

# **Official Transcript of Proceedings**

## **NUCLEAR REGULATORY COMMISSION**

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on the Medical Uses of Isotopes

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UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

+ + + + +

SPRING 2016 MEETING

+ + + + +

THURSDAY,

MARCH 17, 2016

+ + + + +

The meeting was convened in room T-2B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 1:00 p.m., Philip O. Alderson, M.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

PHILIP O. ALDERSON, M.D., Chairman

FRANCIS M. COSTELLO, Agreement State  
Representative

VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

RONALD D. ENNIS, M.D., Radiation Oncologist

STEVEN R. MATTMULLER, Nuclear Pharmacist

DARLENE F. METTER, M.D., Diagnostic Radiologist

MICHAEL O'HARA, Ph.D., FDA Representative

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

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Physician

JOHN J. SUH, M.D., Radiation Oncologist

LAURA M. WEIL, Patients' Rights Advocate

PAT B. ZANZONICO, Ph.D., Vice-Chairman

NON-VOTING: ZOUBIR OUHIB

MEMBER SELECT: RICHARD GREEN

NRC STAFF PRESENT:

DANIEL COLLINS, Director, Division of Material

Safety, State, Tribal and Rulemaking Programs

DOUGLAS BOLLOCK, ACMUI Designated Federal  
Officer

SOPHIE HOLIDAY, ACMUI Alternate Designated  
Federal Officer and ACMUI Coordinator

MARYANN ABOGUNDE, NMSS/MSTR/MSEB

SAID DAIBES, Ph.D., NMSS/MSTR/MSEB

MICHAEL FULLER, NMSS/MSTR/MSEB

ESTHER R. HOUSEMAN, OGC/GCLR/RMR

DONNA-BETH HOWE, Ph.D., NMSS/MSTR/MSEB

ANTHONY C. MCMURTRAY, NMSS/MSTR/MSLB

SCOTT W. MOORE, NMSS

GRETCHEN RIVERA-CAPELLA, NMSS/MSTR/MSEBKATIE

TAPP, Ph.D., NMSS/MSTR/MSEB

MEMBERS OF THE PUBLIC PRESENT:

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BETTE BLANKENSHIP, American Association of  
Physicists in Medicine (AAPM)

SUE BUNNING, Society of Nuclear Medicine and  
Molecular Imaging (SNMMI)

ROBERT DANSEREAU, New York State Department of  
Health

WILLIAM DAVIDSON, University of Pennsylvania

LYNNE FAIROBENT, American Association of  
Physicists in Medicine (AAPM)

SANDRA GABRIEL, International Atomic Energy  
Agency

CAITLIN KUBLER, Society of Nuclear Medicine and  
Molecular Imaging (SNMMI)

RICHARD MARTIN, American Association of  
Physicists in Medicine (AAPM)

ERIC PERRY, Kentucky Department for Public Health

MICHAEL PETERS, American College of Radiology

KAREN SHEEHAN, Fox Chase Cancer Center

MICHAEL SHEETZ, University of Pittsburgh

CINDY TOMLINSON, American Society for Radiation  
Oncology

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

(1:01 p.m.)

CHAIRMAN ALDERSON: Welcome. This is Dr. Alderson speaking. We're going to call the spring meeting of the ACMUI to order and I'm going to turn the floor over to Doug Bollock of the NRC.

MR. BOLLOCK: Thank you, Dr. Alderson.

As the Designated Federal Officer for this meeting, I am pleased to welcome you to this public meeting of the Advisory Committee on the Medical Uses of Isotopes.

My names is Doug Bollock, I am the Branch Chief of the Medical Safety and Events Assessment Branch and I have been designated as the Federal Officer for this Advisory Committee in accordance with 10 CFR Part 7.11.

Present today as the Alternate Designated Federal Officer, Sophie Holiday, our ACMUI Coordinator.

This is an announced meeting of the Committee and is being held in accordance with the rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission.

This meeting is being transcribed by the NRC and it may also be transcribed or recorded by others.

The meeting was announced in the February

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1 4, 2016 Edition of the Federal Register, Volume 81, Page  
2 6056 through 6057.

3 The focus of the Committee is to advise the  
4 staff on issues and questions that arise in the medical  
5 use of byproduct material.

6 The Committee provides counsel to the  
7 staff, but does not determine or direct the actual  
8 decisions of the staff or the Commission.

9 The NRC solicits the views of the Committee  
10 and validates their opinions.

11 I request that whenever possible, we try to  
12 reach a consensus on the various issues that we'll  
13 discuss today. But, I also recognize there may be  
14 minority or dissenting opinions.

15 If you have such opinions, please allow  
16 them to be read into the record.

17 At this point, I'd like to perform a roll  
18 call of the ACMUI members participating today.

19 Dr. Philip Alderson?

20 CHAIRMAN ALDERSON: Here.

21 MR. BOLLOCK: Dr. Pat Zanzonico?

22 VIEC CHAIRMAN ZANZONICO: Here.

23 MR. BOLLOCK: Mr. Frank Costello?

24 MEMBER COSTELLO: Here.

25 MR. BOLLOCK: Dr. Vasken Dilsizian?

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1 MEMBER DILSIZIAN: Here.

2 MR. BOLLOCK: Dr. Ronald Ennis?

3 MEMBER ENNIS: Here.

4 MR. BOLLOCK: Dr. Sue Langhorst?

5 MEMBER LANGHORST: Here.

6 MR. BOLLOCK: Mr. Steve Mattmuller?

7 MEMBER MATTMULLER: Here.

8 MR. BOLLOCK: Dr. Darlene Metter?

9 MEMBER METTER: Here.

10 MR. BOLLOCK: Dr. Michael O'Hara?

11 MEMBER O'HARA: Here.

12 MR. BOLLOCK: Dr. Christopher Palestro?

13 MEMBER PALESTRO: Here.

14 MR. BOLLOCK: Dr. John Suh?

15 MEMBER SUH: Suh, Yes.

16 MR. BOLLOCK: Suh, sorry, Dr. Suh, I

17 apologize.

18 And, Ms. Laura Weil?

19 MEMBER WEIL: Here.

20 MR. BOLLOCK: Thank you.

21 I confirm that we do have a quorum.

22 Also at the table, we have Mr. Zoubir Ouhib.

23 Mr. Ouhib has been selected as the ACMUI Therapy Medical

24 Physicist and is pending screening clearance, but may

25 participate in the meeting today. However, at this

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1 time, he does not have voting rights.

2 I would also like to recognize Mr. Richard  
3 Green. He has been selected as the next ACMUI Nuclear  
4 Pharmacist but cannot sit at the table as Mr. Steve  
5 Mattmuller currently holds that position.

6 I would also like to add that this meeting  
7 is being webcast, so other individuals may be watching  
8 online.

9 We have a bridge line available and that  
10 phone number is 888-864-0940. The passcode to access  
11 the bridge line 84114 followed by the pound sign.

12 Individuals who would like to ask a  
13 question or make a comment regarding a specific issue  
14 the Committee has discussed should request permission  
15 to be recognized by the ACMUI Chairperson, Dr. Philip  
16 Alderson.

17 Dr. Alderson, at his option, may entertain  
18 comments or questions from members of the public who are  
19 participating with us today.

20 Comments and questions are usually  
21 addressed by the Committee near the end of the  
22 presentation after the Committee has fully discussed  
23 the topic.

24 We ask that one person speak at a time as  
25 this meeting is being closed captioned.

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1 I would also like to add that handouts and  
2 agenda for this meeting are available on the NRC's  
3 public website.

4 At this time, I ask that everyone on the  
5 call who is not speaking to place their phones on mute.  
6 If you do not have the capability to mute your phone,  
7 please press star six to utilize the conference line  
8 mute and unmute functions.

9 At this point, I'd like to turn the meeting  
10 over to Mr. Dan Collins, Director of the Division of  
11 Material Safety, States, Tribal and Rulemaking  
12 Programs, for some opening remarks.

13 MR. COLLINS: Thank you, Doug.

14 I'd like to take this opportunity to  
15 welcome everyone to the spring 2016 ACMUI meeting.

16 As, Doug mentioned, I am the Division  
17 Director for the Division of Material Safety State  
18 Tribal and Rulemaking Programs and I replaced Josie  
19 Piccone who retired in early December.

20 Other organizational changes within the  
21 office of NMSS that you may be aware of is that Scott  
22 Moore is currently the Acting Office Director pending  
23 the arrival of Mr. Mark Dapas in July of this year.

24 And also, Joel Munday is the Acting Deputy  
25 Office Director and, when Mr. Dapas arrives, Scott Moore

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1 will revert back to being the permanent Deputy Office  
2 Director.

3 So, I'll just take a moment to note that  
4 this is Mr. Mattmuller's last ACMUI meeting as the ACMUI  
5 Nuclear Pharmacist and we'd like to thank Mr. Mattmuller  
6 for your eight years of dedicated service to the staff  
7 and to the Committee.

8 And, tomorrow, we'll hear a special  
9 presentation from Scott Moore, as well as some farewell  
10 remarks from Mr. Mattmuller.

11 And with -- and, as Doug noted, with Mr.  
12 Mattmuller's departure, we have selected Mr. Richard  
13 Green as the next ACMUI Nuclear Pharmacist and we're  
14 thankful that Mr. Green could be here today.

15 ACMUI, just to review a couple of the more  
16 recent ACMUI activities for members of the public who  
17 may be listening, ACMUI held a teleconference on October  
18 28th of last year to discuss the draft ACMUI  
19 Subcommittee Report on the ACMUI review and comments of  
20 three Petitions for Rulemaking.

21 Those were PRMs 20-28, 20-29 and 20-30  
22 which dealt with linear no threshold model and standards  
23 for protection against radiation.

24 And, the Committee's report has been  
25 provided to a working group for further review and

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1 evaluation.

2 Also, ACMUI held a teleconference on  
3 January 6th of this year to discuss the draft ACMUI  
4 subcommittee report on the ACMUI's review and comments  
5 on the draft final rule for Title 10 of the Code of  
6 Federal Regulations, Part 35, Medical Use of Byproduct  
7 Materials. And, the staff is diligently working to  
8 resolve comments from the Committee and from OAS at this  
9 time.

10 Since the summer of 2015, both the ACMUI and  
11 the staff have received numerous letters from  
12 stakeholders, patients and congressional staff members  
13 related to the training and experience requirements for  
14 authorized users for alpha, beta and gamma emitters  
15 under 10 CFR 35.390, as well as participating in  
16 briefings on Capitol Hill.

17 ACMUI held a teleconference last Thursday,  
18 March 10, 2016, to discuss the draft ACMUI Subcommittee  
19 report on the training and experience requirements for  
20 authorized users of alpha, beta and gamma emitters under  
21 10 CFR 35.390.

22 And, as a result of that Subcommittee's  
23 hard work in addressing these issues, a new Subcommittee  
24 was formed to review and evaluate training and  
25 experience requirements across all modalities.

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1                   During the fall of 2015 ACMUI meeting, the  
2                   ACMUI endorsed the draft Yttrium-90 microsphere  
3                   brachytherapy 35.1000 licensing guidance. The NRC has  
4                   issued Revision 9 of that guidance; that was issued on  
5                   February 17th of this year.

6                   And, later on today, you'll hear a  
7                   presentation from Dr. Tapp regarding that guidance and  
8                   addition areas under consideration.

9                   Tomorrow, you'll hear a presentation from  
10                  Doug Bollock regarding the OIG's audit of the NRC's  
11                  oversight of medical use of nuclear material.

12                  And also tomorrow, you'll hear from Sophie  
13                  Holiday and Mr. Perry from Kentucky regarding draft  
14                  licensing guidance for the Leksell Gamma Knife  
15                  Perfexion and Leksell Gamma Knife Icon.

16                  And, with that, I'll turn this over to  
17                  Sophie for the next item in the agenda which is a review  
18                  of past ACMUI recommendations and NRC responses to those  
19                  recommendations.

20                  Thank you.

21                  MS. HOLIDAY: Good afternoon. I hope  
22                  everyone is well after having a nice lunch.

23                  Okay, so this is a very familiar piece of  
24                  our meeting. At every meeting we go over old business  
25                  which is recapping all of the recommendations and

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1 actions that were put forth by the Committee and/or  
2 staff and noting any changes.

3 So, a lot of what you hear today will not  
4 be much different from what you heard in October, being  
5 that for the 2007 chart, all the items that are listed  
6 as open or open and delayed are included in the current  
7 rulemaking that the Committee, as Dan said, had a  
8 teleconference this past January on.

9 So, we will now move on --

10 MEMBER LANGHORST: May I ask a question on  
11 this?

12 MS. HOLIDAY: Yes, ma'am.

13 MEMBER LANGHORST: Just for our new  
14 members, I wanted to make note of Item 3 which was  
15 approved by ACMUI on June 12, 2007. So, it predates all  
16 of us on the Committee.

17 ``NRC staff should revise the regulation so  
18 that Board Certified individuals who were certified  
19 prior to the effective date of recognition or were  
20 certified by previous recognized Boards listed in  
21 Subpart J of the previous editions of Part 35 are  
22 grandfathered.''

23 I just want to let you know of that long  
24 listing recommendation.

25 MS. HOLIDAY: Thank you.

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1           Okay, so we will move on to 2008. So,  
2           again, all the items in 2008 are also included in the  
3           current Part 35 rulemaking.

4           So, if you will go on to the 2009 chart,  
5           there's only two items and, both of these are also  
6           included in the current Part 35 rulemaking.

7           And so, we go on to 2011, as I've said, for  
8           the past few years, 2010 is not included because we did  
9           close all of the recommendations and actions on that  
10          chart. And, they are not, subsequently, included in  
11          the current Part 35 rulemaking.

12          So, then we come to 2011, and the majority  
13          of these are also included in the current Part 35  
14          rulemaking.

15          I would like to call to your attention that  
16          Item Number 1 has to deal with the patient release  
17          criteria. This is pending, because, as you are aware,  
18          there are two patient release efforts going on here at  
19          the NRC, both by the Office of Research and by the Office  
20          of Nuclear Material Safety and Safeguards.

21          Item 6 is the indefinite open action item  
22          from the Committee to review its reporting structure on  
23          an annual basis, which you will hear from me later on  
24          this afternoon.

25          Item 11 has to deal with ACMUI's

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1 endorsement of ASTRO's approach for permanent implant  
2 brachytherapy. And, this is pending, well, open but  
3 pending at the current time.

4 Item 13 has to deal with the written  
5 attestation which is also included in the current Part  
6 35 rulemaking.

7 The same goes for Items 14 and 15.

8 Item 16, again, has to deal with the patient  
9 release criteria as well as Item 32.

10 So, this brings me to the 2012 chart.  
11 There is only one item on there. And, again, that's the  
12 same reiteration of the previous recommendation in 2011  
13 which is to continue reviewing the Committee's  
14 reporting structure on an annual basis. So, it was  
15 reaffirmed during the 2012 meeting.

16 However, I will note that, while this item  
17 is listed on the 2012 chart, I would like to ask the  
18 Committee's permission to close the 2012 chart since  
19 this is a reiteration of the 2011 recommendation.

20 CHAIRMAN ALDERSON: You'd like to do that  
21 now?

22 MS. HOLIDAY: Yes.

23 CHAIRMAN ALDERSON: Okay.

24 You've heard that Sophie would like the  
25 Committee to think about or are there people who would

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1 like to discuss that item?

2 Seeing no discussion, would someone like to  
3 move approval?

4 MEMBER LANGHORST: I'll move approval.

5 CHAIRMAN ALDERSON: Is there a second?

6 MEMBER MATTMULLER: Second.

7 CHAIRMAN ALDERSON: Okay. Further  
8 discussion?

9 All in favor?

10 (Chorus of aye.)

11 CHAIRMAN ALDERSON: Opposed?

12 Abstentions?

13 Pass as unanimous.

14 MS. HOLIDAY: Thank you.

15 Okay, this brings us to 2013. As many of  
16 the members on the Committee are aware, in 2013, the  
17 ACMUI was provided with the draft proposed Part 35 rule  
18 and this is -- we spent two public teleconferences on  
19 March 5th and March 12th of 2013 receiving the  
20 Committee's comments in response to that draft proposed  
21 rule.

22 So, Items 1 through 13 are all included in  
23 the current Part 35 rulemaking.

24 Item 21 has to deal with the  
25 germanium/gallium-68 generator where the ACMUI

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1 recommended that NRC provide regulatory relief. As  
2 we've heard from Mr. Mattmuller this morning during the  
3 Commission meeting and you will also hear from Dr.  
4 Daibes on tomorrow after -- tomorrow morning, I'm sorry,  
5 with an update on staff's efforts related to the  
6 decommissioning funding plan requirements for the  
7 germanium/gallium-68 generator.

8 Item 25 had to deal with the Committee's  
9 recommendation to re-establish the Rulemaking  
10 Subcommittee to review and address the staff's response  
11 to the draft proposed Part 35 rulemaking.

12 I would like to put forth a request to close  
13 this item since the Rulemaking Subcommittee presented  
14 its report in January of this year and the Committee  
15 endorsed that report and that is now with staff for  
16 review.

17 CHAIRMAN ALDERSON: All right, we'll now  
18 consider that request.

19 Further discussion of this item?

20 Seeing none, a motion to approve?

21 MEMBER LANGHORST: So moved.

22 CHAIRMAN ALDERSON: Is there a second?  
23 There is.

24 All in favor?

25 (Chorus of aye.)

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1 CHAIRMAN ALDERSON: Any opposed?

2 Any abstaining?

3 That's passed unanimously.

4 MS. HOLIDAY: Thank you.

5 MEMBER LANGHORST: May I --

6 CHAIRMAN ALDERSON: Yes?

7 MEMBER LANGHORST: Sue Langhorst.

8 I just wanted to point out on Item 8, again,  
9 it's that essentially gathering clause of anyone, at  
10 this point in time who is Board-Certified, so I just,  
11 again, that's our longstanding stance and  
12 recommendation to the NRC.

13 Thank you.

14 CHAIRMAN ALDERSON: So noted.

15 MS. HOLIDAY: Thank you.

16 Okay, so then we will move on to the 2014  
17 chart.

18 And, the first item which is Item 6 also has  
19 to deal with the same germanium/gallium-68 topic.  
20 You'll, again, hear from Dr. Daibes tomorrow on that  
21 topic.

22 Items 10, 11 and 12 all have to do with the  
23 Subcommittee's report related to the Yttrium-90  
24 microspheres brachytherapy licensing guidance.

25 I have noted this in red because, as this

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1 was discussed during the October meeting, the  
2 Committee's recommendations were included in the then  
3 draft revision of that guidance which was endorsed  
4 during the October 2015 meeting.

5 You will hear a presentation from Dr. Katie  
6 Tapp later on this afternoon in regards to that topic.

7 Are there any comments, questions or  
8 concerns with my closing these three items?

9 CHAIRMAN ALDERSON: We'll try again. Are  
10 there items for discussion here?

11 Hearing none, a motion to approve the  
12 request?

13 MEMBER LANGHORST: So moved.

14 CHAIRMAN ALDERSON: And is there a second?

15 All those in favor?

16 (Chorus of aye.)

17 CHAIRMAN ALDERSON: Opposed or  
18 abstaining?

19 None, thank you.

20 MS. HOLIDAY: Thank you.

21 Moving on to 2015. So, the first item on  
22 this chart is Item 7. I apologize for those of you in  
23 the back, the print is rather small, but it is available  
24 in your meeting handout.

25 During the March meeting, and also

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1 reiterated during the fall 2015 meeting, the ACMUI had  
2 recommendations related to that normal occurrence  
3 criteria.

4 So, this item is still listed as open as we  
5 are waiting on staff's review and evaluation to revise  
6 the NRC's abnormal occurrence criteria policy  
7 statement.

8 Item 9 has to deal with the Subcommittee  
9 that was created to review and evaluate the 700 training  
10 experience hours related to the authorized users of  
11 alpha, beta and gamma emitters under 35.390.

12 I will tie this also to, and I am jumping  
13 just a bit ahead, I will tie this to the teleconference  
14 that took place just last week. So, both items are  
15 related.

16 So, I am requesting to close Item 9, as that  
17 Subcommittee completed their work in the October 2015  
18 meeting related to evaluating whether or not those 700  
19 hours was the sole contributing factor with placing  
20 hardship on the patient community.

21 CHAIRMAN ALDERSON: All right, same as the  
22 past few, is there further discussion on that particular  
23 item?

24 Seeing none, a motion to approve its  
25 closing?

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1                   There's a -- yes, there is a motion and a  
2                   second.

3                   All right, all in favor?

4                   (Chorus of aye.)

5                   CHAIRMAN     ALDERSON:           Opposed     or  
6                   abstaining?

7                   None.

8                   MS. HOLIDAY:   Thank you.

9                   CHAIRMAN ALDERSON:   Thank you.

10                  MS. HOLIDAY:   Item 12 and Item 13 and 14  
11                  have to deal with the Subcommittee's report and  
12                  discussion about the phrase "patient intervention."

13                  Item 14 in particular, Dr. Thomadsen  
14                  previous ACMUI Chairman requested that staff provide an  
15                  update during this meeting on staff's response and  
16                  action to that Subcommittee report.

17                  At this time, I would like to inform you all  
18                  that, based on the prioritization of workload,  
19                  including patient release and the Part 35 rulemaking,  
20                  we've not been able to address the patient intervention  
21                  Subcommittee report. But, we will address that as soon  
22                  as staff resources are available.

23                  CHAIRMAN ALDERSON:   Thank you.

24                  MS. HOLIDAY:   Are there any questions or  
25                  comments related to Item 12 through 14?

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1 CHAIRMAN ALDERSON: There appear to be  
2 none.

3 MS. HOLIDAY: Great, thank you.

4 I'm sorry, this also includes Item 15 as  
5 well.

6 Okay, Item 16, again, has to deal with the  
7 training and experience for Alpha and Beta Emitters  
8 Subcommittee that presented their report on last week.  
9 So, while it's not noted open, I am also requesting to  
10 close that item as well.

11 CHAIRMAN ALDERSON: All right, is there  
12 discussion of this?

13 Just for the benefit of people who might be  
14 listening from the general public, you will hear later  
15 that we have, in fact, formed a standing Subcommittee  
16 to look at training and experience requirements across  
17 the broad spectrum, and that Committee will begin its  
18 work shortly after this meeting.

19 So, this is not to suggest that we are  
20 walking away from this very important issue at all.

21 That having been said, questions or  
22 comments about Sophie's motion to close this particular  
23 item?

24 Seeing none, a motion to approve?

25 And a second?

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1 All in favor?

2 (Chorus of aye.)

3 CHAIRMAN ALDERSON: Opposed or  
4 abstaining?

5 It's unanimous.

6 Thank you.

7 MS. HOLIDAY: Thank you.

8 Items 17 through 19 have to deal with the  
9 comments and recommendations provided by the  
10 Radioactive Seed Localization Subcommittee.

