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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:

SCOTT W. MOORE, Acting Director, Office of
Nuclear Material Safety and Safeguards

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

GRETCHEN RIVERA-CAPELLA, NMSS/MSTR/MSEBKATIE

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

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MEMBERS OF THE PUBLIC PRESENT:

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

2 (1:01 p.m.)

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

7 MR. BOLLOCK: Thank you, Dr. Alderson.

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

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

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

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

24 This meeting is being transcribed by the
25 NRC and it may also be transcribed or recorded by

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1 others.

2 The meeting was announced in the February
3 4, 2016 Edition of the Federal Register, Volume 81,
4 Page 6056 through 6057.

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

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

11 The NRC solicits the views of the
12 Committee and validates their opinions.

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

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

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

21 Dr. Philip Alderson?

22 CHAIRMAN ALDERSON: Here.

23 MR. BOLLOCK: Dr. Pat Zanzonico?

24 VIEC CHAIRMAN ZANZONICO: Here.

25 MR. BOLLOCK: Mr. Frank Costello?

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1 MEMBER COSTELLO: Here.

2 MR. BOLLOCK: Dr. Vasken Dilsizian?

3 MEMBER DILSIZIAN: Here.

4 MR. BOLLOCK: Dr. Ronald Ennis?

5 MEMBER ENNIS: Here.

6 MR. BOLLOCK: Dr. Sue Langhorst?

7 MEMBER LANGHORST: Here.

8 MR. BOLLOCK: Mr. Steve Mattmuller?

9 MEMBER MATTMULLER: Here.

10 MR. BOLLOCK: Dr. Darlene Metter?

11 MEMBER METTER: Here.

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

13 MEMBER O'HARA: Here.

14 MR. BOLLOCK: Dr. Christopher Palestro?

15 MEMBER PALESTRO: Here.

16 MR. BOLLOCK: Dr. John Suh?

17 MEMBER SUH: Suh, Yes.

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

19 apologize.

20 And, Ms. Laura Weil?

21 MEMBER WEIL: Here.

22 MR. BOLLOCK: Thank you.

23 I confirm that we do have a quorum.

24 Also at the table, we have Mr. Zoubir

25 Ouhib. Mr. Ouhib has been selected as the ACMUI

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1 Therapy Medical Physicist and is pending screening
2 clearance, but may participate in the meeting today.
3 However, at this time, he does not have voting rights.

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

9 I would also like to add that this meeting
10 is being webcast, so other individuals may be watching
11 online.

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

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

20 Dr. Alderson, at his option, may
21 entertain comments or questions from members of the
22 public who are participating with us today.

23 Comments and questions are usually
24 addressed by the Committee near the end of the
25 presentation after the Committee has fully discussed

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1 the topic.

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

4 I would also like to add that handouts
5 and agenda for this meeting are available on the NRC's
6 public website.

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

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

16 MR. COLLINS: Thank you, Doug.

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

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

23 Other organizational changes within the
24 office of NMSS that you may be aware of is that Scott
25 Moore is currently the Acting Office Director pending

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1 the arrival of Mr. Mark Dapas in July of this year.

2 And also, Joel Munday is the Acting
3 Deputy Office Director and, when Mr. Dapas arrives,
4 Scott Moore will revert back to being the permanent
5 Deputy Office Director.

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

11 And, tomorrow, we'll hear a special
12 presentation from Scott Moore, as well as some
13 farewell remarks from Mr. Mattmuller.

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

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

24 Those were PRMs 20-28, 20-29 and 20-30
25 which dealt with linear no threshold model and

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1 standards for protection against radiation.

2 And, the Committee's report has been
3 provided to a working group for further review and
4 evaluation.

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

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

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

25 And, as a result of that Subcommittee's

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1 hard work in addressing these issues, a new
2 Subcommittee was formed to review and evaluate
3 training and experience requirements across all
4 modalities.

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

10 And, later on today, you'll hear a
11 presentation from Dr. Tapp regarding that guidance
12 and addition areas under consideration.

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

16 And also tomorrow, you'll hear from
17 Sophie Holiday and Mr. Perry from Kentucky regarding
18 draft licensing guidance for the Leksell Gamma Knife
19 Perfexion and Leksell Gamma Knife Icon.

20 And, with that, I'll turn this over to
21 Sophie for the next item in the agenda which is a
22 review of past ACMUI recommendations and NRC
23 responses to those recommendations.

24 Thank you.

25 MS. HOLIDAY: Good afternoon. I hope

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1 everyone is well after having a nice lunch.

2 Okay, so this is a very familiar piece of
3 our meeting. At every meeting we go over old business
4 which is recapping all of the recommendations and
5 actions that were put forth by the Committee and/or
6 staff and noting any changes.

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

13 So, we will now move on --

14 MEMBER LANGHORST: May I ask a question
15 on this?

16 MS. HOLIDAY: Yes, ma'am.

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

21 ``NRC staff should revise the regulation
22 so that Board Certified individuals who were
23 certified prior to the effective date of recognition
24 or were certified by previous recognized Boards
25 listed in Subpart J of the previous editions of Part

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1 35 are grandfathered.''

2 I just want to let you know of that long
3 listing recommendation.

4 MS. HOLIDAY: Thank you.

5 Okay, so we will move on to 2008. So,
6 again, all the items in 2008 are also included in the
7 current Part 35 rulemaking.

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

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

16 So, then we come to 2011, and the majority
17 of these are also included in the current Part 35
18 rulemaking.

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

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1 Item 6 is the indefinite open action item
2 from the Committee to review its reporting structure
3 on an annual basis, which you will hear from me later
4 on this afternoon.

5 Item 11 has to deal with ACMUI's
6 endorsement of ASTRO's approach for permanent implant
7 brachytherapy. And, this is pending, well, open but
8 pending at the current time.

9 Item 13 has to deal with the written
10 attestation which is also included in the current
11 Part 35 rulemaking.

12 The same goes for Items 14 and 15.

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

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

21 However, I will note that, while this
22 item is listed on the 2012 chart, I would like to ask
23 the Committee's permission to close the 2012 chart
24 since this is a reiteration of the 2011
25 recommendation.

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1 CHAIRMAN ALDERSON: You'd like to do that
2 now?

3 MS. HOLIDAY: Yes.

4 CHAIRMAN ALDERSON: Okay.

5 You've heard that Sophie would like the
6 Committee to think about or are there people who would
7 like to discuss that item?

8 Seeing no discussion, would someone like
9 to move approval?

10 MEMBER LANGHORST: I'll move approval.

11 CHAIRMAN ALDERSON: Is there a second?

12 MEMBER MATTMULLER: Second.

13 CHAIRMAN ALDERSON: Okay. Further
14 discussion?

15 All in favor?

16 (Chorus of aye.)

17 CHAIRMAN ALDERSON: Opposed?

18 Abstentions?

19 Pass as unanimous.

20 MS. HOLIDAY: Thank you.

21 Okay, this brings us to 2013. As many
22 of the members on the Committee are aware, in 2013,
23 the ACMUI was provided with the draft proposed Part
24 35 rule and this is -- we spent two public
25 teleconferences on March 5th and March 12th of 2013

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1 receiving the Committee's comments in response to
2 that draft proposed rule.

