

**Official Transcript of Proceedings**  
**NUCLEAR REGULATORY COMMISSION**

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                                  of Isotopes: Open Session

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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

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## 6 MEETING

7 + + + + +

## 8 OPEN SESSION

9 + + + + +

10 MONDAY,

11 APRIL 16, 2012

12 The meeting was convened in Room T2-B3 of  
13 Two White Flint North, 11545 Rockville Pike,  
14 Rockville, Maryland, at 10:45 a.m., Bruce Thomadsen,  
15 Ph.D., ACMUI Vice Chairman, presiding.

16 MEMBERS PRESENT:

17 BRUCE THOMADSEN, Ph.D., Acting Chair

18 DARICE BAILEY, Agreement State Representative

19 MILTON GUIBERTEAU, M.D., Diagnostic Radiologist

20 SUSAN LANGHORST, Ph.D., Radiation Safety Officer

21 STEVE MATTMULLER, Nuclear Pharmacist

22 CHRISTOPHER PALESTRO, M.D., Nuclear Medicine  
23 Physician

24 JOHN SUH, M.D., Radiation Oncologist

25 ORHAN SULEIMAN, Ph.D., FDA Representative

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1 MEMBERS PRESENT (Continued):

2 WILLIAM VAN DECKER, M.D., Nuclear Cardiologist

3 LAURA M. WEIL, Patients' Rights Advocate

4 JAMES WELSH, M.D., Radiation Oncologist

5 PAT ZANZONICO, Ph.D., Nuclear Medicine Physicist

6  
7 NRC STAFF PRESENT:

8 PAMELA HENDERSON, Acting Deputy Director,  
9 Division of Materials Safety and State Agreements

10 CHRIS EINBERG, Designated Federal Officer

11 ASHLEY COCKERHAM, Alternate Designated Federal  
12 Officer

13 MICHAEL FULLER, Alternate Designated Federal  
14 Officer

15 SOPHIE HOLIDAY, Alternate ACMUI Coordinator

16 REGINALD AUGUSTUS, FSME/DWMEP/DURLD/SP

17 NEELAM BHALLA, FSME/DILR/RB-B

18 SUSAN CHIDAKEL, OGC/GCLR/RMR

19 JACKIE COOK (via telephone), RIV/DNMS/NMSB-B

20 SAID DAIBES, Ph.D., FSME/DMSSA/LISD/RMSB

21 SANDRA GABRIEL, RI/DNMS/MB

22 LATISCHA HANSON (via telephone), RIV/DNMS/NMSB-A

23 DONNA-BETH HOWE, Ph.D, FSME/DMSSA/LISD/RMSB

24 HARRIET KARAGIANNIS, RES/DE/RGDB

25 ED LOHR, FSME/DILR/RB-B

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1 NRC STAFF PRESENT (Continued):

2 AARON McCRAW (via webcast), RIII/DNMS/MIB

3 PATRICIA PELKE (via webcast), RIII/DNMS/MLB

4 GRETCHEN RIVERA-CAPELLA, FSME/DMSSA/LISD/RMSB

5 SHIRLEY XU, FSME/DMSSA/LB

6  
7 MEMBERS OF THE PUBLIC PRESENT:

8 DARRELL BROWN, Fox Chase Cancer Center

9 KEITH BROWN, University of Pennsylvania

10 PETER CRANE (via telephone), *No Affiliation*

11 ROBERT DANSEREAU, NYS Dept. of Health

12 MOHAN DOSS, Fox Chase Cancer Center

13 BRYAN EDWARDS, Fox Chase Cancer Center

14 LYNNE FAIROBENT, AAPM

15 TRACI HOLLINGSHEAD, Avera McKennan

16 DEEPIKA JALOTA, Bayer HealthCare Pharm.

17 RALPH LIETO, St. Joseph Mercy Hospital

18 GARY LUNGER (via webcast)

19 ANDREW McKINLEY, ASNC

20 JANETTE MERRILL, SNM

21 MARY E. MOORE, Philadelphia VA Medical Ctr.

22 DONNA MOSLEY, Fox Chase Cancer Center

23 MICHAEL PETERS, ACR

24 SOBHA PHILLIPS, Fox Chase Cancer Center

25 KATHRYN PRYOR, Health Physics Society

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1 MEMBERS OF THE PUBLIC PRESENT (CONTINUED) :

2 JOE RODGERS, Theragenics

3 GLORIA ROMANELLI, ACR

4 KAREN SHEEHAN, Fox Chase Cancer Center

5 MICHAEL SHEETZ, University of Pittsburgh

6 MICHAEL N. STEPHENS, Florida Dept. of Health

7 CINDY TOMLINSON, ASTRO

8 RICHARD VETTER, Health Physics Society

9 GARY E. WILLIAMS, VA NHPP

10 DAVID WILLIAMSON, University of Pennsylvania

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TABLE OF CONTENTS

1

2 Opening Statements ..... 5

3 Old Business ..... 13

4 Fundamental Concepts in Patient ..... 25

5       Advocacy

6 Electronic Signatures Subcommittee ..... 42

7 Medical Events Subcommittee Report ..... 47

8 Permanent Implant Brachytherapy ..... 67

9 Status of Commission Paper on

10       Patient Release ..... 110

11 Radiation Therapy Implications

12       from Anomalous Variations of the

13       Nuclear Decay Law ..... 123

14 Statement from Peter Crane ..... 141

15

16

17

18

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

(10:50 a.m.)

1  
2  
3 ACTING CHAIR THOMADSEN: Welcome to the  
4 spring ACMUI meeting. I want to thank you all for  
5 joining us. Dr. Malmud cannot be with us for medical  
6 reasons, and we send him all of our best for a speedy  
7 recovery.

8 And to open the program, Mr. Einberg.

9 MR. EINBERG: Okay. Thank you, Dr.  
10 Thomadsen. I'm not sure if we can turn up the  
11 microphone for Dr. Thomadsen, or if you could speak  
12 up, but we are getting indications from the back that  
13 you need to talk a little louder.

14 Good morning. I'm going to open the  
15 meeting. I'm the Designated Federal Officer for this  
16 meeting. I am pleased to welcome you to this public  
17 meeting of the Advisory Committee on the Medical Uses  
18 of Isotopes.

19 My name is Chris Einberg. I am the Chief  
20 of the Radioactive Materials Safety Branch, and I have  
21 been designated as the Federal Officer of the Advisory  
22 Committee in accordance with 10 CFR Part 7.11.

23 Present today as the Alternate Designated  
24 Federal Officers are Mike Fuller, who is the team  
25 leader for the Medical Radiation Safety Team, and

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1 Ashley Cockerham, who is the coordinator for this  
2 meeting.

3 This is an announced meeting of the  
4 Committee. It is being held in accordance with the  
5 rules and regulations of the Federal Advisory  
6 Committee Act and the Nuclear Regulatory Commission.  
7 The meeting was announced in the March 13, 2012,  
8 edition of the Federal Register, Volume 77,  
9 page 14837.

10 The function of the Committee is to advise  
11 the staff on the issues and questions that arise in  
12 the medical use of byproduct material. The Committee  
13 provides counsel to the staff but does not determine  
14 or direct the actual decisions of the staff or the  
15 Commission.

16 The NRC solicits the views of the  
17 Committee and values their opinions. I request that,  
18 whenever possible, we try to reach a consensus on the  
19 procedural issues that we will discuss today. But I  
20 also recognize there may be minority or dissenting  
21 opinions. If you have such opinions, please allow them  
22 to be read into the record.

23 At this point, I would like to perform a  
24 roll call of the ACMUI members who are participating  
25 today. As Dr. Thomadsen mentioned, Dr. Leon Malmud,

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1 who is the Chairman of this Committee, is not in  
2 attendance. And I will go through the roll call right  
3 now. Dr. Bruce Thomadsen, who is the Acting Chairman  
4 for this meeting today.

5 ACTING CHAIR THOMADSEN: Present.

6 MR. EINBERG: Ms. Darice Bailey, state  
7 government representative.

8 MEMBER BAILEY: Present.

9 MR. EINBERG: Dr. Mickey Guiberteau,  
10 diagnostic radiologist.

11 MEMBER GUIBERTEAU: Present.

12 MR. EINBERG: Dr. Sue Langhorst, radiation  
13 safety officer.

14 MEMBER LANGHORST: Present.

15 MR. EINBERG: Mr. Steve Mattmuller, nuclear  
16 pharmacist.

17 MEMBER MATTMULLER: Present.

18 MR. EINBERG: Dr. Christopher Palestro,  
19 nuclear medicine physician.

20 MEMBER PALESTRO: Present.

21 MR. EINBERG: Dr. John Suh, radiation  
22 oncologist.

23 (No response.)

24 He is here today. I note that he is here.  
25 He stepped out of the room.

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1 Dr. Orhan Suleiman, FDA representative.

2 MEMBER SULEIMAN: Present.

3 MR. EINBERG: Dr. William Van Decker,  
4 nuclear cardiologist.

5 MEMBER VAN DECKER: Present.

6 MR. EINBERG: Ms. Laura Weil, patients  
7 rights advocate.

8 MEMBER WEIL: Present.

9 MR. EINBERG: Dr. James Welsh, radiation  
10 oncologist.

11 MEMBER WELSH: Present.

12 MR. EINBERG: Dr. Pat Zanzonico, nuclear  
13 medicine physicist.

14 MEMBER ZANZONICO: Present.

15 MR. EINBERG: Okay. With that, we do have a  
16 quorum. And so we have at least seven members, and we  
17 can go ahead and participate -- proceed.

18 I now ask that the NRC staff members who  
19 are present identify themselves. I will start with the  
20 individuals in the room.

21 MS. HENDERSON: Pam Henderson, Acting  
22 Deputy Director.

23 MR. EINBERG: Thank you.

24 MR. FULLER: Mike Fuller, team leader,  
25 Medical Radiation Safety Team.

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1 MR. EINBERG: Okay. I see that Dr. Sandy  
2 Gabriel is in the audience also from Region I.

3 MS. RIVERA-CAPELLA: Gretchen Rivera-  
4 Capella from the Medical Radiation Safety Team, NRC.

5 MR. EINBERG: Thank you.

6 MS. HOLIDAY: Sophie Holiday, also with the  
7 Medical Radiation Safety Team, NRC.

8 MS. COCKERHAM: Ashley Cockerham with the  
9 Medical Radiation Safety Team, NRC.

10 MR. EINBERG: Okay. Thank you. Are there  
11 anybody from the regions on the phone?

12 MS. COOK: Jackie Cook, Region IV.

13 MR. EINBERG: Thank you.

14 MS. HANSON: Latischa Hanson, Region IV,  
15 DNMS.

16 MR. EINBERG: Thank you. Anybody else from  
17 the regions?

18 (No response.)

19 Anybody I missed on the phone or --

20 (No response.)

21 Okay. I would also like to add that this  
22 meeting is being webcast, so other individuals may be  
23 watching online.

24 We have a bridge line that is available,  
25 and that phone number is 888-566-9152. The passcode to

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1 access the bridge line is 23793-pound. Once again, the  
2 number is 888-566-9152. The passcode is 23793-pound.

3 Following a discussion of each agenda  
4 item, the Acting Chairman, Dr. Bruce Thomadsen, at his  
5 option, may entertain comments or questions from  
6 members of the public who are participating with us  
7 today.

8 At this point, I would like to turn the  
9 meeting over to Ms. Pam Henderson, who has some  
10 opening remarks she would like to make. And Ms.  
11 Henderson is the Acting Deputy Division Director for  
12 the Division of Materials Safety and State Agreements.

13 MS. HENDERSON: Good morning, and welcome  
14 to the spring ACMUI meeting. Brian McDermott, the  
15 Director, is representing NRC at the Organization of  
16 Agreement States Board of Directors meeting in  
17 Wisconsin, and, therefore, he is unable to be here.

18 In Dr. Malmud's absence, the current ACMUI  
19 Vice Chairman, Dr. Thomadsen, will act as the Chair.  
20 Thank you, Dr. Thomadsen, for acting in this capacity.

21 We would like to extend a warm welcome to  
22 Ms. Darice Bailey. She was appointed as the new ACMUI  
23 Agreement States representative on March 26, 2012.  
24 Ms. Bailey has been interacting with the ACMUI members  
25 and staff over email and phone for the past several

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1 weeks, and we look forward to working with her over  
2 the course of the next four years.

3 We are happy to announce that Mr. Steve  
4 Mattmuller has been reappointed to serve a second term  
5 on the ACMUI. We appreciate Mr. Mattmuller's  
6 willingness to serve and for his valuable  
7 contributions to the Committee over the past four  
8 years.

9 On April 3rd, the Organization of  
10 Agreement States and the Conference of Radiation  
11 Control Program Directors met with the Commission to  
12 discuss medical event definitions for permanent  
13 implant brachytherapy, the expanded, increased control  
14 requirements for 10 CFR Part 37, and various other  
15 topics that impact our co-regulators in the states.

16 On April 24th -- next week -- NRC staff  
17 and ACMUI members and various medical stakeholders  
18 will be meeting with the Commission to discuss medical  
19 event definitions for permanent implant brachytherapy.  
20 The meeting will provide an opportunity for the  
21 Commission to receive important feedback from all  
22 interested parties before voting on the paper that is  
23 before them at this time. Dr. Welsh and Ms. Weil will  
24 be representing the ACMUI at that meeting.

25 On March 16th, the Commission approved the

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1 Part 37 final rule with minor changes. Publication is  
2 expected this summer. The effective date of this new  
3 regulation will be one year after the publication  
4 date, and that is when NRC licensees will need to meet  
5 the new Part 37 requirements.

6 Agreement States will have three years  
7 from the date of publication to adopt compatible  
8 regulations.

9 During the meeting today and tomorrow, we  
10 will be covering a range of topics, including  
11 electronic signatures, patient advocacy, patient  
12 release, radium-223 chloride, medical event  
13 definitions for permanent implant brachytherapy,  
14 strontium/rubidium generators. We look forward to  
15 hearing the Committee's views on these important  
16 issues.

17 And with that, I will hand it back to Dr.  
18 Thomadsen.

19 ACTING CHAIR THOMADSEN: Thank you very  
20 much. And are there any questions from the Committee?

21 (No response.)

22 In that case, we will move on to the next  
23 presentation by Ms. Cockerham on Old Business. And  
24 that is under Tab Number 3 in your book.

25 MS. COCKERHAM: Good morning. For Tab

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1 Number 3, I have new, updated handouts for you. So I'm  
2 going to pass these around. So you can pull out  
3 everything that is in your binder behind Tab 3.

4 And while those are going around, I will  
5 just start by saying I know a lot of these  
6 recommendations are from 2007 and '08. They seem very  
7 old and they seem to still be lingering around, but  
8 the good news is that almost all of them are included  
9 in either the permanent implant brachytherapy, the  
10 medical event definition, rulemaking that is currently  
11 undergoing, and also there is a Part 35 expanded  
12 rulemaking that is ongoing. So we are taking action on  
13 many of these items.

14 So for these old lists, I am actually  
15 going to go through them very quickly. I am not going  
16 to read the recommendations in detail. I can tell you  
17 for Items 2, 3, 6, 7, 8, 10, 25, all of those items  
18 are currently included in the Part 35 expanded  
19 rulemaking.

20 And then, when we get to Item 30, this is  
21 a recommendation for something that is in 10 CFR  
22 35.1000. So the things that are 1000 uses, I believe  
23 the Elekta Perfexion, there is also a few items on  
24 here, if you look at Items 34 and 35, that deal with  
25 ophthalmic treatments, NeoVista, all of these things

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1 that are Part 1000 uses are not being moved into the  
2 regulations at this time. That's why they say "open"  
3 and "delayed."

4 So for -- we stopped at Item 30, so for 31  
5 I said -- 31 and 32 are both included in the Part 35  
6 expanded rulemaking. And then for Items 34 and 35,  
7 that deals with the ophthalmic devices, and I  
8 mentioned that those will be considered for a future  
9 rulemaking, but not with the current expanded Part 35  
10 or the current medical event definitions for permanent  
11 implant brachytherapy rulemakings.

12 For Items 36, 37, and that's it for that  
13 chart, those are both also included in the Part 35  
14 expanded rulemaking.

15 So if we move on to 2008, Item 2 is also  
16 included in the Part 35 expanded rulemaking. And  
17 Number 5 is, as I said before, it's about Elekta  
18 Perfexion. It is not included in the current  
19 rulemakings, but it will be considered for a future  
20 rulemaking.

21 For Item Number 9, this deals with the  
22 abnormal occurrence criteria. And this version of the  
23 abnormal occurrence criteria was discussed during the  
24 ACMUI teleconference on December 15, 2011. The ACMUI  
25 reaffirmed this recommendation with the addition of

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1 the letter S to physicians, and this recommendation  
2 that the NRC provide it to Research staff to propose  
3 to the Commission.

4 For Item 19, the Permanent Implant  
5 Brachytherapy Subcommittee report, this is currently  
6 in the permanent implant brachytherapy subcommittee  
7 proposal of the medical event definitions for  
8 permanent implant brachytherapy rulemaking.

9 For Item 22, this is regarding yttrium-90  
10 microspheres. Again, this is a 10 CFR 35.1000 use, and  
11 it will be considered to be moved to rulemaking at a  
12 future time. Right now it is still in guidance phase.  
13 So this is the same as the Elekta Perfexion and the  
14 NeoVista ophthalmic device.

15 For Items 26 and 27, these are regarding  
16 permanent implant brachytherapy, and they are included  
17 in that rulemaking. And the last three items numbers  
18 28, 29, and 30 are all in the Part 35 expanded  
19 rulemaking.

20 For 2009, Item Numbers 2 and 10 are  
21 included in the Part 35 expanded rulemaking. And for  
22 Item 9, that is just adding Dr. Welsh and Dr.  
23 Langhorst and Mr. Mattmuller to the Medical Events  
24 Subcommittee. And Dr. Suh was subsequently added in  
25 2011, but we will get to that.

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1 Any questions on any of these old  
2 recommendations? We are kind of seeing a trend here.  
3 It is either part of a current rulemaking, so the  
4 recommendation is under consideration, or it is a  
5 Part 1000 use, which we will consider at a future  
6 date.

7 Okay. So for 2010, the ACMUI will provide  
8 a list of action items for NRC staff based on the  
9 recommendations provided in the Patient Release  
10 Subcommittee report. This was still just lingering as  
11 an open item, but I know at the last meeting Dr.  
12 Langhorst stated that the Subcommittee felt it had  
13 addressed all issues in its report and that this item  
14 could be closed. And so I am just documenting that  
15 this item is now closed.

16 For 2011, I am actually going to start  
17 with Item Number 6. ACMUI created an action item to  
18 reevaluate its satisfaction with the reporting  
19 structure annually, and this recommendation was made  
20 in January of 2011.