11 I have Item 17 as being closed because this  
12 motion did not pass. So, after this meeting, I will be  
13 closing this item from this chart.

14 Items 18 and 19, I have left open because  
15 my working group revising that guidance is still working  
16 on that. I am hoping that we will be able to provide  
17 the Committee with draft guidance early summertime for  
18 your 60-day review and comment period.

19 Okay, are there any questions related to  
20 Items 17 through 19?

21 CHAIRMAN ALDERSON: There are none.

22 MS. HOLIDAY: Great.

23 Item 20 is, again, when the ACMUI endorsed  
24 the Y-90 Microspheres Subcommittee report. So, I have  
25 this closed. So, I will be removing this as well.

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1 CHAIRMAN ALDERSON: Very good.

2 MS. HOLIDAY: And Item 21, I am also  
3 closing because all of you are here today for the spring  
4 2016 meeting.

5 Okay, item 22 has to deal with, again, the  
6 AO Criteria Subcommittee report. As I stated before,  
7 NRC staff is currently reviewing and evaluating the  
8 Subcommittee's report as well as all of the other  
9 comments that were received pertaining to the revisions  
10 of the NRC's Abnormal Occurrence Criteria Policy  
11 Statement.

12 So, when staff has completed its review, as  
13 was stated in the Commission meeting this morning, the  
14 Committee will receive a memorandum explaining whether  
15 or not or why we did accept and did not accept some of  
16 the Committee's recommendations.

17 Item 23, the ACMUI endorsed the NUREG-1556,  
18 Volume 9 Subcommittee report. I have left this item  
19 open, because, as you are aware, the NUREG-1556, Volume  
20 9 has not been finalized yet.

21 And, you will also hear from Dr. Katie Tapp  
22 this afternoon regarding those efforts.

23 And then, the last item for 2015, a  
24 Subcommittee was created to propose the appropriate  
25 criteria for medical event reporting or events other

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1       than permanent implant brachytherapy.

2                   We will hear from that Subcommittee after  
3       our break this afternoon.

4                   And now, we are into our current year, 2016.  
5       So, Items 1 through 15 all have to deal with the  
6       Subcommittee's report that had the recommendations  
7       related to the draft final rule.

8                   Again, all of these items are open as staff  
9       is reviewing and evaluating the comments from both the  
10      Committee and the Organization of Agreement States.

11                   Are there any comments or questions related  
12      to these items?

13                   CHAIRMAN ALDERSON:   There is, yes.

14                   Sue Langhorst?

15                   MEMBER LANGHORST:   Yes, I just wanted to  
16      point out Item 7, that again, we're talking about  
17      grandfathering all Board-Certified individuals and on  
18      licensing guidance that that be addressed on how you  
19      deal with the various issues that current, if you don't  
20      accept that, that's how you get someone authorized.

21                   CHAIRMAN ALDERSON:   But, I think that this  
22      is a very important topic considering that we're going  
23      to be discussing in detail training and experience.  
24      So, this will almost surely come up for some  
25      reconsideration.

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1 MS. HOLIDAY: Absolutely.

2 CHAIRMAN ALDERSON: Thank you, Dr.  
3 Langhorst.

4 MEMBER LANGHORST: Mostly for the new  
5 members, I wanted to let you know how longstanding this  
6 recommendation has been.

7 CHAIRMAN ALDERSON: Right, thank you.

8 MS. HOLIDAY: Thank you.

9 And then, the last item that I have that is  
10 not listed on here because it didn't quite make the print  
11 cutoff time is, again, the Committee had a  
12 teleconference last Thursday on March 10th to discuss  
13 the training and experience for authorized users of  
14 alpha, beta and gamma emitters under 10 CFR 35.390.

15 The Committee unanimously endorsed or  
16 approved the Subcommittee's report.

17 The report contained recommendations that  
18 included maintaining the current 700 hours for training  
19 and experience and also to establish a standing  
20 Subcommittee that will review the training and  
21 experience requirements across all modalities under 10  
22 CFR Part 35.

23 Do you all accept my addition to the table?

24 CHAIRMAN ALDERSON: So, are there any  
25 additions or corrections to Ms. Holiday's report?

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1                   There is a hand from Dr. Langhorst.

2                   MEMBER LANGHORST:   Yes, on Item 13 that you  
3                   have there, I found this very confusing when we were  
4                   going through and I just want to suggest adding one word.

5                   MS. HOLIDAY:    Sure.

6                   MEMBER LANGHORST:   In reading it first  
7                   when we were making our review, it sounded like you  
8                   didn't have to send any paper in.   And so, what it really  
9                   means is you don't have to submit additional copies of  
10                  your license application or license amendment.

11                  So, I would just suggest that it might say  
12                  submit additional copies because you have to submit  
13                  something.

14                  CHAIRMAN ALDERSON:   For those who might be  
15                  listening on the phone, would you just read the sentence  
16                  and you would like it now to be amended.

17                  MEMBER LANGHORST:   Yes.

18                  ``The Committee endorsed the elimination  
19                  of the requirement to submit additional copies of NRC  
20                  Form 313, Application for a Materials License or a  
21                  letter containing information required by NRC Form 313  
22                  when applying for a license, an amendment or a  
23                  renewal.''

24                  CHAIRMAN ALDERSON:   Very good.

25                  All right, so that's your proposal, that's

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1 your motion, is there a second?

2 There's a second.

3 All right, do we wish to discuss that or  
4 does someone want to move the question?

5 No question, a second?

6 All in favor of adding this additional word  
7 say aye?

8 (Chorus of aye.)

9 CHAIRMAN ALDERSON: Opposed or  
10 abstaining?

11 None, it's passed unanimously.

12 MS. HOLIDAY: Thank you.

13 I will note that, while I'll make the change  
14 on this chart, these are items that were explicitly  
15 called out from the report that has been finalized,  
16 which will be included in the Commission paper as the  
17 Committee's unfettered opinions or unfettered votes.

18 But, members of that rulemaking working  
19 group are in this room so they are aware of your  
20 recommendation.

21 MEMBER LANGHORST: Thank you very much.

22 Sue Langhorst.

23 Thank you very much for that.

24 I just -- because this is just such a  
25 standalone thing, I thought it would be helpful to

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1 include that word additional because it made no sense  
2 to me as an RSO.

3 If I'm not supposed to send in a 313 copy,  
4 how am I going to ask for an amendment?

5 MS. HOLIDAY: Absolutely.

6 MEMBER LANGHORST: So, it's just, right  
7 now, I send in my original and I have to send in a copy.

8 MS. HOLIDAY: Absolutely.

9 MEMBER LANGHORST: That's all it states.  
10 So, thank you.

11 MS. HOLIDAY: You're welcome.

12 Okay, this concludes my portion of old  
13 business. Are there any questions, comments or  
14 concerns related to?

15 MEMBER PALESTRO: I have one question.

16 So, I didn't see indicated anywhere, you  
17 know, that Dr. Alderson had, in fact, formed the  
18 Subcommittee for evaluation of training.

19 MS. HOLIDAY: You're correct. I have not  
20 added that yet. I was going to wait until he mentioned  
21 it during --

22 CHAIRMAN ALDERSON: Pat is going to  
23 mention it in a few minutes.

24 MS. HOLIDAY: And just leave it at --

25 CHAIRMAN ALDERSON: And, that was Dr.

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1 Palestro speaking.

2 MS. HOLIDAY: Thank you.

3 CHAIRMAN ALDERSON: Any other amendments,  
4 discussion about Sophie Holiday's report?

5 Hearing none, Sophie, thank you very much.

6 MS. HOLIDAY: Thank you.

7 CHAIRMAN ALDERSON: Okay, so this brings  
8 us to the part of this particular session known as Open  
9 Forum.

10 And so, at this particular time, we will  
11 open the floor to discussions of medical topics of  
12 interest.

13 We'll begin with discussions among the  
14 ACMUI. It is possible, given the interest from the  
15 audience that we may, in fact, invite them to make  
16 comments after we've had sufficient time to discuss  
17 these items on our own.

18 And, this is the place where I will  
19 mentioned very briefly that this morning, we did meet  
20 with the Commission, the Commissioners, and we  
21 discussed -- Dr. Palestro led the discussion on training  
22 and experience issues.

23 We indicated to the Commissioners at that  
24 time, as Mr. Collins actually noted earlier, briefly in  
25 his comments, that we had formed a standing Subcommittee

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1 to address training and experience requirements.

2 And, by standing, and we have that not ad  
3 hoc, but standing Committee, we will presume that this  
4 Committee will be functioning at each and every meeting  
5 as we go forward.

6 And as things may change in the medical  
7 community relating to what might be effective and  
8 appropriate training and experience for a particular  
9 issue, that Committee will already be there and will be  
10 charged with reviewing those things and bringing them  
11 to our attention and to the attention of the NRC.

12 So, that Subcommittee, standing  
13 Subcommittee, has been formed. Chris Palestro will be  
14 the Chair. Sue Langhorst is a member of that Committee.  
15 John Suh is a member of that Committee. Laura Weil is  
16 a member of that Committee. And, Darlene Metter is a  
17 member of that Committee.

18 So, I thank you very much and just wanted  
19 to make those comments to get this open session started.

20 So, I now will turn the floor over to  
21 members of the ACMUI who can introduce topics of  
22 interest that they may wish to discuss.

23 The floor is open.

24 Yes, Dr. Ennis?

25 MEMBER ENNIS: I've been hearing about

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1 efforts of other part of the federal government who are  
2 greatly concerned about security related to the  
3 isotopes and the possible previous changes to their  
4 security requirements, eventual search requirements  
5 for a variety of aspects.

6 And --

7 CHAIRMAN ALDERSON: Yes, please start over  
8 in case the people listening from outside couldn't hear  
9 you --

10 MEMBER ENNIS: Absolutely.

11 CHAIRMAN ALDERSON: -- as you made these  
12 comments.

13 MEMBER ENNIS: So, I have become aware of  
14 an effort by some other branches of the federal  
15 government exploring the possibility of increasing  
16 regulation of what I call high activity radioactive  
17 sources out of a concern for terrorism.

18 A lot of proposals I've heard flying around  
19 and wanted to know from my colleagues whether we think  
20 that this is something that we ought to evaluate and  
21 weigh in on?

22 CHAIRMAN ALDERSON: All right, so, Dr.  
23 Langhorst has her hand up and she will get to comment  
24 just after I make a brief context statement.

25 I think that at some point in this

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1 discussion, we might want to ask our NRC colleagues if  
2 they are aware of these issues and, if they are, they  
3 might expand upon the knowledge just to put to the table  
4 as to what might be going on.

5 But, Dr. Langhorst?

6 MEMBER LANGHORST: I have something to  
7 address there.

8 CHAIRMAN ALDERSON: Very good.

9 MEMBER LANGHORST: So, on Monday, in the  
10 Federal Register, there was an NRC Request for Comment  
11 on Part 37. That's the security regulations.

12 And, going through a lot questions and  
13 answers, or asking questions of licensees, in  
14 particular.

15 For those of you who may not know, this  
16 rule, Part 37, has been in effect since March 19, 2014  
17 -- '15 -- '14. No, it was published then.

18 UNKNOWN PARTICIPANT: In '13 -- 2013, it  
19 became effective.

20 MEMBER LANGHORST: Right, but you didn't  
21 have to implement it until a year later, wasn't it 2014  
22 for NRC licensees?

23 Agreement States had up to three years, so  
24 those Agreement States who hadn't already adopted this  
25 security requirement are due to have it in place by March

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1 19, this week. Okay?

2 I looked at this and thought, do I want to  
3 suggest, because my very small Subcommittee who worked  
4 on the original Part 37, they're long gone.

5 But, really, the question and answer part  
6 of it, I think I would encourage licensees to submit  
7 their answers to NRC on what it means in a medical  
8 environment.

9 So, I just wanted you to be aware that's  
10 Federal Register, Volume 81, March 14, 2016 and it  
11 starts on Page 13263.

12 CHAIRMAN ALDERSON: Thank you, Dr.  
13 Langhorst.

14 MEMBER LANGHORST: Thank you.

15 CHAIRMAN ALDERSON: Given that the  
16 Agreement States are involved in this, I wonder if Mr.  
17 Frank Costello would like to make a comment?

18 MEMBER COSTELLO: I do.

19 Pennsylvania is -- I'm sorry. There we go,  
20 now you can hear me.

21 Pennsylvania is adopting it tomorrow,  
22 which happens to be just in time planning for us. We're  
23 one day ahead of March 19th.

24 I would say that, while some Agreement  
25 States adopted it early, I think most Agreement States

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1 are adopting it just in time.

2 We have no running time on this. I'm just  
3 starting inspecting Part 37 this coming week for the  
4 first time.

5 But, I think, though, that for the most  
6 part, Part 37 does not impose, I think it only imposes  
7 administrative changes on top of what was there from the  
8 orders.

9 Now, there are administrative changes and  
10 there's a fair number of them, but I don't think the  
11 actual security sources are very much different than the  
12 orders.

13 But, there are administrative changes and  
14 I expect in the beginning to find a number of places  
15 where licensees have to fix things.

16 I think that's been true with the other  
17 Agreement States as well.

18 And, I think, having listened to NRC speak  
19 about this, I think the NRC's experience in its running  
20 time over the last few years is that, for the most part,  
21 most of the violations identified were administrative  
22 in nature.

23 CHAIRMAN ALDERSON: So, for those who  
24 might know exactly what that means, just could you give  
25 us one --

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1 MEMBER COSTELLO: Yes.

2 CHAIRMAN ALDERSON: -- example of an  
3 administrative change that this particular requirement  
4 would lead to?

5 MEMBER COSTELLO: Sure.

6 Right now, there wasn't a requirement  
7 before to have periodic training and now, there's a  
8 requirement for periodic training.

9 There's a requirement for periodic audits,  
10 both of the access program or the security program  
11 itself.

12 There's a requirement to have a security  
13 plan and written security procedures.

14 These are what I think of as being  
15 administrative changes.

16 But, the locks and the alarms and such will  
17 be there.

18 Not to say there's not a fair number of  
19 those administrative changes, but I think the sources  
20 will be secured pretty much the same as they have been  
21 in the past.

22 And, I think the NRC, in their inspections,  
23 have been finding for the violations they've had over  
24 the last couple of years, they've largely been  
25 administrative.

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1 CHAIRMAN ALDERSON: All right.

2 Would the NRC -- Dr. Langhorst has her hand  
3 up again.

4 MEMBER LANGHORST: I'm sorry, I wanted to  
5 make one mention about this Federal Register, the  
6 comments are due by May 13 this year. So, I just wanted  
7 to make mention of that. I forgot to do that before.

8 CHAIRMAN ALDERSON: Good, thank you.

9 Dr. Collins?

10 MR. COLLINS: This is Daniel Collins.

11 Just to provide some additional context to  
12 the Federal Register that Dr. Langhorst referenced, the  
13 NRC is required by Congress to perform an evaluation of  
14 the effectiveness of Part 37. And, that is what that  
15 Federal Register is associated with and that the NRC's  
16 report to Congress is due by the end of calendar year  
17 2016.

18 So, it's looking at the effectiveness of  
19 the rule, not specifically the effectiveness of the  
20 NRC's implementation or the Agreement States'  
21 implementation of the rule.

22 CHAIRMAN ALDERSON: Okay.

23 Yes, Mr. Costello?

24 MEMBER COSTELLO: This is for Dan.

25 I mean, I know that you're here now, you

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1 just came from Region I; can you confirm that, for the  
2 most part, the violations that the NRC's been finding  
3 for the last couple of years, I think have largely been  
4 administrative in contact nature?

5 MR. COLLINS: Yes, so Frank, anecdotally,  
6 what I would say is at least Region I's experience is  
7 that the vast majority of the violations we saw were  
8 things where licensees assumed that the new Part 37 was  
9 only codifying the previous increased control orders  
10 and licensees didn't fully understand that there were  
11 additional requirements in Part 37 related to training  
12 and documentation of programs such as Frank described.

13 So, yes, largely administrative in nature.

14 CHAIRMAN ALDERSON: I'll ask for one other  
15 clarification -- yes?

16 MR. FULLER: Well, I'd just like to mention  
17 that we've been talking the last several minutes about  
18 NRC's regulations in 10 CFR Part 37.

19 But, I believe Dr. Ennis's question had  
20 something to do with something totally unrelated, which  
21 is some recent initiatives and actions and meetings and  
22 so forth by other federal agencies that have to do with  
23 security of sources that might affect the medical  
24 community.

25 So, I would just like to point that out as

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1 an observation so that we didn't lose track of that  
2 question.

3 CHAIRMAN ALDERSON: That's good, thank  
4 you.

5 That was Mike Fuller of the NRC.

6 Would someone like to give an example for  
7 our audience of one or two quotes of high activity,  
8 radioactivity sources that might be affected by this  
9 particular security regulation?

10 MEMBER ENNIS: So, the number one is cesium  
11 blood irradiators. So, cesium blood irradiators are  
12 the most cost-effective way to sterile blood supply, but  
13 they're a high activity sources that are considered by  
14 some to have some risk associated with that.

15 CHAIRMAN ALDERSON: Yes, that's good.

16 MEMBER ENNIS: Some of the talk that would  
17 be even to go to the point of banning that. There are  
18 alternative technologies that are more expensive. So,  
19 that would be one example.

20 CHAIRMAN ALDERSON: Good.

21 MEMBER ENNIS: Radioactive material uses  
22 for a Gamma Knife, radioactive material used for high  
23 dose rate brachytherapy are all among the isotopes that  
24 are included in the category being discussed.

25 And, again, regulation proposals that I've

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1 heard include outright banning, include increasing the  
2 security requirements that would be excessively --  
3 well, extremely expensive and might make institutions  
4 decide they couldn't afford to offer those services to  
5 have those types of equipment anymore or requirements  
6 of insurance policies, less something happen to your --  
7 and that you would held accountable to a hospital that  
8 might make the hospital decide that that cost was too  
9 much to bear.

10 CHAIRMAN ALDERSON: Okay.

11 Dr. Langhorst?

12 MEMBER LANGHORST: Because I missed the  
13 last meeting of ACMUI, I sat and watched the webcast of  
14 that meeting and there was a presentation on that exact  
15 topic. I'll point you back to that presentation where  
16 groups are -- and NRC is part of that effort to look at  
17 having government licensees like I guess VA hospitals  
18 and so on look at how they can replace those types of  
19 high level sources.

20 So, I'd just point you back to the last  
21 meeting where that was discussed.

22 CHAIRMAN ALDERSON: So, we have one of the  
23 members of the public who's in the audience here who  
24 would like to speak at this time.

25 Please identify yourself.

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1 MS. FAIROBENT: Thank you, Dr. Alderson.

2 Lynne Fairobent with the American  
3 Association of Physicists in Medicine.

4 And, to perhaps answer your question  
5 directly, there are a number of initiatives going on to  
6 look at this. There is currently a draft report being  
7 coordinated through the Department of Homeland Security  
8 and the National Nuclear Security Administration that  
9 has many participants on it.

10 The first chapter is going to address  
11 cesium chloride irradiators, not only in medical use but  
12 industrial use.

13 That group has been meeting for well over  
14 a year. The draft report, hopefully, will be prepared  
15 by the end of this calendar year. It has been delayed.

16 Secondly, Senator Carper has an amendment  
17 to the Energy Water Appropriations Bill that is very  
18 similar to the bill that was introduced last year by  
19 Senator Feinstein which the community was able to not  
20 have go forward, which directed NRC to prepare a report  
21 later that simply addressed the progress made with  
22 living under Part 37.

23 The language from Senator Carper's bill is  
24 very similar. It -- right now, we do not believe it's  
25 going to move. We are watching it very closely.

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1 In fact, I have had meetings within the last  
2 three weeks with Senate Energy Committee staff and House  
3 Energy and Water Committee staff. There is a  
4 consortium of groups that are paying very close  
5 attention to this.

6 Some of the language that is a little  
7 troubling in Senator Carper's amendment, if it goes  
8 through, rather than saying Category I and II sources  
9 as defined consistent with the International Atomic  
10 Energy Agency's definitions leaves it to NRC to define  
11 what is Category I and Category II.

12 And, currently, for medical use, the only  
13 Category I and II sources are Gamma Knife, ViewRay and  
14 blood irradiators. HDR brachytherapy is not under  
15 Category II if your license condition is 20 curies or  
16 less.

17 And, I believe almost all licenses were  
18 amended to keep brachytherapy under the 22 curie limit  
19 which triggers it to Category II.

20 So, yes, there is a lot of movement. There  
21 remains extensive discussions in various places on The  
22 Hill in various committees with both individual  
23 representatives and Senate offices as well as  
24 committees of jurisdiction.

25 CHAIRMAN ALDERSON: Thank you for your

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1 comment, Ms. Fairobent.

2 Are there other comments from members of  
3 the ACMUI or here in the audience today?

4 I don't know if we have anyone listening  
5 online. Is there anyone listening online that would  
6 like to discuss, make a comment on this item?

7 Hearing none, I believe that we have no  
8 further comments at this.

9 Dr. Ennis, anything final to say?

10 MEMBER ENNIS: Only to ask whether we think  
11 it's appropriate for us to weigh in on this and evaluate  
12 this at this time or not? And, maybe whether the NRC  
13 feels that that would be helpful or useful or not?

14 CHAIRMAN ALDERSON: Right, so, let's  
15 direct that question to Mr. Bollock and Mr. Collins.

16 The question is, is this an important issue  
17 that you believe that the ACMUI should look into and  
18 render some advice regarding?

19 MR. COLLINS: I think at this point I would  
20 echo the thoughts that Dr. Langhorst offered earlier  
21 that, if you have specific impacts that you're aware of  
22 on the medical community of the security regulations,  
23 we certainly want to hear from that.

24 So, but, I don't know that this necessarily  
25 would require you to, you know, start some separate

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1 effort on that.

2 CHAIRMAN ALDERSON: All right.

3 Any other questions or comments on this  
4 issue?

5 Dr. Langhorst?

6 MEMBER LANGHORST: I don't have any.

7 CHAIRMAN ALDERSON: Oh, on another issue,  
8 Dr. Langhorst?

9 MEMBER LANGHORST: If we're ready to move  
10 on.

11 CHAIRMAN ALDERSON: I think we are ready to  
12 move on.

13 MEMBER LANGHORST: Okay.

14 I just noticed that there's no update of  
15 where we are on new Part 35. So, I just wondered --

16 CHAIRMAN ALDERSON: Sophie, would you  
17 comment on that, please?

18 MS. HOLIDAY: Yes.

19 As I stated during old business -- this is  
20 Sophie Holiday -- staff is currently working on  
21 reviewing and evaluating the comments received from the  
22 Committee and the Organization of Agreement States.

23 So, at this time, that's all I can really  
24 say. They're working very diligently to address all  
25 comments received.

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1                   So, when we're able, if something has  
2                   changed, we will inform the Committee.