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

5 Item 21 has to deal with the
6 germanium/gallium-68 generator where the ACMUI
7 recommended that NRC provide regulatory relief. As
8 we've heard from Mr. Mattmuller this morning during
9 the Commission meeting and you will also hear from
10 Dr. Daibes on tomorrow after -- tomorrow morning, I'm
11 sorry, with an update on staff's efforts related to
12 the decommissioning funding plan requirements for the
13 germanium/gallium-68 generator.

14 Item 25 had to deal with the Committee's
15 recommendation to re-establish the Rulemaking
16 Subcommittee to review and address the staff's
17 response to the draft proposed Part 35 rulemaking.

18 I would like to put forth a request to
19 close this item since the Rulemaking Subcommittee
20 presented its report in January of this year and the
21 Committee endorsed that report and that is now with
22 staff for review.

23 CHAIRMAN ALDERSON: All right, we'll now
24 consider that request.

25 Further discussion of this item?

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1 Seeing none, a motion to approve?

2 MEMBER LANGHORST: So moved.

3 CHAIRMAN ALDERSON: Is there a second?

4 There is.

5 All in favor?

6 (Chorus of aye.)

7 CHAIRMAN ALDERSON: Any opposed?

8 Any abstaining?

9 That's passed unanimously.

10 MS. HOLIDAY: Thank you.

11 MEMBER LANGHORST: May I --

12 CHAIRMAN ALDERSON: Yes?

13 MEMBER LANGHORST: Sue Langhorst.

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

19 Thank you.

20 CHAIRMAN ALDERSON: So noted.

21 MS. HOLIDAY: Thank you.

22 Okay, so then we will move on to the 2014
23 chart.

24 And, the first item which is Item 6 also
25 has to deal with the same germanium/gallium-68 topic.

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1 You'll, again, hear from Dr. Daibes tomorrow on that
2 topic.

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

6 I have noted this in red because, as this
7 was discussed during the October meeting, the
8 Committee's recommendations were included in the then
9 draft revision of that guidance which was endorsed
10 during the October 2015 meeting.

11 You will hear a presentation from Dr.
12 Katie Tapp later on this afternoon in regards to that
13 topic.

14 Are there any comments, questions or
15 concerns with my closing these three items?

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

18 Hearing none, a motion to approve the
19 request?

20 MEMBER LANGHORST: So moved.

21 CHAIRMAN ALDERSON: And is there a
22 second?

23 All those in favor?

24 (Chorus of aye.)

25 CHAIRMAN ALDERSON: Opposed or

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1 abstaining?

2 None, thank you.

3 MS. HOLIDAY: Thank you.

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

8 During the March meeting, and also
9 reiterated during the fall 2015 meeting, the ACMUI
10 had recommendations related to that normal occurrence
11 criteria.

12 So, this item is still listed as open as
13 we are waiting on staff's review and evaluation to
14 revise the NRC's abnormal occurrence criteria policy
15 statement.

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

20 I will tie this also to, and I am jumping
21 just a bit ahead, I will tie this to the
22 teleconference that took place just last week. So,
23 both items are related.

24 So, I am requesting to close Item 9, as
25 that Subcommittee completed their work in the October

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1 2015 meeting related to evaluating whether or not
2 those 700 hours was the sole contributing factor with
3 placing hardship on the patient community.

4 CHAIRMAN ALDERSON: All right, same as
5 the past few, is there further discussion on that
6 particular item?

7 Seeing none, a motion to approve its
8 closing?

9 There's a -- yes, there is a motion and
10 a second.

11 All right, all in favor?

12 (Chorus of aye.)

13 CHAIRMAN ALDERSON: Opposed or
14 abstaining?

15 None.

16 MS. HOLIDAY: Thank you.

17 CHAIRMAN ALDERSON: Thank you.

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

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

25 At this time, I would like to inform you

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1 all that, based on the prioritization of workload,
2 including patient release and the Part 35 rulemaking,
3 we've not been able to address the patient
4 intervention Subcommittee report. But, we will
5 address that as soon as staff resources are available.

6 CHAIRMAN ALDERSON: Thank you.

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

9 CHAIRMAN ALDERSON: There appear to be
10 none.

11 MS. HOLIDAY: Great, thank you.

12 I'm sorry, this also includes Item 15 as
13 well.

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

19 CHAIRMAN ALDERSON: All right, is there
20 discussion of this?

21 Just for the benefit of people who might
22 be listening from the general public, you will hear
23 later that we have, in fact, formed a standing
24 Subcommittee to look at training and experience
25 requirements across the broad spectrum, and that

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1 Committee will begin its work shortly after this
2 meeting.

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

5 That having been said, questions or
6 comments about Sophie's motion to close this
7 particular item?

8 Seeing none, a motion to approve?

9 And a second?

10 All in favor?

11 (Chorus of aye.)

12 CHAIRMAN ALDERSON: Opposed or
13 abstaining?

14 It's unanimous.

15 Thank you.

16 MS. HOLIDAY: Thank you.

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

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

23 Items 18 and 19, I have left open because
24 my working group revising that guidance is still
25 working on that. I am hoping that we will be able

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1 to provide the Committee with draft guidance early
2 summertime for your 60-day review and comment period.

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

5 CHAIRMAN ALDERSON: There are none.

6 MS. HOLIDAY: Great.

7 Item 20 is, again, when the ACMUI
8 endorsed the Y-90 Microspheres Subcommittee report.
9 So, I have this closed. So, I will be removing this
10 as well.

11 CHAIRMAN ALDERSON: Very good.

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

15 Okay, item 22 has to deal with, again,
16 the AO Criteria Subcommittee report. As I stated
17 before, NRC staff is currently reviewing and
18 evaluating the Subcommittee's report as well as all
19 of the other comments that were received pertaining
20 to the revisions of the NRC's Abnormal Occurrence
21 Criteria Policy Statement.

22 So, when staff has completed its review,
23 as was stated in the Commission meeting this morning,
24 the Committee will receive a memorandum explaining
25 whether or not or why we did accept and did not accept

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1 some of the Committee's recommendations.

2 Item 23, the ACMUI endorsed the NUREG-
3 1556, Volume 9 Subcommittee report. I have left this
4 item open, because, as you are aware, the NUREG-1556,
5 Volume 9 has not been finalized yet.

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

8 And then, the last item for 2015, a
9 Subcommittee was created to propose the appropriate
10 criteria for medical event reporting or events other
11 than permanent implant brachytherapy.

12 We will hear from that Subcommittee after
13 our break this afternoon.

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

18 Again, all of these items are open as
19 staff is reviewing and evaluating the comments from
20 both the Committee and the Organization of Agreement
21 States.

22 Are there any comments or questions
23 related to these items?

24 CHAIRMAN ALDERSON: There is, yes.

25 Sue Langhorst?

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

8 CHAIRMAN ALDERSON: But, I think that
9 this is a very important topic considering that we're
10 going to be discussing in detail training and
11 experience. So, this will almost surely come up for
12 some reconsideration.

