



UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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OPEN SESSION MEETING

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MONDAY, APRIL 15<sup>th</sup>, 2013

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The Open Session portion of the meeting was convened in Room T-2B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 9:30 a.m., Leon S. Malmud, M.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

LEON S. MALMUD, M.D., Chairman

BRUCE THOMADSEN, Ph.D., Vice Chairman

DARICE G. BAILEY, Agreement State Representative

MILTON GUIBERTEAU, M.D., Diagnostic Radiologist

SUSAN LANGHORST, Ph.D., Radiation Safety Officer

STEVEN MATTMULLER, Nuclear Pharmacist

CHRISTOPHER J. PALESTRO, M.D., Nuclear Medicine  
Physician

JOHN SUH, M.D., Radiation Oncologist

ORHAN SULEIMAN, Ph.D., FDA Representative

WILLIAM VAN DECKER, M.D., Nuclear Cardiologist

LAURA WEIL, Patients' Rights Advocate

JAMES WELSH, M.D., Radiation Oncologist

NRC STAFF PRESENT:

ALLISON MACFARLANE, Ph.D., NRC Chairman

MARK SATORIUS, Director, Office of Federal and State  
Materials and Environmental Management Programs

BRIAN MCDERMOTT, Director, Division of Materials  
Safety and State Agreements

CHRIS EINBERG, Chief, Radioactive Materials Safety  
Branch, Designated Federal Officer

SANDRA GABRIEL, Ph.D., Acting Medical Radiation Safety  
Team Leader

ASHLEY COCKERHAM, ACMUI Co-Coordinator, Alternate  
Designated Federal Officer

SOPHIE HOLIDAY, ACMUI Co-Coordinator

NEELAM BHALLA, FSME/DILR/RPMB

SUSAN CHIDAKEL, OGC/GCLR/RMR

JIM DWYER, RI/DNMS/MB

SARA FORSTER, RIII/DNMS/MLB

CASSANDRA FRAZIER, RIIIDNMS/MLB

MICHAEL FULLER, COMM/OCM

LATISCHA HANSON, RIV/NMSB-A

VINCENT HOLAHAN, Ph.D., FSME

DONNA-BETH HOWE, Ph.D., FSME/MSSA/RMSB

DEBORAH JACKSON, FSME/DILR

ED LOHR, FSME/DILR/RPMB  
 ANGELA MCINTOSH, FSME/MSSA/RMSB  
 KIMYATA MORGAN-BUTLER, Ph.D., FSME  
 KEVIN NULL, RIII/DNMS/MLB  
 PATTY PELKE, RIII/DNMS/MLB  
 GRETCHEN RIVERA-CAPELLA, FSME/MSSA/RMSB  
 RONALD ZELAC, Ph.D, FSME/MSSA/RMSB

MEMBERS OF THE PUBLIC:

ROBERT DANSEREAU, NY STATE DEPT OF HEALTH  
 WILLIAM DAVIDSON, UNIV OF PENNSYLVANIA  
 KAREN LANGLEY, UNIV OF UTAH  
 ANDREW MCKINLEY, ASNC  
 JOE RODGERS, THERAGENICS CORPORATION  
 GLORIA ROMANELLI, ACR  
 MICHAEL SHEETZ, UNIV OF PITTSBURGH  
 MICHAEL STEPHENS, FL BUREAU OF RADIATION CONTROL  
 CINDY TOMLINSON, ASTRO  
 NANCY WERSTO, FDA  
 PAUL YURKO, VETERANS HEALTH ADMINISTRATION

TABLE OF CONTENTS

	<u>PAGE</u>
4. Opening Statements	5
5. Special Presentation	12

6.	Old Business	16
7.	ACMUI Webpage Update	23
8.	Draft Guidance for 10 CFR Part 35 Rulemaking	28
9.	Medical Related Events	59
17.	Abnormal Occurrence (AO) Subcommittee Report	105

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

2 CHAIRMAN MALMUD: Opening statements will be made  
3 by Mr. Einberg and Mr. McDermott.

4 MR. EINBERG: Okay, thank you, Dr. Malmud. As the  
5 designated federal officer for this meeting, I am pleased to  
6 welcome you to the public meeting of the Advisory Committee  
7 of the Medical Uses of Isotopes. My name is Chris Einberg.

1 I am the chief of the Radioactive Materials Safety branch,  
2 and I've been designated as the federal officer for the  
3 Advisory Committee in accordance with 10 CFR Part 7.11.

4 Present today as the alternate designated federal  
5 officer is Ashley Cockerham, ACMUI coordinator. This is the  
6 announced meeting of the committee. It is being held in  
7 accordance with the rules and regulations of the Federal  
8 Advisory Committee Act and the Nuclear Regulatory  
9 Commission. The meeting was announced at the March 6th,  
10 2013 edition of the Federal Register, Volume, Page 14593.  
11 The function of the committee is to advise the staff on  
12 issues and questions that arise on the medical use of  
13 byproduct material. The committee provides counsel to the  
14 staff but does not determine or direct the actual decisions  
15 of the staff or the Commission. The NRC solicits the views  
16 of the committee and values their opinions. I request that  
17 whenever possible, we try to reach a consensus on the issues  
18 that we will discuss today, but I also recognize there may  
19 be minority or dissenting opinions. If you have such  
20 opinions, please allow them to be read into the record.

21 At this point, I would like to perform a roll call  
22 of the ACMUI members participating today. Dr. Leon Malmud,  
23 ACMUI chairman, hospital administrator.

24 CHAIRMAN MALMUD: Here.

25 MR. EINBERG: Dr. Bruce Thomadsen, vice chairman,  
26 therapy medical physicist.

27 VICE CHAIRMAN THOMADSEN: Here.

28 MR. EINBERG: Ms. Darice Bailey, agreement state

1 representative.

2 MEMBER BAILEY: Here.

3 MR. EINBERG: Dr. Mickey Guiberteau, diagnostic  
4 radiologist.

5 MEMBER GUIBERTEAU: Present.

6 MR. EINBERG: Dr. Sue Langhorst, radiation safety  
7 officer.

8 MEMBER LANGHORST: Here.

9 MR. EINBERG: Mr. Steve Mattmuller, nuclear  
10 pharmacist.

11 MEMBER MATTMULLER: Here.

12 MR. EINBERG: Dr. Christopher Palestro, nuclear  
13 medicine, physician.

14 MEMBER PALESTRO: Here.

15 MR. EINBERG: Dr. John Suh, radiation oncologist.

16 MEMBER SUH: Here.

17 MR. EINBERG: Dr. Orhan Suleiman, FDA  
18 representative.

19 MEMBER SULEIMAN: Here.

20 MR. EINBERG: Dr. William Van Decker, nuclear  
21 cardiologist.

22 MEMBER VAN DECKER: Present.

23 MR. EINBERG: Ms. Laura Weil, patients' rights  
24 advocate.

25 MEMBER WEIL: Here.

26 MR. EINBERG: Dr. James Welsh, radiation  
27 oncologist.

28 MEMBER WELSH: Present.

1 MR. EINBERG: Dr. Pat Zanzonico, nuclear medicine  
2 physicist.

3 MEMBER ZANZONICO: Here.

4 MR. EINBERG: We do have a quorum, so we can  
5 proceed. Okay. I now ask that the NRC staff members who  
6 are present to identify themselves. I'll start with the  
7 individuals in the room here.

8 MR. MCDERMOTT: Brian McDermott, director of the  
9 Division of Materials Safety and State Agreements and the  
10 Office of Federal and State Materials and Environmental  
11 Management Programs.

12 MR. EINBERG: Very good. Ashley, would you like  
13 to introduce yourself?

14 MS. COCKERHAM: This is Ashley Cockerham. I'm  
15 part of the Medical Radiation Safety team.

16 DR. GABRIEL: Sandy Gabriel, acting team leader,  
17 Medical Radiation Safety team.

18 MS. CHIDAKEL: Susan Chidakel, Office of General  
19 Counsel.

20 MS. COCKERHAM: And Sophie Holiday just stepped  
21 out. She's also part of the Medical Radiation Safety team.

22 MR. EINBERG: Do we have anybody from the regions  
23 on the line? Region I? Is the line open? Ashley, can you  
24 check with Theron? Is there anybody with Region I?

25 MS. COCKERHAM: They're currently dialing into the  
26 bridge.

27 MR. EINBERG: Oh, they're dialing in. Okay.

28 AUTOMATED OPERATOR: Your passcode has been

1 confirmed. Please stand by as you are joined to your  
2 conference. There are three parties in conference including  
3 you.

4 MR. EINBERG: Welcome to the people who are on the  
5 line. We're going through the opening remarks here. I'm  
6 doing a role call and wanted to see if there's anybody from  
7 Region I on the line, NRC staff, Region 3, or Region 4.  
8 Also is anybody from NRC staff from headquarters on the  
9 line? Dr. Zelac?

10 DR. ZELAC: Yes, I am on the line.

11 MR. EINBERG: Okay. Thank you. I would also like  
12 to add that this meeting is being webcast, so other  
13 individuals may be watching online. We have a bridge line  
14 available and that phone number is 888-864-0940. The pass  
15 code to the bridge line is 90108#. Following a discussion  
16 of each agenda item, the ACMUI Chairman, Dr. Leon Malmud, at  
17 his option, may entertain comments or questions from members  
18 of the public who are participating with us today. We ask  
19 that one person speak at a time as this meeting is also  
20 closed-captioned. At this point I would like to turn the  
21 meeting over to Mr. McDermott, director of the Division of  
22 Materials Safety and State Agreements for a few opening  
23 comments.

24 MR. MCDERMOTT: Thanks Chris and good morning  
25 everyone. I'd like to welcome you back to NRC for your  
26 spring 2013 in-person meeting. So it's nice to have you  
27 here and have the opportunity interact on a person-to-person  
28 basis. For our larger audience, I do want to just note that

1 the ACMUI did hold two public teleconferences in March to  
2 discuss the ACMUI's rulemaking subcommittee report and that  
3 the final committee report was received by NRC on April 9th,  
4 and we appreciate that. This can be found on the ACMUI  
5 webpage and also in the agency's ADAMS system.

6 Just looking ahead to the agenda here for the next  
7 two days, later on today we will have the opportunity to  
8 discuss the draft guidance for the proposed draft expanded  
9 Part 35 Rulemaking. This is an opportunity for the  
10 committee to understand that guidance document. And we'll  
11 also have the opportunity to hear about the AO subcommittee  
12 report as your recommendations on the AO criteria. That  
13 subcommittee was chaired by Dr. Langhorst. And this will be  
14 included in the Commission paper that's due sometime this  
15 summer, so important to make sure the committee's aligned  
16 and I understand you plan to vote on that this meeting.

17 Tomorrow we'll have two presentations from the  
18 National Nuclear Security Administration and the Center for  
19 Medicare and Medicaid Services in relation to Molybdenum-99  
20 production and reimbursement policy. We'll also have a  
21 presentation on the ViewRay licensing guidance. This is the  
22 -- something the staff is working on to ensure the  
23 availability of that new technology and make sure it gets in  
24 the right place in terms of licensing. Presentation will be  
25 given tomorrow by Dr. Sandy Gabriel of the NRC and Sophie  
26 Holiday. The guidance is still pre-decisional, so we won't  
27 inform the ACMUI work public of the licensing decision at  
28 this time. It's just an update -- the working group that is

1 working on the guidance actually meets later this week. But  
2 that will be a good update for you all.

3           And then one other note since your last in-person  
4 meeting, in March this year we had the publication of the  
5 long awaited Part 37 on the security of byproduct materials,  
6 so that rule goes into place in March and a year from March  
7 is when the NRC licensees will have to be in compliance.  
8 The agreement states have an additional two years beyond  
9 that, so a total of three years to have their compatible  
10 regulations in place. Presently there's a working group  
11 that's made up of NRC staff as well as agreement state  
12 representatives working on some of the implementation  
13 details. And the key part right now is the communication  
14 plan to help get the word out. Although there's been a lot  
15 of discussion about that rulemaking over the last few years,  
16 that communication plan is part of what we do when we have  
17 significant rulemaking like that come out.

18           And finally, as many of you know, this is Dr.  
19 Malmud's last meeting with the ACMUI. He has provided  
20 steady and very calm leadership for the committee since  
21 2004. He's always provided the NRC staff with reasoned  
22 advice. His service has been very much appreciated and  
23 valued by the NRC staff and Commission. And to that note,  
24 we have a special guest this morning. I'd like to introduce  
25 NRC Chairman Macfarlane.

26           Before you set up here for you. The Honorable  
27 Allison Macfarlane was sworn in as chairman of the U.S.  
28 Nuclear Regulatory Commission in July of 2012. She was

1 initially nominated by President Obama and confirmed by the  
2 Senate to a term that expires June of this year. However,  
3 just last month president Obama nominated Dr. Macfarlane for  
4 a five-year term to the Commission. Dr. Macfarlane, an  
5 expert on waste issues, holds a doctorate in geology from  
6 Massachusetts Institute of Technology and a Bachelor's  
7 Degree of science in Geology from the University of  
8 Rochester. Prior to beginning her term as the NRC's 15th  
9 chairman, Dr. Macfarlane was an associate professor of  
10 environmental science and policy at George Mason University  
11 in Fairfax, Virginia. Please join me in welcoming Chairman  
12 Macfarlane.

13 [applause]

14 NRC CHAIRMAN MACFARLANE: Thank you very much.  
15 Can you all hear me? Okay? Yeah I'm a doctor too, but of  
16 inanimate objects.

17 [laughter]

18 So it's a pleasure to join you all this morning  
19 and to be here on -- and to represent the Commission on --  
20 to honor Dr. Leon Malmud. Dr. Malmud has made significant  
21 contributions to the ACMUI -- I'm getting used to all these  
22 acronyms here -- since his appointment in 2002. He was  
23 appointed chairman of the committee in 2004 and during that  
24 time he's overseen the Commission's -- the committee's work  
25 on a number of high priority issues of great importance to  
26 the NRC. His technical and administrative acumen, and in  
27 particular his deep understanding of the NRC's regulatory  
28 practices -- which is no small feat I can assure you -- have

1 made him a strong leader and an effective spokesperson for  
2 the committee in his interactions with the Commission. I  
3 should note that Dr. Malmud's work on this committee has  
4 been so well respected by his colleagues that he has served  
5 an unprecedented three terms as chairman. And under his  
6 leadership the staff has enjoyed a positive relationship  
7 with the committee and I know the staff is very, very  
8 appreciative of that. So thanks to his efforts, the  
9 committee is well placed to continue its successful work  
10 after his departure. So Dr. Malmud, on behalf of the  
11 Commission, I'd like to present you with this flag which was  
12 flown over the U.S. Capitol, and this pin which -- I'm not  
13 going to open the endless boxes, you can do that -- as  
14 tokens of NRC's great appreciation for your service. So my  
15 colleagues and I definitely want to convey our deep  
16 gratitude to all of your service.

17 CHAIRMAN MALMUD: Thank you

18 [applause]

19 Yeah we can do a handshake.

20 NRC CHAIRMAN MACFARLANE: Handshake?

21 CHAIRMAN MALMUD: Okay

22 NRC CHAIRMAN MACFARLANE: Okay? Great. Here you  
23 go! Try to keep track of this.

24 [laughter]

25 And I think you even have a letter from congress.

26 CHAIRMAN MALMUD: Oh. Thank you very much.

27 NRC CHAIRMAN MACFARLANE: You're welcome. Got it?

28 CHAIRMAN MALMUD: Yes. Thank you.

1 NRC CHAIRMAN MACFARLANE: Thank you.

2 CHAIRMAN MALMUD: Can I say a word or two?

3 NRC CHAIRMAN MACFARLANE: Please.

4 CHAIRMAN MALMUD: It's been a genuine honor and  
5 privilege for me to serve with this committee and your  
6 predecessor. This group represents a considerable fund of  
7 knowledge of various disciplines related to radiation  
8 patients. Every member of this committee, current and past,  
9 that I've worked with has had the best interests of the  
10 public in mind, the patients obviously, and the interaction  
11 between the NRC and us as we struggle to make the right  
12 decisions for the ultimate outcome, which is patient safety  
13 and public safety.

14 Each of you is a scholar in his or her own right.  
15 And it's unusual to have a committee as diverse as this one  
16 with the knowledge that all of you have, and it's truly been  
17 an honor for me. In addition to that, I would like to thank  
18 the members of the NRC staff who have made this work easier  
19 for us, who have worked earnestly to accept our opinions  
20 even when they differ, and to integrate them into final  
21 decisions that are in the best interest of patients and the  
22 public. The group here at the NRC is similarly  
23 distinguished and dedicated as all of you are. So for me  
24 it's been a joy to try and bring us all together and come to  
25 the final decisions and recommendations which are -- serve  
26 our patients and the members of the public so well. And I  
27 thank all of you for your participation and cooperation  
28 at every level. It's been a true joy. Thank you very much.

1 [applause]

2 MR. MCDERMOTT: Thank you Dr. Malmud. So Dr.  
3 Malmud's retirement from the committee also requires that  
4 NRC appoint a new chair of the committee. As such I'd like  
5 to announce that Dr. Thomadsen has agreed to serve as  
6 chairman of the ACMUI and that Dr. Guiberteau has agreed to  
7 serve as vice chair. So I'd like to welcome you both to --

8 [applause]

9 So at the conclusion of our meeting on Tuesday,  
10 there'll be the passing of the gavel, of the baton or  
11 whatever it's going to be --

12 [laughter]

13 -- and we appreciate the [inaudible] for the  
14 committee. Now I will turn it back over to Dr. Malmud.

15 CHAIRMAN MALMUD: And I will turn it immediately  
16 over to Ashley Cockerham.

17 MS. COCKERHAM: Good morning. I am going to start  
18 with 2007. I'm just going to go through the part of the  
19 recommendations that have been updated or any items that  
20 have changed since the last meeting. So we're going to drop  
21 down to item number 35 and this says, "NRC staff should not  
22 revise 10 CFR 35.491 intended for ophthalmologists to  
23 include training and experience for the new intraocular  
24 device; this is the NeoVista device." We actually issued  
25 guidance on this in April of 2009 so this recommendation is  
26 closed. NRC decided to regulate this obviously under Part  
27 10 CFR 35 Part 1000, and we have current guidance on this.  
28 So it's not a part of the regulations but we did consider

1 the ACMUI's recommendation in writing the guidance. So I'm  
2 going to close that one out for this chart.

3           We move on to 2008. Item number nine: This deals  
4 with the AO subcommittee report, and we're going to be  
5 discussing this item this afternoon. For item number 28,  
6 okay -- I'm going to attempt this one -- this deals with the  
7 rulemaking 10 CFR 35.65 and transmission sources. The ACMUI  
8 recommendation is the NRC staff should revise 10 CFR 35.65  
9 to clarify it does not apply to medical uses. This is in  
10 the current rulemaking and the way it's being approached --  
11 this recommendation is partially accepted. So the essence  
12 or the intent of the ACMUI's recommendation is in the  
13 rulemaking, but we're not removing transmission sources from  
14 35.65. I'm going to look at Sandy Gabriel very quickly to  
15 make sure I'm following this correctly. Or Donna-Beth, if  
16 you want to go ahead.

17           DR. HOWE: Yes, you see in the proposed rule that  
18 the transmission sources are still in 35.65, but if they're  
19 being used for the patient, then they move to 35.500. And  
20 we've made it so that a 35.200 authorized user is  
21 automatically authorized for the use of the transmission  
22 sources under 35.500. That's in the proposed rule.

23           MS. COCKERHAM: Okay, so I'm seeing Dr. Langhorst  
24 shaking her head in agreement. So this is a good thing. So  
25 you're -- you agree that we incorporated the essence of what  
26 the ACMUI wanted. I'm going to mark this as partially  
27 accepted because we didn't fully accept exactly what is  
28 written here.

1           MEMBER LANGHORST: As I remember my one main point  
2 was to make sure that if you were approved for 35.200 that  
3 automatically got you into 35.500 if that's the path NRC was  
4 going with this.

5           MS. COCKERHAM: Okay. So that's reflected in the  
6 proposal -- the draft, the draft proposed rule. Is that  
7 correct?

8           MEMBER VAN DECKER: Dr. Howe?

9           DR. HOWE: No, no.

10          MEMBER VAN DECKER: Oh, I'm sorry. I was -- Van  
11 Decker. I was trying to ask a question of clarification  
12 since it's important. Since it's irrespective of where it  
13 sits, a 200 user, .290 trainee, will be able to use Gd-  
14 153line sources in their work under this current construct,  
15 as we put it together correct?

16          DR. HOWE: Yes, in some cases if the line sources  
17 are aggregated to be greater than what's in 35.65 --

18          MEMBER VAN DECKER: Right.

19          DR. HOWE: -- then they'll automatically come  
20 under 35.500. If they aren't aggregated, but they're being  
21 used on a patient, it'll come under 35.500 and the 200 user  
22 is automatically authorized. And you don't have to list on  
23 a normal license.

24          MEMBER VAN DECKER: Can I get your last part again  
25 please? So you don't have to change --

26          DR. HOWE: Excuse me?

27          MEMBER VAN DECKER: The last part of the sentence  
28 I didn't hear.

1 DR. HOWE: Oh the last part of the sentence is you  
2 don't have -- if the source is eligible to be under 35.65,  
3 which has certain maximum activities, then that source does  
4 not have to be listed on a license.

5 MEMBER VAN DECKER: Thank you.

6 MS. COCKERHAM: Okay, so I'm going to update this  
7 chart to say that it is partially accepted.

8 MEMBER VAN DECKER: Thank you.

9 MS. COCKERHAM: And it is a part of the part  
10 rulemaking. Okay. Next I'm going to move to 2009. Okay, I  
11 wanted to make a point on item number two. We have a  
12 recommendation that was made at the May 7th, 2009 meeting,  
13 and this deals with parenteral administration of either beta  
14 or low-energy photon emission. We were -- basically we were  
15 separating out alpha. I wanted to draw to the attention  
16 that in this subcommittee report, the rulemaking  
17 subcommittee report that was submitted recently, the  
18 committee, I believe, recommended that all -- alpha, beta,  
19 everything -- be included in (G)(3), and this recommendation  
20 is saying betas in one group, alphas in another group under  
21 (G)(4). So there's just a -- just noting that there's a  
22 contradiction of two different ACMUI recommendations; so if  
23 we want to note that the subcommittee report supersedes this  
24 one, I don't know if the committee wants to retract this  
25 one, or how we want to document it, but this one's on the  
26 record. So if someone went back and looked at this and said  
27 NRC is doing a proposed rule in accordance with this  
28 recommendation, that's not your final recommendation. Does

1 that make sense?

2 CHAIRMAN MALMUD: Yes.

3 MS. COCKERHAM: Would you like me to just mark it  
4 as superseded or would you like me to officially -- I don't  
5 know if we officially retract them or --

6 CHAIRMAN MALMUD: What do you recommend we do as a  
7 committee?

8 MS. COCKERHAM: Some sort of indication that this  
9 is no longer your recommendation.

10 CHAIRMAN MALMUD: Would someone care to comment?

11 MEMBER ZANZONICO: Pat Zanzonico. I mean I think  
12 our intent from the subcommittee report was that they not be  
13 separated so that the latest recommendation supersedes this  
14 one.