3                   CHAIRMAN ALDERSON: Thanks very much.

4                   MEMBER LANGHORST: Thank you.

5                   CHAIRMAN ALDERSON: Any other questions or  
6                   comments from people here at the meeting?

7                   Hearing none, we'll move on to the next part  
8                   of this session which is Medical Related Events. And,  
9                   Dr. Howe will present the latest update on Medical  
10                  Related Events.

11                  DR. HOWE: Thank you, Dr. Alderson.

12                  This is probably one of the most important  
13                  presentations you get for the year in that it is a review  
14                  of medical events that have happened over fiscal year  
15                  2015.

16                  So this gets to -- you get a glimpse of how  
17                  licensees are doing in treating patients.

18                  First, to put things into perspective, we  
19                  don't have a lot of diagnostic medical events because  
20                  of the thresholds on dose.

21                  And, each year, there are about 150,000  
22                  therapeutic procedures.

23                  Each year, I present you with the medical  
24                  events that happened in the last fiscal year, so fiscal  
25                  year 2015 and I give you a perspective of what happened

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1 in the previous year.

2 As you can see, there are a few more medical  
3 events in 2015. One thing that you should keep in mind  
4 is that 57 medical events is not a large number.

5 We are talking about -- we've got three  
6 diagnostic medical events. The diagnostic medical  
7 events are probably out of millions of diagnostic  
8 procedures.

9 The others are therapeutic and there are  
10 the denominator -- the cumulative denominator is  
11 probably a couple hundred thousand for that.

12 So, these are not large numbers.

13 The increases happened in diagnostic.  
14 They happened in therapeutic, unsealed material,  
15 happened in manual brachytherapy, also in the HDR Gamma  
16 Knife arena and, we actually had a few less emerging  
17 technology.

18 So, let's look at the diagnostic. I did  
19 this by modality, so it's a 35.200, imaging and  
20 localization.

21 We had three medical events. We had two  
22 technetium medical events. In both cases, the  
23 multi-dose vial was injected into the patient instead  
24 of the procedure that they were supposed to receive.

25 In some cases, it is because they confused

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1 the multi-dose vial with the dose they were supposed to  
2 give. One suggestion was to use color coding. We  
3 don't encourage color coding because you put the wrong  
4 color on and you think you're safe and you're not.

5 And, the other is they just reach for the  
6 wrong thing and they get the multi-dose vial.

7 And, in each case, this is about the only  
8 time you're going to get over 5 rads whole body for  
9 diagnostic.

10 The next diagnostic one was sodium  
11 iodine-123. In this case, they were supposed to give  
12 300 microcuries. They gave 3.69 millicuries and the  
13 thyroid was exposed to over 50 rad.

14 The physician asked for the correct dosage,  
15 but because they were going to scheduling this patient  
16 during a therapy time, the technologist ordered the  
17 wrong dosage.

18 They contributed it to be part of the  
19 scheduling and that they would normally have associated  
20 the numbers with diagnostic, but they didn't pick up on  
21 it because they were in therapy time slots.

22 So, they're going to go back and make sure  
23 all the diagnostic procedures are done in the diagnostic  
24 time slots.

25 Moving on to the therapeutic unsealed

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1 material, we have eight medical events. We had one with  
2 I-124, we had six with I-123 and we had one with  
3 radium-223.

4 In the I-124 was a pediatric case. There  
5 was a leak at the intravenous connector. It wasn't  
6 visible because there was a lot of gauze over that area  
7 and so they didn't know that they had a leak until they  
8 had delivered only a small -- about half of the I-124  
9 that they had expected to administer.

10 In I-131, I've got six medical events. In  
11 the first case, the patient had a low glomerular  
12 filtration rate score. And, the first physician  
13 ordered 509 millicuries. The second physician looked  
14 at the low score and said, I think this patient is better  
15 suited for a lesser amount of activity.

16 And so, both physicians ordered the  
17 material. So, the first physician ordered the 50  
18 millicuries, the second physician ordered the 35  
19 millicuries.

20 When it came time to give the  
21 administration, they picked up the wrong syringe and  
22 they gave the 50 when they were supposed to give the 35.

23 We had an administration of 30 millicuries  
24 instead of 3 millicuries. In that case, the written  
25 directive was incorrect. The written directive was

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1 written for 3 millicuries but the intended dose was  
2 always 30 millicuries.

3 And so, no one paid attention to the written  
4 directive. And so, now there's going to be, for a  
5 corrective action, the authorized user is supposed to  
6 complete the authorization section before  
7 administration.

8 I'm not sure what that means because a  
9 written directive always has to be dated and signed by  
10 the authorized user before administration. Okay?

11 Then we gave 1.57 millicuries instead of 2  
12 millicuries. In this case, they measured it. It was  
13 less than 20 percent, but they really weren't paying  
14 attention to the fact it was less than 20 percent and  
15 that would trigger a medical event.

16 So, from now on, the corrective action is  
17 to do two independent measurements and review the dose  
18 to make sure it's within 20 percent.

19 They delivered 142 millicuries instead of  
20 30. It was the wrong patient. They misidentified the  
21 patient.

22 They administered 75 millicuries instead  
23 of 150 millicuries. And, this one, you can almost guess  
24 the reason. The dose came in two capsules, one capsule  
25 was given, the other capsule staying in the container.

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1                   And, each time I talk about an  
2 administration, this is a different licensee medical  
3 event.

4                   The final one for the therapy is the  
5 radium-223. In this case, they delivered two dosages.  
6 But, the written directive was for only one dosage.

7                   But, instead of reading the prescribed  
8 dose, they injected two dosages instead of the one. So,  
9 they gave essentially about 100 percent more radium-223  
10 than they were supposed to.

11                  So, corrective action, they're going to  
12 have technologists verify the patient information and  
13 the prescribed dosage.

14                  Moving on to manual brachytherapy, it's not  
15 very -- we don't have manual brachytherapy generally in  
16 places outside of the prostate, but we did end up with  
17 a tunnel one this time.

18                  In this case, they checked the patient and  
19 two and a half hours after the linens were changed, the  
20 oncologist came in and determined that one of the  
21 strands that was going through the nose was missing and  
22 they did a survey and found out the strand was in the  
23 linen.

24                  They retrieved the stand, they put the  
25 strand back in. The patient received the dose they were

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1 supposed to receive through the nose.

2           However, there could have been an exposure  
3 to the skin and they did a calculation and determined  
4 that this patient -- because it was in the bed linens,  
5 had received up to 51 rem to the skin and reported it  
6 as a medical event for the wrong treatment site.

7           Prostate patient, we've got eight  
8 different locations. We have one location with two  
9 patients. So, we have a total of nine patients.

10           And, in the first one, there were two  
11 patients with palladium-103 implants. The medical  
12 events were identified by the regulator.

13           They identified irregularities with one of  
14 the authorized user's practices and they looked at the  
15 procedures that he had done and identified two medical  
16 events where one patient received 37 percent and the  
17 other received 66 percent of the prescribed dose.

18           The next licensee was also identified  
19 during inspection. And, in this case, the dose was 73  
20 percent of what was prescribed. There was not any  
21 additional information on this particular case.

22           We have a partial dose was intended, but the  
23 full dose was given. It was a human error. They didn't  
24 confirm the documentation of the implanted dose and so  
25 they thought it was -- it was supposed to be a partial

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1 dose with one accelerator boost and, instead, they gave  
2 a full dose.

3 They delivered a different from what was  
4 ordered.

5 In the first case, it says they were  
6 supposed to administer 18,000 rads, instead, they gave  
7 14,000 rads. And, they ordered an air kerma but it was  
8 not prescribe in air kerma.

9 In the second case, they didn't give you why  
10 it was different, but they ordered -- there was a  
11 difference between what was ordered and what was  
12 delivered.

13 The difference was about 22 percent, so it  
14 sounds like it's probably an air kerma versus millicurie  
15 event.

16 Wrong site, so for at least two of the  
17 cases, the wrong site was attributed to poor or  
18 uncalibrated ultrasound devices.

19 In the first case, 30 percent of the seeds  
20 were planted outside of the treatment site.

21 In the second case, all of the seeds were  
22 implanted into the penile bulb and the dose to the  
23 unintended area was 10,000 rads.

24 Another wrong site, 20 of the seeds, 29  
25 percent of the total prescribed, were implanted into the

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1 bladder.

2 In this case, the median lobe of the  
3 prostate protruded into the bladder and so 20 of the  
4 seeds were put into the bladder.

5 So, their corrective action was procedure  
6 modification and additional training of personnel.

7 Moving on to the HRD Teletherapy Gamma  
8 Knife modalities, the 35.600 events, there were a total  
9 of 17 for the HRDs, 16. That's not expected, most of  
10 them are going to be in HDR.

11 The first location was not specified.  
12 There was one medical event for a nose, there were 11  
13 for gynecological procedures, three for breasts and  
14 then we had one Gamma Knife medical event that had eight  
15 patients involved.

16 So, they are broken down into what was the  
17 basic cause, wrong patient, one error, bad treatment  
18 plan, three medical events, wrong site - seven, source  
19 fell out - one, physicists error - two, and equipment  
20 problems and failures - two.

21 So, the one that wasn't specified, the  
22 patient received a less dose than prescribed. But the  
23 reason it's a medical event is because they treated the  
24 patient with someone's treatment plan.

25 So, they're not retraining people and

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1 requiring them to verify the patient's identity.

2 In the nose, they wrote the written  
3 directive. They gave it to a junior physicist to  
4 develop the treatment plan. He didn't develop the  
5 treatment plan correctly and so they administered over  
6 71 percent more dose than was in the written directive.

7 So, the other interesting part of this is  
8 the authorized medical physicist and the authorized  
9 user, neither one of them identified this before the  
10 treatment was given. So, even though it was reviewed  
11 by both.

12 Now, we move into the gynecological ones.  
13 I have 11 of these. The largest number is seven and for  
14 wrong site, and many of them in the wrong site are going  
15 to have radiation induced damage to skin and other body  
16 parts.

17 So, they were trying to administer to the  
18 vagina and the outer vaginal mucosa and the upper thigh  
19 received the entire dose.

20 The applicator was improperly placed and  
21 the sources were inferior to the treatment site and  
22 exterior to the treatment site and they had vagina  
23 burning.

24 The next wrong site, another case where the  
25 sources were inferior to the treatment site and exterior

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1 to the opening of the vagina and they ended up with  
2 radiation burns.

3 And, the contributor that they attributed  
4 to it was that they had poor film quality because the  
5 patient was obese and they thought they had it in the  
6 proper location but they were off considerably.

7 We had two skin radiation burns on both  
8 upper thighs. The skin dose was 4,000 rad, a depth of  
9 two-tenths of a centimeter. And, there was also 33  
10 percent less dose to the intended site than prescribed.

11 And, in this case, they attributed it to  
12 either the assembly of the vaginal cylinder application  
13 was done incorrectly or it became loose while in the  
14 patient.

15 Another wrong site, fraction dose was  
16 delivered to the wrong site.

17 In this case, there were several physicians  
18 involved. The first physician gave the first fraction,  
19 the second physician gave the second fraction.

20 Even though it said the first fraction was  
21 given correctly, the second physician had difficulty  
22 inserting the applicator due to edema and tenderness and  
23 went to a smaller applicator.

24 And then they reviewed the post-treatment  
25 images from the week before and found that the source

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1 was at least seven centimeters short of the intended  
2 position.

3 Another wrong site, in this case, the  
4 second fraction, they had a close-ended catheter but it  
5 wasn't fully seated. They were about 15 centimeters  
6 proximal to the prescribed treatment site.

7 Now, their corrective action is to verify  
8 the position of the cylinder and the length of the  
9 transfer tube catheter.

10 Another wrong site, this was the tissue  
11 three centimeters inferior to the treatment site  
12 received 400 rad.

13 In the post-treatment imaging, they  
14 realized that the cylinder applicator had become loose  
15 from the holder and it shifted three centimeters.

16 They are now going to verify that the  
17 applicator is immobilized and that the clamp is where  
18 it should be.

19 Another wrong treatment, in this case, the  
20 treatment site received only 20 percent of the intended  
21 dose. They inserted the vaginal cylinder three  
22 centimeters distal to the vaginal cuff.

23 They all -- their corrective action is to  
24 always use four segments. They didn't indicate whether  
25 they used fewer or what happened. But, now they're

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1 going to use four. And, they're going to pay close  
2 attention to patient movement. And, they're going to  
3 do additional imaging.

4 Source fell out, the physician enters the  
5 room and finds the cylinder on the treatment table. So,  
6 there was a failure to secure the cylinder in place and  
7 the inability to view the cylinder from the camera. So,  
8 they weren't able to identify it earlier.

9 So, they administered 1,200 rad instead of  
10 1,800 rad.

11 Physicist error, this is -- I could have  
12 also put this in wrong patient. The physicist put up  
13 the correct treatment plan and there was a delay and so  
14 he pulled up another treatment plan and was looking at  
15 it.

16 So, they inadvertently selected and  
17 delivered an incorrect treatment plan on the third  
18 fraction.

19 So, they're now going to verify the  
20 treatment plan.

21 This -- I'm sorry -- the last one wasn't  
22 where the physicist brought up the wrong patient, this  
23 is the one with the wrong patient.

24 The last one, they just had multiple  
25 treatment plans, they brought up the wrong treatment

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1 plan.

2 In this one, the physicist had the right  
3 treatment plan up, there was a delay. He decided to  
4 pull up another one and review it and then the patient  
5 is brought in. And so, the physicist repeats the  
6 parameters from memory but not by looking at the  
7 treatment plan.

8 So, they gave the wrong treatment to the  
9 wrong patient.

10 Equipment problems, I didn't get a lot of  
11 information on this one, but two AMPs felt they had to  
12 stop the procedure. So, they engaged the emergency  
13 stop. They terminated the treatment. They retracted  
14 the source in the shielded position.

15 But, when they went to restart, they found  
16 that the timer wasn't counting down. The timer was  
17 increasing.

18 So, at that point, they decided that they  
19 should just terminate the treatment. There was a  
20 problem with the device.

21 They called in the manufacturer. I don't  
22 believe the manufacturer was able to replicate their  
23 problem.

24 Now, we've got three breast treatments, all  
25 of them are with the SAVI device.

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1           You've got 3,000 rads to an unintended  
2           site. They didn't realize they hadn't given the right  
3           procedure until the patient came with pain and redness  
4           at the incision site.

5           They had to remove 21 cubic centimeters of  
6           tissue. They had to suspend the treatment while they  
7           investigated the problem areas. And, they've decided  
8           to use a second physicist for an independent evaluation  
9           of the treatment plan.

10          Many times with a SAVI device, it's because  
11          they confuse the tip end from the connector end and they  
12          believe they're giving the dose within the SAVI, but  
13          they're actually giving it outside into the skin.

14          Another SAVI medical event, and this case,  
15          they gave the full 13,000 rads to the entrance site.  
16          And, this was definitely one in which they delivered it  
17          to the connector end and not to the tip end.

18          So, the dwell positions within the  
19          applicator were not accurately reconstructed in the  
20          treatment planning computer. And, they had difficult  
21          identifying the starting position and the multiple  
22          catheter HDR treatment within the system.

23          And, the final one with the SAVI, the  
24          fractional event occurred while they were sending out  
25          the check cable. So, they gave very little of the dose.

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1                   And, they determined that the check cable  
2                   was frayed about a half a centimeter behind the weld  
3                   junction and it ends up this facility had three other  
4                   cables, or a total of three cables, with similar  
5                   fraying.

6                   In talking to the inspector that went out  
7                   on this inspection and looking at the images, the  
8                   licensee believed they had to do a quality control test  
9                   or quality assurance test with a very sharp bend in the  
10                  guide wire.

11                  And so, they did essentially a 180-degree  
12                  bend in the wire and that was not what the manufacturer  
13                  is asking for. And, that put too much stress on the --  
14                  they believe they put too much stress on the cable and  
15                  was the primary reason for the fraying.

16                  And, we haven't seen this issue with any  
17                  other licensees.

18                  Moving to another modality, this is the  
19                  Gamma Knife. And, this is one of the earlier Gamma  
20                  Knives. This is not the Perfexion, this is one with the  
21                  helmet and with the collimator plugs.

22                  And, in this case, page three of the written  
23                  directive said where the plugs should be, but it was  
24                  absent from -- during the equipment preparation.

25                  And so, they didn't put plugs in where they

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1       should have put plugs in.       Instead, they had  
2       collimators.   So, they received -- so they gave 71 rem  
3       to the wrong site.

4               And, from now on, they're going to move the  
5       plug use to the first page so that they don't have a  
6       problem with having it misplaced and not finding it.

7               So, now we move into 35.1000 which are our  
8       other medical uses or emerging technologies.   We had 20  
9       medical events involving 31 patients.

10              The Perfexion had one medical event  
11       involving eight patients and then we had I-125 seed  
12       localization,   one medical event,   Yttrium-90  
13       microspheres, we had 18 events, TheraSpheres had eight  
14       with 12 patients, SIR-Spheres had ten with one patient  
15       each.

16              So, for the Perfexion, the manufacturer  
17       came in and did some servicing.   And, when they did the  
18       servicing, they did a workaround or a shortcut or  
19       something so that when they aligned the table, it was  
20       misaligned.

21              And, they went back later and determined  
22       that this table was misaligned for eight patient  
23       treatments.

24              And so, Elekta, the manufacturer, is still  
25       evaluating the service issue.   And, these eight

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1 administrations may also be abnormal occurrences.

2 For the radioactive seed localization,  
3 this is a diagnostic procedure, but using a seed that  
4 could be a therapeutic seed.

5 So, in this case, due to illness, the  
6 patient wasn't able to return in the five days and didn't  
7 have the seeds removed until 26 days after implantation.

8 And so, the patient received 83 rads  
9 instead of the 18 rads.

10 And, the programmatic review identified  
11 that there were other patients that also did not come  
12 back within the five days and they used the term "much  
13 later than five days," but that those patients did not  
14 receive a medical event because of the dose criteria.

15 For the Yttrium-90 microspheres, this is  
16 generally out largest group of medical events, so I'm  
17 going to go through the TheraSpheres first and then when  
18 I finish the TheraSpheres, I'll go into the SIR-Spheres.

19 We've got multiple patients, five patients  
20 in one case, we've got the wrong site. We've got low  
21 flow rate in arteries. We have kinks. We have  
22 radiation detector for two cases and remained in the  
23 vial of the tubing for two.

24 So, there were five patients that were  
25 administered less than 80 percent of the prescribed

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1 dose. And, they discovered this after the fact when  
2 they did imaging of the tubes and they discovered the  
3 excess dose was found in the hubs of the catheters.  
4 And, all patients were treated with small catheters.

5 The next medical event was that they  
6 administered it to the wrong lobe. They intended it to  
7 go into the left lobe, they delivered it to the right  
8 lobe.

9 So, they injected the microspheres into the  
10 wrong hepatic artery.

11 Next medical event, they administered less  
12 than they had intended and they attributed it to the size  
13 and physical condition of the patient's arteries. It  
14 caused low flow and because of the flow, they couldn't  
15 get all of the microspheres in.

16 The next administration was less than they  
17 had expected because they had kinking that was noted at  
18 the junction of a rigid hub and so the microspheres  
19 didn't go into the patient.

20 The next administration is about 62 percent  
21 of what was intended. After they completed the  
22 procedure, they found out that their Rados detector  
23 erroneously indicated zero mR per hour which would  
24 indicate that the microspheres were all into the patient  
25 and they found out later that the Rados detector was

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1       erroneous and that most of the microspheres were left  
2       in the vial.

3               The next case was another problem area with  
4       a Rados detector that they -- a different licensee said  
5       contributed to the event where the activity was  
6       concentrated in the plunger attached to the vial.

7               Next medical event, the microspheres were  
8       trapped in the vial for some unknown reason.

9               The next medical event, most of the dose  
10       remained in the D tubing and with lesser amounts in the  
11       micro-catheter and in the vial.

12              So, these are cases where the microspheres  
13       just don't make into the patient.

14              And, let's move to SIR-Spheres, we have the  
15       wrong site, four of them in the wrong site. We have an  
16       error in calculation. We have two delivery system  
17       issues. We have one operator error and crimping or  
18       occluded catheters, the tube.

19              Okay, the first one was, this was a  
20       facility's first yttrium-90 microsphere patient and,  
21       instead of putting the microspheres into the hepatic  
22       artery, they put them into the renal artery. And, they  
23       gave a dose of over a thousand Gray to the kidney.

24              And so, they have decided that they are  
25       going to make more formal written check lists to

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1 complete prior to the administration. They're going to  
2 have additional mapping images and make sure that the  
3 catheter is where it's supposed to be. And then, a  
4 second physician will review things.

5 Next wrong site, the microspheres went --  
6 some microspheres went into the stomach. In this case,  
7 they put in the post-treatment scans, they indicated the  
8 microspheres were in the stomach. They calculated that  
9 about 54 rem was delivered to the stomach area.

10 Small bowel, in this case, the physician  
11 felt that the microspheres were not going in the right  
12 place so he stopped the treatment.

13 And then, they imaged the patient and they  
14 discovered that 3,000 rads had gone to the small bowel.

15 Wrong liver site, so in this case, they  
16 administered more radiation than they had expected to  
17 the posterior portion of the right lobe.

18 What they did was they gave an  
19 administration intended for the anterior portion of the  
20 right lobe of the liver. They had a color coding  
21 procedure in place. They didn't have their color  
22 coding correctly.

23 So, they've decided to discontinue the  
24 color coding and only have one dosage of microspheres  
25 at a time in the interventional radiology suite.

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1                   So, in this case, they had two different  
2                   administrations that were supposed to be given, it's one  
3                   after the other and they gave the wrong one first.

4                   Dose calculation error, in this case, the  
5                   physician -- there was shunting and so the physician  
6                   prescribed an activity based on 20 percent of the lung  
7                   shunting.

8                   But, there was also a pre-reduction and a  
9                   post-reduction activity value on the written directive.  
10                  And, when they calculated the activity that they wanted  
11                  to give, they used the wrong number. They used the  
12                  pre-reduction number to calculate what they were going  
13                  to give and they should have used the post-reduction  
14                  number. So, they gave too much activity.

15                  We have less administration here. In this  
16                  case, they had air bubbles that were collecting in the  
17                  tube. And so, they decided that they needed to stop and  
18                  see what was going on with the air bubbles.

19                  And, they discovered that the kit was set  
20                  up incorrectly, that they air was entering the device  
21                  through an uncovered needle.

22                  We don't get a lot of medical events from  
23                  setting up the -- recognizing that the device is set up  
24                  incorrectly.

25                  Then, we have another medical event which

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1 is not quite -- a little more than half was administered  
2 and the device came apart during the procedure and the  
3 microspheres were lost in the apparatus.

4 We don't have too many medical events for  
5 devices coming apart during a procedure.

6 So, those two cases are device-related  
7 issues or poor training on the facility for putting the  
8 devices together correctly.