13 MS. HOLIDAY: Absolutely.

14 CHAIRMAN ALDERSON: Thank you, Dr.
15 Langhorst.

16 MEMBER LANGHORST: Mostly for the new
17 members, I wanted to let you know how longstanding
18 this recommendation has been.

19 CHAIRMAN ALDERSON: Right, thank you.

20 MS. HOLIDAY: Thank you.

21 And then, the last item that I have that
22 is not listed on here because it didn't quite make
23 the print cutoff time is, again, the Committee had a
24 teleconference last Thursday on March 10th to discuss
25 the training and experience for authorized users of

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1 alpha, beta and gamma emitters under 10 CFR 35.390.

2 The Committee unanimously endorsed or
3 approved the Subcommittee's report.

4 The report contained recommendations that
5 included maintaining the current 700 hours for
6 training and experience and also to establish a
7 standing Subcommittee that will review the training
8 and experience requirements across all modalities
9 under 10 CFR Part 35.

10 Do you all accept my addition to the
11 table?

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

14 There is a hand from Dr. Langhorst.

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

19 MS. HOLIDAY: Sure.

20 MEMBER LANGHORST: In reading it first
21 when we were making our review, it sounded like you
22 didn't have to send any paper in. And so, what it
23 really means is you don't have to submit additional
24 copies of your license application or license
25 amendment.

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1 So, I would just suggest that it might
2 say submit additional copies because you have to
3 submit something.

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

7 MEMBER LANGHORST: Yes.

8 ``The Committee endorsed the elimination
9 of the requirement to submit additional copies of NRC
10 Form 313, Application for a Materials License or a
11 letter containing information required by NRC Form
12 313 when applying for a license, an amendment or a
13 renewal.''

14 CHAIRMAN ALDERSON: Very good.

15 All right, so that's your proposal,
16 that's your motion, is there a second?

17 There's a second.

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

20 No question, a second?

21 All in favor of adding this additional
22 word say aye?

23 (Chorus of aye.)

24 CHAIRMAN ALDERSON: Opposed or
25 abstaining?

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1 None, it's passed unanimously.

2 MS. HOLIDAY: Thank you.

3 I will note that, while I'll make the
4 change on this chart, these are items that were
5 explicitly called out from the report that has been
6 finalized, which will be included in the Commission
7 paper as the Committee's unfettered opinions or
8 unfettered votes.

9 But, members of that rulemaking working
10 group are in this room so they are aware of your
11 recommendation.

12 MEMBER LANGHORST: Thank you very much.

13 Sue Langhorst.

14 Thank you very much for that.

15 I just -- because this is just such a
16 standalone thing, I thought it would be helpful to
17 include that word additional because it made no sense
18 to me as an RSO.

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

21 MS. HOLIDAY: Absolutely.

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

25 MS. HOLIDAY: Absolutely.

1 MEMBER LANGHORST: That's all it states.

2 So, thank you.

3 MS. HOLIDAY: You're welcome.

4 Okay, this concludes my portion of old
5 business. Are there any questions, comments or
6 concerns related to?

7 MEMBER PALESTRO: I have one question.

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

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

14 CHAIRMAN ALDERSON: Pat is going to
15 mention it in a few minutes.

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

17 CHAIRMAN ALDERSON: And, that was Dr.
18 Palestro speaking.

19 MS. HOLIDAY: Thank you.

20 CHAIRMAN ALDERSON: Any other
21 amendments, discussion about Sophie Holiday's report?

22 Hearing none, Sophie, thank you very
23 much.

24 MS. HOLIDAY: Thank you.

25 CHAIRMAN ALDERSON: Okay, so this brings

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1 us to the part of this particular session known as
2 Open Forum.

3 And so, at this particular time, we will
4 open the floor to discussions of medical topics of
5 interest.

6 We'll begin with discussions among the
7 ACMUI. It is possible, given the interest from the
8 audience that we may, in fact, invite them to make
9 comments after we've had sufficient time to discuss
10 these items on our own.

11 And, this is the place where I will
12 mentioned very briefly that this morning, we did meet
13 with the Commission, the Commissioners, and we
14 discussed -- Dr. Palestro led the discussion on
15 training and experience issues.

16 We indicated to the Commissioners at that
17 time, as Mr. Collins actually noted earlier, briefly
18 in his comments, that we had formed a standing
19 Subcommittee to address training and experience
20 requirements.

21 And, by standing, and we have that not ad
22 hoc, but standing Committee, we will presume that
23 this Committee will be functioning at each and every
24 meeting as we go forward.

25 And as things may change in the medical

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1 community relating to what might be effective and
2 appropriate training and experience for a particular
3 issue, that Committee will already be there and will
4 be charged with reviewing those things and bringing
5 them to our attention and to the attention of the
6 NRC.

7 So, that Subcommittee, standing
8 Subcommittee, has been formed. Chris Palestro will
9 be the Chair. Sue Langhorst is a member of that
10 Committee. John Suh is a member of that Committee.
11 Laura Weil is a member of that Committee. And,
12 Darlene Metter is a member of that Committee.

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

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

19 The floor is open.

20 Yes, Dr. Ennis?

21 MEMBER ENNIS: I've been hearing about
22 efforts of other part of the federal government who
23 are greatly concerned about security related to the
24 isotopes and the possible previous changes to their
25 security requirements, eventual search requirements

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1 for a variety of aspects.

2 And --

3 CHAIRMAN ALDERSON: Yes, please start
4 over in case the people listening from outside
5 couldn't hear you --

6 MEMBER ENNIS: Absolutely.

7 CHAIRMAN ALDERSON: -- as you made these
8 comments.

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

14 A lot of proposals I've heard flying
15 around and wanted to know from my colleagues whether
16 we think that this is something that we ought to
17 evaluate and weigh in on?

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

21 I think that at some point in this
22 discussion, we might want to ask our NRC colleagues
23 if they are aware of these issues and, if they are,
24 they might expand upon the knowledge just to put to
25 the table as to what might be going on.

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1 But, Dr. Langhorst?

2 MEMBER LANGHORST: I have something to
3 address there.

4 CHAIRMAN ALDERSON: Very good.

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

8 And, going through a lot questions and
9 answers, or asking questions of licensees, in
10 particular.

11 For those of you who may not know, this
12 rule, Part 37, has been in effect since March 19,
13 2014 -- '15 -- '14. No, it was published then.

14 UNKNOWN PARTICIPANT: In '13 -- 2013, it
15 became effective.

16 MEMBER LANGHORST: Right, but you didn't
17 have to implement it until a year later, wasn't it
18 2014 for NRC licensees?

19 Agreement States had up to three years,
20 so those Agreement States who hadn't already adopted
21 this security requirement are due to have it in place
22 by March 19, this week. Okay?

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

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1 But, really, the question and answer part
2 of it, I think I would encourage licensees to submit
3 their answers to NRC on what it means in a medical
4 environment.