15 MS. COCKERHAM: Okay.

16 MEMBER ZANZONICO: So you just note that.

17 MS. COCKERHAM: I'm happy to do that.

18 CHAIRMAN MALMUD: That's noted. Thank you.

19 MS. COCKERHAM: Okay. For item number -- actually  
20 there's nothing to say about item number 10 that's part of  
21 the current rulemaking. Moving on to 2011, items 13, 14,  
22 and 15 are all dealing with the attestations, and these are  
23 all on the current Part 35 expanded rulemaking. Items 19,  
24 20, and 32 -- okay, for item 19 Mr. Mattmuller had asked  
25 that NRC staff for the ACMUI to post the organizational  
26 chart on the FSME website. We have done that and during my  
27 website presentation we'll show you where that is on the NRC  
28 website. For item 20, Dr. Langhorst requested the NRC staff

1 place historical documents on the ACMUI website and also  
2 give a brief history and add ACMUI past membership. The  
3 majority of that information has also been added to the  
4 website and I'll cover that in my website presentation. For  
5 item 32, this deals with the AO criteria and this is going  
6 to be discussed later this afternoon.

7           Okay. For 2012 starting with item number three  
8 this is dealing with radium-223 dichloride. The ACMUI  
9 issued their subcommittee report and advised the NRC that it  
10 should be licensed under 35.300. And we accepted that  
11 recommendation and on January 10th we issued a memo to our  
12 regional offices transmitting the licensing decision for  
13 radium-223 dichloride. This is a publicly available  
14 document. We also issued letters to our agreement states,  
15 and to Bayer, and we published information in FSME, our  
16 office quarterly newsletter, and on the medical list server.  
17 For items five, six -- I'm sorry -- five, seven, and eight,  
18 those all deal with radium-223 dichloride so all of those  
19 will be closed as that licensing decision is final. We jump  
20 back up to number six. Dr. Malmud had asked the NRC to find  
21 data on events in which the radio pharmacy had dispensed the  
22 incorrect amount of a radiopharmaceutical or the incorrect  
23 radiopharmaceutical and we provided this information to the  
24 committee last October. For item 10, this is dealing with  
25 the abnormal occurrence, the AO subcommittee. As I've  
26 mentioned we will be discussing that this afternoon and  
27 that's also for items 11 -- so 10 and 11 are dealing with  
28 AO. And then for item 12 this was the recommendation to

1 have the meeting today. And we are all here. So we will  
2 close that.

3 For this last chart, these -- this 2013 chart is  
4 from our March -- the two March teleconferences so every  
5 item on here is regarding the current Part 35 rulemaking,  
6 and NRC staff will include the final ACMUI rulemaking report  
7 and its recommendations in a paper to the commission  
8 regarding the draft proposed expanded 10 CFR Part 35  
9 Rulemaking. And just to note that this -- the final ACMUI  
10 report was submitted to NRC staff on April 3rd -- April 9th  
11 -- thank you, Sophie -- and it's available on the ACMUI  
12 public webpage and that's all I have for this speech. Any  
13 questions or comments or changes to any of these?

14 CHAIRMAN MALMUD: Are there any questions? Yes,  
15 Dr. Langhorst.

16 MEMBER LANGHORST: Thank you. Ashley on 2009, I  
17 just out of curiosity, question number nine is about the  
18 medical event subcommittee. I just wondered why that's  
19 being carried on. I mean the subcommittee was formed and --

20 MS. COCKERHAM: We can close that out.

21 MEMBER LANGHORST: Okay.

22 MS. COCKERHAM: It's still an existing  
23 subcommittee but it --

24 MEMBER LANGHORST: Right.

25 MS. COCKERHAM: -- fit the membership changes as  
26 the membership changes.

27 MEMBER LANGHORST: Right, and I just noted that  
28 Ms. Gilley's no longer on that.

1 MS. COCKERHAM: Thank you.

2 MEMBER LANGHORST: You're welcome.

3 MS. COCKERHAM: We'll update that.

4 MEMBER LANGHORST: You're welcome.

5 ASHLEY COCKERHAM: Any other comments? Okay.

6 That's all I have.

7 CHAIRMAN MALMUD: Any questions for Ms. Cockerham?

8 No questions? Back to the report. You're up next?

9 MS. COCKERHAM: Yes.

10 [laughter]

11 CHAIRMAN MALMUD: The next item is the webpage  
12 update.

13 MS. COCKERHAM: Yes.

14 CHAIRMAN MALMUD: Which you also handle.

15 MS. COCKERHAM: Yes. So for the main page,  
16 basically we've condensed things down a little bit. Most of  
17 the information is still the same. The membership and  
18 history and -- or we added history, which is what Dr.  
19 Langhorst asked for. So if you look at the bulleted list on  
20 history we can go to that. And here we have some  
21 information that actually dates the ACMUI back to the  
22 Manhattan Project, so if anyone's interested in reading how  
23 you originated, all that information is contained here up  
24 through the Atomic Energy Commission, and through the NRC,  
25 and to the current name now. And here is the list of  
26 historical members, to the best of our ability [laughs].  
27 Yeah. So we'll just keep adding to this list as individuals  
28 rotate off the committee and keep a running list of things

1 here. The other thing -- the main thing that we've changed  
2 here, there used to be individual links for meeting  
3 transcripts, meeting summaries, meeting agendas. All of  
4 those were listed as bullet points near the bottom of the  
5 page; now if you look on the right hand side it says related  
6 information. All of the ACMUI committee meeting and  
7 subcommittee report information is all contained on this  
8 page. So the first link is the meeting and related  
9 documents. If you click on that, it is all separated by  
10 year. This is very similar to how the Commission public  
11 meeting website looks and how the ACRS website looks. It's  
12 separated out by year, so if you put 2012 -- now we have  
13 charts where everything relating to one particular meeting  
14 is in one place. So you don't go to an agenda page that  
15 lists all of the agendas for the ACMUI. You go to which  
16 meeting you want to go to and then you would have the agenda  
17 and then the transcripts are all available, and then any  
18 meeting handouts, the e-binders that we now get, direct  
19 links to all of those. And it's all on the public website  
20 in one place.

21 We go back to subcommittee reports. These were all  
22 initially listed on the ACMUI home page; it said "related  
23 information" and all of the subcommittee reports were  
24 listed. Now we list them out by year and they all have  
25 titles, topics, you can see, and we'll just keep adding to  
26 this as new subcommittee reports are issued. Did we have  
27 any other major changes?

28 MS. HOLIDAY: Membership page.

1 MS. COCKERHAM: The membership page -- so the  
2 membership page, we have the lovely group photo. So we've  
3 been taking more of those as you come in so we have the most  
4 current membership on the website each time, and then you're  
5 individual bios and individual photos are all still listed  
6 here. And if you ever have any updates to your bios,  
7 changes, employment, or professional societies, things like  
8 that, it's very easy for us to update your information. You  
9 can always provide that to Sophie or to me.

10 I believe that's it. Any comments or questions?  
11 I know a lot of this -- oh the FSME website. Do you want to  
12 go to FSME external? Okay. While Sophie's doing that I can  
13 entertain any questions.

14 CHAIRMAN MALMUD: Questions for Ms. Cockerham?  
15 Dr. Langhorst?

16 MEMBER LANGHORST: I just want to thank you very  
17 much for all this work and I really look forward to  
18 exploring some of the history and looking at past  
19 membership. I find it very helpful in giving me a base in  
20 working with a committee and learning some of the  
21 discussions that have happened in the past. So I thank you  
22 very much for everyone's effort on that.

23 MS. COCKERHAM: You're welcome. I have to give  
24 credit. We had a gentleman who was here, Jeff Kowalczyk, was  
25 on rotation I believe it was the last meeting, and he really  
26 was the driver for getting all this done. And then Sophie  
27 and I kind of just saw it through.

28 MEMBER GUIBERTEAU: I want to thank you, too. And

1 also on behalf of our stakeholders because I think you know  
2 websites can either be friendly or intimidating, and I think  
3 this is very nice for those who are interested, you know, in  
4 medical use of isotopes to really come on and easily find  
5 the documents that they need.

6 MS. COCKERHAM: Thank you.

7 CHAIRMAN MALMUD: Since thanks to you are being  
8 offered I want to echo those thanks. You've been an  
9 extraordinary help to me personally over the time that you  
10 were in the position that Sophie is in currently, and I want  
11 to publically thank you for having made what could have been  
12 difficult task much easier.

13 MS. COCKERHAM: Thank you.

14 MS. HOLIDAY: I don't know how to get to that to  
15 go on.

16 MS. COCKERHAM: Just go to Google.

17 [laughter]

18 Yeah. I wouldn't know how to navigate there from  
19 our internal website either. Under at -- go to the top --  
20 FSME the tab, it says FSME office directory, kind of in the  
21 middle on the right. There you go. So if you look here you  
22 can see the link has already been clicked. ACMUI is now  
23 listed under our FSME directory, and it links directly to  
24 your new and improved ACMUI webpage. Over there in the back  
25 -- and if you go through this webpage and you find anything,  
26 links, you know, when you're reading or information that you  
27 think should be added that we're missing, please let us  
28 know. It's easy to add now that we kind of have the

1 framework and the actual pages in place, it's much easier to  
2 manage now. Okay. That's it for me.

3 CHAIRMAN MALMUD: Thank you.

4 MS. COCKERHAM: Thanks.

5 CHAIRMAN MALMUD: We are now 15 minutes ahead of  
6 schedule. We can take a break if that's okay with Mr.  
7 Einberg.

8 MR. EINBERG: Okay, that's fine.

9 CHAIRMAN MALMUD: In which I'll re-resume at 11:00  
10 in order to maintain the schedule that's been shared to the  
11 public?

12 MR. EINBERG: Yes, sir.

13 CHAIRMAN MALMUD: So we will resume at 11:00  
14 promptly. Thank you.

15 [break] [resume at 11:00am]

16 MEMBER ZANZONICO: Okay, well, I guess I'll begin  
17 then. So, good morning everyone. And what I'll be doing is  
18 kicking off. And literally, we'll just be kicking off. I  
19 understand this is intended to be an open discussion among  
20 the ACMUI and the NRC staff on the draft guidance to the  
21 2013 proposed expanded 10 CFR 13 Rulemaking. And as I  
22 mentioned earlier, both with respect to the subcommittee  
23 report on rulemaking and on -- this being the case, I really  
24 have to extend my personal thanks to Sophie Holiday, who was  
25 really invaluable in both efforts. So, by way of  
26 introduction, and this is sort of a user's perspective, so  
27 it may not reflect rigorously the NRC's perspective, but  
28 from a user perspective, the regulatory guidance or reg

1 guide provides practical instructions, the emphasis on the  
2 word "practical," on compliant preparation of license  
3 applications. And so, the regulations themselves, which are  
4 often, at least for me, difficult to read and interpret,  
5 define officially the why, while the reg guides describe the  
6 how. And the reg guides are indexed to the applicable  
7 regulations, to the applicable sections of the Code of  
8 Federal Regulations. And it's a resource used by licensees  
9 for regulatory compliance overall as well as license  
10 applications, because we all know the reg guides include,  
11 among other things, these invaluable model procedures for  
12 virtually all aspects of use of the medical use of  
13 radioactive materials from the point of view of radiation  
14 safety, and though we have found those model procedures to  
15 be invaluable. So as I say, I think the scope and utility  
16 of the reg guides extend well beyond license application,  
17 but to compliant performance and execution of a license, as  
18 well.

19           So, again, the official scope of the regulatory  
20 guide is with respect to compliant preparation of licensed  
21 applications. And in the latest reg guide, there is really  
22 very extensive documentation and forms provided on the  
23 training and experience requirements for authorized users,  
24 authorized nuclear pharmacists, authorized medical  
25 physicists and authorized radiation safety officers. It  
26 also describes the record-keeping requirements. And as I  
27 said, the model procedures, which are very often extensively  
28 relied upon by licensees for compliance implementation of

1 their licenses, and the draft reg guide also includes and  
2 number of sample forms. So, the reg guide we're considering  
3 at the moment consists of three parts. There's a part on  
4 medical licenses, that's Volume 9, Consolidated Guidance  
5 About Material Licenses for Medical Use Licenses. Part 2 is  
6 for commercial and radio pharmacies, that's Volume 13. And  
7 only those sections that are affected by the proposed rule,  
8 where there are changes in the proposed rule are included,  
9 and they are redlined very helpfully to identify the  
10 specific changes between the proper Part 35 in the proposed  
11 rule. And then there is a - also very helpful Part 3 with  
12 Q-and-A, questions and answers, that provides additional  
13 useful information for licensees beyond simply license  
14 preparation. So we'll use a comprehensive document  
15 complementing the proposed rule itself.

16           So, my overall take on looking carefully at both  
17 the proposed rule and the draft guidance, is that it really  
18 recapitulates accurately and comprehensively -- the draft  
19 guidance does -- the visions in the proposed rule, it has  
20 material on the associate RSOs, training and experience  
21 issues relating to resolution of the Ritenour petition. It  
22 indicates or documents the elimination of preceptor  
23 attestation requirements for board-certified individuals.  
24 It also changes the attestation language to now read in  
25 multiple points in the reg guide that the attester is able  
26 to independently fulfill radiation safety-related duties and  
27 it eliminates attestation to the effect of competency. A --  
28 it also includes a seven-year rather than five-year

1 inspection servicing requirement for gamma stereotactic  
2 radiosurgery units. It documents the requirement for  
3 testing of every generator elution rather than the first  
4 generator elution prepare and breakthrough. The requirement  
5 for notification of the NRC by licensees of generator  
6 elutions with out of tolerance and with breakthrough. It  
7 includes the authorization for use of alpha emitters, which  
8 was recommended by the subcommittee. And also, includes  
9 information on the new activity-based definition of a  
10 medical event for permanent implant brachytherapy. These,  
11 again, are largely addressed in the question-and-answer  
12 section.

13           So, simply summarized, as I said, I think the  
14 draft guidance reliably recapitulates the proposed  
15 rulemaking, in that it incorporates all of the changes, as  
16 far as I can see, from the prior to the proposed rulemaking.  
17 You know, the important changes are highlighted -- are  
18 highlighted, a red line. It provides very well structured  
19 forums for training and education requirements for all  
20 authorized professionals consistent with the new attestation  
21 requirements and so forth. And, in the Q-and-A section, it  
22 includes useful supplemental information on the proposed  
23 rule or consistent with the proposed rule. But overall the  
24 NRC staff has really done a very good job in generating the  
25 draft regulatory guidance and I think it -- for the end  
26 users, for the licensees, it really is a very helpful,  
27 complete and so forth reg guide.

28           So, that really completes what I had to say. Here

1 are the usual list of abbreviations and acronyms used in the  
2 presentation. But otherwise, that concludes my formal  
3 presentation.

4 CHAIRMAN MALMUD: Thank you, Doctor Zanzonico.  
5 Are there comments from the staff or question? Doctor  
6 Langhorst.

7 MEMBER LANGHORST: Thanks, Pat, very much for that  
8 summary. I just want to express my appreciation for the  
9 NUREG documents, as one of those people who has to do  
10 licensing and having just gone through hopefully the last  
11 renewal of a license I'll ever have to do. These new reg  
12 documents are invaluable. I know, Pat, you were referring  
13 to them as regulatory guides, and those really are a little  
14 bit different section than the NUREG documents, the 1556  
15 documents. I have a question, and maybe Doctor Howe can  
16 explain this a little bit. It's -- the first section  
17 obviously is Volume 9 and then Volume 13 is the --

18 [coughing]

19 -- [unintelligible]. Where will the question and  
20 answer section of this guidance for Part 35 -- where will  
21 that reside in these various guidance documents?

22 DR. HOWE: I think what we're expecting to do is  
23 to put the questions and answers up on what the medical  
24 toolkit so that they're available on the website to anyone  
25 that needs them.

26 MEMBER LANGHORST: It was unclear if they going to  
27 be in any of the NUREGs or not.

28 DR. HOWE: No, because the whole reason we came up

1 with the Qs and As is because they don't deal with  
2 submitting a license application, right? They deal with,  
3 well, once you've got a license, how do you understand  
4 changes in the regs? So, they won't go in the NUREG Volumes  
5 9 or 13.

6 MEMBER LANGHORST: Thank you for that  
7 clarification --

8 [coughing]

9 CHAIRMAN MALMUD: Other questions or comments for  
10 members of the committee? Yes, please.

11 MEMBER MATTMULLER: And maybe we're stealing part  
12 of Leon's thunder, but, at this point, what we saw for the  
13 proposed regulations, will those be modified at all by what  
14 our subcommittee reported on for the current regulations --  
15 rather be -- I guess, the term would be the final proposed  
16 regulations that go into the Federal Register for official  
17 public comment?

18 DR. HOWE: Yeah, this document was development to  
19 match one-on-one the draft proposed that you reviewed. It  
20 does not include --

21 [coughing]

22 -- the thing concerning your recommendations.  
23 Your recommendations and other recommendations will be fed  
24 into how the proposed rule is modified, and when it goes  
25 out, then we will also have --

26 [coughing]

27 -- this to match any rules text changes that  
28 appear in the proposed rules. So, this is an early draft

1 proposed guidance document and it will have to match the  
2 proposed rules. And right now, we don't have a proposed  
3 rule. We're still working on comments.

4 MEMBER SULEIMAN: Just for -- Orhan Suleiman --  
5 just for clarification, what we -- what this is as a draft-  
6 proposed rule that hasn't been published yet in the Federal  
7 Register.

8 DR. HOWE: That's correct.

9 MEMBER SULEIMAN: And after it's published in the  
10 Federal Register, it will still be a proposed rule for  
11 public comment, after which the NRC will take in all the  
12 input, convene, and at some point, publish a final rule.

13 DR. HOWE: Yes. Our intent is to publish the  
14 availability of the guidance, but when we do publish the  
15 availability of the guidance, this guidance may be revised  
16 to match the proposed rule. So, it may not be exactly what  
17 you're seeing right now. And then we have a final guidance  
18 that comes out with the final rule.

19 CHAIRMAN MALMUD: Thank you. Doctor Langhorst.

20 MEMBER LANGHORST: Thank you. I'm going to say  
21 that this will really make me look like a regulatory geek -  
22 [laughter]

23 -- so I just want you guys to understand this. On  
24 the docket for the proposed rulemaking, will these guidance  
25 documents be under that same docket number or will they be  
26 in a separate document -- docket, excuse me -- docket  
27 number? I ask that because Part 37 you found the rule in  
28 one place and then you found the guidance document, if you

1 were lucky, in a completely different docket number. And I  
2 found that very confusing, so I hope NRC puts this all  
3 together so the commenters know where to find all the  
4 documents involved with the regulations.

5 CHAIRMAN MALMUD: Ms. Bhalla, do you have any  
6 insight regarding that perhaps?

7 MS. BHALLA: Sure. Yeah. Good morning, this is  
8 Neelam Bhalla from NRC. With regard to the docket numbers,  
9 we are pretty much bound by administration -- administrative  
10 procedures, so I'm pretty sure that the proposed rule has a  
11 -- is our docket number, I even remember the number, but the  
12 guidance is going to be under a separate docket -- separate  
13 docket number. But now that you have brought this forward,  
14 we would go back to admin and see if we can merge these.  
15 But I really have my doubts. So, I think it's set to go  
16 under a separate docket number.

17 MEMBER LANGHORST: At the very least -- this is Sue  
18 Langhorst again -- at the very least, make it very clear  
19 this is where you find this, and this is where you find this  
20 because I don't think it was as clear as it could have been  
21 in the Part 37 development. So, I know that's a totally  
22 different rule, but I just encourage you to make sure that  
23 the public and us, those who will be commenting on this know  
24 where to look for guidance and where to look for proposals.

25 DR. HOWE: I think what may help is we have control  
26 over the medical toolkit and for folks that know and use the  
27 medical toolkit, we've got a place in there for rulemaking  
28 and also for guidance. And so, we'll make sure that we have

1 the draft rule up there and we'll make sure we have the  
2 draft guidance up on the medical toolkit. And that way --  
3 that's where we're planning -- that's where I'm planning on  
4 putting the draft guidance.

5 MEMBER LANGHORST: Thank you so very much.

6 CHAIRMAN MALMUD: Any other comments or questions for  
7 Dr. Howe? I just wanted to just get back to this -- initial  
8 comments you made, so my understanding then is that the  
9 draft guidance is going to be divided into two NUREGs? And  
10 then the Q&A is not going to be a hard copy document, for  
11 lack of a better term, but it will just be posted on the  
12 website.

13 DR. HOWE: That's our plan right now. We're -- as  
14 we indicated on our cover, we're not revising the NUREGs,  
15 the two NUREGs, right now, the medical NUREG or the  
16 commercial nuclear pharmacy NUREG because we've got another  
17 working group that's revising that for other reasons. And  
18 so, when they get to the end of their product, our  
19 supplemental information that you're reading here will be  
20 folded into it. So, there will be a NUREG guide that covers  
21 the rule and the other changes that are having to be made to  
22 the reg guide to bring them up to speed, because a lot has  
23 happened in the 10 years since they were last published.  
24 And, so that will happen for the commercial pharmacy and the  
25 medical, but the Qs and As, we do have a section on a  
26 medical toolkit that talks about Qs and As and we'll work  
27 this up on our medical toolkit so that it's publicly  
28 available at any time.

1           MEMBER ZANZONICO: So, that's -- this, with  
2 respect to the logistics of the rollout, because you say  
3 that updating the NUREGs is a separate effort. So, I'm sure  
4 you do this, but how do you kind of ensure that these things  
5 are rolled out simultaneously so that there's not discrepant  
6 information out there for the licensees?

7           DR. HOWE: We've got a separate working group that  
8 -- Ashley's actually in charge of the one for the Volume 9  
9 for the medical licensees, and then someone else is involved  
10 for the Volume 13, the commercial nuclear pharmacy. And  
11 we've got a project manager in in FSME that's responsible  
12 for the whole thing, so we'll be working closely with them  
13 to make sure that these things come out at the same time,  
14 that at the very final part, our information as based on the  
15 final rule is inserted into the NUREG document with the  
16 other updates that they're doing.

17           MEMBER ZANZONICO: So there will be an old NUREG  
18 out there at the same time the new rule is in effect.

19           DR. HOWE: I don't think so. I think the idea is  
20 that we can't make these changes to the rule -- to the reg  
21 guide, until the rule comes into effect because then it  
22 could change again. But the other group is working on other  
23 issues and we're going to mail them at the same time. And  
24 instead of having a number of different volumes coming out,  
25 like one for this one, then two weeks later there's another  
26 one for the other one, we're going to try to merge them  
27 together so there's one revision.

28           MEMBER GUIBERTEAU: And Doctor Howe, when do you

1 anticipate that this particular document will be posting?

2 DR. HOWE: This particular document will be posted  
3 when the -- well, the proposed guidance will be posted at  
4 the same time that the proposed rule goes out, or within a  
5 day or two.

6 CHAIRMAN MALMUD: Thank you. Mr. McDermott.

7 MR. MCDERMOTT: I'd just like to add for  
8 everybody's benefit, the Commission's established  
9 expectations of policy for the staff relative to rulemaking  
10 that come into play here. And so, part of what you're  
11 seeing is their direction to the staff to have proposed  
12 guidance documents available at the same time the draft --  
13 the proposal for a draft rule goes to the Commission. So,  
14 you all got the early view on it and get to provide your  
15 comments and then they may get incorporated. But -- so,  
16 it's really two steps. In the past, which remains true  
17 today, is that when the final rule is available and approved  
18 by the Commission, the final guidance has to be available.  
19 So, we're doing things a little earlier now at this proposed  
20 rule stage where we have to have both the rule text and the  
21 guidance documents coming together. So, we would not have a  
22 situation, as Dr. Zanzonico mentioned, where we get the rule  
23 out and don't have any guidance. The Commission has made  
24 sure that we understand the importance of having those two  
25 things together.