9 We had 42 percent delivered during the set  
10 up. The patient's catheter was disconnected to flush  
11 out air bubbles. We had another one with air bubbles.

12 But, in this case, they forgot to reconnect  
13 the catheter and administered the microspheres without  
14 reconnecting the catheter and they didn't go into the  
15 patient.

16 Then they had another one for 78 percent.  
17 They had crimping in the tube near the three-way  
18 stopcock and the manufacturer determined the cause was  
19 abnormally high concentrations of microspheres during  
20 administration.

21 We have 52 percent of the dose delivered.  
22 The physician concluded that the catheter was clogged  
23 when injecting the microspheres and because he was  
24 meeting considerable resistance.

25 So, they lost some sources when the

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1 catheter was disconnected. And then, the manufacturer  
2 looked at it and decided that there was blood in the  
3 catheter and the blood in the catheter caused the  
4 microspheres to clog and that it wasn't sufficiently  
5 flushed prior to infusion.

6 And those are all the medical events that  
7 we saw in FY 2015.

8 I will tell you that there were probably  
9 about 78 medical events that were tagged in NMED as  
10 medical events, but in reviewing them, they were really  
11 on 57 that met NRC's criteria.

12 CHAIRMAN ALDERSON: Well, thanks, Dr. Howe  
13 for that thorough report.

14 I have a couple of comments and then we'll  
15 ask the ACMUI if they have questions or comments.

16 Now, I'm always going to assure all my  
17 colleagues are always sad to hear of these individual  
18 medical events and the patients who incurred them.

19 When we look at these reports, we would try  
20 to look for some trending, though, that would give us  
21 some idea of how useful interventions could be  
22 recommended or made.

23 So, I have just two comments the trending.

24 Given the low number of these events, as Dr.  
25 Howe stressed, compared to the overall number of patient

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1 encounters during a year, when we go back to the table  
2 that was on slide three, these are very, very small  
3 numbers of events. And one would, you know, question  
4 the statistical nature of these events from year to  
5 year.

6 The question I have is that, we have here  
7 two years and, of course, we've doing -- you, the NRC,  
8 has been doing this for a number of years. So, in fact,  
9 you have data already in your warehouse of FY '13, '12,  
10 '11, other years.

11 I wonder if it would be useful to the  
12 Committee, instead of seeing two years, to actually see,  
13 let's say, five? Because you already have the data,  
14 it's not a lot of work.

15 And so, if under 35.400 here, it says five  
16 and then nine or ten, that really doesn't worry us, but  
17 if it were one, one, one, five, nine, we might say, my  
18 goodness, there might be a trend there and we'd want to  
19 focus on that.

20 So, I just make the general suggestion that  
21 perhaps since the data are available that we simply  
22 report five years instead of two.

23 Do I have comments from the Committee on  
24 that?

25 Dr. Zanzonico?

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1 VICE CHAIRMAN ZANZONICO: Well, I think  
2 the problem, and this comment has been made before,  
3 without knowing the denominator, an impaired trend  
4 could be misleading.

5 I think the use of microspheres, for  
6 example, continues to increase. So, you would expect  
7 a proportional increase in medical events.

8 So, I'm not sure that multi-year trending  
9 without knowing the denominator would be helpful. And,  
10 in fact, it might be misleading.

11 CHAIRMAN ALDERSON: And so, my response to  
12 that comment, I understand that concern. Is that  
13 without multi-year trending, you won't see it anyway.

14 And so, if you do multi-year trending and  
15 you see something, then you can ask that question and  
16 then you can find the answer is that there are a lot more  
17 procedures and so we don't need to worry.

18 But, if you don't do multi-year trending,  
19 you'll never know it even it does happen.

20 That would be my response to that question.

21 DR. HOWE: And, I think for the Yttrium-90  
22 microspheres, we always have many more medical events  
23 from the Yttrium-90 microspheres because of delivery  
24 problems and it's probably an order of magnitude higher  
25 in medical events than any other modalities that we're

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1 looking at.

2 CHAIRMAN ALDERSON: Are there any other --  
3 yes, Mr. Costello?

4 MEMBER COSTELLO: Yes, I agree. I think  
5 having five years would be good. And, I'd hope that new  
6 modalities like 35.1000, that what we'd see would be a  
7 learning curve, that there might be some in the  
8 beginning of it, might be more then as time goes by even  
9 with increasing numbers of treatments, I would hope that  
10 the percentage of that would go down.

11 CHAIRMAN ALDERSON: Other comments on that  
12 suggestion?

13 Yes, Dr. Palestro?

14 MEMBER PALESTRO: Yes, I think your  
15 suggestion to look at trending is certainly very useful  
16 and I don't want to complicate things with un-founding  
17 issues, but I think just looking at the numbers, or I  
18 should say, rather than just looking at the numbers,  
19 looking at trends that are increasing or decreasing.

20 I'd also like to look at the individual  
21 events themselves. For example, when you're talking  
22 about TheraSpheres and so forth, you have things like  
23 the wrong site, low flow reads and so forth to see are  
24 there particular subgroups in which these events are  
25 occurring.

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1 CHAIRMAN ALDERSON: Yes, so, that's the --

2 DR. HOWE: So, in other words, what you're  
3 looking for is something similar to this slide where  
4 I've given a reason?

5 MEMBER PALESTRO: Yes, yes.

6 CHAIRMAN ALDERSON: Yes. Okay.

7 DR. HOWE: In addition to the five?

8 CHAIRMAN ALDERSON: Yes, that's a good  
9 comment. That's an excellent comment, I accept that as  
10 an amendment to the suggestion.

11 Are there other comments from the ACMUI?

12 Yes, Mr. Ouhib?

13 MR. OUHIB: Yes, Zoubir Ouhib.

14 I think what I would be looking for is that  
15 looking at all these errors, what is the common factor.  
16 And looking at that, I see like quite few that really  
17 are training-related type of things.

18 You know, a device that's disconnected and  
19 you're still injecting, perhaps even the use of the  
20 detector and so on and so forth.

21 So, I think there's a lot that's sort merge  
22 toward that component.

23 CHAIRMAN ALDERSON: Good.

24 Yes, Mr. Costello again?

25 MEMBER COSTELLO: And, these comments, Dr.

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1       Howe, I think are appropriate.

2               I think that the depth of investigation  
3       that the various regulatory agencies do varies a lot  
4       from event to event.

5               And to some, they do get closer to a root  
6       cause and some others, they just say, operator error.  
7       And, I think that it's hard to evaluate the cause of  
8       these things when I think the depth of the investigation  
9       varies so much from event to event.

10              I think if you'd look at the stuff that's  
11       in NMED, you'll see that, that some of those are some  
12       superficial review and some of them, it's a real in depth  
13       one.

14              CHAIRMAN ALDERSON:   Yes?   Dr. Langhorst  
15       and then Ms. Weil?

16              MEMBER LANGHORST:   Dr. Howe, I always  
17       appreciate your report on this because it really  
18       condenses things down and it really is, I know, a whole  
19       lot of work.

20              Mr. Costello mentioned one of my questions,  
21       so thank you, Frank, for bringing that up on the  
22       variation.  Because, it's about a little more than half  
23       are from Agreement States rather than NRC licensed  
24       states.  So, there's lots of variability between NRC  
25       inspections versus some Agreement States.  So, I know

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1       that's a variable.

2                   One suggestion I have for your acronyms for  
3       your fiscal year, would you always put down that it's  
4       October 1st through September 30th?   Because fiscal  
5       years are different for all sorts of different people.  
6       And, I think it'd just be easily put in there.

7                   But, the one question that I have is, I know  
8       there's been previous discussions about making NMED or  
9       some portion of NMED data a little more available to  
10      licensees as a whole.   Because that isn't necessarily  
11      available to all licensees.

12                  And, I just wonder if NRC is considering  
13      that more?

14                  DR. HOWE:   We've looked at that quite  
15      extensively and, for a number of reasons, NMED will not  
16      be available to the public.

17                  Doug?

18                  MR. BOLLOCK:   But, Donna-Beth's report and  
19      I believe Dr. Suh's report and the next meeting, those  
20      are now available on our public website.   So, these  
21      slides, if they're not already available, they will be  
22      shortly after this meeting.

23                  And, that's the plan to take these, you  
24      know, and they have been, if you look at the 200 pages  
25      of slides that are up on the presentation.   But now, we

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1 specifically pull these presentations out to make them  
2 easily available and easier to find for licensees,  
3 general public in regards to medical events.

4 DR. HOWE: And, they'll be on the medical  
5 tool kit.

6 MEMBER LANGHORST: Thank you very much. I  
7 think that'll be very helpful for licensees. It may not  
8 give them all the data that is at least available, but  
9 it certain is helpful.

10 And, I don't know if there's any way to tie  
11 things to event notifications because those are also on  
12 the web. But, at least that might be something else  
13 that could add to a licensee's knowledge.

14 So, again, that would be a lot of work and  
15 I appreciate that amount of work.

16 CHAIRMAN ALDERSON: Ms. Weil was next.

17 MEMBER WEIL: Thank you for this report, as  
18 always staying --

19 DR. HOWE: Can you turn your microphone on,  
20 please? You should get a green on it. There we go.

21 MEMBER WEIL: It would be useful to know,  
22 in all cases, what the corrective action was and the  
23 outcome for the patient.

24 I assume when you don't report it, it's  
25 because it has -- that information's not available to

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1       you.

2                   DR. HOWE: That's correct. Not everyone  
3       give a corrective action. Not everyone gives the  
4       effect on the patient.

5                   Many times, they'll write, there's no  
6       adverse effect expected for the patient. I only have  
7       a short amount of space on the slides, so I may not write  
8       that statement every time.

9                   But, I feel like the ones with the radiation  
10      burns and the major effects should be--.

11                  MEMBER WEIL: Does it cost the -- I mean,  
12      not money, but is there a cost to the licensee for not  
13      providing information about the corrective action? Do  
14      you go back, do they get dinged again for an incomplete  
15      report?

16                  DR. HOWE: We try to get as much  
17      information as we can. We have a contractor that runs  
18      the NMED program and he tries to get information and they  
19      try to go back to the Agreement States. But, sometimes  
20      you just can't get any more information.

21                  If it's an NRC licensee, it's fairly easy  
22      for us to go back to the Regions and ask for additional  
23      information and get it. But, it's a little more  
24      difficult on the Agreement States.

25                  MEMBER WEIL: It seems to me that there's

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1 an opportunity for, you know, evasion and obfuscation  
2 on the part of the licensee by not providing that  
3 information. And, that shouldn't go unpunished, if you  
4 will.

5 MEMBER COSTELLO: Can I make another  
6 comment?

7 CHAIRMAN ALDERSON: Yes, Mr. Costello  
8 would like to comment on that.

9 MEMBER COSTELLO: These reports really are  
10 provided by the regulator; the information, I think  
11 comes to the NRC from the States who get the information  
12 from the licensee.

13 So, it's not necessarily true that the  
14 licensees is withholding things. It comes out of the  
15 interaction between the regulator and the licensee, how  
16 much information I get.

17 So, maybe if the regulators pushed a little  
18 harder, we'd get more information. It's the licensee's  
19 fault necessarily that all the information's not there.  
20 Sometimes it is, but sometimes we, the regulator, could  
21 be more aggressive in getting that information.

22 MEMBER WEIL: One other comment, if I may?

23 It's important to note that many of these  
24 events are identified by the regulator during an  
25 inspection as opposed to being self-reported by the

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1       licensee.

2                       So, when we're looking at trending and the  
3       denominator, we can't really -- we shouldn't assume that  
4       this is the number of medical events that actually  
5       occur. This is just ones that surface.

6                       CHAIRMAN ALDERSON: Dr. Zanzonico had a  
7       comment to make.

8                       DR. HOWE: Let me just a quick comment.

9                       I report the information that was reported  
10       in the fiscal year because, if there was a medical event  
11       that happened three or four years that wasn't identified  
12       three or four years ago, if I just reported what happened  
13       in that year, that would be lost forever.

14                      But, I report what's reported in that so  
15       that we may have events in here that are a couple of  
16       years-old or a year-old or six months old.

17                      And, I do that to try to make sure we have  
18       captured everything that is available to us.

19                      CHAIRMAN ALDERSON: Dr. Zanzonico?

20                      VICE CHAIRMAN ZANZONICO: I have a comment  
21       and a question.

22                      The comment is, if you haven't seen these  
23       procedures firsthand, they are very complicated, very  
24       labor intensive and there's lots of opportunity for  
25       errors.

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1           And it's remarkable that if these -- this  
2           is microspheres I'm referring -- that if these numbers  
3           are anywhere near accurate, it certainly is under  
4           reporting because it's self-reporting, it's remarkably  
5           low for procedures of this complexity.

6           And, I know, at least at Memorial, the  
7           interventional radiologists are getting, what's the  
8           word, more adventurous and are doing more and more  
9           difficult cases by this procedure because they've had  
10          such results.

11          And, that, inevitably, I think, even in  
12          very skilled hands is going to lend itself to events that  
13          may or may not be construed as medical events.

14          But, that's just a comment.

15          But, my question is, it struck me that there  
16          were several microsphere events, the ones on slides 42,  
17          47 and 48, which, perhaps, were patient intervention.

18          And, I guess the question is, you know,  
19          unexpected or abnormal anatomy or complex anatomy that  
20          led to microspheres being deposited in the wrong  
21          location.

22          In other words, it wasn't clear that there  
23          was an identifiable user error in some of these.

24          DR. HOWE: I only remember one where it  
25          said that the vessels were giving a really hard push and

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1 so he stopped.

2 VICE CHAIRMAN ZANZONICO: Right.

3 DR. HOWE: The size or the physical  
4 condition of the patient's arteries caused the low flow  
5 condition. I don't remember another one being  
6 attributed --

7 VICE CHAIRMAN ZANZONICO: Well, I don't  
8 think truly, if any of them truly were over and not  
9 medical events.

10 But, I guess my question is, do you ever  
11 sense that with the new guidance that's being prepared,  
12 if that -- if any of these would or would no longer be  
13 considered medical events?

14 DR. HOWE: With the existing guidance, we  
15 had a provision in the existing guidance that, if you  
16 had arterial constriction or other things and low blood  
17 pressure and there were certain things you had, if you  
18 had those and you could document that on the final  
19 written directive, then it wouldn't be a medical event.

20 So, that's in the existing guidance. And,  
21 Dr. Tapp will talk to us more about the guidance that's  
22 being developed.

23 So, we do have one provision already and  
24 then the ACMUI has given a couple of other things to look  
25 at and that's coming out in this --

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1 CHAIRMAN ALDERSON: All right, so is there  
2 another comment? Did you have your hand up, Steve?

3 Mike Fuller has his hand up, also. So,  
4 Steve, you'll be first, Steve Mattmuller and then Mike  
5 Fuller.

6 MEMBER MATTMULLER: Steve Mattmuller.

7 Just to go back to the first two events  
8 regarding the bulk dose of technetium and it really  
9 struck me as being odd because that would entail that  
10 someone would have to take a bulk dose of vial of  
11 technetium and draw a dose from it and not assay it --

12 DR. HOWE: Absolutely.

13 MEMBER MATTMULLER: -- and then inject it.

14 And, so it struck me as being very odd.

15 And, actually, in the one report, it says  
16 it's a bulk syringe. And then, in the other one, it  
17 doesn't say vial, so I'm assuming that -- and it's always  
18 hard because it's always incomplete data or information  
19 in these report.

20 So, my assumption for that one is that  
21 they're both bulk doses and syringes which makes it a  
22 little bit, I don't know if it makes it worse for this  
23 situation, but a little bit easier to get mixed up.

24 And, that sticks out to me because I  
25 thought, gosh, that could happen at my place because we

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1 do prepare a large kit of Myoview.

2 And then, my initial thoughts was to put it  
3 in a vial and ship the vial to our sister hospital two  
4 miles away until I realized my packaging was approved  
5 only for a unit with syringe carrier and not in the  
6 multi-dose vial.

7 So, for some of you who are wondering what  
8 I'm going to do when I get off of this table, and I hope  
9 my administrator is not listening to me because this is  
10 a task I've put off for a few years. I need to do testing  
11 of my packaging for multi-dose vial because that's the  
12 preferred way of shipping it.

13 So, for those two, I think it's more of a  
14 syringe where it would be easier to mix up and,  
15 unfortunately, for those two, that's what happened.

16 A little worry you need for other reasons,  
17 but it's a very uncommon practice. So, surprised this  
18 has happened.

19 In regards to the event that happened at  
20 Sloan Kettering in New York, I wasn't sure if this was  
21 really a medical event.

22 DR. HOWE: Because I did not identify  
23 locations, you will have to give more of a description.

24 MEMBER MATTMULLER: Okay, sorry about  
25 that. So, it's --

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1 DR. HOWE: What modality are we talking  
2 about?

3 MEMBER MATTMULLER: We're talking about  
4 the I-124.

5 DR. HOWE: Oh, okay, so that's the  
6 pediatric case.

7 MEMBER MATTMULLER: Right. And, I-124 is  
8 a beta emitter and so, it's not a therapeutic  
9 radionuclide, it would be used for diagnostic imaging,  
10 so I'm not sure why it would need a written directive.

11 DR. HOWE: So, the --

12 VICE CHAIRMAN ZANZONICO: Could I -- I was  
13 involved in that.

14 MEMBER MATTMULLER: Yes, yes.

15 VICE CHAIRMAN ZANZONICO: None of it was my  
16 fault.

17 MEMBER MATTMULLER: So he says.

18 DR. HOWE: Of course.

19 VICE CHAIRMAN ZANZONICO: This was an  
20 investigational study for treatment of cerebellar  
21 pontine glioma which is a uniformly fatal childhood  
22 brain cancer.

23 And, in this study, the surgeon, under  
24 image guidance, inserts a catheter through the skull  
25 directly into the tumor in the cerebellum. And,

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1 because the I-124 was being delivered so locally and it  
2 is a beta emitter, it's a therapeutic dose.

3 So, this is --

4 MEMBER MATTMULLER: It's a positron  
5 emitter.

6 VICE CHAIRMAN ZANZONICO: Yes, it's --  
7 well, which is a beta.

8 MEMBER MATTMULLER: Yes.

9 VICE CHAIRMAN ZANZONICO: And so, you get  
10 the local dose. You get on the order of 1,500 rads per  
11 millicurie instilled to the tumor volume.

12 So, this is being used as a true  
13 theragnostic study.

14 MEMBER MATTMULLER: Theragnostic?

15 VICE CHAIRMAN ZANZONICO: You both image  
16 the therapy dose by PET to do the dosimetry but you also  
17 with the same administration delivering presumably a  
18 therapeutic dose as well.

19 MEMBER MATTMULLER: Okay.

20 VICE CHAIRMAN ZANZONICO: So, in a way,  
21 it's a new category. It's a true theranostic study.

22 CHAIRMAN ALDERSON: Thank you.

23 Mr. Fuller?

24 MR. FULLER: Yes, Mike Fuller.

25 Dr. Alderson, I know you had asked if maybe

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1 we could expand the period of time under which we are  
2 reporting to the perhaps five years. And, at the risk  
3 of having Donna-Beth get mad at me, I was going to  
4 suggest to perhaps think about, because it would take  
5 a lot of work for us for one year and then each year after  
6 that, I don't think it would be that much of a burden  
7 on us.

8 But, we have, as you've indicated, several  
9 years of data and, at least and to create maybe some  
10 curves over a longer period of time, so you can might  
11 see -- because then you could sort of tease from that  
12 long-term trends or longer year curves that you could  
13 observe and then still the shorter term, three to five  
14 to seven, what have you, that information would also be  
15 available.

16 So, I would just like to offer that, if you  
17 wanted more than five years, you know, don't hesitate  
18 to ask for that again.

19 The first year, it would take quite a bit  
20 of work and we'll find somebody to help Donna-Beth. But  
21 then, after that, it's really not going to be much of  
22 a burden on us to just kind of keep up with the long-term  
23 data and present that.

24 CHAIRMAN ALDERSON: Well, thank you.

25 So, we heard earlier that there may be many

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1 confounding factors if you look out over time and we made  
2 the suggestion that, if we found any trends or thought  
3 there were any trends, then we could ask about those  
4 confounding factors in those issues.

5 And so, if the Committee is willing to  
6 accept Mr. Fuller's volunteer motion, we could, in fact,  
7 look forward to learning over a period of time about a  
8 little longer spectrum of time regarding the medical  
9 events.

10 Would someone wish to make a motion to that  
11 effect?

12 VICE CHAIRMAN ZANZONICO: Sure.

13 MEMBER COSTELLO: Moved.

14 CHAIRMAN ALDERSON: So moved, says Pat and  
15 Mr. Costello.

16 Is there a second to that?

17 MEMBER COSTELLO: Second.

18 CHAIRMAN ALDERSON: Is there further  
19 discussion?

20 Hearing none, those in favor?

21 (Chorus of aye.)

22 CHAIRMAN ALDERSON: Opposed or  
23 abstaining?

24 That is accepted unanimously.

25 Thank you, Mr. Fuller.

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1 Yes, I believe Mr. Costello has a comment  
2 before we adjourn.

3 MEMBER COSTELLO: Yes, it strikes me that  
4 the stuff this Committee has been working on over the  
5 last year, we've talked about the guidance for shunting  
6 and people keep thinking about where the guidance for  
7 shunting, it might affect some of these events that you  
8 talked about as being taken from events that is perhaps,  
9 not even events.

10 We talked about -- have talked about  
11 forever going from dose-based regime to an  
12 activity-based regime for permanent brachytherapy.  
13 And, I think we had a case that are like 66 percent of  
14 the dose, for I assume on a dose-based. And, I don't  
15 know if that would have been an event on activity-based.

16 I don't want to hear, I'm just saying it  
17 could be affected by it.

18 And also, we mentioned patient  
19 intervention. Well, we've made recommendations for  
20 patient intervention. I think we're being held up for  
21 more pressing work.

22 But, I think that when that's adopted, they  
23 also affect, maybe even reduce, the number of medical  
24 events if you take a broader view of what patient  
25 intervention may be.

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1                   These are all three topics that we've been  
2                   working on over the last year.

3                   CHAIRMAN ALDERSON:   Yes, excellent.

4                   I will ask at this point if there are any  
5                   members of the public who wish to comment on any of these  
6                   recent discussions over the last several minutes,  
7                   please speak now.

8                   Hearing none, I assume that there are no  
9                   comments there.

10                  So, I think that we're now ready to break  
11                  for a short time.   We will reconvene at 3:00 which is  
12                  about 17 minutes from now to continue the agenda.

13                  (Whereupon, the above-entitled matter went  
14                  off the record at 2:43 p.m. and resumed at 3:01 p.m.)

15                  CHAIRMAN ALDERSON:   We're going to call  
16                  the meeting to order and get started on the next section.