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

8 CHAIRMAN ALDERSON: Thank you, Dr.
9 Langhorst.

10 MEMBER LANGHORST: Thank you.

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

14 MEMBER COSTELLO: I do.

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

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

20 I would say that, while some Agreement
21 States adopted it early, I think most Agreement States
22 are adopting it just in time.

23 We have no running time on this. I'm
24 just starting inspecting Part 37 this coming week for
25 the first time.

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1 But, I think, though, that for the most
2 part, Part 37 does not impose, I think it only imposes
3 administrative changes on top of what was there from
4 the orders.

5 Now, there are administrative changes and
6 there's a fair number of them, but I don't think the
7 actual security sources are very much different than
8 the orders.

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

12 I think that's been true with the other
13 Agreement States as well.

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

19 CHAIRMAN ALDERSON: So, for those who
20 might know exactly what that means, just could you
21 give us one --

22 MEMBER COSTELLO: Yes.

23 CHAIRMAN ALDERSON: -- example of an
24 administrative change that this particular
25 requirement would lead to?

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1 MEMBER COSTELLO: Sure.

2 Right now, there wasn't a requirement
3 before to have periodic training and now, there's a
4 requirement for periodic training.

5 There's a requirement for periodic
6 audits, both of the access program or the security
7 program itself.

8 There's a requirement to have a security
9 plan and written security procedures.

10 These are what I think of as being
11 administrative changes.

12 But, the locks and the alarms and such
13 will be there.

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

18 And, I think the NRC, in their
19 inspections, have been finding for the violations
20 they've had over the last couple of years, they've
21 largely been administrative.

22 CHAIRMAN ALDERSON: All right.

23 Would the NRC -- Dr. Langhorst has her
24 hand up again.

25 MEMBER LANGHORST: I'm sorry, I wanted

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1 to make one mention about this Federal Register, the
2 comments are due by May 13 this year. So, I just
3 wanted to make mention of that. I forgot to do that
4 before.

5 CHAIRMAN ALDERSON: Good, thank you.

6 Dr. Collins?

7 MR. COLLINS: This is Daniel Collins.

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

15 So, it's looking at the effectiveness of
16 the rule, not specifically the effectiveness of the
17 NRC's implementation or the Agreement States'
18 implementation of the rule.

19 CHAIRMAN ALDERSON: Okay.

20 Yes, Mr. Costello?

21 MEMBER COSTELLO: This is for Dan.

22 I mean, I know that you're here now, you
23 just came from Region I; can you confirm that, for
24 the most part, the violations that the NRC's been
25 finding for the last couple of years, I think have

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1 largely been administrative in contact nature?

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

11 So, yes, largely administrative in
12 nature.

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

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

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

24 So, I would just like to point that out
25 as an observation so that we didn't lose track of

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1 that question.

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

4 That was Mike Fuller of the NRC.

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

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

15 CHAIRMAN ALDERSON: Yes, that's good.

16 MEMBER ENNIS: Some of the talk that
17 would be even to go to the point of banning that.
18 There are alternative technologies that are more
19 expensive. So, 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
24 that are included in the category being discussed.

25 And, again, regulation proposals that

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1 I've heard include outright banning, include
2 increasing the security requirements that would be
3 excessively -- well, extremely expensive and might
4 make institutions decide they couldn't afford to
5 offer those services to have those types of equipment
6 anymore or requirements of insurance policies, less
7 something happen to your -- and that you would held
8 accountable to a hospital that might make the hospital
9 decide that that cost was too 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
14 of that meeting and there was a presentation on that
15 exact topic. I'll point you back to that
16 presentation where groups are -- and NRC is part of
17 that effort to look at having government licensees
18 like I guess VA hospitals and so on look at how they
19 can replace those types of 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
23 the members of the public who's in the audience here
24 who 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
6 to look at this. There is currently a draft report
7 being coordinated through the Department of Homeland
8 Security and the National Nuclear Security
9 Administration that has many participants on it.

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

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

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

24 The language from Senator Carper's bill
25 is very similar. It -- right now, we do not believe

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1 it's going to move. We are watching it very closely.

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

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

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

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

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

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1 CHAIRMAN ALDERSON: Thank you for your
2 comment, Ms. Fairobent.

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

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

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

10 Dr. Ennis, anything final to say?

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

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

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

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

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1 So, but, I don't know that this
2 necessarily would require you to, you know, start
3 some separate effort on that.

4 CHAIRMAN ALDERSON: All right.

5 Any other questions or comments on this
6 issue?

7 Dr. Langhorst?

8 MEMBER LANGHORST: I don't have any.

9 CHAIRMAN ALDERSON: Oh, on another issue,
10 Dr. Langhorst?

11 MEMBER LANGHORST: If we're ready to move
12 on.

13 CHAIRMAN ALDERSON: I think we are ready
14 to move on.

15 MEMBER LANGHORST: Okay.

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

18 CHAIRMAN ALDERSON: Sophie, would you
19 comment on that, please?

20 MS. HOLIDAY: Yes.

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

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1 So, at this time, that's all I can really
2 say. They're working very diligently to address all
3 comments received.

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

6 CHAIRMAN ALDERSON: Thanks very much.

7 MEMBER LANGHORST: Thank you.

8 CHAIRMAN ALDERSON: Any other questions
9 or comments from people here at the meeting?

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

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

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

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

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

24 And, each year, there are about 150,000
25 therapeutic procedures.

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1 Each year, I present you with the medical
2 events that happened in the last fiscal year, so
3 fiscal year 2015 and I give you a perspective of what
4 happened in the previous year.

5 As you can see, there are a few more
6 medical events in 2015. One thing that you should
7 keep in mind is that 57 medical events is not a large
8 number.

9 We are talking about -- we've got three
10 diagnostic medical events. The diagnostic medical
11 events are probably out of millions of diagnostic
12 procedures.

13 The others are therapeutic and there are
14 the denominator -- the cumulative denominator is
15 probably a couple hundred thousand for that.

16 So, these are not large numbers.

17 The increases happened in diagnostic.
18 They happened in therapeutic, unsealed material,
19 happened in manual brachytherapy, also in the HDR
20 Gamma Knife arena and, we actually had a few less
21 emerging technology.

22 So, let's look at the diagnostic. I did
23 this by modality, so it's a 35.200, imaging and
24 localization.

25 We had three medical events. We had two

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1 technetium medical events. In both cases, the multi-
2 dose vial was injected into the patient instead of
3 the procedure that they were supposed to receive.

4 In some cases, it is because they
5 confused the multi-dose vial with the dose they were
6 supposed to give. One suggestion was to use color
7 coding. We don't encourage color coding because you
8 put the wrong color on and you think you're safe and
9 you're not.

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

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

15 The next diagnostic one was sodium
16 iodine-123. In this case, they were supposed to give
17 300 microcuries. They gave 3.69 millicuries and the
18 thyroid was exposed to over 50 rad.

19 The physician asked for the correct
20 dosage, but because they were going to scheduling
21 this patient during a therapy time, the technologist
22 ordered the wrong dosage.

23 They contributed it to be part of the
24 scheduling and that they would normally have
25 associated the numbers with diagnostic, but they

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1 didn't pick up on it because they were in therapy
2 time slots.