21 So sometime this year we will need the  
22 Committee to return to this, so I guess we can put  
23 that as an agenda item for the next meeting, to  
24 evaluate its satisfaction with the reporting  
25 structure. And this deals with reporting to NRC staff

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1 at the division level where it currently does, or  
2 reporting directly to the Commission or some sort of  
3 other option.

4 For Item 7, Dr. Malmud will serve as the  
5 reviewer to screen I-131 cases for the ACMUI Medical  
6 Events Subcommittee. That is just an ongoing thing.  
7 The Medical Events Subcommittee will report to us  
8 later today.

9 For Item 9, ACMUI recommended a three-  
10 month notice for future public stakeholder workshop  
11 meetings. I went ahead and closed this item out. The  
12 workshops are over. But I think the NRC understands  
13 that ample notice is requested for public meetings.

14 For Item 10, this is regarding the public  
15 stakeholder workshops. The Committee requested that we  
16 have one of those workshops in August, which was a  
17 couple of months later than I think what we had  
18 proposed. And we did in fact have it in August in  
19 Houston.

20 For Item 11, this deals with permanent  
21 implant brachytherapy. And the ACMUI's Permanent  
22 Implant Brachytherapy Subcommittee report was  
23 finalized on February 7, 2012. It included  
24 recommendations for post-implant dosimetry but did not  
25 separate prostate implant brachytherapy from other

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1 types of permanent implant brachytherapy.

2 So I guess the point here is that this  
3 recommendation is kind of superseded by your  
4 subcommittee report. So I can actually say I had put  
5 "partially accepted," and what I will do is go ahead  
6 and close this recommendation out, since your  
7 Subcommittee report is the final statement on this.

8 Any questions or comments on that?

9 (No response.)

10 Okay. Item Number 12 says that we would  
11 have the next meeting. This was for last fall, so I  
12 would just close this item out so it is not lingering  
13 open. You recommended we have a September meeting, and  
14 we had a September meeting.

15 For Items 13, 14, and 15, all of these  
16 items deal with attestation. And the last item deals  
17 with -- oh, they're all dealing with attestation, and  
18 they are all included in the Part 35 expanded  
19 rulemaking.

20 Then, we'll jump to Item 19, and Mr.  
21 Mattmuller asked the NRC staff to add ACMUI to the  
22 organizational chart on the FSME website. We are still  
23 working on this. I have identified two websites that I  
24 think the ACMUI can be added to. We just need to work  
25 through the process of going through our contractors

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1 and getting ACMUI added to that.

2 I did look at the NRC website as a whole,  
3 like the public website. And there is a very high  
4 level organizational chart. It does not include  
5 organizations like the Advisory Committee on Reactor  
6 Safety or Advisory Committee on Reactor Safeguards. I  
7 believe I've got that right. And, really, it only goes  
8 down to about the office level, and there is an office  
9 level, and then there is the division level, and  
10 that's where the ACMUI reports to the division level.

11 So I don't think that ACMUI would be  
12 included on that chart, is that the chart that you had  
13 envisioned? I'm not sure it is or would it be more on  
14 the Office of Federal and State Programs and  
15 Environmental -- Office of Federal and State Materials  
16 and Environmental Management Programs website?

17 MEMBER MATTMULLER: I'm sorry. I can't keep  
18 up with your shorthand. I think the intent was greater  
19 visibility for the Committee.

20 MS. COCKERHAM: Okay.

21 MEMBER MATTMULLER: And so I will let you  
22 decide where best that can occur.

23 MS. COCKERHAM: Okay.

24 MEMBER MATTMULLER: That or work in  
25 somewhere.

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1 MS. COCKERHAM: I guess I just wanted the  
2 Committee to know that I did look on the big picture,  
3 front page website. The NRC organizational chart,  
4 which starts with the Commissioners at the top, and  
5 then it has the Executive Director, but that chart  
6 only goes down to our Office Director.

7 And if this Committee reports at a  
8 division level, the Committee would not be on that  
9 page, but there are many other places it could be and  
10 I have identified two other websites where I think we  
11 could get this included. So we will be working on  
12 that.

13 For Item 20, Dr. Langhorst requested that  
14 NRC staff place historical documents and past ACMUI  
15 membership information on the ACMUI website. This is  
16 something we are still working on, but it is noted and  
17 it's open.

18 For Item 21, this is the Electronic  
19 Signature Subcommittee, and that Subcommittee will be  
20 reporting to us during that agenda item during today's  
21 meeting.

22 Item 22, I just closed out this item. This  
23 is the abnormal occurrence criteria. This is the  
24 teleconference that the Committee had on  
25 December 15th, so I closed out that this discussion

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1 was tabled.

2 Item 23 is where Dr. Malmud added Dr. Suh  
3 to the Permanent Implant Brachytherapy Subcommittee.

4 Item 24, the Permanent Implant  
5 Brachytherapy Subcommittee will revise the  
6 Subcommittee report and provide it to the full  
7 Committee. And they did do this, so I have closed out  
8 this item. That October report was actually followed  
9 up by a February report, so we have moved on even  
10 since this point.

11 Item 26, NRC staff will provide an advance  
12 copy of the Permanent Implant Brachytherapy  
13 Subcommittee report to the Agreement States. This is  
14 because we did not have an Agreement States  
15 representative currently on the Committee. And Ms.  
16 Bailey participated in the teleconference as a member  
17 of the public on behalf of the Agreement States. So I  
18 have gone ahead and closed out this item.

19 Item 27, ACMUI planned to hold a spring  
20 meeting today and tomorrow. I closed this out because  
21 we're here.

22 This would be Item 28. I don't see a  
23 number, but it is Item 28 here. 28, 29, 30, and 31,  
24 all of these items here that I have marked closed,  
25 they are all modifications to the October Permanent

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1 Implant Brachytherapy Subcommittee report. All of  
2 these changes were incorporated into the report, and  
3 the report was finalized on October 18th and posted to  
4 the public website. So this is just noting all of  
5 those changes that were made, so I have closed out all  
6 of those items.

7 And I believe this would be Item 32. ACMUI  
8 reaffirms the 2008 abnormal occurrence criteria as  
9 stated in the handout with the amendment that "S" be  
10 added to the end of "physician," which I discussed  
11 before, I think I mentioned this from a previous item.  
12 The bottom line is, the recommendations that you have  
13 made for abnormal occurrence criteria, the latest  
14 information has been provided to the Office of  
15 Research, and they are providing that to the  
16 Commission.

17 For the last chart, this is 2012, ACMUI  
18 recommended two changes to the Permanent Implant  
19 Brachytherapy Subcommittee report. Those two changes  
20 were made to the report and included in the final  
21 revised report that is dated February 7, 2012. And  
22 these ACMUI recommendations in that February 7th  
23 report were transmitted to the Commission in a SECY  
24 paper or a Commission paper, and that paper is SECY-  
25 12-0053.

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1 Are there any questions on any of these  
2 recommendations or their status?

3 ACTING CHAIR THOMADSEN: Yes. Dr. Van  
4 Decker.

5 MEMBER VAN DECKER: Yes, if I could. You  
6 know, I noticed on the agenda actually that there is  
7 not an actual topic point for discussion of an update  
8 on the expanded Part 35 rulemaking, as far as what has  
9 gone on since the public meetings of last summer and  
10 our last meeting in September. Since a lot of these  
11 items are on that, can you just give us some concept  
12 of timeline of what has gone on in the last six months  
13 and where we see that playing out?

14 MS. COCKERHAM: Sure. Actually, Mike has a  
15 presentation on the agenda, and I believe he may  
16 discuss that. I don't know if it states that it's a  
17 rulemaking update, but it is on permanent implant  
18 brachytherapy. I don't have an agenda in front of me.  
19 Is Mike on there?

20 MEMBER VAN DECKER: He is on for permanent  
21 implant brachytherapy, but not for Part 35 expanded.

22 MS. COCKERHAM: Mike, I can ask, are you  
23 going to cover that information for the Part 35  
24 expanded rulemaking?

25 MR. FULLER: This is Mike Fuller. No, it is

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1 not on the agenda and we probably won't cover that  
2 this time. The decision was made not to add the  
3 expanded Part 35 rulemaking to this particular agenda  
4 because, really, nothing has changed much since the  
5 last meeting that we had in September. In other words,  
6 we continue to work through items the writing team is  
7 working. They are developing the preliminary rule  
8 text.

9 In other words, since the last meeting we  
10 haven't really tasked any milestones, so there really  
11 wasn't anything to update. We did ask that folks from  
12 our Rulemaking Division, you know, be here to answer  
13 questions throughout the course of the next day or so.

14 ACTING CHAIR THOMADSEN: Dr. Van Decker.

15 MEMBER VAN DECKER: So for an old man's  
16 memory, then, can you just remind me what your  
17 timeline for publication of a draft rule is?

18 MR. FULLER: These are estimates, of  
19 course, because we don't have that specified just yet  
20 in the form of, you know, formal direction from the  
21 Commission. But we are still anticipating a  
22 publication -- the publication of a draft -- I mean,  
23 of a proposed rule sometime either late this calendar  
24 year, anywhere until spring of next -- of 2013.

25 MEMBER VAN DECKER: Thank you, sir.

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1                   ACTING    CHAIR    THOMADSEN:    Any    other  
2                   questions for Ms. Cockerham?

3                   (No response.)

4                   Seeing none, thank you very much for the  
5                   update.

6                   Our next presentation is by Ms. Weil on  
7                   Fundamental Concepts in Patient Advocacy.

8                   MEMBER WEIL: Thank you very much. I would  
9                   like to talk about patient advocacy in general, health  
10                  advocacy writ large, if you will, and to discuss for a  
11                  moment my role on the ACMUI as a patient advocate. I  
12                  am a non-technical non-scientific member of a  
13                  technical committee, and my perspective, therefore, is  
14                  unfettered by professional loyalties in the clinical  
15                  realm.

16                  And I am able perhaps to make use of my  
17                  limited scientific knowledge to focus more clearly on  
18                  the very zoomed-out public health issues of patient  
19                  advocacy as well as the very zoomed-in patient  
20                  perspective. So defining patient advocacy or health  
21                  advocacy, which is the broader perspective, is often  
22                  very difficult.

23                  But one could say that a primary role is  
24                  supporting individual patient choice, enabling  
25                  autonomous decision-making, promoting patient and

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1 public safety, and increasing access to health  
2 services and the quality of those health services.

3           There are two sets of underpinnings for  
4 this particular perspective, and I would like to  
5 borrow from the tradition of the protections of human  
6 subjects in clinical research, specifically the  
7 Belmont report, which was isolated -- which was  
8 drafted by the National Commission for the Protection  
9 of Human Subjects in Biomedical and Behavioral  
10 Research in 1979, because it was written in response  
11 to the Tuskegee syphilis study and the public outcry  
12 over the way people were treated in that particular  
13 study well into the 1970s, these three ethical  
14 principles were identified, which can be used much  
15 more broadly to define concepts of patient advocacy in  
16 the larger world of any medical encounter.

17           So the first principle is beneficence,  
18 which is a fairly straightforward idea of maximizing  
19 benefit and minimizing risk to patients.

20           The second principle of respect for  
21 persons identifies patients as autonomous beings with  
22 rights, preferences, and person-specific values, and  
23 the third principle of justice discusses equality in  
24 terms of sharing of the burdens and benefits of  
25 research in the Belmont perspective. But in the

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1 broader patient advocacy perspective, one could  
2 interpret this to talk about the justice and equality  
3 of access to health care services in general.

4 The second underpinning, the concept of  
5 rights, is a more legalistic form when we start to  
6 think as rights-only in the statutory sense. Statutory  
7 rights are rights that are either legislated or  
8 codified and are enforceable by courts and law  
9 enforcement agencies.

10 There is a very strong tradition of  
11 grievance and redress, which supports these rights in  
12 a way that everyone understands. In the normative  
13 tradition, it is a much more flexible kind of rights.  
14 The rights represent the prevailing values in a  
15 society and are not necessarily enforceable. These are  
16 rights that are often characterized as what ought to  
17 be or what should be.

18 If we look at statutory rights again, an  
19 example would be the Emergency Medical Treatment and  
20 Active Labor Act, which was -- which prevents  
21 hospitals from dumping patients who have no ability to  
22 pay for emergency care. It relates only to emergency  
23 care, but it promises that every patient has the right  
24 to present to an emergency room and receive a medical  
25 evaluation and receive emergency care if needed,

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1 without any respect to the patient's ability to pay.

2 This was in response to a number of  
3 incidents where patients were refused admission to  
4 emergency departments and sent down the road to the  
5 local municipal or county hospital, or to the hospital  
6 where their insurer would pay for care. And there were  
7 some deaths associated with that, including deaths to  
8 kids.

9 So in the normative tradition, we could  
10 look at this as an example of *Rowe v. Wade*. This is a  
11 statutory law that is being somewhat modified in the  
12 normative tradition by prevailing values of society.  
13 *Rowe* clearly stated that a woman has a right to  
14 terminate a pregnancy.

15 In the current discussions, this law is  
16 now being shifted a bit by local legislative and  
17 political activities to try to change that standing to  
18 match more clearly the values of local communities,  
19 states, and perhaps even of the federal law.

20 This third category, which I have called  
21 the Professional Codes of Ethics category, is really a  
22 category about implied rights. And I would like to  
23 cite as an example a professional Code of Ethics, the  
24 American Medical Association's Code of Medical Ethics,  
25 which puts out norms of behavior for clinicians and

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1 the implied rights that patients have based on those  
2 norms of professional behavior.

3 To be specific, I would like to talk about  
4 the AMA's code about medical ethics that talks about  
5 medical errors. And I would like to quote, "Patients  
6 have a right to know when a medical error or  
7 unexpected adverse event has occurred, whether or not  
8 the patient has actually been harmed."

9 So while patients have no statutory right  
10 to know of a medical error that has not caused  
11 substantial injury, clearly the AMA's Code of Ethics  
12 implies that because physicians have an ethical  
13 obligation to disclose, patients, therefore, have a  
14 right to know. And there are other examples of these  
15 kinds of professional norms that imply rights to  
16 patients, but they are not enforceable in any court.

17 If we go back to Belmont for a moment, the  
18 Belmont report identifies respect for persons as the  
19 underlying ethical principle behind patient autonomy.  
20 And there are enablers and there are barriers to  
21 autonomy, of course, and I would like to just give a  
22 few examples.

23 Some of the enablers of autonomy are full  
24 information from clinicians about treatment options,  
25 transparency about how those treatment options have

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1 been arrived at and chosen, and access to care.  
2 Barriers to autonomy would be geography and payment  
3 issues, and both of those play into that access  
4 sphere.

5 In rural areas, patients have very limited  
6 access to choice of provider or to perhaps centers of  
7 excellence, because there are more limited numbers of  
8 health care providers in some areas.

9 Insurance issues certainly play into  
10 access. Decisions about treatment options are often  
11 made based on insurance coverage rather than patient  
12 choice.

13 And this last category as an example,  
14 provider bias, is something that isn't often cited as  
15 a barrier to autonomy, but it is clear that health  
16 care providers have biases about treatment. They have  
17 choices that they prefer; they have reasons for  
18 recommending certain things that sometimes aren't  
19 based in clinical decision, but, rather, based on  
20 personal bias.

21 And some of those bias issues involve  
22 gender and racial considerations. There has been  
23 enough in the literature that describes decision-  
24 making by clinicians that is based in gender or racial  
25 considerations rather than clinical considerations

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1 that it does have an impact on patient autonomy.

2 So there are issues before the ACMUI that  
3 have patient advocacy issues fairly firmly embedded in  
4 them. The first would be the permanent implant  
5 brachytherapy discussion about medical event  
6 definition.

7 Now, if we look at the American Medical  
8 Association's clear description of physician  
9 responsibility regarding disclosure of departures from  
10 the expected plan of care, then our medical event  
11 definition might leave patients not able to know that  
12 there has been a departure if the departure does not  
13 reach the level of medical event definition, whereas  
14 the AMA's Code of Ethics would suggest that perhaps  
15 the patient should have been told when there was a  
16 departure from what was the anticipated plan.

17 It is often stated that patients don't  
18 want to know, that they would prefer not to be told  
19 about what a clinician might consider a fairly  
20 insignificant departure. But there is good evidence  
21 among surveys of patients that patients do want to  
22 know, they do wish to be told, and it does affect  
23 their future medical decision-making.

24 So I would like to cite just a couple of  
25 surveys that have been done of patients. One is Witman

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1 in Archives of Internal Medicine who states -- and I  
2 am going to quote -- "Virtually all patients -- 98  
3 percent -- desired some acknowledgement of even minor  
4 errors. Patients were significantly more likely to  
5 consider litigation if the physician did not disclose  
6 the error."

7 Witman goes on to describe the discrepancy  
8 in litigation as being 12 percent of patients who had  
9 a discussion about the medical error with their  
10 physician were likely to take their suit to court  
11 versus 20 percent who found out about the treatment  
12 error or the adverse event on their own.

13 Another study, Hobgood in Academic  
14 Emergency Medicine, said that a majority of  
15 respondents wish to be informed immediately of any  
16 medical error. And they talk about this being 76  
17 percent. And of those 76 percent, 88 percent wanted to  
18 have full disclosure of the error's extent.

19 Now, med mal insurers know this well, and  
20 run training programs to assist physicians in learning  
21 how to disclose medical errors and adverse events  
22 effectively, honestly, and with some degree of  
23 apology, because they know that this is protective of  
24 the physician as opposed to being an unwelcome  
25 exposure.

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1           And I would like to pose that physician  
2 reluctance is more likely driven by a misplaced fear  
3 of litigation and a lack of models in having these  
4 discussions, because it is certainly not something  
5 that is generally taught in medical school, or it may  
6 be self-deceptions about patients' actual preferences.

7           Another issue that is relevant in the  
8 field of patient advocacy that has come before the  
9 ACMUI is the release of patients following 131-iodine  
10 treatment. And the concern here is patient release  
11 instructions and whether or not patients understand  
12 them.

13           And while I would be the last person to  
14 suggest that patients are incapable of understanding  
15 instructions, the timing of those instructions is  
16 problematic in this situation, the degree of  
17 preparation that patients have, the confusing and  
18 often contradictory instructions that patients get  
19 from even within the same facility, the problems of  
20 non-English speakers or limited English speakers, all  
21 really conspire to give me a degree of concern about  
22 whether or not the current situation is allowing  
23 patients to follow these instructions in a way that  
24 protects the public and their families.

25           If we were to extrapolate from the

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1 situation with Emergency Department patients, who are  
2 equally stressed and anxious when they are discharged  
3 from the Emergency Department, we know from a study by  
4 Engel in Annals of Emergency Medicine that 78 percent  
5 of English-speaking patients -- and this doesn't even  
6 attempt to address the problem with non-English  
7 speakers -- 78 percent of patients do not understand  
8 their discharge instructions.

9           So it is reasonable I think to assume that  
10 iodine-131 patients are equally challenged due to  
11 stress and complications, and all of those other  
12 things, to be able to follow those instructions  
13 adequately.