17                  So, we're ready to hear the report on  
18                  Medical Event Reporting for All Modalities Except  
19                  Permanent Implant Brachytherapy and John Suh will be  
20                  reporting for the Subcommittee.

21                  MEMBER SUH:   On October 9, 2015, Dr. Ennis  
22                  provided the ACMUI with the annual presentation on the  
23                  previous fiscal year's medical event reporting which  
24                  still remains extremely low.

25                  Dr. Bruce Thomadsen, the outgoing ACMUI

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1 Chair discussed the incident at his institution where  
2 there was confusion as to whether or not it constituted  
3 a medical event.

4 As a result, this led to the formation of  
5 this Subcommittee to look at that report, medical event  
6 reporting for this.

7 So, in terms of history of medical event  
8 reporting, since the 1970s, there's not been much change  
9 in how medical event reporting has been performed.

10 In 1991, medical event criteria included  
11 the difference between the prescribed and administered  
12 dose of greater than 10 percent. So, that's kind of  
13 been the backbone in terms of the history of medical  
14 event reporting.

15 As a result, the current definitions may  
16 not be appropriate given the advances and technologies  
17 currently used, particularly in radiation oncology.  
18 10 CFR Part 35, Subpart M covers these reports.

19 In terms of the Subcommittee discussions,  
20 the Subcommittee discussed the current medical event  
21 reporting criteria under 10 CFR Part 35.3045.

22 The Subcommittee also reviewed different  
23 scenarios in which the current medical event criteria  
24 were ambiguous and, therefore, required possible  
25 modifications.

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1                   And given the spatial precision of modern  
2                   therapies, a slight shift in significant dose in nearby  
3                   tissues or parts of organs can occur.

4                   And, just to review the current report  
5                   notification of medical events from 35.3045, a licensee  
6                   shall report any event except for an event that results  
7                   from patient intervention in which the administration  
8                   of the byproduct irradiation from byproduct material  
9                   results in the following.

10                  So, a dose that differs from the prescribed  
11                  dose or dose that would have resulted from the  
12                  prescribed dosage by more than 5 rem, effective dose  
13                  equivalent, 50 rem to the organ or tissue or 50 rem  
14                  shallow dose equivalent to skin.

15                  And, total dose differs by prescribed dose  
16                  by 20 percent or more. The total dose differs --  
17                  delivered difference from the prescribed dose by 20  
18                  percent or more or falls outside the prescribe dosage  
19                  range or the fractionated dose delivery differs from the  
20                  prescribed dose for a single fraction by 50 percent or  
21                  more.

22                  Another possibility is where there is  
23                  administration of a wrong radioactive drug containing  
24                  the byproduct material, administration of a radioactive  
25                  drug containing byproduct material by the wrong route

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1 of administration, an administration of a dose or dosage  
2 to the wrong individual or human research subject, an  
3 administration of a dose or dosage delivered by the  
4 wrong mode of treatment or a leaking sealed source.

5 And, in terms of other scenarios, the  
6 licensee shall report any event resulting from  
7 intervention of a patient or human research subject in  
8 which the administration of a byproduct material or  
9 radiation from byproduct material results or will  
10 result in unintended permanent functional damage to an  
11 organ or a physiologic system as it's run by a physician.  
12 I should note that's bolded in red and I'll highlight  
13 that in a little bit.

14 The licensee shall notify by telephone the  
15 NRC Operations Center no later than the next calendar  
16 day of the discovery of the medical event.

17 That's just some background in terms of the  
18 current definition and the notification of a medical  
19 event.

20 So, in terms of medical events that would  
21 need to be covered for the variety of treatment options,  
22 you can see that are listed here.

23 Treatment options such as selective  
24 internal radiation therapy, and we heard a little bit  
25 about the SIR-Sphere and TheraSphere, high dose

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1 brachytherapy which is used for many different organs  
2 right now, including breasts, Gyn, lung, prostate and  
3 skin cancer, also for Gamma Knife radiosurgery or  
4 ViewRay, or low dose rate implants that are non-prostate  
5 related, low dose rate meshes which are sometimes used  
6 for some thoracic malignancies, unsealed sources which  
7 could be intravenous or oral and IPAC brachytherapy.

8 We had discussed whether or not defining  
9 medical events by modalities was perhaps preferable and  
10 the thinking was that it may be easier for the licensee  
11 to determine if a medical event occurred.

12 It may be easier to inspect and regulate and  
13 it may facilitate programs, procedures and education to  
14 prevent future events.

15 Since the delivery systems at risk are very  
16 different for each of these modalities, the specific  
17 medical event for each modality may provide some  
18 advantages, but the Subcommittee did not favor  
19 modality-specific medical events just because that  
20 would require individualizing the definition of medical  
21 events for each of the modalities which was just shown  
22 previously.

23 In terms of recommendations from the  
24 Subcommittee, the Subcommittee felt that medical event  
25 reporting should allow identification of the medical

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1 event and provide a forum to discuss how to avoid and  
2 reduce the likelihood of such an event.

3 The definitions of a medical event  
4 reporting need to be broad, simply and consistent so  
5 reports are easily applicable by an authorized user,  
6 applicable by regulators and process focused to  
7 eliminate any ambiguity of what constitutes a medical  
8 event.

9 The Subcommittee believes that the part of  
10 the definition based on, quote, unintended permanent  
11 functional damage to an organ or a physiologic system  
12 as defined by a physician, end of quotes, needs  
13 reconsideration, especially the word unintended.

14 The Subcommittee also believes that the  
15 creation of a subsection within the current definition  
16 of medical event reporting be considered to address the  
17 newer oncology modalities that prescribe doses to  
18 volumes.

19 And, finally, the Subcommittee believes  
20 that any proposed changes must not encroach on the  
21 practice of medicine.

22 Thank you.

23 CHAIRMAN ALDERSON: Thank you, Dr. Suh.

24 This report is now open for comment.

25 Mr. Costello?

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1                   MEMBER COSTELLO: Well, you gave a lot of  
2 good arguments. You have a lot of events to the  
3 regulator and then you said the Committee decided not  
4 to go that direction.

5                   As soon as you got to that point, I was  
6 thinking why not go that direction?

7                   MEMBER SUH: So, it's -- there's a lot of  
8 different -- so, again, there are, I think, benefits to  
9 try and do it per modality. I think the difficulty is  
10 going to be to try to define medical events for every  
11 single modality is going to be a very big undertaking  
12 and it's probably going to a very long time as well.

13                   And, I think it's going to keep it simple  
14 and also not create a lot of different what if scenarios.

15                   The thinking was from the Subcommittee is  
16 that it's going to be easier if we amended the current  
17 definition of medical events rather than try and create  
18 separate medical event definitions for every single  
19 modality.

20                   And, as you saw in that list, there's about  
21 ten different modalities that we'd have to define.  
22 And, that, again, would be a very big undertaking to try  
23 to do it for every single modality.

24                   CHAIRMAN ALDERSON: Dr. Langhorst?

25                   MEMBER LANGHORST: Sorry, I may be a little

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1 dense these days, but did we have a written report, a  
2 draft report? So, we didn't have anything to read on  
3 this other than the slides?

4 MS. HOLIDAY: Dr. Langhorst, this is  
5 Sophie.

6 I think the idea is that Dr. Suh's  
7 Subcommittee would be presenting their discussion and  
8 this would serve as more like a forum or a discussion  
9 amongst the Committee members.

10 MEMBER LANGHORST: Okay, thank you.

11 Sorry, I was confused about what it was  
12 supposed to be.

13 MEMBER SUH: Yes, it was a work discussion.  
14 So, actually, I had that discussion with Sophie before  
15 this talk. So, you were not mistaken.

16 CHAIRMAN ALDERSON: Further comments from  
17 the ACMUI?

18 MEMBER COSTELLO: I have one other.

19 CHAIRMAN ALDERSON: Yes, Frank?

20 MEMBER COSTELLO: Where is the  
21 Subcommittee going to go from here? I mean, clearly,  
22 the Subcommittee recognizes that -- I'm sorry.

23 Where is the Subcommittee want to go from  
24 here? I mean, clearly, the status quo isn't perfect as  
25 you have in your slides. What's next?

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1                   MEMBER SUH:    So, I think in terms of what's  
2   next is I think we will need to start the process of  
3   defining what constitutes a medical event for  
4   non-permanent implant for any type of radiation  
5   modality.   So, we're going to need to start that process  
6   defining what constitutes a medical event for these.

7                   And, just given the variety of different  
8   modalities that are being used right now to treat  
9   various conditions, it's going to be a big undertaking.  
10   But, I think we need to start defining what that is going  
11   to be.

12                  MEMBER COSTELLO:   So, this is a work in  
13   progress, then?

14                  MEMBER SUH:    This is a work in progress.

15                  MEMBER COSTELLO:   And, what we can expect  
16   over the next, you tell me, period of time is that you'll  
17   be briefing us on various modalities that you would  
18   recommend that the Committee take and then the NRC take?

19                  MEMBER SUH:    Yes.

20                  MEMBER COSTELLO:   Okay.

21                  MEMBER SUH:    I think just to build on what  
22   Dr. Donna-Beth Howe just presented, I think this also  
23   gives us an opportunity in terms of, kind of, you know,  
24   we're moving more toward, you know, looking at the  
25   education composite piece.   So, I think this also will

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1 tie in very well as in terms of just what constitutes  
2 these medical events.

3 And, I think one of the things I just want  
4 to comment on just from the last part of the meeting,  
5 I think having the information being made more public  
6 I think is very useful I think for, you know, someone  
7 who's been trained to actually look at what they didn't  
8 identify as the right patient I think it very important.

9 I think it's something that, if you look at  
10 some of these various modalities that are being used,  
11 I think there's definitely best practices that can be  
12 learned.

13 CHAIRMAN ALDERSON: Dr. Langhorst?

14 MEMBER LANGHORST: I think that's going to  
15 be great. I loved it and I can't wait to hear what the  
16 Subcommittee comes up with.

17 I encourage you to look specifically at the  
18 35.1000 guidance documents because sometimes they have  
19 some specific guidance about medical event reporting.

20 I know we'll probably be doing that on the  
21 training and experience piece of just what you were  
22 suggesting.

23 So, I just encourage you to look at those  
24 to see if there's anything a little different from the  
25 35.3045 definition.

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1 Thank you.

2 CHAIRMAN ALDERSON: Yes, Dr. Zanzonico?

3 VICE CHAIRMAN ZANZONICO: I just have a  
4 more or less a procedural question. I mean, I think  
5 we've all learned that when regulations or for, in this  
6 instance, medical events are defined in the  
7 prescriptive manner and then trying to update them  
8 wasn't even possible.

9 So, I wondering if maybe a middle ground  
10 with non-modality specific definitions for MEs are in  
11 the red. But, as Sue just pointed out, supplement those  
12 with modality specific guidance documents. Because  
13 that seems like it would give you the flexibility as new  
14 modalities are introduced, so forth and so on, that you  
15 can provide concrete guidance to users for those.

16 But, I mean, I agree putting modality  
17 specific definitions of MEs is like after the work will  
18 work well.

19 So, that's just a comment.

20 CHAIRMAN ALDERSON: Yes?

21 MEMBER WEIL: You mentioned that you were  
22 uncomfortable with the word unintended permanent  
23 functional damage in the slide number ten. And, I'm  
24 wondering what your thinking is there?

25 MEMBER SUH: So, we talked about as a

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1 Subcommittee, we really didn't come up with a better  
2 word than unintended, but we just felt that the  
3 connotation of unintended was probably not what is best  
4 suited in terms of what constitutes a medical event.

5 CHAIRMAN ALDERSON: Yes, Dr. Dilsizian?

6 MEMBER DILSIZIAN: For example, it's you  
7 know, the attention on unintended, for example, you  
8 know, I proposed "unexpected." It's not something  
9 anybody was intending, it's some -- those kind of  
10 things, more of a bad definition than it seems to connote  
11 with unintended.

12 MEMBER WEIL: I can imagine, you know, that  
13 in treating a tumor of some sort that you might damage,  
14 you might cause functional damage intentionally,  
15 though. I mean, it would be part of the therapeutic  
16 goal, no?

17 MEMBER DILSIZIAN: Well, absolutely.  
18 But, this is --

19 MEMBER WEIL: Different?

20 MEMBER DILSIZIAN: -- unintended events.  
21 In essence, if some, you know, we talked about  
22 microsphere therapies, it's going in the wrong  
23 [location] unintentionally, but it's unexpectedly.  
24 So, those are the couple of things I think we're talking  
25 about, right?

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1                   MEMBER SUH:     Yes, yes.     You wanted  
2 something else for the word unintended, and it's  
3 something you felt that unintended was perhaps not the  
4 best verbiage.

5                   CHAIRMAN ALDERSON:   So, Dr. Suh, is it true  
6 then, to follow up on Ms. Weil's question, that when you  
7 came back in slide 14 and, as a recommendation, you again  
8 brought up this phrase and said that it needs  
9 reconsideration, is it primarily the word unintended  
10 that is the thing that is the problem in that phrase?

11                  MEMBER SUH:    I think that was the concern.  
12 I wouldn't say it was necessarily a problem, but I think  
13 some people in the Subcommittee felt that that word was  
14 not the best word for that.

15                  CHAIRMAN ALDERSON:   Right, okay.    So,  
16 that's what brought it here?   Thank you for that  
17 clarification.

18                  Other comments or questions from the ACMUI  
19 on this report?

20                  Anyone else in the audience that wishes to  
21 comment on this report?   Anyone here in the room?

22                  MS. HOLIDAY:     Dr. Alderson, this is  
23 Sophie.

24                  CHAIRMAN ALDERSON:   Yes, Sophie?

25                  MS. HOLIDAY:    If I may, I guess I just want

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1 to remind the Committee of why this Subcommittee was  
2 formed.

3 If you guys will recall during the October  
4 meeting, Dr. Thomadsen, during his farewell  
5 presentation had brought up multiple things. And, one  
6 of the things that he brought up was that there was an  
7 event that occurred at his institution and they thought  
8 that it was a medical event.

9 So, they reported it and their regulatory  
10 authority came back and said, no, it's not a medical  
11 event.

12 So, his institution re-evaluated it and  
13 they still thought that it was a medical event. So, he  
14 formed the Subcommittee because he wanted the Committee  
15 to maybe look at clarifying the medical event reporting  
16 criteria and maybe this discussion, I think, the  
17 objective is to get the Committee as a whole to maybe  
18 discuss different instances at their institutions where  
19 maybe similar things had occurred.

20 And, that way, it could help facilitate the  
21 Subcommittee's work.

22 CHAIRMAN ALDERSON: Well, thank you, Ms.  
23 Holiday.

24 So, would anyone on the Committee like to  
25 help us resolve the ambiguity in medical events by

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1 giving us some examples from their own experience?  
2 Redacted for the appropriate details, of course.

3 Yes, Dr. Zanzonico?

4 VICE CHAIRMAN ZANZONICO: Yes, well,  
5 actually, it was the I-124 incident that was reported  
6 as an ME and there was a lot of disagreement at Memorial  
7 over whether this was reportable or not.

8 I did not think it was reportable. And,  
9 what had happened was, the catheter was put in place and  
10 the infusion, since it's directly into the brain, has  
11 to be done very slowly, microliters per minute to avoid  
12 brain swelling.

13 And so, the amount of activity that was  
14 injected into the body that was injected in the slow rate  
15 of injection meant that the patient was awake with the  
16 catheter in place and these are children.

17 And, in the past, when a small body of  
18 activities were used, it was done completely in the OR  
19 while they were under anesthesia.

20 And, the children, people doing what they  
21 do, move and the catheter didn't come out, but the  
22 connector was loosened.

23 I think that can be interpreted as patient  
24 intervention. Nothing was done incorrectly by the  
25 surgeon or anyone else involved with the procedure and

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1 so, in that respect, it was a -- I thought it was not  
2 a medical event even though the activity delivered was  
3 easily 50 percent from that that was prescribed.

4 I mean, I think that's the kind of thing  
5 where there's sort of a grey area as to whether patient  
6 intervention resulted in the under dosing or over dosing  
7 or something incorrectly was done that resulted in that  
8 and so forth.

9 CHAIRMAN ALDERSON: So, given, just to  
10 follow up on your comment, given, then, that you clearly  
11 an expert, didn't feel it was a medical event. How did  
12 this event get reported? How was that decided that it  
13 should be reported?

14 VICE CHAIRMAN ZANZONICO: Well, I was -- it  
15 was put in by the RSO.

16 CHAIRMAN ALDERSON: I see. So, it's the  
17 RSO?

18 VICE CHAIRMAN ZANZONICO: It's the RSO's  
19 fault. It was.

20 And, I think it was just a matter of an  
21 overabundance of caution and they didn't want the  
22 institution to appear to be in a position that something  
23 that possibly could be construed as a medical event was  
24 being swept under the rug is what I guess.

25 CHAIRMAN ALDERSON: I got it.

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1 Ms. Weil will be next.

2 MEMBER WEIL: If you go back to the purpose  
3 of reporting medical events, and to see it in a positive  
4 opportunities for making a public situation -- these are  
5 opportunities for public discussion or public perusal  
6 of events that have happened.

7 Instead of punishing the clinicians  
8 involved but rather this is a useful thing if you're  
9 going to administer something over a long infusion to  
10 a child who is awake, it's useful for other clinicians  
11 to know that something got loose and maybe to prevent  
12 that from occurring in the future.

13 CHAIRMAN ALDERSON: Okay.

14 Yes, Mr. Zanzonico would like to respond to  
15 that.

16 VICE CHAIRMAN ZANZONICO: Yes, right.

17 CHAIRMAN ALDERSON: And then, we have a  
18 couple of others.

19 VICE CHAIRMAN ZANZONICO: Right. There  
20 is an unintended consequence of that and that is that  
21 practitioners may avoid this sort of procedure because,  
22 you know, these sort of, quote, unquote, risky or  
23 non-standard procedures, because it more likely puts  
24 them in a position of having to report something that  
25 went wrong.

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1           The other point is, these events, even if  
2           they're not reported to a regulator of a medical event,  
3           are reported. They're reported in the peer review  
4           literature as case reports and so forth.

5           So, the information is the disseminated to  
6           the practitioner community. The issue is whether it  
7           rises to the level of requiring reporting to a  
8           regulator. Even if that is being not met, doesn't mean  
9           the information doesn't get disseminated to the people  
10          who can use it.

11          CHAIRMAN ALDERSON: We have many -- many  
12          hands are up. Ouhib?

13          MR. OUHIB: Yes, I'll go back to your  
14          question, and that is we really are not -- even if  
15          they're not certain or not sure that it's a -- the fact  
16          that it's a medical event, you should report it. And  
17          then, eventually, the decision will come afterwards.

18          The other item that I was going to say is,  
19          and regarding your case and Bruce Thomadsen's case, I  
20          think this Subcommittee can really use these cases and  
21          they will help us actually do some more work.

22          Because then we're looking, well, where is  
23          the real issue here? Let's look at this and let's  
24          evaluate this. And then, maybe that will help us sort  
25          of go in a certain direction.

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1 CHAIRMAN ALDERSON: Thank you.

2 I think Dr. Ennis was next.

3 MEMBER ENNIS: Thank you.

4 Two comments. One, just we've talked  
5 about this in this Committee before, but just to Ms.  
6 Weil's comment. The reality is the way a medical event  
7 is used in institutions is not that idealized version  
8 that you just expressed.

9 Now, if we want to somehow take on and  
10 change that whole system and come up with some new idea  
11 or some new thing, that's fine. But, that's just not  
12 how it is and it has big ramifications for the  
13 practitioners in a very public kind of way that can be  
14 very uncomfortable or even politically damaging.  
15 That's number one.

16 Number two, just to give a little more  
17 flavor to what we are talking about from a radiation  
18 oncology perspective, these criteria really fit an era  
19 where radiation was given as a big square box aimed  
20 straight at a part of the body or maybe from two angles  
21 or three angles where the dose that was distributed  
22 within the tissue was uniform and large.

23 And now, what we do is much smaller,  
24 précised and less homogeneous. So, there are scenarios  
25 that can come up, I'll give you a couple of examples,

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1       that just don't fit.

2               So, a simple example would be, if I was  
3       treating, let's say, the left side of someone's  
4       abdominal pelvic area and there are a number of organs  
5       in there that are getting exposed just because they're  
6       nearby and there's a tumor there.

7               And, if I sit the patient up in such a way  
8       that a couple of inches off, is that a medical event?

9               The same organs are getting exposed, but  
10       differing amounts of them. So now, maybe more of their  
11       liver's getting exposed than before. How much more is  
12       a medical event? Or is it a medical event?

13              Their colon is getting -- you get the idea.  
14       And, it's not wrong body sites, it's the same body site,  
15       it's a little off, volume wise. How much off to what  
16       degree?

17              Another example might be, if I'm treating  
18       a volume and it's inhomogeneous now, so, I'm  
19       purposefully treating a spot within that -- with double  
20       dose and I'm treating some other spots, but half of that  
21       dose.

22              And, something happens where that  
23       distribution of dose is not delivered correctly, upside  
24       down, wrong -- again, so different organs are getting  
25       different doses than what was intended, if you will,

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1 but, again, how egregious was that and what -- how do  
2 we define when that reaches some kind of threshold of  
3 a medical event?

4 So, I think from a radiation oncology  
5 perspective, this whole volume issue in particular and  
6 inhomogeneity just makes it -- the prior things  
7 inapplicable.

8 CHAIRMAN ALDERSON: There was another  
9 comment over here. Mr. Costello?

10 MEMBER COSTELLO: Tomorrow, Mr. Bollock is  
11 going to talk a little bit about the OIG report. And,  
12 one of the recommendations was to clearly define the  
13 purpose of medical event reporting in a publically  
14 available document and classify the reporting  
15 requirements.

16 I think the uncertainty is the need for  
17 clarification underlies a lot of our discussion. It  
18 underlies patient intervention. It underlies the way  
19 you talk about with the --

20 And, with all due respect of what you're  
21 going to say tomorrow, Doug, I think it's something that  
22 the Committee should consider taking up.

23 I mean this purpose of the medical event  
24 goes back decades, maybe the early '80s, something like  
25 that, 1980. It's you know, 36 years old. And, therapy

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1 has changed a lot since 1980. Okay?

2 And, maybe for clarifying the purpose of  
3 it, it's something that the Committee should undertake  
4 and make it modern, make it for the 21st century.

5 And, I'm going to mention this tomorrow  
6 after you give your talk, but I think underlying a lot  
7 of our discussions that we've had for a while is this  
8 lack of clarity, what the purpose of the rule is.

9 And, reasonable people can differ what the  
10 purpose of the rule because it was put out in 1980, it  
11 could be clearer now in 2016.

12 So, that's really a comment. It's, you  
13 know, a lot of discussions we've had from prostate and  
14 the seeds dose versus activity to, you know,  
15 microspheres to patient intervention to a lot of these  
16 things. I think what made my mind, would drive some of  
17 that is lack of clarity. Why are we even doing this?