3 So, they're going to go back and make
4 sure all the diagnostic procedures are done in the
5 diagnostic time slots.

6 Moving on to the therapeutic unsealed
7 material, we have eight medical events. We had one
8 with I-124, we had six with I-123 and we had one with
9 radium-223.

10 The I-124 event was a pediatric case.
11 There was a leak at the intravenous connector. It
12 wasn't visible because there was a lot of gauze over
13 that area and so they didn't know that they had a
14 leak until they had delivered only a small -- about
15 half of the I-124 that they had expected to
16 administer.

17 With I-131, I've got six medical events.
18 In the first case, the patient had a low glomerular
19 filtration rate score. And, the first physician
20 ordered 50 millicuries. The second physician looked
21 at the low score and said, I think this patient is
22 better suited for a lesser amount of activity.

23 And so, both physicians ordered the
24 material. So, the first physician ordered the 50
25 millicuries, the second physician ordered the 35

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1 millicuries.

2 When it came time to give the
3 administration, they picked up the wrong syringe and
4 they gave the 50 when they were supposed to give the
5 35.

6 We had an administration of 30
7 millicuries instead of 3 millicuries. In that case,
8 the written directive was incorrect. The written
9 directive was written for 3 millicuries but the
10 intended dose was always 30 millicuries.

11 And so, no one paid attention to the
12 written directive. And so, now there's going to be,
13 for a corrective action, the authorized user is
14 supposed to complete the authorization section before
15 administration.

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

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

24 So, from now on, the corrective action is
25 to do two independent measurements and review the

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1 dose to make sure it's within 20 percent.

2 They delivered 142 millicuries instead of
3 30. It was the wrong patient. They misidentified
4 the patient.

5 They administered 75 millicuries instead
6 of 150 millicuries. And, this one, you can almost
7 guess the reason. The dose came in two capsules, one
8 capsule was given, the other capsule staying in the
9 container.

10 And, each time I talk about an
11 administration, this is a different licensee medical
12 event.

13 The final one for the therapy is the
14 radium-223. In this case, they delivered two
15 dosages. But, the written directive was for only one
16 dosage.

17 But, instead of reading the prescribed
18 dose, they injected two dosages instead of the one.
19 So, they gave essentially about 100 percent more
20 radium-223 than they were supposed to.

21 So, corrective action, they're going to
22 have technologists verify the patient information and
23 the prescribed dosage.

24 Moving on to manual brachytherapy, it's
25 not very -- we don't have manual brachytherapy

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1 generally in places outside of the prostate, but we
2 did end up with one this time.

3 In this case, they checked the patient
4 and two and a half hours after the linens were
5 changed, the oncologist came in and determined that
6 one of the strands that was going through the nose
7 was missing and they did a survey and found out the
8 strand was in the linen.

9 They retrieved the strand, they put the
10 strand back in. The patient received the dose they
11 were supposed to receive through the nose.

12 However, there could have been an
13 exposure to the skin and they did a calculation and
14 determined that this patient -- because it was in the
15 bed linens-- had received up to 51 rem to the skin
16 and reported it as a medical event for the wrong
17 treatment site.

18 Prostate patient, we've got eight
19 different locations. We have one location with two
20 patients. So, we have a total of nine patients.

21 And, in the first one, there were two
22 patients with palladium-103 implants. The medical
23 events were identified by the regulator.

24 They identified irregularities with one
25 of the authorized user's practices and they looked at

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1 the procedures that he had done and identified two
2 medical events where one patient received 37 percent
3 and the other received 66 percent of the prescribed
4 dose.

5 The next licensee was also identified
6 during inspection. And, in this case, the dose was
7 73 percent of what was prescribed. There was not any
8 additional information on this particular case.

9 We have a partial dose was intended, but
10 the full dose was given. It was a human error. They
11 didn't confirm the documentation of the implanted
12 dose and so they thought it was -- it was supposed to
13 be a partial dose with one accelerator boost and,
14 instead, they gave a full dose.

15 They delivered a different from what was
16 ordered.

17 In the first case, it says they were
18 supposed to administer 18,000 rads, instead, they
19 gave 14,000 rads. And, they ordered an air kerma but
20 it was not prescribed in air kerma.

21 In the second case, they didn't give you
22 why it was different, but they ordered -- there was
23 a difference between what was ordered and what was
24 delivered.

25 The difference was about 22 percent, so

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1 it sounds like it's probably an air kerma versus
2 millicurie event.

3 Wrong site, so for at least two of the
4 cases, the wrong site was attributed to poor or
5 uncalibrated ultrasound devices.

6 In the first case, 30 percent of the seeds
7 were planted outside of the treatment site.

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

11 Another wrong site, 20 of the seeds, 29
12 percent of the total prescribed, were implanted into
13 the bladder.

14 In this case, the median lobe of the
15 prostate protruded into the bladder and so 20 of the
16 seeds were put into the bladder.

17 So, their corrective action was procedure
18 modification and additional training of personnel.

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

23 The first location was not specified.
24 There was one medical event for a nose, there were 11
25 for gynecological procedures, three for breasts and

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1 then we had one Gamma Knife medical event that had
2 eight patients involved.

3 So, they are broken down into what was
4 the basic cause, wrong patient, one error, bad
5 treatment plan, three medical events, wrong site -
6 seven, source fell out - one, physicists error - two,
7 and equipment problems and failures - two.

8 So, the one that wasn't specified, the
9 patient received a less dose than prescribed. But
10 the reason it's a medical event is because they
11 treated the patient with someone's treatment plan.

12 So, they're not retraining people and
13 requiring them to verify the patient's identity.

14 In the nose, they wrote the written
15 directive. They gave it to a junior physicist to
16 develop the treatment plan. He didn't develop the
17 treatment plan correctly and so they administered
18 over 71 percent more dose than was in the written
19 directive.

20 So, the other interesting part of this is
21 the authorized medical physicist and the authorized
22 user, neither one of them identified this before the
23 treatment was given. So, even though it was reviewed
24 by both.

25 Now, we move into the gynecological ones.

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1 I have 11 of these. The largest number is seven and
2 for wrong site, and many of them in the wrong site
3 are going to have radiation induced damage to skin
4 and other body parts.

5 So, they were trying to administer to the
6 vagina and the outer vaginal mucosa and the upper
7 thigh received the entire dose.

8 The applicator was improperly placed and
9 the sources were inferior to the treatment site and
10 exterior to the treatment site and they had vaginal
11 burning.

12 The next wrong site, another case where
13 the sources were inferior to the treatment site and
14 exterior to the opening of the vagina and they ended
15 up with radiation burns.

16 And, the contributor that they attributed
17 to it was that they had poor film quality because the
18 patient was obese and they thought they had it in the
19 proper location but they were off considerably.

20 We had two skin radiation burns on both
21 upper thighs. The skin dose was 4,000 rad, a depth
22 of two-tenths of a centimeter. And, there was also
23 33 percent less dose to the intended site than
24 prescribed.

