released patients.

14 So those are the four key topics that we  
15 will be trying to focus this meeting on. However, as  
16 I said earlier, Neelam Bhalla and Ed Lohr will be  
17 providing you with an overview of many other topics  
18 that are currently being considered for rulemaking.  
19 And if time allows -- and, again, at the discretion  
20 of Dr. Malmud -- we may open -- maybe late tomorrow  
21 open those up, some of those other topics up if  
22 people would like to provide us with their insights  
23 and their comments on those as well.

24 So with that being said, again, we are  
25 here to listen for the most part, and we are prepared

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1 to answer questions on these topics to clarify  
2 issues, and so forth. But we really want to hear  
3 your views.

4 And with that, are there any questions  
5 for me at this point about process and what we plan  
6 to do or hope to do over the next two days?

7 CHAIR MALMUD: Sue?

8 MEMBER LANGHORST: Mike, we are focusing  
9 on four issues in today's -- or this week's meetings.  
10 The workshops, you will talk about all of the issues,  
11 or will they only focus on these four also?

12 MR. FULLER: We are planning to focus on  
13 the same four issues. And just to be clear, the  
14 Commission directed us to hold a series of workshops  
15 for the purpose of gaining stakeholder input, public  
16 stakeholder input on the medical event definitions as  
17 it relates to permanent implant brachytherapy.

18 Because we knew we were in the process,  
19 in the early stages of rulemaking activities for what  
20 we have been referring to as our expanded Part 35  
21 rulemaking, which has 28 or 30 topics, we looked at  
22 those to see which ones would either be of the most  
23 interest, the most controversial perhaps, or the ones  
24 that had gotten the most attention in the past.

25 And recognizing that there is limited

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1 time to have a facilitated discussion on these topics  
2 and to have them be really worthwhile, we are going  
3 to limit those to those same four topics.

4 CHAIR MALMUD: Jim, you had a comment?

5 MR. LUEHMAN: Just to -- I mean, I think  
6 that one of the purposes of this discussion with the  
7 Committee is that, as Mike said, we have chosen four  
8 which, based on public -- previous public comment,  
9 interaction previously with the Committee, or  
10 interaction within the staff, that we think are going  
11 to be the primary focus of those workshops.

12 But if the Committee, in its wisdom  
13 today, wants to tell us that we -- that there is  
14 probably another one that is probably one that we  
15 should be ready to highlight, I mean, I think that  
16 that will make those upcoming meetings/workshops that  
17 much more beneficial, that we will be really prepared  
18 to talk -- we think we are prepared to talk about the  
19 issues the majority of the medical community and  
20 stakeholders want to talk about.

21 But if there is one -- if there is an  
22 issue buried in there that we hadn't anticipated,  
23 hopefully we can -- we can, you know, tease that out  
24 today, so that the staff will be better prepared for  
25 what we thought was, you know, maybe a non-

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1 controversial issue in those 28 that might be more  
2 controversial or more complex than we anticipated.

3 MEMBER LANGHORST: Okay.

4 CHAIR MALMUD: Thank you. Dr. Van  
5 Decker?

6 MEMBER VAN DECKER: Would you be willing  
7 to comment a little bit on timeline in your mind, A?  
8 B, whether you see these workshops more than being a  
9 couple in June, and whether there are some coming in  
10 the fall? And the second main question is the  
11 involvement of the Agreement States in all of this,  
12 because we know the three-year timeline to move  
13 things through the Agreement States and what that  
14 really means in the long run for trying to get things  
15 to happen in the nation.

16 MR. FULLER: Well, concerning the  
17 timeline, that issue is still before the Commission  
18 as far as a decision goes. We have a paper up there  
19 now that they have not voted on. I do know that  
20 Neelam and Ed are prepared to talk a little bit  
21 about, you know, what typically -- what requirements  
22 there are for rulemaking as far as the timeline.

23 As far as any additional public meetings,  
24 stakeholder meetings, the meetings we are discussing  
25 or planning to have in June are early in the process

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1 before there is a proposed rule. And, again, Neelam  
2 and Ed can make sure I am being -- saying the right  
3 things here.

4 But my understanding is, is that these  
5 are an opportunity for us to gain early comments and  
6 early insights from the public and key stakeholders.  
7 And we are planning to have participation by  
8 Agreement States in these workshops. I probably  
9 should have mentioned that earlier.

10 The real challenge for us, to be real  
11 clear, has been getting contracts in place for  
12 putting these workshops on to help with the  
13 logistics, and so forth. And we think we are very  
14 close. We have actually awarded a contract within  
15 the last couple of days, and we have had some good  
16 meetings with our contractors. So we are moving  
17 forward. We should have some dates and locations  
18 very soon.

19 MR. LUEHMAN: And the other thing I would  
20 just add to what Mike said is we are also very  
21 cognizant that there is a lot of professional -- the  
22 major professional societies that have their meetings  
23 during the late spring, the summer, and the fall.  
24 And we have been in our planning, though we don't --  
25 can't bring forth the dates, the specific dates

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1 today, in our planning we have been very cognizant of  
2 those types, and we are trying to work around, as  
3 best we can, all of those dates.

4 MR. FULLER: And the other thing I will  
5 mention, too, is that as soon as -- that has been our  
6 big, big hang-up. As soon as we have the dates and  
7 locations nailed down, then we will be working  
8 extremely hard to do, you know, outreach. And we  
9 have already outreached to some organizations on this  
10 and had some informal discussions with different  
11 folks in the states. So, again, hopefully we will  
12 have some really good news on this just in a matter  
13 of days.

14 The other thing, though, to answer your  
15 question, Dr. Van Decker, with regards to  
16 opportunities for additional public participation,  
17 again, this is all pre-proposed rule, pre-rulemaking,  
18 or pre-drafting of rule language. Once there is a  
19 proposed rule drafted, then we will follow our normal  
20 process for public participation in that as well.

21 So this is -- this two days, and the  
22 workshops in June, are opportunities for the staff to  
23 hear from key stakeholders and co-regulators and  
24 everyone, members of the public, to get early insight  
25 into the types of things that we need to be focused

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1 on, such that when we do get busy writing proposed  
2 rule language that we have that information available  
3 to us and we take that into consideration.

4 CHAIR MALMUD: Thank you. Ms. Fairobent?

5 MS. FAIROBENT: Dr. Malmud, thank you.

6 Lynne Fairobent with the American Association of  
7 Physicists in Medicine. I just have two comments, if  
8 I might, to the presentation that we just heard.  
9 First, to consider the ACMUI meeting and public  
10 workshop to discuss rulemaking activities, I find  
11 very ironic.

12 To bury that type of statement in a SECY  
13 paper to the Commission and saying you are  
14 considering this meeting a public workshop to discuss  
15 these, but not to present it that way in the March  
16 29th Federal Register announcing this meeting, I  
17 think is indicative of why you do not have a larger  
18 public here today.

19 Second, NRC continues to schedule public  
20 workshops with less than eight weeks' notice to the  
21 community that is being impacted. We have in the  
22 past asked for a longer time. To schedule two  
23 workshops of this significance on this particular  
24 rulemaking, even if you are focusing only on four --  
25 maybe the four most significant items of the 28 in

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1 the draft rulemaking, is insufficient notice to the  
2 community to adequately present and participate in  
3 order that NRC can receive the best input from the  
4 public early on in the process.

5 CHAIR MALMUD: Thank you for your  
6 opinion. May I ask what you believe would be more  
7 optimal notice than eight weeks?

8 MS. FAIROBENT: We are being told by our  
9 members -- and I am hearing through the community --  
10 that it takes three to six months notice in order to  
11 be able to schedule time off and away from the office  
12 in order to participate adequately in public  
13 workshops.

14 And particularly, scheduling public  
15 workshops in the middle of major scientific  
16 professional societies' meetings when many members  
17 are only being allowed, if at all possible, to travel  
18 to one professional meeting in a year, really is  
19 impacting the community to provide the adequate input  
20 that the NRC might need as they promulgate  
21 regulation.

22 CHAIR MALMUD: If I may, we of course  
23 have no control over the travel budgets of the  
24 members of any professional organization which may  
25 want to send representatives to a public meeting. So

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1 that's not an issue that we can deal with.

2           However, the issue of timing is something  
3 that we might be able to address to make -- to  
4 establish the meeting at a time when the calendar  
5 does not show a major scientific meeting conflicting  
6 with these presentations. Would that be a reasonable  
7 approach for us to take with respect to your  
8 concerns?

9           MS. FAIROBENT: I think that we would  
10 appreciate any help at all in obtaining farther  
11 notice about rulemakings. This happened with the  
12 Part 20 rulemakings. Again, it was reflective of  
13 NRC's contracting procedures to hire facilitators.  
14 And I think continuing to compress the community such  
15 that they can provide and participate really is  
16 providing a negative impact. That is my view.

17           I'm hearing it from the community. I  
18 don't know if anybody else has heard it from any of  
19 their members, but I'm certainly hearing that at  
20 meetings, and at both professional society and at  
21 public workshop meetings.

22           CHAIR MALMUD: Thank you for  
23 communicating that to us.

24           Dr. Welsh?

25           MEMBER WELSH: Jim Welsh. I agree with

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1 the opinion of Dr. Fairbrent that we just heard from  
2 the AAPM. And I suspect that if we are considering  
3 this ACMUI meeting to be part workshop, that we are  
4 not going to resolve all of the issues during this  
5 one meeting, and this might present an opportunity to  
6 announce that in six months when we have our next  
7 ACMUI meeting it could also be a workshop, if this  
8 particular session works out to our satisfaction  
9 today and proves to be a viable venue. That way, we  
10 could continue our discussion with all of the members  
11 involved and with adequate notice to AAPM and other  
12 stakeholder organizations.

13 CHAIR MALMUD: Other comments? Dr.  
14 Suleiman?

15 MEMBER SULEIMAN: I think maybe the  
16 workshop confuses. I think we have got enough issues  
17 to discuss. I think it sounds like you're scheduling  
18 open public workshops in the future, so I don't think  
19 anybody is going to be denied an opportunity to  
20 participate.

21 I absolutely agree with Lynne. I think  
22 there are too many meetings by too many groups. I  
23 have trouble all the time -- I don't know about the  
24 rest of you, but I do -- and I can't get to these  
25 meetings. I can't prepare for them. And I think

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1 it's an indication of our times. Sometimes a lot of  
2 information is flowing too fast for people to digest  
3 it. I think that, to me, is a more palpable concern.

4 But aside from that, I think let's have  
5 our discussion, and you'll have more discussions in  
6 the future on this, so you will give other  
7 stakeholders an opportunity.

8 But I absolutely agree. I usually don't  
9 like -- for meetings where I am asked to participate;  
10 I used to say six to 12 months. Forget that. That  
11 doesn't seem to be the case at all anymore, so it's  
12 difficult. A little bit more lead time would be  
13 nice.

14 CHAIR MALMUD: So you are in favor of a  
15 longer lead time of about six months?

16 MEMBER SULEIMAN: Well, that's just --  
17 the longer, the better for me.

18 CHAIR MALMUD: I have a question for NRC  
19 staff, and that is, when is the effort -- these  
20 workshops supposed to be completed?

21 MR. FULLER: Well, currently we have  
22 tentative dates that are the second and third week in  
23 June and -- the second week of June and the third  
24 week of June. And we -- I guess we can share the  
25 frustration, because we have been working very, very

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1 hard to try to get these dates nailed down for a  
2 considerable amount of time. And I will just leave  
3 it at that.

4           However, if the Committee would like to  
5 provide us with a recommendation that we postpone  
6 them or do something to allow more time, you know, we  
7 would be happy to receive that. But keep in mind  
8 that what we have tried to do -- the real challenge  
9 for us has been to account for the various  
10 professional society meetings and not to have them at  
11 the same time, to try to have it in different parts  
12 of the country, so that folks who might be at one at  
13 a time near when we are scheduling ours could have at  
14 least some time off in between.

15           But also, we are trying to work with a  
16 rulemaking schedule that is a multi-year schedule.  
17 And if we delay the workshops very much, it will have  
18 a real impact on when we can actually get the  
19 proposed rules out and meet those deadlines and those  
20 milestones.

21           So we do share in the frustration. We  
22 agree that it would be better to have more lead time  
23 to make our announcements, and we have been working  
24 as hard as we can to get as much time in advance as  
25 possible, and we have had our challenges.

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1 CHAIR MALMUD: Are there further comments  
2 regarding this issue?

3 MEMBER MATTMULLER: This is Steve  
4 Mattmuller. I would suggest perhaps trying to  
5 piggyback some of these workshops to the professional  
6 meetings to lessen the burden on the travel funds for  
7 some of these people, because then it is much easier  
8 for them to schedule and to attend the professional  
9 meeting and then stay for another day or two for the  
10 workshop meeting than to make two separate trips.

11 I know last fall I became a volunteer for  
12 a workshop, because it happened to piggyback onto an  
13 ACMUI meeting here in D.C., and so -- but I came as a  
14 member of the SNM, and they said, "You're here, you  
15 know, can you do this for us?" And so it worked out  
16 in that regard, because the professional  
17 organizations have travel constraints also.

18 MR. FULLER: And I do appreciate that  
19 comment, and we have had -- we have had that comment,  
20 and we have also had the exact opposite comment. And  
21 that is that while it may seem to make sense for  
22 travel dollars, away-from-the-office time is  
23 something that is also something that people had a  
24 hard time with.

25 So we have actually tried to learn from

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1 experience that organizations with NRC had done this  
2 very thing, and there was a tremendous amount of  
3 negative feedback for piggybacking.

4 But we -- again, I do appreciate that  
5 comment, and it is something that we did wrangle with  
6 early on.

7 Just to let you know, we are in the  
8 process now -- we did finally get a contract awarded  
9 for doing -- setting up these particular workshops.  
10 And we had -- late last week we had our kickoff  
11 meeting with the contractor, and they have been  
12 directed in their focus and they have assured us that  
13 they are going to work on nothing but nailing down  
14 these locations and these dates.

15 And hopefully within a matter of days we  
16 will have something that we can then work very, very  
17 hard to get out the word, recognizing that eight  
18 weeks is not very much time for people to prepare. I  
19 understand that, and we are going to try to work with  
20 that as best we can.

21 Also, keep in mind that we have had --  
22 the focus of this is on permanent implant  
23 brachytherapy. We have had a pledge on the part of  
24 -- at least on ASTRO's part that they are willing to  
25 participate, although I know we have probably made

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1 things hard on them as well.

2 And so we are still hopeful and still  
3 optimistic somewhat that we can have a fruitful  
4 discussion on the issues at these workshops. But,  
5 yes, it has been a real challenge for us.

6 MR. LUEHMAN: I would just like to add,  
7 Dr. Malmud, just quick two things. One is that, as  
8 Mike said earlier, I will reiterate, I mean, if the  
9 collective wisdom of the Committee is that we need to  
10 -- that we should move it out further, if that is the  
11 recommendation, then, you know, we will take that  
12 under consideration.

13 But as Mike also said, that this is --  
14 you know, this process has only got so much time in  
15 it. And if we want to have stakeholder meetings  
16 before the rulemaking, then if we put the rule -- if  
17 the put the stakeholder meetings out too far, we are  
18 going to then start impacting the rulemaking  
19 schedule, which I think that is going to get negative  
20 reactions from stakeholders, too. So there is -- you  
21 know, it is sort of a zero-sum gain in that regard.

22 The second thing I would say is, as far  
23 as characterizing this ACMUI meeting as a workshop,  
24 again, I appreciate Dr. Suleiman's comments on -- you  
25 know this isn't really a workshop. I think that what

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1 we wanted to do is to be informed by the Committee as  
2 to the subjects, whether we are hitting the mark, or  
3 whether the subject matter that we see as the main  
4 subjects for the workshop, if we are in the correct  
5 place.

6 To the extent that the public wants to  
7 offer comments on that, or on the particular  
8 subjects, at the Chair's discretion, that's fine.  
9 That sort of gives us a leg up. But, really, we  
10 intend to -- the two meetings that we intend to hold  
11 away from Rockville are -- with a lot more notice are  
12 really going to be, if you will, the two true  
13 workshops that we are going to have before them.

14 I think it's inescapable that, you know,  
15 if we start talking about those subjects today, to  
16 the extent that they are on the agenda, that we may  
17 get public comment, and that would put us that much  
18 further ahead. But, you know, we may also get  
19 comment from the Committee that we haven't got all  
20 the right subjects or -- and that's why we are here  
21 to listen.

22 CHAIR MALMUD: Dr. Langhorst.

23 MEMBER LANGHORST: Mike, how can the  
24 public interact with the workshops, and how -- what  
25 are other avenues for the public to interact on this

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1 pre-rulemaking effort?

2 MR. FULLER: I appreciate that question.  
3 Not only are there going to be workshops that will  
4 have facilitated discussions on these various issues,  
5 but there will be a webinar where folks will be able  
6 to see and hear the presentations, and be able to see  
7 the slides, and hear the audio discussion while  
8 they're going on. And there will be an opportunity  
9 for people to participate from remote locations, as  
10 well.

11 MEMBER LANGHORST: Okay. Are there are  
12 other avenues for people to participate, or  
13 organizations to participate in this pre-rulemaking  
14 effort, other than those two workshops?

15 MR. FULLER: I'm going to yield to one of  
16 our rulemaking experts who can, perhaps, answer that  
17 question.

18 MS. BHALLA: Yes. What we also plan to  
19 do besides the workshop is post the draft rule text  
20 for most of the items which are out there, so we'll  
21 be very -- we'll put what the understanding is, what  
22 the draft rule text will be. Basically, it'll be  
23 asking for comments. But when we do the proposed  
24 rules, we will not be addressing those comments  
25 comment-by-comment, which we generally do at the

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1 proposed rule stage going to the final rule. But we  
2 will take into consideration what the comments will  
3 be on these proposed rulemakings.

4 CHAIR MALMUD: Thank you, Ms. Bhalla.

5 MEMBER LANGHORST: Thank you.

6 CHAIR MALMUD: May we assume, though,  
7 that we have heard from a member of the public that  
8 these meetings should be scheduled no sooner than six  
9 months after the announcement? Am I correct in  
10 having heard that suggestion?

11 MS. FAIROBENT: Lynne Fairobent. Dr.  
12 Malmud, I said typically, we're hearing that it takes  
13 at least three months, so three to six months would  
14 be optimal for people for planning, and six to eight  
15 weeks is very tight scheduled. We're about eight  
16 weeks out now from the second week of June. The  
17 Federal Register Notice doesn't appear for another  
18 two or three weeks with the final dates in it. We're  
19 getting close to less than six weeks notice.

20 Perhaps, and I believe you me, I don't  
21 want to drag out the rulemaking process any longer.  
22 It's been dragged out enough, but maybe having the  
23 two workshops a week apart, if someone can't make the  
24 second week of June, they're probably not going to be  
25 able to make the third week of June. So, if there's

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1 more time between the two workshops themselves, you  
2 may be able to pick up more people, even if there's  
3 less than three or six months notice.

4 CHAIR MALMUD: Thank you. We've heard a  
5 suggestion.

6 MR. FULLER: Okay.

7 CHAIR MALMUD: Thank you. Are there any  
8 other issues with regard to the item on the table at  
9 the moment? Ms. Bhalla.

10 MS. BHALLA: I, also, just want to bring  
11 it to the attention, since there was a comment with  
12 regard to an announcement, in the Federal Register,  
13 even though, for example, this meeting was the  
14 meeting announcement, well, we could not -- in the  
15 Federal Register, they have their own rules, so we  
16 could not put it under Meeting Announcements, so it  
17 was issued under proposed rules. And that's just a  
18 rule of the Federal Register, itself. So, therefore,  
19 when we sent the list of -- through the list of  
20 announcements, we were able to characterize that this  
21 meeting would -- it is ACMUI's meeting, so the  
22 announcement was for the meeting. However, it was  
23 announced through the proposed rule section. So, I  
24 will -- even for June meetings, or whenever those  
25 meetings will be, please look for the announcement

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1 under the proposed rules, and not in the meetings.  
2 And just the way the Federal Register works. So,  
3 just a little note.

4 CHAIR MALMUD: Thank you for that  
5 information. Any other comments from either Mr.  
6 Fuller or Mr. Luehman? If not, then we'll move on to  
7 the next item on the agenda, which will be that of  
8 Ms. Bhalla and Mr. Lohr; that is the Overview of Part  
9 35 Expanded Rulemaking.

10 MEMBER WELSH: Dr. Malmud.

11 CHAIR MALMUD: Yes, this is a question  
12 from Dr. Welsh.

13 MEMBER WELSH: To finish up our last  
14 discussion, I'm wondering if it might be appropriate  
15 to propose including in the next ACMUI meeting some  
16 dedicated time for workshop activities, so that we  
17 might have sufficient notice that would, perhaps,  
18 address the question that was just raised. And this  
19 could be in addition to the ones that are already  
20 being scheduled in June, not to replace them, but in  
21 addition. But, as we heard, with less than six weeks  
22 notice, some people or members of stakeholder  
23 societies might not be able to attend. ACM, my  
24 members might not be able to attend, but if we know  
25 six months in advance that an hour, or two, or three,

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1 or whatever might be appropriate for the be workshop-  
2 related event, we could put that on the agenda for  
3 next time to give adequate notice.

4 CHAIR MALMUD: Dr. Welsh is suggesting  
5 that our next ACMUI meeting, which will be scheduled  
6 in the fall, would be an opportunity to incorporate  
7 some hours of a workshop. What's NRC Staff's  
8 response to that suggestion?

9 MR. FULLER: Well, I can -- I think the  
10 Staff's position, as always, is that we are -- for  
11 the ACMUI, we're here to support you in these  
12 meetings, so if you would like to have some time  
13 dedicated in the fall meeting to continue the  
14 discussions, to continue the opportunity to provide  
15 the Staff with your comments and insights on the  
16 various things that are undergoing rulemaking, I  
17 don't believe, and I'd have to defer to the  
18 rulemaking experts, but I really don't believe, at  
19 least on the key topics that we're focused on right  
20 now, that there's any reason why we couldn't continue  
21 to hear from the ACMUI members, the ACMUI as a  
22 Committee, or individuals who represent various  
23 professional societies, and so forth. To me, it  
24 sounds like it would be another good opportunity for  
25 us to hear from our key stakeholders.

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1 CHAIR MALMUD: The Chair would like to  
2 entertain a motion, therefore, from Dr. Welsh, that  
3 that be incorporated into the next meeting, and see  
4 what the members of the Committee feel about it.  
5 Would you care to make that motion?

6 MEMBER WELSH: So moved.

7 CHAIR MALMUD: So moved. Is there a  
8 second to Dr. Welsh's motion?

9 MEMBER VAN DECKER: I have a question.

10 CHAIR MALMUD: Before the question, it's  
11 seconded by Dr. Thomadsen. Now, we have a question  
12 from Dr. Van Decker.

13 MEMBER VAN DECKER: I guess my mind set  
14 would be hearing what you believe that the time line  
15 for the proposed draft rule is going to be, and how  
16 long -- four more months of waiting over the summer  
17 is going to delay things. There are pieces of this  
18 that, obviously, have been talked about now for  
19 several years since the rule came out, and everything  
20 that slows things down as the yin and yang of life,  
21 but discussion is good, just depends on what the  
22 timing --- the approach timing was to start with,  
23 from a brachytherapy part of the pool, anyway.

24 MEMBER WELSH: I'd like to respond.

25 CHAIR MALMUD: Dr. Welsh.

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1                   MEMBER WELSH: I would certainly hope  
2 that we would not need to have another stakeholders  
3 meeting in six months. But given that this has  
4 dragged out for so long, and it's so controversial,  
5 in all reality I suspect that we will not have full  
6 resolution following the June discussion. And,  
7 therefore, it might be reasonable to have something  
8 on the schedule that would be easily postponed or  
9 cancelled. And we could certainly find alternative  
10 topics to discuss in this Committee, but if we do  
11 have something reserved, as far as specific time, if  
12 we do not resolve this situation in June like we  
13 hoped, at least we will have a schedule to follow  
14 discussion that people will be aware of, the public  
15 can be aware of.

16                   CHAIR MALMUD: Thank you. Other comments  
17 with regard to the motion on the table? That's the  
18 motion of Dr. Welsh to incorporate some hours in our  
19 next meeting, which will be in the fall, for the  
20 workshop? Mr. Mattmuller.