14           The CardioGen strontium/rubidium generator  
15 issue that we are going to discuss later I believe  
16 also raises an issue about disclosure. If the patients  
17 exposed do not reach the threshold for medical event,  
18 it is questionable whether they will be told that they  
19 have been exposed to a potentially damaging isotope  
20 inadvertently.

21           So these are the kinds of issues that are  
22 within the realm of patient advocacy that have become  
23 -- come before this Committee. And this is a list of  
24 references that I have cited.

25           Thank you very much for your attention.

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1                   ACTING CHAIR THOMADSEN: Thank you very  
2 much for your presentation. Questions or comments from  
3 the Committee?

4                   MEMBER ZANZONICO: I have a question. It is  
5 sort of a general question. There are often issues in  
6 terms of communicating with patients where there is  
7 controversy, if not out and out disagreement among  
8 themselves, regarding the level of hazard, if any. And  
9 this is certainly the case with respect to radiation  
10 controversy, like the linear non-threshold hypothesis,  
11 et cetera, et cetera.

12                   How does one deal with that? In other  
13 words, how does one kind of candidly convey hazard or  
14 lack of hazard in the face of uncertainty or  
15 controversy among specialists in the field?

16                   MEMBER WEIL: That's an interesting  
17 question, and you could zoom out a bit and look at  
18 regional variations of practice. Also, in that  
19 different recommendations will be made to patients  
20 depending on where they seek care, there are regional  
21 preferences, there are regional sets of beliefs, one  
22 could look at this as medicine in the normative  
23 tradition.

24                   I don't know the answer to your question  
25 specifically. One says that medicine is an art rather

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1 than a science, and I suspect that there is some truth  
2 to that about radiation exposure as well, the way one  
3 interprets the modeling and the numbers. I really  
4 can't answer you, but it is a very interesting issue.

5 ACTING CHAIR THOMADSEN: Thank you. Any  
6 other questions? Dr. Welsh.

7 MEMBER WELSH: A couple of comments and  
8 questions. One, I am not sure I would agree with one  
9 of your statements, and correct me if I misunderstood  
10 what you said. But as far as disclosures and  
11 transparencies on your second-to-the-last slide, you  
12 mentioned that much of this is certainly not taught in  
13 medical school.

14 I'm not sure where that statement comes  
15 from, because as far as I know almost all medical  
16 school curricula in the United States do incorporate a  
17 good deal of ethical training in the curriculum now.  
18 And examples would be the courses called Patients,  
19 Ethics, and Society, and a variety of other names. But  
20 I would take issue with that particular statement.

21 MEMBER WEIL: Yes. And I probably wasn't  
22 clear about what I meant. What I was talking about was  
23 very few residents have an opportunity to witness an  
24 attending physician have a disclosure discussion with  
25 a patient in the hospital.

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1           It is to say, they just don't get the  
2 chance to witness it done well, and mostly that is  
3 because those discussions, if they happen, happen in a  
4 very private way with the physician and the patient,  
5 and rarely are residents invited into that process. At  
6 least that is my experience in my hospital career.

7           MEMBER WELSH: I would reply that that has  
8 not been my experience. And most of the time the  
9 residents are asked to witness these types of  
10 discussions, which may happen once or twice,  
11 fortunately, during a four-year residency training  
12 program, for example. But that has not been my  
13 personal observation.

14           That leads me to another question, which  
15 is, in order for a physician to demonstrate competence  
16 or capability in taking care of patients in his or her  
17 chosen specialty, they must go through required  
18 training and educational experience, residency  
19 program, medical school, et cetera, and then go on to  
20 take a rigorous board of specialty board examination  
21 to become board-certified.

22           How does one become an adequate patient  
23 advocate? And the question comes up because I wonder  
24 how a patient advocate can truly assure that he or she  
25 represents and advocates on behalf of the patients and

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1 truly reflects those desires and opinions of the  
2 patients.

3 And in the patient release controversy  
4 that is before the ACMUI, we are hearing statements  
5 that patients want this, patients want that, but it  
6 becomes confusing as to how we can know that the  
7 statements that I am reading about what patients want  
8 are truly correct. Can you enlighten us on this?

9 MEMBER WEIL: Well, the first rule of  
10 Advocacy in general with a capital A, I mean, not just  
11 patient advocacy but advocacy when you are  
12 representing someone, you have to take yourself as  
13 much as possible out of the equation and attempt to  
14 represent what you hear from your client or from the  
15 community that you are advocating for, and to try to  
16 actuate those desires separate from any personal bias  
17 that you might have.

18 Now, one only does that imperfectly, of  
19 course. But one has to attempt to do that in an  
20 impartial way.

21 I am not sure particularly which  
22 statements you are referring to, but I can tell you  
23 that when I talk about the iodine-131 patients I spent  
24 a long time talking to patients at the Thyroid Cancer  
25 Survivors Association's meeting in December, talking

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1 about their experience with patient release.

2 I have no personal experience there, so I  
3 am not talking about my own experiences. I am talking  
4 about what patients have told me.

5 And the best that I could answer that  
6 question is to say that I am simply a recipient of  
7 information from patients and try to represent them in  
8 this Committee. Does that get to what you are at or is  
9 there more?

10 MEMBER WELSH: It does. But it raises the  
11 larger question of how reliable a patient advocate's  
12 voice can truly represent the patient's opinions at  
13 large. And to go back to the controversy at hand with  
14 the I-131 patient release issue, we hear a lot of  
15 opinions, and we hear a lot of comments that these  
16 particular assertions that are made by one person or  
17 another reflect the thyroid patients at large.

18 And I am left scratching my head about  
19 whether or not I can really believe that, because to  
20 my knowledge, unlike what we are trying to do in  
21 medicine, which is move towards evidence-based  
22 medicine, scientific medicine, medicine that is based  
23 on sound scientific improvement principles, I am not  
24 sure that the same is done presently in patient  
25 advocacy.

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1           And, therefore, when I hear that most  
2 patients would like to be kept in the hospital for  
3 their I-131 treatment, I wonder if what I am hearing  
4 is truly reflecting the majority opinion of patients,  
5 or if it might be the opinion of one or two advocates  
6 that may be advocates, maybe they're not correct  
7 advocates. It leaves me questioning the whole process.  
8 I'm not sure how to solve this situation.

9           MEMBER WEIL: I don't think any patient  
10 advocate can presume to speak for all patients. Our  
11 job is simply to raise questions. And you're right,  
12 it's not a scientific process. It probably needs some  
13 testing in some kind of fact-gathering survey to  
14 determine what Patients with a capital P want. But I  
15 don't think that that would really solve anything.

16           I think one could safely say that patients  
17 want to safeguard the public from danger in this  
18 iodine-131 scenario from exposure to radiation.  
19 Whether that means they should be isolated in  
20 hospitals, whether they want to be isolated in  
21 hospitals, whether they simply want better instruction  
22 on how to protect people around them, these are all  
23 open questions.

24           And this advocate's role is to raise  
25 questions, not to prescribe for patients or to presume

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1 to speak for all patients. Patients are very able to  
2 speak for themselves.

3 ACTING CHAIR THOMADSEN: Thank you. Any  
4 other comments?

5 (No response.)

6 Thank you, Ms. Weil.

7 We are running a bit ahead of schedule.  
8 Point of order, can we take up the next item, or do we  
9 break early for lunch?

10 MR. EINBERG: I would suggest we break for  
11 lunch early and take up the item after lunch, in case  
12 people tuned in on the conference line or members of  
13 the public want to listen in on these agenda items.

14 ACTING CHAIR THOMADSEN: Fine. So we stand  
15 adjourned until 1:30.

16 (Whereupon, at 11:43 a.m., the proceedings in the  
17 foregoing matter recessed for lunch.)

18

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

(1:30 p.m.)

ACTING CHAIR THOMADSEN: I would like to call the Committee back to order after lunch.

The first item of business is the report of the Electronic Signatures Subcommittee, which I chaired. You have at Tab 5 the report.

The Subcommittee was charged to look into electronic signatures, and we found that there is already a federal policy on this, which you have in the report. And the government has had standards for electronic signatures since 1999. The policy follows international protocols and was written by NIST, and it approves the use of electronic signatures for documents using passwords or PINs or the types of digitized signatures, as you might find in the supermarket checkouts.

So we find that the Subcommittee was not really necessary, that there is a policy in the government for that, and that we just recommend that the NRC recognize electronic signatures as per the government policy.

I think at this point I would ask if there was a motion by the Committee to accept and endorse the Subcommittee's report.

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1 MEMBER WELSH: So moved.

2 ACTING CHAIR THOMADSEN: We have motion;  
3 Dr. Welsh has made the motion. Do we have a second

4 MEMBER ZANZONICO: Second it.

5 ACTING CHAIR THOMADSEN: We have a second  
6 by Dr. Zanzonico. Discussion?

7 MR. EINBERG: Yes.

8 ACTING CHAIR THOMADSEN: Mr. Einberg.

9 MR. EINBERG: I'd like to thank the  
10 Subcommittee for looking at this issue, and this is  
11 something that, you know, we have been kind of  
12 struggling with for a while to make sure that when we  
13 do implement an electronic signature policy here at  
14 the agency that it doesn't have any kind of  
15 deleterious effect with licensees and it clear and  
16 simple to implement or licensees are already using  
17 electronic signatures.

18 So from that standpoint, did the  
19 Subcommittee find or look at whether this law would  
20 have any kind of negative impact on licensees, or what  
21 impact would this have if we were to adopt this kind  
22 of recommendation?

23 ACTING CHAIR THOMADSEN: In looking at  
24 this, it seemed there would be no deleterious effects,  
25 in that you don't have to do anything in particular;

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1 all this would be doing would be saying that the NRC  
2 could accept from any user in any record an the  
3 electronic signature as were it a written signature.

4 MR. EINBERG: Okay. And then, because there  
5 are electronic signature systems out there. And just  
6 so I'm clear that, you know, that this can show that  
7 they are already complying with this law.

8 ACTING CHAIR THOMADSEN: The policy, the  
9 federal policy, recognizes all of these softwares as  
10 being valid. But they go farther than that to  
11 acknowledge essentially any form of electronic  
12 signature over which the signer has control.

13 MR. EINBERG: I see. Okay.

14 ACTING CHAIR THOMADSEN: That's where the  
15 supermarket-type signatures apply, or if you have any  
16 other way of indicating your approval uniquely.

17 MR. EINBERG: Okay. So some of the things  
18 that we touched upon when the Subcommittee was formed  
19 were issues such as authentication, repudiation, data  
20 integrity, records retention and inspection. And so  
21 this law would address all of these various aspects.

22 ACTING CHAIR THOMADSEN: Yes.

23 MR. EINBERG: Okay.

24 ACTING CHAIR THOMADSEN: It does not  
25 address record retention. That does not seem to

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1 be part of the charge.

2 MR. EINBERG: I guess we were looking at  
3 records inspection. We have a requirement to inspect  
4 hard copy records or be sure the signatures are sound  
5 even if the records are not necessarily hard copy, but  
6 to have records inspectable. And so from that  
7 standpoint we wanted to ensure that, you know,  
8 whatever we adopt is inspectable as well.

9 ACTING CHAIR THOMADSEN: Right. The  
10 electronic signatures would have to be maintained as  
11 any other records.

12 MR. EINBERG: Okay.

13 ACTING CHAIR THOMADSEN: For example, as  
14 far as being able to pull them up if you were being  
15 inspected.

16 MR. EINBERG: Okay. May I turn to the staff  
17 and see if they have any questions?

18 ACTING CHAIR THOMADSEN: Please.

19 MR. EINBERG: From the medical team, are  
20 there any questions or comments.

21 (No response.)

22 There are no questions at this time.

23 ACTING CHAIR THOMADSEN: Fine. Dr. Welsh.

24 MEMBER WELSH: So since electronic  
25 signatures have been used regularly for several years

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1 in medical practice, they have to be compliant with  
2 certain rules, restrictions, regulations, JCAHO  
3 perhaps.

4           Wouldn't it be reasonable to propose that  
5 if it is used and approved by JCAHO that it could be  
6 reviewed by NRC and, if deemed acceptable, adopted  
7 rather than have NRC try to create something new and  
8 independent that would, therefore, have to be reviewed  
9 to be assured that it is JCAHO-compliant as well?  
10 Wouldn't it be easier to go the other way around?

11           ACTING CHAIR THOMADSEN: Do you have any  
12 reason to think there is a discrepancy with the Joint  
13 Commission policy? I would guess that they are  
14 following NIST, which is the policy that we, as a  
15 Subcommittee, have, or rather, are endorsing.

16           MEMBER WELSH: I think you're right.

17           ACTING CHAIR THOMADSEN: Dr. Langhorst.

18           MEMBER LANGHORST: I have a question for  
19 NRC. If when adopting this, is there a chance that NRC  
20 will accept electronic submissions for amendments and  
21 license renewals? Is that coming anytime soon?

22           ACTING CHAIR THOMADSEN: Mr. Einberg?

23           MR. EINBERG: I am not prepared to answer  
24 that right now.

25           MEMBER LANGHORST: That's okay. Just know I

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1 have the question in mind.

2 MR. EINBERG: Okay.

3 MEMBER LANGHORST: As do other RSOs.

4 MR. EINBERG: It has been discussed, but  
5 there are no details so I am not prepared to give you  
6 a definitive answer on that.

7 ACTING CHAIR THOMADSEN: Any other  
8 questions or comments?

9 (No response.)

10 In that case, I will call the vote. All  
11 those in favor say aye.

12 (Chorus of ayes.)

13 Opposed, no.

14 (No response.)

15 And abstentions.

16 (No response.)

17 It is passed unanimously. Thank you very  
18 much.

19 Dr. Welsh, you're back up with the Medical  
20 Events Subcommittee Report.

21 MEMBER WELSH: Thank you, Mr. Chairman.  
22 Thanks for the opportunity to present the fiscal year  
23 2010-2011 medical events summary.

24 Beginning with the 35.200 series, the  
25 diagnostic medical events, we see that there were a

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1 total of four found in the NMED database. One case was  
2 an I-123 treatment that was contaminated with I-131.  
3 An oral I-123 capsule was given, but imaging revealed  
4 peaks for both I-131 and I-123, and it was discovered  
5 that the cap was contaminated with I-131.

6 A total of 380 rad to the thyroid of a  
7 child was estimated.

8 Another case was what is described as a  
9 technical medical event, because it was a very low  
10 dose, but it did exceed what was called for by more  
11 than 20 percent. It was actually just about 21  
12 percent, and the discrepancy was on the order of 20  
13 microcuries. Nonetheless, it meets the definition.

14 Another case was I-123 being intended.  
15 However, I-131 was administered. Five millicuries of  
16 I-131 was given instead of the I-123.

17 In another case, a more concerning case,  
18 an indium-111 octeotride scan was ordered, but  
19 strontium-89 was given. And this is a bit concerning,  
20 perplexing. Apparently, it is due to human error in  
21 which the strontium-90 vial, syringe was picked up and  
22 used instead of the octeotride scan. And a dose of  
23 63 rem to the bone marrow was given.

24 Moving on to the 300 series, there are a  
25 total of nine medical events, but the asterisk there

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1 indicates that a couple of cases are in the gray zone  
2 because no written directive was prepared, because the  
3 intention was diagnostic. But therapeutic isotopes or  
4 doses were administered.

5           There were four I-131 medical events in  
6 this category, two samarium-153 EDTMP medical events.  
7 One case was due to use of a lead syringe, which is a  
8 bit ironic in that the lead syringe has been proposed  
9 to solve one problem but may have inadvertently caused  
10 a new problem.

11           I can tell you that it is difficult to use  
12 the lead syringes when administering this type of  
13 treatment because you can't really see as clearly as  
14 you might need to. All of these cases were perhaps due  
15 to human error.

16           How an I-131 administration could be given  
17 in the absence of written directive is unclear, but  
18 this did happen.

19           Moving on to the 400 series, manual  
20 brachytherapy. The good news is that there haven't  
21 been any manual afterloader medical events for quite  
22 some time now. The last ones were back in 2010.

23           Similarly, there were no strontium-90 eye  
24 application or eye-applicator brachytherapy medical  
25 events.

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1           And the last vascular brachytherapy event  
2 was back in 2010, but very few of these are being  
3 performed nowadays.

4           Unfortunately, the same pattern is not  
5 true for permanent implant brachytherapy. I don't know  
6 if we set any records this past year, but it is pretty  
7 close. Certainly, there is no difference, no major  
8 difference or major improvement in this particular  
9 area. There were 30 medical events involving 94  
10 patients recorded, or rather, reported during this  
11 particular period.

12           Importantly, 81 patients in 17 medical  
13 events were reported during this period but actually  
14 occurred more than six months prior to the period in  
15 question. And some of them were as far back as 2003,  
16 and this corroborates an assertion made by the ACMUI a  
17 while back. This was a pattern that was predictable.

18           As far as the specifics, isotope data was  
19 not available for all the patients, but at least 18  
20 had used palladium-103. Thirty-four at least had  
21 Iodine-125, and at least one patient involved cesium-  
22 131.

23           As expected, the most common cause of  
24 medical events during this timeframe was underdosing  
25 treatment site, for example, D-90 less than 80

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1 percent. And there were at least 39 cases in this  
2 category.

3 The second most frequent cause, as  
4 expected, was overdose based on D-90. There were at  
5 least 18 identified, meaning that at least 60 percent,  
6 and perhaps more, of the medical events in this  
7 category were attributed to this dubious criterion of  
8 the use of D-90.

9 There was one I-125 normal tissue overdose  
10 due to an incorrect seed placement. There was one  
11 medical event using palladium that was a wrong dose  
12 that involved the wrong set of seeds. Two sets of  
13 seeds were ordered. The older set was implanted, even  
14 though it was for May 12, 2011, and the correct set  
15 should have been put in on June 10th.

16 Because this was more than a half-life  
17 difference, there was a significant underdosing  
18 because of the 17-day half-life. This probably would  
19 have been more significant if it was cesium-131, and  
20 maybe less so if it was I-25. But, nonetheless, wrong  
21 seeds qualifies as a medical event of course.

22 Another medical event was reported  
23 involving an aborted procedure. And this one probably  
24 should not be a medical event, because upon my review  
25 of the situation the authorized user did absolutely

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1 the right thing.

2 The authorized user aborted the procedure  
3 after eight seeds were implanted, and the authorized  
4 user realized that the anatomy was going to preclude  
5 adequate placement of the lateral two columns of  
6 seeds, and, therefore, called off the procedure,  
7 because of patient's anatomy. Nonetheless, it was  
8 described as an underdose-based medical event.

9 There was a case involving cesium-131.  
10 That was an overdose due to administration of a full  
11 treatment of 114 gray when the prescription called for  
12 a partial treatment of 85 gray. There was another case  
13 in which the wrong activity was administered. The  
14 seeds were ordered in air kerma strength but delivered  
15 in millicuries. And another overdose was due to the  
16 wrong activity entered into the software. Millicuries  
17 were entered instead of air kerma.