18 And, now, may be the time for the Committee  
19 to put its mark on that.

20 That's all.

21 CHAIRMAN ALDERSON: Thank you, Mr.  
22 Costello, for that comment.

23 Dr. Langhorst?

24 MEMBER LANGHORST: Another aspect to what  
25 Frank was bringing up is, what is the regulatory

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1 measure? What do you measure?

2 And, a lot of these differences in dose an  
3 inspector cannot do those calculations. And so, is  
4 that -- how do you balance that? If it's a dosage of  
5 radioactive or a radiopharmaceutical, you can see I was  
6 supposed to have prescribed five millicuries. We gave  
7 three, that's a -- you can see that. That's right there  
8 in the documentation.

9 But, as far as the dose goes, you have to  
10 rely on the institution to make those calculations and  
11 so one. And so, it's a difficulty that, how do you  
12 inspect on that?

13 And, I want to address what Laura has  
14 brought up, too, is you want your institution to bring  
15 those issues forward. And in the, I'll say the  
16 idealized way, that's part of your safety culture.

17 But, you want to be able to bring that  
18 forward without fear of repercussion.

19 And, I'll tell you as an RSO, having to have  
20 reactive inspections, I feel the repercussion because  
21 it's never, oh, let's see what we can learn, it's what  
22 did you do wrong and how can we give you a violation?

23 I mean, I hate to say it that way, but that's  
24 the way it happens.

25 So, I think we'll be discussing it more as

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1 we talk about the OIG report tomorrow. But, how do you  
2 have a regulatory environment with regulations that you  
3 have to enforce and also be supportive of a safety  
4 culture in bringing those things forward. And, it's  
5 not an easy balance.

6 CHAIRMAN ALDERSON: I think that's an  
7 excellent comment.

8 Dr. Metter?

9 MEMBER METTER: Well, I think, and you're  
10 right, I can give you an example.

11 Before when Y-90s first came out and the  
12 dose delivery was 60 percent. And so, I was concerned  
13 and I said this is a medical event. I went ahead before  
14 the -- regarding to dose delivered due to stasis, it came  
15 out.

16 And so, I brought it to our RSO and then we  
17 found that it [the revised guidance] had just been  
18 written the month before in June. And so, it turns out  
19 it wasn't [a medical event]. And so, the RSO wrote to  
20 my department chair and said, well, no, this isn't met.  
21 This isn't a medical event.

22 I got reprimanded for bringing it up by my  
23 department chair. And, I was not supposed to anything  
24 like that unless I get it cleared by the department chair  
25 who didn't understand what a medical event was.

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1                   So, you are correct, there's a lot of other  
2 things that go on because they don't anything to look  
3 bad for the department, but in the end, it wasn't a  
4 medical event, but the process was difficult and, you  
5 know, and it's difficult to bring things up like this  
6 because of other issues that are involved.

7                   CHAIRMAN ALDERSON: And, these are very  
8 important comments and I just want to set a context  
9 before I go back to Mr. Costello for the next question  
10 is that we all are very familiar with the quality  
11 assurance movement. It is everywhere. And, it is said  
12 again and again that that is a non-punitive approach.  
13 We are all trying to improve.

14                  But, we didn't think that way about the QA  
15 movement when it started, go back, I don't know what it  
16 was, 15 years ago or so, it was very much punitive in  
17 all of our cultures.

18                  But, enough people spoke up and it's not  
19 that punitive anymore. It's less punitive.

20                  And so, at some point, as part of these  
21 discussions on medical events, we, as a Committee,  
22 should consider whether, you know, you've got to start  
23 somewhere. We should be speaking up and making it clear  
24 that we think that the regulatory culture on this should  
25 not be punitive.

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1                   So, I just put that out there as an  
2 observation. And now, I believe the next comment was Mr.  
3 Costello.

4                   MEMBER COSTELLO: So, you brought up, you  
5 know, how do we, as inspectors, evaluate these things?  
6 And, the real answer is largely we don't. Okay?  
7 There's no way I can look at results of a CT and know  
8 where the seeds are and calculate dose. I mean, I don't  
9 do that.

10                  For many cases, I simply rely and trust our  
11 licensees to calculate doses properly and calculate --  
12 and figure out which activities put there properly.  
13 And, then that's what I identify.

14                  As far as the punitive, you know, that  
15 varies probably from regulator to regulator and I'd say  
16 that I think we try not to, sometimes it may feel that  
17 way. But, I don't think it's ever our intention to do  
18 that.

19                  And, the other observation I had is, often  
20 times, we find that it is the better programs that are  
21 reporting the medical events. The better -- it's not  
22 the, you know, marginal programs who's reporting or  
23 anything, they don't report anything because, if I may  
24 say bluntly, they wouldn't know a medical event if it  
25 fell on their head. Okay?

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1 But, it's the prestigious organizations  
2 that have good quality programs that have internal  
3 debates whether this is -- they're the ones reporting  
4 it.

5 There are programs, I know, are not the best  
6 that we never hear from. I don't have an answer for  
7 that. Your institutions rule bound and those are the  
8 ones that we get reports from.

9 So, if we, as regulators, are making you  
10 feel -- being punished for doing the right thing,  
11 following the safety culture, then we've got to a better  
12 job.

13 CHAIRMAN ALDERSON: Dr. Metter?

14 MEMBER METTER: I think what you brought up  
15 with quality assurance in the past is correct, it was  
16 a retrospective thing about, if you didn't follow the  
17 rules, you're going to get punished.

18 Now, I believe the new culture is quality  
19 improvement. And so, it's more of a just culture where  
20 you're not individually penalized as individuals but  
21 more the systems and I think the systems cause this sort  
22 of problem. And, I think that's kind of what you're  
23 reflecting.

24 CHAIRMAN ALDERSON: Thank you.

25 Mr. Ouhib?

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1 MR. OUHIB: Yes, I think you brought a very  
2 good point. And, there are some sort of a disconnect.  
3 There is a perception and there are facts.

4 And, I think there was one -- somebody had  
5 one slide earlier where it is time to have the ACMUI,  
6 NRC and professional organizations sort of get together  
7 and discuss this together, basically, to come up with  
8 a better, you know, a culture of safety, you know, and  
9 everybody is online.

10 CHAIRMAN ALDERSON: Very good.

11 Other comments?

12 Well, I think if there was a concern, Dr.  
13 Suh, that this might stop at this point or you had no  
14 other --

15 MEMBER SUH: No, no.

16 CHAIRMAN ALDERSON: We have resolved that  
17 very clearly. So, this is a challenging, interesting  
18 area. We're going to hear more about it tomorrow.

19 Any final comments, Dr. Suh?

20 MEMBER SUH: So, I just wanted to just to  
21 -- I think it's been a great discussion. I think it is  
22 very important that, as a Committee, we look at the  
23 process and not punish the people. I think it is  
24 something that we have to do a better job of.

25 And, I fully agree that there are some

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1 institutions where a mistake has happened, there's  
2 repercussions. And, as a physician and as an  
3 authorized user, you don't want to go there.

4 But, I mean, it's okay John. Not  
5 necessarily like that, you know, depending where you are  
6 at what institution. So, I think we're getting better  
7 at that, but --

8 You know, and I think the other thing, too,  
9 is I think, well, for a lot of physicians, making --  
10 admitting to a mistake is very hard for them to do.

11 I think sometimes for that -- so, I would  
12 venture that there is under reporting that goes on.

13 And, I think for high quality institutions,  
14 you want to do what's right. You want to have a just  
15 culture and say, this was not done correctly and, as a  
16 result, we need to report it.

17 And, I do like the fact that there's going  
18 to be greater transparency. And, I think one of the  
19 things that I can personally do is that, you know, for  
20 the trainees that we have, I think it's good for them  
21 to read about these events.

22 Hey, they didn't check the right site.  
23 And, one of the things that I think is very important  
24 is doing a fundamental time out can avert some of the  
25 medical events that we heard earlier today.

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1 I mean, just simply just asking for your  
2 name and your birth date and which part of the body are  
3 you treating? And, if the patients says you're  
4 supposed to be treating here with radiosurgery and I'm  
5 going to treat here, I'd better think long and hard  
6 before I sit the patient in the machine and push the  
7 button.

8 CHAIRMAN ALDERSON: Those are great  
9 comments, Dr. Suh. And so, I think as your Committee  
10 moves forward, we'll be able to bring some of those  
11 things forward in a more official way.

12 So, I want to thank everybody who  
13 contributed to this very good discussion and to the  
14 great Committee report for their work and we'll move  
15 forward with this.

16 Thank you.

17 So, I think we're ready, if Katie Tapp is  
18 ready to start, we're ready to move on to the next  
19 presentation which is on NUREG-1556, Volume 9 Update.

20 DR. TAPP: Thank you, I'm here right now to  
21 discuss NUREG-1556, Volume 9 Update.

22 NUREG-1556 is the consolidated guidance  
23 about material licenses. Volume 9 is specific to  
24 medical use licenses.

25 Currently, there are two updates going on

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1 with Volume 9. The first update is associated with the  
2 rulemaking. This update is on the bottom here in this  
3 chart and its current has just received comments from  
4 ACMUI and Agreement States.

5 As we discussed before, the NRC is looking  
6 at these comments and going through the resolutions and  
7 initiating to send up the final rule to the Commission.

8 In addition, there is an update to the  
9 sections that are not associated with the rulemaking.  
10 That is the top part of this chart.

11 We have received comments from the steering  
12 committee that's involved with updates to all the 1556  
13 volumes and from NRC staff and from the ACMUI members.

14 We're resolving those comments now and are  
15 planning to send this report for public comments.

16 This revision will not include the updates  
17 that are associated with the rulemaking. This will be  
18 sent out without those updates.

19 As you can see from this table, it will be  
20 after we get direction from our Commission for that and  
21 as well as receiving the public comments for the updates  
22 that are not associated with the rulemaking, we'll bring  
23 those two together and then we'll issue it for final  
24 publication.

25 The updates not associated with the

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1 rulemaking are associated with comments that were  
2 received but not addressed during Revision 2 to this  
3 document.

4 Revision 2 was associated with the NARM  
5 rule where we included naturally occurring and  
6 accelerated produced isotopes.

7 In addition, we have new comments from the  
8 public and from NRC and Agreement States staff including  
9 both inspectors and licensing staff.

10 We received ACMUI recommendations and  
11 we're incorporating those into the documents as well as  
12 updates to references that have occurred and get other  
13 guidance documents since the last revision.

14 We're going to reflect the movement of  
15 going more electronic-based. This new document will  
16 include hyperlinks so we can move throughout the  
17 document. It's a very large document, so this will  
18 allow movement easily throughout the document as well  
19 as to regulations and other guidance documents.

20 We are also adding consistencies between  
21 all the volumes. There is 21 volumes in NUREG-1556 and  
22 we want to make sure they're consistent, especially in  
23 areas that are the same between volumes.

24 For example, reciprocity, when an  
25 Agreement State licensee comes across and goes into an

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1 NRC space, they have to send in a letter for reciprocity.  
2 We want to make sure that it's consistent between the  
3 volumes of what they have to do to do this.

4 And finally, at the end, we'll bring in the  
5 rulemaking updates with the final publication.

6 As I said, we have received ACMUI  
7 recommendations. We received ten on October 8, 2015.  
8 We are looking at those comments to incorporate.

9 As was said this morning from Sophie  
10 Holiday, we will issue a memo explaining if there is any  
11 differences that the staff incorporates that are not  
12 fully incorporated or not incorporated the same way that  
13 it has been recommended or if no action was taken on that  
14 recommendation. We're going to explain why the staff  
15 made that determination.

16 One recommendation that was made was the  
17 comment period extension. The ACMUI recommended that  
18 NUREG-1556, Volume 9 have a longer public comment period  
19 than the other 1556 volumes because of the complication  
20 with medical use licenses.

21 I believe that it was recommended for 90  
22 days. Working through it right now, the staff is  
23 recommending a 60-day public comment period.

24 This is double the amount of time that is  
25 allowed to other volumes. It was recognized this is a

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1 complicated volume.

2 The ACMUI has provided, as I said, nine  
3 other recommendations and we are going through those  
4 with our working group and incorporating those.

5 And moving on to any questions?

6 VICE CHAIRMAN ZANZONICO: Pat Zanzonico.

7 I'm a little confused, I'm a little  
8 confused by this approach because, if I understand  
9 correctly, there will only be two reg guides published,  
10 one without the rulemaking section and with within a  
11 year of one another.

12 Because it says draft Volume 9 Guidance  
13 published and then it says below that then there's an  
14 arrow connecting the two lines where you'll publish a  
15 final version with the rulemaking changes incorporated.

16 DR. TAPP: So, the draft Volume 9 Guidance  
17 published will be published for public comment. It is  
18 not going to be published final.

19 VICE CHAIRMAN ZANZONICO: No, understood.  
20 But, even with that, it still seems confusing to, you  
21 know, perspective stakeholders to comment on what is  
22 essentially an incomplete version and then, within a  
23 year, comment on the final complete version.

24 DR. TAPP: The public has already had an  
25 opportunity to comment on the rulemaking version. We

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1 did not want to confuse people by putting it back out.

2 As we're going the parallel paths, we  
3 wouldn't have to wait for all that to be finalized, wait  
4 for the Commission. It would add a large delay to our  
5 publication. So, we were doing it in parallel paths so  
6 we can issue the final publication as soon as after the  
7 final rulemaking is done.

8 The public has to have -- or we want to give  
9 the public a chance to comment on all changes. So, this  
10 was a pathway that would allow the public to see both  
11 the rulemaking changes as well as the non-rulemaking  
12 changes.

13 But, the public will have a chance to see  
14 both.

15 VICE CHAIRMAN ZANZONICO: I guess we agree  
16 to disagree --

17 DR. TAPP: But, I take your comment.

18 VICE CHAIRMAN ZANZONICO: -- in terms of  
19 this approach.

20 CHAIRMAN ALDERSON: Other questions or  
21 comments?

22 Dr. Langhorst?

23 MEMBER LANGHORST: Pat, you're right, it  
24 is very confusing.

25 And, I have been trying to think of how to

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1 help in this effort, especially as you put out a draft  
2 of the non-rulemaking changes.

3 And, I wonder if maybe you can designate  
4 those parts that are involved in the rulemaking in some  
5 way to say, this was reviewed, this was updated in the  
6 rulemaking and point them in that direction so that  
7 they're not giving you feedback on stuff that isn't up  
8 to date with the rulemaking.

9 And, it is going to be confusing with the  
10 comments that you bring back, but I don't know how better  
11 to help.

12 I will say, and I think my licensing people  
13 at Region III know this, I love the NUREG-1556 series.  
14 And, it is very helpful to me as a radiation safety  
15 officer in developing licensing -- license amendments,  
16 license applications and so on.

17 And, I commend you for making things  
18 consistent and trying to make sure that if you have  
19 regulatory guidance that you keep it in one location so  
20 you only have to update that one and you reference it,  
21 and especially by hyperlinks is great. I know it's not  
22 the greatest for those who still have to look at paper,  
23 but at least I think that is the way to go.

24 And, I know it's a big effort and I really  
25 thank you all for all the work you're doing on it.

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1 DR. TAPP: Thank you.

2 MEMBER LANGHORST: Thank you.

3 CHAIRMAN ALDERSON: Yes, Dr. Zanzonico?

4 VICE CHAIRMAN ZANZONICO: Not to beat this  
5 horse to death, but my concern is that you're going to  
6 get a segment of users who are going to see the draft  
7 guidance and say, okay, this is the law of the land, this  
8 is what I'm going to follow and almost be completely  
9 unaware of the subsequent final publication.

10 I mean, this two-step approach, and I  
11 understand the rationale for doing it from a logistical  
12 point of view, but it seems almost destined to create  
13 problems among, you know, a segment, perhaps most of,  
14 you know, the user base.

15 DR. TAPP: I have just a quick response.

16 The staff is well aware that this could  
17 create confusion. We want to be as clear as possible  
18 when we issue this for public comment and we take the  
19 suggestions here as how to do that.

20 CHAIRMAN ALDERSON: Yes, Dr. Howe?

21 DR. HOWE: I think it's helpful to know  
22 that when she puts out her draft and it does not include  
23 any of the rulemaking, then it will pertain to the  
24 existing Part 35.

25 So, you won't have a draft that says, oh,

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1 your training experience, you don't need an attestation  
2 anymore. It will still say you need an attestation.

3 Now, as soon as the rule is final, we'll  
4 have guidance to say you don't need the attestation  
5 anymore. That will come back together on the final  
6 NUREG and you will have to absolutely follow in Part 35.

7 But, on the draft, that'll be out before the  
8 final rule comes out. So, you won't be confusing people  
9 between what's in the existing regulations because it  
10 doesn't have any regulatory changes. It just has  
11 consistency.

12 VICE CHAIRMAN ZANZONICO: I'm already  
13 confused. The problem is the proximity in time. I  
14 mean, if I get a draft guidance and then six months  
15 later, you've got a second draft guidance, you know, if  
16 I were a more casual user, I wouldn't be expecting  
17 something revised that if the first draft guidance said  
18 you still needed attestation, I would continue  
19 indefinitely or I can foresee a number of users  
20 continuing to indefinitely based on that guidance.

21 DR. HOWE: And, one of the things that we  
22 had to kind of focus on was, what if we had -- we have  
23 Revision 2 out there now, right, that's the current one,  
24 Revision 2. This will be Revision 3.

25 Well, we were faced with Revision 3 coming

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1 out and then within a very short period of time, maybe  
2 a month or two, Revision 4 coming at us.

3 And, we thought that was going to be a lot  
4 more confusing as to, well, why have you revised it twice  
5 in three months when it's taken you ten years before?

6 So, we're bringing these things up parallel  
7 with the idea, they will come together and will be one  
8 huge revision to Volume 9. Because, we think that's  
9 going to be, in the end, the clearest that -- what Volume  
10 9 are you dealing with? I'm dealing with Revision 3.  
11 Okay, it's all in Revision 3. You don't confuse 3 and  
12 4 because they're two or three months apart.

13 CHAIRMAN ALDERSON: Yes, Mr. Fuller:

14 MR. FULLER: Yes, this is Mike Fuller.

15 And, Dr. Zanzonico, just know that we feel  
16 your pain. This is not something that we're trying to  
17 pull on, you know, pull the wool over anybody's eyes.

18 Staff has struggled with this for several  
19 years. You know we've been in rulemaking for many  
20 years.

21 We have requirements that when we propose  
22 a rule, we publish a proposed rule. We must publish the  
23 draft guidance, which we did. And we got comments on  
24 that. That's part of the rulemaking process.

25 Then, and we keep talking about parallel

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1 paths, we have an obligation to revise this guidance  
2 irrespective of the rulemaking. That's a fact of life.  
3 That's just we have to do that. It's not an option for  
4 us.

5 So, we have -- the staff has been put in a  
6 position of having to do two different things at the same  
7 time that involve NUREG-1556, Volume 9. Again, it's a  
8 fact of life.

9 Now, we are doing the best that we can to  
10 clarify for the various audiences, those folks that are  
11 interesting in having the guidance in response to the  
12 current rule and then those folks who are very much  
13 involved and interested in our new 10 CFR Part 35 rule.

14 Once, and I'm now repeating what everybody  
15 else has said, once we publish the final rule, once we  
16 get direction from the Commission to publish the final  
17 rule, shortly after that, all of that draft guidance  
18 that's contained in 1556 will be made final and that will  
19 feed into Katie's project and we'll publish it just one  
20 time as final.

21 So, again, you know, like I said, we feel  
22 your pain and we understand. We explained it as best  
23 that we can. When we publish the 1556, Volume 9 draft  
24 3, for public comment, we will try to make this very,  
25 very clear for everyone involved.

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1 But, it's, as I said, we are where we are  
2 and we are obligated to do both of these things which  
3 are different things. And, that's the best way I can  
4 describe it.

5 CHAIRMAN ALDERSON: Further comments?

6 Yes, Mr. Mattmuller?

7 MEMBER MATTMULLER: Would it be helpful,  
8 as I understand it, there's going to be one more chance  
9 for the public to comment on the draft, would it be  
10 helpful to have, maybe not this whole graph, but at least  
11 part of this to explain to the public, okay, you're  
12 commenting on this part of it here and that the new  
13 guidance relative to the new final rule has already been  
14 worked on?

15 So, just to help them keep the two processes  
16 separate.

17 DR. TAPP: That is a good comment and we'll  
18 look into that.

19 CHAIRMAN ALDERSON: We'll ask if anyone is  
20 on the line right now who's a member of the public who  
21 wants to comment about this issue? Is there anyone on  
22 the line that wishes to comment?

23 There are no such comments.

24 More comments from within the room here?  
25 Members of the ACMUI? I'm sorry, I missed somebody.

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1 Yes, sir?

2 MR. MCMURTRAY: Hello. I'm Tony  
3 McMurtray. I'm the overall Senior Project Manager for  
4 the NUREG-1556 project. So, I've got all 21 volumes  
5 that I'm trying to work with Katie and others to move  
6 through.

7 I appreciate all the comments that we have  
8 here. As we've said, we'll work with our admin. We'll  
9 probably put up in the draft a comment section, maybe  
10 this time line or something specific for this.

11 We also have this issue with the Volume 13,  
12 Radiopharmaceuticals, because there's going to be  
13 language also in that volume that's going to come from  
14 the rulemaking that's going to come in.

15 Just as some background, some of the key  
16 things that we're trying to do with the overall  
17 NUREG-1556 series, we're putting security information  
18 in there to address the Part 35 rulemaking that happened  
19 for security and we're doing a lot of things with  
20 consistency and bringing all the volumes into a  
21 consistent standpoint.

22 We just -- if you want to look and see what  
23 some of this information looked like, we just issued for  
24 final report Industrial Radiography, Volume 2 last  
25 week. So, you can go on our public website and look at

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1       that. You can see some of that standard information  
2       that's in there.

3               But, as Katie mentioned, things like  
4       Agreement State information, an update on the Agreement  
5       State map, reciprocity, all those sort of things, we've  
6       updated that, some of the things as far as electronic  
7       submittals. There's a lot of new information like that  
8       that we've added in.

9               So, we appreciate the comments and we'll  
10       work to try to clarify this both for Volume 9 and Volume  
11       13 when we put those out.

12              CHAIRMAN ALDERSON:       Thank you, Mr.  
13       McMurtray.

14              Are there questions for Mr. McMurtray?

15              MEMBER MATTMULLER:       Just one quick  
16       comment.

17              I think if you could put this out there,  
18       then put a little red arrow to tell the public, you are  
19       here.

20              CHAIRMAN ALDERSON:       Okay, that's a nice  
21       sound suggestion.

22              Thank you very much.

23              Other questions or comments about this  
24       topic?

25              Hearing none, thank you --

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1 DR. TAPP: Thank you.

2 CHAIRMAN ALDERSON: -- Dr. Tapp.

3 I think that we're ready to go on to the next  
4 item on the agenda which is Sophie Holiday talking about  
5 the Committee Reporting Structure.