21                   MEMBER MATTMULLER: Yes. I peeked ahead  
22 at their Integrated Plan, and the Staff hopes to  
23 consolidate comments from all the workshops July  
24 through September of this year, our next meeting  
25 would be in October. And if you look further down

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1 after Proposed Rules, they still have three public  
2 meetings, so I think that's going to be ample  
3 opportunity. I don't know if we need to add one more  
4 opportunity at this point for public discussion.

5 CHAIR MALMUD: Are you speaking in favor  
6 of Dr. Welsh's motion, or against it?

7 MEMBER MATTMULLER: Against it.

8 CHAIR MALMUD: Against it. Because you  
9 feel the work will have been completed by September.

10 MEMBER MATTMULLER: I think the first  
11 draft will be completed by September. And then after  
12 that with the proposed rule, they still plan three  
13 public meetings to comment on the proposed  
14 rulemaking. So, I think there's going to be ample  
15 opportunity to guide the NRC in this regard. So,  
16 yes, I'm against it.

17 CHAIR MALMUD: Are you concerned about  
18 the issue raised by the member of the public with  
19 regard to adequate notice for these meetings?

20 MEMBER MATTMULLER: I am sensitive to  
21 that.

22 CHAIR MALMUD: That's what's triggering  
23 off this consideration --

24 MEMBER MATTMULLER: Yes.

25 CHAIR MALMUD: -- for incorporating an

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1 additional hearing for members of the public to  
2 participate in the workshop. All right. Other  
3 comments from Members of the Committee? DR.  
4 Suleiman.

5 MEMBER SULEIMAN: I stepped out for a  
6 minute. These are not new issues.

7 CHAIR MALMUD: Correct.

8 MEMBER SULEIMAN: These didn't come to us  
9 fresh, never heard of before. So, these are issues  
10 that have been out there for a long time, so I think  
11 we should take that into consideration. I think  
12 these issues -- I'd be surprised if we get any new  
13 perspectives on this. It's just going to be a lot of  
14 people weighing in on their own different  
15 perspectives.

16 CHAIR MALMUD: Thank you. Dr.  
17 Guiberteau.

18 MEMBER GUIBERTEAU: I feel exactly what  
19 was just said, that this issues have been here, and  
20 they're important issues to practicing stakeholders.  
21 And I think we've been waiting quite a while for  
22 these to be resolved, and I, personally, would not  
23 like to see anything done that would delay a final  
24 rule.

25 CHAIR MALMUD: Thank you. Other comments?

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1 Dr. Langhorst.

2 MEMBER LANGHORST: I would, certainly,  
3 like to hear at our next meeting what is the status  
4 of the rulemaking process, and where you all are at  
5 that point in time. And that might give a balance to  
6 both sides, so that we could add some additional  
7 comments, if necessary, to hear where the NRC Staff  
8 is at that point in time.

9 CHAIR MALMUD: Thank you. Dr. Thomadsen.

10 VICE CHAIR THOMADSEN: I'm sure that we  
11 will hear where we are at that time. I don't think  
12 that that addresses, at all, the issue that's on the  
13 table, because the issue on the table is whether or  
14 not stakeholders will have the time -- the lead time  
15 necessary to make their views known at these  
16 meetings. I think that that's the issue that's on  
17 the table right now.

18 CHAIR MALMUD: Dr. Welsh.

19 MEMBER WELSH: And I would like to remind  
20 the Committee that the motion is phrased so that if  
21 the issue is resolved, we don't need to have a  
22 stakeholder meeting. If the question at hand is  
23 fully answered in the June or subsequent stakeholder  
24 meeting, this tentatively proposed reserved time at  
25 the ACMUI meeting in October may not prove to be

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1 necessary. But I feel that it's reasonable and wise  
2 to reserve such time, if, in my opinion, the more  
3 likely event, which is we still don't have complete  
4 consensus, comes true, at least we will have ample  
5 opportunity for public notification and gathering so  
6 that we can continue this important discussion.

7 CHAIR MALMUD: Dr. Thomadsen.

8 VICE CHAIR THOMADSEN: I don't understand  
9 what you mean that the issue could be resolved. If  
10 the whole issue is trying to get input from people  
11 who feel -- from organizations that feel they don't  
12 have notice to give the input, how could that be  
13 resolved ahead, before?

14 MEMBER WELSH: Frankly, I don't think  
15 that it will possibly be resolved ahead of time.  
16 That's why I'm pushing forward with this particular  
17 agenda item. I don't think that we will have  
18 resolution before -- within the next few months. I'm  
19 just not optimistic that we'll have all the answers  
20 by the next meeting month.

21 CHAIR MALMUD: Dr. Guiberteau.

22 MEMBER GUIBERTEAU: I'm a little bit  
23 concerned about how we would do this, because I would  
24 feel that reading the minutes of this meeting, if we  
25 decided to save time, or reserve some time in

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1 October, and I was a stakeholder, and I could make  
2 one of the June meetings, but it would be more  
3 convenient for me to come in October, then I might,  
4 indeed, decide that I would just wait until October,  
5 because this is likely going to be an opportunity.  
6 And if it isn't an opportunity, then we have really  
7 misled some of the stakeholders. So, I mean, I'm  
8 just concerned about how -- the logistics of this  
9 proposal.

10 CHAIR MALMUD: Dr. Welsh.

11 MEMBER WELSH: If I might reply to that,  
12 that's a very good point. However, I think all the  
13 stakeholders involved want nothing more than to see  
14 this done expeditiously, but correctly. And,  
15 therefore, those who are given adequate notice about  
16 the June meeting will be here. The stakeholder  
17 societies will have some representation. It might  
18 not be the individuals who we'd like to have there,  
19 because with such short notice, people's schedules  
20 can't be arranged. But I think everybody wants to  
21 have this done as efficiently as possible, and I  
22 don't think that we have to worry that organizations,  
23 such as ASTRO, would not have a representative at the  
24 June meeting, because we have made an announcement  
25 that there's going to be discussion in October. I

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1 just don't think that we have to worry about that  
2 kind of an issue.

3 MEMBER GUIBERTEAU: But I think we need  
4 to treat all stakeholders equally. So, I mean, I  
5 don't think we can presume some stakeholders --  
6 certain stakeholders will be sure to be here, that  
7 we would exclude -- that would include everyone. So,  
8 my feeling is that whatever we do needs to be, I  
9 think, definitive, and fair, or not at all.

10 CHAIR MALMUD: Thank you. Are there  
11 other comments?

12 MS. BHALLA: Yes. Neelam Bhalla from  
13 NRC. Dr. Malmud, also, one of the things that's  
14 being considered, or we would be waiting, NRC would  
15 be waiting for the ACMUI's final report on permanent  
16 implant brachytherapy. We have that report right  
17 now, but it's an interim report, and it seems like  
18 ACMUI asked for -- that they'll make it final report  
19 based on -- also, get the information at these public  
20 workshops. So, in our schedule going forward, we had  
21 put that report as coming up at the ACMUI fall  
22 meeting, so if we are going to extend the public  
23 workshop, or public participation going into ACMUI's  
24 fall meeting, then I guess our concern would be that  
25 that report may not be finalized, perhaps, by the end

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1 of the year. And that report is going to be for the  
2 staff as forming the regulatory basis for the medical  
3 event definition for permanent implant brachytherapy.  
4 So, that's just one thing we would like to take into  
5 consideration.

6 CHAIR MALMUD: Thank you. Dr.  
7 Guiberteau.

8 MEMBER GUIBERTEAU: I'm somewhat  
9 unfamiliar with the process, so are we locked into  
10 June now? Is that -- do both of the meetings have to  
11 be in June?

12 MR. LUEHMAN: The answer to that is no.  
13 But I think as was expressed by Dr. Van Decker, and  
14 others, and I think we said it is, if we don't have  
15 the -- if we extend those pre -- they're really pre  
16 proposed rule meetings, then that's going to,  
17 potentially, delay when the proposed rule gets out,  
18 which it just extends the schedule. So, the real --  
19 the tradeoff here is giving everybody optimal  
20 participation versus extending the schedule. I think  
21 we hear some of both here.

22 I mean, I think we've heard people --  
23 members of the Committee say, including yourself,  
24 that the issues are well known. There's really no  
25 surprise on the major issues, and that we've gotten

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1 input from many of the groups before on these issues,  
2 likely not to be anything new. And then Dr. Van  
3 Decker said, therefore, sort of why extend it? Be  
4 very careful about extending it.

5 So, that's going to be the tradeoff. The  
6 tradeoff is -- the answer is, if the Committee feels  
7 strongly that we haven't given the stakeholders  
8 enough time for the meetings, and you make a  
9 recommendation that you think we ought to extend it,  
10 all we're saying is that you need to take into  
11 account that by making that recommendation, if the  
12 staff goes back, considers that with management and  
13 with the Commission, that the potential outcome from  
14 that is an extension of the whole schedule. Because,  
15 unfortunately, under the APA and all the things --  
16 the Administrative Policy Act, there are certain  
17 hoops we have to do, and there's certain amounts of  
18 time we have to give once we get into the actual  
19 rulemaking process. And once we're there, we can't  
20 save very much time there. So, there's not a lot of  
21 places we could save time.

22 If we move these meetings further down  
23 the road, it's likely that the rulemaking is going to  
24 move further down the road.

25 MEMBER GUIBERTEAU: I appreciate that

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1 answer.

2 CHAIR MALMUD: Dr. Thomadsen.

3 VICE CHAIR THOMADSEN: Since you've  
4 already said that issues waiting until October,  
5 although to get our input, although October then  
6 would be possibly kind of late for getting  
7 stakeholder input, and ours at the same time, at  
8 least getting stakeholder input into our statement,  
9 perhaps we could find a middle ground, and have one  
10 of the meetings delayed until August. That would  
11 give time for the input to be incorporated into our  
12 statement, and into the NRC staff's planning. And  
13 that would also give at least the three months that  
14 we're requested by the professional organization to  
15 be able to plan their travel.

16 CHAIR MALMUD: That is a question from  
17 Dr. Thomadsen to NRC Staff. Is it possible to delay  
18 one of these workshops until August, rather than  
19 having them both in June?

20 MR. FULLER: Well, I guess the answer is  
21 yes, it is possible. But the impact of that is not  
22 fully known right now, because we've really looked at  
23 the other things that we have to work our schedule  
24 around through the June, early July time frame. I  
25 know there is -- there are other professional society

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1 meetings that are later in the summer, or earlier in  
2 the fall, and I don't know exactly what those  
3 schedules are, but that would have to be looked at,  
4 and evaluated, and see what other -- there might be  
5 some other consequences that we are not aware of  
6 right now, but we could certainly look into it.

7 MR. LUEHMAN: I think, to follow-on with  
8 Mike, I mean, the other thing that we're trying to  
9 do, also, too, is get some -- touch on a couple of  
10 geographic locations more -- the west side of the  
11 country, and the eastern half of the country, and to  
12 -- I guess, as Mike is saying, is we could -- we'll  
13 definitely look into it, if that's the sense of the  
14 Committee, because -- but given that we want to get  
15 one in the east, one on the west, we have the  
16 additional professional society meetings, and we have  
17 some of the -- we already have other activities  
18 internal to the staff going on, we'll look at that.  
19 We don't know, as Mike said, just sitting here what  
20 all the ramifications of that would be on the  
21 schedule. But we can definitely look at that, and  
22 get back to the Committee, as to what those impacts  
23 might be to move one of the meetings a couple of  
24 months later in the year.

25 CHAIR MALMUD: Thank you. Dr. Welsh's

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1 motion remains on the table. Does anyone care to  
2 call the motion?

3 VICE CHAIR THOMADSEN: Could you repeat  
4 the question?

5 CHAIR MALMUD: Would you -- it's been  
6 requested that you repeat your motion, Dr. Welsh.

7 MEMBER WELSH: I propose that we reserve  
8 some time at the next ACMUI meeting in the fall for  
9 stakeholder meeting purposes should such additional  
10 stakeholder meetings be necessary.

11 CHAIR MALMUD: Thank you for repeating  
12 the motion. All in favor of the motion?

13 (Show of hands.)

14 CHAIR MALMUD: Three in favor. Any  
15 opposed to the motion?

16 (Show of hands.)

17 CHAIR MALMUD: Seven opposed.  
18 Abstentions?

19 (Show of hands.)

20 CHAIR MALMUD: One. The motion does not  
21 carry. May I ask a question of the Committee? Would  
22 the Committee care to institute a policy that in the  
23 future when public meetings are -- when public  
24 workshops are planned, that there be a minimum number  
25 of months notice prior to the meetings in order to

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1 satisfy the concerns of at least several  
2 organizations that would like to be represented? Dr.  
3 Welsh?

4 MEMBER WELSH: I fully agree with that.  
5 And part of the reason why I bring all this to the  
6 surface now is that my personal circumstances have  
7 changed, so that I need to give three months notice  
8 for any kind of time away. And this matter, which is  
9 near and dear to my heart, I will not be able to  
10 participate in, most likely, if there's a stakeholder  
11 meeting in June, because it's within the three months  
12 already. So, I agree with you, Dr. Malmud, that the  
13 three months is necessary leeway.

14 CHAIR MALMUD: Well, thank you. I wasn't  
15 making a statement. I was asking a question. But if  
16 that expresses your feelings, that's fine. Dr.  
17 Thomadsen, did you wish to say something?

18 VICE CHAIR THOMADSEN: I was going to  
19 make the motion, but I think Dr. Welsh is in the  
20 process of making the motion. Would you care to make  
21 that as a motion?

22 CHAIR MALMUD: Three months notice for  
23 workshops in the future, not including the current  
24 ones that are planned.

25 MEMBER WELSH: I would like to propose as

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1 a motion that three months minimum lead time be  
2 provided for future stakeholder --

3 CHAIR MALMUD: Dr. Thomadsen has  
4 seconded. Is there any discussion of that motion?  
5 If not, all in favor of the motion?

6 (Show of hands.)

7 CHAIR MALMUD: It's unanimous. Unless  
8 there -- is there a negative? Any abstention? No,  
9 it's unanimous. So, the motion carries unanimously  
10 with regard to future workshops, not those already  
11 scheduled. I hope that is agreeable to NRC staff,  
12 and it could be worked into future plans beyond those  
13 that have already planned for and agreed upon. Thank  
14 you. And I hope that will address the concerns of  
15 the parties. I see a thumb up, which means that we  
16 have addressed the concerns of at least one  
17 professional organization in establishing that  
18 policy. Thank you.

19 And if we may, we'll move on to the next  
20 item on the agenda, which is Dr. Bhalla. Thank you  
21 for being so patient, Dr. Bhalla. Did I promote you?  
22 I'm sorry. It's Ms. Bhalla.

23 MS. BHALLA: Good morning, Dr. Malmud,  
24 Members of ACMUI, and members of the public, and, of  
25 course, the NRC staff here. I'm Neelam Bhalla, and

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1 Ed Lohr from Rulemaking Branch. So, we are here just  
2 to give a very quick overview of the -- of what's  
3 ahead for us for this rulemaking.

4 Okay, a little bit of the background  
5 about Part 35 Rulemaking. Part 35 is the medical use  
6 of radioactive materials. So, as you all know, this  
7 rule, Part 35, was revised in its entirety in 2002.  
8 There were issues relating to training and experience  
9 regulations, so that part got finalized in 2005. And  
10 then in 2007 and 2009, some of the parts were  
11 revised, and those have been discussed before, so I'm  
12 not going to go into that right now.

13 So, where the need came for this expanded  
14 rulemaking, basically, the items were identified  
15 through implementation of Part 35. And, also, some  
16 of the issues were brought forward by the ACMUI.  
17 And, also, there was a petition for rulemaking.

18 In total, we have about 28 issues in this  
19 expanded rulemaking. And these potential changes  
20 have been presented in the past at various ACMUI  
21 meetings. We have as a handout available for  
22 everyone the actual list of these 28 or so items, so  
23 if you want to -- yes, it's also for the members.  
24 It's there for you in the binder.

25 MEMBER LANGHORST: I don't see that.

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1 MS. HOLIDAY: Dr. Langhorst, I put them  
2 onto your desk.

3 (Off the record comments.)

4 MS. BHALLA: Sorry about that. Okay. So,  
5 you know, although you have the whole list in front  
6 of you, we have just highlighted a few items that we  
7 think may be a little bit -- need more discussions,  
8 et cetera. So, those items would be in this  
9 rulemaking is the amendment of the preceptor  
10 attestations. So, these will be related to -- well,  
11 the preceptor attestation is a very big part in the  
12 training and experience requirement for the  
13 individuals who want to be on various NRC licenses.  
14 So, there'll also be the -- again, with regard to  
15 training and experience is the Ritenour petition.  
16 And this petition was filed by AAPM.

17 And then one of the items would be an  
18 increase in frequency of measurement of molybdenum-99  
19 testing. And then one of the items would be -- we  
20 put it here, Associate RSOs on a medical use license.  
21 And we think some of these items are a little bit --  
22 they need discussions.

23 Going to then what about the ME rule, the  
24 Medical Event rule? Very quickly, as you all know,  
25 this rule was -- proposed rule was published in the

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1 Federal Register August 6 of 2008. Then there were  
2 issues with that, and our working group worked on it,  
3 and there was the repropose rule that was provided  
4 to the Commission in June of 2010. Then the  
5 Commission disapproved the publication of that  
6 repropose rule, and that happened in August of 2010,  
7 last year.

8 So, what's happening with the expanded  
9 rulemaking is there is a working group that has  
10 already started to work on this rule. And the  
11 working group has members from staff from NRC, OAS  
12 and CRCPD. And we are developing the proposed rule  
13 package. And what's happening with the ME Rule is  
14 that, as you know, since morning, the workshops have  
15 been discussed. And the schedule is to have these,  
16 my slide says June 2011, but at least I get the  
17 feeling one would be happening in June, and I don't  
18 know about the others. But these workshops are very  
19 important, so far as the ME Rule is concerned. And  
20 we do plan to in the workshops, as I said, we do plan  
21 to have some of these other issues from the expanded  
22 rulemaking. And as Jim had asked the Committee  
23 before, if you do feel there are issues that we do we  
24 need to discuss, we would be happy to include those  
25 in the forthcoming workshops.

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1 And also in your agenda, there's  
2 discussion, and Jim, and Mike had also alluded to  
3 well, there are other issues; for example, the  
4 patient release -- there'll be discussions in the --

5 I think it's planned for tomorrow, so there'll be  
6 discussions on that, that if there is a need to do  
7 the rulemaking. So, this is -- basically, we just  
8 wanted to give you an overview on where we are in  
9 this expanded rulemaking.

10 We have some supplemental slides, so if  
11 you have more questions, you can look at them.  
12 Basically, they talk a little bit more detail on the  
13 ME Rule. And, also, they have -- we have put forward  
14 just what the schedule will be going forward. So,  
15 with that, that's all we are presenting.

16 CHAIR MALMUD: Thank you. Are there  
17 questions or comments?

18 MEMBER ZANZONICO: A question.

19 CHAIR MALMUD: Thank you. Pat.

20 MEMBER ZANZONICO: Pat Zanzonico. So,  
21 the workshops are usually dedicated to specifics of  
22 these main issues, or any of the 28 items, or any of  
23 the main issues be discussed or addressed by  
24 stakeholders at any one of the workshops?

25 MS. BHALLA: Well, the workshops are,

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1 basically -- you know, the Commission direction was  
2 to have the workshop on the Medical Event definition,  
3 because when we went up to the Commission, the  
4 Commission said go -- they disapproved the rule as it  
5 was proposed, and they said to go and seek out public  
6 stakeholder input on that. So, since this expanded  
7 rule is also coming up, we thought this is an  
8 efficient use of time and resources to include some  
9 of those issues also, which may come as somewhat  
10 controversial, or where folks may have some comments.  
11 And, therefore, we, perhaps, gain from those comments  
12 going forward and putting the rule package together.

13 MEMBER ZANZONICO: So, stakeholders would  
14 have an opportunity to bring up any issue of concern  
15 at any workshop?

16 MR. LUEHMAN: Yes. We will have some  
17 sessions -- again, I think we said earlier, we -- as  
18 Neelam just said, the Medical Event Rule, obviously,  
19 is going to be a main focus, because the Commission  
20 directed that. We have chosen -- we have discussed a  
21 number of the other what we'll call big ticket items  
22 that would be in Part 30, from the expanded Part 35  
23 that we think would likely get stakeholder comments,  
24 the grandfathering provisions, and some other -- two  
25 or three other selected ones, but there will be an

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1 opportunity at the -- whether or not there is a  
2 formal session on that piece. If there are comments  
3 that stakeholders want to provide, comments on other  
4 various parts of the 28, or submit their comments in  
5 writing, or both, they'll have that opportunity.

6 MEMBER ZANZONICO: So, in the formal  
7 announcement of the workshop in the Federal Register,  
8 even though it will be advertised, so to speak, as a  
9 Medical Event Rulemaking Workshop, will be  
10 specifically stated that there'll be opportunity to  
11 address other issues than Medical Events?

12 MR. FULLER: Yes, our plans currently are  
13 to -- in the Federal Register Notice to specify what  
14 is currently for issues that are either  
15 controversial, complex, or what we believe to be of  
16 interest to our stakeholders. However, there's no  
17 reason why we couldn't also list all of the rest of  
18 them so that people understand that those are  
19 available, if they --- we could be -- again, we're  
20 going to be in the listening mode, so if someone  
21 moves to the microphone and wants to provide us with  
22 their insights and their comments, and so forth, we  
23 will be happy to receive them.

24 MEMBER ZANZONICO: I'm just concerned  
25 that a potential stakeholder may not attend a

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1 particular meeting if they're not aware in advance  
2 formally that there's an opportunity to address other  
3 -- address issues other than the one that's the  
4 advertised topic of the workshop. So, that will be  
5 included explicitly -- that opportunity will be  
6 included explicitly in the workshop announcements.

7 MR. FULLER: Yes.

8 MEMBER ZANZONICO: Okay.

9 CHAIR MALMUD: Thank you. Dr. Van  
10 Decker.

11 MEMBER VAN DECKER: A comment, and then a  
12 question. I guess, you know, now looking at your  
13 time line slides, I guess I should have read in the  
14 beginning, I guess we're talking about -- since the  
15 fact that 85 percent of the states are Agreement  
16 States, that this whole package, even if we stay to a  
17 tight time line, is not really universal until 2017.  
18 Okay.

19 And then my question, I guess, not per se  
20 to personally put Ms. Gilley on the spot, although  
21 she always believes I do that. In this list of 28,  
22 since we've only -- and I agree with you about the  
23 four pulled out. The UC stuff in here, the Agreement  
24 States are going to start being a little bit more  
25 concerned about because if that's the case, those are

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1 ones we want to get highlighted up front rather than  
2 the problems we've had in the past coming to  
3 Agreement State approval at the end, and all of a  
4 sudden an 11:59 issue.

5 MEMBER GILLEY: I think the four that had  
6 -- Ms. Gilley. I think the four that have been  
7 identified are ones that the Agreement States are  
8 looking at. I would ask NRC if they would consider,  
9 since they do have such a major impact on the  
10 operations in the Agreement States, if there's some  
11 way to get some opportunity for relief from the  
12 compatibility requirements. If States wanted to go  
13 ahead and adopt a rule, that would address some of  
14 these issues prior to your timeline of 2014.  
15 Currently, that's not allowed, because we have to be  
16 compatible with yours, and you're actually holding up  
17 the process of Agreement States with regulations that  
18 work for medical activities by that compatibility  
19 rule.

20 MS. BHALLA: This -- I think the  
21 Agreement States are given three years to adopt, but  
22 there's nothing that prohibits an Agreement State to  
23 do that, to revise their regulation sooner than three  
24 years, unless there is some law against it.

25 MEMBER GILLEY: May I --

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1 CHAIR MALMUD: Yes, please.

2 MEMBER GILLEY: Debbie Gilley. Again,  
3 yes, there is. It's compatibility with IMPEP, and  
4 it's a Compatibility B, which means we have to be  
5 identical to NRC. Our regulations have to be in  
6 content identical, so if you don't change your  
7 Medical Event or permanent implants until 2014, any  
8 state that takes the initiative to change theirs to  
9 adopt to the activity-based versus dose-based would  
10 be found incompatible with NRC.