18 These are examples of what we call this  
19 morning standard or expected medical event  
20 definitions. And there are a few patients that fall  
21 into this category every so often. But it might be an  
22 opportunity for getting rid of this particular subtype  
23 of error once and for all.

24 ACMUI has previously recommended  
25 standardization of activity, and I think air kerma was

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1 recommended. I don't know if it would be possible to  
2 enforce that. It was just a recommendation by the  
3 ACMUI. Societies can recommend it, but suppose if a  
4 statement came from NRC. Practitioners would listen,  
5 and everybody would use the recommended units and this  
6 type of error would go away.

7           There was an example of an underdose  
8 attributed to seeds that supposedly moved out of  
9 place. A procedure was done in October, but the  
10 medical event was identified almost six months later,  
11 March of the next year when the patient returned for a  
12 post-implant CT scan.

13           When we have intervals of this long, which  
14 are not advocated, these things can happen. And the  
15 question will always remain unanswered about whether  
16 or not the seeds truly moved or the patient's anatomy  
17 changed. Unfortunately, for this particular authorized  
18 user and medical facility, it is described as a  
19 medical event. But I personally am skeptical that  
20 seeds can truly move, but it underscores the concept  
21 of having scans done at the appropriate time for post-  
22 implant dosimetry.

23           Several licensees had medical events that  
24 involved more than one patient, and one stands out  
25 very obviously. Thirty-five patients, all from the

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1 same facility, were involved in medical events.  
2 Fourteen of these had no written directive, 20 of  
3 these had no post-implant dose recorded, and of these  
4 patients 17 didn't even have post-implant CT.

5 The authorized user was removed from the  
6 license, the program was permanently suspended, and  
7 perhaps this was appropriate.

8 But at another facility there were two  
9 medical events that were identified during a review of  
10 12 cases done in 2008. These were both underdoses  
11 using the D-90 criteria. And, not surprisingly, to  
12 quote the NMED report, "The NRC is reviewing this  
13 event and has not yet determined that it is a  
14 reportable medical event."

15 Nevertheless, in December of 2008, this  
16 facility permanently terminated its program, and the  
17 last procedure was done in December of 2008. One  
18 wonders, in contrast to the previous facility that  
19 shut down, which was appropriate, whether this was  
20 perhaps unnecessary.

21 Perhaps the most interesting thing that  
22 came from our annual review this year were  
23 retractions. Here is an example of a retracted  
24 overdose in which the facility conducted a  
25 comprehensive review of 44 procedures done since 2003.

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1           This particular overdose involved a D-90  
2 that was more than 20 percent of the prescription. But  
3 the overdose was retracted and the medical event was  
4 retracted when a new post-implant dosimetry study, a  
5 post plan was generated which determined that the D-90  
6 value no longer met the reportable criteria.

7           And this slide title should probably say  
8 "Underdoses," but it illustrates the same concept. Two  
9 medical events involving four patients that were based  
10 on calculated underdoses to the prostate that was  
11 believed to be due to prostate swelling. And these  
12 medical events were subsequently retracted after the  
13 team concluded that the pre-dose to the prostate was  
14 in fact within 20 percent of the prescription.

15           Here, are some of the details, which I  
16 won't go into, from the NMED database, that led them  
17 to state that this was due to prostate swelling. Same  
18 thing with the other event which occurred due to  
19 prostate swelling. And this corroborates our point  
20 that we have been making for many years now that there  
21 can be instances in which a calculated dose to the  
22 prostate would meet the definition of "medical event"  
23 and perhaps be a perfectly good implant in reality.

24           Up to this point, it has been largely  
25 hypothetical. So I think these particular events are

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1 important because they document for the first time  
2 what we have been saying for several years now. You  
3 can't have a definition that works on Monday but  
4 doesn't work on Tuesday. That is exactly what is going  
5 on here.

6           These so-called medical events were  
7 retracted upon repeat imaging, at a more appropriate  
8 time perhaps. Importantly, the D-90s in these cases  
9 were initially 44 percent. And that indicates to me  
10 that even our previous threshold of a D-90 of 60  
11 percent might not really represent a true underdose if  
12 that D-90 is calculated during the adenomatous period.

13           And, therefore, my assertion that the use  
14 of D-90 in any form or fashion is perhaps not  
15 appropriate for regulation, and I feel stronger than  
16 ever about that assertion because of this data.

17           As far as Gamma Knife, there were two  
18 events, and this is where the NMED database becomes a  
19 little bit cumbersome. The Perfexion unit is Gamma  
20 Knife treatment. I include it here in the 600 series,  
21 although maybe it belongs in 1000.

22           A dose of 1,600 centigray was prescribed  
23 to multiple lesions, but there was erroneous labeling  
24 of one of the tumor sites resulting in delivery less  
25 than, that is, much less than what was prescribed. And

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1 the hospital suggested that Elekta make improvements  
2 to site identification. So this is an example  
3 involving the Perfexion unit.

4 There was another Gamma Knife medical  
5 event involving Model C malfunction. It was reported a  
6 few months later. The patient was prescribed  
7 2,000 centigray per lesion to 10 separate lesions.  
8 Following treatment of the third lesion, the couch  
9 failed. The physicist and the neurosurgeon entered the  
10 room and manually pulled the couch out of the unit.  
11 The physicist's badge read a dose of one millirem peak  
12 dose and two millirem superficial dose equivalent.

13 This one I am going to save for next year,  
14 because, and I apologize, it is from the next year's  
15 reporting period. So at least we know we will have  
16 something to talk about next year.

17 Moving on to other events in the 600  
18 series, appreciate Dr. Thomadsen for putting together  
19 this table. But you can see that it looks like 12  
20 versus eight, but when you go down to the Gamma Knife  
21 we didn't include Gamma Knife in this particular  
22 table, because some Gamma Knife is in 1000, some is in  
23 600. There were two events there, so the difference is  
24 really 12 versus eight, not very significant.

25 There were no frequently encountered

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1 problems. Two involved lung treatments. Both had  
2 problems with the dwell position identification. One  
3 patient, rather, one event involving two patients,  
4 involved the wrong length, one was the wrong transfer  
5 tube; two breast applicator problems; a lobe puncture  
6 and a SAVI catheter split; and one case in which a  
7 treatment planning problem was encountered.

8           There was one event in the 600 LDR remote  
9 afterloading scenario, that was a biliary treatment  
10 where the catheter shifted during treatment occurred.  
11 The patient only received 124 centigray of the  
12 intended prescription of 2000 centigray. And this was,  
13 again, a low dose rate remote afterloader procedure.

14           Moving on to the Part 1000, there are 11  
15 in this category. Maybe one more for the Perfexion,  
16 three SIR-spheres, eight with the glass microspheres  
17 or TheraSpheres. Not very different from 2010,  
18 although there was a slight increase in the number of  
19 microsphere events in Part 1000 this time around.

20           In fact, in this table where we have LDR  
21 remote afterloader, there probably should be one  
22 there, which I included in the 600 section. And,  
23 similarly, one in the Perfexion, which I included with  
24 the Gamma Knife, which underscores some of the  
25 difficulties we have when using this NMED database

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1 because it is kind of cumbersome. We are used to  
2 reporting things in terms of the CFR, but that is not  
3 the way the NMED database is organized at present.

4 Three of the TheraSphere cases are  
5 described here. One was a misread prescription,  
6 clearly human error; another involved the wrong  
7 artery, interventional team intentionally tried a  
8 different route; in another patient, there was stasis  
9 during the first fraction and pain during the second  
10 fraction, which caused the team to discontinue.

11 And since this is a patient-related  
12 phenomenon, one might argue that the authorized user  
13 and the team did the right thing by discontinuing the  
14 procedure. But it was deemed as a medical event.

15 Eight of the microsphere cases in this  
16 reporting period involved the glass microspheres. One  
17 was the wrong site due to duodenal shunting. Another  
18 was a wrong dose due to an error in ordering. Five  
19 were low doses due to technical problems, such as  
20 clumping, leaking, needle insertion into the vial,  
21 catheter problems. And one was another clear human  
22 error in which the wrong site was treated.

23 And I guess that is pretty much it. There  
24 might be a question, is that a gorilla? This is an  
25 800-pound gorilla in the room that represents the

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1 strontium/rubidium generator situation. And rather  
2 than try to do it just here, we have a special  
3 session, special set of sessions tomorrow which will  
4 address this particular topic.

5 So I will stop at this point.

6 ACTING CHAIR THOMADSEN: Thank you very  
7 much, Dr. Welsh. Do we have questions? Yes, Dr.  
8 Zanzonico.

9 MEMBER ZANZONICO: I am just a little  
10 confused. If you have numbers on the slide with the  
11 permanent implant prostate brachytherapies, it says 30  
12 medical events involving 94 patients. And then, 17  
13 medical events, 81 patients.

14 MEMBER WELSH: Yes.

15 MEMBER ZANZONICO: What I'm  
16 misunderstanding apparently is it's like more patients  
17 than medical events.

18 MEMBER WELSH: Yes.

19 MEMBER ZANZONICO: So what exactly  
20 happened? I mean, I would have thought there would  
21 have been like a one-to-one correspondence

22 MEMBER WELSH: No. This is not uncommon.  
23 When an institution reports a medical event, that  
24 medical event could include multiple patients within  
25 that same event. It has got something to do with the

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1 reporting scheme or the definition.

2 MEMBER ZANZONICO: Okay.

3 MEMBER WELSH: And this is not at all  
4 uncommon.

5 MEMBER ZANZONICO: Okay. So that's a  
6 systemic error?

7 ACTING CHAIR THOMADSEN: This is systemic.

8 MEMBER ZANZONICO: Okay. Okay. So it's not  
9 necessarily a patient by patient accounting.

10 MEMBER WELSH: It is not. In some ways, it  
11 would be better if the number of medical events meant  
12 the number of patients, but this is the way it is  
13 right now.

14 MEMBER ZANZONICO: And so just another  
15 question. So with the proposed change in the  
16 definition of "medical event" from your Subcommittee,  
17 I gather that probably over half of those would not be  
18 medical events?

19 MEMBER WELSH: Perhaps more than 60 percent  
20 would not be.

21 MEMBER ZANZONICO: Yeah.

22 MEMBER WELSH: That's because at least 60  
23 percent of the events were only D-90 failures.

24 MEMBER ZANZONICO: Were based on the D-90.

25 MEMBER WELSH: Yes, were based on D-90.

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1 Now, that doesn't mean that if we used the more  
2 appropriate modern definition that there wouldn't be  
3 medical events in that subset, but the use of D-90 is  
4 probably capturing many inappropriately capturing  
5 events, that is, cases that are not truly medical  
6 events.

7 MEMBER ZANZONICO: And one other question  
8 if I may.

9 ACTING CHAIR THOMADSEN: Certainly.

10 MEMBER ZANZONICO: What was the logic of  
11 the agency in characterizing stopping the treatment in  
12 the case of the TheraSpheres when stasis occurred? I  
13 mean, that sounds like the exactly right thing that  
14 should have been done.

15 MEMBER WELSH: Yes. It would seem that in  
16 that particular case, because of stasis, you can stop  
17 the procedure or perhaps because of medical concerns,  
18 such as pain. The decision should be with the  
19 authorized user and the team to discontinue the  
20 procedure.

21 But I think Dr. Thomadsen might be more  
22 familiar with the specifics in this case, so I will  
23 ask him.

24 ACTING CHAIR THOMADSEN: In the NMED  
25 database where I got the information, it didn't say

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1 anything more than the users said it should be  
2 withdrawn, but the agency said no. That's all I can  
3 tell you. There is no justification.

4 MEMBER ZANZONICO: It doesn't seem to make  
5 sense.

6 ACTING CHAIR THOMADSEN: Yes. Dr.  
7 Langhorst.

8 MEMBER LANGHORST: Yes. And was that NRC  
9 regulated state or an Agreement State, or do you  
10 remember?

11 ACTING CHAIR THOMADSEN: It was an  
12 Agreement State.

13 MEMBER WELSH: I would agree that from the  
14 limited description that we have it probably shouldn't  
15 have been labeled as a medical event.

16 ACTING CHAIR THOMADSEN: Dr. Langhorst.

17 MEMBER LANGHORST: A question I have, and I  
18 don't know that it is tracked in the NMED database,  
19 and I'm still trying to learn that system, and it may  
20 be one that we might want to consider going forward on  
21 the microsphere medical events. It might be  
22 interesting to know if the authorized users are  
23 interventional radiologists or radiation oncologists.

24 I just thought that was a question that I  
25 had as far as, if we have any more, is there any

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1 correlation there. So I just raise the question; not  
2 expecting anyone to be able to answer that, but  
3 for discussion.

4 MEMBER WELSH: I think that is a very good  
5 question that is presently not answered with the data  
6 that is in the NMED database as far as I can tell. But  
7 I think that question is important for the Y-90  
8 microspheres as well as the I-131 thyroid treatments.

9 I would like to know how many events per  
10 year might be due to radiation oncologists, nuclear  
11 medicine physicians versus endocrinologists, who, as I  
12 have stated in the past, in my opinion might not have  
13 the training, well, they do not have the same degree  
14 of training in the use of ionizing radiation as the  
15 other two professionals.

16 It would be very difficult to answer the  
17 overall question of appropriateness of non-radiation  
18 oncologist/non-nuclear medicine physician being  
19 appropriate for being authorized user from this  
20 database, because we don't always have the  
21 denominators.

22 But if we could have denominators and we  
23 could see trends over years, we could answer the  
24 question of whether or not an inordinate number of  
25 medical events can be attributed to those who have

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1 less training than those who have the detailed  
2 residency-focused training.

3 ACTING CHAIR THOMADSEN: I do think that it  
4 is an excellent question, and it is an issue that  
5 needs exploring. I can tell you that in the  
6 microsphere cases that there are none of those that  
7 would have anything to do with who the authorized user  
8 was.

9 Any other comments or questions? Mr.  
10 Einberg.

11 MR. EINBERG: Dr. Howe pointed out that we  
12 do not have a requirement to report who the authorized  
13 user is, and, as such, that's why it is not tracked in  
14 the NMED database.

15 ACTING CHAIR THOMADSEN: Thank you. Any  
16 other comments? Yes, Dr. Van Decker.

17 MEMBER VAN DECKER: Just since Dr. W is our  
18 denominator person, you know, obviously, there is a  
19 lot of prostate brachytherapy programs that seem to  
20 have closed here, do you have any sense, from volume  
21 of denominator, what is going on with the denominator  
22 in that category right now? And then, as an adjunct,  
23 the denominator in the sphere therapy category, is  
24 that going up, one going down, as far as denominators  
25 go?

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1                   MEMBER WELSH: It's a good question.  
2 Unfortunately, I don't have the answer for you this  
3 year. We did have the denominators last year. It is  
4 not a trivial process to obtain them. It is fairly  
5 expensive, and we have elected to collect those  
6 denominators for a more comprehensive report every  
7 other year or every two years rather than annually.

8                   But I can tell you that my distinct  
9 impression, in the absence of proof, I must admit, it  
10 is that prostate brachytherapy continues to decrease  
11 sharply.

12                   MEMBER ZANZONICO: Can I just follow up?

13                   ACTING CHAIR THOMADSEN: Dr. Zanzonico.

14                   MEMBER ZANZONICO: Is that a decrease in  
15 permanent implant brachy or to all sort of invasive or  
16 aggressive forms of treatment of prostate cancer?

17                   MEMBER WELSH: It is probably more specific  
18 to prostate, that is, permanent prostate implant  
19 brachytherapy. There is an increase in the use of  
20 intensity-modulated radiation therapy. There are more  
21 proton therapy facilities available.

22                   But I am not sure that prostatectomy has  
23 taken the same hit as permanent implant brachytherapy  
24 has. It may have; I just don't have the information.  
25 But I know that in the world of prostatectomy the use

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1 of robotic surgery has perhaps kept that process going  
2 strong, whereas a number of factors, perhaps in no  
3 small part the negative publicity of medical events,  
4 has caused a noticeable decline in the use of  
5 permanent implant brachytherapy for prostate cancer.

6 MEMBER ZANZONICO: So it is not related  
7 necessarily to this, you know, this high profile  
8 controversy about the value of PSA and just  
9 aggressively treating prostate cancer as opposed to  
10 watchful waiting and this kind of thing that  
11 is causing it.

12 MEMBER WELSH: Not for this particular  
13 reporting period. In years to come it may.

14 MEMBER ZANZONICO: Right, it may.

15 MEMBER WELSH: But, there could be a sharp  
16 decrease overall, but I don't think for the periods  
17 that we are talking about presently.

18 ACTING CHAIR THOMADSEN: Dr. Suleiman.

19 MEMBER SULEIMAN: Yes. I think I will add  
20 to Dr. Zanzonico's question or answer. I think you are  
21 going to see dynamic changes, both with different  
22 alternative modalities for treatment, some of it being  
23 driven by evidence-based outcomes, some of it being  
24 driven by reimbursement rates, and a whole bunch of  
25 other factors.

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1           So I think it is interesting to consider,  
2 I mean, safety is one of them. So if the medical event  
3 criteria could be trusted to be consistent across all  
4 modalities, it would be a real good metric to see  
5 that, you know, this modality is safer than some other  
6 modality. But I think it is good, but I don't know  
7 why. I think you are probably right about the IMRT  
8 displacing some of this.

9           ACTING CHAIR THOMADSEN: Thank you.

10           MEMBER WELSH: There is no doubt that there  
11 are financial motivations for choosing one treatment  
12 over another or directing patients in one direction or  
13 another. But I think a fact that is supported by the  
14 literature that remains clear, the fact remains that  
15 permanent implant brachytherapy is effective and, if  
16 done properly, is very safe and effective.

17           ACTING CHAIR THOMADSEN: Thank you, Dr.  
18 Welsh.

19           Now we have Mr. Fuller. Are you concerned  
20 that we are too far ahead of schedule? I see you  
21 looking at your watch.

22           MR. FULLER: Excuse me, Mr. Chair.

23           ACTING CHAIR THOMADSEN: Mr. Fuller will be  
24 talking about permanent implant brachytherapy.

25           MR. FULLER: Well, to answer your question,

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1 I was looking at my watch, and we are quite ahead,  
2 well, a bit ahead of schedule. My only concern is is  
3 that sometimes people look at the agenda and they plan  
4 to join in at a particular time. And so if we get  
5 halfway through it, and so forth, I do concern myself  
6 with that. But...

7 ACTING CHAIR THOMADSEN: Would you prefer  
8 for us to take a break right now?

9 MR. FULLER: I will leave it entirely up to  
10 the Committee. It is just a sensitivity that we have,  
11 but it it is up to you.

12 ACTING CHAIR THOMADSEN: Right.

13 MR. FULLER: It is your meeting.

14 ACTING CHAIR THOMADSEN: We understand. Is  
15 there a sense of the Committee? Shall we try to stay  
16 on schedule for those who may be calling into this? Is  
17 there an objection to taking a break now and resuming  
18 at 3:00, when we are supposed to take up this topic?