26 CHAIRMAN MALMUD: Thank you. Mr. Mattmuller.

27 MEMBER MATTMULLER: Yes. Dr. Howe, on Page 15 --

28 DR. HOWE: On which one are you on?

1 MEMBER MATTMULLER: Page 15.

2 DR. HOWE: Okay.

3 MEMBER MATTMULLER: Second paragraph in regards to  
4 production of radioactive drugs that refers to 206AA. And  
5 for the life of me, I couldn't find Appendix AA.

6 DR. HOWE: Oh. You were only given the parts of  
7 the reg -- of the NUREG that we revised. And so, if we did  
8 not revise Appendix AA, then you will not see it.

9 MEMBER MATTMULLER: Thank you for that  
10 clarification.

11 CHAIRMAN MALMUD: Other questions or comments?

12 MEMBER VAN DECKER: Yes, Dr. Van Decker. Just  
13 one more clarification because I'm trying to get straight.  
14 The proposed rule will be published within a couple of days  
15 the proposed draft guidance is published to match the  
16 proposed rule that we've been discussing. Somewhere in the  
17 midst of all this, there's a second process looking at the  
18 NUREG. So, I assume that whatever that process is and  
19 whatever that input is is also open to comment once it gets  
20 published. And so when the proposed draft guidance document  
21 gets published a couple of days after the proposed rule, it  
22 will have both reflections of the rule plus reflections of  
23 this second process for comment at the same time? Or is it  
24 non-commentable pieces of the process?

25 DR. HOWE: There will be an opportunity to  
26 publicly comment on the changes that are being made to the  
27 NUREG that have nothing to do with the rulemaking.

28 MEMBER VAN DECKER: Okay.

1 DR. HOWE: That will come out at a different time.  
2 It is the final document where they merge them together.  
3 So, you'll have -- we're going to call this a supplement to  
4 those NUREGs and my feeling -- my belief is that they will  
5 stay separate so that you'll get to comment. The other ones  
6 are dealing with security and other issues that don't  
7 involve rulemaking. And they're across the board for all of  
8 our NUREGs. And so, you'll get a chance to comment on  
9 those, then you get a chance to comment on these, and then  
10 in the end, they'll merge together.

11 MEMBER VAN DECKER: All right.

12 CHAIRMAN MALMUD: Dr. Van Decker?

13 MEMBER VAN DECKER: I accept that as a clear  
14 clarification of where this is going.

15 [laughter]

16 MEMBER VAN DECKER: In my mind.

17 DR. HOWE: Anyway, okay.

18 CHAIRMAN MALMUD: Other comments or questions?  
19 Dr. Van Decker?

20 MEMBER VAN DECKER: I just have one more  
21 tangential comment. You know, I just happened to be looking  
22 through some of this and recognizing that in our attempt to  
23 be simplistic in preceptor paperwork of this 313A form, we  
24 now have a series of 313A forms relating to all the  
25 different subgroupings of training and experience, which  
26 made me nervous when I first slipped through it, but looking  
27 at the one that would reflect my constituency the most, I  
28 think it would probably work just fine. So, as long as

1 everyone else is satisfied with the piece of their  
2 constituency, it's okay. But, you know, for a variety of  
3 reasons, it does make things a little bit more diverse, but  
4 it's a complicated subject and I don't think this was an  
5 unreasonable way to approach it.

6 DR. HOWE: When we published the forms in response  
7 to the 2002 rule, we were still operating under the model  
8 that we should have one form and it should cover everybody.  
9 And we got a lot of comments that said, "This is way too  
10 confusing. I don't know what I'm supposed to do. I don't  
11 know how I'm supposed to throw it out." And so we went back  
12 and we revised the forms after 2000, and split them into the  
13 313A series. So each type of authorized user or medical  
14 physicist or pharmacist was covered by a form that grouped  
15 similar uses. And so, that's not a new concept and we're  
16 carrying it on because we've gotten positive comments.

17 CHAIRMAN MALMUD: Doctor Langhorst?

18 MEMBER LANGHORST: In regard to the 313A forms,  
19 they are forms that you can use or you can submit the same  
20 type of information, and I know I kind of like the one that  
21 was all together because we have a lot of -- our authorized  
22 users who do a lot of different things, and so we have  
23 combined some of those in our own use of those forms and  
24 trying to meld those, so, I appreciate the forms out there.  
25 And they're very easy to fill out when you've got the simple  
26 -- I don't mean simple -- when you've got the one use, but  
27 if you have multiple uses, you have that option of combining  
28 that -- some of that similar information.

1 DR. HOWE: And Sue brought out an important point.  
2 The NRC form 313, which is how you apply for a license,  
3 that's a requirement. The use of the NRC form 313A series,  
4 are voluntary.

5 CHAIRMAN MALMUD: Doctor Langhorst.

6 MEMBER LANGHORST: Doctor Malmud, I have a  
7 logistics question. Are we going to just step through this  
8 NUREG document or are we -- should we bring up points that  
9 we don't think may be covered in what our Part 35 report  
10 suggests, or how are we to tackle this stuff?

11 CHAIRMAN MALMUD: It seems to me that we should  
12 bring up the questions that you have. Do we need to go  
13 through this in a stepwise fashion in part of the document?

14 CHAIRMAN MALMUD: Whatever your preference is.

15 MEMBER LANGHORST: I don't think so, but I didn't  
16 know what others' preference was.

17 CHAIRMAN MALMUD: Is there is preference to go  
18 through the whole document step-by-step, or just to raise  
19 questions with what's relevant to it? Dr. Zanzonico?

20 MEMBER ZANZONICO: Well, my preference would be  
21 not to go through the whole document --

22 [laughter]

23 -- having gone through the whole document.

24 [laughter]

25 CHAIRMAN MALMUD: We've been all waiting to hear  
26 the recommendation.

27 [laughter]

28 CHAIRMAN MALMUD: That's the answer to your

1 question, Dr. Langhorst.

2 MEMBER LANGHORST: Okay, then I'm going to be  
3 leaping through my comments here to see if I have any to  
4 bring out.

5 CHAIRMAN MALMUD: All right. Shall we wait for  
6 you to lead?

7 MEMBER LANGHORST: No, you should not wait for me,  
8 please.

9 MEMBER MATTMULLER: Mr. Mattmuller. While we're  
10 waiting -- as you'll hear me talk tomorrow about the  
11 schedules, maybe this is why this has really stuck in my  
12 mind. But Appendix AA in 30.33, I'm not seeing Appendix AA  
13 listed in 30.33.

14 DR. HOWE: Are you talking about the regulations?

15 MEMBER MATTMULLER: Or is Appendix AA referred to  
16 an appendix in the different guide?

17 DR. HOWE: What page are you on and which -- are  
18 you on Part 1, 2?

19 MEMBER MATTMULLER: I'm still back on page 15.

20 DR. HOWE: But are you on Part 2? You're in the  
21 pharmacy side. I've got two page 15s. Oh, okay. Are you  
22 on Appendix C on page 15? We now have each -- Part 1 goes 1  
23 through to the end. And Part 2 goes 1 through to the end.  
24 So I've got two page 15s.

25 MEMBER MATTMULLER: Sorry. This is page 15 of the  
26 document Sophie sent us two weeks ago. Production of PET  
27 radioactive drugs.

28 DR. HOWE: Oh, okay. That Appendix double A is

1 the appendix in the reg guide, but we did not change --

2 MEMBER MATTMULLER: Change to any reg guide, okay,  
3 I'm sorry. I was looking in the regs and didn't see it.

4 DR. HOWE: No, it's not the regs. It's in the reg  
5 guide.

6 MEMBER MATTMULLER: Okay. Thank you.

7 CHAIRMAN MALMUD: Dr. Langhorst? Ready?

8 MEMBER LANGHORST: One of your recommendations  
9 that the committee made with regard to the associate  
10 radiation safety officer was to allow broad scope type A  
11 licensees to have an exemption to be able to internally  
12 approve those and list them, much like they do for  
13 authorized users, authorized nuclear pharmacists, authorized  
14 medical physicists. If the staff puts that in, then will  
15 they -- will you then also be modifying the NUREG 1556  
16 Volume 11? I warned you it's going to be geeky, Volume 11,  
17 which has to do with broad scope licensees?

18 DR. HOWE: If we accept it, it would be for Part  
19 35 broad scopes. And we address the Part 35 broad scopes in  
20 Volume 9.

21 MEMBER LANGHORST: The volume 9, okay.

22 DR. HOWE: Volume 9. So, it would stay in volume  
23 9.

24 MEMBER LANGHORST: Okay. It might be worth  
25 revising when you get around to revising volume 11 someday,  
26 as I know that that references medical broad scopes  
27 sometimes, too.

28 DR. HOWE: It should send them over to Part 35 for

1 things that deal with medical stuff.

2 MEMBER LANGHORST: Thank you.

3 CHAIRMAN MALMUD: Thank you, Dr. Langhorst. Did  
4 you wish to take another leave?

5 MEMBER LANGHORST: Yes, because I'm looking for my  
6 next comment, so I --

7 CHAIRMAN MALMUD: All right. While you're doing  
8 that, are there other questions from members of the  
9 committee, or comments? Although we will await your next  
10 comment, Dr. Langhorst. Oh no, Mr. Mattmuller. I'm sorry.

11 MEMBER MATTMULLER: We work together. I'll buy  
12 her some time. This is looking in terms of gallium 68 -- or  
13 excuse me, gallium 67, how that might be licensed in the  
14 future, because the gallium itself won't be used as is, but  
15 it will be used as part of a, in FDA terms, as a component  
16 to part of the radiopharmaceutical. And so, looking at how  
17 or why you would list it in the application, have you given  
18 any thought as to gallium 68? I'm getting my numbers mixed  
19 up. I'm sorry, gallium 68, the positron radionuclide, how  
20 that might be dealt with in the future.

21 CHAIRMAN MALMUD: Excuse me, for clarity, are you  
22 referring to gallium 67 citrate or gallium 68?

23 MEMBER MATTMULLER: I apologize. I said 67. I  
24 mean 68. The PET rating. Investigational right now.

25 CHAIRMAN MALMUD: Yes. Okay. Thank you. That's  
26 the question. Sorry.

27 DR. HOWE: We don't necessarily regulate by  
28 specific drugs. We regulate by medical modalities. And so,

1 if it is being used for a modality that's currently in here,  
2 it would come under that modality. There are special cases  
3 where we put things into 1,000, that's understood. So, if  
4 it's a PET drug it's going to be used for imaging, then it  
5 would come under 200. We don't -- you would have to list  
6 the isotope, but your use would be 200. And so it wouldn't  
7 be any different. We don't list all the isotopes that are  
8 being used under 200 in the reg guide. It would be up to  
9 the licensee to list them, what they're planning on using.  
10 Does that answer your question?

11 MEMBER MATTMULLER: Well, actually the answer I  
12 was hoping to hear that as long as the product has FDA  
13 approval as diagnostic, that it would fit under 35.200. But  
14 the other reason I asked is because looking at the form on  
15 Page 96, there are a few individual radionuclides that have  
16 been singled out, such as F-18, O-15, and C-11.

17 DR. HOWE: You list the -- you generally list the  
18 kind of the isotopes you're going to be using, but your  
19 approved use for it will be under the modalities. And you  
20 have to list some isotopes if you have a lot of them. And  
21 what page were you on for that?

22 MEMBER MATTMULLER: Ninety-six.

23 DR. HOWE: Ninety-six. And one of the things --  
24 the reason that you're -- you have a list of F-18, is this  
25 was meant for someone that is producing a PET radioactive  
26 drug under 30 to 32J. So that's the non-commercial  
27 distribution of production. You've got the accelerator,  
28 you're part of a consortium, and you're making it for non-

1 commercial distribution. And the same with the Oxygen-15  
2 and the Carbon-11, so we were listing those because you are  
3 making huge amounts of those. But if you were the recipient  
4 of it, it would probably come under any byproduct material  
5 permitted under 35.200, which is the example given above  
6 that.

7 CHAIRMAN MALMUD: Does that answer?

8 MEMBER MATTMULLER: I think so, yes.

9 CHAIRMAN MALMUD: Dr. Langhorst?

10 MEMBER LANGHORST: I'm sorry. I'm desperately  
11 trying to find the page number in the packet here versus  
12 what I had on my e-book, and it's not meshing. But, this  
13 has to do -- my question has to do with the training for  
14 staff directly involved in administration or care of  
15 patients administered byproduct material for which a written  
16 directive is required. This has to do with the vendor  
17 training required for those things under 35 --

18 DR. HOWE: Six hundred?

19 MEMBER LANGHORST: Six hundred, yes. I just asked  
20 -- and I was confused by this as we were doing our review of  
21 the proposed rule -- I think it needs some clarification and  
22 I think it would be really helpful here in the guidance  
23 document about who has to take that vendor training. I --  
24 it's not clear to me if you're saying obviously the  
25 authorized users, the authorized medical physicists, but all  
26 of the radiation workers or operators -- I think there needs  
27 to be some additional clarification of who you're expecting  
28 to take this vendor training prior to first use of a new

1 unit or after manufacturer upgrades that affect operational  
2 and safety of the unit. So, I just -- I think it needs just  
3 a little bit more explanation of who all you're talking  
4 about. And I think it needs -- and I may have missed it in  
5 subsequent descriptions, but then what's your expectation of  
6 new people coming on that it doesn't have to necessarily be  
7 vendor training or you're saying it should be vendor  
8 training. I was a little confused by that and I think this  
9 part of your guidance could explain that a little bit better  
10 in your own mind. So, I give you that recommendation.

11 DR. HOWE: I think what I'm hearing from you is  
12 that's probably something we ought to address in our Qs and  
13 As because that's where we get into a little bit more detail  
14 about why things are done the way they are.

15 MEMBER LANGHORST: Okay.

16 DR. HOWE: Clearly in the regulations when we  
17 require vendor training, we're requiring vendor training for  
18 the authorized user and the authorized individuals, and  
19 because we don't have requirements on the other folks below,  
20 we're assuming that they're getting it. But they're not the  
21 folks we list on the license so --

22 MEMBER LANGHORST: Okay.

23 DR. HOWE: -- we would assume that you are giving  
24 vendor training to everybody that needs it.

25 MEMBER LANGHORST: And I'm just not clear that  
26 that's -- you're saying that clearly to me. So, I'll ask  
27 you to look at that and kind of bolster that a little bit in  
28 whatever form you think is best.

1 DR. HOWE: Yeah, and that occurs more often after  
2 you've gotten your license.

3 MEMBER LANGHORST: Right.

4 DR. HOWE: So, that would be more for the Qs and  
5 As section.

6 MEMBER LANGHORST: Okay. Thank you. I'm going to  
7 look for my next comment. [laughs]

8 CHAIRMAN MALMUD: Doctor Suh.

9 MEMBER SUH: Yes, so, on Page 159 of this document  
10 -- I'm just looking for things that I know a little bit  
11 about, since I'm a teletherapy gamma stereotactic  
12 radiosurgery..., full inspection servicing.

13 DR. HOWE: [affirmative]

14 MEMBER SUH: It appears that this sentence was  
15 added, this is on full inspection service and replacement at  
16 intervals not to exceed five years. It says for each  
17 teletherapy, and not to exceed seven years for each gamma  
18 stereotactic radiosurgery unit. The area in red, is that  
19 new proposal then?

20 DR. HOWE: Yes, the area in red is the new  
21 proposal.

22 MEMBER SUH: Does such a similar type of proposal  
23 exist for high dose rate brachytherapy as well, in terms of  
24 when the sources should be replaced?

25 DR. HOWE: No, because the high rate -- high dose  
26 rate remote afterloaders, they change them frequently. And  
27 so we don't have an issue of years. I think they're -- but  
28 we don't have a requirement for when you change and when you

1 have to do a full service.

2 MEMBER SUH: Okay, because, as some of you may  
3 know, the replacement of a gamma knife radiosurgeries source  
4 is quite expensive. I mean, \$800,000 to a million dollars,  
5 and I guess the only questions I have is, is it a good idea  
6 for us to put a stipulation in terms of when these sources  
7 should be replaced?

8 DR. HOWE: The current regulations require them to  
9 be exchanged at five years. And we felt that what we were  
10 getting were a lot of exemptions to go beyond the five  
11 years, and so we expanded it out to seven to give licensees  
12 more flexibility.

13 MEMBER SUH: I suspect that there may be some  
14 centers that are even beyond seven years, with the cost of  
15 replacement. Again, it's just more of a -- I just wanted to  
16 point that out.

17 CHAIRMAN MALMUD: Thank you. Doctor Langhorst.

18 MEMBER LANGHORST: I wanted to add to that that  
19 it's not only just the cost, but it's also the availability  
20 of the equipment to do that change-out. I know we are -- we  
21 had to put off ours because the equipment just wasn't  
22 available then. So, there's a lot of resources to take into  
23 account to get the slightest change planned and executed.

24 CHAIRMAN MALMUD: Back to you, Dr. Suleiman.

25 MEMBER SULEIMAN: I keep on seeing through here a  
26 reference to curies and millicuries. Is -- are you guys  
27 going to make an effort to include SI units? Just because  
28 somebody's got to make that point, I mean.

1 DR. HOWE: That would be the other group that's  
2 revising the reg guides because that's a more generic  
3 question that has to go across the boards for all the reg  
4 guides, all the NUREGs.

5 MEMBER SULEIMAN: I mean, I know some in the  
6 scientific community or some of the societies are actually  
7 starting to remove reference to the old units. So, as a  
8 minimum, we should at least have both of them, you know.

9 DR. HOWE: I think for most things in here we're  
10 supposed to have both. That's the NRC. Maybe we were last.

11 MEMBER ZANZONICO: If I would say, look, as long  
12 as you brought up the issue of units, is there going to be a  
13 transition from the effective dose equivalents? That also  
14 seems like a dated quantity at this point.

15 DR. HOWE: We're not looking at that right now.

16 MEMBER ZANZONICO: Okay.

17 CHAIRMAN MALMUD: Doctor Welsh.

18 MEMBER WELSH: If I might ask for further  
19 clarification regarding Dr. Suh's point; if I'm reading this  
20 correctly, it is not insisting upon replacement of the  
21 cobalt at seven years. It's just advising about full  
22 inspection and servicing, correct? It is not mandating a  
23 change in the isotope at that point.

24 DR. HOWE: The concept is there may be parts of  
25 the gamma knife unit that can only be fully inspected and  
26 serviced when there are no sources. And so it is expected  
27 to go along with the source exchange, and with a teletherapy  
28 unit, you don't necessarily have to exchange the sources at

1 the five-year point, or you may exchange them earlier. But  
2 you don't -- you can do your full service and inspection  
3 without exchanging the sources. But the gamma knife, you've  
4 got to exchange all your sources to get into the areas that  
5 would be too much of a high radiation area to look at. And  
6 so, the concept is it's done at source exchange. That's  
7 what this particular test is supposed to be. Other tests  
8 that are lesser that you can do while the sources are in,  
9 you're supposed to keep doing those. But this is supposed  
10 to be your full service and inspection. And that was part  
11 of the rule change that we made.

12 MEMBER WELSH: So, if that is the case, then I  
13 would concur with Dr. Suh that this is a potential concern  
14 that goes beyond the monetary issue of how expensive it is  
15 to exchange the sources, because at five years or even seven  
16 years, it could be that the clinical dose rate is still  
17 acceptable for the practitioners to continue to use that  
18 gamma knife without necessarily exchanging the sources at  
19 this very expensive cost. So, I'm just wondering if five  
20 years is inappropriate, but seven years may still be a  
21 little bit restrictive.

22 DR. HOWE: I would take that to be a comment more  
23 on the proposed rule because we are taking the proposed rule  
24 and implementing it into guidance.

25 CHAIRMAN MALMUD: Dr. Langhorst.

26 MEMBER LANGHORST: Dr. Malmud, I didn't have any  
27 other comments that didn't touch upon what Dr. Howe had just  
28 said, that we'd already discussed on our recommendations for

1 the draft proposed rule.

2 CHAIRMAN MALMUD: Thank you. I think a member of  
3 the NRC staff did have a comment. Ms. Bhalla?

4 MS. BHALLA: Yeah, about the regulation that has  
5 to do with the service of the -- full service of the gamma  
6 knife or our teletherapy unit, for a five-year -- at  
7 strength now at five year, and it is to -- if you read that  
8 whole regulation, it is to assure the shutter mechanism of  
9 the unit. So, in gamma knife, the staff has determined that  
10 the beams are all -- or the sources are all fixed. And the  
11 shutter where you control the beam for where it's hitting  
12 the decrease volume, is based -- is by using the plugs on the  
13 helmet. So, therefore, the shutter mechanism is like a  
14 stationary mechanism, so that when you -- your -- you are  
15 quite assured that that mechanism is still functional, even  
16 when you have gone beyond the five years. And it so happens  
17 that when exemptions came to NRC, they asked for the seven  
18 years. Seven years seemed to be a more workable solution  
19 for these -- for the gamma knives. Now if you go back to a  
20 teletherapy unit, there the source drawer mechanism, the  
21 actually -- the culmination is not a fixed system. It is a  
22 moveable system in terms of -- I think if you all -- maybe  
23 some of us can remember the teletherapy unit where the  
24 source drawer is actually coming in and out, and they're  
25 having cases of sources being stuck. So, therefore, it was  
26 always -- and that part of the servicing could only be done  
27 when the source is out. And you have a 5 curie source, I'm  
28 just saying, even after it has decayed to one-half life, is

1 a still -- is a very important source. So, in order to  
2 service a teletherapy unit for the source, in and out  
3 mechanism needs that source to be out. And therefore, it  
4 was decided upon way back when that this should be done, the  
5 source, that the servicing of, to ensure the shutter  
6 mechanism, needs to be done at the same time that the source  
7 is being replaced. And therefore, it was efficient. It was  
8 workable to have that source out, replace the source, and at  
9 the same time while the source is out of the unit, that they  
10 could actually go in and do the servicing of the shutter  
11 mechanism. So therefore, the -- for the teletherapy, we  
12 have still kept it as five years. But for the gamma knife,  
13 it's gone to a seven year. So, that's the long explanation  
14 for what we are doing here.

15 CHAIRMAN MALMUD: Thank you for the explanation.  
16 Does that answer the question? Certainly clarifies it. Is  
17 there another item you wish to present to us? That's it.  
18 Any other items? If not, thank you, Dr. Howe. Dr.  
19 Zanzonico? Are there any other items to be brought before  
20 the committee now before the break for lunch at noon? NRC  
21 staff, anything you want to mention? Sophie, Ashley,  
22 anything? Chris?

23 MR. EINBERG: Yeah, I would suggest that we're  
24 running considerably ahead of schedule. Right now we look  
25 towards the afternoon. The afternoon we had time allotted  
26 to discuss the rulemaking guidance further until 2:30. I  
27 would suggest that when we come back or during lunch time  
28 we'll take a look at the agenda and see if we can move some

1 items from tomorrow's agenda to today to fill that time  
2 slot.