6 MS. HOLIDAY: Hello, again.

7 And, I think I'm going to up Donna-Beth and  
8 say, *this* is the most important presentation that you'll  
9 hear --

10 CHAIRMAN ALDERSON: We all say that.

11 MS. HOLIDAY: All year long.

12 So, today, I'm going to speak to you about  
13 what is the current reporting structure, talk about or  
14 give you your annual review. As I said earlier this  
15 afternoon, this is a recommendation from the Committee  
16 put forward for us to review your structure on an annual  
17 basis, talk about your meeting frequency and then open  
18 it up for discussion.

19 So, many of you are very familiar with this  
20 chart. You just saw it this morning in Dr. Alderson's  
21 presentation. This is simply just to say that you, the  
22 Committee, reports to Dan Collins who is the Director  
23 of the Division of Materials Safety, States, Tribal and  
24 Rulemaking Programs, which is within the Office of  
25 Nuclear Material Safety and Safeguards.

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1 And, of course, our office, NMSS, falls  
2 under the purview of the Executive Director for  
3 Operations, Victor McCree, which some of you also got  
4 to meet after the meeting.

5 And then, the EDO relays staff's positions  
6 and things of that nature to the Commission.

7 The dotted line simply represent that each  
8 of these individuals, and I did not have a dotted line  
9 for the Director of MSTR, but this is not to say that  
10 the dotted line does not exist, it's simply to say that  
11 all of these individuals have an Open Door Policy, which  
12 simply means that, at any time you guys wish to come in  
13 and speak to them, you have that opportunity. You just  
14 have to arrange it with their secretaries.

15 And, lastly, that box at the bottom, MSEB,  
16 represents our branch, which Doug is the Branch Chief  
17 of - the Medical Safety and Events Assessment Branch.

18 Like I said last year, while it may seem  
19 like you report to me, you do not. Our branch just  
20 oversees and supports the day-to-day activities of the  
21 Committee.

22 So, in an annual review in September of  
23 2012, the ACMUI reiterated their recommendation to have  
24 an annual review of your reporting structure. This is  
25 the sixth annual review that we have conducted since

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1 then.

2 I think my best quote that I like to say  
3 comes from the ACMUI Bylaw Subcommittee Report in which  
4 Dr. Zanzonico presented the Committee with the option  
5 to continue reporting to our office, NMSS, or directly  
6 to the Commission.

7 And, in that report, it stated, verbatim,  
8 "the working relationship between the NRC and ACMUI  
9 remains excellent. The reporting structure through  
10 NRC staff continues to function effectively and the  
11 associated logistical overhead associated with direct  
12 reporting to the Commission, e.g. the need for more  
13 frequent meetings, did not and does not now justify any  
14 change in the ACMUI's reporting structure."

15 Comparatively, we have another federal  
16 advisory committee, the ACRS, Advisory Committee on  
17 Reactor Safeguards, this is actually one of their  
18 meeting rooms. And, they report directly to the  
19 Commission.

20 So, on an annual basis, this Committee  
21 reviews if you would like to be similar to ACRS and  
22 report directly to the Commission or continue reporting  
23 to staff or rather the management in NMSS.

24 So, we meet here at Headquarters twice a  
25 year in the spring and in the fall. Your spring

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1 meetings are usually between March and April and your  
2 fall meetings are usually between September and  
3 October.

4 We hold ad hoc teleconferences on an as  
5 needed basis. That means approximately each year, we  
6 have between two to three teleconferences, although  
7 some years, you know, you may have less or you may have  
8 more. It just depends on what the need is.

9 So, at this time, I would like to open it  
10 up for discussion.

11 Is the Committee satisfied with continuing  
12 to report to NMSS or would you prefer to report directly  
13 to the Commission?

14 Are you agreeable to two in-person meetings  
15 or would you like more or would you like less?

16 What other changes would you like to see?

17 Thank you.

18 CHAIRMAN ALDERSON: Thank you, Ms.  
19 Holiday.

20 Now, those are three separate questions.  
21 I hope we can discuss them in three separate orders.

22 So, the first question was, does this -- is  
23 this ACMUI happy with its current reporting structure  
24 or would we prefer to report directly to the Commission?

25 So, let's try to address that single

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1 question.

2 Mr. Costello?

3 MEMBER COSTELLO: I have a question about  
4 something the Chairman said today. And, the impression  
5 I got was, if we were working and reporting directly to  
6 the Commission, I'm sorry --

7 That the Chairman said if we were reporting  
8 to the Commission like ACRS is, you couldn't have people  
9 who are actively engaged as members appear, you'd wind  
10 up having people who are retired.

11 I don't know -- understand why that is, but  
12 if that is the case, then clearly we benefit by not  
13 reporting directly to the Commission because look at all  
14 the practical experience you're getting now.

15 But, is that true?

16 MS. HOLIDAY: I will paint the picture like  
17 this, ACMUI meets here twice a year. ACRS meets here  
18 ten times a year in-person.

19 And, your meetings are usually -- they're  
20 here for in-person full committee meetings as well as  
21 subcommittee meetings.

22 MEMBER COSTELLO: So, I gather that means  
23 that it's not required by law that they be retired, but  
24 no one here could give up that much time to come here  
25 ten times a year for meetings. And so, practically, it

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1 has the effect of not being able to have people who are  
2 currently practitioners be able to do the work.

3 Thank you.

4 CHAIRMAN ALDERSON: Additional comments?

5 Yes, Dr. Zanzonico?

6 VICE CHAIRMAN ZANZONICO: I think we will  
7 recognize that the medical component of the NRC overall  
8 is a relatively small component and the concerns and  
9 knowledge of the Commission is -- that's a small portion  
10 of the overall concerns.

11 And so, if we, for whatever reason, decided  
12 it was advantageous to report directly to the  
13 Commission, we frankly would be dealing with  
14 individuals who have much less familiarity, much less  
15 knowledge, et cetera, et cetera, of all of the issues  
16 used in medical applications of byproduct materials.

17 And, I think we would spend a lot of our time  
18 explaining and re-explaining things and much less time  
19 productively in, frankly, discussing real issues.

20 So, I think given how the -- what the NRC  
21 does overall and how it's configured, I think we're far  
22 better off working through the staff than working  
23 directly with the Commission.

24 CHAIRMAN ALDERSON: Other comments on this  
25 particular question?

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1           The first two comments both favor  
2 continuing our current reporting structure. Are there  
3 any people who would speak against that particular idea?

4           Hearing none, I think we have resolved that  
5 question. We would like to continue with the current  
6 structure.

7           I believe the second question had to do with  
8 two meetings a year at the Headquarters. So, that issue  
9 is, we currently meet twice a year and is the ACMUI  
10 pleased with that? Thinks that a good frequency of  
11 meetings or feel that we should meet at some other  
12 frequency?

13           So, those who might wish to comment on that,  
14 please do so.

15           MEMBER COSTELLO: I think two is the right  
16 number.

17           CHAIRMAN ALDERSON: Mr. Costello thinks  
18 two is the right number.

19           Several people are nodding their heads in  
20 agreement at this point.

21           Dr. Zanzonico, would you like to comment?

22           VICE CHAIRMAN ZANZONICO: Our meeting is  
23 ending at 1:00, so we don't even need two full days for  
24 this meeting. So, two is enough and three we'd just be  
25 sitting around staring at each other. I think it's the

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1 right number of meetings.

2 CHAIRMAN ALDERSON: So, it seems that the  
3 consensus of the Committee is that the two meetings a  
4 year is the correct amount.

5 Am I hearing anyone speak against that?  
6 No, so we agree that two meetings a year would be fine.

7 And, remind me of what the third point was?

8 MS. HOLIDAY: Are there any other changes  
9 that you would like to see?

10 CHAIRMAN ALDERSON: Right, a more open  
11 question. Are there any other changes you would like  
12 to see?

13 So, if anyone would like to see any, please  
14 -- Dr. Ennis?

15 MEMBER ENNIS: We talked, I guess, earlier  
16 this morning about that we need to get more feedback from  
17 -- I apologize.

18 We talked this morning, there were comments  
19 that the Commission made this morning, I believe, that  
20 getting more feedback from NRC staff to ACMUI with why,  
21 what was the thinking in adopting or not adopting  
22 particular recommendations.

23 And, along those lines, and consistent with  
24 kind of the overarching theme here, is there -- ought  
25 there be a time and place for NRC to give feedback to

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1       ACMUI in general about their performance, if you will,  
2       I think we're doing a great job, but what would you like  
3       to see better or worse or strengths and weaknesses, is  
4       that something that is done? Should be done?

5               MS. HOLIDAY: So, actually, you may be  
6       familiar, Dr. Ennis, and many of the members are, every  
7       two years, staff writes a paper to the Commission which  
8       is our biennial evaluation of the Committee.

9               So, when I had you guys forms, there were  
10       questions that you had to answer about the Committee's  
11       interactions, staffs interaction with the Committee,  
12       things of that nature.

13               On the other side, staff also has to  
14       evaluate the Committee.

15               So, both the staff's position and the  
16       Committee's position or evaluation is included in that  
17       Commission paper. And, we, too, agree with you that we  
18       are very satisfied with the Committee.

19               CHAIRMAN ALDERSON: Mr. Costello?

20               MEMBER COSTELLO: I have one issue maybe to  
21       refer to the table. I believe that years ago, that  
22       there was no cardiologist on the ACMUI because back  
23       then, that was all done by nuclear medicine physicians  
24       and now we have the benefit of nuclear cardiologists.

25               We've had recent discussions, a lot of

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1 recent discussions, about alpha and beta emitters and  
2 the role of medical oncologists.

3 Were there any reason to consider including  
4 the oncologist, someone who's not a radiation  
5 oncologist, but a medical oncologist as a member of the  
6 Committee? Is that someone who can contribute to our  
7 discussion we have about the, you know, the alpha and  
8 beta emitters, is that a viewpoint that we're missing  
9 with our current membership?

10 CHAIRMAN ALDERSON: So, I think it's  
11 appropriate for the ACMUI to comment on that question  
12 before we go to Dr. Langhorst and her next question.

13 So, would people like to comment on that  
14 issue? Should we have a medical oncologist on the  
15 ACMUI?

16 Dr. Ennis?

17 MEMBER ENNIS: A lot of what we're doing is  
18 not oncological related. So, a lot of their expertise  
19 would not be particular helpful and they may not be  
20 interested. But, also not necessarily needed.

21 I think that having radiation oncologists  
22 who bring the oncology background and the radiation  
23 background really suffices, I think, unless people feel  
24 otherwise, for that knowledge.

25 And, obviously, we can always have guests

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1       come as we and just see, to bear -- give us their  
2       expertise for those certain things where needed.

3               CHAIRMAN ALDERSON:   Yes.

4               Yes, Dr. Dilsizian?

5               MEMBER DILSIZIAN:     This is nuclear  
6       cardiology, but nuclear cardiology I think they do nine  
7       million procedures per year in this country. So, it's  
8       not just a cardiology specialty, it's actually works  
9       with ionizing radiation and they have expertise in it.

10              And, wherein, oncology, ionizing radiation  
11       is really not part of their training and there's a  
12       subspecialty, certification board of ASNC which is NRC  
13       recognized. So, it's not the same.

14              CHAIRMAN ALDERSON:   Other comments to this  
15       particular question?

16              Dr. Suh and then Dr. Palestro?

17              MEMBER SUH:    So, I also concur with the two  
18       previous individuals. I think the value-added for  
19       having medical oncology as part of the ACMUI would be  
20       very limited because I think their scope and knowledge  
21       would be very limited.

22              And also, on the current Committee, it's  
23       radiation oncology. I think the oncology perspective  
24       would be reserved.

25              CHAIRMAN ALDERSON:   Dr. Palestro?

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1 MEMBER PALESTRO: I would agree with Dr.  
2 Suh and the previous comments.

3 In addition to that, I think that with the  
4 open forums that we have, there's also the opportunity  
5 for oncologists and whoever else wanted to contribute  
6 and offer information or even use radiopharmaceuticals,  
7 that's more than ample.

8 But, I would also point that we don't have  
9 any physician on the Board, nor do I think it's  
10 necessary, to have an endocrinologist on the Board to  
11 address issues of radiation pertaining matters and they  
12 even have a certification board for that.

13 CHAIRMAN ALDERSON: Would anyone else like  
14 to comment on this question?

15 Mr. Costello, I think the consensus of  
16 those commenting is that we do not need a medical  
17 oncologist on this Committee, but could call one if we  
18 needed their expertise.

19 MEMBER COSTELLO: Thank you.

20 CHAIRMAN ALDERSON: Good.

21 Are there any other comments on this  
22 question of other things the Committee -- oh, yes, Dr.  
23 Langhorst was going to make a comment.

24 MEMBER LANGHORST: Thank you very much.

25 I know one of the things that we have

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1 discussed during this kind of annual review and so on  
2 is the level of medical use or medical team support and  
3 the challenges that they face as far as funding and being  
4 able to do their jobs.

5 That's always a concern. We've already  
6 heard a few instances where they've not been able to work  
7 on things we presented to them because they don't have  
8 the resources to do so.

9 I think the extensive time of getting Part  
10 35 rulemaking through is hard to believe. And, there's  
11 no -- you saw on what Sophie went through this morning  
12 that there are things that are pending the next Part 35  
13 rulemaking.

14 Well, I'm pretty sure most of us won't even  
15 be alive when that starts.

16 So, I just want -- I'm sorry, I'm talking  
17 about the Committee here.

18 I just want to say that the funding for the  
19 medical team and, if we go back to last fall and the  
20 report on abnormal occurrences, they're all medical. I  
21 mean, there's very few, but that's not the focus that  
22 NRC puts on things.

23 So, I just wanted to make mention of that.  
24 And, we think that there should be a little more funding  
25 for the medical team.

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1 CHAIRMAN ALDERSON: Thank you.

2 Other -- yes, Dr. Ennis?

3 MEMBER ENNIS: I think that's very  
4 interested, I hadn't thought of that, but if there were  
5 more staff like to Part 35, would that -- is it realistic  
6 to think that if there had been more staff that could  
7 have been done in significantly less time?

8 MR. BOLLOCK: In regards to that, the  
9 current Part 35 rule, I don't know that that would  
10 necessarily have sped it up that much. I'm sure every,  
11 you know, every bit of resource helps.

12 And, we have a lot of our staff helped with  
13 the Part 35 working group. But, there is a lot of other  
14 factors that, internal, external factors, and changing  
15 factors over the past ten years that delayed the rule,  
16 not so much our staff resource.

17 And, I think my staff can attest that when  
18 it came down for the time for that working group to get  
19 back together and go over the comments and work on it,  
20 we put -- we shift effort and we've been able to do it  
21 fairly well. We've been flexible enough.

22 You know, but as anything, any  
23 organization, we have our challenges with resources.  
24 As just look around the room, you may see that Ashley  
25 Cockerham is no longer with us. So, right now, we're

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1 looking at filling her position. So, right now, we're  
2 one staff down.

3 Actually, for a number of months, we're two  
4 staff down because we also fill other roles in the Agency  
5 and I have another member of the medical team helping  
6 out the division. And, that just happens.

7 So, as far as more people on the -- I think  
8 as long as we are fully staffed to what we're supposed  
9 to have, we can get a lot of work done. Unfortunately,  
10 that's not always the case and we weren't able to get  
11 to the patient intervention, we weren't able to get to  
12 that in the past year with the rule and with patient  
13 release project and five or six working groups for  
14 35.1000 guidance.

15 So, but, you know, we appreciate the  
16 endorsement to get more resources. I wish, you know,  
17 I wish we had more resources. I wish I had more money  
18 for -- to get out to the -- more societies and send more  
19 staff out to the processional societies and, you know,  
20 train everybody as much as possible.

21 Unfortunately, you know, we are in an -- our  
22 current budgetary environment is we are shrinking. I  
23 think we'll still be able to do everything we need to  
24 do, I'm confident of that. But, we're not going to be  
25 able to expand on that, unfortunately, not in the near

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1 future.

2 CHAIRMAN ALDERSON: Ms. Weil?

3 MEMBER WEIL: Lest I put myself in the  
4 unenviable place of trying to make more work for the  
5 team, it would be useful for us, I think, as a Committee,  
6 to hear more reports from the working groups.

7 We have only half a day tomorrow and we  
8 would do our work better if we understood the context  
9 in which it all fits into place.

10 I know that you do stuff that we don't hear  
11 about much or certainly not every time. And, while I'm  
12 sure you don't want us meddling in everything you do,  
13 I think we could be more productive if we had the bigger  
14 picture.

15 CHAIRMAN ALDERSON: Mr. Costello?

16 MEMBER COSTELLO: Kind of in support of  
17 what Sue had to say. While the, and the reason why I  
18 think it's important is you provide as many resources  
19 as they can to the medical side of the program.

20 While medical -- the NRC program is a  
21 relative small part of what they do. If you think of  
22 the number of people in America who are actually  
23 affected by what we do, it's probably almost anyone you  
24 know knows someone who's either having a diagnostic  
25 test, having a treatment or knows someone who is.

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1                   Probably, you're talking hundreds of  
2 millions of people who are affected one way or another  
3 by what we do.

4                   And, all due respect to the other side of  
5 the house here, I think the routine impact that they may  
6 have on those hundreds of millions of people may not be  
7 so immediate as what we do here.

8                   So, I'm just tooting our own horn here.  
9 What we do here is very important. What your team does  
10 is very important. And, I rather hate the idea of  
11 having to have cuts at all.

12                   CHAIRMAN ALDERSON: Are there any other  
13 comments on this topic?

14                   Well, thank you, and I believe that  
15 terminates our discussion of new issues.

16                   And, we'll now move on to Katie Tapp, again,  
17 who will talk to us about the update on Yttrium-90  
18 Microspheres Brachytherapy Licensing Guidance.

19                   DR. TAPP: Thank you.

20                   I'm now going to discuss the update to the  
21 Yttrium-90 Microsphere Brachytherapy Licensing  
22 Guidance.

23                   What I'm going to go over today is an  
24 outline of what was changed in the Revision 9 that was  
25 recently issued. It was issued on February 12, 2016 as

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1 final.

2 In addition, I'm going to discuss the NRC  
3 and Agreement State working groups consideration for a  
4 potential future updates of what we're actually going  
5 to be looking at for the possibly Revision 10.

6 First, with the Revision 9 changes, the  
7 first change, large change to this licensing guidance,  
8 was to specifically exclude reporting of medical events  
9 that are due to static or emergent patient conditions.

10 In addition, we're also excluding events  
11 that are caused by shunting when shunting was evaluated  
12 prior to treatment in accordance with manufacturers'  
13 procedures.

14 This was a -- these both were  
15 recommendations from the ACMUI and they were  
16 incorporated into this revision.

17 With the removal of the reporting of the  
18 events with shunting, the shunting dose and activity is  
19 no longer required to be documents on the written  
20 directive.

21 Additional training or additional changes  
22 is to the training experience section where we are  
23 allowing interventional radiologists certified by the  
24 American Osteopathic Board of Radiology to be deemed  
25 status for authorized user as well as this guidance is

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1 an updated format which includes a Table of Contents and  
2 easier to use to be able to use.

3 And this is something that's going to be  
4 done for all of our Part 35.1000 licensing guidances in  
5 the future.

6 Now, I'm going to shift gears to future  
7 considerations.

8 We wanted to get that last revision out  
9 quickly because we knew those were important updates.  
10 I believe all the updates are important, but those were  
11 some that the ACMUI recommended that we get out and to  
12 review and issue as soon as we possibly could.

13 Now, we are going on and doing future  
14 considerations to look as see if there's more revisions  
15 necessary for this document.

16 I'll go over each of these considerations  
17 separately.

18 The first one is on long-lived impurities.  
19 In 2007, the NRC was notified that there were long-lived  
20 impurities in the Yttrium-90 microspheres, both in  
21 TheraSpheres and SIR-Spheres. These impurities are  
22 created by the manufacturing process themselves.

23 The working group is considering potential  
24 updates to this section because we're hearing that there  
25 might not be impurities in the TheraSpheres -- in some

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1 of the microspheres.

2 The working group is considering this  
3 update to either the section of the guidance document  
4 itself or to the IN document, the Information Notice  
5 that was issued in 2007.

6 The next consideration is to the autopsy  
7 and cremation. This was a topic that was discussed by  
8 Dr. Zanzonico at a previous ACMUI meeting.

9 The microspheres, when they're injected  
10 into a patient, they become trapped in the patient in  
11 the capillary beds. These are permanent.

12 As you know, the Yttrium-90 has a short  
13 half-life and will probably decay away. But, there is  
14 considerations to the long-lived impurities. These  
15 are something to be considered then during autopsy and  
16 cremation upon the death of a patient.

17 The working group is considering if  
18 information needs to be added to the licensing guidance  
19 to provide guidance to individuals in regards to autopsy  
20 and cremation.

21 Finally, we're considering the training  
22 and experience section. This was not open in the last  
23 revision, but we are opening this now to look at it  
24 closer.

25 In particular, to the pathways that we

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1 allow -- that we grant authorized users.

2 What we're looking at, specifically, is the  
3 two pathways that interventional radiologists become  
4 authorized users.

5 The first pathway is to receive their three  
6 clinical hands on cases under the supervision of an  
7 authorized user.

8 The second pathway is to have a  
9 representative from the manufacturer come out and to  
10 complete their three clinical hands on experience with  
11 the manufacturer there.

12 The working group is evaluating as if that  
13 manufacturer pathway is still necessary. That pathway  
14 was added because there was not as many authorized users  
15 for Yttrium-90 when it first started.

16 As we are aware that this procedure is  
17 growing, there are becoming more authorized users, so  
18 we're evaluating if that pathway is still necessary.

19 The schedule of this, the working group is  
20 working currently on looking at these considerations  
21 and if we decide that a new revision is necessary, the  
22 draft is expected here in the spring.

23 This would then allow for the ACMUI to look  
24 at the draft and provide a comment period as well as an  
25 Agreement State review. And then, we expect to issue

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1 this in the summer.

2 Leave that open to the now discussion.

3 CHAIRMAN ALDERSON: Questions on this  
4 update?

5 Dr. Langhorst?

6 MEMBER LANGHORST: I have a little more  
7 generic question. On licensing guidance, typically  
8 you don't open that up for any public comment, is that  
9 correct?

10 DR. TAPP: That is correct.

11 MEMBER LANGHORST: I feel that's a lost  
12 opportunity. I mean, it wouldn't necessarily need a  
13 long public comment period, but in making these various  
14 revisions, well, I think that would be helpful. Just  
15 my opinion.