11 MR. LOHR: If I may, I believe there is  
12 confusion here. I believe Neelam was saying that  
13 during the period following our final rule, they have  
14 up to three years. Her comment indicated they can  
15 adopt it during the first year if they so choose.  
16 You're absolutely right, Debbie, that before the  
17 final rule goes into the Federal Register, the states  
18 for compatibility cannot adopt them ahead of time.

19 MEMBER GILLEY: So, that's two and a half  
20 years that we're sitting there waiting for NRC to do  
21 regulations for us to be able to adopt them to  
22 maintain compatibility.

23 CHAIR MALMUD: That is correct. Thank  
24 you for bringing that to our attention. Yes, Mr.  
25 Mattmuller.

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1                   MEMBER MATTMULLER: Yes, Steve  
2 Mattmuller. Could you please explain in a little bit  
3 more detail on the direct final rule process?  
4 Because some of the next talks, they talk about it  
5 briefly, but from my perspective looking at some of  
6 these issues on this list, it seems like they'd be  
7 prime candidates for a DFR.

8                   MS. BHALLA: To the DFR the process in  
9 itself is a fast-track process where if NRC is not  
10 anticipating any comments, then we do a proposed rule  
11 and a companion final rule, issue them out at the  
12 same time. Usually, the comment period is also  
13 lessened. It's 30 days. And then if we don't have  
14 any substantive comment, then we issue for the  
15 effective date. So, sure, it's a fast-track process,  
16 it's the shorter process, and we can do -- in this  
17 list, I'm sure there are a few items that we can do  
18 it that way. But this is -- these are then the  
19 problems that happen in rulemaking.

20                   There is the OMB, which says we can only  
21 process one part of that Part 35 at one time. So, if  
22 we have something up the pipe, then that's it. They  
23 are only going to look at that. And then if next one  
24 comes, that's going to wait. So, there is that -- we  
25 have that risk.

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1           And, also, it's the same, pretty much the  
2 same group that's working on this expanded  
3 rulemaking; and, therefore, if time is taken out to  
4 get a final rule, to issue some of these things,  
5 which even health and safety-wise, they don't fall  
6 into a very high priority, so if we do the -- another  
7 direct final rule, it's going to take away time from  
8 the expanded rulemaking which the group is working  
9 on.

10           And another thing is, for the Agreement  
11 States, then they have to go and amend their rules  
12 for those set of amendments that we would do as a  
13 direct final rule. So, these are the things which  
14 kind of go against doing another direct final rule,  
15 because it's going to just further delay the expanded  
16 rulemaking.

17           MEMBER MATTMULLER: If I could, a follow-  
18 up?

19           CHAIR MALMUD: Steve.

20           MEMBER MATTMULLER: When you mentioned  
21 Office of Management and Budget, when they do a  
22 review of the particular part, how long does that  
23 take?

24           MS. BHALLA: Generally, they have one OMB  
25 officer who's looking at and going through all of the

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1 rules, which are, I believe, which -- from all the  
2 agencies, so it's -- we have had our rules going up  
3 there, and then we ask for extensions because this is  
4 beyond NRC staff's control. So, it could be three  
5 months, it could be four months, it could be -- so,  
6 it does -- it's -- and there is nothing we can do  
7 about it. It slows the process.

8 CHAIR MALMUD: Thank you. Debbie?

9 MEMBER GILLEY: Debbie Gilley. Is it not  
10 true that if this was an urgency from the  
11 Commissioner's level, that they could allocate  
12 resources for us to fast-track this regulation, much  
13 like they did the regulations for the 2005 Energy  
14 Policy Act?

15 MR. LOHR: May I? The Commission can  
16 direct the staff to take a fast-track, if you will.  
17 But because of the APA, and because of ACMUI's  
18 interactions, and because of the Agreement States'  
19 interactions on the comments that go on in the rule,  
20 very little time can be saved from what we've already  
21 proposed. We have looked at this in the Integrated  
22 Plan I believe that Steve has, and I believe you all  
23 have seen, and proposed the fastest track we feel can  
24 be actually accomplished.

25 There are things that we cannot change in

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1 timeline, for example, the public comment period, or  
2 the period of time that ACMUI has to give their  
3 comments back to us, or the Agreement States' comment  
4 period back to us. So, those things add up  
5 tremendous amounts of time in the rulemaking process.  
6 I do not believe we can shave very much more off and  
7 still have a valid rule at the end.

8 CHAIR MALMUD: Dr. Suleiman.

9 MEMBER SULEIMAN: Let me give you my  
10 perspective on predicting how long it takes Office of  
11 Management and Budget to review regulations. It's  
12 unpredictable. I mean, we've had stuff from FDA,  
13 depending on how simple it is, and routine it is, go  
14 through in a couple of months, and I've -- we've had  
15 legislation -- we've had rulemaking involved with  
16 radiation safety that have taken years. And if you  
17 have a change of administration, you have a new tier  
18 of people who want to reexamine what's going up to  
19 them. And I get asked this all the time, and I've  
20 never become an accurate predictor, so I think once  
21 it clears the Nuclear Regulatory Commission, it's a  
22 whole lot more uncertain than you may think. I mean,  
23 that's just what I've shared in previous experience,  
24 it could apply here. That's why I think there's  
25 always this tendency not to -- if you can do it some

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1 alternative way, it would be more effective.

2 CHAIR MALMUD: Thank you. Yes?

3 MEMBER SUH: Yes, I just have a general  
4 question. Do we have -- in terms of rulemaking,  
5 what's like the shortest time period for rulemaking,  
6 the longest period, and like the medium? Do we have a  
7 sense of how long it takes to have process go through  
8 rulemaking?

9 MS. BHALLA: Sure. In general, the --  
10 when the Commission asks us to go ahead and do a  
11 rulemaking, in general, for the most rules, the  
12 Commission gives us one year to do a proposed rule,  
13 and then another year to do a final rule. In fact,  
14 that's our routine process. It's in our -- I think  
15 it's in the Commission processes, and our process.  
16 And then depending on the complexity of the rule, the  
17 Commission may consider giving more time, or we may  
18 ask, staff may ask more time.

19 And, also, if the regulatory basis is  
20 very well defined, well developed, the Commission may  
21 want to give us a little bit less time. But, in  
22 general, that's the time line there is.

23 MEMBER SUH: And is there a time period  
24 where it's considered too long? Like you have, let's  
25 say X number of years goes by, is it considered --

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1           MR. LUEHMAN: Well, I think that a number  
2 of years ago, the Commission tasked the staff to,  
3 because of the length of time rulemakings were done,  
4 there was a big task force that looked at that, the  
5 length of time that it was taking rulemakings to get  
6 through. We came across with a more -- we came up  
7 with a revised process that includes the time lines,  
8 the typical time lines that Neelam is talking about,  
9 as well as a prioritization process across the Agency  
10 for all rulemakings, both -- in all the areas, so  
11 there's a common prioritization so that we can use --  
12 make sure that we have resources where the most  
13 important rules are.

14           I think that we have on a typical rule  
15 pretty much achieved the time lines that Neelam is  
16 talking about, but the Medical Event Rule is an  
17 exception to that. I mean, the fact is that the staff  
18 did propose a Medical Event Rule, and the Commission  
19 denied that rule, was not happy with the rule based  
20 on stakeholder comments. So, obviously, we're back  
21 at it again, so that, obviously, didn't meet -- I  
22 mean, it went through the process, but it didn't meet  
23 the Commission's expectations, so the Medical Event  
24 Rule is going to end up taking a lot longer than the  
25 time line that's been laid out. So, I think it does

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1 depend upon, as Neelam said the complexity and the  
2 amount of controversy or agreement there is on a  
3 particular rule.

4 CHAIR MALMUD: Dr. Van Decker.

5 MEMBER VAN DECKER: I would just make a  
6 comment now being an old man, that the last time this  
7 rule was fully opened up from the first public  
8 workshop in Philadelphia in `96 to the time  
9 everything got finalized, I think was about six and a  
10 half years. I don't think any of us want to go  
11 through that again. So, hopefully, the comments this  
12 time will be pointed and we'll move along from the  
13 community basis.

14 CHAIR MALMUD: Thank you for that  
15 historical perspective. Dr. Langhorst.

16 MEMBER LANGHORST: Neelam, before we let  
17 you go, would you go through the item numbers and  
18 tell us the four item numbers, so I can make sure I  
19 have the right ones that you mentioned.

20 MS. BHALLA: Okay. There is Item 9, no,  
21 sorry, not 9, Item 10 is related to grandfathering of  
22 certain certified individuals. That relates to  
23 Ritenour petition.

24 MEMBER LANGHORST: Yes.

25 MS. BHALLA: Then Item 11 is to amend

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1 preceptor attestation requirements, and that will be  
2 across Subparts D-D and so on, because there are all  
3 these different users, and so on.

4 Okay. Then we have Item 15. Okay. Item  
5 15 is about the increasing the frequency of quality  
6 breakthrough tests. 16 is actually going forward  
7 with that, not only measuring, but then with  
8 reporting requirements of the failed test. And then  
9 Item 12 is to allow -- here we said Assistant RSOs to  
10 be named on the license, but I think in my slide we  
11 said Associate RSOs. And that's -- it some work  
12 coming from what the working group is working on.  
13 And these are the things the working group also  
14 discusses. And it will be open to -- when we have --  
15 in fact, even now, the right title we want to give  
16 the Associate RSOs, or is it the Assistant RSOs, or  
17 do we want to have something other than that.

18 So, I believe these are the items --

19 MEMBER LANGHORST: And then 28, the  
20 Medical Event, or not?

21 MS. BHALLA: Yes.

22 (Off the record comments.)

23 MS. BHALLA: Yes, it's somewhat related  
24 to the Medical Event, but we -- when the group  
25 started to work on Medical Event definition, this was

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1 kind of left out for the expanded rulemaking. So,  
2 it's very similar. All 28 is saying is that right  
3 now in the regs, it's a Medical Event when a wrong  
4 radionuclide is used, but there's no provision for  
5 when a wrong brachytherapy -- isotope is used for  
6 brachytherapy. So, it's not completely going into  
7 the ME Rule, but it was pulled out to do it at this  
8 point, at the expanded rule.

9 MEMBER LANGHORST: Okay. So, then  
10 there's the Medical Event definition for  
11 brachytherapy, that's an additional thing.

12 MS. BHALLA: Right.

13 MEMBER LANGHORST: Okay.

14 MS. BHALLA: Yes, that's a qualifier.  
15 This list does not have that.

16 MEMBER LANGHORST: Okay.

17 MS. BHALLA: It doesn't have the Medical  
18 Event definition.

19 MEMBER LANGHORST: And then the  
20 discussion of patient release criteria.

21 MR. LUEHMAN: We're going to -- that's a  
22 topic for discussion tomorrow. That's not presently  
23 in the expanded rulemaking.

24 MEMBER LANGHORST: Right. But that will  
25 be discussed at the workshops.

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1 MR. LUEHMAN: The need to -- yes. Well,  
2 if you have a sense --

3 MEMBER LANGHORST: I'm just trying to  
4 clarify what --

5 MR. LUEHMAN: Right. But that's really  
6 to get a sense of the need to do rulemaking in that  
7 area, on that particular subject, rather than like  
8 what the rulemaking -- what the language would be.

9 CHAIR MALMUD: Mr. Fuller.

10 MR. FULLER: Yes, just so -- Dr.  
11 Langhorst, just so I understand your question. Your  
12 question was what things we are currently planning to  
13 discuss during the workshops in June?

14 MEMBER LANGHORST: That's what I was  
15 trying to --

16 MR. FULLER: Yes. That really, at this  
17 point in time, what we are planning to discuss are  
18 Items 10, 11, the Medical Event definition as it  
19 relates to permanent implant brachytherapy, and the  
20 need for rulemaking, and the public dose limits  
21 related to patient release, whether they should be  
22 based on a per annual basis, or on a per episode  
23 basis.

24 MEMBER LANGHORST: Okay. I'm sorry I did  
25 not ask that in a clear manner.

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1 MR. FULLER: That's okay. Those are the  
2 four that we are currently planning --

3 MEMBER LANGHORST: Focusing on.

4 MR. FULLER: Planning to focus on,  
5 exactly, in those workshops.

6 MEMBER LANGHORST: Okay.

7 MR. FULLER: The others are certainly --  
8 and any of the 28 are certainly -- when we get to  
9 the point in time in those workshops where the public  
10 can provide us with their comments and so forth, and  
11 we would be happy to entertain comments on any of  
12 those.

13 MEMBER LANGHORST: Thank you.

14 MEMBER GUIBERTEAU: Will the topic, Item  
15 11, also include the preceptor attestation issues in  
16 6, 8, and 24?

17 MS. BHALLA: They are different; 6, 8,  
18 and 24 are a little bit different, because the Item  
19 10 is based on -- we have -- a paper was done -- no,  
20 Item 10 is -- yes, is Ritenour petition, or Item 11.  
21 Sorry. So, anyway, Item 11 has to do with --  
22 actually, we have a Commission direction on it, and  
23 it's -- basically, what it's going to -- it's saying  
24 is that for the board-certified individuals take away  
25 the preceptor attestations, and then for the

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1 alternate pathway, to have these attestations, the  
2 change of the wording itself. And then who can  
3 actually provide it. There is a provision that -- to  
4 be considered is that maybe radiology -- the  
5 residency directors can provide these attestations.  
6 So, this is the -- where there's the other things are  
7 more in terms of if you're going through the details  
8 of the existing regulations, then there are certain  
9 changes that need to be made, but not, necessarily,  
10 it doesn't involve all the changes in 11.

11 But just to give a little bit of a  
12 cautionary note here, that when we go into  
13 rulemaking, as you will see, that these are the items  
14 we start with, and then as the working group further  
15 explores that, okay, if we are making a change here  
16 within our Part 35, or whatever, which may not be so  
17 obvious on this list, or may not be on here on that  
18 list, but when we do the rule, you would see it that  
19 we may amend something, we call it the conforming  
20 changes, so that's part of the rulemaking process.  
21 But these three are separate, and not so involved as  
22 Item 11.

23 MEMBER GUIBERTEAU: Right. But I think  
24 if we're going to identify certain areas, it would be  
25 helpful to those in preparation for attending and

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1 commenting on a specific area to group some of these  
2 together, so that they will know that it isn't only  
3 this one area in number 11 in terms of what we're  
4 talking about, but there are other attestation issues  
5 here. And I think that sometimes the stakeholders  
6 have pretty definite ideas about how these may be  
7 connected in a way that maybe we don't appreciate.  
8 So, my understanding is that it might be useful to do  
9 some groupings of those, so that people will know  
10 that those are all on the table, in our line of focus  
11 here in terms of amending the rule so that they'll be  
12 prepared to comment on all of them, if they wish to.

13 CHAIR MALMUD: Dr. Guiberteau, you are  
14 suggesting that this list be regrouped so that  
15 someone who is not familiar with these discussions  
16 could focus on specific areas, and be prepared to  
17 make comments at a public meeting. Am I correct?

18 MEMBER GUIBERTEAU: Yes.

19 CHAIR MALMUD: That's just a suggestion  
20 to regroup these, not to change them, but to regroup  
21 them for presentation.

22 MR. LUEHMAN: I think the staff thinks  
23 that that's fair comment. I think that the point  
24 Neelam was making is that the one that we're  
25 concentrating on -- I mean, we could do that. I

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1 think the one that we're concentrating is the one  
2 that's going to be sort of the most changed, and  
3 there's going to be some other changes in some other  
4 areas relative to attestation, but they're not going  
5 to be as, I don't want to use the word "significant,"  
6 but as extensive with changes. But we can definitely  
7 alert the stakeholders that in addition to whatever  
8 number it is, number 11, that there are other planned  
9 changes in other sections to attestation, and list  
10 those so that they're aware of those.

11 CHAIR MALMUD: Thank you. If we ay,  
12 we'll move on to the next item on the agenda. That's  
13 going to be a lengthy discussion, which you'll note  
14 begins before lunch, and then runs through the  
15 afternoon. It's now 11:25, and my question is, shall  
16 we break early for lunch, since we took no coffee  
17 break this morning, and begin this discussion after  
18 lunch, or are we, because of the agenda having been  
19 made public, bound to the agenda for those members of  
20 the public who might wish to participate? And, also,  
21 what are the feelings of the Committee? Dr. Welsh?

22 MEMBER WELSH: Well, I have a relevant  
23 question, which is do we have representation from  
24 ASTRO, who indicated ahead of time that they wished  
25 to participate?

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1 CHAIR MALMUD: They indicated to me that  
2 via third-party that they would be here at 1:00 in  
3 the afternoon session, but might be here earlier.  
4 What's the answer?

5 MS. TOMLINSON: Hi, Cindy Tomlinson from  
6 ASTRO. Our representative will be here at  
7 approximately 1:00, but he was fully aware that there  
8 would be a discussion prior to the 1:00.

9 CHAIR MALMUD: Thank you. So, the  
10 question now goes to our own Committee. Would you  
11 prefer to break now for lunch, and then come back and  
12 start this discussion after lunch? Dr. Thomadsen?

13 VICE CHAIR THOMADSEN: Is the order of  
14 things that -- the first thing is you are going to be  
15 giving a background of this?

16 CHAIR MALMUD: Yes.

17 VICE CHAIR THOMADSEN: And then we go  
18 directly into public comment, et cetera? Is that the  
19 idea?

20 CHAIR MALMUD: As part of -- well, we  
21 will have ASTRO present here.

22 VICE CHAIR THOMADSEN: Well, that's at  
23 1:00.

24 CHAIR MALMUD: That's at 1:00.

25 VICE CHAIR THOMADSEN: Yes.

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1 CHAIR MALMUD: Yes, but we have other  
2 things to present, as well.

3 VICE CHAIR THOMADSEN: Okay.

4 CHAIR MALMUD: Would you prefer --

5 VICE CHAIR THOMADSEN: I would like to  
6 see, maybe we get the background presented now on  
7 schedule and then --

8 CHAIR MALMUD: In that case, we are --

9 VICE CHAIR THOMADSEN: If that timing is  
10 --

11 CHAIR MALMUD: In that case, Mr. Fuller,  
12 you're on.

13 MR. LUEHMAN: We've got about five  
14 minutes of background.

15 MR. FULLER: Very brief. And, in fact,  
16 if you want me to repeat this after lunch, I will be  
17 happy to do that, because it is pretty brief.

18 Okay. Again, in the way of introduction,  
19 the introductory slide, I'm Mike Fuller, and I'm the  
20 Team Leader for the Medical Radiation Safety Team  
21 here at the NRC.

22 Okay. In preparing for this  
23 presentation, I wanted to take a look at sort of the  
24 historical record behind the issue of permanent  
25 implant brachytherapy and the Medical Event

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1 definition related to that. So, with that in mind, I  
2 looked at -- starting back -- and I imagine this may  
3 have even started before, but the -- in SECY-05-0234,  
4 the Staff recommended for all permanent implant  
5 brachytherapy that a Medical Event should be defined  
6 in terms of total source strength, and not absorbed  
7 dose.

8 So, then subsequent to that, in Staff  
9 Requirements Memorandum, or SRM SECY-05-0234, the  
10 Commission approved the Staff's recommendation. So,  
11 then we fast-forward to - let me get the next slide -  
12 in SECY-08-0080, the Staff provided the Commission  
13 with the proposed modified rule for the use of total  
14 activity rather than absorbed dose. And in the Staff  
15 Requirements Memorandum in response to that SECY  
16 paper, the Commission approved the proposed rule.

17 Okay. So, then in SECY-10-0062, the  
18 Staff provided the Commission with a repropose rule  
19 that actually added activity-based criteria for the  
20 definition of a Medical Event for permanent implant  
21 brachytherapy, plus some requirements for training,  
22 and some other requirements. And it added the  
23 activity-based criteria to the dose-based criteria  
24 that is there. And the reason for that was that  
25 Staff recognized that as a result of the events

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1 related to the VA Philadelphia events, or incidents,  
2 that many of the medical events that had been  
3 identified as medical events would not have been  
4 captured as medical events had we had an activity-  
5 based only medical event definition in the rule.

6 So, in SRM SECY-10-0062, the Commission  
7 disapproved the repropoed rule, and directed the  
8 Staff to hold a series of public stakeholder  
9 workshops. So, that's why we're here today, as we  
10 have discussed some this morning.

11 Now, as a way of prompting some  
12 discussion, and we've heard some of this already this  
13 morning, we wanted to provide a question that would  
14 help maybe focus some of the discussion this  
15 afternoon; and that is, how do we appropriately  
16 balance between the medical community's desire to  
17 define a medical event in terms of clinical  
18 significance with NRC's need to have mistakes in the  
19 process reported, even though there may not be an  
20 actual negative consequence to the patient?

21 I think Steve Mattmuller commented on  
22 that this morning in response to a comment that Dr.  
23 Welsh had made, and we hear it a lot. Now, I think  
24 that's really about all I'm going to say about that,  
25 because, again, we really want to hear from the

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1 Committee, and members of the Committee, and members  
2 of the public who are available on their perspective  
3 on how do we make this appropriate balance between  
4 these various needs? So with that, I will conclude  
5 my opening comments.

6 CHAIR MALMUD: Thank you for the  
7 introduction. Are there any questions or comments  
8 for Mr. Fuller? If there are none, I would suggest  
9 that we break and regroup promptly at 1:00. Thank  
10 you, see you then.

11 (Whereupon, the proceedings went off the  
12 record at 11:31 a.m., and went back on the record at  
13 1:03 p.m.)

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## A F T E R N O O N S E S S I O N

1:03 p.m.

CHAIR MALMUD: On the record. Ladies and gentlemen, it is 1:00 p.m. and I would ask the Committee to reassemble. We are up to Agenda Item 8 which is the Permanent Implant Brachytherapy Rulemaking. Mr. Fuller will continue the discussion on permanent implant brachytherapy.

MR. FULLER: Thank you.

Did you want to --?

MR. LUEHMAN: Yes.

Mr. Chairman, before we start on that during the lunch break we on the staff conferred on the issue of the workshops. And I don't think that we have an objection to exploring moving one of the workshops probably to the August time frame so that there's enough separation. The exact date I guess we'll pursue.

I guess the real question for the Committee would be and we're talking to the rulemaking people is they don't think that that's going to in any way affect the schedule. The one thing that it will affect though obviously is if we move one as late as August will be potentially the Subcommittee's time. It shrinks the Subcommittee's

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1 time to give the full committee the final report on  
2 that. And if that's not an objection to the  
3 Committee that we shoot for the beginning of August  
4 and they've got approximately a little bit less than  
5 two months then to finalize the report. If that's  
6 not objectionable to them, we could move it like I  
7 said into August which would give the separation.

8 Really the place where the time does  
9 start impacting the schedule is after the ACMUI  
10 meeting, the next ACMUI meeting because I think that  
11 the rulemaking schedule is really predicated on  
12 getting the final Subcommittee report and being able  
13 to use that in development of the tech basis. So if  
14 that was going to be delayed, then that would start  
15 delaying the schedule. But if we move the meeting,  
16 the second meeting, to maybe the end of July/early  
17 August where we can find the right date, if that  
18 gives the Subcommittee enough time then after that  
19 second meeting to do their work, we could pursue  
20 that.

21 CHAIR MALMUD: Thank you, Mr. Luehman. I  
22 think we have to ask the members of the Subcommittee  
23 what their opinions are.

24 Dr. Welsh.

25 MEMBER WELSH: I can say as Chair of the

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1 Subcommittee and the one who has done a large volume  
2 of the writing synthesizing the other Subcommittee  
3 members' opinions I think that our report can easily  
4 meet the deadline. I think that we're still waiting  
5 to hear from some input from critical stakeholders to  
6 see whether or not we've gotten it right. We believe  
7 we have. And if what we hear from ASTRO and other  
8 stakeholder organizations echoes what is written in  
9 the Subcommittee report it should be relatively quick  
10 and easy and that's what I'm anticipating.

11 I would like to hear from other members  
12 of the Subcommittee to see if there's any dissension.

13 CHAIR MALMUD: Other opinions from other  
14 members of the Subcommittee? Dr. Thomadsen.

15 VICE CHAIR THOMADSEN: I would second  
16 what Jim just said.

17 CHAIR MALMUD: And Member Langhorst  
18 agrees?

19 MEMBER LANGHORST: I think it can be  
20 prepared.

21 MR. LUEHMAN: Okay. Then we will pursue  
22 trying to move one of the meetings and still we have  
23 a -- We're probably right now just say for a target  
24 point the beginning of August sometime having one of  
25 the meetings in the June and one of the meetings in

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1 August so that hopefully that will give enough  
2 separation. Because I mean I think the point was a  
3 good point that if you have a conflict with one week  
4 in June the next week in June you might have a  
5 similar conflict. And it also gives a little bit  
6 more notice for those stakeholders and even Committee  
7 members who have the same problems that Mr.  
8 Mattmuller enumerated about getting approval. So  
9 we'll go ahead and pursue that.