25 And, in this case, they attributed it to

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1 either the assembly of the vaginal cylinder
2 application was done incorrectly or it became loose
3 while in the patient.

4 Another wrong site, fraction dose was
5 delivered to the wrong site.

6 In this case, there were several
7 physicians involved. The first physician gave the
8 first fraction, the second physician gave the second
9 fraction.

10 Even though it said the first fraction
11 was given correctly, the second physician had
12 difficultly inserting the applicator due to edema and
13 tenderness and went to a smaller applicator.

14 And then they reviewed the post-treatment
15 images from the week before and found that the source
16 was at least seven centimeters short of the intended
17 position.

18 Another wrong site, in this case, the
19 second fraction, they had a close-ended catheter but
20 it wasn't fully seated. They were about 15
21 centimeters proximal to the prescribed treatment
22 site.

23 Now, their corrective action is to verify
24 the position of the cylinder and the length of the
25 transfer tube catheter.

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1 Another wrong site, this was the tissue
2 three centimeters inferior to the treatment site
3 received 400 rad.

4 In the post-treatment imaging, they
5 realized that the cylinder applicator had become
6 loose from the holder and it shifted three
7 centimeters.

8 They are now going to verify that the
9 applicator is immobilized and that the clamp is where
10 it should be.

11 Another wrong treatment, in this case,
12 the treatment site received only 20 percent of the
13 intended dose. They inserted the vaginal cylinder
14 three centimeters distal to the vaginal cuff.

15 They all -- their corrective action is to
16 always use four segments. They didn't indicate
17 whether they used fewer or what happened. But, now
18 they're going to use four. And, they're going to pay
19 close attention to patient movement. And, they're
20 going to do additional imaging.

21 Source fell out, the physician enters the
22 room and finds the cylinder on the treatment table.
23 So, there was a failure to secure the cylinder in
24 place and the inability to view the cylinder from the
25 camera. So, they weren't able to identify it

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1 earlier.

2 So, they administered 1,200 rad instead
3 of 1,800 rad.

4 Physicist error, this is -- I could have
5 also put this in wrong patient. The physicist put
6 up the correct treatment plan and there was a delay
7 and so he pulled up another treatment plan and was
8 looking at it.

9 So, they inadvertently selected and
10 delivered an incorrect treatment plan on the third
11 fraction.

12 So, they're now going to verify the
13 treatment plan.

14 This -- I'm sorry -- the last one wasn't
15 where the physicist brought up the wrong patient,
16 this is the one with the wrong patient.

17 The last one, they just had multiple
18 treatment plans, they brought up the wrong treatment
19 plan.

20 In this one, the physicist had the right
21 treatment plan up, there was a delay. He decided to
22 pull up another one and review it and then the patient
23 is brought in. And so, the physicist repeats the
24 parameters from memory but not by looking at the
25 treatment plan.

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1 So, they gave the wrong treatment to the
2 wrong patient.

3 Equipment problems, I didn't get a lot of
4 information on this one, but two AMPs felt they had
5 to stop the procedure. So, they engaged the
6 emergency stop. They terminated the treatment. They
7 retracted the source in the shielded position.

8 But, when they went to restart, they
9 found that the timer wasn't counting down. The timer
10 was increasing.

11 So, at that point, they decided that they
12 should just terminate the treatment. There was a
13 problem with the device.

14 They called in the manufacturer. I don't
15 believe the manufacturer was able to replicate their
16 problem.

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

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

23 They had to remove 21 cubic centimeters
24 of tissue. They had to suspend the treatment while
25 they investigated the problem areas. And, they've

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1 decided to use a second physicist for an independent
2 evaluation of the treatment plan.

3 Many times with a SAVI device, it's
4 because they confuse the tip end from the connector
5 end and they believe they're giving the dose within
6 the SAVI, but they're actually giving it outside into
7 the skin.

8 Another SAVI medical event, and this
9 case, they gave the full 13,000 rads to the entrance
10 site. And, this was definitely one in which they
11 delivered it to the connector end and not to the tip
12 end.

13 So, the dwell positions within the
14 applicator were not accurately reconstructed in the
15 treatment planning computer. And, they had difficult
16 identifying the starting position and the multiple
17 catheter HDR treatment within the system.

18 And, the final one with the SAVI, the
19 fractional event occurred while they were sending out
20 the check cable. So, they gave very little of the
21 dose.

22 And, they determined that the check cable
23 was frayed about a half a centimeter behind the weld
24 junction and it ends up this facility had three other
25 cables, or a total of three cables, with similar

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1 fraying.

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

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

13 And, we haven't seen this issue with any
14 other licensees.

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

19 And, in this case, page three of the
20 written directive said where the plugs should be, but
21 it was absent during the equipment preparation.

22 And so, they didn't put plugs in where
23 they should have put plugs in. Instead, they had
24 collimators. So, they received -- so they gave 71
25 rem to the wrong site.

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

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

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

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

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

22 And so, Elekta, the manufacturer, is
23 still evaluating the service issue. And, these eight
24 administrations may also be abnormal occurrences.

25 For the radioactive seed localization,

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1 this is a diagnostic procedure, but using a seed that
2 could be a therapeutic seed.

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

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

9 And, the programmatic review identified
10 that there were other patients that also did not come
11 back within the five days and they used the term "much
12 later than five days," but that those patients did
13 not receive a medical event because of the dose
14 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
18 when I finish the TheraSpheres, I'll go into the SIR-
19 Spheres.

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

25 So, there were five patients that were

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1 administered less than 80 percent of the prescribed
2 dose. And, they discovered this after the fact when
3 they did imaging of the tubes and they discovered the
4 excess dose was found in the hubs of the catheters.
5 And, all patients were treated with small catheters.

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

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

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

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

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

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1 the patient and they found out later that the Rados
2 detector was erroneous and that most of the
3 microspheres were left in the vial.

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

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

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

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

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

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

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1 And so, they have decided that they are
2 going to make more formal written check lists to
3 complete prior to the administration. They're going
4 to have additional mapping images and make sure that
5 the catheter is where it's supposed to be. And then,
6 a second physician will review things.

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

13 Small bowel, in this case, the physician
14 felt that the microspheres were not going in the right
15 place so he stopped the treatment.

16 And then, they imaged the patient and
17 they discovered that 3,000 rads had gone to the small
18 bowel.

19 Wrong liver site, so in this case, they
20 administered more radiation than they had expected to
21 the posterior portion of the right lobe.

22 What they did was they gave an
23 administration intended for the anterior portion of
24 the right lobe of the liver. They had a color coding
25 procedure in place. They didn't have their color

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1 coding correctly.

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

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

8 Dose calculation error, in this case, the
9 physician -- there was shunting and so the physician
10 prescribed an activity based on 20 percent of the
11 lung shunting.

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

20 We have less administration here. In
21 this case, they had air bubbles that were collecting
22 in the tube. And so, they decided that they needed
23 to stop and see what was going on with the air
24 bubbles.

25 And, they discovered that the kit was set

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1 up incorrectly, that they air was entering the device
2 through an uncovered needle.