16 CHAIRMAN ALDERSON: Is anyone else on the  
17 ACMUI like to extend that discussion with a further  
18 opinion?

19 It appears not.

20 MS. HOLIDAY: Dr. Alderson?

21 CHAIRMAN ALDERSON: Yes, Sophie?

22 MS. HOLIDAY: This is Sophie.

23 If I could, Dr. Langhorst, while we don't  
24 necessarily post licensing guidance documents for  
25 public comment, on our NRC's medical use licensee

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1 toolkit, where these licensing guidance documents are  
2 housed, there is a statement there that says, at any  
3 time, the medical community or members of the public,  
4 something along those lines, have the option or the  
5 ability to inform NRC if changes are necessary for  
6 guidance.

7 That is the reason why Revision 9 for the  
8 Y-90 guidance has been issued. And, it's also the  
9 reason why the ACMUI had a Radioactive Seed Localization  
10 Subcommittee formed because staff received comments  
11 from a few members of the public regarding the  
12 recentness or the outdatedness, rather, of the RSL  
13 guidance.

14 So, there are opportunities for that to  
15 happen at any time members of the public can do so.

16 Thank you.

17 CHAIRMAN ALDERSON: Thank you for that  
18 clarification.

19 Yes, Dr. Langhorst?

20 MEMBER LANGHORST: And, I appreciate that.  
21 But, it's a little bit different if you're saying, okay,  
22 here's what we're planning to update and if you can get  
23 some feedback on that immediately rather than trying to  
24 develop the justification for redoing a licensing  
25 guidance, that's much more onerous for an RSO to propose

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1 or others in a licensee than it is to at least have some  
2 opportunity of input, at least to see it and maybe even  
3 go through their ACMUI representative, I don't know.

4 But, it is a little frustrating in that way,  
5 from my perspective.

6 CHAIRMAN ALDERSON: Dr. Palestro?

7 MEMBER PALESTRO: I have a question, I  
8 guess, it's really directed toward the staff. Why  
9 aren't they posted for public comment?

10 DR. TAPP: Sure. These are licensing  
11 guidances for the license reviewers for evaluating  
12 modalities that are regulated under 10 CFR 35.1000.

13 35.1000 modalities are emergent  
14 technologies that we're trying -- that we use under this  
15 pathway under licensing guidance for the review because  
16 they are coming out faster than our rulemaking process  
17 can adapt the medical use.

18 In the regulations, when we do regulations,  
19 we have to have a public comment period. As you guys  
20 are well aware, once we do public comment period, that  
21 does add extra time. So, that would add extra time to  
22 these modalities when we're trying to get out guidance  
23 that can be used quickly for emerging technologies that  
24 are moving very quickly.

25 CHAIRMAN ALDERSON: Dr. Zanzonico?

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1 VICE CHAIRMAN ZANZONICO: Yes, I fully  
2 second what Sue was suggesting. I mean, these are very  
3 complicated procedures and to generate a licensing  
4 guidance for any purpose without the input of the  
5 practitioners, the people doing them, is almost certain  
6 to generate an inadequate document.

7 I mean, you really need the input of people  
8 who do these procedures. There are so many points and  
9 steps where something can go wrong and interpret or  
10 misinterpret it as a medical event.

11 I mean, as Sue said, it's a real missed  
12 opportunity not to solicit the input of the  
13 practitioners in this area.

14 CHAIRMAN ALDERSON: Dr. Langhorst?

15 MEMBER LANGHORST: I can certainly  
16 understand the hesitation to just open it up for public  
17 comment and then you get all these comments and you have  
18 address each of them.

19 What is, and I don't know how you do this  
20 because I know there's rules and requirements that don't  
21 allow you to, but to have a few people who do these things  
22 on your working group would be wonderful and would have  
23 an opportunity of bringing the medical community into  
24 the regulatory development of these things and give you  
25 that valuable perspective.

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1                   Because, you guys don't have physicians  
2                   working at Agreement States or at the NRC.

3                   And so, I don't know if there's any  
4                   possibility of being able to do that. I'm sure there  
5                   probably isn't and I'm not saying that you have to then  
6                   have an ACMUI member on there, because heaven knows, you  
7                   guys don't want to have a third meeting at all.

8                   So, that's our frustration because these  
9                   are being done in what appears to be a vacuum.

10                  CHAIRMAN ALDERSON: So, these interesting  
11                  comments are on the spectrum of communications which we  
12                  talked this morning to the Commission about.

13                  I'm not saying by making that comment that  
14                  means this is one beyond the top of the priority list,  
15                  maybe it would, maybe it wouldn't, but it's on that  
16                  communication spectrum.

17                  And, you're right, that if you had an open  
18                  website, well, there'd be a lot of comments that would  
19                  be perhaps hard to field and it might take, you know,  
20                  somebody assigned to that area.

21                  But, in this day of social media and people  
22                  communicating with each other so quickly all the time,  
23                  a number of organizations are literally developing  
24                  groups who communicate this way, as one of the things  
25                  they do to communicate with their constituencies.

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1           So, it isn't beyond the realm of the  
2       discussions we might have about communication that we  
3       might be thinking about whether the NRC might eventually  
4       want to do something on that spectrum.

5           Ouhib, you have a comment?

6           MR. OUHIB: Yes.

7           So, my question to you is, what you're going  
8       to be working on is based on what and who's feedback  
9       exactly?

10          DR. TAPP: The original revision, Revision  
11       9, was actually based on recommendations from a  
12       Subcommittee from the ACMUI which was then the ACMUI's  
13       recommendations.

14          The changes there were all ACMUI  
15       recommendations. There was no additional ones.

16          But, with the other ones, some of these are  
17       from members of the public or manufacturers have  
18       submitted comments to the NRC as well as the cremation  
19       and autopsy section was an ACMUI presentation in the  
20       past that the staff took up.

21          So, we do communicate with groups and  
22       manufacturers when we do these working groups. But, we  
23       don't have standard process to make them open for public  
24       comment in draft form. We do discuss changes and things  
25       we're looking at with practitioners.

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1 MR. OUHIB: Yes, to simplify the process,  
2 would it be beneficial to approach professional  
3 organizations, basically, and they will be able to  
4 perhaps guide you a little bit in that. And, I mean like  
5 ASTRO, AAPM and so on and so forth instead of, if you  
6 cannot go to the public, perhaps you can go to these  
7 professional organizations and they will be able to  
8 provide you some valuable feedback.

9 MS. HOLIDAY: Dr. Alderson, this is  
10 Sophie. If I could weigh in at this time?

11 CHAIRMAN ALDERSON: Please.

12 MS. HOLIDAY: I'd like to respond to Dr.  
13 Langhorst and Mr. Ouhib. I'll go with Mr. Ouhib first  
14 because I don't want to lose my memory.

15 So, as far as going to the professional  
16 societies, we still treat the professional societies as  
17 members of the public. If you are not an NRC employee,  
18 you're considered the public, or another federal  
19 agency, you're grouped under as a member of the public.

20 As far as getting feedback from the medical  
21 community and who participates on these working groups,  
22 these working groups really, in the most recent years,  
23 or for the past five, six years, maybe more than that,  
24 these 35.1000 guidance documents have been developed by  
25 a joint working group.

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1 By joint, I mean members from both NRC staff  
2 and from the Agreement States.

3 As we've heard over and over again, we have  
4 37 Agreement States which make up over 87 percent of the  
5 medical use licensees in the country.

6 So, the beauty of our working groups is that  
7 we get both NRC's perspective as well as the Agreement  
8 States' license reviewers. And, I will pick on my  
9 co-chair who's here from my Icon Working Group, Mr. Eric  
10 Perry works for the Kentucky Department for Public  
11 Health. So, he's also on my working group as a non-NRC  
12 staff person.

13 The working groups also have the ability to  
14 reach into our resources, and that is the ACMUI. The  
15 ACMUI serves as both an advisory committee, but you can  
16 also serve as medical consultants.

17 Our working groups have been able to use  
18 members on the ACMUI when we need that expertise.

19 For example, when the ViewRay Licensing  
20 Guidance was developed, my working group did reach out  
21 to Dr. Suh as a gamma stereotactic radiosurgery  
22 radiation oncologist for his expertise.

23 Likewise, the Y-90 Microspheres Working  
24 Group was able to rely on the Y-90 ACMUI Subcommittee  
25 and their recommendations. And, that Subcommittee was

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1       comprised of many of the physicians that represent the  
2       medical community that administers this procedure.

3               So, we always have that ability to  
4       incorporate the advice and the expertise and the  
5       knowledge from the medical community.

6               While we don't post it for public comment,  
7       these documents are considered pre-decisional, but  
8       because the ACMUI are NRC special government employees,  
9       that's why we are able to give them to you for your review  
10      and your comment before we move it forward.

11              Likewise, we also send the guidance in the  
12      draft form to the NRC regions where our license  
13      reviewers are, as well as the Agreement States for their  
14      review and comments as well.

15              So, not only are we getting comments from  
16      NRC staff, we're getting them from Agreement States  
17      staff and the ACMUI.

18              Thank you.

19              CHAIRMAN ALDERSON: Thank you.

20              Yes, Dr. Howe?

21              DR. HOWE: I think one of the things to  
22      remember is that we're talking about emerging  
23      technologies. And so, while some of them that you were  
24      talking about now, Yttrium microspheres have been here  
25      for a number of years.

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1           We also have others coming down the pike  
2           that have not been used yet. So, we don't have the  
3           professional societies out there with the experience  
4           for it. We don't have the medical use licensees out  
5           there with experience for it.

6           But, there's a tremendous push to get them  
7           out so they can have these. So, many cases where these  
8           emerging technologies, we have to come up with a  
9           regulatory framework. If they can get out and get into  
10          the medical community where they can be used, we try to  
11          go with the fastest route we can and that is guidance  
12          on our website versus a much more structured guidance  
13          document like the 1556 series where we really have to  
14          go through the full rulemaking kind of a process.

15          So, that's one reason you don't see things  
16          necessarily in the beginning. But, as Sophie has  
17          indicated, once we put them up on the website, and you  
18          guys do get a chance to look at it, but once we put them  
19          up on the website, they're not in concrete. They are  
20          considered now working documents that anyone can  
21          respond to and you guys can look at again.

22          So, that's one reason we try to get them up  
23          quickly. The idea that maybe we aren't all inclusive  
24          but we're trying to get them up as fast as we can so that  
25          the medical community really has access to it.

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1 CHAIRMAN ALDERSON: So, Dr. Howe, when you  
2 put guidance up on the website, is there something on  
3 the website that says if you, you being the person who's  
4 looking at the site, have comments on this guidance and  
5 then some sort of hotlink where they can click and then  
6 send a message or is it just out there for them to read?

7 DR. HOWE: We do have, I think Sophie  
8 talked about it earlier, we have a statement up on the  
9 website that they can make comments at any time and  
10 submit them to us.

11 CHAIRMAN ALDERSON: Okay.

12 DR. HOWE: I think, do we have -- Sophie,  
13 do we have like an email that we bring them to medical  
14 questions?

15 Yes, so we have a system set up so they can  
16 bring them in to us and then we constantly monitor this  
17 email system --

18 CHAIRMAN ALDERSON: That's good.

19 DR. HOWE: -- to try and answer questions.

20 CHAIRMAN ALDERSON: Good, okay.

21 Mr. Fuller?

22 MR. FULLER: Yes, just one more thought  
23 about this.

24 I'm reminded that the Yttrium-90  
25 microsphere update Revision 9 as it is that Katie's been

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1 talking to us about, I just think back, you know, what  
2 kind of prompted this.

3 You know, it was the ACMUI as the result of  
4 reviewing, and I kind of thought of this as a real  
5 success story, they ACMUI was reviewing the medical  
6 event information that Dr. Howe had reported out on and  
7 there was some good discussion about is this, you know,  
8 do we have the right medical event definition and so  
9 forth for Yttrium-90 microspheres?

10 This Committee formed a Subcommittee. Dr.  
11 Guiberteau headed that up. And, I remember when he made  
12 his presentation on what changes were needed to this  
13 guidance.

14 He said, you know, I'm not an expert so I  
15 reached out to my colleagues who are. And, he brought  
16 a very, very strong compelling argument with lots and  
17 lots of information that the staff was able to then use  
18 as our basis for why we realized that changes were  
19 appropriate.

20 And, that's what we got. I mean, we got  
21 what we felt like and this Committee felt like was  
22 excellent information from the medical community and  
23 from the actual experts in the field.

24 And so, I kind of see this as a, again, sort  
25 of a success story.

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1           We are challenged when we realize that, as  
2       regulatory agency, we have certain tools in our  
3       toolboxes to actually develop these regulatory tools or  
4       these regulatory -- or these ways in this new framework  
5       for emerging medical technologies.

6           We are very, very interested in doing this  
7       quickly and in a very agile and nimble way. We are able  
8       to update things without going into rulemaking and so  
9       forth.

10          So, adding another layer, and I know it  
11       doesn't sound like much, but if you really think about  
12       what we would have to, we would have to do everything  
13       that we're doing now and then we would add another step  
14       of publishing it for public comment, receiving those  
15       comments, forming a working group, looking at each and  
16       every one of those comments, deciding which ones were  
17       reasonable and which ones were maybe outside of the  
18       scope.

19          And then, bringing that back to the ACMUI  
20       for your review of our responses to those comments.

21          I mean, it goes against the original  
22       objective of 35.1000, in my opinion, of being very, very  
23       responsive to the needs of the medical community.

24          So, I'll just leave it at that.

25          CHAIRMAN ALDERSON: Thank you, Mr. Fuller.

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1 We have a comment from the audience.

2 MS. FAIROBENT: Yes, Lynne Fairobent with  
3 the American Association of Physicists in Medicine.

4 While I appreciate the concept of what was  
5 started with 35.1000 way back in 2002 when the rule was  
6 originally drafted, the intent was never that we would  
7 regulate forever by guidance under 35.1000.

8 Nothing has been moved out of 35.1000 and,  
9 remember, it is guidance and the Agreement States do not  
10 have to comply with it.

11 And, while I recognize it was an attempt to  
12 expeditiously address emerging technologies, I'm not so  
13 sure it's been the success that we all thought it might  
14 be.

15 And, I agree with Dr. Langhorst, I believe  
16 it was who said, with just posting of the guidance, there  
17 is not opportunity for the public input.

18 And, yes, there is a link and there is  
19 discussion, but if one looks at doing rulemaking in a  
20 timely fashion in accordance with NRC documentation, I  
21 would argue that over ten years to do a Part 35  
22 rulemaking is not timely regulation.

23 CHAIRMAN ALDERSON: Thank you, Ms.  
24 Fairobent.

25 Do we have other comments from the

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1 Committee?

2 MEMBER COSTELLO: I have a question.

3 CHAIRMAN ALDERSON: Oh, you have a  
4 question? Frank Costello has a question.

5 MEMBER COSTELLO: I appreciate what you  
6 did with the Subcommittee's recommendations. I think  
7 you're very proud of what you did, actually.

8 I do have a question, though. When you  
9 talked about shunting, you're excluding shunting when  
10 shunting's evaluated as part of treatment, I think, then  
11 you say in accordance with the manufacturer's  
12 procedure. Well, there are only two manufacturers.  
13 Right?

14 Are those, as an inspection regulator, are  
15 those procedures unambiguous and easy to come by?

16 DR. TAPP: They are. The procedures do  
17 have -- the manufacturers do have their procedures on  
18 their website. So, if you're talking about like  
19 package inserts, they are publically available  
20 documents. They describe the shunting evaluation  
21 procedures that they recommend that be followed.

22 So, inspectors can see those on publically  
23 available websites and we can provide those, too.

24 MEMBER COSTELLO: So, they're expecting  
25 them, the licensees, to follow what the manufacturers

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1 recommend for evaluating shunting to lung or whatever.

2 And, if they're not doing that, if they're  
3 not doing that and they have shunting to the lung or they  
4 have shunting to the GI tract, then that might be a  
5 problem.

6 DR. TAPP: Yes. And, the procedures are  
7 generalized for this procedure for the pre-treatment  
8 shunting evaluation. I think we've heard of it before  
9 is the pre-treatment where they inject the tech-99m MAA  
10 and evaluate that by imaging or the angiograms with the  
11 contrast.

12 They are in both manufacturer procedures,  
13 they are only about a paragraph long discussing that.

14 MEMBER COSTELLO: But, there is something  
15 there?

16 DR. TAPP: Yes.

17 MEMBER COSTELLO: That if anything  
18 happens, I can go on the manufacturer's website and look  
19 up that procedure and then say, Mr. Licensee, did you  
20 follow this?

21 DR. TAPP: Yes.

22 MEMBER COSTELLO: Okay, thank you.

23 CHAIRMAN ALDERSON: Do have other  
24 questions or comments?

25 VICE CHAIRMAN ZANZONICO: I just have a

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1 couple of specific questions that I might be  
2 misunderstanding some things.

3 But, we said training and experience  
4 allowed interventional radiologists certified, but I  
5 mean that's in addition to allow training and experience  
6 for ABR certified individuals who have the AU  
7 designation. This is in addition to that?

8 DR. TAPP: This is in addition to what was  
9 there before for ABR. It is interventional  
10 radiologists subspecialty as well.

11 VICE CHAIRMAN ZANZONICO: And, further on  
12 when you discussed training and experience, you said  
13 current license guidance, et cetera, et cetera,  
14 provided by either an AU Pathway 1 or the manufacturer.

15 But, isn't the manufacturer -- does that  
16 mean a non-AU who received -- I mean, because an 'or'  
17 implies that a non-AU who receives a manufacturer  
18 training could be effectively an AU for this procedure.  
19 Is that the intent?

20 DR. TAPP: This is the current guidance  
21 that's out there right now is it is an AU or a  
22 manufacturer representative. It is not specified that  
23 that manufacturer representative had to be an AU in the  
24 current guidance.

25 That is what we are looking at evaluating.

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1 VICE CHAIRMAN ZANZONICO: Somehow that  
2 doesn't seem right.

3 MEMBER COSTELLO: I remember that the  
4 manufacturer's representative doesn't -- isn't even a  
5 physician.

6 DR. TAPP: That is correct. That is how  
7 it's currently --

8 VICE CHAIRMAN ZANZONICO: So that means a  
9 non-AU who went through the manufacturer's training  
10 could administer these?

11 DR. TAPP: They do have to have training  
12 beforehand and they do have to, for this pathway, they  
13 do have to be an interventional radiologist in training  
14 or certified. But, yes, that is correct, the three  
15 cases would be under supervision from a manufacturer  
16 representative, it is not specified they have to be a  
17 physician.

18 VICE CHAIRMAN ZANZONICO: Something just  
19 doesn't seem right.

20 MEMBER COSTELLO: In fact, they're often  
21 not a physician, they're an evaluator.

22 DR. TAPP: Yes. That's what --

23 MEMBER COSTELLO: I mean, know who these  
24 people are and they're often not physicians.

25 DR. TAPP: This is why the working group

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1 has received comments and we are evaluating this pathway  
2 to see if it's still necessary because there are a lot  
3 more authorized users.

4 This is something the staff is evaluating.  
5 It was not yet a recommendation from the ACMUI.

6 CHAIRMAN ALDERSON: Dr. Metter?

7 MEMBER METTER: I have a question.

8 So, let's say you have an authorized user  
9 who's -- sorry.

10 So, let's say you have a nuclear medicine  
11 physician who's an authorized user for Y-90  
12 microspheres and you have an interventional radiologist  
13 who does the arteriogram and then administers the Y-90  
14 but is not an authorized user, but it's under the  
15 licensee of the nuclear medicine physician. Can that  
16 interventional radiologist be the prompter for the  
17 three therapies for their training?

18 DR. TAPP: They're not an AU?

19 MEMBER METTER: Correct.

20 DR. TAPP: Under current guidance, if  
21 they're following this guidance, that does not sound  
22 like they could be the AU doing -- or they could be the  
23 supervisor for these three cases.

24 MEMBER METTER: Okay.

25 DR. TAPP: It would have be a nuclear

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1 medicine AU.

2 MEMBER METTER: Okay, thank you.

3 CHAIRMAN ALDERSON: Are there other  
4 questions about this report?

5 Hearing none, Mr. Bollock, I think that  
6 we've reached the end of today's sessions. Did you have  
7 anything you'd like to say in closing?

8 MR. BOLLOCK: No, just thank you all and I  
9 guess Sophie has something before we all leave.

10 CHAIRMAN ALDERSON: We have a couple of  
11 logistical issues, too, that I'd like to --

12 MS. HOLIDAY: A couple of logistical  
13 issues.

14 CHAIRMAN ALDERSON: -- bring out, but  
15 they're not, you know -- pardon me.

16 MS. HOLIDAY: I'd just like to remind  
17 everybody, I know it's a little bit confusing on the  
18 agenda, we are returning for our open session at 8:00  
19 a.m. tomorrow, not 8:30 a.m. So, I'm asking staff and  
20 ACMUI members to arrive by 7:45 so we can start on time.

21 Make sure to take your name badges off as  
22 you don't run off with them and forget them tomorrow.

23 CHAIRMAN ALDERSON: So, we begin at 8:00  
24 a.m. tomorrow?

25 MS. HOLIDAY: 8:00 a.m. tomorrow.

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1 CHAIRMAN ALDERSON: Yes.

2 And, so I just -- I turned the microphone  
3 off because we're --

4 So, just a couple of issues that I -- the  
5 more serious one that I want to bring up is I'm  
6 personally very interested in and hope all of you are,  
7 too, in what Ms. Houseman's going to, you know, talk to  
8 us about tomorrow.

9 And, as Ms. Houseman -- and she's worked  
10 hard in preparing some slides. It should be a great  
11 discussion.

12 Now, when -- so, I'm a little concerned that  
13 it's at 1:00 to 2:00 p.m. Has that been moved up?

14 MS. HOLIDAY: It should be 12:00 to 1:00.

15 CHAIRMAN ALDERSON: Good, it is 12:00 to  
16 1:00. Pat and I were both confused about it, but it's  
17 12:00 to 1:00, that's very good because I think a lot  
18 of people, not me in this case, but a lot of people plan  
19 to get away and their air transportation on the basis  
20 of a 1:00 p.m. close or approximately that.

21 And, this is an important session. This may  
22 well engender a number of questions and discussion.  
23 So, I just wanted to make sure, so we're starting that  
24 at noon, that's excellent.

25 MS. HOLIDAY: Yes, I think you were looking

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1 at an old version.

2 CHAIRMAN ALDERSON: Well, it may be,  
3 there's several versions laying around here on the  
4 table.

5 The other issue is, you know, very  
6 logistical and more social than anything else and that  
7 is, that usually, this evening after we part, we usually  
8 congregate downstairs at the hotel for an hour or so.

9 And, if people -- pardon me? Or more, or  
10 many more, so, for those, so it's now ten minutes to  
11 five, so what do you say, 5:30 downstairs? Does that  
12 seem reasonable?

13 So, to get there and grab a big table and  
14 save some chairs and then we'll all sort of gather  
15 around.

16 Okay, well, that's great.

17 Thanks everybody, I think it's been a great  
18 day.

19 (Whereupon, the above-entitled matter went  
20 off the record at 4:49 p.m.)

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