10 CHAIR MALMUD: Okay. Thank you.

11 MR. LUEHMAN: Thank you.

12 MR. FULLER: Well, shortly before lunch,  
13 I gave a very brief background. I gave some brief  
14 background information about at least where it seems  
15 to me where we are when it comes to the medical event  
16 definition as it relates to permanent implant  
17 brachytherapy. And I finished that up by asking or  
18 posing this question. Now there are many other  
19 questions that others may have related to this issue  
20 that would be good starting points for providing us  
21 with your insights or comments.

22 But I'll just put this one out there  
23 hopefully to sort of generate some discussion. And  
24 again it's how do we appropriately balance the needs  
25 of the medical community and their desires to have

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1 the medical event in terms of clinical significant  
2 with our needs to have problems and mistakes in  
3 process identified earlier and reported to us before  
4 there is harm or less than a good outcome. So with  
5 that again I'd like to be quiet and listen and hear  
6 what you folks have to say.

7 CHAIR MALMUD: Thank you.

8 Dr. Welsh, are you prepared to lead off  
9 the discussion?

10 MEMBER WELSH: Thank you, Dr. Malmud.

11 So I would say that I and certainly all  
12 members of the Medical Events and Permanent Implant  
13 Brachytherapy Subcommittee if not all members of this  
14 Committee as a whole fully concur with your  
15 sentiments that we want to carefully analyze the  
16 definition of medical event so that it is of clinical  
17 significance and also can capture trends before they  
18 become clinically significant. It's a very fine line  
19 between those two and I appreciate that.

20 But one of the struggles that we have had  
21 in recent months if not years now is an assumption  
22 that in our effort to achieve this balance we are  
23 assuming that NRC is always going to decline our  
24 offers of activity- or source-strength definitions in  
25 favor of the dose-based definitions. Could you

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1 please comment on whether or not NRC truly adheres to  
2 a dose-based definition or this is a misconception on  
3 our part that you insist on dose-based parameters?

4 MR. LUEHMAN: I'll start and, Mike, you  
5 can add in. I think that one thing that we -- I mean  
6 reading the regulation itself and not just the  
7 medical event definition but associated regulations  
8 when you look at the definitions in Part 35 and you  
9 look at the written directive regulation, the word  
10 "dose" in various forms whether it be prescribed  
11 dose, actual dose -- what are some other variations  
12 on dose that are -- absorbed dose are used through  
13 that definition, I mean, through those discussions.

14 One of the problems that we see is that I  
15 think that it's fairly clear in reading that both  
16 activity and dose can be read into the regulations as  
17 far as what is permissible to be used when delivering  
18 or when writing the written directive. But then you  
19 get into the medical event definition which then is  
20 pretty straightforward in the word in the use of  
21 dose. And the problem that we have is if you use  
22 activity then how do you assure if you deliver an  
23 activity that you have met the dose criteria for  
24 reporting. Or how is that consistently and properly  
25 converted so that you know whether you have to make a

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1 medical event report?

2 MR. FULLER: If I might follow up on what  
3 Jim said, to answer your question, Dr. Welsh, at this  
4 point in time and where we are in the process and  
5 given the direction from the Commission to go out and  
6 seek input and comments from our key stakeholders and  
7 other members of the public we are very much in a  
8 posture right now of listening to whatever you think  
9 is best representing yourself, the ACMUI, the larger  
10 medical community that you are involved with.

11 And so I would not want to say that we  
12 are going to insist on anything. We really want to  
13 hear what you think and we are prepared to listen and  
14 accept that and to take that forward as part of our  
15 deliberations and the work that we have to do along  
16 with others.

17 CHAIR MALMUD: Thank you.

18 Dr. Suleiman.

19 MEMBER SULEIMAN: Okay. What I have to  
20 say is pretty straightforward. I think it's  
21 important for the medical community to know what the  
22 radiation absorbed doses they're giving to the  
23 subject, to the patient. I think to apply it at a 20  
24 percent limit or guideline or whatever is  
25 inappropriate because different exams have different

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1 levels of precision and accuracy.

2           So unless it's modality-specific or  
3 examination-specific or disease-specific, you're  
4 going to cross into that practice of medicine  
5 tolerance you know where if you're actually calculate  
6 the dose for some types of radiotherapies --  
7 radioactive therapies -- and I'm not going to get  
8 anymore specific whether it's what organ or what type  
9 of radiation. Sometimes you may be off by 50 or 100  
10 percent and that may well be accepted practice in the  
11 medical community. You may have other modalities  
12 where and I think we use external beam therapy where  
13 you probably have the best level of precision and  
14 accuracy out there.

15           So to try to characterize for all  
16 therapies 20 percent I think is problematic. And I  
17 think you may want to say depending on what it is.  
18 And I would defer to the medical community. They  
19 would know. I think the most important thing is they  
20 should know what the dose is and then they could  
21 self-regulate saying "Wait a minute. This is way  
22 outside current practice" or "This is within the  
23 normal tolerance that we'd expect in medical  
24 practice."

25           So I think the fundamental problem is

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1 we're trying to make a general regulation for all  
2 medical procedures when, in fact, different medical  
3 procedures have different levels of precision and  
4 accuracy when you're talking about dose. I think  
5 that's fundamental. I don't know how you would  
6 address that within the current system.

7 I think the 20 percent whether it's an  
8 administered activity. To me if you know what the  
9 administered activity is and you know what the  
10 patient dimensions are you can calculate dose so  
11 they're inherently related. So that seems to be more  
12 of a calculational or technical issue.

13 The more fundamental question is where do  
14 you do start really restricting practice and people;  
15 it will alter their behavior just to comply with the  
16 regulations. But it could in some cases result in  
17 poor medical practice.

18 You may see people intentionally under-  
19 dose just so they don't get hit by the -- I take a  
20 more examination-specific approach rather than across  
21 the board 20 percent.

22 CHAIR MALMUD: This is Malmud. Dr.  
23 Suleiman, do you therefore feel that the limits  
24 should be set depending upon the organ which is being  
25 treated? For example, for the prostate, you have the

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1 specific situation which would differ, of course,  
2 from other organs. Is that what you're suggesting?

3 MEMBER SULEIMAN: Without being any more  
4 specific, yes.

5 CHAIR MALMUD: That's fine.

6 MEMBER SULEIMAN: But you may be treating  
7 the prostate with different sources of radiation  
8 which may in turn also change that level of ability  
9 to deliver something accurately.

10 CHAIR MALMUD: Yes.

11 Does anyone else want to offer any  
12 comments about this? We have other radiation  
13 oncologists or radiation oncology physicists here?

14 Dr. Welsh, back to you.

15 MEMBER WELSH: If there are no other  
16 comments, I will add a little bit more. I don't want  
17 to sound brusque here, but I do have to say that I  
18 have an air of skepticism in part based on your  
19 previous presentation just an hour or so ago in which  
20 you stated that the SECY-05-0234 paper the medical  
21 event should be defined in terms of the total source  
22 strength, not absorbed dose. And then in the SECY-  
23 08-0080 paper the modified rule would use total  
24 activity rather than absorbed dose.

25 So it sounds like going back many years

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1 the concept of absorbed dose was not favored. It  
2 seemed like activity has been promulgated. And that  
3 is what we have stated several times in the ACMUI at  
4 these meetings and in our Subcommittee reports.

5 Yet I know that the SECY-10-0062  
6 repropose rule instead of switching from dose to  
7 activity it simply added another definition which  
8 included activity which did not solve the problem in  
9 the first place, but added more complexity to the  
10 definition overall.

11 And so I guess it may be a rhetorical  
12 question because I know the answer. But could you  
13 explain to us why the SECY-10-0062 repropose rule  
14 did adhere to our initial recommendations of using  
15 activity instead of dose?

16 MR. FULLER: Well, that does predate me a  
17 little bit. But I've done some research and had a  
18 number of conversations. So I'll give it my best  
19 shot. But if I don't get it exactly right, I'll rely  
20 upon some of my colleagues here to fill in some of  
21 the gaps.

22 But it is my understanding that in  
23 accordance with the recommendations from the ACMUI  
24 and direction from the Commission many years ago we  
25 were directed to write a rule that was activity-based

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1 for permanent implant brachytherapy. Currently, we  
2 have no rule that is specific to permanent implant  
3 brachytherapy. Our rules are designed for our actual  
4 state manual brachytherapy of which permanent implant  
5 brachytherapy is a subset of that. And I guess a  
6 further subset of that would be prostates.

7 So we did propose a rule and it went out  
8 for public comment. And there were some -- any  
9 number of comments that it wasn't received as the  
10 perfect rule. I'm not sure exactly for what reasons  
11 or what the comments were necessarily focused on.

12 And then we had the incident at the VA in  
13 Philadelphia. And based upon an analysis of those  
14 medical events it was apparent to the staff at that  
15 time and maybe to others -- again I'm not sure  
16 exactly how much involvement there was on the part of  
17 the ACMUI membership -- it was at least clear to the  
18 people who did the evaluation and the analysis that  
19 many -- and I'm not sure of the exact percentage --  
20 of those medical events would not have been reported  
21 had the medical event definition been entirely  
22 related to activity.

23 And so it was based upon that analysis  
24 and that understanding that the staff went back to  
25 the Commission and had a repropose rule which you

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1 have described. And the Commission and as a result  
2 of the paper and the meeting last July which I know a  
3 number of people from the ACMUI participated in we  
4 received the staff requirements memorandum in August  
5 which said that they had not approved that repropoed  
6 rule and for us to go back again and get it done.  
7 And get it done right is the way I received that  
8 message.

9 So that's why we're here today and that's  
10 why we'll be having a continuation of these  
11 discussions.

12 CHAIR MALMUD: DR. Thomadsen.

13 VICE CHAIR THOMADSEN: My understanding  
14 from the Blue Ribbon Panel report and subsequent  
15 paper from Michael Hagan that if you look at the VA  
16 events using possibly a more current version of the  
17 dose base. And I think that would be based on  
18 something like a D-90 of 80 percent instead of the  
19 entire target being plus or minus 80 percent. If you  
20 look at that and you look at a pure number-based  
21 definition pretty much you come up with the same  
22 number of events.

23 Have you seen both of those?

24 MR. FULLER: I have heard what you have  
25 described, but I have not studied that report. There

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1 may be others here who have. But I haven't. But,  
2 yes, I have had that. That was reported to me that  
3 or to us as a staff that -- And it was presented to  
4 us in a number of different ways or described in a  
5 number of different ways.

6 I've heard the description you had that  
7 if we used a different dose-base criteria and went  
8 back and reevaluated. I've also heard that if you  
9 did the imaging, the post implant imaging, later and  
10 then did an evaluation of that versus activity the  
11 numbers become as far as the number of medical events  
12 much closer.

13 VICE CHAIR THOMADSEN: I think at the VA  
14 that would have been -- No, they didn't have that  
15 data to look at unfortunately.

16 MR. FULLER: Right.

17 MEMBER SUH: So, in terms of prostate  
18 brachytherapy, just speaking from the Department  
19 there's a lot of these. We do over 300 cases a year.  
20 And if you look at the current definition of what's  
21 you know if you look at dose-based implant our  
22 brachytherapist who does over 300 a year feels that  
23 in terms of medical event reporting there would be a  
24 portion of the cases that he has done which would be  
25 "perhaps medical events."

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1           And there are a lot of things that a  
2 radiation oncologist when they actually do the  
3 brachytherapy they can't control. And if there's  
4 some shrinkage of the prostate depending on what  
5 method you use to localize how the prostate weight  
6 defined. So I think that putting a definite number  
7 criteria in terms of what's considered a medical  
8 event really doesn't take into account the individual  
9 differences that one may see when performing a  
10 prostate brachytherapy implant.

11           So I think it handcuffs the physician in  
12 terms of what he or she may be able to provide the  
13 patient, what they feel to be best. And I think one  
14 of the things that had been shown time and time again  
15 is that patients are not a number. You know, each  
16 patient has individual differences that you need to  
17 take into account.

18           So one of my big concerns is that  
19 prostate implant which has been shown for many years  
20 to be very effective treatment and also treatment  
21 that has few side effects that the perception out in  
22 the public may be it's not perhaps a safe treatment.  
23 And therefore some of these patients may decide to go  
24 to other treatments that perhaps may have less of a  
25 track record or perhaps more expensive as well.

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1           So I think it's something that I think  
2 this group needs to take into account as well because  
3 you're trying to balance out what's perception versus  
4 reality. And my understanding is that I think what  
5 the proposed rules are and I think where we would  
6 like to see this, there are differences right now.  
7 But I think it's important that we take into account  
8 the individual differences that one sees when  
9 actually performing a prostate implant because it's  
10 not a cookie-cutter approach. There are going to  
11 some differences depending on what -- to help with  
12 how the prostate is done. And also each institution  
13 has individual variations as well.

14           In my opinion I think it is important  
15 that the NRC does not regulate the practice. I mean  
16 it's something that physicians have some control over  
17 this. They need to do what's best for the patient.

18           MR. FULLER: Thank you.

19           CHAIR MALMUD: Other comments?

20           (No verbal response.)

21           May I kind of turn this discussion around  
22 a bit and ask if you've all had a chance to read the  
23 letter from ASTRO. All members of the Committee had  
24 the opportunity to read it. They're nodding their  
25 heads. It's unanimous. Everyone has had an

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1 opportunity to read it.

2 For the minutes, I would simply state  
3 that ASTRO is the professional organization, the  
4 American Society for Radiation Oncology, which  
5 governs the practice of radiation oncology  
6 professionally. And it presented to us a very  
7 concise, thoughtful and meaningful letter regarding  
8 what it regards as an optimal solution to the  
9 problem.

10 And that solution is expressed in the  
11 letter on pages two and three in which they discuss  
12 first of all brachytherapy clinical practice  
13 guidelines and then the definition of medical event  
14 and what they believe is an inappropriate rule for  
15 permanent implant brachytherapy. And this group  
16 represents the majority of those who practice the  
17 specialty. So we see that as an offering of a  
18 solution to the problem in their proposal.

19 At the same time, we recognize that we  
20 have a responsibility to the public to be concerned  
21 about situations in which ASTRO's recommendations, if  
22 they were implemented, and were not carried out  
23 according to ASTRO's recommendations could create  
24 problems for patients which need to be recognized  
25 first and addressed.

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1           If the problem were to occur, a  
2 theoretical problem, emanating from a theoretical  
3 application of ASTRO's recommendations, there would  
4 be two means of addressing it. One would be through  
5 the medical staff regulations of each individual  
6 institute with regard to the practice of medicine,  
7 the quality of the practice of medicine. And the  
8 other would be with respect to the radiation  
9 implications which are, of course, of what's concern  
10 to us at the ACMUI and to the NRC.

11           In our discussions of this issue overall  
12 putting aside the ASTRO recommendation for a moment,  
13 I don't believe that there's a single solution, a  
14 single solution which would be able to capture every  
15 inappropriate treatment in advance and prevent it  
16 from occurring nor detect every less than optimal  
17 therapy and deal with it afterwards from a radiation  
18 perspective. These issues generally are detected  
19 within the quality control of the department  
20 providing the service and, of course, through the  
21 hospital or other healthcare organization's internal  
22 quality controls.

23           So I don't think we're going to find a  
24 foolproof solution in any of the offerings that we  
25 have, either ASTRO's or ours. However, having that

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1 background and having read ASTRO's letter more than  
2 once, I wonder if we were to propose ASTRO's letter  
3 as a solution to the issue of prostate brachytherapy  
4 if that would create a problem for the NRC.

5 And that I must ask NRC staff because I  
6 have the feeling and I hope my Committee will  
7 validate my feeling that we're in favor of this, of  
8 the ASTRO recommendation. Do I read the Committee's  
9 minds correctly?

10 MR. FULLER: May I ask a question?

11 MR. LUEHMAN: No, let the Committee  
12 answer.

13 MR. FULLER: I'm sorry. Well, here's  
14 what I would like if you could indulge me. I noticed  
15 a lot of people going and getting it and reading it  
16 as you're speaking. And I know there is someone here  
17 from ASTRO who is prepared to actually read. Would  
18 now be a good time perhaps for all of our benefits to  
19 have that letter read and then we could continue  
20 discussing? Would that be acceptable?

21 CHAIR MALMUD: Yes.

22 MR. FULLER: I see everybody reading  
23 while you're talking.

24 CHAIR MALMUD: They are reading it. But  
25 they had knowledge before I made the statement that

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1 they had read it once already.

2 MR. FULLER: I was talking about the  
3 people who are in the audience.

4 CHAIR MALMUD: Yes. The public, yes. By  
5 all means. Why don't we at this point -- I'll take  
6 your advice as sound advice.

7 MR. FULLER: Thank you.

8 CHAIR MALMUD: And ask the representative  
9 from ASTRO if that representative would introduce  
10 himself and then go through the document with us.

11 DR. SONG: Yes. Thank you, Dr. Malmud  
12 and Committee Members. My name is Danny Song and I  
13 thank you for the opportunity to make this statement  
14 on behalf of the American Society for Radiation  
15 Oncology. I am an Associate Professor and Clinical  
16 Director for the Department of Radiation Oncology at  
17 Johns Hopkins University. I'm also Director of  
18 Brachytherapy Services at Johns Hopkins and I have  
19 over seven years of experience in performing prostate  
20 as well as endobronchial brachytherapy. And I  
21 maintain an active brachytherapy service as well as a  
22 Federally-funded research program in prostate  
23 brachytherapy.

24 As you know, ASTRO is the largest  
25 radiation oncology society in the world with more

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1 than 10,000 members. We specialize in treating  
2 patients with radiation therapies. ASTRO's highest  
3 priority has always been ensuring patients receive  
4 the safest, most effective treatments.

5           ASTRO, however, believes that the current  
6 definition of medical event for permanent implant  
7 brachytherapy, one that relies on absorbed dose, is  
8 particularly problematic and requires practitioners  
9 to report events that may very well fall within the  
10 range of what is considered to be medically  
11 acceptable.

12           I'd like to describe a little bit about  
13 permanent implant brachytherapy for those who are not  
14 familiar. It is a highly effective way of delivering  
15 radiation tailored to the shape of the tumor while  
16 sparing surrounding normal tissues.

17           The benefits of brachytherapy are that it  
18 is a cost effective, minimally invasive outpatient  
19 procedure that avoids hospitalization. It allows the  
20 patient a rapid recovery and rapid return to normal  
21 activity. It produces excellent ten-year outcomes  
22 with relatively low morbidity.

23           The high degree of accuracy achievable in  
24 prostate implants is partially due to technological  
25 improvements. But quality implants still require

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1 skill, adequate training and attention to detail.

2 Permanent prostate brachytherapy is given  
3 by inserting small seeds of iodine, cesium or  
4 palladium directly into the prostate gland. The  
5 seeds are temporarily radioactive and deliver the  
6 radiation to the prostate over several weeks to  
7 months. After losing their activity, the seeds  
8 remain in the prostate and are then harmless.

9 It is recognized that the dose  
10 distributions following implantation are never quite  
11 exactly the same for each patient as those planned  
12 prior to the implant because the prostate gland  
13 swells and/or changes shape during and after the  
14 procedure. Because dose distributions may differ, it  
15 is important to document that actual dose that the  
16 prostate and the normal adjacent tissues will receive  
17 over the life of the implant.

18 This can only be determined if a post  
19 implant dosimetric assessment is performed. While  
20 the timing of such assessment may vary in part due to  
21 half-life of the particular or based on the  
22 particular isotope involved, post implant dosimetry  
23 scans are generally obtained at intervals varying  
24 from one day to one month post implant.

25 Under Part 35 Section 35.3045, it is

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1 deemed to be a medical event if the total dose  
2 delivered differs from the prescribed dose by 20  
3 percent or more. However, ASTRO believes that such a  
4 rule is not appropriate for permanent implant  
5 brachytherapy because if the NR definition is rigidly  
6 applied many medical acceptable and appropriate  
7 implants will be deemed to be medical events creating  
8 unnecessary patient apprehension.

9 An ASTRO working group found that the  
10 current definition of medical events was not suitable  
11 for permanent implant brachytherapy because the  
12 prostate volume enhanced the resultant calculated  
13 prostate absorbed dose depends on many factors  
14 including the timing of the imaging, the imaging  
15 modality selected, the observer variability and  
16 prostate contouring, the planning margins used. If  
17 the current dose base medical event definition  
18 remains in force many properly executed implants  
19 would be improperly classified as a medical event  
20 leading to a detrimental effect on brachytherapy  
21 practice.

22 Instead of a rule based on absorbed dose,  
23 ASTRO strongly recommends using an activity, i.e.  
24 source strength-based rule, where 20 percent, greater  
25 than 20 percent, or source strength implanted outside

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1 the treatment site would define a medical event for  
2 regulatory purposes. This is because the total  
3 source strength implanted with and around the  
4 prostate is under control of the authorized user.  
5 But the subsequent prostate volume and the resulting  
6 dose of the prostate is not.

7 A source strength-based criterion greater  
8 than 20 percent of source strength implanted outside  
9 the planning target volume will correctly identify as  
10 medical events cases in which a large number of  
11 sources have been improperly implanted outside the  
12 treatment site but would be less likely to generate  
13 spurious medical events than a dose-based definition.

14 ASTRO does acknowledge one scenario where  
15 a source strength-based criterion would not  
16 adequately identify a medical event and this would be  
17 when all or most of the sources are erroneously  
18 implanted within a small region of the target volume  
19 leaving a substantial portion of the treatment site  
20 uncovered. Under this circumstance, some of the  
21 target will be overdosed and other areas would be  
22 underdosed. To address this rare event, ASTRO  
23 recommends that the authorized user be required to  
24 affirm in writing on the written directive after the  
25 implant is completed that the distribution of the

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1 sources within the treatment site was as intended per  
2 the pre-implant written directive.

3 The investigation of the permanent  
4 implant brachytherapy procedures at the Philadelphia  
5 VA has brought attention to this issue and you had  
6 discussed a Blue Ribbon Panel was assembled to review  
7 the cases to determine if the implants were medically  
8 inappropriate. This panel found that many of those  
9 implants previously considered to be medical events  
10 under the current definition were in fact medically  
11 acceptable and proper. Thus, ASTRO is very concerned  
12 that if the current dose-based definition for  
13 permanent implant brachytherapy medical events  
14 remains many properly executed and medically  
15 acceptable implants will erroneously be labeled as  
16 medical events.

17 In the absence of reforming the  
18 definition of medical event that relies on dose-based  
19 rules, it is difficult to accurately predict how many  
20 medically acceptable implants in this country would  
21 be mislabeled as medical events. Such a situation  
22 would be harmful to the public welfare as it will  
23 create undue apprehension in patients and the general  
24 public about the safe and effective medical  
25 procedure. And it would continue to occupy the NRC,

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1 state regulatory bodies and licensees with thousands  
2 of man hours of unnecessary and clinically  
3 irrelevant, costly investigations.

4 Enforcement of this rule would also lead  
5 to decreased patient access to what is well accepted  
6 as a successful and cost effective treatment which  
7 clearly would not be in the patient's best interest.

8 Another factor compounding the definition  
9 of medical event is the revision of medical  
10 directives. It is very important that the definition  
11 of medical event and the rules surrounding written  
12 directives take into account clinical practice  
13 realities so that certain medically acceptable  
14 implants are not labeled as medical events.

15 Current regulations require that  
16 revisions to the written directive be made before  
17 implantation begins. The reason the pre-implantation  
18 written directive cannot be changed is that the pre-  
19 implant written directive serves as the basis for  
20 determining if a medical event has occurred.

21 ASTRO would like to emphasize that many  
22 authorized users perform real-time, adaptive  
23 interactive planning whereby the written directive  
24 and the source strength to be implanted are based on  
25 the actual volume which is dynamically determined

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1 during the procedure rather than based on the pre-  
2 implant volume. ASTRO believes that real-time  
3 planning is a more accurate method of implementation  
4 because it takes into account such alterations in the  
5 prostate volume and shape.