3 CHAIRMAN MALMUD: Thank you. Then, in the  
4 meantime, we will take a break, which is scheduled to begin  
5 at noon. And we'll reconvene at 1:30. We'll reconvene in  
6 this room at 1:30.

7 Thank you.

8 [break] [resume at 1:30pm]

9 CHAIRMAN MALMUD: Okay, ladies and gentlemen,  
10 there are a number of changes to the agenda, and it's been  
11 distributed to you. If you'll take a look at it, you'll see  
12 that some meetings have been shifted; others have not. And  
13 Ashley can explain to you why the agenda was moved in the  
14 fashion that it has been moved.

15 MS. COCKERHAM: Okay, this is Ashley. And  
16 previously item 15, that was going to be on the agenda for  
17 tomorrow, is going to be -- is the new item number 9. So  
18 Dr. Donna-Beth Howe is going to present on medical events.  
19 Everything tomorrow morning will remain the same. We'll  
20 take a break. What was item number 17 is now item 15. What  
21 was item 18 is now item 16. And item 16 is now item 17 but  
22 it remains at the same time. And then we'll have a closing  
23 session with Sophie, and we'll end at 12:15 instead of 2:30.

24 CHAIRMAN MALMUD: Thank you. And we'll move right  
25 on to the next item on the agenda, which is Dr. Howe's  
26 discussion of medical-related events.

27 DR. HOWE: Thank you, Dr. Malmud. Every year I  
28 give you a -- can I get my slide? I give you a quick

1 overview of the medical events that happened for the last  
2 fiscal year. So in the case, we're talking about Fiscal  
3 Year 2012, which ended October 1st, 2012.

4           The first thing I'd like to do in these  
5 presentations is give you a little bit of a perspective.  
6 Where were we in 2011 and where were we in 2012? In 2011,  
7 we had 58 medical events reported, and in 2012 we had 48.  
8 So we have a slight decrease. Now you have to keep in mind  
9 that we've got probably about 7,000 medical use licensees,  
10 so this is a very small number, so we're not really talking  
11 about statistical significance in any one of these points.  
12 And in 2011 -- and between 2011 and 2012, we have roughly  
13 two to three diagnostic medical events. That would be  
14 medical events involving radiopharmaceuticals that are used  
15 under 35.200. We have a decrease in the number of medical  
16 events for 35.300 use, which would be those requiring  
17 written directives from six in 2011 and two to 2012.

18           And when you look at 35.400, that's manual  
19 brachytherapy, and most of the manual brachytherapy is going  
20 to be prostate brachytherapy. And we've had a decrease from  
21 26 down to 15. We're starting to see a tailing off of the  
22 additional medical events being reported from prostate  
23 brachytherapy as a result of heightened interest after the  
24 VA prostate brachytherapy events.

25           And then we get to 35.600, which are teletherapy  
26 HDR units and gamma knife units. This year, well, we're not  
27 going to see any in teletherapy but I have had one in the  
28 past for teletherapy. And we're staying about the same from

1 12 in 2011 to 13 in 2012.

2 In 35.1000, which are the "other uses," this would  
3 include at the perfection and the yttrium microspheres in  
4 addition to some other modalities that we don't see used  
5 very often. The intravascular brachytherapy is one that we  
6 do see. Some of the others haven't gone back into use, like  
7 the gliasite, yet. Oh, we've seen an increase from 11 to  
8 20. And I'd like to talk about that in a little bit more  
9 detail later. So that's quite a few for 35.1000 because  
10 these are devices that are not used as much as the other  
11 radiopharmaceuticals and devices.

12 Yes, Jim?

13 MEMBER WELSH: Could you explain the question mark  
14 on that slide?

15 DR. HOWE: This was back in the 2011. There were  
16 two that -- there was kind of a question whether they should  
17 be included with this year or maybe included with another  
18 year. I think if you go back to year 2011 notes, you'll  
19 find a better explanation.

20 Okay, let's look at -- now we'll look by  
21 modalities. I've also indicated patients if -- normally  
22 when we have a medical event, it's one event, one patient.  
23 In some cases, we have multiple events or we have multiple  
24 patients. And so in this case with 35.200, we had two  
25 different licensees reporting for medical events. In the  
26 first case -- and we very rarely get diagnostic medical  
27 events. In the first case, the nuclear pharmacy filled vial  
28 label for valium with gallium, and resulted in over 5 rem

1 doses to the patient.

2           In the second case -- this is the tail results of  
3 the strontium-82/rubidium-82 generator problems that evolved  
4 from Bracco Diagnostics product a year before. And when  
5 they finally completed all of the whole-body scans that they  
6 were able to do, it ended up that there were three patients  
7 out in Nevada that exceeded 5 rem whole body exposures. And  
8 that 5 rem is exclusively from the strontium contaminants.

9           I will say that it took us significant amount of  
10 time to get the patients identified and into the whole-body  
11 scan, and so the rubidium-82, which is the primary isotope  
12 that gives the dose. By that time was through maybe  
13 anywhere between 7, 9, or 10 half-lives. So if it wasn't  
14 picked up, that doesn't mean it wasn't there earlier.

15           In 35.300, most of our medical events in 35.300  
16 are for oral sodium iodide 131. And this year's no  
17 different. We routinely have cases where two or more  
18 capsules were provided in a vial and only one of them was  
19 given to the patient. We had another case like that this  
20 year. It ends up that the medical use licensee returned the  
21 vial to the pharmacy and packaged it, did everything they  
22 were supposed to, but they must not have done measurement,  
23 because when they returned it to the pharmacy, the first  
24 thing the pharmacy notices is that there's a reading and  
25 there's still a pill left in the vial. So this is something  
26 we see happening a lot.

27           In another case, we had a prescription for the  
28 prescribed dose and the written directive was 100

1 millicuries. But this particular licensee had changed its  
2 processing. So written directives no longer went directly  
3 the nuclear medicine; they went through an emission office.  
4 And there was also an emission order, which had signature of  
5 the authorized user but had 150 millicuries written on it.  
6 But it wasn't the written directive. And so the nuclear  
7 medicine department never got the written directive, so they  
8 gave what -- they gave -- they were intending to give 150  
9 millicuries from the emission order, which was not a written  
10 directive. And so the licensee -- this was -- had just  
11 changed their procedures about a month or two before, and  
12 they -- this was the first I-131 that they had given. So  
13 they decided that they were going to go back to their old  
14 procedures to make sure the written directives went directly  
15 to nuclear medicine so that they would be in the department.

16           Okay, now we have 35.400, which is manual  
17 brachytherapy. We had 11 medical events and not all of them  
18 were prostate. We had a brachymesh medical event and the --  
19 see if I go into detail on that one -- yes. On the  
20 brachymesh -- and then for the prostate, we had 10 medical  
21 events, but we had 22 patients. We're still seeing the tail  
22 results of -- in this case, agreement states going back and  
23 reviewing more prostate brachytherapy procedures and finding  
24 during inspection medical events that had not been reported  
25 previously. And so that's why we have more patients than  
26 reports.

27           For the brachymesh, the device failed. They gave  
28 the brachymesh implantation and four days later they did a -

1 - it was a long treatment. Four days later, they came back  
2 and did an x-ray and a sizable number of the seeds were not  
3 found on the x-ray. They started with 50; they only found  
4 38. And they proceeded to x-ray this patient about every  
5 week after that to see what was going on. And probably  
6 within a month, all of the seeds were gone. Some of them  
7 stayed in the abdomen, but most of them disappeared. So it  
8 was a problem with device failure that the brachymesh did  
9 not hold up, and the seeds got loose. They thought the  
10 patient may have coughed some up and then that's how they  
11 got into the abdominal cavity, so -- in the abdomen, rather.  
12 So that was a first for us. We haven't had a brachymesh  
13 medical event previous to this.

14           And now we've got the prostate medical events. We  
15 had one licensee with multiple events. So that had 13  
16 patients. We had another licensee that had three separate  
17 reports of one patient apiece. And then we had six separate  
18 licensees with one patient each. And we had a total of 22  
19 patients.

20           We had some pretty interesting medical events  
21 here. We had a leaking I-125 seed. We don't have those  
22 very often. It ends up they -- the licensee discovered that  
23 there was a potential for leaking I-125 seeds when they were  
24 checking the packing material for the seeds that came into  
25 them, a month after they gave the procedure. So they went  
26 back and they contacted the manufacturer, and it became a  
27 "one said this, the other said that," and no one would take  
28 responsibility. But they went back and checked the patient.

1 Sure enough, there was an -- it was a thyroid uptake. So  
2 the leaking seed was implanted into the patient. And at  
3 this point, they haven't resolved whether it was a  
4 manufacturing problem or it was something in the  
5 transportation or the loading of the seeds; so no one is  
6 taking responsibility at this point.

7           Okay, now, you're going to see this coming up  
8 quite a few times in other medical events or other  
9 modalities. And it's been a long time since we really had  
10 wrong patient. But we've had -- in FY 2012, we had at least  
11 three wrong patients in different therapy events. In this  
12 case, you had two patients that were coming consecutively,  
13 but they said, one day after the other, they needed the same  
14 number of seeds. They -- the written directives were pretty  
15 similar. The dose was the same. And they ended up giving  
16 the -- using the treatment plan for Patient 2 on Patient 1  
17 days. And then they discovered it after they'd given the  
18 administration. So that's a wrong patient. Even if they  
19 got the right amount, it still would have been a wrong  
20 patient. And they also discovered they gave about 73  
21 percent of the prescribed dose.

22           We have a wrong side that was -- they implanted  
23 around the penile bulb instead of the prostate. That's  
24 something we see quite frequently.

25           And we had one licensee that had 13 medical  
26 events. Seven of them were underdoses to the prostate, and  
27 in those seven that were underdoses, there were two  
28 overdoses to the rectum. We also had five overdoses to the

1 rectum. They attributed human error, and they also  
2 attributed the fact that they weren't discovered more  
3 quickly, and maybe the rest of them could have been  
4 prevented -- but the fact that they were not comparing their  
5 studies to medical event criteria.

6           We had a patient that passed two strands and  
7 received only 54 percent of the dose that was intended. We  
8 had one which there was a volume increase. When they did  
9 the original image, they thought the prostate was a certain  
10 volume when -- on the day of the post-surgery check, the  
11 prostate volume had doubled in size. They did another CT  
12 slightly after that, and the size of the prostate had  
13 decreased but not back to the original volume. And even  
14 when they did the second estimate, the dose to the prostate  
15 was still estimated at 62 -- 68 percent. So we had a  
16 medical event on that one.

17           We had three patients that were -- the procedure  
18 was performed in 2009, and they were underdoses to the  
19 prostate. And that was from the one licensee that made  
20 three different reports.

21           And we had also a cesium 131 underdose in 2007,  
22 which they attributed to human error. Many of these, they  
23 attributed it to the fact that the licensees were not  
24 checking to see if their procedures were in accordance with  
25 the written directive and whether they had medical events.

26           Okay, now we get -- yes, Dr. Malmud. No?

27           CHAIRMAN MALMUD: Go on, please.

28           DR. HOWE: Okay. Now we get to the 35.600 medical

1 events. Most of these are HDRs. We did have a gamma knife.  
2 I always divide them into anatomical region, just for  
3 interest. And I also split them out for MammoSite or  
4 MammoSite-like procedures because that was at one time  
5 fairly new. And we seem to have a number of medical events  
6 on those types of procedures. So we've got probably the  
7 greatest variety of anatomical parts we ever had for medical  
8 events.

9 [laughter]

10 We've got the MammoSite, we've got sacral, we've  
11 got common bile duct, we have an arm, we have nose, and then  
12 we have the typical GYN medical events.

13 So for the MammoSite, this was another wrong  
14 patient. They had two patients, and they gave the wrong  
15 treatment to the wrong patient. Now, it ends up that they  
16 must treat their patients all very similarly because the  
17 dose and the treatment looked the same, and the problem was  
18 the wrong name on the treatment plan when they delivered it.  
19 So they were fortunate that the treatments were very  
20 similar, and so there was no medical consequence, and the  
21 person actually received about 95 percent of the dose.

22 In the sacral region, they tried to figure -- they  
23 calculated the planes that they were supposed to be  
24 delivering the dose to. And the difference in the planes  
25 was 3 millimeters, but when they import -- when they input  
26 the data, they put 3 centimeters. And so you had two  
27 treatment plans that were -- got a lot more dose than they  
28 were supposed to get. So we have that kind of error. So

1 it's one of those human errors, where they don't get the  
2 right units.

3           The common bile duct; they were going to give two  
4 -- they gave two fractions 4 centimeters from the desired  
5 location. They had to correct the dwell position after the  
6 catheter migrated. But when they corrected where the source  
7 was going to be, they moved it in the wrong direction. So  
8 the catheter migrated in one direction, and they should have  
9 moved the source up to fix where it was, and they moved it  
10 in the opposite direction, so they ended up nowhere near the  
11 treatment site.

12           We had a left arm -- I don't remember when we had  
13 an arm. And in that case, they wanted to give one  
14 treatment, and then they decided that they weren't going to  
15 give one treatment -- one treatment of 200 centigrade --  
16 they were going to give eight fractions. And what they  
17 wanted to do was not divide the one treatment of 200  
18 centigrade by eight, but to give eight separate fractions of  
19 200 centigrade. And so there was a mistake by the folks  
20 there. And they thought they should be dividing by four --  
21 by eight -- and give 24 centigrade each. Instead, they were  
22 supposed to give 200 centigrade per fraction. And it took  
23 them two fractions before they realized the mistake that  
24 they made.

25           Okay, and we had the sides of the nose. In this  
26 case, they were supposed to get two fractions. The dwell  
27 time was correct, but they entered the data into the system  
28 incorrectly. And so they overdosed the treatment site. And

1 they found their error two-thirds of the way through the  
2 procedure.

3           Now to the GYNs. Many times we'll have medical  
4 events but there won't be consequences that can be seen. In  
5 this case, we had a number of consequences. First one was  
6 reddening of the skin to the upper thigh. In this case,  
7 they needed a replacement catheter. The catheters that they  
8 normally use were no longer being manufactured. So they  
9 used a replacement. The replacement was a slightly larger  
10 catheter than what they were used to, so it got stuck at a  
11 constriction in the tandem. So it didn't deliver to the  
12 treatment side but delivered the HDR dose to the upper  
13 thighs. In this case, it was evenly distributed dose.

14           In the second case -- another case in which they  
15 did not get the source into the -- where it was supposed to  
16 be was outside of the body, and they actually saw necrotic  
17 tissue. So this is probably one of our more significant  
18 medical events in a long time. Every once in a while, we do  
19 get necrotic tissue being seen. So this was a pretty high  
20 dose to the inner thigh.

21           In the third case, the guide wire -- it was a  
22 drift error -- and it terminated the procedure just as it  
23 was getting started. And they weren't able to correct that,  
24 and so they had to terminate the procedure totally. So that  
25 was an underdose.

26           We had a case where the tandem wasn't fully  
27 inserted. So for the first fraction, the rectum received  
28 more than it was supposed to, and then the vaginal tissue

1 received a 70 percent overdose.

2           In the next one, they were using channel 1 and  
3 channel 3. They completed the run with channel 1 with no  
4 problems. And then they got an error message that channel 2  
5 wasn't doing something right. Well, they weren't using  
6 Channel 2. So they questioned that. They tried to clear  
7 the error statement. They couldn't clear the error  
8 statement. They called the manufacturer. The manufacturer  
9 tried to talk them through things, and that didn't help. So  
10 they terminated the procedure and then they had the  
11 manufacturer come in and look at things. And they never  
12 really said what the problem was. But they appeared to  
13 claim -- to blame dust. And so now part of their corrective  
14 measures are to keep the HDR unit covered with a dust cover  
15 when it's not being in operation. So one has to infer from  
16 their corrective action of what the problem may have been.

17           They had a treatment planning software malfraction  
18 -- malfunction. They correctly put things into the  
19 software, but it erroneously recalculated dwell times, and  
20 it printed out an incorrect dose to the verification point.  
21 And so that's -- they went back to the manufacturer, and I  
22 think the manufacturer issued a correction warning to other  
23 folks on that.

24           And the last one, there was really no reason  
25 given. They expected to receive 1500 centigrade, and  
26 instead they received 1000. They did say for corrective  
27 actions that they plan on using the QA software in the  
28 future. So that gives you a hint that maybe they were --

1 should have been checking, and this time they didn't check  
2 or they -- somebody checked and they just didn't use the QA  
3 software so that -- they believe that led to the problem.

4           Gamma knife. In this particular case, the --  
5 there was a mechanical failure. They latch the fasteners  
6 that keep the frame or the head connected to the couch. And  
7 so when that failed, they had to terminate the procedure. I  
8 think they tightened the screws down later and they  
9 continued. So -- and that would be a conventional Gamma  
10 Knife.

11           So when we move into 35.1000, we see we've got a  
12 Perfexion medical event. That's the newer model of the  
13 Gamma Knife. And we've got 19 yttrium-90 microsphere  
14 medical events, which we had 21 patients. And one of the  
15 things that -- we'll be asking the ACMUI is if they would  
16 like to look into some of these yttrium-90 microsphere  
17 medical events and give us a perspective on what's going on.

18           Is this a statistically significant number? No.  
19 You're never going to find a statistically significant  
20 number in a medical event. There's just too few of them  
21 reported. But there are also fewer patients who are  
22 microspheres than you see for some other procedures. So,  
23 percentage-wise, they're about 0.3 percent medical event  
24 rate. That's not a large number compared to regular  
25 pharmaceuticals, but I think we would like to have the ACMUI  
26 look into this.

27           Okay, what happened with the Perfexion? Well, the  
28 patient was being treated. They needed to get up. They

1 fell. They dislodged the stereotactic frame. The licensee  
2 reattached the frame, went back, did all the things that  
3 should have done to start off the procedure. And the  
4 problem was that the treatment didn't restart at the correct  
5 location. So.

6           Now for our microspheres. We have a case where 10  
7 to 15 percent of the spheres went into the spleen, the  
8 gastric fundus and the duodenum. And they believe there's  
9 potential permanent functional damage from that case. There  
10 was also incorrect positioning of the catheter. So they  
11 gave the wrong treatment site. They put it into the left  
12 hepatic artery and not the -- they put it into the right and  
13 not into the left. Once again, we've got a wrong patient.  
14 They received the dose from another patient. They labeled  
15 the doses with initials, but the technician gave the wrong  
16 vial. So the initials weren't the same. And they had  
17 expected to receive 143 millicuries. Instead they received  
18 48 millicuries.

19           We had two incorrect doses prepared and delivered,  
20 and that was two treatment sites in one patient. They  
21 weren't following the protocol, so they got 40- and 27  
22 percent less than prescribed.

23           Sixty-three percent of the activity remained in  
24 the device. They -- one of the manufacturers now recommends  
25 a hemostat being put on one tube. They put it on the wrong  
26 tube. It deformed the tubing and restricted the flow.  
27 Another case, 77 percent was delivered. They think the  
28 technician who injected the microspheres failed to empty the

1 syringe. We don't have a lot of detail on that.

2           Seventy-eight percent was delivered. Some adhered  
3 to the bottom of the septum. Thirty-six percent was  
4 delivered. They said the arteries were too small. It  
5 slowed the flush. And when you get a slow flush, then you  
6 don't keep the microspheres up in solution, and they settle.

7           Seventy-seven percent was delivered. Also, again,  
8 they were blaming low flush rate to prevent the reflux of  
9 the vessels into the stomach, and the microsphere settled in  
10 the tubing before completion of administration.

11           I will say we had probably a 50-50 breakdown  
12 between the two manufacturers. So between the MDS Nordion  
13 TheraSpheres and the SIR-Spheres. Seventy-one percent was  
14 delivered. The microspheres became lodged in the  
15 administration line at the stopcock. Seventy-one percent  
16 was delivered. They couldn't determine the cause.

17           Seventy-eight percent: The microspheres remained  
18 in the delivery vial. It was harder to push the plunger on  
19 three flushes. We had 76- and 56 percent delivered. Low  
20 flow rate through delivery, precipitation using low flow --  
21 they believe there's a precipitation effect when you have  
22 low flow rates.

23           Seventy-one percent delivered: the aggregate of  
24 the microspheres in the delivery vial and the hub of the  
25 micro -- catheter.

26           Seventy-three percent delivered: flow clamp wasn't  
27 fully open in that position, and the microspheres played it  
28 out in the flow tube.

1           Sixty percent delivered: They think stasis  
2 occurred. We thought that there may have been vessel spasm  
3 or small fragile vessels. And it was also a slow delivery  
4 stasis malfunction of system. This was TheraSphere, so  
5 TheraSpheres doesn't get -- reach stasis. SIR-Spheres does  
6 but TheraSpheres doesn't because TheraSpheres are much  
7 smaller.

8           Forty-eight percent were delivered. They ended up  
9 using two vials because they couldn't get the material in  
10 the first vial. So they only got 18 percent of what was  
11 supposed to be delivered. But they changed out to another  
12 vial and they were able to get 91 percent of that. They  
13 believed it was a malfunction of the delivery plunger, and  
14 that blood backed up into the catheter on the first vial,  
15 and it ran into the overpressure valve.

16           Nine percent was delivered. Ninety percent of it  
17 remained in the catheter.

18           And then we've got two patients. The work sheets  
19 were switched. Each got the other's dose. The first  
20 reached stasis at 35 percent above the prescribed dose, and  
21 the second at 56 percent less than prescribed dose. So  
22 that's another wrong patient.

23           And that concludes the medical events that we had  
24 for 2012. And as I said before, we have the medical events  
25 subcommittee look at things, and we're hoping this year that  
26 they will spend a little more time looking at the  
27 microsphere issues, and maybe go back a few years and see  
28 what seems to be the issues.

1 Any questions? Yes, Laura.

2 MEMBER WEIL: I have two questions -- one you can  
3 probably get to pretty quickly. Why do you count -- why  
4 don't you count medical events per patient rather than per  
5 institution or licensee I suspect?

6 DR. HOWE: We generally report events as reported  
7 to our headquarters operational office. And so a licensee  
8 can call in once or they can call in multiple times. And so  
9 we tend to call -- each one's -- we'll get a different event  
10 number until we decide that maybe it's the same thing going  
11 on, and we'll tie them back to the first event. So there's  
12 really not a rhyme or reason. Many of our multiple events  
13 are due to the licensee discovering way after the fact that  
14 they've had a medical event, and then going back and looking  
15 at other patients, and so they tend to report all at one  
16 time a number of patients that were involved.

17 MEMBER WEIL: I wonder if representing it that way  
18 serves the purpose of protecting patients.

19 DR. HOWE: I will tell you that in the vast  
20 majority of the medical events we get, it's only one  
21 patient. And it's very unusual that we get multiple  
22 patients or two patients, it's unusual. But we have had  
23 medical events, especially way after the fact where we've  
24 had high application of 500 patients. And instead of having  
25 500 individual reports, we end up with one. I don't know  
26 how to answer your question other than that.

27 MEMBER WEIL: Okay. So, my other question is  
28 unanswerable, I suspect. So, given the number of medical

1 events that are found retrospectively, can you offer any  
2 kind of a wild ballpark figure about what percentage of  
3 medical events are actually reported around the time of  
4 occurrence?