19 (No response.)

20 Hearing none, we stand adjourned until  
21 3:00.

22 (Whereupon, the proceedings in the foregoing matter  
23 went off the record at 2:12 p.m. and went  
24 back on the record at 2:58 p.m.)

25 ACTING CHAIR THOMADSEN: Welcome back. And

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1 we will pick up with Mr. Fuller's presentation on the  
2 update on proposed changes related to permanent  
3 implant brachytherapy.

4 MR. FULLER: Thank you, Dr. Thomadsen. It  
5 is a pleasure to be here today to provide the ACMUI  
6 with an update on the proposed changes to 10 CFR Part  
7 35 related to permanent implant brachytherapy.

8 The purpose of my presentation this  
9 afternoon is to provide the ACMUI with an update on  
10 the more recent developments related to staff's  
11 proposed changes to the medical event definition for  
12 permanent implant brachytherapy.

13 I know that most of you are very familiar  
14 with the history associated with this issue but for  
15 some of you a brief history may be helpful. And for  
16 all of us, I think a bit of background should add some  
17 context to my presentation.

18 In 2005, the Commission directed the staff  
19 to develop a proposed rule to modify both the written  
20 directive requirements and the medical event reporting  
21 requirements to be activity-based instead of dose-  
22 based, as had been recommended by this committee.

23 In 2008, the Commission approved  
24 publication of a proposed rule to amend pertinent Part  
25 35 sections involving permanent implant brachytherapy.

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1 However, during late summer and early fall of 2008, a  
2 substantial number of medical events involving  
3 permanent implant brachytherapy were reported to the  
4 NRC. Based on its evaluation of that information at  
5 the time, the staff believed that a number of these  
6 medical events would not have been categorized as  
7 medical events under the proposed rule. So in 2009,  
8 the Commission sought further advice from this  
9 committee and directed the staff to work with the  
10 ACMUI to provide recommendations to the commission on  
11 regulatory changes for permanent implant brachytherapy  
12 programs.

13 In 2010, the Commission disapproved  
14 publishing a revised proposed rule and directed the  
15 staff again to work closely with the ACMUI and others  
16 from the broader medical and stakeholder community to  
17 develop revised medical event definitions that protect  
18 the interest of patients, allow physicians the  
19 flexibility to take actions that they deem medically  
20 necessary, while continuing to enable the Agency to  
21 detect failures in process, procedure and training, as  
22 well as any misapplication of byproduct material by  
23 authorized users.

24 Additionally, the Commission directed  
25 staff to hold a series of stakeholder workshops to

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1 discuss issues associated with the medical event  
2 definition, which was done last summer. I would note  
3 that these workshops that the NRC staff learned a  
4 great deal from the medical community about their  
5 needs related to the medical event definition.

6 On Tuesday February 7, 2012, the  
7 committee, the ACMUI, held a public teleconference and  
8 endorsed the ACMUI Permanent Implant Subcommittee  
9 report and provided NRC staff with recommendations for  
10 changes to the medical event definition for permanent  
11 implant brachytherapy.

12 On April 5, 2012, NRC staff provided the  
13 Commission with the staff's recommendations for  
14 changes to the medical event definition. Those  
15 recommendations were in the form of a SECY paper,  
16 specifically SECY-12-0053. The paper was made public  
17 on April 10th, which was last Tuesday, and we provided  
18 to you the entire ACMUI on that same day. This  
19 presentation will focus on the recommendations that  
20 the ACMUI provided to the staff and whether staff  
21 differed from those recommendations in our paper to  
22 the Commission.

23 I should make it clear that my  
24 presentation is not intended to detail the staff's  
25 recommendations but rather to go over those

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1 recommendations that we received from the ACMUI. As I  
2 indicated in the previous slide, we only -- Our paper  
3 was only made public last Tuesday. And so in  
4 preparation for this presentation, there really wasn't  
5 enough time to even develop a presentation on the SECY  
6 paper itself. Next week, Dr. Ron Zelac will be making  
7 that specific presentation to the Commission. And it  
8 is probably appropriate that that presentation be made  
9 to the Commission as opposed to going over a great  
10 deal of detail at this point in time. And again, at  
11 the time that we were putting together this  
12 presentation, while we were very hopeful that we would  
13 have the staff's paper public at this time, we had no  
14 guarantee and I would like to thank those who helped  
15 us make that happen. There were special accommodations  
16 made on the part of the Commission last week to get  
17 this paper out and make it public right away.

18 So again, I will be talking about  
19 primarily what we heard from the ACMUI and how we may  
20 have differed. But then since the paper is public now,  
21 when we get to the end of the presentation and the  
22 questions and answers, I will be happy to address any  
23 questions that folks have about the staff's paper.

24 So, the ACMUI recommendations for the  
25 target if greater than 20 percent of the sources fall

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1 outside the treatment site and as long as that is not  
2 resulting from patient-related causes such as edema or  
3 source migration after placement, the ACMUI  
4 recommended that this situation be defined as a  
5 medical event.

6 For normal tissue, there are two criteria.  
7 For neighboring structures such as the bladder or  
8 rectum and in prostate implants as an example, the  
9 dose to at least five contiguous cubic centimeters  
10 exceeds 150 percent of the dose prescribed to the  
11 clinical target volume or the planning target volume  
12 or for intra-target structures. And again using the  
13 prostate as an example, the urethra in this case, the  
14 dose to at least five contiguous centimeters exceeds  
15 150 percent of that structure's expected dose based  
16 upon the approved pre-implant dose distribution.

17 Other ACMUI recommendations for what would  
18 constitute a medical event involve using the wrong  
19 radionuclide, using the wrong activity or source  
20 strength as specified in the written directive,  
21 delivered to the wrong patient, delivered directly to  
22 the wrong site or body part with the exceptions of  
23 seed migration, edema and other patient-related  
24 factors or source displacement following placement, as  
25 long as the first criteria, a few slides back, is not

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1 violated. In other words, if less than 20 percent of  
2 the seeds are implanted outside the treatment site but  
3 at some distance from the treatment site, then a  
4 medical event has occurred.

5 I recall the discussion on this point when  
6 we were in Houston and I remember that there was quite  
7 a bit of consensus amongst the panelists that this  
8 situation should be considered an ME, a medical event,  
9 that is. However, I want to let folks know that I  
10 believe that the staff will have to be very careful to  
11 ensure that the rule language is crafted in a manner  
12 that makes the requirement clear, concise, and  
13 unambiguous. And I say that because in the current  
14 rule when we think in terms of wrong treatment site,  
15 which is what I think we are really getting to here,  
16 there is a dose-based criteria associated with that.  
17 So I just want to let folks know that I see this as  
18 not insurmountable because we did include it in our  
19 recommendations, but it is going to take some care on  
20 the part of the staff as we develop rule language.

21 Another ACMUI recommended criteria for  
22 what would constitute a medical event is delivering,  
23 using the wrong modality and finally, I mean or using  
24 the leaking sources.

25 Another ACMUI recommendation was that the

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1 authorized user should provide a statement attesting  
2 that the implanted sources have been placed in  
3 accordance with the final plan distribution.

4 So, NRC staff recommendations. What did we  
5 do? The staff incorporated all of the ACMUI  
6 recommendations in the staff recommendations to the  
7 Commission with one exception and I will talk briefly  
8 about that exception.

9 One recommendation from the ACMUI's  
10 revised final report but not incorporated in staff's  
11 recommended medical event criteria involves possible  
12 bunching of implanted radioactive seeds in the  
13 treatment site, instead of being distributed as the  
14 authorized user had planned before the start of the  
15 procedure. We recommended that NRC staff require that  
16 the authorized user affirm in writing on the written  
17 directive after the implant is completed that the  
18 distribution of the sources within the treatment site  
19 was as intended per the pre-implant written directive.

20 The staff contends that appropriate  
21 regulation for patient protection from undeclared or  
22 unrecognized bunching exists through two existing  
23 requirements and the authorizing user affirmation is  
24 unnecessary.

25 One of the existing requirements is the

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1 present 10 CFR 35.40 entitled "Written Directives"  
2 section that requires completion of the written  
3 directive after the implantation. This affords the  
4 authorized user an opportunity to acknowledge any seed  
5 bunching that may have been done intentionally or that  
6 may have been unavoidable.

7           The second existing requirement is in the  
8 present 10 CFR 35.41 "Procedures for Administrations  
9 Requiring a Written Directive." This section requires  
10 licensees to develop, implement, and maintain written  
11 procedures that provide high confidence that, among  
12 other things, each administration is in accordance  
13 with the written directive and, if applicable, with  
14 the treatment plan. To accomplish this objective,  
15 these written procedures have to include conducting  
16 post-implant assessment of each implant procedure.  
17 Bunching that is not declared and explained in the  
18 preceding written directive would become apparent  
19 through this assessment and follow-up medical  
20 remediation could be considered.

21           Moreover, this paper includes a  
22 recommended medical event criteria involving observed  
23 dose to normal tissue structures. In order to evaluate  
24 the doses to normal tissues and structures, or at  
25 least to assess whether variances from expected

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1 results are significant, imaging to determine the  
2 positions and locations of the implanted sources is  
3 essential. Here also, bunching that is not declared  
4 and explained in the written directive would become  
5 apparent and follow-up medical remediation could be  
6 considered.

7 Okay, so what are the next steps? There  
8 are actually a couple that are missing on this slide.  
9 My apologies.

10 Okay, as I mentioned before, next week we  
11 have a Commission meeting on April 24th where staff,  
12 NRC staff as well as two members of the ACMUI and  
13 other stakeholders will be addressing the Commission  
14 on this issue and discussing the staff's  
15 recommendations. After that meeting, and one of the  
16 main purposes of that meeting is to help the  
17 Commission prepare as they get ready to vote on  
18 staff's recommendation. So after that and hopefully  
19 fairly soon, we will be receiving the Commission  
20 votes. And then typically the way that works, is once  
21 they have all voted, then based upon what they say, we  
22 get what is called a Staff's Requirement Memorandum,  
23 or an SRM. And it is in that SRM that we will be given  
24 the direction on what to do next in the form of  
25 rulemaking.

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1 Two more points I would like to -- two  
2 more things in the process that I somehow  
3 inadvertently left off of the slides that you see but  
4 are on my slides is shortly after we get the SRM we  
5 can begin developing what is called a regulatory  
6 basis. A regulatory basis is what our rulemakers need,  
7 the folks that are specialists when it comes to  
8 developing rules and new regulations. That regulatory  
9 basis will be developed by the NRC staff or staff from  
10 the medical team and then provided and once accepted  
11 by the folks who do the rulemaking, then we can  
12 incorporate this into the expanded Part 35 rulemaking  
13 effort which is currently underway.

14 So then after that, we will have hopefully  
15 in a reasonable amount of time, a proposed rule. So  
16 again, our plan is and our hopes are that this will be  
17 incorporated by the end of the summer into the  
18 expanded, the ongoing expanded Part 35 rulemaking. I  
19 know we have discussed that a number of times in the  
20 past and that proposed rule should be out and again,  
21 we don't have a hard and fast date right now but our  
22 hopes are to have that late, at the very earliest,  
23 would be the very end of 2012. More likely, it would  
24 be sometime next spring, springtime of 2013.

25 That concludes my presentation. I am happy

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1 to answer any questions. As I indicated before, when  
2 we put this together with had great hopes that the  
3 permanent implant brachytherapy, that the staff's  
4 recommendations to the permanent implant brachytherapy  
5 program would be public and I have had people say that  
6 they are. But that was just last Tuesday.

7 ACTING CHAIR THOMADSEN: Any questions for  
8 Mr. Fuller? Yes, Ms. Weil?

9 MEMBER WEIL: Can you help me understand  
10 the imaging requirement, which isn't really a  
11 requirement, I gather, but it is somehow implied in  
12 your slide number 11.

13 MR. FULLER: Yes, and let me go to our  
14 actual paper on this because I want to make sure that  
15 I get this just right.

16 One of the things that we did here, loud  
17 and clear from the workshops last summer, was a strong  
18 consensus that post-implant imaging should be a  
19 requirement. And so we have incorporated that. Let me  
20 see if I can find it exactly but we have incorporated  
21 that in our recommended changes to the Commission. So  
22 in fact if the Commission agrees that that should be a  
23 requirement, then that will be a new requirement.

24 MEMBER WEIL: And what is the nature of  
25 that imaging requirement timing-wise?

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1 MR. FULLER: Well the timing is in our  
2 recommendations to the Commission would be within 60  
3 days. So our understanding from what we heard during  
4 the workshops and from what we heard from this  
5 committee is that 30 days is, for the majority of  
6 cases, for I guess standard, if you will, for post-  
7 implant imaging and dosimetry. But we have also heard  
8 that there are exceptions and there are cases in which  
9 folks really can't get back exactly when they need to  
10 and so forth and so on.

11 So for our recommendations in the paper,  
12 we suggested a time frame of 60 days, which should  
13 give people ample time. And again, there are certainly  
14 situations where someone might not be able to get back  
15 at all and there should be or there are provisions in  
16 our recommendations as well for that.

17 But to get to your point and to answer  
18 your question directly, we believe that the  
19 requirement to have policies and procedures in place  
20 that provide high confidence that the procedure is  
21 conducted in accordance with the authorized user's  
22 written directive or intention, coupled with this new  
23 recommendation for post-implant imaging would provide  
24 the licensee with ample information and data to be  
25 able to make an assessment on this bunching issue.

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1 ACTING CHAIR THOMADSEN: Dr. Zanzonico.

2 MEMBER ZANZONICO: So I have a question  
3 that is about the ME based on seeds implanted directly  
4 into the wrong site of the body. Now I think as you  
5 said on the slide, that would be first to sort of  
6 remote sites from the target site. So for neighboring  
7 sites or intratarget normal structures, that is  
8 accounted for by the dose-based criteria.

9 MR. FULLER: Right and we followed the  
10 ACMUI recommendation. In fact, both of these are ACMUI  
11 recommendations.

12 MEMBER ZANZONICO: Right. So this, I guess  
13 it is 4D in one of your write-ups, this refers to  
14 seeds being implanted more remote than neighboring  
15 sites.

16 MR. FULLER: Yes.

17 MEMBER ZANZONICO: And it says, this again  
18 is a little picayune but it says seeds, plural. I  
19 mean, is there some regulatory specification of number  
20 of seeds or just any seed or seeds that wind up remote  
21 from the intended target?

22 MR. FULLER: Right, and when we were  
23 discussing this again, I think it was discussed  
24 briefly, very briefly in New York but it was actually  
25 a topic that got quite a bit of discussion in Houston

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1 where folks discussed the fact that any number of  
2 seeds. So I could have said seed or seeds that are  
3 implanted clearly as a mistake that that ought to  
4 constitute a medical event.

5 There was very, very strong agreement it  
6 seems, which actually surprised me a little bit. And  
7 when I went back over it again the next day and  
8 summarized everything, no one disagreed with me when I  
9 said this is what I thought I heard.

10 And so the way that we think of this and  
11 the language that has been in and around the rule for  
12 a long, long time, although not in the current rule  
13 specifically like this, we refer to these instances or  
14 these cases as wrong treatment site, which is  
15 different than normal tissue normal structure, which  
16 is in close proximity. So, I really believe that we  
17 will be able to deal with that effectively but I just  
18 wanted to remind folks that in the past, wrong  
19 treatment site has a dose-based criterion associated  
20 with it and this recommendation did not. And again,  
21 not that we can't deal with that but I think what  
22 types of questions that I expect to receive as we work  
23 on this language is that how far is far. How far away  
24 is far away? How far away is distant? Those are the  
25 things that we are going to have to wrangle with. And

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1 again, I think we can be successful but I also think  
2 that we are going to have to be careful, that we do  
3 not write proposed rule language that ends up putting  
4 us in a situation where we now have an interpretation  
5 that was something that, you know, in other words,  
6 unintended consequences for things like this or things  
7 that I am concerned about and I think all of the  
8 medical team is a little concerned about at this  
9 point.

10 MEMBER ZANZONICO: Can I just follow-up?  
11 Can I just ask a question for some of the brachy  
12 specialists on the committee?

13 And this is completely my own ignorance  
14 but what I picture in terms of seed implantation is a  
15 seed gun or some dispenser that is inserted into  
16 tissue. Is it always, is the tip of the gun, for lack  
17 of a better term, always inserted directly into the  
18 target tissue or do you sometimes have to traverse  
19 normal structures to get the intended point of  
20 deposition into the target structure or is the target  
21 structure always exposed?

22 ACTING CHAIR THOMADSEN: Dr. Welsh.

23 MEMBER WELSH: I'll take a stab at  
24 answering that question.

25 You would almost always traverse some

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1 normal tissue in order to get to your target in  
2 clinical practice. The only way around that would be  
3 with an intra-operative approach and intra-operative  
4 brachytherapy is a very different situation from what  
5 we are generally talking about here.

6           What we are generally talking about here  
7 alludes to primarily prostate brachytherapy. But the  
8 reason why this bullet point D is so critically  
9 important is because we have generalized beyond  
10 prostate brachytherapy. And I think the majority of us  
11 feel that if your aim is to treat the left breast and  
12 you put a seed in the right breast, even if it is one  
13 seed, you have committed an error. And if your  
14 intention is to implant the prostate and you start  
15 implanting the lung, there is a major error, whether  
16 it is one seed or how many. So in that context, wrong  
17 site is a medical event irrespective of how many seeds  
18 have placed.

19           MEMBER ZANZONICO: I guess what I am trying  
20 to get at is, you know envisioning simple mindedly  
21 this insertion method. Is it possible someone could be  
22 too quick on the trigger, so to speak and  
23 inadvertently deposit or insert a seed along the path  
24 of the needle near but not in the intended site and  
25 should that not or not be an ME?

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1 MEMBER WELSH: I think I can reply to that.

2 ACTING CHAIR THOMADSEN: Dr. Welsh.

3 MEMBER WELSH: That scenario that you are  
4 describing does not uncommonly occur. With prostate  
5 brachytherapy, for example, when we withdraw the MIC  
6 applicator, the seeds can be vacuumed back out of the  
7 area that they were originally correctly implanted  
8 into and, therefore, you can have this migration  
9 effect. But I think that is very different from being  
10 quick to jump the gun when you are in completely the  
11 wrong organ. And if you are in the wrong organ, the  
12 wrong body site, there is no excuse for that. And that  
13 is why I think wrong site belongs here. But we do have  
14 to be careful when we are talking about seeds that  
15 have migrated into the perineum or into the bladder or  
16 have migrated through and wound up embolized in the  
17 lung, which does happen with prostate brachytherapy as  
18 an example. But those seeds were not directly placed  
19 in the wrong site.