6 For those performing real-time adaptive  
7 planning implantation the total source strength to be  
8 implanted is determined interoperatively during the  
9 procedure and not pre-implant. Furthermore, even  
10 those performing brachytherapy using pre-planned  
11 techniques will often modify their plan if  
12 interoperatively they find major discrepancies in the  
13 gland or organ volume from the volumes determined  
14 during the pre-plan. Allowing flexibility to deal  
15 with real life clinical situations that become  
16 apparent during the operation improves clinical  
17 outcomes.

18 Accordingly, ASTRO recommends that the  
19 written directive refer to the total source strength  
20 implanted after administration but before the patient  
21 leaves the post treatment recovery area rather than  
22 an arbitrary pre-implantation written directive. We  
23 appreciate both the ACMUI's and the NRC's  
24 deliberations on this issue and look forward to  
25 working with the NRC to revise this definition so

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1 that patients have access to safe and medically  
2 appropriate procedures.

3 CHAIR MALMUD: Thank you, Dr. Song. A  
4 copy of this letter will be given to the court  
5 transcriber so that it's included in the minutes  
6 having just read the letter to us.

7 Are there comments now with regard to the  
8 letter? Dr. Fisher?

9 MEMBER FISHER: Darrell Fisher. As a  
10 person who represents patient rights, I'm really  
11 quite impressed with the in-depth consideration that  
12 this letter gives the treatment of cancer in  
13 patients. And I think that that should be among our  
14 first and foremost considerations.

15 I know that in the slide we have in front  
16 of us we have a disclaimer even if there is no actual  
17 negative consequences to the patient. But I think  
18 what the patient really wants is an effective  
19 therapy, one that delivers sufficient radiation to  
20 the tumor or to the cancer cells present to result in  
21 an effective treatment. That's what the patient  
22 wants.

23 If there's a 20 percent increase to a  
24 dose to an adjacent normal tissues as a result of  
25 therapy, that's not of major concern to the patient.

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1 The patient wants to be cured of cancer. And the  
2 patient realizes that there is going to be radiation  
3 exposure to normal tissues as a result of undergoing  
4 a patient therapy.

5 I think that the letter does represent my  
6 views and should be a fair representation of the  
7 rights and views of the educated patient population.

8 CHAIR MALMUD: Thank you, Dr. Fisher. I  
9 believe Dr. Welsh was next.

10 MEMBER WELSH: Thank you, Dr. Malmud. My  
11 comments are that you have probably noticed the  
12 similarity between this ASTRO letter and the ACMUI  
13 Medical Events Subcommittee, Permanent Implant  
14 Subcommittee, report even though that report is still  
15 in preliminary phases. It's virtually identical in  
16 many ways. And I believe that both documents  
17 achieved the goal of identifying trends that could  
18 lead to potential medical harm to a patient, yet are  
19 not likely to miss true medical events that are of  
20 significance. In this regard, these proposed  
21 definitions are less likely to include a large number  
22 of medically acceptable implants and mislabel them as  
23 medical events.

24 And as Dr. Song mentioned in this letter  
25 patient apprehension is an unwanted side effect of

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1 identifying too many medically acceptable implants as  
2 medical events. If the term "medical event" or  
3 "misadministration" is applied too freely, it does  
4 cause patient concern and it does cause in my opinion  
5 people to steer clear of a very viable, safe and  
6 effective modality of treatment.

7 And as I stated in 2004 there were 41,790  
8 prostate implants constituting about 20 percent of  
9 prostate cancer treatments. That fell to only 17,490  
10 in 2009 falling to a very low level of eight percent  
11 of prostate treatments with the caveat that there are  
12 new competing modalities such as the robotic prostate  
13 techniques that have emerged in that time frame.

14 I still believe that inappropriate  
15 labeling of good implants as medical events has  
16 contributed to this decline. So it's not  
17 hypothetical in my opinion. It's real. And  
18 therefore it underscores why we need to change this  
19 definition.

20 This ASTRO definition and the  
21 Subcommittee's recommendation would not have labeled  
22 all of the VA series as medical events. A fair  
23 fraction of these implants would have been considered  
24 acceptable medical procedures. But I don't think  
25 that we would have missed so many either. It would

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1 have gone under the radar and VA would not have been  
2 identified as having a problem.

3 So I do think that ASTRO's definition  
4 which again is similar to the Subcommittee's  
5 suggestion is quite appropriate and would identify  
6 trends that need to be identified and also not cause  
7 undue alarm that's not called for.

8 CHAIR MALMUD: Thank you, Dr. Welsh.  
9 Other comments? Dr. Zanzonico.

10 MEMBER ZANZONICO: First, I wanted to  
11 thank Dr. Song and ASTRO for their really thoughtful  
12 statement and analysis. And I don't want to speak as  
13 the Committee but it captures the sentiment of most  
14 of us.

15 Just kind of a logistical or practical  
16 question I have in terms of addressing the fact that  
17 the physicians properly may implant seeds sort of  
18 interactively and change on the fly appropriately in  
19 the interest of the patient, would these definitions  
20 of a misadministration -- And I'm thinking in  
21 particular not only of an inappropriate source  
22 strength implanted, but inappropriate placement, too  
23 many seeds being placed in one portion of the  
24 treatment area inappropriately. Would that require  
25 before the patient leaves the treatment area some

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1 post treatment imaging study that's not normally or  
2 routinely performed at the present time? And, if so,  
3 should that be a component of the regulation?

4 Otherwise it's not clear how even if the treating  
5 physician documents post treatment that they have  
6 changed or implanted seeds in what they deemed a  
7 medically appropriately way. That it was in fact  
8 accomplished if there were such an imaging study.

9 CHAIR MALMUD: May I address your  
10 question to Dr. Song who is a practicing radiation  
11 oncologist?

12 MEMBER ZANZONICO: Please.

13 CHAIR MALMUD: And the question is this,  
14 Dr. Song. We've heard a number of presentations in  
15 the past and I as a non-radiation oncologist recall  
16 that the tumor is first stage with imaging. Then the  
17 treatment is decided. And then there is a post  
18 treatment imaging and that has a follow-up in one or  
19 two months. Am I correct? Are there two post  
20 treatment images, one immediately following therapy  
21 and one a month or two later?

22 DR. SONG: I would say the most common  
23 practice is for people to obtain a scan one month  
24 after the procedure.

25 CHAIR MALMUD: So not immediately but

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1 prior to and one month after.

2 DR. SONG: Yes. As mentioned, there is a  
3 fair amount of variability in there.

4 CHAIR MALMUD: Yes. And we heard that  
5 the variability includes the instrumentation used to  
6 image. Some departments are using CT. Others are  
7 using ultrasound. And that it has moved from  
8 ultrasound to CT, but not everywhere. Is that a fair  
9 summary of what is going on in the United States?  
10 I'm not speaking Johns Hopkins.

11 DR. SONG: Right. I would say that most  
12 centers use CT scans and it has been generally the  
13 standard for quite a while. There are some centers  
14 that are now implementing MRI because there is less  
15 of a challenge in identifying the boundaries of the  
16 prostate on MRI in the presence of seeds which do  
17 cause an effect on the CT.

18 CHAIR MALMUD: Dr. Zanzonico, does that  
19 answer your question?

20 MEMBER ZANZONICO: Well, it answers it  
21 insofar as I have a better understanding of what's  
22 currently done. But my question remains. Is that  
23 adequate in terms of capturing a medical event where  
24 a physician on the fly to use my term implants seeds  
25 in a certain arrangement.

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1           But how do you know if the next image  
2 thereafter is one month after the fact that the seeds  
3 may have been placed properly but just because of  
4 biological processes been displaced and at one month  
5 appears to be a medical event because of what appears  
6 to be a misplacement of the seeds? Whereas, if you  
7 did an immediate post treatment image, you would  
8 either know that or not because it wouldn't be time  
9 for intervening biology, so to speak.

10           CHAIR MALMUD: Dr. Welsh.

11           MEMBER WELSH: So I'd like to just add to  
12 Dr. Song's comments. There is a lot of variability.  
13 But one procedure that is very commonly employed is  
14 use of an x-ray right after the procedure is done.

15           That is done for a couple of purposes.  
16 One is a simple seed count to make sure that you've  
17 done everything that you thought you'd done in terms  
18 of putting the seeds into the patient's body and  
19 figuring out if you're going to have to look around  
20 the room for a missing seed or if a seed might have  
21 traveled to the lung or elsewhere.

22           But I think your suggestion is sage  
23 advice and perhaps it would be very reasonable in  
24 addition to the x-ray which is typically done review  
25 the ultrasound with extra scrutiny to be able to say

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1 after the procedure whether or not this treatment has  
2 been performed such that the distribution of sources  
3 is in accordance to the authorized users pre-implant  
4 written directive with the understanding that  
5 ultrasound is not perfect and that things change  
6 significantly interoperatively. But your suggestion  
7 is reasonable.

8 The practical solution would be to review  
9 the ultrasound because getting a CT scan right after  
10 implant can be challenging. And x-ray does not  
11 satisfy your question.

12 MEMBER ZANZONICO: It would not. A  
13 portable would not.

14 MEMBER WELSH: It would not satisfy the  
15 purposes of being able to say with certainty that  
16 you've placed the seeds where you intended to place  
17 them according to the directive.

18 CHAIR MALMUD: May I ask? I'm a little  
19 puzzled. Is ultrasound routine post therapy?

20 MEMBER WELSH: Ultrasound is done during  
21 the therapy.

22 CHAIR MALMUD: In the placement of the  
23 seeds.

24 MEMBER WELSH: Yes.

25 CHAIR MALMUD: But not a summary at the

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1 end. Is that standard nationally? Is that standard,  
2 for example, at Hopkins?

3 DR. SONG: One is always looking at the  
4 ultrasound during the procedure and, as my own  
5 personal practice, yes, I do review the ultrasound to  
6 determine how the seed placement is and particularly  
7 if there are any additional areas that I need to add  
8 a seed or two. But I think ASTRO included this  
9 reference just as a theoretical possibility because  
10 one could imagine that situation.

11 I am challenged and they do admit with  
12 the rare event. I'm challenged to really envision a  
13 situation where that would occur where an implant is  
14 complete and yet the authorized user realizes that  
15 most of the activity was put in one part of the  
16 prostate. Because if you're using your ultrasound to  
17 determine that that's the case, then most likely one  
18 would have made a change or alteration during the  
19 procedure to keep that from happening.

20 CHAIR MALMUD: Our concern is what  
21 happens when the physician therapist does not do  
22 that. What happens when 20 percent of the seeds are  
23 in the bladder by mistake, not because the prostate  
24 is swollen but because they were mistakenly placed in  
25 the bladder or if they're grouped together and

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1 there's no record of this having occurred?

2 DR. SONG: Well, that would be  
3 demonstrated on the post implant CT scan.

4 CHAIR MALMUD: And is a post implant CT  
5 scan the national standard for radiation oncology in  
6 brachytherapy?

7 DR. SONG: That is. Yes, that is  
8 considered a standard to be a post implant dosimetric  
9 assessment.

10 CHAIR MALMUD: Does that apply at the --  
11 What I'm trying to drive at and maybe indirectly is  
12 that if our practice standards in the profession  
13 don't at the same time protect the patient from  
14 radiation damage, then there's a need for the NRC to  
15 say "Wait a minute. You don't have standards that  
16 protect the patient from these radiation accidents or  
17 misadministrations or outcomes and therefore we must  
18 at the NRC begin to look at this." Whereas we would  
19 hope that the medical practice standards would be so  
20 thorough as to prevent this.

21 So I guess what I'm really doing is  
22 asking you a question.

23 DR. SONG: Yes, there are standards.

24 CHAIR MALMUD: How standard -- There are  
25 standards.

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1 DR. SONG: I know the American  
2 Brachytherapy Society which is another body and has  
3 membership consisting of people who practice  
4 brachytherapy. They do have practice standards which  
5 include a recommendation for post implant dosimetry  
6 as well as -- and Dr. Thomadsen can correct me if I'm  
7 wrong. But the American Association of Physicists in  
8 Medicine also has position papers on brachytherapy  
9 which recommend post implant dosimetry.

10 CHAIR MALMUD: And Dr. Thomadsen wants to  
11 make a comment.

12 VICE CHAIR THOMADSEN: And that is  
13 correct. In addition to saying that same thing, both  
14 standards recommend CT because at the end of a  
15 procedure ultrasound can't identify reliably all of  
16 the seeds that have been placed. As a matter of  
17 fact, there is often a large percentage that cannot  
18 be because of the orientation of the seed with  
19 respect to the ultrasound beam. So the standard is  
20 in both cases doing CT.

21 CHAIR MALMUD: I'll ask a naive question.  
22 Are the seeds I-131 seeds in some cases?

23 DR. SONG: I would say the majority of  
24 patients. Personally I used palladium most of the  
25 time. But yes.

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1 CHAIR MALMUD: I-131.

2 DR. SONG: Iodine-125. I'm sorry. It's  
3 125.

4 CHAIR MALMUD: And the half-life of I-125  
5 is?

6 DR. SONG: Roughly 60 days.

7 CHAIR MALMUD: About two months.

8 DR. SONG: About two months, yes.

9 CHAIR MALMUD: So that at two months if  
10 these seeds have been placed in the wrong place the  
11 damage would have been done to the tissue other than  
12 the target organ.

13 DR. SONG: That's correct.

14 CHAIR MALMUD: And at that point what --  
15 What we're trying to figure out is how do we prevent  
16 a recurrence of what happened at the Philadelphia VA  
17 without limiting the abilities of physicians such as  
18 yourself to practice brachytherapy. And that's a  
19 conundrum for us is protecting the patient from that  
20 unusual outcome while sustaining a very valuable  
21 therapy.

22 Dr. Welsh, please. You're more expert in  
23 this area.

24 MEMBER WELSH: Please correct me if I'm  
25 wrong. My memory is failing a bit here. But I

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1 recall the VA -- As Dr. Song stated there are  
2 standards from the American Brachytherapy Society,  
3 from AAPM, from others, but they are not regulations.  
4 The VA had some equipment problems and post implant  
5 dosimetry was not routinely performed on many of the  
6 patients that were in this series of medical events.

7           Therefore, one could argue that standards  
8 were not followed, not NRC regulations mind you, but  
9 American Brachytherapy Society standards perhaps.  
10 Therefore, the NRC insists on post implant dosimetry  
11 and NRC insisted on post implant dosimetry being back  
12 to where the American Brachytherapy Society, AAPM,  
13 etc., opposed these standards I suspect that this  
14 series of medical events would have been averted  
15 because the post implant dosimetry would have caught  
16 many of these. Before you do another one, let's  
17 reassess this program.

18           There is no way to prove this point. But  
19 I'm strongly suspicious I guess.

20           CHAIR MALMUD: Does that mean that the  
21 NRC should establish a regulation in the absence of  
22 enforcement of a practice standard by the specialty  
23 society to ensure that when something like this  
24 happens that it doesn't happen again by the same  
25 therapist? Namely, you made a mistake. We caught it

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1 and it can't happen again because we caught it and  
2 we've now made an issue of this.

3 MEMBER WELSH: I would say the answer is  
4 yes. NRC perhaps should weigh in on this because  
5 it's one thing to be in violation of a society's  
6 standards. You would get a reputation to maybe not  
7 being a great doctor. Your patient volumes will  
8 suffer and you get a bad reputation.

9 But if you're the only doctor in town  
10 perhaps so what? If people don't listen to you, so  
11 what? But if NRC says, "This is a violation.  
12 There's going to be fine" then perhaps you're not  
13 going to practice this much longer. Or if insurance  
14 says, "You're violating the standards and you're not  
15 meeting our definition of somebody who should be  
16 practicing and getting paid for this" those are two  
17 approaches which would change physician behavior more  
18 than a society's statement which I would like to  
19 believe that everybody would adhere to. But as we  
20 see if the equipment is not working and post implant  
21 dosimetry was not absolutely mandated -- a number of  
22 patients didn't have the post implant dosimetry --  
23 this leads to the current state of affairs.

24 CHAIR MALMUD: Thank you.

25 We have other members of the radiation

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1 oncology profession here. Would any of you care from  
2 the perspective of either a therapist or a physicist  
3 to comment on what Dr. Welsh just said about the NRC  
4 being a regulatory body that establishing a standard  
5 of practice to do a post therapy CT when it is not  
6 enforceable? It is recommended, but not enforceable  
7 by the specialty society. I'll ask you after I ask  
8 them.

9 MEMBER SUH: So this is John Suh. In  
10 terms of what Dr. Welsh just mentioned, in terms of  
11 quality standards, I think if you look at what was  
12 done at the VA hospital the quality standards were  
13 probably not up to what high volume places in  
14 brachytherapy would have advised. So, as a result,  
15 some mishaps occurred.

16 And again with the definition that's up  
17 there saying it's a mistake that you have a deviation  
18 greater than 20 percent I think is really sending the  
19 wrong message. And whether or not the NRC can  
20 regulate a quality standard, if that's something  
21 that's within the purview of the NRC, perhaps that  
22 can drive behavior.

23 There's no question that for quality if  
24 you can show that your quality is not good as a  
25 result of not following standards that's one way of

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1 changing behavior. And I think that pay for  
2 performance is perhaps one means of trying to change  
3 behavior that's less than optimal in terms of patient  
4 care.

5 From prostate brachytherapy, again it's a  
6 very effective therapy. It's shown to have low  
7 morbidity and I think it's important that the  
8 physicians are not so handcuffed that they will not  
9 do this procedure and not offer it.

10 Now in terms of talking about quality I  
11 think the other aspect of things is that I'm also a  
12 firm believer that if you're doing a procedure and  
13 you do it often you're going to be much better at it  
14 than someone who does it twice a year or three times  
15 a year. So I think along with quality standards I  
16 think the other question is, is there perhaps a  
17 certain number of cases that should be done to really  
18 be considered an expert user?

19 CHAIR MALMUD: I appreciate your  
20 comments, but I would make two additional comments.  
21 Number one, the VA was operating under the umbrella  
22 of one of the leading medical institutions in the  
23 United States, the University of Pennsylvania. So it  
24 was not operating without the assumption of  
25 supervision.

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1           How that supervision worked is a long  
2 story or didn't work is another story. But that was  
3 an assumption. So this wasn't a renegade, small  
4 operation.

5           The other issue is that we come back to  
6 the question and that is how do we prevent what  
7 happened there at least in one case that we have seen  
8 amply covered in the news of a man who sustained  
9 considerable physical disabilities as a result. How  
10 do we prevent that from occurring and at that same  
11 time not tying the hands of radiation oncologists?  
12 And that's a struggle that we have and that we're  
13 asked to address on behalf of the public to neither  
14 constrain radiation oncology in a practice of  
15 brachytherapy and deny patients who could benefit  
16 from this generally very superior therapy and at the  
17 same time pick up incidents that occur which warn the  
18 organization that they're having a problem in their  
19 department which requires immediate reviews so that  
20 another patient doesn't have the same problem.  
21 That's the real issue.

22           And generally these things are handled by  
23 hospital quality control, quality assurance  
24 committees and so on. It's failed there. I don't  
25 want to accuse -- I shouldn't say it's failed. It

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1 didn't seem to work there.

2           And the challenge that we have is to make  
3 sure that what happened does not occur and yet allow  
4 the therapy to thrive appropriately. And I'm trying  
5 to get advice from each of you as to how we should  
6 draft something to submit to the NRC as an advisory  
7 committee to assist the NRC and to work with ASTRO in  
8 ensuring that this important therapy continues to be  
9 provided but in a safer environment than recent  
10 history has shown has occurred.

11           Dr. Welsh.

12           MEMBER WELSH: So just to reemphasize my  
13 point. What I'm saying, strongly suggesting, is that  
14 post implant dosimetry which is an important quality  
15 assurance component of a good brachytherapy program  
16 not be recommended or strongly urged by ASTRO, ABS,  
17 Jim Welsh says you should, but should be insisted  
18 upon by NRC if it's within their purview or the  
19 insurance companies so that you don't get paid if you  
20 don't have quality programs. So I'd like comments or  
21 feedback on this very specific point.

22           CHAIR MALMUD: Dr. Thomadsen.

23           VICE CHAIR THOMADSEN: We can't deal with  
24 insurance companies. We can only deal with the NRC.  
25 No matter what criterion we use for evaluating

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1 whether or not there has been a medical event it  
2 needs to be based in some respect on an image because  
3 you can't evaluate either for doses or where seeds  
4 are with respect to the target without that. And as  
5 such an image after the procedure seems to be  
6 necessary.

7 CHAIR MALMUD: Dr. Welsh.

8 MEMBER WELSH: I agree with what Dr.  
9 Thomadsen is saying. And I would perhaps extend it  
10 to say that irrespective of what that image shows  
11 because we haven't clearly defined what we're going  
12 to do with the post implant dosimetry today I think  
13 we are able to say that post implant dosimetry should  
14 be done as part of a program that is doing  
15 brachytherapy. If you're not doing post implant  
16 dosimetry with some form of acceptable imaging, you  
17 probably shouldn't be doing prostate brachytherapy at  
18 all.

19 CHAIR MALMUD: Debbie.

20 MEMBER GILLEY: Yes. I think that  
21 authorization may already be in NRC regulations and  
22 it's the procedures for administering requiring a  
23 written directive. And it specifically says, "Each  
24 administration is in accordance with the written  
25 directive." And I know no other way you can tell if

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1 you didn't follow the written directive then you do  
2 some type of test afterwards to verify that you've  
3 followed that written directive. So you almost have  
4 to do some type of post dosimetry CT to validate that  
5 you followed the written directive.

6 CHAIR MALMUD: But almost have to doesn't  
7 mean must.

8 MEMBER GILLEY: I look to the experts to  
9 this table to tell me another way to validate it.

10 CHAIR MALMUD: A specific requirement.  
11 You wanted to say something, Dr. Suleiman.

12 MEMBER SULEIMAN: Well, back to imaging,  
13 I mean even in oncology, the criteria that uses  
14 response evaluation criteria for solid tumors is  
15 accurate to within 30 or 50 percent. And I think a  
16 lot of the -- I mean imaging is very, very sloppy in  
17 oncology in terms of monitoring in terms of trials  
18 over long periods of time.

19 So I think that imprecision and  
20 inaccuracy contributes to this issue here. When you  
21 take an image it's just not done in a standard way  
22 today. So that imprecision is factored in, in how  
23 the practice is.

24 But my point I'm looking at the  
25 statement. I think everybody agrees that it's

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1 important to do a dose calculation. Now whether  
2 that's reportable to the NRC or not it's done. It's  
3 become very obvious that there has to be a post  
4 operative radiation dose calculation, a final dose  
5 estimate, whether it's activity or -- I would prefer  
6 radiation as a dose.

7           And when that image or when you do the  
8 dose calculation, when it's done, clearly there's a  
9 certain amount of uncertainty whether it's done  
10 immediately for seed count or whether it's done  
11 before you get an edema or whether it's a month later  
12 or six months later. That's going to vary. So you  
13 have to specify time if you're talking about change.

14           I think the big issue that I have  
15 problems with and I said it earlier is the 20  
16 percent. And I would not write that in regulation.  
17 I would basically defer to -- I wouldn't say 20  
18 percent is good or bad. I would defer to the  
19 community and say, "At what point is this difference  
20 in final radiation dose calculation bad? At what  
21 point? Is it 50 percent? Is it 100 percent?"

22           Years ago the debate was over how much  
23 medicine you could give somebody. I said, "Well, a  
24 gallon of penicillin people would say probably is too  
25 much." It's not a case of is there a level at which

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1 it's not appropriate. The question is at what point  
2 do you think it's serious enough to be considered a  
3 reportable medical event? And that's where the 20  
4 percent has to be thrown out.

5 And I wouldn't write it into the  
6 regulation. I would kick that into guidance. And  
7 default to the profession to define that you have to  
8 do a post operative dosimetry calculation at these  
9 following times. And if the dose calculation based  
10 on what you did initially, real time or whatever, is  
11 more than 100 percent, is more than 200 percent, is  
12 more than 500 percent, it's a reportable medical  
13 event to the NRC. But I would feel that 20 percent  
14 is too low which is why you have the controversy you  
15 have right now.

16 CHAIR MALMUD: Thank you.

17 Further comments? Dr. Thomadsen.

18 VICE CHAIR THOMADSEN: Ms. Holiday, could  
19 I have the slides?

20 MS. HOLIDAY: Yes.

21 (Off the record discussion.)