5 DR. HOWE: I think most of our medical events are  
6 recorded close to the occurrence time if the licensee is  
7 following the requirements in 35.40, which used to have a  
8 name. They called it the management program. But it was --  
9 it's a program in which they're supposed to go back and  
10 assure that administrations are in accordance with the  
11 written directives. And that program used to have a number  
12 of prescriptive things in it where you were supposed to  
13 check the charts every quarter or every year. We took out  
14 the prescription part of it, and that enabled people to  
15 identify events a little more quickly.

16 The other thing that I've noticed over the years  
17 is many medical events are identified the nanosecond after  
18 the administration is given. They're giving a dose to Mrs.  
19 Jones, and two seconds after they have injected it, somebody  
20 says, "Oh, hi, Mrs. Smith." And they go, "Oh," [laughs]  
21 "you know, I've got a problem here." And in the old days  
22 when we had about 400 medicals at the time because the  
23 diagnostics had a much lower threshold, that -- we saw that  
24 all the time. And I think you -- it's kind of similar here.  
25 Every once in a while, somebody will come by and they'll  
26 recognize the patient and say, "Oh, I didn't know you were  
27 in today for this." And then they start looking at it. But  
28 I'm not sure I can give you a better answer. But I think

1 most of us -- most of them are found. We could go back and  
2 look.

3 And our requirement is that they have to report  
4 the medical event within 24 hours of identification. So the  
5 identification may come at some later time.

6 CHAIRMAN MALMUD: Other question for Dr. Howe.  
7 Dr. Welsh.

8 MEMBER WELSH: So if I might continue that  
9 discussion that was brought up by Laura. I agree that the  
10 majority of events are reported relatively promptly, but in  
11 recent years, with the states going back to reviewing all  
12 the prostate brachytherapy, for example. That's been going  
13 on for the past x number of years. We have seen an  
14 increased number of medical events that are describing cases  
15 2007, 2008, et cetera. But I think that the obligation of  
16 reporting to the NRC is being honored. Within a couple of  
17 days of being alerted that after 2008, the state has  
18 identified that there was a misadministration involving  
19 Patient Smith and now the obligation to report to the NRC is  
20 being kept. But I think that right now even we are in an  
21 unusual era where the states are going back and reviewing  
22 cases, case after case after case, and I think my former  
23 state of Wisconsin, there are more prostate brachytherapy  
24 cases from days in the distant past that who knows how long  
25 this situation will be going on, but I think that's the  
26 explanation for the anomaly.

27 DR. HOWE: I think we've also in the past as we've  
28 done IMPEP, which are the inspection programs for the

1 agreement states and for the NRC, our regions, we find that  
2 sometimes the IMPEP brings to light something that wasn't  
3 reported before, and we'll get -- all of the sudden we'll  
4 get a lot of medical events that were reported for previous  
5 years from one state or another, and you can almost, when  
6 you're doing a medical events, you can go "Oh, that state  
7 must have just had an IMPEP, because I'm seeing a number of  
8 medical events."

9           MEMBER WEIL: But my concern, which maybe I didn't  
10 state clearly enough, is that if all of these things are  
11 coming to light now through retrospective reviews, they  
12 weren't reported contemporaneously. They weren't reported  
13 at the time of the occurrence, so I wonder what percentage  
14 of events are not being reported now that may be discovered  
15 at some point in the future, but it's just -- it is --  
16 granted, it's a delayed reporting, but it underlies a  
17 failure to report initially.

18           DR. HOWE: Yes. Except the rule is upon  
19 discovery, not upon occurrence.

20           MEMBER WEIL: Absolutely --

21           DR. HOWE: so they're meeting the letter of the  
22 law, but your concern is --

23           MEMBER WEIL: My concern is --

24           MEMBER WEIL: The patient.

25           DR. HOWE: The patient has to make certain  
26 decisions. It would be nice for the patient to be able to  
27 know earlier.

28           MEMBER WEIL: Absolutely.

1 DR. HOWE: But sometimes that information just  
2 doesn't come to light for a while.

3 CHAIRMAN MALMUD: Dr. Suleiman?

4 MEMBER SULEIMAN: Orhan Suleiman. Why are the  
5 states undergoing this retrospective -- is that a -- why are  
6 the states undergoing these retrospective reviews? Did I  
7 miss that, or does it just happen periodically by state?

8 DR. HOWE: I think when we had the VA Philadelphia  
9 Prostate Implant Brachytherapy medical advance, there was  
10 increased emphasis, or prostate brachytherapy came into more  
11 of a focal point. And so many of the states are going back  
12 and looking to see what happened in their states, and that's  
13 why we're seeing the retrospective ones.

14 MEMBER SULEIMAN: Thank you.

15 CHAIRMAN MALMUD: Do you have another question,  
16 or...

17 MEMBER ZANZONICO: Question. The issue of stasis  
18 states with stasis is I don't think that unusual. So my  
19 question is, how uncomfortable are you that it's not being  
20 underreported or over reported? In other words, sort of a  
21 non-medical event stasis episode, just bad luck. At the  
22 time the administration, they couldn't push in all the  
23 microspheres, but everything else was done properly; that to  
24 me doesn't sound like a medical event. So any of these you  
25 think medical events? And on the other side of the coin,  
26 are people -- are their events that may qualify as medical  
27 events based on the criteria for these being unreported  
28 because the practitioner is interpreting them as just sort

1 of a physiologic result?

2 DR. HOWE: We always have that issue and that's --  
3 one way to tell whether things are being identified at the  
4 licensee side is whether they're inspector identified. When  
5 our state inspectors go in, they do it performance-based, so  
6 they're not going to be looking in depth at everything, but  
7 if they do find in their questioning, at least looking into  
8 medical events for a certain area, they may identify there  
9 were potential medical events that weren't reported.

10 For stasis, we've got two different yttrium  
11 microsphere products. One product has very small  
12 microspheres, and they just don't have stasis with those  
13 microspheres. The other product has much larger  
14 microspheres and they identified early on that they weren't  
15 going to be able to get all of the activity in, and that the  
16 capillary beds would fill up. And we'd already put the  
17 TheraSphere into 35.1000, which is the evolving technology  
18 where the other use is and when the SIR-Spheres came down  
19 and we realized that you would have spaces and it wasn't the  
20 licensee's fault. It was the fact that these spheres were  
21 too big to get all of them into the capillary bed. We  
22 rewrote the medical event definition for the SIR-Spheres to  
23 say that it was either you gave the activity you were  
24 supposed to give or stasis happened. If you wrote in the  
25 written directive, you are going to give so many millicuries  
26 or stasis for the SIR-Spheres, and stasis occurred, we would  
27 not consider that a medical event. Otherwise we would have  
28 -- I think over a third of the SIR-Spheres are stasis, but

1 we didn't want people to try to force the spheres in to  
2 prevent a medical event, and have them backflow into the  
3 intestinal tract and cause radiation to induce ulcers.

4 MEMBER ZANZONICO: So you're basically relying on  
5 the notes of the doctors saying that they couldn't deliver  
6 the whole dose because it was just physiological.

7 DR. HOWE: Well, I think most of them know the  
8 word stasis, and they write it in their written directive.  
9 And we don't really question that for the very larger  
10 spheres, but we get it for TheraSphere, it's always a  
11 question because spheres are small enough they should go in  
12 and fill the capillary bed. Because they can get a lot more  
13 activity in a smaller number of spheres. They have much  
14 higher activity.  
15 I'm not sure I answered the question.

16 MEMBER ZANZONICO: No, you did.

17 CHAIRMAN MALMUD: Doctor Welsh.

18 MEMBER WELSH: So, I might follow up on this point  
19 by saying that we say that the TheraSphere being smaller,  
20 glass microspheres never experience stasis, but I've learned  
21 in medicine to really never say never, and I'm wondering  
22 what example that we talked about earlier where it might  
23 have been spasm of the vessel or a one in a million case of  
24 stasis with the smaller glass microspheres, could be an  
25 example of something that's not supposed to happen.

26 DR. HOWE: And I believe we've recently revised  
27 the guidance for the TheraSphere side to indicate that it's  
28 not a medical event if you have small vessel spasm and a few

1 other descriptors of that nature. Ashley, do you want to  
2 pipe in here?

3 MS. COCKERHAM: This is Ashley. That's correct.

4 DR. HOWE: Okay. And that's is one of the  
5 beauties of having the 35.1000 is as we find out there are  
6 more experience with things and there are things we hadn't  
7 anticipated, or licensees haven't anticipated. It's fairly  
8 easy for us to modify and come into.

9 CHAIRMAN MALMUD: Dr. Welsh.

10 MEMBER WELSH: So, that being the case, is the one  
11 example that we were talking about earlier still truly a  
12 medical event, or could it be an example where there was no  
13 true medical event?

14 DR. HOWE: It depends on when we change the  
15 guidance as to whether it would still be considered a  
16 medical event or not. And, you know, medical events for us  
17 is not a bad thing. If you lie about it, and then you get  
18 into escalate enforcement space, that's a bad thing; but to  
19 report one is not a bad thing for us. We will give you an  
20 additional inspection, but things happen.

21 CHAIRMAN MALMUD: Dr. Suleiman.

22 MEMBER SULIEMAN: This always bothers me because  
23 the spheres were considered medical devices. They're used  
24 for humanitarian use, so they're not used for normal,  
25 healthy individuals. The issue of the distribution is  
26 clearly not uniform, so the dosimetry is a joke as far any  
27 kind of true accurate estimate, and there's always a  
28 question about what's normal variability in these patients.

1 So what's -- is this, in fact, a medical event or is this  
2 just practice of medicine for that specific population of  
3 patients, and again, specifically a group that's designated  
4 for humanitarian use purposes because they're very seriously  
5 ill.

6 DR. HOWE: To get to your dose question, we  
7 recognized early on that people were not going to be able to  
8 calculate doses, and so we have that's part of it being in  
9 1000, is that we recognize that if you were intending to  
10 deliver a certain activity, we do deliver what you thought  
11 was going to be some kind of dose, then we would go with the  
12 activity; so we recognize they can't measure dose, and we've  
13 taken that out of the equation for the yttrium-90  
14 microspheres.

15 Only half of the patients are on humanitarian  
16 reasons. The SIR-Spheres folks got a full PMA, so they can  
17 be used for any medical usage. It's just the TheraSphere  
18 that are still restricted to the humanitarian device  
19 exception.

20 CHAIRMAN MALMUD: Any questions for Dr. Howe? Oh,  
21 I'm sorry. Ashley, did you have your hand up?

22 MS. COCKERHAM: Yes.

23 CHAIRMAN MALMUD: Oh well, Dr. Langhorst first,  
24 please.

25 MEMBER LANGHORST: Dr. Howe, you mentioned about  
26 the rate of the microspheres medical events. Do you have  
27 updated numbers on the numbers that are done each year? And  
28 I wondered -- wanted to ask our subcommittee chairman if we

1 might want to have new numbers this year as we prepare our  
2 review.

3 DR. HOWE: I believe we have numbers that we can  
4 make available to the subcommittee.

5 MEMBER LANGHORST: Okay.

6 MS. COCKERHAM: So there's actually two questions.  
7 Are you talking specifically about microspheres or all  
8 medical events?

9 DR. HOWE: Yes.

10 MS. COCKERHAM: Both?

11 DR. HOWE: Both.

12 MS. COCKERHAM: For microspheres, yes we do have  
13 that information from the manufacturers and that is actually  
14 what I wanted to talk to the committee about. We touched on  
15 it earlier about having maybe a teleconference this summer  
16 to maybe look into microspheres and a little further because  
17 we have those denominator numbers. So we can talk more  
18 about that later. The other answer is we did finally get  
19 money to purchase the IMV reports, which are for all  
20 modalities, and we should have those reports very, very  
21 shortly if we don't already have them. Oh, maybe one of the  
22 two was available. Okay, we have the radiation therapy  
23 benchmark report. So it sounds like the nuclear medicine  
24 one was not available yet.

25 MEMBER LANGHORST: Okay. Thank you very much.

26 MS. COCKERHAM: Can I touch on one more thing,  
27 since I have it up on the screen --

28 DR. HOWE: And I think up on the slides, we've got

1 the revision that we've made to the written directive that  
2 says, "Administration must be performed in accordance with  
3 the directive. If the procedure must be modified due to  
4 emergent patient conditions that prevent administration in  
5 accordance with the written directive, artery spasm or  
6 sudden change in blood pressure, then you should document  
7 such change as a written directive within 24 hours after  
8 completion of the administration. The modification to the  
9 written directive should be included as the reason for the  
10 administration, administering the -- not administering the  
11 intended dose activity." So we've modified the guidance for  
12 that, and then we've also asked that licensees now record  
13 the amount of activity that's delivered to the treatment  
14 site.

15 MS. COCKERHAM: This is Ashley, I would add, this  
16 is published in June of 2012. So I'm not sure if that other  
17 medical event occurred that you were asking about, and  
18 whether or not this guidance specifically would apply.

19 DR. HOWE: I'd have to look.

20 MS. COCKERHAM: Okay.

21 MEMBER WELSH: I might ask if this verbiage  
22 applies equally to the glass and resin microspheres?

23 DR. HOWE: We did not distinguish between the two  
24 for this particular part of the guidance. Am I correct,  
25 Ashley?

26 MS. COCKERHAM: Correct.

27 CHAIRMAN MALMUD: Does that answer your question?

28 MEMBER WELSH: Yes, thank you.

1           CHAIRMAN MALMUD: Other questions for Dr. Howe?  
2 Dr. Van Decker.

3           MEMBER VAN DECKER: Just as an interested  
4 observer, looking at the institutions and states that have  
5 been reporting, recognizing that they shouldn't be small  
6 portions of the country concentrated, your guidance here has  
7 had reiterations of education to all providers such that  
8 we're doing the same thing across all the states right now,  
9 or we have some reason why we should have clustered  
10 reporting to some degree?

11           DR. HOWE: I think when we put our guidance up on  
12 the website, we --

13           MEMBER VAN DECKER: By some high quality  
14 performers?

15           DR. HOWE: We also put out on our medical  
16 listserver that we changed it. So we notified people that  
17 way. But I'm not sure we notified any other way. Many  
18 times our changes may come as a result of a request from a  
19 manufacturer, and so the manufacturer will go back and tell  
20 all of its customers the changes we have made.

21           MEMBER VAN DECKER: Whisper down the lane?

22           DR. HOWE: I think they do more than whispering.  
23 Ashley, can you --

24           MS. COCKERHAM: I believe, on this last revision,  
25 we probably did an agreement state letter, we call FSME  
26 letters, so we would have communicated that with the  
27 agreement states. At a bare minimum, it went out on a  
28 listserv, because any time I revise the guidance letter it

1 always goes on our public website.

2 CHAIRMAN MALMUD: Ms. Bailey, did you have your  
3 hand...

4 MEMBER BAILEY: I kind of got lost in some of the  
5 -- a FSME letter usually means we would send a -- very  
6 analogous, maybe just a cover letter on top of it, agreement  
7 states would go out to their licensees. So it would follow  
8 suit that all licensees received it. Now we're aware that  
9 everybody receives a stack of papers. Ours -- these kind of  
10 things often come up -- our licensees appear to be very  
11 concerned about whether something is a medical event or not,  
12 and it seems -- I can't say nine times out of 10, although  
13 it seems like a lot of phone calls. This just happened, or  
14 we just discovered this, how do we deal? And that's the  
15 time we'll end up -- we'll be going back to things like  
16 this. We'll go, "Well, that relates to that letter you  
17 received, did you apply that?" Then they can go back. So a  
18 lot of things are noticed to the states. The licensee has  
19 done their parts. Then there's a lot of going back and  
20 forth trying to make determinations, and that may be an  
21 answer to your question earlier, why states maybe go back in  
22 retrospect. IMPEPs coming up, there's a question, how many  
23 medical events did you have? And you go back and look, and  
24 you might see, oh yeah, we determined that one was, and our  
25 database doesn't indicate that we let NRC know. So a lot of  
26 it is reporting type information, but the events were worse.  
27 The regulations were put in...

28 DR. HOWE: Enforced?

1 MEMBER BAILEY: I guess for lack of a better word.

2 CHAIRMAN MALMUD: Thank you. Dr. Van Decker.

3 MEMBER VAN DECKER: My question just revolved  
4 around, you would assume there would be a bell-shaped curve  
5 from among the states where you saw reporting.

6 DR. HOWE: [laughs] I can't respond.

7 CHAIRMAN MALMUD: At this -- Dr. Welsh.

8 MEMBER WELSH: Dr. Howe, I don't mean to delve too  
9 much into the specifics, but that case about the arm sarcoma  
10 brachytherapy is a little perplexing to me. Did that  
11 patient not receive the full prescribed dose in the end? In  
12 other words, if the first two fractions were .2 gray rather  
13 than the .25 gray, .25 rad, instead of the 2 grey, the 200  
14 centigray, that was intended. Did you authorize the use of  
15 the device and see not compensate for those two fractions?

16 DR. HOWE: That information is not necessarily in  
17 the event report, but we would hope that -- having a medical  
18 event does not preclude that the physician goes back and  
19 does what needs to be done to rectify; so we would hope that  
20 they went back and decided what they needed to do to give  
21 correct doses.

22 MEMBER WELSH: But my question is why -- on what  
23 basis would it qualify as a medical event?

24 DR. HOWE: Because you've got -- we have a  
25 definition of medical event that shows if, in any given  
26 fraction, you are less than what you intended to give, then  
27 you're a medical event; and that's why I said medical events  
28 are not necessarily bad things. Things happen, and we don't

1 -- we've heard many statements where we hear, well you  
2 prevented us from doing the right thing. No, you can always  
3 go back and do the right thing. You may still have a  
4 medical event, but you can always go back and do the right  
5 thing. We expect you to go back and do the right thing.

6 MEMBER WELSH: If I could just reply to that,  
7 after being in this room for so many years, I understand  
8 that it's not considered a bad thing from the NRC's  
9 perspective, but from a patient and physician perspective,  
10 the word medical event still is perhaps misperceived as  
11 something worse than it truly is.

12 DR. HOWE: And I think no matter what word we  
13 pick, misadministration, medical event, whatever word we  
14 pick, will always be misunderstood.

15 MEMBER BAILEY: Ma'am?

16 CHAIRMAN MALMUD: I heard a voice.

17 MEMBER BAILEY: Over here.

18 [laughter]

19 MEMBER BAILEY: I have a question from our  
20 Advisory Committee relating to that. In that a medical  
21 event is not a big deal to the NRC, ergo to us, in that  
22 respect. Do you see that the medical event reporting is  
23 then used by other entities that see it as a big event?  
24 Either JCAHO or the middle management, safety organizations?  
25 We're told if we report it to you, then it's a bad event in  
26 some other grouping. Is that true? Are they used otherwise  
27 negatively? That's a concern. It's an -- unintended  
28 consequences.

1           CHAIRMAN MALMUD: I think we all, as providers,  
2 have the same concern about having medical events reported  
3 when they clinically do not appear to affect the quality of  
4 the patient care. For example, what Dr. Welsh described was  
5 correctible with an additional amount. However, if it were  
6 the third or fourth such instance in which it had not been  
7 reported, and then it was discovered retroactively that this  
8 was a pattern, the pattern could have been interrupted had a  
9 medical event been reported, even though there were no  
10 consequences to the medical event reporting except for a  
11 significant anxiety surrounding the first instance. But  
12 that might have prevented the second, third and fourth,  
13 which may have been overdoses instead of under doses or a  
14 series of events. So that's the problem that we have as  
15 providers, as physician providers. And being concerned  
16 about being overly alert -- not overly alert, but overly  
17 anxious about issues that do not affect the quality of  
18 patient care and having to deal with a considerable amount  
19 of paperwork. But as human beings we generally try to avoid  
20 pain, and the provider will generally try to prevent the  
21 pain of an investigation, even though there's no significant  
22 outcome to it. So, we're careful for the same reason we  
23 stop for red lights in the middle of the night when there's  
24 no traffic around. We just stop because those are the  
25 rules. At least I hope you do.

26           At any rate, I think that's the balance we've been  
27 trying to achieve and I understand Dr. Welsh's question and  
28 I sympathize with it, not as a radiation oncologist, but as

1 a nuclear physician in terms of reporting things that we  
2 think are inconsequential. On the other hand, when we've  
3 had events at my own institution, going back a number of  
4 years, it was a useful anxiety-provoking experience to have  
5 the NRC look at it, and those things didn't happen again.

6 MEMBER BAILEY: Thank you.

7 DR. HOWE: And it's kind of anecdotal, but back  
8 when we were receiving diagnostic medical events and we  
9 getting 400 to 500 a year, we saw a pattern in some places  
10 where the physicians were being penalized for reporting  
11 medical events so they didn't report them. And then there  
12 would be a disgruntled employee and they would report it  
13 later, and then you would have escalated enforcement action  
14 and it got a lot worse, and we have tried very hard to put  
15 out the message that a medical event is not necessarily  
16 harmful to the patient. In a medical event things happen,  
17 you have to report it. It's much worse if you don't. So...

18 CHAIRMAN MALMUD: Dr. Suleiman?

19 MEMBER SULEIMAN: I mean FDA basically takes a  
20 two-tier approach. I mean you have the severe adverse event  
21 which is death or life-threatening, which people understand  
22 is serious and then you have the adverse event, which could  
23 be anything, and is looked at sort of as a low census -- it  
24 is just early detection if you get enough of those happen,  
25 but it's an extremely imperfect process. I think we  
26 understand that. With your medical criteria you don't  
27 really have a two-tier, it's either all-or-none.

28 DR. HOWE: To some extent we do have a two-tier as

1 to what we do with the information. Our medical event  
2 threshold is very low. I mean it's not harm, and it never  
3 has been harm; so we are trying to pick up the errors that  
4 may, if not corrected, lead to harm. So, you've got to  
5 report at a fairly low threshold. That doesn't mean  
6 everything is down at that low threshold; we have a number  
7 of things that are at a much higher threshold and those we  
8 categorize as abnormal occurrences and they get reported to  
9 Congress. So we do have two tiers of seriousness, but not  
10 from the reporting. We set it low enough to catch  
11 everything we think we need to catch and then we do  
12 something different with the higher ones.

13 CHAIRMAN MALMUD: There were some other hands.  
14 Dr. Welsh.

15 MEMBER WELSH: I think that this why it's so  
16 critically important to have a high quality definition for  
17 medical event. Because the reality is that, although you'll  
18 never find any proof of this because it is not going to be  
19 written, hospitals and physician groups will compete and  
20 they will take advantage of the fact that a medical event or  
21 misadministration has occurred at Hospital A down the street  
22 you and try to get the edge on them. And if Hospital A does  
23 10 times more brachytherapy and does a great job with it but  
24 have had two medical events in the past year, Hospital B  
25 might unscrupulously take advantage of this unintended  
26 misuse of the term and misinterpretation of the term and say  
27 "our hospital has not had a medical event in the past five  
28 years or so," even though they are not doing much

1 brachytherapy, insinuating that in some way or another they  
2 have a better brachytherapy program. That's another  
3 unfortunate reality of human nature, and it just underscores  
4 the importance of having good medical event definition in  
5 the first place, and it is also maybe is a good segue to the  
6 next topic of abnormal occurrence, which I think, at least  
7 in my mind, is that higher threshold tier that is worthy of  
8 to keep in mind.