20 MEMBER ZANZONICO: Okay. That was my  
21 concern.

22 ACTING CHAIR THOMADSEN: Dr. Langhorst.

23 MEMBER LANGHORST: The question that I have  
24 is on the attestation. And your point is that the  
25 current regulations allow the authorized user in that

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1 final completion of the written directive  
2 clarification on what actually was able to be  
3 implanted. Is that correct?

4 MR. FULLER: Again, that is a piece of it.  
5 I think what we tried to describe in our paper was  
6 that there are three things that in combination makes  
7 the need, in staff's estimation, the need for a  
8 written attestation unnecessary.

9 So it is not just the fact that there is  
10 an opportunity for the post-implant -- completion of  
11 the written directive after implantation but before  
12 completion of the procedure, which we also have tried  
13 to clarify in the staff's recommendations.

14 But that coupled with the requirement that  
15 you have policies and procedures that provide high  
16 confidence and coupled with what we are recommending  
17 as a new requirement for post-implant imaging, that  
18 those three things together make the need for a  
19 written attestation to be unnecessary.

20 MEMBER LANGHORST: Okay, my question is on  
21 the completion of the written directive. If a  
22 physician authorized user cannot implant all the seeds  
23 that were planned as we had talked about in one of the  
24 medical events, is that still a medical event if the  
25 physician documents that they changed their mind or

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1 were unable to do that? Are you recognizing that that  
2 may not be a medical event? Is that -- I'm trying to  
3 get is that what you are allowing for here or am I  
4 stretching it too much?

5 MR. FULLER: I certainly don't want to try  
6 to get out ahead of where we might be directed. But  
7 the current recommendations from the staff really  
8 don't change any aspect of it very much. The only  
9 thing we did was clarify what was the completion of  
10 the procedure. I think you will still need to compare,  
11 in general terms, what was intended and what did you  
12 achieve. And it is really that now.

13 And this is really where we get ourselves  
14 in a bit of a pickle, I guess, and it is always  
15 imperfect because you are going to have some  
16 situations where you simply did not successfully  
17 complete the procedure. There are going to be other  
18 cases -- and I mean for whatever reason it was  
19 unavoidable.

20 You are going to have other situations  
21 where mistakes were made. And so we have to have a  
22 rule that sort of accounts for that as well. So while  
23 our direction from the Commission was that we needed  
24 provide the medical or the authorized user or the  
25 medical professionals the flexibility that they need

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1 to be able to react to things that unforeseen. We have  
2 to provide -- We have to be accommodating to that  
3 situation.

4 What we want to avoid and what we will be  
5 working on when we actually develop the real language  
6 is that situation where someone simply didn't do what  
7 they really wanted to do, they recognize that they  
8 haven't and then they have changed the written  
9 directive to document what they did and not what they  
10 intended to do. And that is still something that we  
11 are struggling with and we are hoping to get more  
12 clarification.

13 ACTING CHAIR THOMADSEN: Dr. Suleiman.

14 MEMBER SULEIMAN: I have two or three  
15 questions but one of them sort of tails with yours  
16 because I am still confused.

17 You go in, you have got 50 seeds,  
18 arbitrary number. You wind up implanting 40 of them.  
19 You think you have put them in very randomly, very  
20 uniformly, I mean and so I think this is an enough. I  
21 would like to stop there and recalculate the dose and  
22 figure maybe you need to go back and do a second  
23 procedure. Would that be a reportable event? Or they  
24 go in and they deviate and then they say we deviated  
25 from the written directive and this is why. Would that

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1 be a reportable medical event?

2 MR. FULLER: No, it shouldn't --

3 MEMBER SULEIMAN: Okay.

4 MR. FULLER: -- because again, the  
5 objective is to make sure that the dose that was  
6 delivered was what was intended, recognizing,  
7 especially in these types of manual procedures, that  
8 the medical practitioner has to have the flexibility  
9 to react to things that happen or that they find or  
10 they discover while they are in the middle of a  
11 procedure.

12 MEMBER SULEIMAN: Okay now my other two  
13 much more black and white questions. Wrong site. Now  
14 there is a difference between left or right, wrong  
15 patient, and unintended migration from an adjacent  
16 site. One is, I think, within that gray area of  
17 uncertainty associated with the practice of medicine  
18 and the inherent precision or lack thereof. Another  
19 one is just a flat out mistake.

20 And the second question, which is kind of  
21 related to that, I think I know the answer which is  
22 why I am asking it. If somebody writes the written  
23 directive wrong, puts a decimal point, is off by a  
24 factor of ten but they go ahead and administer the  
25 written dose appropriately but they are off by a

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1 factor of ten, that is not a medical event. Correct?

2 MR. FULLER: That is always -- Yes, the way  
3 the rule is currently written is that if you make a  
4 mistake when you write the written directive and then  
5 you carry out the procedure in accordance with that  
6 written directive, it is not a medical event. That is  
7 true.

8 MEMBER SULEIMAN: That runs counter to the  
9 intent of all of this. I mean, if people make an  
10 honest mistake, they need to be able to fess up to it.  
11 A patient's health may be --

12 MR. FULLER: Agreed. I think -- Well I  
13 don't want to speculate. Go ahead.

14 MEMBER LANGHORST: I'll speculate. Sue  
15 Langhorst. It is not correct but is that where NRC can  
16 regulate? I mean, that is, again, that is the practice  
17 of medicine and maybe that is how the physician wanted  
18 to make that written directive and it may be wrong in  
19 every other circle but NRC can't regulate everything  
20 medically.

21 And you are right, it is not the correct  
22 thing to do for the patient and it should be looked at  
23 in another round, but does it have to be in the NRC  
24 space? You have to define it in some way.

25 MEMBER SULEIMAN: Well, I don't care if the

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1 NRC doesn't regulate it as such. I would hope that  
2 somebody could assure me that that is covered by his  
3 professional practice or the hospital or something.  
4 But I would think, if nobody else is picking it up,  
5 then the NRC should pick it up.

6 I mean, writing a mistake that gives you  
7 -- and it is easy to do with our base ten system, you  
8 can be off by a factor of ten. And that does happen.  
9 That does get picked up periodically.

10 MR. FULLER: Yes, I mean I will say this  
11 about that. We do, as a matter of policy, which all of  
12 these rules have to be in compliance with -- you know,  
13 our Commission has issued a statement on the medical  
14 use of radioactive material. And it is clear that when  
15 it comes to therapy that it is okay, if you will, or  
16 appropriate in accordance with the Commission to  
17 regulate the use of this. But we are limited in that  
18 our regulations should be such that they are to ensure  
19 that what the authorized user has written in their  
20 written directive is what the other folks that they  
21 work with comply with.

22 In other words, licensees have to have  
23 policies and procedures in place to ensure that what  
24 the written directive says is what is ultimately  
25 carried out. And so that is the way it is currently as

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1 a matter of policy.

2 So I don't know if that is entirely  
3 satisfactory but -- And again, this whole thing about  
4 the post-implant written directive completion and so  
5 forth and so on, you know again that is one of those  
6 situations which we have struggled with for many years  
7 because of the fact that we really need to be very --  
8 We are treading a thin line there as far as getting  
9 over into regulating the practice of medicine and we  
10 have to be very careful.

11 ACTING CHAIR THOMADSEN: Any other  
12 questions? Dr. Welsh.

13 MEMBER WELSH: I don't want to belabor this  
14 point unnecessarily but I would just say that I think  
15 I disagree with Dr. Langhorst's assertion that this  
16 should not be NRC territory. Because when we are  
17 talking about written directives and deviations from  
18 the written directives, I can't think of anything else  
19 that would cover such controversies.

20 And in my opinion, like I said I don't  
21 want to get too far off the main point, if there is  
22 something wrong with the written directive,  
23 irrespective of whether the treatment was done in  
24 exact accordance with the mistake in the written  
25 directive or done differently, something is wrong and

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1 I would think that that should be of interest to NRC  
2 and perhaps qualifying as a medical event. But I don't  
3 think that that is the main gist of the topic here and  
4 I don't want to stray too far.

5 ACTING CHAIR THOMADSEN: Dr. Langhorst.

6 MEMBER LANGHORST: My point is that NRC  
7 cannot, I mean, it is not how the NRC regulations are  
8 written right now. So if it is in accordance with what  
9 the written directive said, that that is where NRC  
10 space is. If the written directive is wrong, NRC does  
11 not have authority under its current regulations.

12 Now, granted it needs to be looked at  
13 because patient safety, correct medical procedures and  
14 so on. That still goes on in looking at what went  
15 wrong. And as an RSO, I look at those things because I  
16 consider it a near-miss and I would like to know what  
17 went wrong here and how we can make sure it is  
18 unlikely to happen again?

19 So my only point was NRC doesn't have that  
20 regulatory authority at this point in time. That is  
21 not to say that you should not look at the event and  
22 correct what went wrong.

23 ACTING CHAIR THOMADSEN: Dr. Welsh.

24 MEMBER WELSH: A quick response would be  
25 that I understand and I recognize the controversy and

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1 the problem but as we saw from our medical event  
2 report this morning there were occasions where the  
3 intention was to give partial treatment and full  
4 treatment is administered for prostate brachytherapy  
5 as the example and they were flagged as medical  
6 events.

7 So there is precedent for treatment that  
8 is delivered that is not what was intended being a  
9 medical event. And so logically it would make sense if  
10 what is written down is not what was intended,  
11 particularly if it was followed, should be a medical  
12 event. It would seem illogical that if my intention  
13 was to give a partial treatment to the prostate  
14 because they are going to get external beam and I give  
15 a full treatment, it is a medical event, unless I have  
16 written that I -- If I have made two mistakes, it goes  
17 away but if I made one mistake it is labeled a medical  
18 event.

19 So there seems to be something  
20 inconsistent there that might be subject for a future  
21 discussion and examination.

22 ACTING CHAIR THOMADSEN: Thank you, Dr.  
23 Welsh. Any other comments? Yes, Dr. Suleiman.

24 MEMBER SULEIMAN: Yes, this is directed to  
25 Dr. Langhorst. So if the NRC doesn't look into it, who

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1 would catch that factor of ten error? Okay? If NRC  
2 can't get involved, who, which agency, which  
3 professional group, which institution will hold that  
4 individual responsible for making a factor of ten  
5 mistake?

6 I mean if that exists, then this is a moot  
7 argument but I want to know where is the assurance  
8 that the patient is going to get the right dose or if  
9 a mistake has occurred they uncover it? I mean, if you  
10 can answer that, then I will back off.

11 MEMBER LANGHORST: Well, I mean I can't  
12 tell you a federal agency who would be looking at that  
13 but in looking at review of patient charts and this  
14 looks like an error, then in my institution they would  
15 look at what went wrong in having a factor of ten  
16 mistake. And it may be that we find so that a medical  
17 physicist would know to question that perhaps in the  
18 future if it was greatly outside the norm. But I can't  
19 tell you a federal agency that would be looking at  
20 that or a regulatory agency that would be looking at  
21 that. It is how you look at errors in any medical  
22 practice.

23 ACTING CHAIR THOMADSEN: Dr. Guiberteau.

24 MEMBER GUIBERTEAU: I agree with Sue. I  
25 mean, I think there is no guarantee that even if you

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1 made this a regulation that it would be caught because  
2 physicians in practice are able to use drugs off-label  
3 at their discretion. They are able to use their  
4 judgment to apply, even if that is faulty judgment,  
5 the doses of drugs or radioactivity that they feel is  
6 appropriate. If they are in error, there are  
7 procedures in most institutions, well in fact all  
8 institutions that are accredited, in terms of peer  
9 review committees, departmental peer review  
10 committees. And almost every accredited organization  
11 requires, you know, institution requires peer review  
12 which includes chart reviews. And there are also state  
13 medical boards that cover these issues if there are  
14 breaches that come up that cannot be cured at the  
15 local level.

16 You know, I think it is a difficult  
17 problem. And I do understand the concern. On the other  
18 hand, I don't think that the NRC's purview or intent  
19 is to tie the hands of those of us practicing  
20 medicine. And I would strongly agree with Sue that  
21 this is not an area that we need to get into.

22 I think that if there is overwhelming  
23 evidence about this, that it can be addressed through  
24 various professional societies and state  
25 organizations, if you feel it isn't strenuous enough.

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1 But I don't think we need to tie the hands of honest  
2 folks practicing medicine. A mistake is a mistake, not  
3 matter where it occurs. But on the other hand, it  
4 isn't a mistake, I think, in terms of the regulations.  
5 If it is not a mistake in terms of the regulations, I  
6 don't think that we should be involved.

7 ACTING CHAIR THOMADSEN: Dr. Welsh.

8 MEMBER WELSH: I didn't want to belabor  
9 this point but it seems like the subject is going on.  
10 I would have to strongly disagree with the statements  
11 I have just heard. And the reason is that if we are  
12 talking about written directives, this is an NRC term.  
13 And I can tell from, maybe it is just my personal  
14 experience but when I talked about written directives  
15 to hospital administrators or even other physicians  
16 who are outside the specialties represented at this  
17 table, they are clueless. And therefore, I am not  
18 confident that when there is some discrepancy within  
19 the written directive, that anybody other than the NRC  
20 or the states would be able to step up and address  
21 this particular concern.

22 I am not as confident that other  
23 professional organizations or other entities within  
24 hospitals or advocacy groups are going to want to  
25 tackle questions relating to an NRC definition, which

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1 is the written directive. And outside of the NRC  
2 environment, written directive is a foreign concept to  
3 many medical practitioners and administrators.

4 MEMBER GUIBERTEAU: Dr. Guiberteau. As much  
5 as I understand that concern, I don't think it is  
6 grounds for the NRC to invade the practice of medicine  
7 and that is exactly what you are asking the NRC to do.

8 ACTING CHAIR THOMADSEN: Dr. Welsh.

9 MEMBER WELSH: Well I strongly disagree  
10 with that assertion because if a mistake is made, and  
11 that is we are talking about, errors in the written  
12 directive, irrespective of whether the procedure is  
13 carried out in accordance to that erroneous written  
14 directive or not, a mistake has been made. And  
15 therefore, I don't think that it is NRC encroaching on  
16 medical practice if they say a mistake has been made  
17 using, in respect to our term, the written directive,  
18 and we are going to investigate. So I am not sure that  
19 this is really encroaching on the practice of medicine  
20 but I feel that this conversation is going,  
21 encroaching on territory that might not be relevant to  
22 Mr. Fuller's initial discussion.

23 ACTING CHAIR THOMADSEN: Dr. Suleiman.

24 MEMBER SULEIMAN: Yes, my intent here was  
25 just to calibrate. I thought that somebody who is off

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1 by a factor of ten was more dangerous than being off  
2 by misplacing the treatment field a little bit  
3 adjacent. And so I just want to be assured that  
4 somebody, people if they are going to be off by a  
5 factor of ten and there is no ramifications for that,  
6 then they may continue to not worry about it. So I  
7 think there has to be something to constrain such  
8 really wrong behavior.

9           Whereas, I think sometimes the imaging and  
10 the slight migration in my opinion may be over  
11 regulation; whereas, I think in this case it is almost  
12 ignoring where it is very safety related. I think I  
13 just want to hear that there are other methods that  
14 are picked up that force the user to make sure that  
15 when they write something they are doing it correctly.

16           I mean, that is what the whole medical  
17 physics community is around, making sure you are  
18 documenting.

19           MEMBER GUIBERTEAU: Again, that is what  
20 peer review is for and that is what peer review is all  
21 about. For instance, if I review a chart that Dr.  
22 Welsh has treated a patient and I look at his written  
23 directive and say my goodness, I would have treated  
24 with one and a half times this dose, is that then a  
25 mistake? You know, if he did what he wrote on the

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1 written directive, then that is what he intended to do  
2 and what he did. Whether it agrees with my assessment  
3 of what he should have done is entirely different.

4 MEMBER SULEIMAN: Well I'm not saying  
5 difference of opinion. I am saying simple mathematical  
6 mistake, where somebody wrote down the wrong number.

7 MEMBER GUIBERTEAU: Well what if the same  
8 occurs on -- What if I write you a prescription for  
9 digitalis and I triple the dose by mistake? Who is  
10 responsible for that? It is a peer review issue if  
11 there are issues with the patient's treatment.

12 ACTING CHAIR THOMADSEN: Dr. Welsh?

13 MEMBER WELSH: I will just quickly counter  
14 that. There is a fundamental difference between a  
15 prescription which we have in prostate brachytherapy  
16 as the example and the prescription for digitalis, as  
17 you were talking about, versus the written directive,  
18 which is an NRC term, and NRC-specific issues that  
19 only the Nuclear Regulatory Commission tells us what  
20 does and does not need a written directive. And  
21 therefore, I still feel that if there is a mistake in  
22 the written directive, it remains in NRC territory and  
23 it wouldn't be outside of their purview to address  
24 this question.

25 The prescription would be a different

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1 issue, however.

2 ACTING CHAIR THOMADSEN: There is also the  
3 problem that, to the best of my knowledge, I don't  
4 think there is 100 percent compliance with peer review  
5 for all cases.

6 Any other comments? Hearing none -- Oh,  
7 Dr. Van Decker.

8 MEMBER VAN DECKER: Well I have a  
9 tangential topic so I want to stop -- I think Dr.  
10 Guiberteau is trying to tell me his length in medicine  
11 by picking digitalis as a medicine, the foxglove  
12 plant.

13 Before you leave and I know I touched this  
14 point this morning and I know that this is -- and I'm  
15 not looking for exact -- There is a lot of different  
16 things going on at the same time. And can I just talk  
17 timeline for a bit? Because I am starting to see how  
18 far this is going so we all have a sense of this.

19 So timeline-wise, stop me at any point in  
20 time that I am incorrect because I am from North  
21 Jersey.

22 You are essentially telling us that we are  
23 going to go into ten months of kind of quiet here.  
24 And during that ten months we are going to see an SRM  
25 clearly on the brachytherapy piece. And I assume you

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1 are intimating that we are going to see an SRM on the  
2 expanded Part 35 because they are coming back together  
3 to be looked at together down the line. And so  
4 therefore, that kind of has to happen before a draft  
5 proposed rule comes out next spring.

6 MR. FULLER: Yes, let me explain that. We  
7 have already sent the paper up over a year ago to the  
8 Commission and explained that our intention, we called  
9 it the Integrated Plan Paper and made a presentation  
10 here on that, where our intention was to include the  
11 expanded Part 35 rulemaking is underway. A lot of  
12 preliminary rule techs has already been drafted and so  
13 forth. A lot of that, there has been a lot of work  
14 done on that. The intention is to fold this into that  
15 rulemaking and then they will work together from that  
16 point. We won't need two Staff Requirements Memoranda  
17 to make that happen.

18 We will get an SRM after this paper is  
19 discussed and so forth. We will develop a regulatory  
20 basis and part of that regulatory basis will be to, in  
21 accordance with what we have already described in the  
22 paper to the Commission to include in that expanded  
23 Part 35. So as long as our Division of  
24 Intergovernmental Liaison and Rulemaking accept that,  
25 then that is exactly what will happen. And we can't

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1 delay the rulemaking schedule from what we described a  
2 year or so ago.