22 CHAIR MALMUD: Public comments. Would  
23 you care to introduce yourself?

24 MR. MOWER: I'm Dr. Herbert Mower. I'm  
25 with the American Association of Physicists in

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1 Medicine and I'm a radiation therapy physicist.

2 I strongly support what ASTRO has  
3 written. In looking at -- and of course the slide  
4 just disappeared -- But it says in there even if  
5 there is no actual negative consequence to the  
6 patient.

7 Now I'm not a physician. But does not a  
8 psychological consequence constitute a negative  
9 consequence if you've told the patient that they have  
10 a medical event and then come back later and say it  
11 wasn't a medical event? So I feel like we kind of  
12 overlook it and we only look at what the radiation  
13 problem is.

14 The other question that comes up is I'm  
15 not sure when you talk about 20 percent and I would  
16 like some clarification on this. If we exceed the  
17 dose by 20 percent, where? Is this some point within  
18 the prostate? Is this some predetermined point  
19 before when we did the preplan? Because as we're all  
20 aware the closer you get to that seed you have  
21 grossly exceeded 20 percent of any dose you think you  
22 were specifically in the prostate tumor volume. Two  
23 hundred percent? Two thousand percent? You are  
24 grossly over that 20 percent number.

25 So if you're going to end up finding

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1 something by 20 percent of dose, 50 percent of dose,  
2 100 percent of dose, we have to somehow or other  
3 determine some portion of volume to which that  
4 applies. Or else it has absolutely no physical  
5 meaning.

6 CHAIR MALMUD: Thank you.

7 Dr. Welsh.

8 MEMBER WELSH: I do have a comment before  
9 Dr. Thomadsen begins his discussion here. This  
10 morning during our Subcommittee report on byproduct  
11 medical events, I pointed out that there was one  
12 highly unusual and slightly surprising frankly case  
13 in which 39 out of 41 seeds were within the target  
14 but were all implanted along a isoline. And this is  
15 the nightmare that we have been having for our  
16 Subcommittee in terms of coming up with an  
17 appropriate definition that is strictly activity-  
18 based.

19 It turns out that upon review of that  
20 particular incident it was not a medical event  
21 because the seeds were within the target volume. Yet  
22 if the D-90 is one percent, it's hard to comprehend  
23 how this would not be a medical event. Therefore, I  
24 think we have to acknowledge that there were some  
25 deficiencies with the initially proposed Medical

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1 Event Subcommittee report, its recommendation.

2 The ASTRO recommendation that we've just  
3 heard now perhaps solves this problem with the  
4 statement that "the authorized user will be required  
5 to affirm in writing on the written directive after  
6 the implant is completed that the distribution of  
7 sources within the treatment site was as intended for  
8 the pre-implant written directive." So that may  
9 solve the problem.

10 But I think Dr. Thomadsen has another  
11 solution that I think is worthy of some discussion.

12 CHAIR MALMUD: Thank you.

13 And, with that introduction, we'll ask  
14 Dr. Thomadsen to make his presentation.

15 VICE CHAIR THOMADSEN: I won't take  
16 entire credit for this in that I worked with Dr.  
17 Welsh on this unless he doesn't want to have anything  
18 to do with this anymore.

19 (Laughter.)

20 And I'll preface this myself by saying I  
21 strongly endorse ASTRO's take on it. And I strongly  
22 endorse their larger report which hasn't been  
23 duplicated here but is summarized in their statement.  
24 What the intention here is to try to take the ideas  
25 behind that and address some of the practical

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1 problems in the implementation.

2 Mr. Fuller, sorry to interrupt. You have  
3 the clicker. Could you advance to the next?

4 MR. FULLER: Be happy to.

5 VICE CHAIR THOMADSEN: Thank you.

6 Jumping right in, here's a definition of  
7 medical event. For a target, and this is strictly  
8 for prostate -- permanent prostate implant. For the  
9 target that the D-90 is less than 70 percent for the  
10 clinical target volume and simultaneously less than 5  
11 percent of the sources occupied any octant of the  
12 PTB, except by design whereas somebody has wanted to  
13 escalate the dose or protect a region. The rationale  
14 for this is that in the RTOG-protocols, a minor  
15 deviation is the D-90 running between 90 percent and  
16 80 percent. So obviously a D-90 of 80 percent is  
17 completely acceptable. It's not considered ideal,  
18 but it's acceptable and the patients are still  
19 allowed in protocols. So our threshold would have to  
20 be lower than that and it's quite arbitrary at 70  
21 percent.

22 It's not too important where that is,  
23 because this is just a screening procedure that you  
24 find that dose on whatever post-impact imaging that  
25 one does. If that low dose is resultant from the

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1 seed distribution being something abnormal, for  
2 example, what Dr. Welsh has pointed out where all the  
3 sources ended up in one part of the prostate, then  
4 you have a medical event. But if the distribution  
5 of the sources was within the realm of normal, and in  
6 each octant, an octant taken because it's just half  
7 in each of the three axes, a normal distribution  
8 would have 12.5 percent in each. But you shift those  
9 around and the fact that you're dealing with a  
10 template means you can't get that.

11 But if each octant has five percent, you  
12 have done a pretty good job of distributing the  
13 sources around and the low dose might be from the  
14 edema. It might be from some migration. It might be  
15 from a lot of possible medical conditions.

16 And that would not be a medical event if  
17 the sources had been distributed correctly.

18 But that matter, as pointed out in some  
19 of the VA nominal events that later were deemed  
20 probably not events, the distribution may not have  
21 been ideal in which case that would be a screening  
22 here, but the dose was still above what would be  
23 considered adequate for treating the prostate.

24 And so without failing both of those you  
25 have what would be an acceptable treatment. And for

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1 a medical event, you would have to have a failure  
2 both in the dose distribution and in the seed  
3 distribution.

4 You will notice that there's no upper  
5 bound for the dose and the target as far as anybody  
6 has ever bound in the literature. There is no upper  
7 bound as far as what would be allowed for the  
8 prostate implants per dose in the target volume. As  
9 we just heard from the AAPM spokesperson, right near  
10 the source you have a singularity. The doses become  
11 extremely large anyways. So trying to have upper  
12 bound is meaningless.

13 Could I have the next slide, please?

14 The other side of a medical event is  
15 doses to normal tissue which at the moment is just  
16 point doses and some arcane holdovers from other  
17 types of exposures that the tissues might have.  
18 Looking at data as far as normal tissue responses to  
19 radiation doses that are excessive and looking for  
20 toxicity, in the bladder and the rectum, there is  
21 pretty good literature that says that the dose to the  
22 maximum dose to a 5 cc volume is what seems to be  
23 appropriate to look for normal tissue toxicity. And  
24 volumes lower than these are not predictive.

25 Also, looking at what data we have if we

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1 were to use the dose to 5 cc's at the bladder or  
2 rectum that exceeded 150 percent of the prescription  
3 dose, that seems to be right in the ballpark. We  
4 could discuss and argue whether it's 150 or some  
5 other value, but that's -- I'm throwing this out as a  
6 proposal.

7           The other thing to worry about is the  
8 urethra. While there is no upper level on what dose  
9 we should have in the target, the urethra does have  
10 some maximum dose. Once again, it should be a  
11 volume-based dose and so the other normal tissue that  
12 we would worry about is that the dose to the urethra  
13 post-implant dosimetry not exceed 150 percent of the  
14 value that was based on the planned dose it would  
15 have otherwise gotten, because it will get some dose  
16 that's higher than the prescription dose, normally,  
17 and you just want to make sure that you aren't  
18 exceeding unduly.

19           And if we go back to the dose to the  
20 prostate on previous slide, the dose is something --  
21 yes, if you could get that -- the dose would be the  
22 dose on the -- that would be prescribed just at the  
23 beginning of the implant. And this is something  
24 that's usually intended ahead of time. You look at  
25 the patient. You look at the prostate on the image

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1 just before you do the implant. You say I have in  
2 mind that I would like to give a particular dose.

3 The assessment of the number of seeds is  
4 not decided ahead of time at all and we don't have a  
5 prescribed number of seeds to get that dose because  
6 in the real time implants, you don't know until  
7 you're done how many seeds you needed in order to get  
8 that dose to the target. And if you do live-time  
9 replanting in the operating room, which is the state-  
10 of-the-art at the moment, then you don't know until  
11 things are done what it is.

12 Can you go two slides forward, please?

13 So the feature of the definition is  
14 definition would catch an event where all sources  
15 were bunched. It would not signify as a medical  
16 event an impact where the sources missing an octant  
17 if you had something that was uncovered, but the dose  
18 was at least about a 70 percent of the prescribed  
19 dose.

20 Next slide, please.

21 And let's see, I already talked about  
22 that first point. So let's see, I talked about both  
23 of these here.

24 Next slide, please.

25 I think this is the last one. And having

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1 a volume for the normal tissue tolerances -- very  
2 high variations that you get in dose that you  
3 sometimes see. If you just look for a point dose  
4 somewhere and it does have literature support as far  
5 as being a relevant quantity for the toxicity.

6 I think that's it. No more slides, I  
7 think. That's the proposal to try to take some of  
8 the recommendations and put them into a language that  
9 could be practically evaluated by the regulators and  
10 the practitioners. And yet, not end up with an  
11 excessive number of medical events such as some of  
12 the definitions might, nor to ignore the need from --  
13 or the feeling from patients that their doses may be  
14 being compromised. That's it.

15 CHAIR MALMUD: Thank you, Dr. Thomadsen.  
16 Comments regarding Dr. Thomadsen's --

17 MEMBER ZANZONICO: I have two questions.  
18 First of all, this is all technically doable and  
19 routine, these quantities that are alluded to. So  
20 that doesn't hold anything special.

21 VICE CHAIR THOMADSEN: Yes.

22 MEMBER ZANZONICO: The other question I  
23 have is that the interactive seed placement that Dr.  
24 Song alluded to earlier, that's to achieve these  
25 prescribed doses at these index points. It's not to

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1 change a dose on the fly, but to achieve a dose.

2 Okay.

3 VICE CHAIR THOMADSEN: And that's what we  
4 do in our implants. We do lifetime planting.

5 MEMBER LANGHORST: Dr. Malmud?

6 CHAIR MALMUD: Yes.

7 MEMBER LANGHORST: Sue Langhorst. Would  
8 you then have the authorized user document these  
9 particular points and that would be what the  
10 inspector, either my staff or NRC staff or agreement  
11 staff, to then evaluate in their inspection?

12 VICE CHAIR THOMADSEN: By points you mean  
13 items, not physical point locations?

14 MEMBER LANGHORST: What I mean is the  
15 value that yes, I document that it's not less than 70  
16 percent and not -- that you meet all the points that  
17 you're talking about, that that is documented some  
18 place?

19 VICE CHAIR THOMADSEN: Sure. That's  
20 pretty normal.

21 MEMBER LANGHORST: Right.

22 VICE CHAIR THOMADSEN: But the document  
23 as we explicitly at our place, when we go through our  
24 post-implant dosimetry, we have a checklist that we  
25 just check off. I assume that there would be a note

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1 that somebody would dictate reading the image  
2 afterwards and would say looks like we've met these -  
3 -

4 MEMBER LANGHORST: That you would have to  
5 meet these end documents for inspection purposes.

6 VICE CHAIR THOMADSEN: Yes.

7 MEMBER LANGHORST: Because that would be,  
8 I know a difficulty for my staff unless it is  
9 definitely documented some place in this format or  
10 these various criteria.

11 VICE CHAIR THOMADSEN: I don't know how  
12 they document now. I don't see that there would be  
13 any difference, really.

14 MEMBER LANGHORST: I think it just has to  
15 be clearer that these points have to be documented.

16 VICE CHAIR THOMADSEN: Yes, but I don't  
17 think that's a change for anybody. It's just what's  
18 being documented would be slightly different.

19 CHAIR MALMUD: Dr. Song?

20 MR. SONG: I think, of course, speaking  
21 on behalf of ASTRO, ASTRO's official position is as  
22 in the statement. I presume that this is suggested  
23 as an alternative possibility to the activity-based  
24 rule.

25 I think overall the spirit, and this is

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1 me speaking personally, I think overall the spirit is  
2 reasonable. I think it does reflect clinical reality  
3 and meaningfulness. As Dr. Malmud alluded to, there  
4 are not good data about what exceeds a reasonable  
5 implant in terms of a D-90 above a certain threshold.  
6 There's just, to my knowledge, there's not good data  
7 about what that should be.

8 But below, yes, there's quite a bit of  
9 support for that and I think the D-90 of 70 would be  
10 a reasonable threshold to be able to achieve a good  
11 implant.

12 I think some of the details about the  
13 urethral dose, there may be some uncertainty there in  
14 terms of how do you see the urethra on the post-  
15 implant CT. Does that mean every patient has that  
16 Foley catheter in place?

17 We do a post-implant CT the day after  
18 because one of the reasons is we use a shorter half-  
19 life isotope, but also because the patients don't  
20 want another catheter put in 30 days later. And so  
21 that obviates the need for that. So there would be  
22 some challenges in doing that, but overall, I think  
23 the spirit of it seems very reasonable.

24 CHAIR MALMUD: Dr. Thomadsen?

25 VICE CHAIR THOMADSEN: Just in answer to

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1 the urethral issue, in answer to the urethral issue,  
2 if in doing your post-implant dosimetry, there is no  
3 5 cc volume that exceeds 150 percent of what the  
4 planned urethral dose is. You don't need a catheter  
5 in the urethra to know that the urethra is fine. And  
6 I think that that's most of the cases unless you have  
7 a congregation of sources that all happen to be right  
8 in the urethra.

9 I appreciate the problem and I thought  
10 about that, too. But I think in which case then you  
11 might want to do a second CT with a catheter in  
12 place, but I think the occasions where this would be  
13 the case would be extremely rare, at least looking at  
14 our implant.

15 CHAIR MALMUD: Dr. Welsh.

16 MEMBER WELSH: Jim Welsh. So our purpose  
17 as the Advisory Committee on Medical Use of Isotopes  
18 is to provide you with carefully thought out advice  
19 on medical issues. And I can assure you that for  
20 prostate brachytherapy medical event definition has  
21 been an agonizingly large amount of time, thought,  
22 and effort devoted to this.

23 And that's part of the reason why I might  
24 have been giving Mr. Fuller a hard time. The  
25 question which we've all had in the back of our mind

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1 which is will NRC accept an activity-based definition  
2 such as the one from ASTRO which I personally like  
3 very much or will NRC come back and say no, we still  
4 insist on something that has dose.

5 We've been discussing this internally and  
6 making bets on what the Commission's decision might  
7 be.

8 (Laughter.)

9 But we thought it would be very  
10 reasonable to be prepared should we learn that our  
11 suspicion is correct when that dose-based definition  
12 is something that NRC would like to have in their  
13 definition and therefore this version has come out  
14 which I think is quite consistent with the ASTRO  
15 definition except it's got a little bit of subtle  
16 differences and includes specific parameters in terms  
17 of dose.

18 So our purpose has been to provide you  
19 with sound advice and I think that we have done our  
20 due diligence at this point in providing the two --  
21 what I personally view as very acceptable definitions  
22 for medical events for prostate brachytherapy and  
23 thus our efforts to speed things along and provide  
24 you with the advice you need to make the rule, I  
25 believe has been achieved.

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1 CHAIR MALMUD: Response? Mr. Fuller?  
2 Mr. Luehman, do you feel that the summary of this is  
3 clear or do you still feel there's some ambiguity in  
4 what we've presented?

5 MR. LUEHMAN: I don't think there's any  
6 ambiguity. I just would like to respond to Dr. Welsh  
7 a little bit.

8 I don't think that the NRC -- I think --  
9 I haven't been involved in this since the beginning,  
10 so I can't take ownership for -- I don't really feel  
11 like I have to own necessarily what the staff has  
12 done before. I'll say I'm not a medical physicist,  
13 not a doctor, but as I have gone back and looked at  
14 how we got where we are, we as the staff, and I think  
15 that probably your perception that we're unwilling to  
16 adopt an activity-based regulation is -- I don't  
17 think it's an unwillingness.

18 I think what the staff has tried to do is  
19 they've tried to balance all the parts that I talked  
20 about before and quite frankly, I think Mike and I  
21 have had conversations that they're probably not --  
22 we're probably going to have to fix more than just  
23 the definition in 30.45. We're probably going to  
24 have to look at are the definitions in the  
25 definitions section of part 35 consistent and the

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1 wording consistent with what's in the medical  
2 directive section and consistent with 30.45. Because  
3 I think that what the staff has probably tried to do  
4 and it may come across as an unwillingness is tried  
5 to come up with a definition that sort of satisfies  
6 all the gates. And you can say that it's overly  
7 cumbersome. I won't disagree with that. I think  
8 that quite frankly in order to make this clear and  
9 unambiguous going forward, we're probably going to  
10 have look a little bit more than 30.45.

11 We're going to have to make sure that the  
12 wording that we carefully looked at the wording  
13 that's in -- that carries throughout Part 35, when it  
14 comes to terms that carry forward to medical events.  
15 And that includes, quite frankly, the words in the  
16 Statements of Consideration for the rule. Because if  
17 you put those with what's talked about in the  
18 Statements of Consideration for medical events, when  
19 you take that plus what's in the definition section  
20 of Part 35, the words that are in the written  
21 directive section and the words that are in the  
22 medical event definition itself, my review, this is  
23 just Jim's review and people can disagree with me. I  
24 just don't think -- I just don't think that it all  
25 hangs together really easily, that it's really easy

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1 to understand what the intent was because I think  
2 that slightly different terminology is used in  
3 different places.

4 And so I don't think, Dr. Welsh, I don't  
5 think there's a resistance to it. I just think that  
6 we need to make it all work and I think that that's -  
7 - to reiterate, I think that's why we're here to  
8 listen. We're willing to go back to square one and  
9 make sure that we have a definition that I think as  
10 the Chairman said provides adequate -- that provides  
11 adequate safeguards against that case which I think  
12 that regular practitioners would say would be  
13 something that would be very surprising to them and  
14 way outside of normal medical practice. But that's  
15 kind of what we have to write -- unfortunately,  
16 sometimes, we have to write our regulations for.

17 I think that if you go back and look at  
18 the history of the particular events that got us to  
19 reevaluate the regulation, quite frankly, I think  
20 some of those procedures, we can argue about whether  
21 it was the 90 talked about or whether it was only 20,  
22 but it was still a fairly significant number out of a  
23 large  
24 -- out of a relatively small overall number of cases  
25 and you know, and even the 20 percent or 25 percent

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1 medical event, truly significant medical event  
2 population is way too much.

3 And so we're willing to go back and I  
4 don't think that you're going to find any  
5 unwillingness from the staff. We follow Commission  
6 direction really well and I think that our definition  
7 -- I mean our last direction from the Commission was  
8 a pretty resounding direction.

9 Don't you agree, Mike? What part of the  
10 no don't you understand? So I think that we're  
11 definitely open to an activity-based definition as  
12 long as like the Chairman said, we ensure that  
13 whatever definition we come up with does satisfy our  
14 need to ensure that the worst cases are captured  
15 within that definition.

16 CHAIR MALMUD: Dr. Guiberteau?

17 MEMBER GUIBERTEAU: I had another  
18 question, if you were going to comment on his --

19 MR. FULLER: I was just going to follow  
20 up and also to Dr. Welsh's question. I agree with  
21 Mr. Luehman. We have no -- at this point in time,  
22 there are no preconceived notions about what we will  
23 or will not entertain and -- but I do have a -- I  
24 know we're coming up on a break here in a few  
25 minutes. I have another -- as I was listening to the

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1 presentations, I have another couple of couples that  
2 maybe we could ponder.

3           Number one, currently we have a rule for  
4 manual brachytherapy. We do not have a rule for  
5 permanent implant brachytherapy and at one point in  
6 time that was the direction we got from the  
7 Commission, to develop a rule and activity-based rule  
8 for permanent brachytherapy therapy. But as I listen  
9 to these discussions, we are focused entirely on  
10 prostates.

11           So my question is and what I'd like to  
12 hear from the Committee and others and not only  
13 today, but in future workshops or in workshops we  
14 will have in the future, do we need in your opinion a  
15 rule for permanent implant brachytherapy or do we  
16 need a rule for prostate implant, permanent implant  
17 brachytherapies, specifically for prostates?

18           It's just a question and I'd love what  
19 folks have to say about that.

20           And then my second question is that  
21 requirements for adherence with industry standards is  
22 not without precedence. And so I'd like to know how  
23 people feel about instead of having a rule that is  
24 very, very specific about plus or minus this or that  
25 percentage or what have you, if you would maybe

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1 comment on adopting some standard or heard that there  
2 are standards and what the folks here think about  
3 having a requirement that says you must adopt some  
4 standard or we might identify that or have someone  
5 identify that for us.

6           Again, I'll be quiet now and listen. But  
7 I'm just interested to know the perspective.

8           CHAIR MALMUD: Dr. Thomadsen?

9           VICE CHAIR THOMADSEN: After sort of  
10 living with this question for -- since 2005 or  
11 whatever, six years, we've been addressing permanent  
12 prostate implants. I don't think we've -- we haven't  
13 really had a chance to turn our attention to other  
14 permanent implants. There aren't that many of them  
15 that most of us would have a lot of experience with.  
16 I happen to have had a bunch with other sites, but I  
17 don't think that we're in a position to say whether  
18 this would be a good rule, whatever rule we come up  
19 with for all permanent implants. I feel comfortable  
20 with saying what we've proposed is good for prostate.

21           To your other point, I don't think that  
22 adopting the professional standards would be  
23 particularly good because they're not like a medical  
24 event where you can say operating outside of the  
25 medical event definition is very bad. We need to

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1 look at that. Operating outside of all of the  
2 recommendations of the professional societies are not  
3 -- is not terrible in many cases and some of the  
4 recommendations are set fairly high to try to improve  
5 the quality of performance in the field. But it's  
6 not meant to be a bar below which is considered to be  
7 of danger, is considered to be of very high quality  
8 standards. And as such, that probably does not  
9 belong in the regulation.

10 CHAIR MALMUD: Same subject. Dr. Welsh?

11 MEMBER WELSH: Well, I'll just follow up  
12 with what Dr. Thomadsen said. Well, maybe I'll start  
13 by saying that the ACMUI as a whole and perhaps  
14 especially this Permanent Implant Brachytherapy  
15 Subcommittee has been prone to thinking in terms of  
16 catastrophism, always thinking what if. So in our  
17 propositions that have been outlined in our report,  
18 we always debated internally what if they don't like  
19 it? What alternatives can we come up with?

20 So as I've stated before, the ASTRO  
21 recommendation that you heard today is very similar  
22 to the previous two years of implant subcommittee  
23 iterations, those previous two iterations are very  
24 similar to the ASTRO report.

25 But as far as your two questions, this

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1 was and still is Permanent Implant Brachytherapy  
2 Subcommittee, but we have stated here at the ACMUI  
3 that prostate brachytherapy is so different from the  
4 other permanent implant brachytherapy procedures that  
5 we do feel that perhaps it should be as a separate  
6 category, so you could have either prostate versus  
7 non-prostate or permanent implant brachytherapy in  
8 which seeds are likely to be rearranged because of  
9 anatomy such as with brachymesh procedure or  
10 permanent implant brachytherapy in which seeds are  
11 unlikely to significantly rearrange such as prostate,  
12 perhaps breast. So that's an answer to one of your  
13 questions.

14 As far as the other question, without  
15 adopting standards, I appreciate what Dr. Thomadsen  
16 has said, but I might add to that by saying that it  
17 might not be unreasonable to adopt certain standards  
18 if they have been discussed with ACMUI and others and  
19 it appears that they would be reasonable to adopt.  
20 An example is what I talked about earlier, the  
21 American Brachytherapy Society and others have  
22 recommended post-implant dosimetry. I think it would  
23 be very reasonable for something of that level to be  
24 in the regulations. Perhaps aiming too high could  
25 get us into trouble. Something like insisting on

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1 post-implant dosimetry is very reasonable and if  
2 you're not doing it, that's a medical event and maybe  
3 you need to have that called to your attention. And  
4 if you continue to not do it, then maybe you should  
5 stop doing it altogether.

6 So I'm halfway on that point.

7 CHAIR MALMUD: Thank you. There was  
8 another comment on this?

9 MEMBER GILLEY: I just want to bring it  
10 to your attention that adopting statements by some of  
11 the Agreement States has its own set of difficulties.  
12 It's much easier for us to adopt regulations than it  
13 is reference to a standard.