9 CHAIRMAN MALMUD: Thank you. We have a comment  
10 from Angela McIntosh.

11 MS. MCINTOSH: Yes, I just wanted to point out to  
12 everyone following up on Dr. Howe's comment earlier that a  
13 medical event does not necessarily indicate harm to a  
14 patient, and we try to communicate that message in the event  
15 report; there's a boilerplate statement to every reported  
16 medical event reiterating the fact that a medical event does  
17 not necessarily indicate harm to the patient. So, we do, at  
18 least that way, put it out every time that a medical event  
19 is reported, is reported to us.

20 CHAIRMAN MALMUD: Thank you. Dr. Welsh?

21 MEMBER WELSH: That would be great in an ideal  
22 world, but if then Hospital A, who has been criticized by  
23 Hospital B, because they had two medical events last year,  
24 could get that verification that these medical events are of  
25 not of importance and all those patients who are being told  
26 about let's go to Hospital B because it never had a medical  
27 event are also so informed, it would be truly valuable.  
28 Unfortunately that's never going to happen. And this abuse

1 or taking advantage of the misinterpretation of the severity  
2 of the term is an unfortunate reality.

3 CHAIRMAN MALMUD: Mr. McDermott?

4 MR. MCDERMOTT: I just had a question to get a  
5 sense of the committee's thoughts. Angela mentioned the  
6 fact that NRC puts in a statement that says "this event may  
7 not have resulted in actual harm to the patient." If the  
8 reporting guidance and so forth were changed that the  
9 medical provider, which provides a positive statement on  
10 their assessment of whether or not this was correctible, or  
11 -- would that -- in your opinion, would that help alleviate  
12 or reduce this issue at all?

13 MEMBER WELSH: In my mind the answer's yes.  
14 Because from the patient's perspective, might want to know  
15 if a hospital has had a certain number of medical events is  
16 really having medical events because the definition is  
17 inappropriate or they are just doing so much brachytherapy  
18 that they are within a normal range of medical events per  
19 year for that volume, or if there is possibly something  
20 going on at that institution. If their rate is higher or if  
21 there are medical reasons to be concerned that these medical  
22 events are truly of medical consequence, I think that  
23 information would be valuable to patients. So I think that  
24 maybe it would.

25 DR. HOWE: If there's confusion to licensees when  
26 they have a medical event and they say, "Oh, but there was  
27 no harm to the patient," and they actually think that that  
28 takes away the medical event, and so they think, "Well, I

1 don't have to report this because there was no harm to the  
2 patient," or they don't have to report it because they were  
3 able to adjust things, and that ends up with an issue for us  
4 in the regulatory space. We've seen that a number of times.

5 CHAIRMAN MALMUD: Dr. Thomadsen?

6 VICE CHAIRMAN THOMADSEN: I would answer Mr.  
7 McDermott's question differently. And I would say that I  
8 would think most people would think that was just self-  
9 serving and wouldn't take it seriously. I mean they are  
10 being told these people are having events and of course the  
11 administration is going to say, "Ah, but they happen."  
12 Thank you.

13 CHAIRMAN MALMUD: I think we have heard both  
14 positions on the issue.

15 VICE CHAIRMAN THOMADSEN: Thank you.

16 CHAIRMAN MALMUD: May we move on to the next item,  
17 which is the AO subcommittee report?

18 MR. EINBERG: Excuse me, before we move on.  
19 Ashley, did you want to talk about the medical event  
20 subcommittee telecon, or...

21 MS. COCKERHAM: Correct. Dr. Malmud, if we could.  
22 I gave a short presentation, it was requested by the states,  
23 to have additional information on yttrium-90 microspheres  
24 medical events. Several states have reported more than  
25 other states, and so they brought it to the NRC's attention  
26 during one of their quarterly, monthly -- it's an OAS/CRCPD  
27 phone call. So I actually spoke to that group, put together  
28 a little one-pager that kind of summarized all of the

1 medical events reaching around microspheres from 2007 until  
2 2012, and I had numbers from manufacturers, as I mentioned  
3 earlier, to give me an idea of what the denominators might  
4 be. And we were wondering if the committee could maybe take  
5 a look at the yttrium-90 microspheres medical events a  
6 little further for us. I am also giving a presentation at  
7 the OAS meeting in August, and I think it would be very  
8 helpful for me to have insights from the committee to  
9 provide to the states to communicate whatever the message  
10 might be. I don't even know what the message is yet, we are  
11 just looking into them.

12 CHAIRMAN MALMUD: By all means.

13 MS. COCKERHAM: That would be Dr. Welsh's  
14 subcommittee, so I will get in touch with you more. Could  
15 we schedule a June teleconference? I believe Sophie polled  
16 the subcommittee about their availability in June for a two-  
17 hour teleconference to discuss whatever the subcommittee may  
18 find.

19 CHAIRMAN MALMUD: That question is addressed to  
20 Dr. Welsh?

21 MS. COCKERHAM: Yes.

22 MEMBER WELSH: I have replied regarding my  
23 availability. I don't know what the others on the  
24 subcommittee's availability is, but, I think it's a good  
25 idea.

26 MS. COCKERHAM: I think there's really mixed  
27 availability. We couldn't find one date where all members  
28 were available, but where the majority of the members were

1 available, it was the week of June 17th through 21st, from  
2 2:00 to 4:00 p.m. So if we could pick one of the days that  
3 week. I know that Dr. Thomadsen indicated that he would be  
4 not available and he would be the chair at that time, so Dr.  
5 Guiberteau, it would kind of be at your discretion or choice  
6 as to what day would be best for you. We could pick a date  
7 and an alternate date. You don't have your calendar?

8 MEMBER GUIBERTEAU: No, but I think I am available  
9 every day but Monday that week.

10 MS. COCKERHAM: Okay. So do we want to say --  
11 what's Tuesday's date?

12 MS. HOLIDAY: The 18th.

13 MS. COCKERHAM: Tuesday the 18th from 2:00 to 4:00  
14 p.m. Yes, this would be a full committee meeting to discuss  
15 whatever the subcommittee's findings are.

16 MEMBER LANGHORST: So, the subcommittee has to  
17 come to some findings first, by June, to -- okay.

18 MS. COCKERHAM: And let me tell you the driver for  
19 this is that I present to OAS in August, and my slides are  
20 obviously going to be due before August, so I need to have a  
21 chance to hear from the full committee before I go in front  
22 of the states. So, Tuesday, the 18th from 2:00 to 4:00 p.m.  
23 EDT. Does anyone have ...?

24 MEMBER LANGHORST: I'm looking desperately here.

25 MS. HOLIDAY: Dr. Malmud, this is Sophie. It  
26 might maybe be helpful if I indicate who did tell me that  
27 they were available on the 18th. While there will be 12  
28 members in the committee total at the time, only nine of the

1 12 members indicated that they would be available on that  
2 date. That would be Dr. Suleiman, Dr. Guiberteau, Dr.  
3 Palestro, Ms. Weil, Dr. Welsh, Dr. Langhorst, Dr. Zanzonico,  
4 and Ms. Bailey, and Mr. Mattmuller.

5 CHAIRMAN MALMUD: Were there better days that  
6 week?

7 MS. HOLIDAY: Actually, this whole week, we  
8 wouldn't get everybody but we would have nine of the 12, so  
9 that would be any of the days. But then it varies on which  
10 members are actually available on those days.

11 CHAIRMAN MALMUD: And Dr. Langhorst?

12 MEMBER LANGHORST: And again, what time did you  
13 say?

14 CHAIRMAN MALMUD: 2:00 to 4:00.

15 MEMBER LANGHORST: 2:00 to 4:00 Eastern Daylight  
16 Time?

17 MS. HOLIDAY: Yes, ma'am.

18 MEMBER LANGHORST: Okay.

19 MS. COCKERHAM: Let's tentatively set Tuesday from  
20 2:00 to 4:00 p.m. and then we can pick -- do we want  
21 Wednesday or Thursday as the backup day? Since I'm  
22 choosing, I'll say Thursday because we have a staff meeting  
23 on Wednesdays.

24 [laughter]

25 Is there any other driver?

26 CHAIRMAN MALMUD: Dr. Welsh?

27 MEMBER WELSH: So, I apologize. This is not  
28 exactly what I interpreted the email to be asking. So, just

1 for clarification the subcommittee will have to have  
2 something to present to the full committee for this day, so  
3 it's not like a subcommittee teleconference.

4 MS. COCKERHAM: Correct.

5 MEMBER WELSH: And is Dr. Thomadsen available for  
6 the subcommittee any longer? So, then we will need some  
7 restructuring of this because Dr. Thomadsen was an integral  
8 component of our subcommittee.

9 VICE CHAIRMAN THOMADSEN: Is there rules on the  
10 chair's participation in subcommittees?

11 MS. HOLIDAY: No.

12 MEMBER WELSH: Thank you.

13 MS. COCKERHAM: So, he could participate and do  
14 everything up until the actual meeting day and then you  
15 could represent his views at the meeting. Like I said,  
16 there's no preset -- I'm not presenting an issue. We are  
17 just saying we would like you to look into this and provide  
18 your medical expertise on if you think there may be issues.  
19 And what those issues might be. Only for yttrium-90  
20 microspheres. And narrow your scope. Okay, so I am going  
21 to say Tuesday 2:00 to 4:00 p.m., Thursday as a backup 2:00  
22 to 4:00 p.m. Dr. Thomadsen?

23 VICE CHAIRMAN THOMADSEN: Just will you send out  
24 to us the information that you collected on the  
25 microspheres?

26 MS. COCKERHAM: Absolutely.

27 VICE CHAIRMAN THOMADSEN: Thank you very much.

28 CHAIRMAN MALMUD: Okay, we will move on to the

1 next item on the agenda. And that's the AO subcommittee  
2 report and Dr. Langhorst.

3 MEMBER LANGHORST: Thank you very much. I will  
4 ask if I'm willing to present my slides and then we can  
5 discuss, or if the committee would like we can discuss as I  
6 go along. I am open to either way, so, if someone wants to  
7 ask a question or get into the topic as I am presenting, I'm  
8 open to that.

9 CHAIRMAN MALMUD: Thank you.

10 MEMBER LANGHORST: Okay, thank you very much. So,  
11 this subcommittee was formed as of our last September  
12 meeting, and the charge of the subcommittee, as we have  
13 written up in our list, was to review the refined abnormal  
14 occurrence criteria and provide recommendations to the NRC  
15 staff. So, just a little background because I know whenever  
16 I come back to these topics I kind of forget, "Now where --  
17 how did this come about?" So, in 2008, the committee made  
18 recommendation and in December of 2011 regarding its  
19 recommendation for removal of dose-based abnormal  
20 occurrence, or I will call them AO criterias, for medical  
21 licensees, that those abnormal occurrences should include  
22 significant medical harm. And after our December 2011, this  
23 was essentially the recommendation that the committee  
24 provided to NRC staff.

25 At our September 2012 meeting NRC staff came back  
26 with a more formal way of writing those significant medical  
27 harm, but also with a proposed refinement to add dose-based  
28 screening criteria as listed here. The thought there was to

1 help the staff evaluate medical events to see whether there  
2 needed to be medical consultants to review a given medical  
3 event. So it had to meet -- what they had proposed in their  
4 refinements, it had to meet these dose criteria, and I will  
5 emphasize the "and" resulted in one or more of the following  
6 significant impacts of patient health. And I say patient  
7 but please know that I always mean patient or human research  
8 subject. But I'm going to just be shortening it to patient  
9 in most cases.

10           So I had asked if the subcommittee's presentation  
11 to the full committee to add some additional resources so  
12 you had them handy. One was the portion of the Energy  
13 Reorganization Act of 1974 as amended covering Section 208.  
14 And this is really what defines what is meant by abnormal  
15 occurrence. So it is an unscheduled event incident or event  
16 which the Commission determines is significant from the  
17 standpoint of public health and safety. And so another  
18 resource that I asked be included was the latest policy that  
19 the Commission had approved on the AO criteria. And so in  
20 regard to medical use, if you go to appendix A, and I'm sure  
21 everyone has studied it, there is a category Roman numeral 1  
22 that covers all licensees. And under a of that section is  
23 human exposure to radiation from licensed materials. Now  
24 this applies to all licensees and the exposure to anyone  
25 from radiation radioactive materials and so on. And so it  
26 makes sense that these kinds of exposures are not supposed  
27 to happen, that they are indication of an uncontrolled  
28 situation of radioactive material exposure.

1           As compared to the 10CFR Part 20 dose limits, be  
2 they for occupational dose or for public dose, the dose  
3 limits that are given for exposures to adults, exposures to  
4 a minor, or embryo fetus, they range from two to 10 times  
5 the Part 20 dose limits. Okay? And there's also a criteria  
6 said here that lists the permanent medical harm.

7           At the other part of the AO criteria definitions  
8 is in Roman numeral 3 Item C. And this is where medical  
9 events have been defined as to which one of the medical  
10 events should rise to the point of an abnormal occurrence.  
11 And so this is the section that we were looking at. And it  
12 is a dose-based, and this additional dose or dosage greater  
13 than 50 percent prescribed or the dose or dosages involves  
14 these mistakes or events; wrong pharmaceutical --  
15 radiopharmaceutical, wrong route, and so on. Very similar  
16 to medical event-type criteria. Okay? Do I have everyone?

17           CHAIRMAN MALMUD: Appears that you do.

18           MEMBER LANGHORST: Thank you. I appreciate that.  
19 So the subcommittee began its review in really looking at  
20 the last five years of the AO reports. And in this you  
21 could see the AO reports follow the NRC's fiscal year. And  
22 so you can see for each of the past five years that a full  
23 number of abnormal occurrences reported. The first medical  
24 use column there is when you read each of those abnormal  
25 occurrence reports it really involved embryo fetus exposed -  
26 - unintentionally exposed when the mom received an I-131  
27 therapy, and I will come back to that later. The next  
28 medical use column, the AO 3-C; those are our medical

1 events. And then the last column is all the other AOs that  
2 have been reported that had nothing to do with medical use.  
3 And you can see pretty much every year there weren't any  
4 other abnormal occurrences except for 2011.

5           So this is a reason why we're looking at this. It  
6 seemed like those medical events that we are reporting as  
7 abnormal occurrences seem -- that threshold seems too low.

8           So one of the refined proposals that the staff had  
9 given us was to retitile that section, the AO criteria Roman  
10 numeral 3C, to read for event involving patients and human  
11 research subjects. The subcommittee felt that was a correct  
12 thing to do, that it was not mistaken that that was the only  
13 AO criteria that medical licensees are subject to. They're  
14 subject to the first Roman numeral one, all licensees also.  
15 But this also further defined that this is limited to  
16 medical administration.

17           Now, as I noted, the ACMUI has discussed this  
18 topic several times, and in fact I think a few more times  
19 that I haven't noted. And our subcommittee discussed it yet  
20 again, and we have always come to a conclusion that dose-  
21 based screening criteria would not provide a reliable method  
22 to identified medically significant incidents in all cases.  
23 And so we recommend that should not be used. And so this is  
24 what the subcommittee presents to the committees, should be  
25 that definition of AO criteria that medical events should be  
26 measured. So the medical event involving a patient or human  
27 research subject that, as determined by consultant position  
28 or multiple, deemed qualified by NRC or an agreement state

1 also results -- or results in one or more of the following.  
2 And then the criteria are the same as what NRC staff  
3 proposed in their refined proposal. Unintended or  
4 unexpected permanent function, functional damage to an  
5 organ, an intended or unexpected permanent functional damage  
6 to a physiological system, a significant unexpected adverse  
7 health effect or death.

8 CHAIRMAN MALMUD: That's a motion. No?

9 MEMBER LANGHORST: No. I'm not done yet. But I  
10 see a question.

11 MEMBER SULEIMAN: Orhan Suleiman. I've taken the  
12 prerogative because we never decided whether or not I could  
13 interrupt you now or wait until afterwards. What if an  
14 organ received a very large dose, much higher than any of  
15 the numbers you've tossed around? And you predict that  
16 maybe that organ will die in the future but it's functioning  
17 right then and there. That would not meet your criteria.

18 MEMBER LANGHORST: It's an adverse health effect.

19 MEMBER SULEIMAN: But it hasn't occurred. The  
20 only way you can predict that it's going to occur is because  
21 you're assessing the dose, yet you just excluded dose in the  
22 previous line. It's sort of a circuitous argument that you  
23 wouldn't know until the harm was done. But you may know  
24 what the dose is, but the dose precludes you from reporting  
25 it. Am I clear?

26 MEMBER LANGHORST: Reporting what?

27 MEMBER SULEIMAN: About this is an abnormal  
28 occurrence.

1           VICE CHAIRMAN THOMADSEN: I think that that's not  
2 the case because the situation was that in the medical event  
3 the, a medical consultant would be named. The medical  
4 consultant would look at the dose, say this is likely to  
5 cause harm to the patient, and that would fit this criteria  
6 -- criterion.

7           MEMBER SULEIMAN: So the dose wouldn't be out of  
8 the formula, but it would -- could be a medical event --

9           VICE CHAIRMAN THOMADSEN: It could be used -- it  
10 could be used by the medical consultant.

11          MEMBER LANGHORST: Right. And the medical event  
12 is still being reported. Okay? And is -- as we've  
13 discussed it's being taken very seriously, not only by the  
14 licensee but the regulators as they evaluate what it all  
15 means in this case. Okay?

16          CHAIRMAN MALMUD: I'm seeing other hands raised.

17          MEMBER LANGHORST: Thank you. The subcommittee  
18 did understand the NRC's staff concern about having a  
19 screening criteria to help them judge when a medical  
20 consultant is needed. And I know that we touched on some  
21 points at our September meeting, whether that could be made  
22 part of an AO definition for this. The subcommittee  
23 explored a criteria based on the number of events reported  
24 by a licensee in a year, or maybe a rate of events by a  
25 licensee. We could not come to any consensus on -- I think  
26 we came to a consensus that the rate probably would not be a  
27 realistic thing since we don't always have the numbers, full  
28 numbers of what occurs per licensee, but the subcommittee

1 could not come to a consensus on what would be the right  
2 number of events the licensee may have to report in an AO  
3 year in order to trip that criteria. We did add that  
4 discussion, a summary of that discussion, in our attachment,  
5 too. But we ultimately concluded that there was really no  
6 practical or implementable screening criteria that we could  
7 include in the AO medical event criteria definition.

8 CHAIRMAN MALMUD: Discussion of that point?

9 Hearing none, move on

10 MEMBER LANGHORST: Okay. We did, however, as we  
11 were evaluating what things the NRC could do in a practical  
12 sense, we looked at the NRC's inspection policy regarding  
13 the use of medical consultants. And that I also -- we also  
14 concluded that is an attachment to our report that we sent  
15 to you. And we felt that that set of steps and  
16 considerations that NRC staff takes on when a medical  
17 consultant must be hired, or when a medical consultant may  
18 be hired is a practical tool that the NRC staff could use in  
19 being reasonable about hiring additional resources in  
20 evaluating that.

21 Just waiting for any of my subcommittee members to  
22 pipe in, but that's going to -- that's it.

23 Now, let me come back to our column in our table  
24 considered -- that lists the embryo fetus dosages. So in  
25 that all licensee category of Roman numeral 1 A-3, the ones  
26 that are included in that dose are when a licensee has to  
27 provide NRC notification of unintended to dose to embryo  
28 fetus or nursing child, and that's under the 10 CFR 35.3047.

1 And that criteria for -- that reporting the dose criteria is  
2 exactly the same as the abnormal occurrence dose criteria  
3 for an embryo fetus. So every time you have one of those  
4 notifications it automatically becomes an abnormal  
5 occurrence. The past five years of those AO reports  
6 included notifications of unintended dose to an embryo fetus  
7 that were due to I-131 therapy patients unknowingly being  
8 pregnant at the time of their therapy despite appropriate  
9 pre-treatment pregnancy screening. And we did not feel that  
10 it would be appropriate to change the dose in that criteria  
11 to accommodate this medical situation because it's also  
12 intended to be used if the mother were a member of the  
13 public exposed to radioactive material or radiation dose in  
14 another way.

15           And in addition, this unintended dose to the  
16 embryo fetus can only happen from a medical administration.  
17 So the subcommittee considered that this is not the correct  
18 place to judge whether this is an abnormal occurrence, and  
19 it should be put under the AO criteria Roman numeral 3-C.  
20 So we recommended the following: that in Roman numeral 1-A -  
21 - I'm showing my geekiness again, I can tell -- we should  
22 have an additional point that says that those criteria do  
23 not apply to events included in criteria 3, Roman numeral 3-  
24 C involving medical administrations using byproduct material  
25 to patients or human research subjects. We noted that in  
26 item Roman numeral 1B, transportation events are dealt with  
27 in a similar way.

28           And then to add an item two under this roman

1 numeral 3-C, which remember is entitled "For Events  
2 Involving Patients or Human Research Subjects,"  
3 notifications under 10CFR 35.3047 of an event involving an  
4 unintended dose to an embryo, fetus, or a nursing child that  
5 results in a significant adverse health impact to the  
6 embryo, fetus, or child as determined by a consultant  
7 physician deemed qualified by NRC or agreement state.

8 CHAIRMAN MALMUD: Any comments regarding that  
9 point?

10 MEMBER LANGHORST: I will make note that when you  
11 look at NRC's policy on when to hire a medical consultant,  
12 that when one of these types of notifications is received,  
13 that requires a medical consultant to review it.

14 And then I want to end up with -- if we want to  
15 discuss any of these points. We had three questions that we  
16 included in our attachment to some of the discussions that  
17 we had about what is the difference between medical events  
18 or notifications of embryo, fetus, or child dose versus  
19 abnormal occurrences. Could a minimum number of use-related  
20 event reports per licensee be considered as a screening  
21 criterion for abnormal occurrence definition? And then the  
22 question then if a measure of rate could be used rather than  
23 an absolute number?

24 Members of our abnormal occurrence subcommittee  
25 are listed here, and I thank each and every one of them for  
26 their help and for their dedication to participate in yet  
27 more teleconferences over the past couple of months. And  
28 that completes our summary of what we present to you here.

1           CHAIRMAN MALMUD: Thank you, Dr. Langhorst. Now  
2 that Dr. Langhorst has completed the report, is there any  
3 discussion of her presentation? Oh, Dr. Van Decker?

4           MEMBER VAN DECKER: I think there should always be  
5 a hand up and there should always be someone who wasn't a  
6 member of a subcommittee speaking first. Yeah, I think that  
7 the subcommittee did a great job here. You know, I think,  
8 we struggled with this now about seven years, or eight years  
9 on intermittent discussions, and I think that the going back  
10 to the background of where we were before and trying to get  
11 where we want to be is a useful process here. You know, I  
12 think that what we were looking for was some clinical  
13 filtering to what makes clinical significance, rather than  
14 just exposure to numbers, and I think this does a great job  
15 of trying to capture that, which is exactly what we were  
16 trying to do in 2008 when we had the initial discussion, and  
17 so that's a good thing. And I think that, you know, it has  
18 a lot of common sense saying that, you know, clinical  
19 significance should be judged by, you know, clinical people  
20 involved in care, and I think that's a good piece of this,  
21 and I think trying to avoid too much in the way of absolute  
22 numbers is a good thing.