3 MEMBER VAN DECKER: So then from ACMUI's  
4 perspective in October we will still kind of be in  
5 this silent building period and there may be some  
6 general discussion about the SRM but not much as far  
7 as final definitive stuff but some update.

8 MR. FULLER: Right.

9 MEMBER VAN DECKER: Then in the spring of  
10 2013, which I will ask you to define for me as prior  
11 to ACMUI or after ACMUI, there will be a -- I know.

12 MR. FULLER: I can tell you what our hopes  
13 are.

14 MEMBER VAN DECKER: Okay.

15 There will be a draft proposed rule which  
16 I guess most of us would be pushing to before ACMUI so  
17 that we are in the open commentary period and we have  
18 got open commentary period here with the public at  
19 that time. So that would probably be a good time for  
20 us. And then we will be in an official 90-day  
21 commentary period? Remind me again.

22 MR. FULLER: Well, I'm not exactly sure how  
23 long the comment period will be for, probably longer  
24 than 90 days. I will say this, is that ACMUI is in  
25 accordance with your internal procedures, you will see

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1 a draft proposed rule and have 90 days to provide  
2 staff your comments before it is published. And so  
3 there will be a published, again, the hopes, the  
4 objectives are that it be published early to mid-  
5 spring of 2013. It might be late spring. I mean,  
6 really can't hold me down on that because there is  
7 just a ton of work that is involved and a lot of  
8 coordination with various parties.

9 But one of those parties that according to  
10 procedure, because this is a rulemaking-related major  
11 medical policy issue, you will get 90 days before it  
12 published to provide the staff with your comments.

13 MEMBER VAN DECKER: Okay.

14 MR. FULLER: And then once it goes into  
15 public comment period, once it is published it is  
16 public comment, probably 120 days.

17 MEMBER VAN DECKER: Okay. And so then the  
18 next step would be you would see final rule in fall of  
19 '13 before/after ACMUI at that point in time?

20 MR. FULLER: No. Our hopes are to have a  
21 final rule by the end of 2014.

22 MEMBER VAN DECKER: By the end of 2014.  
23 Okay and throughout this period of time OAS will be  
24 part of the discussion for Compatibility B pieces?  
25 Because here is the reminder of where we are trying to

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1 come to closure here. If you see December 2014 as  
2 final rule and then you have three years of OAS  
3 compatibility, you are talking about a final rule in  
4 December of 2017 for any of the stuff we are talking  
5 about right now, whatever minor decisions you want to  
6 make.

7           You know, so then my question becomes --  
8 Here comes the crux of my question. So when you look  
9 at these medical events between 2014 and 2017, will we  
10 get a mixture of medical events on states that have  
11 not yet transitioned using old medical event issues  
12 and NRC states using new medical event issues? And how  
13 will you track the percentage of states changing over  
14 that three-year period of time? And because I am  
15 getting older these days and I have teenagers, I  
16 wonder whether I will live to 2017 or whether they  
17 will live to 2017. It is even money right now.

18           (Laughter.)

19           MEMBER VAN DECKER: And not to be  
20 difficult, I am just trying to get a sense for where  
21 we are because you know, some of these issues over  
22 five years here or six years is going to be a lot of  
23 mixtures here and how we play into where the  
24 commentary periods they are between when they meet and  
25 what moves that along and what OAS does for three

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1 years. Because if you look at the state turnover when  
2 Revise 35 itself went through, it was not -- as a  
3 matter of fact, it 11th hour for the majority of  
4 states.

5 MEMBER BAILEY: That is probably more the  
6 norm than not.

7 MEMBER VAN DECKER: So if 38 states aren't  
8 going to go until 2017, then we at least have got a  
9 line on what we have as a mixture in-between and that  
10 was my only point.

11 MR. FULLER: Point well taken. It is not  
12 something that we have not thought about and  
13 considered and deal with all the time in rulemaking.

14 MS. FAIROBENT: Mr. Chairman, may I ask a  
15 question?

16 ACTING CHAIR THOMADSEN: Yes, a member of  
17 the public, please.

18 MS. FAIROBENT: Lynne Fairobent with  
19 American Association of Physicists in Medicine. Mike,  
20 just to clarify to follow-up on Dr. Van Decker's  
21 timeline, when you had said you anticipate a proposed  
22 rule at the end of this calendar year to sometime in  
23 the spring of 2013, is that a public proposed rule or  
24 is that the proposed rule for the 90-day review period  
25 for ACMUI and OAS?

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1 MR. FULLER: According to our integrated  
2 plan, which we published back I guess about a year,  
3 year and a half ago, we hope to have a proposed rule  
4 published by initially we were saying the end of 2012  
5 but in all reality we recognize now that we are  
6 probably talking a year or so from now.

7 MS. FAIROBENT: Okay. So in actuality what  
8 you are really saying is you hope to have a pre-  
9 decisional proposed rule for the Advisory Committee  
10 and the Agreement States to review at the end of this  
11 calendar year, which would give them their 90 days  
12 until the spring, which could actually slip, depending  
13 on the extent of the comments received from the  
14 Advisory Committee and OAS.

15 So in actuality we could see a proposed  
16 rule not until the summer of 2013. So that even throws  
17 your timeline, Dr. Van Decker, out potentially longer.

18 I know it is all speculative.

19 MR. FULLER: It is very speculative at this  
20 point. I do know that there is a lot of pressure on  
21 the staff to move this along. And I don't know what  
22 else I can tell you.

23 MS. FAIROBENT: Okay.

24 MR. FULLER: There is a great deal of  
25 pressure on the staff to move this along as quickly as

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1 possible but we have lots and lots of different  
2 procedural requirements that we have as we go through  
3 the rulemaking process.

4 I wish I were a rulemaking expert and then  
5 I could maybe give you a little bit more. But it is a  
6 very deliberative process that we must follow.

7 MS. FAIROBENT: I just wanted to be sure  
8 because I don't think that there was a sense of the  
9 fact that the 90-day period for the pre-decisional  
10 review by the advisory committee in OAS would not  
11 occur much before the end of this calendar year, if  
12 that. That is your earliest time frame, based on what  
13 you said this morning.

14 MR. FULLER: Yes, I mean like I said, we  
15 are going to get direction from the Commission and  
16 then we are going to ride the reg basis and once it is  
17 accepted by the Division of Intergovernmental Liaison  
18 and Rulemaking, then we can start drafting the rule  
19 language.

20 And so you just add that all up and you  
21 are into the fall. I mean --

22 MS. FAIROBENT: Okay, thanks.

23 MR. FULLER: Sure.

24 ACTING CHAIR THOMADSEN: And Dr. Welsh.

25 MEMBER WELSH: I might just say in closing

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1 here that I appreciate how much stress and pressure  
2 the staff has been under and I know that this has been  
3 a topic of conversation and heated debate since I was  
4 sitting over on that side of the room. And you can see  
5 from my position at this point that it is time for me  
6 to retire. But I can see that at this stage, staff has  
7 listened to recommendations from ACMUI from the  
8 stakeholders, from the conversations during workshop  
9 discussions, and there has been a tremendous amount of  
10 work that is clearly evident in this latest SECY paper  
11 and that, from your presentation, the topic has been  
12 debated and considered since 2005 and may go on until  
13 2017 or longer. But I applaud the staff for all the  
14 efforts that have been made and for the cooperation  
15 that I have encountered during these long periods of  
16 time since I have rotated to this present position.  
17 Thank you.

18 ACTING CHAIR THOMADSEN: Thank you very  
19 much. Any other comments? Hearing none, thank you very  
20 much Mr. Fuller.

21 MR. FULLER: Thank you.

22 ACTING CHAIR THOMADSEN: We now have Dr.  
23 Daibes talking on the status of the Commission paper  
24 on patient release.

25 DR. DAIBES: Hi. It is a pleasure to

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1 present here today to ACMUI the status of Commission  
2 paper on patient release. My name is Said Daibes.

3 Our purpose here today is to provide ACMUI  
4 with a status of completion of tasks provided to staff  
5 and the SRM-COMGBJ-11-0003, data collection regarding  
6 patient release.

7 I am going to provide you some background  
8 so you are familiar with some of the information that  
9 has been happening now for the last year or so.

10 The Commission back in 2011 summer  
11 provided to the staff an SRM directing the staff to  
12 multiple tasks. The first one was to evaluate whether  
13 there are gaps in the available data on doses received  
14 by members of the public from release of patients  
15 treated with medical isotopes; and how the agency  
16 could go about collection additional data if needed,  
17 and that is, if indeed there were gaps identified; and  
18 a recommendation, as an alternative option, on the  
19 feasibility of revisiting the dose assessments used to  
20 support the 1997 patient release rulemaking. Those  
21 were three tasks identified from that SRM. And the SRM  
22 also asked for staff's recommended approach on the use  
23 of expert elicitation.

24 Based on the provided SRM and on the  
25 provided task, the staff went out and searched

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1 available technical published data and indeed gaps  
2 were identified in the available empirical data that  
3 was collected and the staff concluded the following.

4           Since the staff has concluded that there  
5 are gaps in the available empirical data regarding  
6 doses being received by members of the public as a  
7 result of release of patients treated with medical  
8 isotopes, these gaps in the available empirical data  
9 relate to the following. Internal doses to the members  
10 of the public from close physical contact with  
11 patients or radioactive contamination from bodily  
12 fluids.

13           Number two, internal and external doses to  
14 members of the public from patients released to  
15 locations other than their primary residences. For  
16 example, houses, apartments, et cetera.

17           By identifying those gaps, staff concluded  
18 the following. They said in developing this  
19 recommendation regarding both the feasibility of  
20 collecting data for the identified gaps and whether  
21 the calculations and assumptions involved in  
22 determining whether a patient may be released should  
23 be reevaluated, the staff considered the following  
24 four options. And this was provided in a notation in  
25 both papers early this year to the Commission.

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1           And the options are the following. And  
2 again, those options were based directly from the  
3 identified gaps in the data.

4           Option 1: Do not pursue any further  
5 research or data collection and do not revisit  
6 calculations and methods described in the NUREGs.

7           Option 2: Perform research or empirical  
8 data collection to fill identified gaps in the  
9 available data.

10          Option 3: As an alternative to collecting  
11 empirical data, revisit calculations and methods  
12 described in the NUREGs' guidance for patient release.

13          And Option 4: Perform analytical and  
14 limited empirical research/data collection and revisit  
15 calculations and methods described in the NUREGs'  
16 guidance for patient release.

17          Upon the submission of that paper, we  
18 recently were informed by the Commission that votes  
19 were in and that an SRM was generated on April 9th  
20 directing staff to pursue Option 4, which is this  
21 option here on the screen. And it says the following  
22 in that SRM.

23          The Commission has approved Option 4,  
24 which would include revisiting calculations and  
25 methods described in Agency Guidance, as well as

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1 limited amount of analytical and empirical data  
2 collected from field measurements. As noted in Option  
3 4, the staff should include informal discussions with  
4 experts in the field, as well as ACMUI as appropriate.

5 At this moment, that SRM is still in  
6 evaluation and staff is putting together a plan to  
7 pursue that data collection. At this moment that is  
8 where we are on the status of this paper. Is there any  
9 questions?

10 ACTING CHAIR THOMADSEN: Any questions from  
11 the committee? Dr. Langhorst.

12 MEMBER LANGHORST: Is the data collection  
13 anticipated to be done only by NRC staff or would NRC  
14 request proposals for others to also do data  
15 collection?

16 DR. DAIBES: That is under evaluation right  
17 now.

18 MEMBER LANGHORST: Okay.

19 DR. DAIBES: So that will be something that  
20 we will need to get back to the committee with that  
21 information.

22 ACTING CHAIR THOMADSEN: Other questions or  
23 comments? Dr. Zanzonico.

24 MEMBER ZANZONICO: It is not so much a  
25 question as a comment. I think given the sentiments

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1 that this whole issue has raised, I mean it would be  
2 my recommendation, and I am speaking just for myself,  
3 not for the ACMUI, that this reevaluation with data  
4 collection would best be done through an external  
5 peer-reviewed vehicle such as a grant as opposed to an  
6 internal NRC effort.

7 I think the more transparent the effort  
8 is, the more satisfactory it would be to everyone  
9 concerned. And most likely, the more scientifically  
10 credible it would be as well. That is just a comment.

11 DR. DAIBES: Thank you.

12 ACTING CHAIR THOMADSEN: And can I ask a  
13 question to the NRC staff? And that is, is there a  
14 possibility that such a project could be funded for  
15 external evaluation?

16 MR. EINBERG: Currently, -- This is Chris  
17 Einberg. Currently the SRM directs us to gather a plan  
18 for collecting a set of data. In our internal  
19 budgeting process here we have provided the staff  
20 resources or we are planning on the staff resources  
21 and contract support for this. The Office of Research  
22 is responsible for putting this plan together. And so  
23 they are in the process of developing the plan for  
24 collection of the data.

25 So we will inform them of our

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1 conversations here today and the concerns and comments  
2 that we have received.

3 ACTING CHAIR THOMADSEN: Very fine. Thank  
4 you.

5 Other questions?

6 MR. EINBERG: Dr. Thomadsen, there was a  
7 member of the public who maybe on the line, may wish  
8 to make a public statement. But if not, that member of  
9 the public wanted his statement put into the record.  
10 So, I would request that with your permission that we  
11 enter his written statement into the record and it  
12 will be part of the transcript that goes out.

13 ACTING CHAIR THOMADSEN: Please do so. And  
14 I know the members of the committee have received  
15 this, at least from discussions I have had, we have  
16 read it and are considering it.

17 MR. CRANE: I am the person who -- My name  
18 is Peter Crane. I am the person who filed that  
19 statement and I would appreciate the opportunity to  
20 deliver it orally.

21 ACTING CHAIR THOMADSEN: This has been read  
22 and is in the record. If you can, we can have just a  
23 few minutes, about three or four minutes, if you could  
24 highlight some points from that.

25 MR. CRANE: Very well. I guess I began by

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1 asking whether anyone was on the committee who would  
2 be comfortable with the idea of their own daughter  
3 without her knowledge cleaning the room and bathroom  
4 of a patient who had just received an outpatient dose  
5 of 200 millicuries of I-131. Is there anyone who would  
6 be content to have their daughter doing such work?

7 ACTING CHAIR THOMADSEN: I don't think that  
8 the committee is going to be dealing with the  
9 hypothetical question right now. Please hit the  
10 points.

11 MR. CRANE: Very well, I will continue. We  
12 know as a matter -- My concern about the paper was  
13 that it reflected that changes had been made at the  
14 instigation of the ACMUI, including deletion of the  
15 staff's intent to tell the commission that it did not  
16 have confidence that members of the public were not  
17 receiving more than five millisieverts of radiation. I  
18 think it is troubling that that was taken out.

19 It seems to me that there is a profound  
20 medical and moral issue that patients are being sent  
21 to hotels while radioactive, that these rooms are  
22 being cleaned by housekeepers who have no awareness  
23 that they are dealing with a contamination situation.  
24 I compared it to a situation in which I know that I  
25 have got a toxic and carcinogenic mess in my basement

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1 and instead of hiring people with hazmat suits I  
2 called the local maid service and have somebody come  
3 out because it is cheaper that way. And I don't see  
4 how that is distinguishable from the provider who  
5 sends a patient off to a hotel except that I get to  
6 see the person I am harming and the provider who sends  
7 a patient to a hotel doesn't have to.

8           The staff wanted to tell the Commission  
9 that I-131 can be transmitted by kissing and  
10 breastfeeding, which is perfectly true and everybody  
11 knows it. And yet the ACMUI somehow told the,  
12 persuaded the staff that it was obligated not to say  
13 this because of the terms of the SRM, which I think  
14 makes no sense.

15           The AMCUI has talked about doses to hotel  
16 workers but it based it on an estimation of the amount  
17 that could be absorbed from bed sheets soaked with  
18 sweat, whereas we know that saliva is a thousand times  
19 hotter, radiologically speaking, than sweat. I think  
20 that this is a gaping hole. We know from *The ASCO Post*  
21 article that patients are being sent to hotels. We  
22 know from the staff's testimony that they have in  
23 fact, that there are doctors justifying sending  
24 patients to hotels, saying it is better to do that  
25 than have them drive home with a loved one.

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1           But the basic principle is informed  
2 consent. If you drive home with your spouse and you  
3 are the patient, the spouse is getting some benefit  
4 and is given informed consent. But there is no  
5 informed consent for the hotel worker and informed  
6 consent is just basic to the way we operate, at least  
7 in this society.

8           The staff wanted to speak of -- Well I'm  
9 sorry, the point is sometimes made that the patient  
10 who gets under 30 millicuries and has an intact  
11 thyroid, is getting this for hyperthyroidism, may be  
12 more of a radioactive hazard than somebody getting  
13 more than 30 millicuries but who is athyreotic. And  
14 that is true but what that calls for is for a thorough  
15 reexamination of the whole rule.

16           There are some valuable data points in the  
17 literature right now. Some of them to be found in the  
18 journal thyroid at the ATA, including an article by  
19 Beasley on release instructions for hyperthyroid  
20 patients who warn that small children may well receive  
21 exposure to radiation levels in excess of the limit of  
22 five milisieverts and he cites a study in which a  
23 three-year-old received 7.2 milisieverts. And bear in  
24 mind that our starting point on all of this is that  
25 our American standards, our NRC standards allow five

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1 milisieverts, whereas, the rest of the world thinks  
2 that one millisievert is the right limit.

3 And as you may know, in 2008 the staff  
4 rejected the idea of the one millisievert limit in a  
5 paper that never even made its way to the Commission.

6 So it seems to me that -- and in addition,  
7 if you look at the regulations of one state after  
8 another, it tells them based on --

9 ACTING CHAIR THOMADSEN: Can you wrap this  
10 up in another minute, please?

11 MR. CRANE: Yes. It tells us that they  
12 should look to a pamphlet put out by the Society of  
13 Nuclear Medicine in 1987. Well, that was the days of  
14 the 30 millicurie rule. Now that we have got people  
15 being sent home with 400 millicuries, it is simply not  
16 good enough to say well look at this old guidance and  
17 change the numbers particularly.

18 Appropriately, I mean Dr. Zanzonico did  
19 great work in NCRP 155 in developing new guidelines.  
20 But those ought to be the basis of guidelines that are  
21 sent out to the whole world. As it is, patients and  
22 licensees are getting guidance that is all over the  
23 map, very irregular. And if you read Dr. Kloos'  
24 article, it is not clear that this guidance is even  
25 being transmitted.

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1 I'm sorry that this is somewhat less  
2 articulate than it would have been if I had been  
3 allowed to read my statement, but I think I have made  
4 the major points I want to and I am happy to respond  
5 to any questions anybody might have.