14 CHAIR MALMUD: Thank you. Dr. Suleiman?

15 MR. SULEIMAN: On the issue of adopting  
16 reference standards, we've had some good and bad  
17 experience. I think the important thing is to take  
18 what's critically important in this other standard  
19 and maybe codify it into a regulation. But when you  
20 adopt another organization's standard that may have  
21 been designed for something completely different, you  
22 run into potential problems from a regulatory  
23 enforcement point of view. But I think the post-  
24 dosimetry, that would be a very important concept to  
25 adopt.

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1 CHAIR MALMUD: Dr. Guiberteau, did you  
2 wish to comment?

3 MEMBER GUIBERTEAU: Actually, Mr. Fuller  
4 asked my question, but I would like to hear from Dr.  
5 Suh on two issues, if he cares to comment. I don't  
6 want to put him on the spot. When you read 30.45 it  
7 pretty much for medical events, except for a few  
8 exceptions, applies to a broader area. And one,  
9 whether you believe that we need a more specific rule  
10 just for organ-specific rule for prostate  
11 brachytherapy. And two, if you could comment on Dr.  
12 Thomadsen's proposal?

13 MEMBER SUH: Sure, in reference to your  
14 first question, prostate brachytherapy, actually I  
15 would support Dr. Welsh's recommendation of the ASTRO  
16 statement where it's an activity-based definition  
17 that the authorized user confirms in writing that the  
18 seeds were placed in the intended organ; in this case  
19 it would be the prostate. And then taking minimum  
20 standards such as from the ABS, post-dosimetry is  
21 performed. So if you had those three parameters, I  
22 think it would encompass what I would like to see  
23 happen.

24 In terms of prostate brachytherapy,  
25 prostate brachytherapy is so much more common than

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1 the other permanent implants that we do with  
2 radiation oncology that I would favor having prostate  
3 brachytherapy be its own entity, rather than trying  
4 to combine it with other prostate implants overall.

5 Your second question? This is a  
6 modification and I think it is a good starting point  
7 if the NRC feels that the ASTRO recommendations are  
8 not acceptable. It's a starting point we could go  
9 with.

10 These are parameters that for someone who  
11 is doing prostate brachytherapy in terms of the D-90  
12 and what doses for bladder and rectum are received.

13 MEMBER GUIBERTEAU: But your first  
14 approach would be, your preferable approach would be  
15 the ASTRO approach?

16 MEMBER SUH: Yes.

17 CHAIR MALMUD: So if I may as Chair,  
18 summarize what the Committee's opinion is. The  
19 Committee feels that the ASTRO approach is the  
20 correct approach to take on behalf of patient welfare  
21 and in the sense of both protecting the patient from  
22 the radiation and protecting the patient from the  
23 anxiety which is provoked by defining a medical event  
24 as something which 10,000 practitioners and 12  
25 members of this Committee feel is not a medical

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1 event.

2 Secondly, that the post-implant dosimetry  
3 be a requirement and if it needs to be established by  
4 the NRC, we would support its establishment by the  
5 NRC in the absence of its requirement and of course,  
6 any other mechanism.

7 . And thirdly that prostate is a unique  
8 organ in this sense and should have a separate set of  
9 guidelines as proposed here.

10 Does that summarize what everyone feels?

11 MEMBER FISHER: Just a question. By  
12 post-implant dosimetry are you talking about activity  
13 placed or actual absorbed dose distributions?

14 CHAIR MALMUD: I have not defined that.

15 (Laughter.)

16 There needs to be an objective measure of  
17 some sort and I would leave that to the wisdom of the  
18 radiation oncologists and the radiation physicists to  
19 determine which measure they wish to employ. It is  
20 clear that in looking back and it's always easy to  
21 look back, the series of events, the unfortunate  
22 events that have occurred in Philadelphia would not  
23 have occurred had there been some measure employed.  
24 That's a deficiency which I think we recognize.

25 And beyond that, I don't think we made a

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1 statement. We did hear comments which said that  
2 these things need to be defined a little bit better  
3 in terms of the measurement and that's not going to  
4 occur at this meeting in this session. But I think  
5 that the principles that the Committee feels are  
6 number one, to be redundant, supportive of the ASTRO  
7 recommendations; number two, requiring a means of  
8 post-implant dosimetry. It seems the current  
9 technology would require either a CT or an MRI to do  
10 that optimally. And the third issue is that prostate  
11 requires a separate set of rules.

12 I'll accept as a motion from Dr. Welsh --

13 (Laughter.)

14 -- if someone cares to second his motion.

15 MEMBER MATTMULLER: Second.

16 CHAIR MALMUD: And it is seconded. Any  
17 discussion, any further discussion of the motion?

18 MEMBER WELSH: Dr. Malmud?

19 CHAIR MALMUD: Dr. Welsh, this is your  
20 motion.

21 MEMBER WELSH: The third component of my  
22 motion, prostate versus non-prostate --

23 CHAIR MALMUD: Yes.

24 MEMBER WELSH: I again reiterate that  
25 there was some discussion within the Subcommittee

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1 about whether instead of prostate versus non-  
2 prostate, it would perhaps be better to have implants  
3 that seek rearrangement can occur versus implants in  
4 which seed rearrangement typically doesn't occur.

5 Having said that, I personally would  
6 favor prostate versus non-prostate, but I know that  
7 we had this internal discussion previously and --

8 CHAIR MALMUD: We recognize that there  
9 will be discussions in the future regarding  
10 brachytherapy and other organs and at that time it  
11 can be decided whether or not the methodology should  
12 be standardized across the organs if it's felt to be  
13 appropriate then or not.

14 But I think at this point, having  
15 struggled with this issue for so long and the issue  
16 having actually become a matter of public interest in  
17 the course of these years of discussion because of  
18 what happened in my native city, but not my  
19 institution --

20 (Laughter.)

21 The -- I think we should try and capture  
22 success in this area and move on to the next one. So  
23 the motion, which has been seconded, is there any  
24 further discussion of this motion? If not, would you  
25 please all in favor say aye.

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1 (Chorus of ayes.)

2 Any opposed? Any abstentions?

3 (No response.)

4 It carries unanimously and I would like  
5 to on behalf of the Committee, thank Dr. Song and  
6 ASTRO for their very thoughtful and concise and  
7 directive letter which we will hopefully submit to  
8 the NRC Commissioners and their staff with their  
9 review and consideration. Thank you.

10 Mr. Fuller? I turn it back to you.

11 MR. FULLER: Well, I am looking at the  
12 agenda and it says we're due for a break about now  
13 and then we come back from 3:30 to 5 to continue  
14 talking about permanent implant brachytherapy, but my  
15 question would be at 3:30, what do we really have  
16 left to talk about?

17 CHAIR MALMUD: At 3:30, I was taught by -  
18 - when I was the Vice President of the University and  
19 I would make a point at the University Cabinet and I  
20 had succeeded, I was told that anything I said from  
21 that point onward would simply take back that which I  
22 had succeeded in achieving.

23 (Laughter.)

24 And therefore silence was the rule. I  
25 would suggest that because this is a public meeting

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1 and the public is expecting us to adhere to the  
2 program for tomorrow, that we take advantage of the  
3 opportunity to dismiss ourselves early today, rather  
4 than move the agenda ahead, if that's acceptable  
5 under the guidelines established by NRC, unless there  
6 is something more to discuss with regard to  
7 brachytherapy which is the subject on the table other  
8 than the prostate.

9 MEMBER LANGHORST: Sue Langhorst. Not  
10 that I'm suggesting we should go longer today, but we  
11 might avail ourselves of -- if there were any points  
12 we wanted to talk about that isn't one of these four  
13 main focus points.

14 CHAIR MALMUD: Is that all right under  
15 the guidelines?

16 MR. LUEHMAN: Yes.

17 CHAIR MALMUD: Then we will accept your  
18 recommendation wholeheartedly.

19 MEMBER LANGHORST: So we might --

20 CHAIR MALMUD: I see Dr. Howe has her  
21 hand up as well.

22 DR. HOWE: I'm wondering if the Chair  
23 would entertain maybe a discussion on what it means  
24 when a physician puts a dose because we hear that  
25 there especially in prostate brachytherapy that there

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1 are two doses. One is 140, one is 160. But we're  
2 finding out when we look at how people are doing  
3 things, 140 means many different things. In some  
4 places you calculate a plan dose base for 140 as a  
5 D-100 when you start out. And then you evaluate.

6 In other places, 140 is a minimum line  
7 and the D-100 that you end up with is really much  
8 higher than that. Even the D-90 which you end up with  
9 is much higher. So it's kind of -- for us, it's very  
10 complicated to understand that not everybody has  
11 articulated things the same way. So could there be a  
12 discussion?

13 CHAIR MALMUD: Absolutely. We'll use the  
14 afternoon session as an opportunity to discuss both  
15 the issues raised by Dr. Langhorst and by Dr. Howe  
16 and we'll reconvene in half an hour at 3:30. Excuse  
17 me.

18 MEMBER GUIBERTEAU: I have another  
19 suggestion and that is if we do have the time and if  
20 Sophie agrees, would it be possible for us to discuss  
21 the dates of the proposed next meeting today rather  
22 than tomorrow as we frequently decide these dates as  
23 people are packing up and leaving and everybody has  
24 seemed to express the fact that they're very busy and

25 CHAIR MALMUD: That's certainly okay with

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1 the Chair.

2 Sophie, is that okay? Can we handle that  
3 this afternoon?

4 MS. HOLIDAY: I don't see a problem with  
5 that. Actually, it will shorten the meeting for  
6 tomorrow. If that's in favor for everybody on the  
7 Committee, we can certainly do that.

8 CHAIR MALMUD: We'd like to do that.

9 MS. HOLIDAY: Certainly.

10 CHAIR MALMUD: So we have three items on  
11 the agenda after 3:30 and I look forward to seeing  
12 you at 3:30.

13 (Off the record.)

14 CHAIR MALMUD: It's now 3:37 and we are  
15 ready to resume our afternoon session. And the items  
16 on the agenda, if taken in order, so we can start  
17 with Dr. Howe's agenda item.

18 Dr. Howe would you care to just throw an  
19 item out for us to deal with --

20 DR. HOWE: The item is --

21 CHAIR MALMUD: -- other than the Japanese  
22 nuclear crisis at the moment.

23 DR. HOWE: The item is when we are  
24 hearing from our licensees, there are generally two  
25 numbers that are thrown out for prostate

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1 brachytherapy, 145 and 160. And it is --

2 CHAIR MALMUD: I can't hear you. Speak  
3 right into it.

4 DR. HOWE: Okay. There are normally two  
5 numbers, 145 and 160. And so we see those numbers  
6 and we think we understand what they mean. Then we  
7 go out and we talk to licensees that we find out not  
8 everybody means the same thing. They're on different  
9 sheets of music. They're not articulating what they  
10 mean by 145 or 160.

11 In one case, for 145, you set that as a  
12 D-100 in your treatment planning because that's the  
13 minimum dose you want to give. In another case, it's  
14 the minimum dose they wanted to give period. And so  
15 they set something else and they deliver maybe an  
16 average of 160, 180. And they draw a line at 140 at  
17 the bottom. And they think they're giving 145  
18 because it means something different. They're not on  
19 the same sheet of music.

20 And so I'd just like to have you guys  
21 address that and how we can get to the point where we  
22 understand and everybody else can understand.

23 CHAIR MALMUD: Thank you for raising the  
24 question. And we have volunteers to tackle it. Mr.  
25 Welsh raised his hand first.

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1                   MEMBER WELSH: So I'm going to ask my  
2 medical physicists to keep me honest here but if I  
3 recall the history behind some of this, the dose used  
4 to be 160 gray. And there was a revision of the  
5 iodine-125 dose rate constant, which was incorporated  
6 into TG-43, leading to a recalculation of the dose as  
7 144, 145 gray, which because the dose that typically  
8 has been prescribed since then.

9                   I don't believe that people are ignorant  
10 of this fact. So I don't think that we've seen 160  
11 as the dose because of holdovers who have not read  
12 the TG-43 update. But what I do think is at the core  
13 of all of this is that the definition of target  
14 volume is not as clear as it could be.

15                   We have emphasized in our committee  
16 meetings and subcommittee discussions that it would  
17 be very reasonable to standardize the terminology  
18 such that the currently used NRC language of I think  
19 it's --

20                   PARTICIPANT: Treatment site.

21                   MEMBER WELSH: -- treatment site was more  
22 appropriately defined as either GTV, CTV, or PTV,  
23 gross tumor volume, clinical target volume, or  
24 planning target volume respectively. And this  
25 perhaps could clarify some of your concerns in your

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1 experiments.

2 DR. HOWE: So if you see a written  
3 directive that says 145 gray, what does that mean to  
4 you?

5 MEMBER WELSH: I would specifically then  
6 ask is that 145 to the GTV? Or 145 to the CTV or the  
7 PTV? And when that question is answered, I would  
8 have a much clearer understanding of exactly what it  
9 is supposed to be. But without that, if it's just to  
10 the treatment site, I could be dealing with any of  
11 them.

12 DR. HOWE: I think they use the treatment  
13 site and then the physician defines what it is based  
14 on ultrasound and gives the plan over to the medical  
15 physicist. But what we found is in some of our  
16 cases, you look at the paperwork. And if you look at  
17 the D values on the treatment plan, D-100 is 145.  
18 That was what they were trying to go for.

19 In other cases, they indicate they start  
20 there but then they deviate from that. And then you  
21 look at what they deliver and they are very  
22 systematic and they delivered like almost routinely  
23 180 gray. But when you ask them what they are doing  
24 in the written directive, it's 145.

25 So it seems to me that they are on two

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1 different sheets of music between the two groups.

2 Dr. Thomadsen?

3 VICE CHAIR THOMADSEN: Well, I guess  
4 there's a lot more than two groups --

5 DR. HOWE: Yes.

6 VICE CHAIR THOMADSEN: -- in that. And I  
7 think that's part of the practice of medicine. And  
8 what we've been talking about for medical events has  
9 been -- it has become quite clear -- and this is what  
10 Dr. Welsh has just been saying -- that we have to be  
11 a lot more precise in what we're calling a medical  
12 event.

13 And it has to be somewhat decoupled from  
14 how a given practitioner wishes to prescribe the dose  
15 because prescribing it to the minimum, prescribing it  
16 to the D-100, prescribing it to the D-90, to the D-  
17 80, all these are quite in acceptance amongst the  
18 medical community. And you wouldn't want to change  
19 that at the moment.

20 DR. HOWE: Well, as far as the NRC is  
21 concerned, as long as the physician has articulated  
22 what they mean, that's what it means at that  
23 practice. So we're not really talking about  
24 comparing this physician to some other practice  
25 because it is internal. That's how we stay out of

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1 the practice of medicine. It is the physician,  
2 internal physician.

3 VICE CHAIR THOMADSEN: Yes.

4 DR. HOWE: But how do we know which sheet  
5 of music they're reading off of? Is that just always  
6 going to be a problem?

7 VICE CHAIR THOMADSEN: I guess that's  
8 always going to be a problem.

9 MR. FULLER: Mike Fuller -- may I ask a  
10 question just for my own clarification? So back to  
11 the ASTRO-recommended definitions and approach, if  
12 that is something that might perhaps ultimately be  
13 adopted, then all of these discussions and the  
14 inconsistency or the differences in the medical  
15 practice around the dose to whatever target, would be  
16 things that we really, from a regulatory perspective,  
17 would not be involved with. Is that a reasonable  
18 assumption?

19 VICE CHAIR THOMADSEN: Well, if I can  
20 answer, that's a really good question because part of  
21 the question would become then if the evaluation is  
22 only that you put the right -- the correct number --  
23 the correct activity or source strength in the  
24 target, that would be correct as long as you define  
25 the target correctly. As it is right now, treatment

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1 site is not adequate to be able to evaluate that.

2 MR. FULLER: If we had --

3 VICE CHAIR THOMADSEN: Like the dose --  
4 using the ASTRO recommendations, all of the question  
5 that Dr. Howe was just asking and what you were  
6 saying about the dose becomes completely irrelevant,  
7 yes.

8 MR. FULLER: And if we had a rule where  
9 we maintained a very general term for treatment site  
10 but somehow had a requirement that the licensee had  
11 to define for themselves what the appropriate target  
12 was or the target volume and used whatever  
13 appropriate, would that also work in the construct of  
14 what ASTRO has recommended?

15 VICE CHAIR THOMADSEN: Sure.

16 CHAIR MALMUD: Dr. Welsh?

17 MEMBER WELSH: If I might comment, in the  
18 ASTRO proposal, the authorized user is to state  
19 explicitly the distribution of sources within the  
20 treatment site was intended per pre-implant written  
21 directive, at this point, it might be a reasonable  
22 time to also say that here is where it needs to be  
23 spelled out clearly whether or not your treatment  
24 site, which, in the written directive, it is the  
25 prescription, is talking about 145 gray to GTV, have

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1 that spelled out, CTV, have that spelled out, or a  
2 PTV, if that is spelled out. Or if it is 160 gray to  
3 one of those.

4 And I think that's quite simple and easy  
5 and reasonable and should solve the dilemma that you  
6 are facing now.

7 CHAIR MALMUD: So, Dr. Welsh, are you  
8 suggesting that the treatment that the -- that the  
9 order for the treatment should specifically state one  
10 of those three options?

11 MEMBER WELSH: Yes, I personally think  
12 that it is very reasonable to state in your written  
13 directive whether you are prescribing x gray to a  
14 GTV, CTV, or PTV. And it should be easy to  
15 incorporate that into a written directive. And if  
16 necessary, to define how you have defined your CTV,  
17 PTV.

18 CHAIR MALMUD: Dr. Suh, do you agree?

19 MEMBER SUH: Yes, I think it would be  
20 wise to have the dose and what your prescription  
21 blind is going to be.

22 CHAIR MALMUD: And Dr. Thomadsen, you  
23 agree?

24 VICE CHAIR THOMADSEN: No, I don't think  
25 it's that simple. I mean it would be very nice to

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1 have that but actually those seem completely  
2 irrelevant whatever dose you are defining in those  
3 cases because that doesn't have anything to do with  
4 defining a medical event. So the written directive  
5 doesn't need the dose specified anywhere in that.

6 MEMBER WELSH: If I might respond, I  
7 simply responded to Dr. Howe's question or concern in  
8 proposing a possible solution.

9 VICE CHAIR THOMADSEN: It seems like it  
10 is a possible solution to a problem that doesn't  
11 exist any more. If this approach were taken, you  
12 wouldn't have that.

13 CHAIR MALMUD: You wouldn't have the need  
14 for it?

15 VICE CHAIR THOMADSEN: You wouldn't have  
16 the need for that as far as the NRC is concerned.

17 CHAIR MALMUD: Well, what would the NRC's  
18 concern be if we -- if the NRC accepted the ASTRO  
19 proposal, what would the NRC's concern be in that  
20 case with regard to excessive or inadequate radiation  
21 to the target?

22 DR. HOWE: Are you directing it to me?

23 CHAIR MALMUD: No, to you, I'm sorry.

24 VICE CHAIR THOMADSEN: Oh, I thought you  
25 were addressing it to the NRC.

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1 MEMBER MATTMULLER: No, I'm sorry, Mr.  
2 Thomadsen.

3 VICE CHAIR THOMADSEN: Can you ask me the  
4 question again? I thought it was addressed to them  
5 so I could sleep during that.

6 CHAIR MALMUD: Dr. Thomadsen?

7 VICE CHAIR THOMADSEN: Yes, okay.

8 CHAIR MALMUD: What do you think the  
9 NRC's concern would be or how could the NRC express  
10 its concern, I'll rephrase my question, how could the  
11 NRC express its concern regarding the appropriateness  
12 of the dose delivery under the ASTRO proposal?

13 VICE CHAIR THOMADSEN: They would not be  
14 assessing the dose delivered but that the implanted  
15 activity or source strength would be delivered. And,  
16 as I -- is that not an allowed way to write a written  
17 directive for an implant now is in source strength?

18 CHAIR MALMUD: Yes.

19 VICE CHAIR THOMADSEN: So I mean that --  
20 you're just going back to the days before dose and  
21 just specifying how much source strength you would be  
22 implanting and they would be evaluating based on  
23 source strength.

24 CHAIR MALMUD: So let's say that the  
25 source strength was correct but it was in the wrong

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1 place, now how would that be evaluated?

2 VICE CHAIR THOMADSEN: The radiation  
3 oncologist would specify that they put the source  
4 strength in the right location at the end of the  
5 implant. That's what it says.

6 CHAIR MALMUD: What if it was supposed to  
7 go into the prostate and it went into the bladder?

8 VICE CHAIR THOMADSEN: That isn't  
9 addressed in the ASTRO guideline. So it would be in  
10 the right location. You have to have no more than 20  
11 percent of the seeds not in the treatment site.

12 CHAIR MALMUD: And what if 40 percent of  
13 the seeds went into the bladder instead of the  
14 prostate?

15 VICE CHAIR THOMADSEN: That would be a  
16 medical event.

17 CHAIR MALMUD: That's a medical event.  
18 Okay. So there's still -- we have not negated the  
19 issue of medical event.

20 VICE CHAIR THOMADSEN: No.

21 CHAIR MALMUD: We want to maintain a  
22 medical event for self-discipline if for no other  
23 reason.

24 VICE CHAIR THOMADSEN: Yes.

25 CHAIR MALMUD: Dr. -- I just wanted the

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1 record to show that. Dr. Welsh?

2 MEMBER WELSH: Dr. Thomadsen brings up an  
3 important point that the ASTRO-proposed definition  
4 does introduce some subjectivity in that the  
5 authorized user, the radiation oncologist, must write  
6 in the written directive that he or she put those  
7 seeds in as intended per the written directive.

8 And if the seeds wound up in the bladder  
9 or the rectum or elsewhere, some might be skeptical  
10 about that authorized user's ability to make the  
11 clear statement that he or should put the seeds in  
12 the right location because it would raise the  
13 possibility that he or she is not identifying the  
14 organ as clearly as would be hoped for, for whatever  
15 reason -- lack of skill, poor imaging quality,  
16 whatever.

17 CHAIR MALMUD: Dr. Welsh, when you say  
18 some, is there a quantification of some having been  
19 misplaced or whatever in another organ? We know that  
20 sometimes a few will migrate. And that sometimes,  
21 from what I've heard, sometimes in placing them in  
22 the prostate since there is an attempt to get the  
23 border of the prostrate as well, if there is a  
24 concern about tumor being near the edge of the  
25 prostate, that some may get into the adjacent tissue,

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1 whether it is rectum or bladder, is there a number  
2 beyond which you would consider it bad practice?

3 MEMBER WELSH: Well, we are proposing  
4 that if 20 percent are beyond what was intended, that  
5 would constitute a medical event.

6 CHAIR MALMUD: So we're still going to  
7 use the 20 figure? Is that correct?

8 MEMBER WELSH: Yes.

9 CHAIR MALMUD: Great. Did Dr. Thomadsen  
10 and Dr. Welsh answer your question, Dr. Howe?

11 DR. HOWE: I'm not sure because I really  
12 do think there's some folks out there that use the  
13 numbers in a totally different manner. Their  
14 understanding of what they're doing doesn't match up  
15 with maybe what other folks' understanding of what  
16 they are doing would be.

17 CHAIR MALMUD: Would it be --

18 DR. HOWE: And I don't think it is a  
19 volume issue. I don't think it is a question of if  
20 they use one of the three volume terminologies then  
21 you'd understand what they're doing.

22 In other words, I see a written directive  
23 that says 145. I see a D-100 that is for 145. And  
24 then when the actual seeds are implanted and you see  
25 the results, you see that they very consistently give

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1 a D-90 of 180 gray.

2 Most of the times when you see people  
3 aiming at a D-100 in the planning stage of 140,  
4 they're going to come out under, maybe a few up. But  
5 this is consistently above that because that's what  
6 delivering 145 means to them. I don't think they're  
7 on the same sheet of music.

8 CHAIR MALMUD: Dr. Howe, have you ever  
9 asked them why they do that? Is it because they feel  
10 that 145 is a lower limit and they're going to give  
11 more? But they're using the number 145 as a lower  
12 limit?

13 DR. HOWE: That's pretty much it.  
14 They're using it as a lower limit. But when you're  
15 talking to them, you don't understand that they're  
16 talking about something totally different than what  
17 you guys at the ACMUI are talking about with 145.  
18 They really are on a different sheet of music.