3 We don't get a lot of medical events from
4 setting up the -- recognizing that the device is set
5 up incorrectly.

6 Then, we have another medical event in
7 which a little more than half was administered and
8 the device came apart during the procedure and the
9 microspheres were lost in the apparatus.

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

12 So, those two cases are device-related
13 issues or poor training on the facility for putting
14 the devices together correctly.

15 We had 42 percent delivered during the
16 set up. The patient's catheter was disconnected to
17 flush out air bubbles. We had another one with air
18 bubbles.

19 But, in this case, they forgot to
20 reconnect the catheter and administered the
21 microspheres without reconnecting the catheter and
22 they didn't go into the patient.

23 Then they had another one for 78 percent.
24 They had crimping in the tube near the three-way
25 stopcock and the manufacturer determined the cause

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1 was abnormally high concentrations of microspheres
2 during administration.

3 We have 52 percent of the dose delivered.
4 The physician concluded that the catheter was clogged
5 when injecting the microspheres and because he was
6 meeting considerable resistance.

7 So, they lost some sources when the
8 catheter was disconnected. And then, the
9 manufacturer looked at it and decided that there was
10 blood in the catheter and the blood in the catheter
11 caused the microspheres to clog and that it wasn't
12 sufficiently flushed prior to infusion.

13 And those are all the medical events that
14 we saw in FY 2015.

15 I will tell you that there were probably
16 about 78 medical events that were tagged in NMED as
17 medical events, but in reviewing them, there were
18 really 57 that met NRC's criteria.

19 CHAIRMAN ALDERSON: Well, thanks, Dr.
20 Howe for that thorough report.

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

23 Now, I'm sure all my colleagues are
24 always sad to hear of these individual medical events
25 and the patients who incurred them.

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1 When we look at these reports, we would
2 try to look for some trending, though, that would
3 give us some idea of how useful interventions could
4 be recommended or made.

5 So, I have just two comments the
6 trending.

7 Given the low number of these events, as
8 Dr. Howe stressed, compared to the overall number of
9 patient encounters during a year, when we go back to
10 the table that was on slide three, these are very,
11 very small numbers of events. And one would, you
12 know, question the statistical nature of these events
13 from year to year.

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

19 I wonder if it would be useful to the
20 Committee, instead of seeing the total events over
21 two years, to actually see, let's say, five? Because
22 you already have the data, it's not a lot of work.

23 And so, if under 35.400 here, it says
24 five and then nine or ten, that really doesn't worry
25 us, but if it were one, one, one, five, nine, we might

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1 say, my goodness, there might be a trend there and
2 we'd want to focus on that.

3 So, I just make the general suggestion
4 that perhaps since the data are available that we
5 simply report five years instead of two.

6 Do I have comments from the Committee on
7 that?

8 Dr. Zanzonico?

9 VICE CHAIRMAN ZANZONICO: Well, I think
10 the problem, and this comment has been made before,
11 without knowing the denominator, an impaired trend
12 could be misleading.

13 I think the use of microspheres, for
14 example, continues to increase. So, you would expect
15 a proportional increase in medical events.

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

19 CHAIRMAN ALDERSON: And so, my response
20 to that comment is that without multi-year trending,
21 you won't see it anyway.

22 And so, if you do multi-year trending and
23 you see something, then you can ask that question and
24 then you can find the answer, i.e. , that there are
25 a lot more procedures and so we don't need to worry.

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

3 That would be my response to that
4 question.

5 DR. HOWE: And, I think for the Yttrium-
6 90 microspheres, we always have many more medical
7 events from the Yttrium-90 microspheres because of
8 delivery problems and it's probably an order of
9 magnitude higher in medical events than any other
10 modalities that we're looking at.

11 CHAIRMAN ALDERSON: Are there any other
12 -- yes, Mr. Costello?

13 MEMBER COSTELLO: Yes, I agree. I think
14 having five years would be good. And, I'd hope that
15 new modalities like 35.1000, that what we'd see would
16 be a learning curve, that there might be some in the
17 beginning of it, might be more then as time goes by
18 even with increasing numbers of treatments, I would
19 hope that the percentage of that would go down.

20 CHAIRMAN ALDERSON: Other comments on
21 that suggestion?

22 Yes, Dr. Palestro?

23 MEMBER PALESTRO: Yes, I think your
24 suggestion to look at trending is certainly very
25 useful and I don't want to complicate things with un-

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1 founded issues, but I think just looking at the
2 numbers, or I should say, rather than just looking at
3 the numbers, looking at trends that are increasing or
4 decreasing.

5 I'd also like to look at the individual
6 events themselves. For example, when you're talking
7 about TheraSpheres and so forth, you have things like
8 the wrong site, low flow reads and so forth to see
9 are there particular subgroups in which these events
10 are occurring.

11 CHAIRMAN ALDERSON: Yes, so, that's the
12 --

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

16 MEMBER PALESTRO: Yes, yes.

17 CHAIRMAN ALDERSON: Yes. Okay.

18 DR. HOWE: In addition to the five?

19 CHAIRMAN ALDERSON: Yes, that's a good
20 comment. That's an excellent comment, I accept that
21 as an amendment to the suggestion.

22 Are there other comments from the ACMUI?

23 Yes, Mr. Ouhib?

24 MR. OUHIB: Yes, Zoubir Ouhib.

25 I think what I would be looking for is

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1 that looking at all these errors, what is the common
2 factor. And looking at that, I see like quite few
3 that really are training-related type of things.

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

7 So, I think there's a lot that's sort
8 merge toward that component.

9 CHAIRMAN ALDERSON: Good.

10 Yes, Mr. Costello again?

11 MEMBER COSTELLO: And, these comments,
12 Dr. Howe, I think are appropriate.

13 I think that the depth of investigation
14 that the various regulatory agencies does vary a lot
15 from event to event.

16 And to some, they do get closer to a root
17 cause and some others, they just say, operator error.
18 And, I think that it's hard to evaluate the cause of
19 these things when I think the depth of the
20 investigation varies so much from event to event.

21 I think if you'd look at the stuff that's
22 in NMED, you'll see that, that some of those are some
23 superficial review and some of them, it's a real in
24 depth one.

25 CHAIRMAN ALDERSON: Yes? Dr. Langhorst

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1 and then Ms. Weil?

2 MEMBER LANGHORST: Dr. Howe, I always
3 appreciate your report on this because it really
4 condenses things down and it really is, I know, a
5 whole lot of work.

6 Mr. Costello mentioned one of my
7 questions, so thank you, Frank, for bringing that up
8 on the variation. Because, it's about a little more
9 than half are from Agreement States rather than NRC
10 licensed states. So, there's lots of variability
11 between NRC inspections versus some Agreement States.
12 So, I know that's a variable.

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

19 But, the one question that I have is, I
20 know there's been previous discussions about making
21 NMED or some portion of NMED data a little more
22 available to licensees as a whole. Because that
23 isn't necessarily available to all licensees.

24 And, I just wonder if NRC is considering
25 that more?

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

4 Doug?

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

10 And, that's the plan to take these, you
11 know, and they have been, if you look at the 200 pages
12 of slides that are up on the presentation. But now,
13 we specifically pull these presentations out to make
14 them easily available and easier to find for
15 licensees, general public in regards to medical
16 events.