23           You know, as far as your three questions go, I'd  
24 just point out for question number two, when you talked  
25 about minimum number per licensee vis-à-vis our last  
26 discussion and Ashley's comment on microspheres, until you  
27 have clear standard definitions and you know you're dealing  
28 with something that's not an interpretive function from

1 something from state to state is obviously an important  
2 piece of this, and obviously the compatibility of the states  
3 in what they define as medical event across the different  
4 issues, that gets the initial capture into an ME group, as  
5 Dr. Suleiman pointed out, from which you will take out some  
6 occasional MEs that you want to raise to a higher level; you  
7 know, I think there's some good common sense in that. But  
8 number two, I think, has to be based on everyone  
9 interpreting the same way and making sure you have a  
10 standard before you get there, and, you know, I would, you  
11 know, personally be supportive of what was presented. I  
12 think that it's a common sense approach to what's going on.

13 CHAIRMAN MALMUD: Thank you, Dr. Van Decker. It  
14 looks as if you have some support from without the  
15 subcommittee. Dr. Suleiman?

16 MEMBER SULEIMAN: I think I'm going to agree with  
17 Dr. Van Decker that number two could -- I mean, you've  
18 already flagged it "medical event." The region of somebody  
19 says, "Well we just have a second medical event from this  
20 site, maybe a third." And I think at that point, you're  
21 just, you know, rather than come up with some descriptive  
22 criteria based on very, very poor information -- I mean, the  
23 intelligent people on the receiving end can look and say,  
24 "Well they're not related." They'll asses that -- well,  
25 that site has a bad history, that site has a good history;  
26 at that time you'll make a smart decision as to whether  
27 these need to be looked at a little more carefully, but I  
28 think for -- to come up with some arbitrary criteria to

1 trigger something would just add some complexity. I think,  
2 keep it simple. I mean, I think the filter through the  
3 medical consultant is good.

4 CHAIRMAN MALMUD: Other comments? Dr. Welsh.

5 MEMBER WELSH: Originally in our subcommittee  
6 conversations, we talked about the possibility of having  
7 three or more as the minimum number for which an abnormal  
8 event might be triggered, but upon further discussion it  
9 seemed to us that for something as severe as death or  
10 irreversible permanent damage, going to three or more was  
11 not in the patients' best interest, NRC's, or clinicians'  
12 best interest for this type of definition, and therefore  
13 some of us were opposed to having three or more. But now,  
14 looking at it from a completely different perspective, in  
15 light of what we were saying, what Ms. Weil said earlier  
16 about the fact that medical event is not necessarily a one-  
17 to-one correlation with one patient and one medical event,  
18 but one medical event could have 90 patients. Now we're  
19 looking at it from a different perspective and wondering if  
20 you have a minimum number of medical events -- a minimum  
21 number of patients within a medical event, if that could  
22 also be justification for an abnormal occurrence, provided  
23 the definition of "medical event" is a sound one. It makes  
24 me wonder about a number of years back, where conceivably it  
25 could be recorded as one medical event, but involving dozens  
26 of patients, should that be considered an abnormal  
27 occurrence in and of itself?

28 CHAIRMAN MALMUD: That's a question to you, Dr.

1 Langhorst.

2           MEMBER LANGHORST: Well, as an RSO, I only thought  
3 one medical event means one patient, and if you have more  
4 than one patient, you have more than one medical event,  
5 because that's all that I've been involved with. And I did  
6 not understand that NRC will look at these things where  
7 there's multiple patients. So while we did start out, and  
8 maybe my wording here should be "medical use related event  
9 reports involving more than three or more patients." We  
10 really did -- we started out with "events" thinking -- my  
11 thought, event and patient is the exact same thing, to three  
12 or more patients, but still we could not come to a consensus  
13 as the subcommittee knows, just what is the right number.  
14 And we were aware that NRC staff felt that that was not  
15 going to be a very useful criterion to them, either, so --  
16 and we understood that.

17           CHAIRMAN MALMUD: Who was next? Okay.

18           VICE CHAIRMAN THOMADSEN: Well -- I can -- one  
19 problem with the definition we came up with, and we talked  
20 about this, is there may be a medical event where you have a  
21 dozen patients involved, none of whom had any particular  
22 consequences, and in the world of quality control this  
23 indicates a process that is greatly out of control, and has  
24 just been lucky so far. And that type of situation would  
25 not be triggered.

26           MEMBER LANGHORST: I know one thing that I  
27 continue to struggle with, and I think the subcommittee did,  
28 too, was the AO criteria under Roman numeral 4, and that's

1 this "other events of interest" and I think that's where  
2 something like that could be brought up, but it's not clear  
3 to me that NRC staff feels comfortable in anything coming to  
4 light there except what maybe comes to light in the press.  
5 I'm not -- I'm still uncertain about it.

6 CHAIRMAN MALMUD: Other comments? Mr. Einberg.

7 MR. EINBERG: Yeah, Roman numeral 4 there, other  
8 items of interest, is a subjective criteria and we as staff  
9 have a lot of debate as to what goes in there when the  
10 annual AO report comes around, whether there is significant  
11 interest in the media, what constitutes significant  
12 interest. So that is a bit of a subjective criteria, would  
13 prefer to stay away from that. The other point I wanted to  
14 ask Dr. Langhorst, was, was there any thought given about  
15 underdose as far as getting a medical consultant for medical  
16 events, in the way it's structured now, even if you have an  
17 underdose, how you would get a medical consultant? Was that  
18 deliberated or...

19 MEMBER LANGHORST: I -- and please, subcommittee  
20 members jump in if you don't think I'm answering this  
21 correctly -- I do believe that the criteria used for  
22 obtaining a medical consultant in the policy, does not  
23 necessarily say that if it's under dose, you have to have a  
24 medical consultant. And we think that's a practical thing,  
25 that you could use this criteria in attachment three to  
26 reasonably say, for instance a Quadramet Samarium-153  
27 patient, there's leakage from the administration, so they  
28 don't get the full dosage; then you have that patient come

1 back later and obtain that full dosage. I think that's very  
2 reasonable that the intent of the administration occurred, I  
3 think it's very reasonable to look at it as a medical event,  
4 to see what went wrong, but it's not really an abnormal  
5 occurrence. So I think your inspection manual gives you  
6 that guidance as to when you need to have a medical  
7 consultant.

8 MR. EINBERG: But the way the criteria -- sorry,  
9 the AO criteria that you're proposing right now would be  
10 that all medical events require a medical consultant, and so  
11 my thought is, was that the intent or -- we have our own  
12 inspection criteria, but the AO criteria would actually bump  
13 the inspector criteria here, so...

14 MEMBER LANGHORST: Well, again, we -- I don't know  
15 how to answer that except that we think that reasonable  
16 judgment can be used in -- when there is a medical  
17 consultant needed to evaluate these medical events. And I  
18 guess that is that point that we raised in September about  
19 whether these criteria could be separated from the AO  
20 definition, and so we think that your criteria, and you  
21 policy, and your inspection manual is a good one to judge  
22 when it's appropriate that you need to have a medical  
23 consultant.

24 CHAIRMAN MALMUD: Dr. Welsh?

25 MEMBER WELSH: If I might jump into this  
26 conversation, I'm not sure I would understand how an  
27 underdose medical event would meet the definition suggested  
28 here of unintended, unexpected permanent functional damage

1 to a system, to an organ, or cause death; so I think self-  
2 screening. Or am I missing something?

3 MR. EINBERG: The only person who can make that  
4 determination -- the NRC staff could not make that  
5 determination. A medical consultant would have to make that  
6 determination, so the point that I was driving towards is do  
7 underdosages need a medical consultant? Because it's highly  
8 -- or it may be unlikely that it would not be any  
9 significant harm to the patient.

10 MEMBER WELSH: So then, I suppose that my reply is  
11 my bias is given that I don't think A, B, C or D, as written  
12 by Sue, would ever be problematic. I would say that we  
13 don't need to have medical consultants review underdoses.

14 MEMBER GUIBERTEAU: It could be argued, however,  
15 that with the underdose they're not getting the treatment  
16 they need and there could be a significant adverse health  
17 effect.

18 MEMBER WELSH: Yes, of course, and I would counter  
19 immediately, that that would be a correctable situation and  
20 not permanent, as words used here in A and B --

21 MEMBER GUIBERTEAU: Oh no, no, no, no, no, it  
22 doesn't say that for C; if you want to put that in there,  
23 that's fine. It only says "a significant, unexpected  
24 adverse health effect," and that would depend on whether it  
25 is correctable.

26 CHAIRMAN MALMUD: Next was Dr. Suleiman.

27 MEMBER SULEIMAN: Mine will be quick, mine will be  
28 quick.

1           CHAIRMAN MALMUD:   Okay.

2           MEMBER SULEIMAN:   Okay, I kind of agree with Dr.  
3   Guiberteau because -- since we're thinking conceptually,  
4   let's say it's some sort of therapeutic dose that grossly  
5   underdosed, the patient somehow leaves the country, it's not  
6   correctible by the time they catch it, and it's going to  
7   affect their health because they may not -- so, I don't want  
8   to go off on these conceptual things, but I could see that  
9   an underdosing could be life-threatening in terms of it  
10   hasn't delivered the right treatment.  So I'm not saying  
11   that should go to an abnormal reporting incident,  
12   necessarily, but assuming that every underdose is going to  
13   be corrected is not a true statement.

14           CHAIRMAN MALMUD:   I think Mr. Mattmuller was next,  
15   and then Dr. Welsh.

16           MEMBER MATTMULLER:  Thank you.  In regards to  
17   Chris's concern, I think he's suggesting -- and I think -- I  
18   agree with him that what he looks at with our criteria, that  
19   every medical event has to be evaluated by a consultant, and  
20   then if the consultant determines it meets A through D,  
21   then, boom, it becomes an AO.  But Sue is also saying, "Use  
22   the criteria you have now and your policy on medical  
23   consultants to determine when a medical event needs to be  
24   reviewed by a medical consultant, and then if he decides  
25   that it meets our criteria then it becomes an AO."  And I  
26   believe in here it says if it's an underdose and then it's  
27   subsequently -- well I think the example that's been bounced  
28   around would not be considered a case that a consultant

1 would have to review.

2 CHAIRMAN MALMUD: Dr. Langhorst?

3 MEMBER LANGHORST: When a licensee has to report a  
4 medical event, in that written report, and I believe in the  
5 notification also, but in the written report -- this is  
6 under 35.3045 and it's -- let me get the numbers right.  
7 It's D1, and I believe it's small Roman numeral 5...

8 MEMBER BAILEY: What page of the volume?

9 MEMBER LANGHORST: It's on 719 in our book. I'm  
10 sorry, Darice, I took your book. It says the licensee needs  
11 to report the effect of any on the individuals who received  
12 the administration, and if -- I mean that -- granted that's  
13 from the licensee and generally when we, at my institution,  
14 have had the unfortunate occurrence of a medical event, we  
15 ask another physician to provide that kind of assessment. I  
16 don't know if -- I had always thought that NRC put in the  
17 comment about "as determined by a consultant physician being  
18 qualified by NRC or an agreement state," that could be  
19 whether you choose that position assessment as being  
20 qualified or not.

21 CHAIRMAN MALMUD: Dr. Thomadsen?

22 VICE CHAIRMAN THOMADSEN: I'm on sort of both  
23 sides of this. For Jim, there are a lot of cases that an  
24 underdose can be made up, in which case, one would not need  
25 a consultant to come in. But there are cases -- for  
26 example, high dose rate cervix case where the dose had been  
27 less than 20 percent, yet you've already, in delivering  
28 that, have used up the sensitivity of surrounding organs

1 because of the different alpha over beta. You cannot go in  
2 and correct that dose, in which case, then maybe a  
3 consultant should brought in. So if they could not -- an  
4 underdose could not be corrected, that might be an occasion  
5 to bring in a consultant.

6 MEMBER WELSH: I might respond that, yes, of  
7 course we're aware that not all underdoses, and we've always  
8 used the adage that perhaps the worst complication is the  
9 recurrence of the cancer, so if an underdose has led to  
10 inappropriate or unexpected recurrence of the cancer,  
11 perhaps is it of significant medical concern. However, the  
12 wording in A and B is permanent. So underdosing should not  
13 cause permanent adverse effects to normal tissue.  
14 Underdosing also, in C, would not be unexpected to lead to a  
15 reduced tumor control probability. So I don't think that  
16 underdosing is -- there's a problem with the wording that we  
17 have here, because underdosing would not cause permanent  
18 functional damage to an organ or tissue or system, and it  
19 would not lead to unexpected sequelae.

20 And as an example, as far as death goes, sure, if  
21 you've underdosed and failed to cure the cancer, you're  
22 going to have some significant -- some significance. But if  
23 you think about what we were talking about earlier with the  
24 Y-90 microspheres and the potential underdosing in these  
25 medical events, these are patients who are terminally and  
26 you're not going to cure them with the Y-90 microspheres;  
27 it's palliative treatment. You can just imagine the  
28 consequences of saying that these underdoses have resulted

1 in patient death and are abnormal occurrences; when, in  
2 fact, that's obviously not going to be the case.

3 I still stand by my initial assertion that  
4 underdosing should be exempted from abnormal occurrence.

5 CHAIRMAN MALMUD: May I ask a question? What it  
6 would be acceptable to use the term "underdosing if not  
7 correctable" be reported? If I were a provider and I  
8 underdosed a patient, I could notify you and then I  
9 corrected it, you'd have a record that I corrected it, but  
10 it's not a significant issue. I mean I made a mistake and I  
11 fixed it, and there was no harm to the patient. So just  
12 insert those two words, "if correctable," or "if corrected"  
13 in the past tense even, by the provider. Then that  
14 eliminates that concern you would have about an underdose  
15 that's not correctable as opposed to an underdose of the  
16 example that Dr. Thomadsen mentioned, which is truly not  
17 correctible without some sequelae.

18 MEMBER LANGHORST: Dr. Malmud, I had to --

19 CHAIRMAN MALMUD: Yes, I just had to get that in  
20 before I asked [unintelligible].

21 MS. MCINTOSH: Actually, I'd like to respond to  
22 that and then make another comment. I think if we're to do  
23 that, we would have to -- that would require a rule change  
24 to the rule. I don't know that we could insert that in the  
25 AO policy, that the licensees would have to report whether  
26 or not it was correctible. I'm not sure about that, but I  
27 don't think so.

28 But the other point I wanted to make with respect

1 to what Dr. Welsh was saying about an underdose, you know,  
2 there's no way a death could, you know, be the consequence.  
3 The staff had initially proposed those for criteria as  
4 individual separate criteria. Only one of them need be made  
5 -- or need be met to be in AO. We didn't present them as  
6 "and" statements, but "this one or this one or this one or  
7 this one." So adverse health effects does stand on its own.  
8 As the staff had presented the criteria to the committee --  
9 now the committee is now presenting the criteria back to --  
10 or recommending, rather, that the criteria be treated as  
11 "and" statements --

12 MULTIPLE SPEAKERS: No, no, no, no.

13 MEMBER LANGHORST: Absolutely not.

14 MS. MCINTOSH: So therefore, each one of those  
15 should be used separately. Only one of them need to be met.

16 CHAIRMAN MALMUD: Thank you for that  
17 clarification. Dr. Langhorst?

18 MEMBER LANGHORST: Yes. I am not certain, Dr.  
19 Malmud, where you are suggesting that wording should go.  
20 Maybe if we --

21 MS. MCINTOSH: As a fourth criterion, as a fifth  
22 criterion.

23 MEMBER LANGHORST: So you're saying as -- under  
24 this, it would be an item E, is that -- or no -- or should  
25 it be in that part B?

26 CHAIRMAN MALMUD: Let's for a moment, if I may,  
27 let's for a moment put aside regulation, put aside law, and  
28 talk common sense. If I made a mistake and gave the patient

1 half the dose I intended and then I corrected it without  
2 harm to the patient by giving the second half of dose,  
3 what's the issue? What harm has been done? Why make an  
4 issue of it? If we feel that -- if it was me in that  
5 situation, then I'm also capable of double-dosing the  
6 patient, then that's a risk; then I should be required to  
7 notify the NRC of this problem and that I corrected it. And  
8 that should be the end of it, because if it happens again,  
9 then we're going to become concerned about the behavior of  
10 the provider. But without looking at the legality, just the  
11 common sense of it, there's no harm done. I'm now turning -  
12 - please, Ms. Weil.

13 MEMBER WEIL: If I understand Dr. Welsh's concern,  
14 with the microspheres, you could underdose by a -- you could  
15 deliver 25 percent of the dose, a significant underdose.

16 CHAIRMAN MALMUD: Yes.

17 MEMBER WEIL: It's not correctible. And yet, it  
18 is not causing -- what we're all dancing around here is the  
19 word "negligence." It's not negligent. It's not anybody's  
20 fault. It was undeliverable for capillary, for mechanics or  
21 whatever. It's a medical event. But because of the  
22 underdosing, it should not rise to the level of abnormal  
23 occurrence. So I don't know that definition, which -- I  
24 agree with you. I think that's where we need to go with  
25 this uncorrected, or correctable, however you want to phrase  
26 it, underdose. But we need to find a way to separate out  
27 those -- maybe it's just the microspheres, I don't know,  
28 where it should be --

1           CHAIRMAN MALMUD: In clinical practice, it's a  
2 little bit different, and that -- let's say that there was  
3 not an adequate of the blood supply to the liver, and the  
4 microspheres went to the lungs. That is --

5           MEMBER WEIL: That's a different story.

6           CHAIRMAN MALMUD: That's a different story, we  
7 agree. But if, for some reason, in the course of the  
8 procedure, the dose wasn't delivered, but it could be  
9 augmented with a second dose, then there's -- what's the  
10 issue?

11          MEMBER WEIL: I don't think it can be.

12          CHAIRMAN MALMUD: Really?

13          MEMBER LANGHORST: May I --

14          CHAIRMAN MALMUD: Dr. Langhorst.

15          MEMBER LANGHORST: I want to address the issue.  
16 The issue is, did the NRC -- did they need to get a medical  
17 consultant in all cases? And in the case, as far as  
18 underdosing, if they have to do this, because they feel,  
19 with the AO criteria in this format that that trumps their  
20 policy, then they get a medical consultant, they look at it,  
21 they said this is not a problem. And so there is some  
22 expense. It may be that an agreement state that brings on  
23 that medical consultant. That's the point that we're  
24 discussing here. They're all medical events, and that  
25 should be looked at. But the question here is, is there  
26 something we can give the NRC to judge, does it need a  
27 medical consultant or not?

28          CHAIRMAN MALMUD: Dr. Thomadsen?

1           VICE CHAIRMAN THOMADSEN: Yeah. I'm not -- I  
2 definitely do not understand Mr. Einberg's comment about  
3 this trumping their policy. If we've stated that the  
4 criterion -- or criteria, I don't remember what -- the word  
5 there -- for bringing in a consultant, as specified in what  
6 you read, with the appropriate citation, then this shouldn't  
7 trump anything because we are stating that is the criteria  
8 for bringing in a consultant, and this -- the rest of this  
9 whole definition does not trigger anything if we specify  
10 that we already have the criteria in the regulation.

11           MEMBER LANGHORST: But the criteria is not in the  
12 regulation, it's in their policy for hiring medical  
13 consultants.

14           VICE CHAIRMAN THOMADSEN: Yeah.

15           MEMBER LANGHORST: Yeah.

16           VICE CHAIRMAN THOMADSEN: But you read it. You  
17 read it, it's in the regulation that you read.

18           CHAIRMAN MALMUD: Mr. Einberg, since we're  
19 discussing --

20           FEMALE SPEAKER: -- regional cycles --

21           MEMBER LANGHORST: Oh, by the licensee, the  
22 licensee has to report that, yeah.

23           VICE CHAIRMAN THOMADSEN: And they can change that  
24 if they want, but I mean, we aren't proposing anything  
25 different from your own guidance as to when you need to  
26 bring in consultants, so I don't see how it's trumping  
27 anything.

28           CHAIRMAN MALMUD: Mr. Einberg?

1           MR. EINBERG: The procedures or the -- Dr.  
2 Langhorst was, I believe, discussing or quoting from are  
3 lower level procedures, or office procedures. What we're  
4 discussing here is the AO criteria. This AO criteria is  
5 approved by the Commission, it becomes a policy, and this is  
6 what we follow. And so if your recommendation is that a  
7 medical consultant has to be brought in for all medical  
8 events, whether it's underdosage or an overdose, and that's  
9 what we follow.

10           But we as staff cannot come with up their own  
11 interpretation here to say, "Oh, it's an underdosage."  
12 That's not what the intent of the ACMUI was or the  
13 Commission because they're ultimately going to approve this  
14 policy.

15           So if it's your intent that underdoses are not  
16 evaluated or don't need to be evaluated, please, it would  
17 help the staff go forward as we try to implement this. The  
18 way it's written right now, because our staff will have to  
19 implement this, we'll get a medical consultant for every  
20 medical event. So -- and if that's your intent, that's  
21 fine, but that's the reality.

22           CHAIRMAN MALMUD: Dr. Welsh.

23           MEMBER WELSH: So if I might respond quickly, my  
24 point in bringing all this up about exempting underdosing as  
25 a category from the need for having medical consultant is  
26 because I don't believe that a medical consultant is  
27 necessary for underdosing if we use these criteria for the  
28 definition of abnormal occurrence, with the possible

1 exception of maybe adding the word "unanticipated death" to  
2 item D. And I just don't think that it would be a good --  
3 it's a necessary use of medical consultant expense for  
4 underdosing to determine if a medical event is an abnormal  
5 occurrence, because we just don't think that they would  
6 qualify.

7 CHAIRMAN MALMUD: Mr. Mattmuller.

8 MEMBER MATTMULLER: A quick question for Dr. Howe,  
9 if she's still here. Okay, or maybe someone else from the  
10 staff. Using the current criteria for when you use a  
11 medical consultant, of the past medical events, how many  
12 times was the consultant brought in on evaluation of the  
13 medical events?

14 MR. EINBERG: Gretchen, do you happen to know what  
15 frequency we use the medical consultants?

16 MS. RIVERA-CAPELLA: It is -- hold on.

17 DR. GABRIEL: May I speak to that please?

18 MR. EINBERG: Dr. --

19 DR. GABRIEL: This is Sandy.

20 MR. EINBERG: Dr. Gabriel.

21 DR. GABRIEL: I don't have statistics, I do know  
22 that the current medical consultant use policy applies to  
23 NRC jurisdictions only. It does not apply to agreement  
24 states, however, the abnormal occurrence criterion would  
25 apply to agreement states. And as Dr. Langhorst has seen,  
26 the current NRC policy requires that for overdose-type  
27 medical events, the medical consultant is required, and when  
28 I worked in the Region I office, we extended that to events

1 that might have been underdosed to the treatment site, but  
2 involved an overdose to other tissue. So a significant  
3 portion of the total number of medical events do end up  
4 using a medical consultant for NRC jurisdiction.

5 MEMBER MATTMULLER: If I could follow up with my  
6 comment. So we're not suggesting that every medical event  
7 be reviewed by a medical consultant. We're suggesting that  
8 medical events that are reviewed per the criteria in your  
9 inspection then, then those events, as are viewed by a  
10 consultant that meet our criteria, those are the ones that  
11 become AO. Did I say that right, Jim?

12 MEMBER WELSH: [affirmative] Exactly.

13 CHAIRMAN MALMUD: Dr. Suleiman.

14 MEMBER SULEIMAN: I think everybody's sort of in  
15 agreement, but we're all grasping at the different parts of  
16 the elephant. I think we don't want every single medical  
17 event to be looked at by a medical consultant. I also think  
18 that underdosing significantly, that could in fact affect  
19 the outcome, and there's no way to recapture -- treated that  
20 patient. Either you've discovered a software glitch that's  
21 given a wrong dose and the patient's now in some godforsaken  
22 country that you can't get back, or it could be any number  
23 of reasons. You've underdosed significantly, and it's going  
24 to probably affect patient outcomes, so I think that would  
25 meet, you know, this criterion and get kicked up.