19 And you don't know that right away. And  
20 I don't know how prevalent that it. That was -- that  
21 was where my question is coming from.

22 CHAIR MALMUD: Is that an issue that  
23 anyone here has come across among our radiation  
24 oncologists and physicists?

25 MEMBER SUH: No.

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1                   VICE CHAIR THOMADSEN: The closest I can  
2 come as an analogy is ICRU-64 recommends reporting  
3 external beam doses at the isocenter whereas lots of  
4 practitioners actually specify the dose at the  
5 periphery of whatever their target is. And a lot of  
6 them -- it's not the absolute periphery but some  
7 fraction like D-90 of the target.

8                   Each of these practices would be giving  
9 quite different specifications for a given dose to a  
10 given target. And unless you know which one it is,  
11 you don't have a clue as to what they've actually  
12 done in the patient.

13                   And it sounds sort of like the practices  
14 you are talking about have some inherent idea as to  
15 where they're giving the dose or how they're giving  
16 the dose that just is not getting translated to the  
17 NRC. And without going into more detail with them,  
18 it would be very hard to tell.

19                   DR. HOWE: Thank you.

20                   CHAIR MALMUD: Dr. Suleiman?

21                   MEMBER SULEIMAN: Yes, I mean my  
22 observation of different professions over time is I  
23 mean as long as these authorized users are qualified,  
24 we've already established some baseline standards for  
25 the people who are using this, as long as they're

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1 doing this dosimetry, if I might that word, in a  
2 standard way and they're doing it before and after,  
3 and they're seeing what the difference is and they're  
4 -- what difference does it make?

5 We've already said these are qualified  
6 people, you know? And I suspect that there are --  
7 the people at this table and the people out in the  
8 field, and the people who never go to any of these  
9 meetings, everybody may do it differently. And as  
10 long as they meet the basic criteria, does it make  
11 any difference?

12 CHAIR MALMUD: Dr. Welsh, were you going  
13 to say something?

14 MEMBER WELSH: I do have a comment. And  
15 that is if we look at the alternative that was  
16 proposed today, eloquently stated by Dr. Thomadsen,  
17 you'll note that the proposed definition of a medical  
18 event has a lower limit, D-90 less than 70, but not  
19 an upper limit, which I think is quite relevant to  
20 what you are saying. So I want to ask Dr. Thomadsen  
21 to comment on that in relevance to what Dr. Howe has  
22 pointed out.

23 And number two, ask Dr. Howe if this  
24 proposed alternative definition would still face the  
25 same challenges that we brought up in the first place

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1 here.

2 CHAIR MALMUD: Dr. Thomadsen?

3 VICE CHAIR THOMADSEN: I think it is not  
4 unusual in practice to, as one is implanting the  
5 prostate, to make sure that you get enough seeds  
6 everywhere that you cover what you want, which may  
7 result in a D-90 well over the target dose that  
8 you've originally prescribed in order to convince  
9 yourself that you've actually covered everywhere that  
10 you want adequately. And there's no evidence that  
11 that's a problem. And there's been no reported  
12 toxicity due to excessive target.

13 MEMBER WELSH: I would agree. I think  
14 that's standard -- common clinical practice. So I  
15 would then ask Dr. Howe if the alternative definition  
16 would face the same difficulties or would the  
17 alternative definition make your problem go away?

18 DR. HOWE: I think the alternative  
19 definition, as I look at it, has an underdose item  
20 number one. And that's the target.

21 And has an overdose in item number two  
22 because you're saying -- you're essentially saying  
23 that overdose to the cancer cells is acceptable,  
24 overdose to the urethra and the bladder and the  
25 rectum are not acceptable. And so that's how you're

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1 defining what you would consider to be an overdose in  
2 this case. And that would probably take care of  
3 things.

4 I mean it's just we hear a number and we  
5 all think we understand what that number means. We  
6 think we understand from our conversations with the  
7 ACMUI what that particular site is going to be doing.  
8 And then we find out they're doing something  
9 different. The number doesn't mean the same thing to  
10 them that it does to everybody else.

11 But this certainly would take care of the  
12 underdose and the overdose. And I think people do --  
13 are on pretty much the same sheet of music for  
14 underdose D-90.

15 CHAIR MALMUD: Thank you. If there's no  
16 further discussion of that issue -- oh, someone --  
17 Jim, were you going to say something?

18 MR. LUEHMAN: Well, I was just going to  
19 say that, you know, when we actually did a -- you  
20 know went out and observed, you know, went and talked  
21 to people at the hospital to get to Dr. Howe's issue,  
22 I think that what we came to understand is that the  
23 typical practice at least there was that the doctor  
24 would say that he was looking for 145 and he was,  
25 without stating it, was really saying that that was

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1 his D-100 so that he'd turn it over to the physicist.

2 The physicist, in order to get that D-100  
3 of 145, would prescribe 165 -- you know, D-90 at 165,  
4 170, something like that. Right, Mike? And then by  
5 doing that, they would ensure that the whole prostate  
6 or the whole target volume got at least 145.

7 And I think really what it came down to  
8 was that if you go back and look at the paperwork,  
9 you see the two numbers. The numbers in all cases  
10 aren't necessarily accurately described as what they  
11 were. There were just two numbers there. One was  
12 145.

13 Then you go to the treatment plan. The  
14 treatment plan says 160 or 165. And you kind of  
15 scratch your head. And if you are the two people who  
16 are doing that and they've done it for a long time,  
17 they understood what those two numbers were. But  
18 just looking at the paperwork after the fact, it  
19 wasn't apparent.

20 It appeared that the doctor wanted 145.  
21 The physicist did something else. But, in fact, one  
22 of -- they're describing two different parameters.

23 CHAIR MALMUD: Are you aware of any  
24 untoward clinical effects from these --

25 MR. LUEHMAN: No, because again I think

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1 that what those physicians told us is very consistent  
2 with what we've heard here, which is there's  
3 significant concern because -- for the treatment of  
4 the patient that you get, that you exceed the  
5 minimum, that you get above the minimum. But getting  
6 too much above, you know, I mean getting it too high  
7 was, again, not a concern.

8 I mean obviously at some really large  
9 threshold, it would be a concern. But, you know,  
10 missing it by, you know, 20 percent or whatever was  
11 not really a concern. The real concern was did you  
12 get enough to make sure that you treated the tumor or  
13 the cancer cells or whatever. So I think what we saw  
14 at the hospitals was very consistent with what has  
15 been described here.

16 CHAIR MALMUD: Thank you.

17 If we may, we'll move on to the next item  
18 on the agenda.

19 MEMBER MATTMULLER: Oh, I'm sorry.

20 CHAIR MALMUD: Excuse me, I'm sorry.

21 MEMBER MATTMULLER: If I could make one  
22 more comment about medical events, I think -- and I  
23 came across this statement in, as I mentioned before,  
24 in SECY-10-0062, where the NRC describes what a  
25 medical event really is, I think in regards to the

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1 rulemaking that is slowly getting underway, that it  
2 would be important to add some of this information  
3 into the regulations as to how a medical event is  
4 defined because I think anyone who looks at it right  
5 now, if they see medical event and it meets this  
6 criteria, it is something bad. And that's not  
7 necessarily the case.

8 And I think the additional explanation as  
9 to what a medical event really is that is provided in  
10 the SECY is important. That ought to be included in,  
11 say, 35.2, that medical event threshold criteria is  
12 designed to detect events that have the potential to  
13 harm the involved patients. The goal of a medical  
14 event is to also detect possible problems before they  
15 arise to that level. They are then defined by the  
16 subsequent section.

17 And I think that is an important  
18 distinction so everyone doesn't say oh, it's a  
19 medical event. It's bad. Harm has happened. Just  
20 the potential for harm. I think that's important to  
21 include in the definition.

22 CHAIR MALMUD: Thank you.

23 I think the next item on the agenda is  
24 yours, Sue.

25 MEMBER LANGHORST: And I did not have any

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1 to bring up. But I thought that might be --

2 CHAIR MALMUD: All right.

3 MEMBER LANGHORST: -- if there was anyone  
4 who wanted to bring up any of the other --

5 CHAIR MALMUD: That was the attachment to  
6 agenda item 5? Or 6 we're on?

7 MEMBER LANGHORST: I forget the number.

8 MS. HOLIDAY: I think it is item number  
9 six.

10 CHAIR MALMUD: Six? Thank you.

11 MEMBER LANGHORST: Yes. This is Sue  
12 Langhorst. I think many of these have been discussed  
13 in previous ACMUI meetings that an individual wanting  
14 to find more about some of this could mine that  
15 information from there. But it might be worth asking  
16 at this point when we have some extra time.

17 CHAIR MALMUD: Are there any questions  
18 regarding these items? There are 26 of the first  
19 side. And on the second side, I think there are just  
20 two more. Twenty-seven, 28.

21 Oh, yes, Dr. Van Decker?

22 MEMBER VAN DECKER: That way I don't have  
23 to reintroduce myself. I like that.

24 I guess my question is for the workshops  
25 where the rest of these are not necessarily a focus

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1 and I can understand why. They are fairly discrete  
2 issues that have had fairly discrete ACMUI input to  
3 them. At those portions where someone might want to  
4 comment on them, I guess this sheet will be more  
5 telegraphic. You know the listing about these is  
6 here. And the solution, at least that we've talked  
7 about, is not quite clear.

8 So I guess, you know, on a communication  
9 basis, that those points some time will be useful to  
10 have, you know, a more expanded situation of this so  
11 that people understand where we're going.

12 MR. LUEHMAN: Yes, no, I think that's a  
13 good comment. I think that, you know, to the extent  
14 that, you know, we can connect that with the -- you  
15 know, where that was discussed or --

16 MEMBER LANGHORST: That would be great.

17 MR. LUEHMAN: -- the ACMUI's endorsement  
18 or comments on that particular session because as Dr.  
19 Langhorst said, the, you know, most -- many of these  
20 -- well, all of these have gone through the pipeline  
21 and are ready to go to rulemaking in some form or  
22 another already. And so we do have input on those  
23 somewhere.

24 And so, yes, if we do that, especially if  
25 we put that out on some kind of -- I don't know, I

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1 think we're going to have like a website or some kind  
2 of documents that are accessible so people can read  
3 beforehand and say do I really have any comments on  
4 this issue? Or is this -- or has this, you know,  
5 part of the waterfront already been covered?

6 CHAIR MALMUD: Okay. That's a good  
7 suggestion. I saw another hand; I believe, earlier,  
8 did I not? Yes, sir? Steve?

9 MEMBER MATTMULLER: I know you would all  
10 be disappointed if I didn't talk about moly-99 at  
11 least once during this committee meeting. And this  
12 is in regards to the frequency of testing, which I'm  
13 fine with.

14 The only suggestion I would have for the  
15 staff in regards to this is to write this such that  
16 you state the frequency but then the actual limit is  
17 referenced to current USP standards. And rather than  
18 putting -- or keeping the current limit as it is  
19 defined now, within the regulation, and in case the  
20 limit changes in the future, as, for example, the  
21 European pharmacopeia limit is higher. And there is  
22 a harmonization process going on between the U.S. and  
23 the European pharmacopeia to where the new monograph  
24 standard for the limit might be higher.

25 And if that were to happen, then it would

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1 take another rulemaking process for that to be  
2 officially recognized versus if the new reg gives the  
3 new frequency and says see USP, then we'll be covered  
4 for anything that happens in the future. And it  
5 wouldn't require another rulemaking.

6 CHAIR MALMUD: Dr. Howe, would you care  
7 to comment? Oh, excuse me? What would you like to  
8 comment?

9 MS. BHALLA: Yes, could you just go and  
10 act again? There are two things. One is how often  
11 you do the test. That is the frequency. That's what  
12 we plan to amend.

13 CHAIR MALMUD: Right.

14 MS. BHALLA: But then there is another  
15 one that you mentioned, the limit itself. And that  
16 we don't plan to do it then this time unless it's  
17 all, you know, ready being done for between the U.S.  
18 and Europe. So I just want to make that  
19 clarification that right now we were not looking at  
20 the limit, the exact, you know, moly or molybdenum  
21 per microcurie of technetium. That was not being  
22 planned to amend. Only like frequency, how often we  
23 are testing that.

24 MEMBER MATTMULLER: Correct. That's my  
25 understanding, too. And that's why I'm suggesting

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1 now that not to put in the .15 microcurie per  
2 millicurie limit to put into the limit of the USP  
3 monograph.

4 DR. HOWE: How soon do you think that  
5 would happen?

6 MEMBER MATTMULLER: Well, the USP  
7 monograph process is similar to the NRC's process.  
8 Maybe a little bit quicker. But it can take several  
9 years. But I would just hate to see the Part 35  
10 rulemaking to be approved and then the USP changes.  
11 And that could take another ten years for it to be  
12 officially employed.

13 CHAIR MALMUD: Sue?

14 MEMBER LANGHORST: Can I ask what the USP  
15 limit is right now?

16 MEMBER MATTMULLER: It is .15  
17 microcuries.

18 MEMBER LANGHORST: So it is exactly what  
19 the NRC has now.

20 MEMBER MATTMULLER: What the NRC has,  
21 right.

22 MEMBER LANGHORST: And if the NRC puts in  
23 the rules to be at the USP limit, when the USP limit  
24 changes, then it just automatically changes for the  
25 regulations --

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1 MEMBER MATTMULLER: Right.

2 MEMBER LANGHORST: -- because it is  
3 linked to that requirement.

4 MS. BHALLA: Yes, you know, we could put  
5 it out as one of the questions when we, you know --  
6 because when we are regulating, it's for all, you  
7 know, all licensees from a very small say diagnostic  
8 facility to all the facilities which they may have  
9 their own pharmacists. So for a small diagnostic  
10 facility to go and find out what the US -- whatever  
11 you mentioned.

12 So I hate to go there and pull out the,  
13 you know, the limit. It's easier for a small  
14 licensee to just -- here is the number. And this is  
15 my limit. So that's the flip side.

16 MR. FULLER: If I might?

17 CHAIR MALMUD: Please, Mike?

18 MR. FULLER: As we stated earlier today,  
19 the purpose for our meeting is to listen today. And  
20 I think we've heard you. And I don't want -- you  
21 know, one of the problems is if we ask -- if we keep  
22 asking NRC staff what they think, then they're going  
23 to tell you what they think.

24 But really we're here to listen to you.  
25 So we did hear what you said. And we will take that

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1 into consideration. And then, again, I appreciate  
2 that perspective and that comment. And we will  
3 certainly take that and consider it. But I don't  
4 want to have an expectation that we'll tell you what  
5 we're going to do because that's not the purpose of  
6 our meeting today.

7 CHAIR MALMUD: Dr. Suleiman?

8 MEMBER SULEIMAN: Okay, I have, again,  
9 from my own experience at FDA, introducing standards  
10 by reference has some real confusion associated with  
11 it. So the pharmacopeia may be changing it. But,  
12 you know, you could be referencing an organization  
13 that could be going in the other direction.

14 And so -- and then you may, if you look  
15 at the reg, you don't get an answer. And then you  
16 have to start searching for it for something else.

17 So my experience with writing regs is you  
18 can consider the other source, you should take that  
19 number and codify it within your regulations. But by  
20 starting to reference other documents, you start down  
21 a very slippery slope where you start -- you may --  
22 where do you stop? So each reg should stand on its  
23 own.

24 I'm not arguing for or against that  
25 number. But I think using -- referencing other

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1 standards, you've got to be careful how you do it.

2 CHAIR MALMUD: Does that answer your  
3 concern?

4 MEMBER MATTMULLER: I understand this  
5 concern but it is also my understanding that the USP  
6 limit has been always been adopted by the NRC. And -  
7 - because it used to be .15 per millicurie and then I  
8 want to say no more than 10 microcuries or nanocuries  
9 -- there was an upper limit.

10 And then maybe 20 years ago it was  
11 changed just to the concentration. And then the regs  
12 had to be again modified to reflect that. And so I  
13 was trying to -- my suggestion is the intent is to  
14 build a little more flexibility in the regs that if  
15 and when USP changes the limit, that when that  
16 becomes official with the USP, it becomes official  
17 NRC limits also.

18 CHAIR MALMUD: When we learn of it, we  
19 will move promptly. Or it may take long enough so  
20 that my successor will move promptly.

21 (Laughter.)

22 CHAIR MALMUD: Other issues for this  
23 afternoon's session? There was one other issue, I  
24 believe.

25 MR. LUEHMAN: The schedule.

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1 CHAIR MALMUD: The schedule of the next  
2 meeting.

3 MS. HOLIDAY: Okay, if you turn to Tab  
4 15, that will include the calendars for September and  
5 October.

6 MEMBER GILLEY: Sophie, did you look to  
7 see when the OAS meeting is?

8 MS. HOLIDAY: I did. It's actually --  
9 OAS is in August.

10 MEMBER GILLEY: Okay.

11 MS. HOLIDAY: Okay. So as you can see,  
12 our October is pretty much taken out of the picture  
13 here. Only a limitation of the possible days. Sorry  
14 for the cut off but this is October. As you can see,  
15 it is pretty dominated by the ASTRO Annual Meeting,  
16 Columbus Day, National Radon Training Conference, and  
17 other holidays. So all that will leave us in October  
18 would pretty much be October 24th and 25th and the  
19 27th and 28th.

20 So I'm proposing that we look at  
21 September, if September is okay for the Committee.  
22 Okay? So if you look for September, the Xs indicate  
23 -- are no-days because typically we don't like to  
24 start a meeting on a Wednesday. It's typically  
25 easier traveling on a Sunday and to have the meeting

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1 on Mondays. But if you wish, we could have it  
2 starting on a Wednesday.

3 I spoke to Dr. Guiberteau about this  
4 earlier. I originally had the 12th and the 13th as  
5 optional days. But I understand that there is  
6 another conference going on.

7 MEMBER GUIBERTEAU: There is a radiology  
8 summit that week.

9 MS. HOLIDAY: There is a radiology summit  
10 going on the week of the 11th. So that would pretty  
11 much mark that week off for us. So my first proposal  
12 dates would be September 19th and 20th.

13 MEMBER SUH: There is a Gamma Knife  
14 Consortium meeting that week.

15 MS. HOLIDAY: Okay.

16 MEMBER GUIBERTEAU: A what?

17 MEMBER SUH: A Gamma knife Consortium  
18 meeting, the North American. It would just affect me  
19 probably.

20 MS. HOLIDAY: Okay.

21 MEMBER SUH: From the 17th to the 19th.

22 MS. HOLIDAY: Okay. September 17th  
23 through 19th. Okay. So would you be able to attend  
24 if we had the meeting on the 22nd and 23rd? Or would  
25 that be too close?

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1 MEMBER SUH: If it's okay with everyone  
2 else.

3 MS. HOLIDAY: Okay. How does September  
4 22nd and 23rd look for the rest of the Committee?

5 MEMBER ZANZONICO: It's fine with me.

6 MS. HOLIDAY: Okay.

7 CHAIR MALMUD: Does it represent a  
8 conflict for anyone? Thursday and Friday, the 22nd  
9 and 23rd?

10 MEMBER FISHER: I'm checking.

11 CHAIR MALMUD: Okay.

12 MEMBER FISHER: It looks clear.

13 CHAIR MALMUD: Dr. Fisher says it looks  
14 clear.

15 MEMBER WELSH: I am okay.

16 CHAIR MALMUD: Sue says it is okay.  
17 Anybody? A conflict for anyone here? If not, the  
18 22nd and 23rd looks satisfactory.

19 MS. HOLIDAY: Okay.

20 CHAIR MALMUD: That's Thursday and  
21 Friday.

22 MS. HOLIDAY: So this will be our first  
23 choice. For a backup date, how does the 26th and the  
24 27th of September look? I'm sorry, how does  
25 September 26th and 27th look as a backup date?

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1 CHAIR MALMUD: A little tight.

2 MS. HOLIDAY: Tight? Okay. Okay. Yes?

3 VICE CHAIR THOMADSEN: Could I ask --

4 MS. HOLIDAY: Yes?

5 VICE CHAIR THOMADSEN: -- what is ASNC?

6 MEMBER VAN DECKER: American Society of  
7 Nuclear Cardiology, sir. You're welcome to come  
8 visit. We're going to have a good time at that.  
9 We'll have about 7,000 people. It's close to  
10 Louisiana.

11 (Laughter.)

12 MS. HOLIDAY: Okay. Well, if that would  
13 be tight, I propose that our backup date be October  
14 24th or 25th.

15 PARTICIPANT: It sounds good.

16 MEMBER SULEIMAN: Oh, wait. 24th, there  
17 is an IRCP meeting in Bethesda, that International  
18 Council on Radiation Protection meeting.

19 MS. HOLIDAY: Okay.

20 MEMBER FISHER: Does that affect any of  
21 us?

22 MEMBER SULEIMAN: I'll probably want to  
23 go. And probably the NRC staff will want to go.

24 MS. HOLIDAY: Okay. Is that -- for my  
25 chain, is that that whole week? Or --

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1                   MEMBER SULEIMAN: That's just that  
2 Monday, the 24th in Bethesda.

3                   MS. HOLIDAY: Okay. So then does October  
4 27th and 28th pose an issue for anyone?

5                   MS. FAIROBENT: There is an FDA meeting  
6 that day, radiological devices meeting.

7                   CHAIR MALMUD: You need to speak into a  
8 mic. Could you speak into the mic please?

9                   MS. FAIROBENT: Sorry, Lynne Fairobent.  
10 There is an FDA meeting that day for radiological  
11 devices advisory panel the 27th and 28th, at least on  
12 their calendar.

13                   MS. HOLIDAY: Okay. Would that affect  
14 any of our committee members here?

15                   CHAIR MALMUD: No, at least no one around  
16 the table that I can see. The 27th and 28th are the  
17 alternates then, right?

18                   MS. HOLIDAY: Okay. And then, of course,  
19 if that falls through, would October 31st and  
20 November 1st pose an issue?

21                   MR. FULLER: I will just mention that all  
22 of these dates, I think, support -- if we are able to  
23 move one of those workshops to the second week of  
24 August or somewhere in that time frame, that should  
25 support, based upon what Dr. Welsh mentioned earlier,

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1 in other words, provide enough time for the Permanent  
2 Implant Brachytherapy Subcommittee to finalize the  
3 report for any of these dates. Would you agree with  
4 that, Dr. Welsh?

5 MEMBER WELSH: Yes.

6 MS. HOLIDAY: Okay. So for our first  
7 choice, we have September 22nd and 23rd. Our first  
8 backup date will be October 27th and 28th. And our  
9 backup backup date is October 31st and November 1st.  
10 Is that okay with the Committee?

11 CHAIR MALMUD: Yes.

12 MS. HOLIDAY: Yes? Okay.

13 And just to touch up on what Mike was  
14 saying about the Part 35 public workshop, it was  
15 recommended that we move our second workshop outside  
16 of June into August. So the reason that Mike  
17 suggested the second week of August is because AAPM  
18 and COMP has a combined meeting July 31st through  
19 August 4th. And there is a national conference for  
20 state legislatures on August 8th through 11th.

21 I'm not sure if that may affect us or  
22 not, but that's on the CRCPD's calendar. So ideally  
23 our only time to have our public workshop would be  
24 either the end of that week of August 8th or the week  
25 after that, which is August 15th through the 19th,

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1 somewhere in there. Because as Debbie mentioned  
2 earlier, the OAS annual meeting will be August 21st  
3 through the 25th. That covers that.

4 CHAIR MALMUD: Okay. Any other items  
5 that we presented to the Committee this afternoon?

6 (No response.)

7 CHAIR MALMUD: Jim?

8 MS. HOLIDAY: Mike?

9 CHAIR MALMUD: Mike?

10 (Laughter.)

11 CHAIR MALMUD: I'm sorry. It's late.

12 MR. FULLER: No, I don't have anything  
13 else. And I pulled a fast one. No, I really don't  
14 have anything else. I certainly do appreciate all of  
15 the efforts and the discussion today. I think it has  
16 been very, very valuable to the NRC staff. And I'll  
17 look forward to another thing tomorrow of hearing  
18 your views.

19 CHAIR MALMUD: In that case, we will  
20 reconvene tomorrow in this room at eight o'clock for  
21 opening remarks. And then grandfathering of the  
22 Ritenour petition.

23 Thank you all.

24 (Whereupon, the above-entitled meeting was concluded  
25 at 4:29 p.m.)

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