6 ACTING CHAIR THOMADSEN: Thank you very  
7 much. Comments from the committee? Dr. Zanzonico.

8 MEMBER ZANZONICO: Pat Zanzonico. Thank  
9 you, Mr. Crane, for your comments. Just several points  
10 of clarification.

11 The analysis on the dosimetry to hotel  
12 workers that was published in the ACMUI report  
13 actually was not limited to exposure from  
14 perspiration. In fact, it included conservative  
15 assumptions about the amount of activity excreted in  
16 urine into bed sheets, really unrealistically  
17 conservative assumptions. And with those, the  
18 projected doses to hotel workers, specifically  
19 housekeepers taking care of those rooms was well, well  
20 under 100 millirem.

21 The issue you raise about informed consent  
22 is well taken but it puts them under scenario that  
23 should people moving to Denver be given informed  
24 consent that they will receive annual doses of 100  
25 millirem greater than individuals in the rest of the

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1 country. I think it is a matter of quantitation. Yes,  
2 the doses to hotel workers will be non-zero but they  
3 will be well under the projected doses, I should say  
4 the projected doses will be well under doses to other  
5 cohorts in the country from natural and other sources  
6 that probably do not receive informed consent. And  
7 again, I am thinking of individuals living in Denver  
8 and other parts of the country where there is higher  
9 cosmic radiation background, higher naturally  
10 occurring radioactivity in soil and so forth and so  
11 on. So it really is a matter of scale.

12 One could, of course, go to one extreme  
13 and say anyone who gets any dose beyond a population  
14 average should be informed consent but it becomes  
15 really impractical. All one can and should do, I think  
16 is make the best technical judgment as to what  
17 projected doses are and even do it conservatively so.  
18 And then make a judgment whether those projected doses  
19 warrant or do not warrant informed consent. And I  
20 think that is what has been done up to this point in  
21 the case of radionuclide therapy patients who are  
22 released from hospitals.

23 ACTING CHAIR THOMADSEN: Thank you, very  
24 much Dr. Zanzonico.

25 MR. CRANE: If I could respond to that Dr.

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1 Zanzonico. First, BEIR VII says that the argument  
2 about Denver and background radiation is irrelevant  
3 and gives an explanation for that.

4 But as far as the bed sheets, it seems to  
5 me that the amount of urine that is going to be  
6 deposited in the bed sheet is trifling compared to the  
7 amount of urine that is going to be put into a toilet.  
8 And if you grant that urine is taken into account, why  
9 not count the toilet and why not count the sink? We  
10 know about saliva. We know also that a lot of common  
11 household products cause radioiodine to volatilize, so  
12 people can be inhaling.

13 What is the reason for not taking into  
14 consideration toilets?

15 ACTING CHAIR THOMADSEN: Thank you very  
16 much, Mr. Crane but we are not going to have a debate  
17 on this right now.

18 MR. CRANE: And just one last point. Okay,  
19 suppose it is under 100 millirem --

20 ACTING CHAIR THOMADSEN: Mr. Crane?

21 MR. CRANE: -- for the hotel worker who  
22 does it once.

23 ACTING CHAIR THOMADSEN: Mr. Crane?

24 MR. CRANE: But suppose he does it ten  
25 times.

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1                   ACTING CHAIR THOMADSEN: Thank you very  
2 much for your comments, Mr. Crane. We are not having a  
3 debate on this issue right now. We are talking about  
4 getting more information in order to look into issues  
5 about this.

6                   Other questions to Dr. Said Daibes about  
7 the proposals?

8                   (No audible response.)

9                   ACTING CHAIR THOMADSEN: Hearing none,  
10 thank you very much.

11                  DR. DAIBES: Thank you.

12                  ACTING CHAIR THOMADSEN: And Dr. Welsh, we  
13 are up to you again.

14                  MEMBER WELSH: Thank you, Mr. Chairman.  
15 Thanks again for the opportunity to discuss matters  
16 before you today.

17                  This will be a far less heavy subject than  
18 the one we just reviewed and is strictly for  
19 informational purposes. It is an interesting subject  
20 and I will keep it strictly at a qualitative level for  
21 this presentation today.

22                  I have to thank my scientific colleagues  
23 who have worked with me on this particular  
24 presentation and subject and introduced me to this  
25 fascinating possible scientific observation.

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1           We know that radioactivity supposedly  
2 decays with a very predictable exponential function.  
3 And from an educational website dealing with  
4 radioactivity, it specifically says that no operation,  
5 physical or chemical, has ever been shown to change  
6 the rate at which radionuclide decays and this  
7 statement in some form or fashion can be found in this  
8 book, *Radiations from Radioactive Substances* by these  
9 very well-known and respected authors, Rutherford,  
10 Chadwick, and Ellis.

11           But we do know that there are some  
12 exceptions. And the exceptions that come to mind  
13 immediately are those involving electron capture,  
14 where the chemistry can affect the half-life and the  
15 affect is relatively small on the order of 0.2 to  
16 maybe 0.8 percent in most cases. But to pick a more  
17 extreme example, beryllium-7 in hydrated form compared  
18 to beryllium oxide where it is covalently bonded to  
19 highly electronegative element that is going to be  
20 pulling its electrons away and therefore making the  
21 electron less accessible for electron capture, the  
22 difference in half-life is on the order of 1.5  
23 percent.

24           Interestingly, isomeric transitions,  
25 including technetium-99m are another category of

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1 isotopes in which half-life changes can occur due to  
2 chemical environment. And in fact technetium-99m was  
3 the first metastable isotope that ever demonstrated  
4 observable half-life change due to the chemical  
5 environment. It is about 0.3 percent different in  
6 sodium or potassium protactinate in physiological  
7 saline versus technetium sulfide as an example.

8 But these are due to electron capture and  
9 isomeric transmissions where conversion electrons may  
10 be less available or covalently bonds and make  
11 electron capture less possible.

12 But in contrast to those two examples of  
13 decay via electron capture and gamma versus internal  
14 conversion, there might be another exception to this  
15 general law. And recent studies have suggested decays  
16 of some isotopes might follow anomalous or demonstrate  
17 various variations that are unexpected. And these  
18 observations now raise the question of whether such  
19 variations could have clinical relevance that has  
20 previously been unrecognized in temporary  
21 brachytherapy, teletherapy and gamma knife  
22 radiosurgery.

23 So where did all this come from? It  
24 actually stems from my flight back from an ACMUI  
25 meeting in which I picked up a *Popular Science*

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1 magazine read it on the flight and it said that while  
2 looking for sources of random numbers, researchers  
3 found disagreement in measured decay rates, which is  
4 odd for something that is supposed to be a physical  
5 constant. Well, apparently they looked further into a  
6 collective data and came across further surprises,  
7 including long-term observations of decays of certain  
8 isotopes demonstrating small seasonal variations so  
9 that the decay was slower and slightly faster in the  
10 winter than in the summer. So radioactivity is  
11 stronger in the winter.

12           So I thought this was scientifically  
13 fascinating but I was fully prepared to dump it until  
14 I came across some further information about a coronal  
15 mass ejection, which was basically a large solar flare  
16 in February of 2011 that meant more than just an  
17 attractive aurora borealis. It meant that certain  
18 radioisotopes will show a decrease in radioactive  
19 decay. I thought that truly is scientifically  
20 interesting from the perspective of someone involved  
21 in nuclear physics and nuclear medicine.

22           So I read on further and found another  
23 article that discussed the scientists at Purdue  
24 noticing the decay rate of an isotope that dropped  
25 during the solar flare and dropped actually before the

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1 solar flare did.

2 So it could be useful in an early warning  
3 of an impending solar storm. That could be relevant to  
4 astronaut health. But then I thought well that is very  
5 interesting because I am a health practitioner and  
6 this is interesting nuclear physics but the phrase  
7 medical isotope caught my attention. So I decided I  
8 must read a little bit more.

9 And the bottom line here where it says  
10 when doctors determine the proper dose of  
11 radioactivity to treat a cancer patient, is what  
12 really hooked me. And when these popular scientific  
13 magazines mentioned this aspect, I decided it is time  
14 to go ahead and read the papers in greater detail.

15 So upon a more detailed examination, I  
16 learned that scientists evaluated databases that were  
17 required in a number of institutions and they found  
18 significant discrepancies in the measured decay rates.  
19 So rather than go into the details, I will just  
20 mention that there are a number of papers that show  
21 quite large discrepancies that were difficult to  
22 dismiss simply on the basis of errors in measurement.  
23 In fact, I think in this particular paper the bottom  
24 line in this abstract says that the seasonal  
25 differences of approximately 0.5 percent can be

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1 present between winter and summer months. So it is  
2 quite fascinating.

3 Then the team from Purdue went ahead and  
4 evaluated things in further depth and observed similar  
5 phenomena. The published literature provides support  
6 of this hypothesis and some of these graphs can be  
7 quite striking in terms of demonstrating a seasonable  
8 variability. This is demonstrating a periodicity with  
9 a timescale and thousands of days. And here is the  
10 paper that talked about that particular December 2006  
11 solar flare.

12 A further study by these teams, indicated  
13 that the swings seemed to be in sync with the earth's  
14 elliptical orbit so that the decay rates oscillated as  
15 a function of distance from the sun. And looking at  
16 further data, they found an interesting recurring  
17 pattern over 33 days, which was surprising to them  
18 because the sun rotates with a period of 28 days and  
19 this was a little bit longer than that. But they  
20 astutely pointed out that the core spins at slightly  
21 different rate than the surface does. So this raises  
22 the possibility of neutrinos, solar neutrinos being to  
23 blame.

24 Well, that is hard to believe, given the  
25 cross-section of neutrinos as they interact with

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1 matter of any sort but it is amenable to  
2 investigation. A sphere should have a greater internal  
3 flux of neutrinos if radioactive, a radioactive  
4 sphere, than a radioactive foil sample. So the  
5 investigators decided to see if the half-life of a  
6 radionuclide depends on its shape. And this, if true,  
7 would be of great interest to medical physicists and  
8 radiation oncologists because the geometry of our  
9 sources, sealed sources varies widely.

10 Some members of the same team who proposed  
11 this phenomenon, went on to test this particular  
12 hypothesis and they found that when comparing a sphere  
13 of gold 198 with a thin foil of gold-198 that despite  
14 the differences in neutrino flux, that there was  
15 really no significant difference in decay rate.

16 But this did not solve the problem because  
17 an inherent challenge with this particular experiment  
18 is that the neutrinos that were proposed to cause the  
19 phenomenon in the first place were solar neutrinos and  
20 they were different from the electron antineutrinos in  
21 the gold-198. We know that solar neutrinos which  
22 supposedly exhibit a flavor and mass state oscillation  
23 that accounts for the solar neutrino deficit might  
24 have a slightly different effect on radioactivity than  
25 electron antineutrinos. So that was a possible way

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1 around it.

2 But there are other more serious  
3 challenges to this hypothesis. One is where the  
4 observed variations in decay rate simply caused by  
5 changes in response of the experimental apparatus  
6 between summer and winter versus the isotope decaying  
7 themselves. So this was examined. And in this  
8 particular paper, the team evaluated this question in  
9 greater depth and concluded that it was quite unlikely  
10 that the observed differences could be attributed to  
11 temperature or humidity changes or any other  
12 environmental changes in the detection systems.

13 Another criticism or challenge to the team  
14 came from radioisotope thermoelectric generator data.  
15 Radium-226 decays by alpha emission but it  
16 demonstrates an annual periodicity. So, does this  
17 phenomenon apply to alpha as well as beta? If true,  
18 Cooper should have been able to demonstrate a  
19 fluctuation in the power of output of the NASA Cassini  
20 satellite because that satellite which was launched in  
21 1997 reached Saturn in 2004, approached as close as  
22 Venus and as far from the sun as Saturn, yet the  
23 plutonium-238, an alpha emitter with a half-life of 88  
24 years did not show any seasonal variation for  
25 variability with proximity to the sun.

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1           So the response to this was that  
2 plutonium-238 and radium-226 are both alpha emitters  
3 but radium-226 that was studied was in secular  
4 equilibrium. In about 200 years, a sample of radium-  
5 226 will have about 42 percent of its photon emission  
6 due to beta decaying daughter products and the  
7 ionization chamber is not going to discriminate where  
8 those photons are coming from. So, while radium 226  
9 decays by alpha decay, the daughters which contribute  
10 significantly to what was being measured do decay by a  
11 beta mechanism and these were perhaps demonstrating  
12 the annual cycle. But in contrast, the plutonium in  
13 the RTG was not in secular equilibrium and, therefore,  
14 no non-alpha emitting daughters were contributing to  
15 any meaningful degree and, therefore, the variation  
16 was not observed.

17           Well, another challenge was put forth and  
18 an experiment conducted by Norman and colleagues that  
19 calculated ratio between two different types of decay,  
20 beta and alpha, for example, and that would be  
21 expected to cancel out any changes in equipment  
22 between summer and winter. And it was assumed that if  
23 there was an annual variation, it would affect  
24 different decay processes differently and, therefore,  
25 the ratios would change but when looking at these

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1 particular sets of isotopes, there was no change  
2 annually.

3 The reply to this is that while americium-  
4 241 as an example decays primarily by alpha, it is  
5 possible that like the radium-226 example, its decay  
6 products which decay via beta mechanisms would be  
7 subject to the annual influence but a more important  
8 and legitimate point may be that different  
9 radionuclides are inherently different.

10 And in beta decay, some may show this  
11 variability, others may not. And if one looks further  
12 into this subject, you will see that although electron  
13 capture half-lives, isotopes which decay via electron  
14 capture in some cases showed variability as a function  
15 of chemical state but others do not. Beryllium-7 as I  
16 mentioned in the early slides demonstrates such a  
17 change in half-life, if it is electrons are bonded,  
18 whereas potassium-40 seems less susceptible to this  
19 particular type of phenomenon. So it is reasonable to  
20 assume that the same thing would be true for beta  
21 decay susceptible to this particular type of  
22 variability.

23 So in summary here, anomalous variations  
24 have been characterized by strong annual  
25 periodicities, as well as short duration deviations.

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1 And it is the short duration deviations from the  
2 apparent decay rate that persists for hours or days  
3 that could be of significant concern to radiation  
4 oncology.

5 The annual periodicity has been observed  
6 in 14 radionuclides thus far, including this set of  
7 isotopes that are used in radiation oncology. But the  
8 annual oscillation amplitude varies from nuclide to  
9 nuclide and is typically less than 0.5 percent and  
10 would never be of clinical relevance. On the other  
11 hand, the short duration deviations which have been  
12 observed only in a small number of radionuclides thus  
13 far but including cobalt-60, strontium/yttrium-90 and  
14 radium-226 could have more important clinical  
15 ramifications. Preliminary analysis of these short  
16 duration deviations suggests changes in apparent half-  
17 life that can persist for up to two days at a time.  
18 And therefore, this could affect HDR or Gamma Knife  
19 efficacy if delivered during this window.

20 It remains unknown whether such short  
21 duration decay rate variations exist in other commonly  
22 used medical isotopes like the ones listed here. And  
23 it also remains uncertain whether short duration  
24 variability if it does exist in these isotopes results  
25 in any clinically relevant dosimetric changes. But

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1 preliminary investigations show flat regions in the  
2 decay curve. Flat regions are called short duration  
3 deviations that can be as significant as 600 percent  
4 in terms of a change in apparent half-life and that  
5 can last as long as two decades.

6 So if the treatment happened to be given  
7 during a period where the half-life differed by as  
8 much as 600 percent, one could anticipate that the  
9 dosimetry could indeed be affected.

10 And of interest, some of the raw data that  
11 was used in coming to these conclusions was acquired  
12 during calibration sequences and precision  
13 measurements or in establishing references. These are  
14 procedures that are quite commonly done by medical  
15 physicists and very familiar to medical physicists.  
16 Therefore, additional investigations could include not  
17 just analysis of archived data but careful evaluation  
18 of existing calibration data from gamma knife units,  
19 from HDR units, from active clinics that are sampling  
20 at frequencies that might be sufficient to detect any  
21 such rate variations.

22 So at this point, I will stop the  
23 discussion, aside from showing some of these slides  
24 from some of the papers that have been published. You  
25 can see that the variability here, which is kind of

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1 odd, is plotted out in other studies and analyses and  
2 in some cases, it can be very striking. And here is  
3 the data from that 2006 solar flare. You can see the  
4 count rate dropping right before the flare, which  
5 opens up the subject of this so-called helioradiology,  
6 where you could use this type of information to  
7 determine if a solar flare which could be of health  
8 significance to astronauts is on its way.

9 And here you can see differences in the  
10 calculated half-lives during these flat periods where  
11 in one situation the calculated half-life might be  
12 estimated at several-fold the calculations in other  
13 areas of the curve.

14 So I will stop it at this point.

15 ACTING CHAIR THOMADSEN: Thank you very  
16 much, Dr. Welsh. Comments or questions for Dr. Welsh?  
17 Dr. Zanzonico.

18 MEMBER ZANZONICO: Well Dr. Welsh, you  
19 elevated the nerdiness of this committee.

20 (Laughter.)

21 MEMBER ZANZONICO: And the question I have,  
22 you would think if this is related to a solar flare  
23 phenomena there would be a geographic effect as well.  
24 In other words, the magnitude of these effects would  
25 differ in different parts of the earth. Is there any

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1 evidence of that? In other words, closer to the North  
2 or South -- North Pole in particular, a more  
3 pronounced effect than near the equator?

4 MEMBER WELSH: Thus far, no. And it is  
5 being investigated but if it were neutrino-based, you  
6 might not expect to see such a variation. These  
7 neutrinos can go through the entire planet quite  
8 readily. But if it is neutrino-based it is hard to  
9 understand how it possibly could make sense because  
10 the cross-sections are just so minuscule.

11 It is subject of investigation and thus  
12 far there is no clear answer to your question but  
13 there have been proposed new particles, things called  
14 nutellas, I think, that I will refrain from discussing  
15 in any depth here. But there is no shortage of  
16 interesting proposed mechanisms but more data is  
17 required.

18 ACTING CHAIR THOMADSEN: Any other  
19 questions or comments? Yes, Dr. Weil?

20 MEMBER WEIL: No.

21 ACTING CHAIR THOMADSEN: In that case, any  
22 last words from the staff for today?

23 MR. EINBERG: Yes, thank you Dr. Welsh for  
24 the presentation.

25 I would ask the committee to be sure to

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1 check their calendars for upcoming meetings and go to  
2 Tab 14. Tomorrow we will be discussing the next ACMUI  
3 meeting. So be prepared to look at your calendars and  
4 see if you have any conflicts. So let's just serve it  
5 as a reminder.

6 And I thank the committee for all the  
7 interesting presentations and discussion today. And we  
8 will reconvene tomorrow morning at eight o'clock.

9 ACTING CHAIR THOMADSEN: We stand  
10 adjourned.

11 (Whereupon, at 4:46 p.m., the foregoing meeting was  
12 adjourned to reconvene on Tuesday, April  
13 17, 2012 at 8:00 a.m.)

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