26 How you decide when to call in the consultant or  
27 not, I really don't know, but I think, again, the staff --  
28 if you're not sure, you bring in the consultant. If it

1 looks like it's pretty black and white and you're in  
2 consensus internally, you know, at that point you kick it up  
3 to an AO. But for us to sort of micro dictate, you know,  
4 call in a medical consultant each and every time, I think we  
5 want to give you some flexibility.

6 MS. COCKERHAM: This is Ashley --

7 CHAIRMAN MALMUD: Who was -- Ashley?

8 MS. COCKERHAM: This is Ashley. Gretchen looked  
9 at the medical consultant use, and it's about five a year.

10 MR. EINBERG: For NRC states?

11 MS. COCKERHAM: For NRC states.

12 MEMBER LANGHORST: I think we've touched upon how  
13 difficult it is to define this in the AO criteria to give  
14 you a screening tool. We've suggested that maybe you may  
15 look at your policy as something practical to implement it,  
16 and in assessing this, but you can't put all of that policy  
17 into AO criteria, and I'm not sure we could adequately put  
18 underdosing in there in a agreeable way. I -- it's not an  
19 easy thing to deal with.

20 CHAIRMAN MALMUD: Dr. Guiberteau.

21 MEMBER GUIBERTEAU: I understand this conundrum  
22 because it is difficult for the staff to be able to decide  
23 whether something rises to the occasion of a consultant or  
24 not, but I'm just wondering if perhaps the medical events  
25 committee, which does have physicians on it could assist you  
26 in sorting these out in terms of -- many of these case on  
27 their face would not rise to the occasions of an abnormal  
28 occurrence, so I don't think you have any reason to go

1 forward with a medical consultant on things that are pretty  
2 obvious. But it might be possible for a committee of --  
3 this committee -- subcommittee of this committee to review  
4 them, and I don't think it would take a lot of time, and  
5 take out the ones that if you want to report these to  
6 Congress as abnormal occurrences, could help decide if the  
7 committee needs more information or more help.

8 CHAIRMAN MALMUD: Mr. Einberg.

9 MR. EINBERG: I think that's a possible solution.  
10 However, the concern I have with that is that, you know, we  
11 have the annual report to Congress that has to be submitted  
12 in a timely fashion and it has its own deadlines. If we  
13 wait for the Medical Events Subcommittee to determine which  
14 ones should be screened and which shouldn't, it would need  
15 to be more on a more real-time basis working with the  
16 subcommittee rather than waiting to have the twice-a-year  
17 full committee meetings. And so that's part of the  
18 practical implementation aspects of working a solution like  
19 that.

20 The other aspect is that if you felt a client make  
21 a statement within your subcommittee report that the staff  
22 could use their own screening -- or determination of their  
23 policies or procedures for underdosages, then we could leave  
24 it up to discretion of the staff there to come up with  
25 something, in perhaps with consultation from ACMUI to  
26 determine something like that. We would need something in  
27 the report as written right now to give us that flexibility  
28 to do so.

1           CHAIRMAN MALMUD: Dr. Welsh.

2           MEMBER WELSH: Just to underscore the complexity  
3 of this, heard earlier today that are a number of Y-90  
4 microsphere medical events this year. Many of them were  
5 underdoses. All of these patients will soon unfortunately  
6 die because this not curative treatment; it is failure to  
7 treatment. Conceivably these underdoses could be  
8 misconstrued as abnormal occurrences because of item D,  
9 death. And I think -- I don't have an answer for it other  
10 than to say perhaps, I think we should change it to say  
11 unanticipated death, but I think it underscores the  
12 complexity of all of this, why I am leaning towards to  
13 steering clear of underdosing as being a criteria for  
14 abnormal occurrence definition.

15           MEMBER SULEIMAN: I think this is an example of  
16 why you got to consider the source. I think radio-labeled  
17 dosimetry isn't an exact science at this point. So the  
18 precision and accuracy of 25- or 50 percent to me would be  
19 completely acceptable as practice of medicine.

20           If you are talking about 50 percent underdosing  
21 in terms of external radiation therapy dose, I don't think  
22 there's a person here who would consider that within the  
23 normal realm of practice, that would be a the gross  
24 underestimate of the dose. I think considering the source  
25 you could make a very binomial decision on that.

26           So that's one of the problems with the whole  
27 reporting criteria, is you try to lump every medical  
28 procedure into this quantitative metric where 10 percent or

1 15 percent, or whatever. Whereas, again, with radiolabeled  
2 therapies, we're not there yet. With external beam therapy,  
3 it's the closest thing to a science-based cancer treatment.  
4 The others are still developing.

5 CHAIRMAN MALMUD: Dr. Palestro.

6 MEMBER PALESTRO: Yeah. You know, the  
7 subcommittee on various teleconferences and emails grappled  
8 with this problem. We were unable to come up with any  
9 criteria that we felt that the NRC could use -- screening  
10 criteria to determine whether medial consultant should be  
11 identified. And I think that this ongoing discussion here,  
12 at least for me, just confirms that fact that we're are  
13 unable to establish any well-defined specific criteria when  
14 a consultant should be called, and I think that I would not  
15 want to try to implement that even with the underdosing,  
16 because it's certainly is very easy to say, well, we know  
17 these people, virtually all, are going to be dead within a  
18 short time. That's probably true most of time, but not  
19 necessarily all the time, and I think the best way to manage  
20 it, though it maybe not the least expensive way, is to have  
21 a consultant review these cases on an individual basis, and  
22 let them make that decision because they are nominally the  
23 experts and they can review all the data.

24 CHAIRMAN MALMUD: Dr. Langhorst.

25 MEMBER LANGHORST: I wanted to pose a question to  
26 Mr. Einberg. Because you state it's an acceptable to have a  
27 consultant, however the wording is now, an agreement state  
28 or NRC, for medical events in order to -- agreement states

1 would NRC feel compelled to order a medical consultant to  
2 review those? Or would you rely on the medical consultant  
3 that the agreement state has used?

4 MR. EINBERG: The agreement states would have the  
5 authority to choose their own, that's all.

6 MEMBER LANGHORST: Thank you.

7 CHAIRMAN MALMUD: May I ask a question of Dr.  
8 Welsh, please? Dr. Welsh, are you concerned about the  
9 hiring of the medical consultant, and the expense, or are  
10 you concerned about the anxiety and fear in the patient  
11 who's told that this is being investigated?

12 MEMBER WELSH: Of course, both.

13 CHAIRMAN MALMUD: Which is the dominant concern?

14 MEMBER WELSH: For the conversation at hand right  
15 now, it is the expense of the medical consultant because I'm  
16 talking about the underdosing possibly being exempted from  
17 abnormal occurrence criteria. And so for that conversation,  
18 I'm focusing on avoiding unnecessary expense and time of  
19 medical consultants because of significant complexity and  
20 the conundrum that will be presented in the example I just  
21 gave about all those Y-90 cases this morning, which will  
22 likely -- the patients likely will be dead, but if -- I  
23 don't think that they deserve consideration for abnormal  
24 event -- abnormal occurrences, and I think that that expense  
25 could be avoided, so that's why I'm focusing primarily on  
26 that aspect.

27 CHAIRMAN MALMUD: So you're concerned about the  
28 expense, but let's say that a medical consultant were

1 brought in, and he or she took a look at the incident and  
2 said, this is just one of the risks of practice, it's just  
3 handled by a letter in the same way you might be asked to  
4 review a potential lawsuit against someone and you say  
5 there's no basis for it in your opinion, versus spending  
6 hours and hours going through the entire case and so on.

7           The expense of that consultant is there, but it's  
8 not necessarily an extensive review if it's cut and dried,  
9 obvious corrected problem. If, on the other hand, the  
10 consultant feels that it's a significant issue, then it  
11 would be pursued. I think the problem the NRC has is that  
12 once it's labeled as a medical event, then their staff at  
13 the lower level that would begin to deal with this are  
14 obligated to pursue it. And -- because they're not going to  
15 make that judgment. We're having difficulty making that  
16 judgment, with all this expertise at this table. They can't  
17 be expected to do that. So they're -- the NRC, I suspect,  
18 is looking for the guidance from us as to where the line is  
19 to be drawn, and it sounds as if that there are unintended  
20 risks from an underdose that can't be corrected. Do I  
21 understand that that can happen? There are unintended risks  
22 from an underdose that cannot be corrected, and therefore,  
23 even though the patient's outcome is predictable, namely  
24 that he or she will die of a disease, that patient hasn't  
25 given adequate opportunity for prolonged life prior to  
26 dying, whether that's a matter of months or years. That  
27 patient has lost that opportunity, and therefore was not  
28 afforded the advantage of the therapy that was being

1 offered. That patient did not get optimal care in that  
2 situation, and then -- because it was not corrected.

3           So these are questions which we struggle with, and  
4 NRC's looking for guidance. And Dr. Langhorst has come up  
5 with this document which is an opinion of a number of  
6 experts in the area who happen to be members of this larger  
7 committee. We don't seem to be able to come to more of a  
8 specific recommendation than that which Dr. Langhorst has  
9 presented as an outcome of the committee, so eloquently  
10 expressed by Dr. Palestro. Dr. Welsh.

11           MEMBER WELSH: My quick reply to that would be  
12 that if we look at the criteria A, B, C, and D, C says a  
13 significant unexpected adverse health effect, and I would  
14 argue that if you grossly underdose a patient, it would not  
15 be unexpected that the malignancy will return, and therefore  
16 still unconvinced that the underdosing deserves to be  
17 screened and put into the abnormal occurrence criteria.

18           CHAIRMAN MALMUD: Thank you. Mr. Mattmuller.

19           MEMBER MATTMULLER: I would think it will because,  
20 remember, we start with medical events. And then the next  
21 filter is when a medical consultant is used per current NRC  
22 guidelines that we've got attached in our report. And our -  
23 - it's policy and use of medical consultants. To your  
24 knowledge, has a medical consultant ever been brought in on  
25 an underdose medical event? This is a question to Dr. Howe.

26           MR. EINBERG: Or Dr. Gabriel.

27           DR. GABRIEL: Current NRC guidance allows the NRC  
28 regions to call in a medical consultant --

1           CHAIRMAN MALMUD: I'm not sure that -- can the  
2 court reporter hear you?

3           COURT REPORTER: Is it Howe or --

4           CHAIRMAN MALMUD: Dr. Gabriel. Dr. Gabriel.

5           DR. GABRIEL: Current NRC guidance allows the  
6 regions to make use of a consultant in situations other than  
7 the ones in which a consultant is required if they believe  
8 it to be appropriate. You know, if there are some unusual  
9 questions.

10          MEMBER MATTMULLER: Right, so I agree. It's  
11 possible, given extenuating circumstances, but not on a  
12 routine basis. So I think we've got a level of protection  
13 in there already -- protection's the wrong word -- criteria  
14 in there to avoid underdosing if that means going to an AO  
15 level, or even being reviewed by a consultant before it  
16 could even be considered an AO.

17          MEMBER WELSH: My quick reply to that --

18          CHAIRMAN MALMUD: Okay, you first, and then Mr.  
19 Einberg.

20          MEMBER WELSH: I would agree 100 percent with you,  
21 had we had this conversation in the morning before Dr.  
22 Howe's presentation. Of all those, underdosing Y90 medical  
23 events, because some of those patients have very limited  
24 life expectancies, and some of them died naturally because  
25 natural history, some will die perhaps because of the  
26 underdosing, but bringing in a medical consultant to  
27 determine whether or not that death, which is item D here,  
28 is due to A or B, what we just said, I think is going to be

1 a serious problem that will not have an answer, but could be  
2 a waste of resources.

3 CHAIRMAN MALMUD: Well, Steve, I mean, Dr. Welsh,  
4 if I may. If the patient -- the patient -- it's a matter of  
5 informed consent. If the patient is told before the  
6 therapy, irrespective of the radiation issue, that this is a  
7 palliative therapy, that what's being offered to you is the  
8 possibility of an extended life, but not necessarily  
9 profoundly extended. And then the therapy is applied  
10 incorrectly, and they do not benefit from the opportunity of  
11 extended number of months or days or weeks. They've been  
12 denied that which could have been given to them had the  
13 therapy been delivered properly. And the risk is that there  
14 may be, certainly not represented at this table, but there  
15 may be someone who doesn't do this correctly and repeats the  
16 same error, and it involves the use of radiation and  
17 therefore, even though there was informed consent, that yes,  
18 the patient and the family understand this palliative care,  
19 death is inevitable, this is for prolonged quality of life  
20 or prolonged number of days of life, and hasn't been offered  
21 the therapy. It's not death that's the issue, it's the fact  
22 that the patient was denied the opportunity. Dr. Welsh?

23 MEMBER WELSH: So my reply to that would be item  
24 C, which is significant unexpected adverse health effect.  
25 And I would argue that underdosing of what could lead to  
26 lack of palliation and perhaps lack of prolongation of life,  
27 as would be expected if the treatment were given properly,  
28 but if the treatment were significantly underdosed, this

1 would not be unexpected, and therefore the verbiage here  
2 takes that into account.

3 CHAIRMAN MALMUD: I'll allow someone else to  
4 comment on that. Mr. Einberg?

5 MR. EINBERG: Yes, I wanted to get back to the  
6 point that Mr. Mattmuller was making regarding that the NRC  
7 has the procedures in place to determine when a medical  
8 consultant should be used. If we go back, how this  
9 discussion came about is we're looking for that threshold  
10 criteria as to when medical consultants should be used. And  
11 so what's in place right now, we don't feel comfortable  
12 with, and we're looking to revise the AO criteria for -- we  
13 do not want to fall back onto the existing, you know,  
14 procedure that we have in place right now for determining  
15 when a medical consultant should be used. Unless it's  
16 deliberate that you're clear in your committee report or  
17 subcommittee report as to when that should be, and so it's  
18 kind of a circular argument. You know, what comes first in  
19 bargaining?

20 CHAIRMAN MALMUD: Ms. Weil.

21 MS. WEIL: I would like to second Dr. Guiberteau's  
22 suggestion, and perhaps explore why this is not logistically  
23 feasible. If we as a committee are here to advise staff,  
24 then why could not ad hoc -- I mean, quickly mobilized  
25 medical events subcommittees be used using the medical  
26 expertise in this room to determine whether or not a medical  
27 consultant is needed?

28 CHAIRMAN MALMUD: Mr. Einberg.

1           MR. EINBERG: Certainly is a possibility to --  
2 rather have an ad hoc committee or then all of the  
3 physicians here can serve as medical consultants to us, as  
4 some of them do. So that's an opportunity to -- if one of  
5 the members of the committee wanted to serve in that  
6 capacity to do evaluations, that's a possible solution as  
7 well. Now, just to clarify, we're not opposed to hiring a  
8 medical consultant for all cases if that's the case. The  
9 cost associated with it -- while there is a cost associated,  
10 would the prudent stewards of the ratepayer's money or the  
11 taxpayer's money -- if necessary, it's not that much of a  
12 cost to be honest.

13           CHAIRMAN MALMUD: Dr. Suleiman.

14           MEMBER SULEIMAN: I've come up with two very  
15 specific plausible scenarios, okay? Let's say in comes the  
16 yttrium, underdosed, I would think any group would say the  
17 uncertainty in that type of procedure is high, I wouldn't  
18 worry about it, it was within the normal practice of  
19 medicine. Scenario number two, in our outpatient world  
20 where we have a lot of people coming from other countries,  
21 somebody -- some patient comes in, they undergo a pretty  
22 high tech external beam therapeutic procedure. For whatever  
23 reasons, the software glitches, the site doesn't figure it  
24 out till maybe two or three days later when this person has  
25 now left the country and is off someplace else and is in no  
26 position to come back. At that point I think an analysis  
27 would show: either number one, you should hold onto the  
28 patient long enough to verify the dose, or there should be

1 some checks and balances for your software to make sure the  
2 equipment is working right.

3           So here's a case you've underdosed, and I think in  
4 today's world is a very plausible scenario, so why wouldn't  
5 that be considered serious enough? It wouldn't necessarily  
6 reflect on the facility, though it could to some degree, but  
7 it also could involve the manufacturer because there could  
8 be some equipment problems there. So not calling it an  
9 abnormal occurrence would deny that mistake the opportunity  
10 to be analyzed and figure out some procedures that would  
11 prevent it from happening in the future. So I think  
12 underdosing could be a reportable abnormal occurrence.

13           CHAIRMAN MALMUD: Ms. Bailey.

14           MEMBER BAILEY: What you just described sounded  
15 like down here at the medical event end, not at the abnormal  
16 occurrence, which is just a policy with what we report to  
17 Congress. So they miss the software glitch, and underdose,  
18 perhaps is a medical event. I think the question is do you  
19 then want to hire a consultant to decide if that goes over  
20 to the group we report to Congress?

21           MEMBER SULEIMAN: Well the way I'd do the  
22 consulting hiring was there'd either be strong consensus  
23 among the NRC staff that they don't need to do it, which  
24 would be a pretty straight decision, there'd be a strong  
25 consensus to hire a consultant. And if there was a split  
26 decision I'd probably still opt to go ahead and hire a  
27 consultant. So I think you have the -- some flexibility  
28 there.

1           CHAIRMAN MALMUD: Is there more discussion  
2 regarding the presentation that Dr. Langhorst has made to us  
3 on behalf of that subcommittee? If not --

4           MEMBER LANGHORST: Can I do a -- just a little  
5 summary?

6           CHAIRMAN MALMUD: Please do.

7           MEMBER LANGHORST: I understand, again, the NRC's  
8 need for some clear cut criteria they can apply to decide  
9 whether there's need for a medical consultant or not. I  
10 don't think that we can add anything to our definition in  
11 the AO criteria policy that can clearly give you that and  
12 cover every occurrence. We understand that you don't feel  
13 comfortable in the -- in the procedures that you have. At  
14 lower level they seem very reasonable to us, but I  
15 understand that if you define your AO criteria like this, it  
16 seems like you have to have a medical consultant every time.  
17 And maybe that's as good as we can get. But there was -- I  
18 think we can all agree there's just not something that we  
19 can readily say will fit in here to give you a screening  
20 tool.

21           CHAIRMAN MALMUD: Dr. Thomadsen.

22           VICE CHAIRMAN THOMADSEN: Well, could we put in  
23 something about using the physicians in this committee to  
24 determine whether you should hire a consultant for abnormal  
25 occurrence? Would that alleviate the problem? I mean, that  
26 could be written in.

27           MEMBER LANGHORST: But wouldn't it be reasonable  
28 that they just use you as a medical consultant to evaluate

1 this? I mean, that seems very expedient, we're on the hook.

2 VICE CHAIRMAN THOMADSEN: How would they want to  
3 handle that?

4 MR. EINBERG: In some regards, we'll need to get a  
5 -- if as written, we'll need to get a medical consultant,  
6 regardless. Now, whether we interject another step in there  
7 to determine whether a medical consultant is necessary,  
8 they're already serving in the capacity as a medical  
9 consultant to make that determination. So I'm not sure  
10 whether it would be useful or not, so -- but you certainly  
11 could write it into a report if the committee felt it was  
12 necessary.

13 CHAIRMAN MALMUD: Dr. Thomadsen, did you...

14 VICE CHAIRMAN THOMADSEN: I don't think the  
15 committee feels that it's necessary. We're trying to treat  
16 the NRC staff, not ourselves.

17 MR. EINBERG: I don't see the need for it.

18 VICE CHAIRMAN THOMADSEN: Okay.

19 CHAIRMAN MALMUD: So, Dr. -- oh, excuse me, Dr.  
20 Welsh?

21 MEMBER WELSH: Yes, I have a question for Sue  
22 regarding a slide that's currently there. Would it be of  
23 any help for item D to say unanticipated or unexpected death  
24 in light of some of the conversation we've had about  
25 underdosing and given that we have not come to a consensus  
26 about underdosing being excluded? Death that is unexpected  
27 or unanticipated might clarify this.

28 MEMBER LANGHORST: I am not sure I can answer that

1 for you. I think it makes it sound unclear if you say  
2 anything other than death.

3 CHAIRMAN MALMUD: Dr. Guiberteau.

4 MEMBER GUIBERTEAU: It seems to me the operative  
5 word here is results in. Really doesn't matter after that.  
6 If we -- the whole point of all this, with the medical  
7 consultants and this language, is to connect the event with  
8 the complications here, and I think result already does  
9 that, so I don't think we need to, you know, really qualify  
10 death there. So I mean, to me, it already says what it  
11 needs to say. The issue here is, you know, I think we're  
12 stuck on, is the medical consultant issue. And I just  
13 wanted to ask Chris, do you have any suggestions?

14 MR. EINBERG: Mr. McDermott here just brought up  
15 the suggestion, if the subcommittee likes the language  
16 that's in the procedure right now, the NRC's internal  
17 procedure, could that be added as a footnote to the  
18 subcommittee report that this is when you would use the  
19 medical consultant?

20 MEMBER LANGHORST: I believe we said that, but --

21 [laughter]

22 [talking simultaneously]

23 MEMBER LANGHORST: -- say that four or five more  
24 times in there. That's what we think we're saying. That's  
25 what we think we're saying.

26 CHAIRMAN MALMUD: Dr. Langhorst, is your summary  
27 that we see now a motion?

28 MEMBER LANGHORST: I have not heard any difference

1 as far as what we've put forward for the report, so I would  
2 so move.

3 CHAIRMAN MALMUD: Is there a second to the motion?

4 MEMBER PALESTRO: Second.

5 CHAIRMAN MALMUD: It's been seconded by Dr.  
6 Palestro. Is there further discussion of the motion?  
7 Hearing none, all in favor, please say "aye."

8 MULTIPLE SPEAKERS: Aye.

9 CHAIRMAN MALMUD: Any opposed? Any abstentions?  
10 Thank you Dr. Langhorst and the members of your committee  
11 for a yeoman's job. Thank you.

12 MR. EINBERG: On behalf of the NRC, thank you  
13 [inaudible].

14 [laughter]

15 [inaudible commentary]

16 CHAIRMAN MALMUD: Is there a statement from --

17 MR. MCDERMOTT: Yes.

18 CHAIRMAN MALMUD: Oh. Mr. McDermott.

19 MR. MCDERMOTT: Yes, I just wanted to inform the  
20 committee and the members of our audience, that news is  
21 reporting two explosions in Boston in the vicinity of Boston  
22 Marathon finish line. They're reporting injuries and just  
23 wanted you to be aware of that.

24 CHAIRMAN MALMUD: Thank you.

25 MS. COCKERHAM: I was reading that they reported  
26 three deaths.

27 MR. MCDERMOTT: There's three deaths reported.

28 CHAIRMAN MALMUD: Thank you for informing us,

1 we'll check the news when we get out of here. And tomorrow  
2 we will meet again at 8:00. The first item on the agenda  
3 tomorrow is 10 CFR Part 35 rulemaking update with Ms. Bhalla  
4 and Ed Lohr. We look forward to that, and then agenda as  
5 you can see has been abbreviated, so that if you want to  
6 make alternate travel plans, you may have the opportunity to  
7 do so, although your -- that's up to you. See you all  
8 tomorrow.

9 [Whereupon, the proceedings were concluded at 5:00pm]