17 DR. HOWE: And, they'll be on the medical
18 tool kit.

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

23 And, I don't know if there's any way to
24 tie things to event notifications because those are
25 also on the web. But, at least that might be

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1 something else that could add to a licensee's
2 knowledge.

3 So, again, that would be a lot of work
4 and I appreciate that amount of work.

5 CHAIRMAN ALDERSON: Ms. Weil was next.

6 MEMBER WEIL: Thank you for this report,
7 as always staying --

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

11 MEMBER WEIL: It would be useful to know,
12 in all cases, what the corrective action was and the
13 outcome for the patient.

14 I assume when you don't report it, it's
15 because it has -- that information's not available to
16 you.

17 DR. HOWE: That's correct. Not everyone
18 give a corrective action. Not everyone gives the
19 effect on the patient.

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

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

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1 MEMBER WEIL: Does it cost the -- I mean,
2 not money, but is there a cost to the licensee for
3 not providing information about the corrective
4 action? Do you go back, do they get dinged again for
5 an incomplete report?

6 DR. HOWE: We try to get as much
7 information as we can. We have a contractor that
8 runs the NMED program and he tries to get information
9 and they try to go back to the Agreement States. But,
10 sometimes you just can't get any more information.

11 If it's an NRC licensee, it's fairly easy
12 for us to go back to the Regions and ask for
13 additional information and get it. But, it's a
14 little more difficult on the Agreement States.

15 MEMBER WEIL: It seems to me that there's
16 an opportunity for, you know, evasion and obfuscation
17 on the part of the licensee by not providing that
18 information. And, that shouldn't go unpunished, if
19 you will.

20 MEMBER COSTELLO: Can I make another
21 comment?

22 CHAIRMAN ALDERSON: Yes, Mr. Costello
23 would like to comment on that.

24 MEMBER COSTELLO: These reports really
25 are provided by the regulator; the information, I

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1 think comes to the NRC from the States who get the
2 information from the licensee.

3 So, it's not necessarily true that the
4 licensees is withholding things. It comes out of the
5 interaction between the regulator and the licensee,
6 how much information I get.

7 So, maybe if the regulators pushed a
8 little harder, we'd get more information. It's not
9 the licensee's fault necessarily that all the
10 information's not there. Sometimes it is, but
11 sometimes we, the regulator, could be more aggressive
12 in getting that information.

13 MEMBER WEIL: One other comment, if I
14 may?

15 It's important to note that many of these
16 events are identified by the regulator during an
17 inspection as opposed to being self-reported by the
18 licensee.

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

23 CHAIRMAN ALDERSON: Dr. Zanzonico had a
24 comment to make.

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

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1 I report the information that was
2 reported in the fiscal year because, if there was a
3 medical event that happened three or four years that
4 wasn't identified three or four years ago, if I just
5 reported what happened in that year, that would be
6 lost forever.

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

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

12 CHAIRMAN ALDERSON: Dr. Zanzonico?

13 VICE CHAIRMAN ZANZONICO: I have a
14 comment and a question.

15 The comment is, if you haven't seen these
16 procedures firsthand, they are very complicated, very
17 labor intensive and there's lots of opportunity for
18 errors.

19 And it's remarkable that if these -- this
20 is microspheres I'm referring -- that if these numbers
21 are anywhere near accurate, it certainly is under
22 reporting because it's self-reporting, it's
23 remarkably low for procedures of this complexity.

24 And, I know, at least at Memorial, the
25 interventional radiologists are getting, what's the

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1 word, more adventurous and are doing more and more
2 difficult cases by this procedure because they've had
3 such results.

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

7 But, that's just a comment.

8 But, my question is, it struck me that
9 there were several microsphere events, the ones on
10 slides 42, 47 and 48, which, perhaps, were patient
11 intervention.

12 And, I guess the question is, you know,
13 unexpected or abnormal anatomy or complex anatomy
14 that led to microspheres being deposited in the wrong
15 location.

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

18 DR. HOWE: I only remember one where it
19 said that the vessels were giving a really hard push
20 and so he stopped.

21 VICE CHAIRMAN ZANZONICO: Right.

22 DR. HOWE: The size or the physical
23 condition of the patient's arteries caused the low
24 flow condition. I don't remember another one being
25 attributed --

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1 VICE CHAIRMAN ZANZONICO: Well, I don't
2 think truly, if any of them truly were over and not
3 medical events.

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

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

15 So, that's in the existing guidance.
16 And, Dr. Tapp will talk to us more about the guidance
17 that's being developed.

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

21 CHAIRMAN ALDERSON: All right, so is
22 there another comment? Did you have your hand up,
23 Steve?

24 Mike Fuller has his hand up, also. So,
25 Steve, you'll be first, Steve Mattmuller and then

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1 Mike Fuller.

2 MEMBER MATTMULLER: Steve Mattmuller.

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

9 DR. HOWE: Absolutely.

10 MEMBER MATTMULLER: -- and then inject
11 it.

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

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

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

23 And, that sticks out to me because I
24 thought, gosh, that could happen at my place because
25 we do prepare a large kit of Myoview.

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

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

13 So, for those two, I think it's more of
14 a 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
17 reasons, but it's a very uncommon practice. So,
18 surprised this has happened.

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

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

25 MEMBER MATTMULLER: Okay, sorry about

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1 that. So, it's --

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

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

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

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

13 DR. HOWE: So, the --

14 VICE CHAIRMAN ZANZONICO: Could I -- I
15 was involved in that.

16 MEMBER MATTMULLER: Yes, yes.

17 VICE CHAIRMAN ZANZONICO: None of it was
18 my fault.

19 MEMBER MATTMULLER: So he says.

20 DR. HOWE: Of course.

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

25 And, in this study, the surgeon, under

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1 image guidance, inserts a catheter through the skull
2 directly into the tumor in the cerebellum. And,
3 because the I-124 was being delivered so locally and
4 it is a beta emitter, it's a therapeutic dose.

5 So, this is --

6 MEMBER MATTMULLER: It's a positron
7 emitter.

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

10 MEMBER MATTMULLER: Yes.

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

14 So, this is being used as a true
15 theragnostic study.

16 MEMBER MATTMULLER: Theragnostic?

17 VICE CHAIRMAN ZANZONICO: You both image
18 and do the therapy dose by PET. You use the injected
19 activity to do the dosimetry, but also with the same
20 administration deliver presumably a therapeutic dose
21 as well.

22 MEMBER MATTMULLER: Okay.

23 VICE CHAIRMAN ZANZONICO: So, in a way,
24 it's a new category. It's a true theragnostic study.

25 CHAIRMAN ALDERSON: Thank you.

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1 Mr. Fuller?

2 MR. FULLER: Yes, Mike Fuller.

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

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

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

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

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1 the long-term data and present that.

2 CHAIRMAN ALDERSON: Well, thank you.

3 So, we heard earlier that there may be
4 many confounding factors if you look out over time
5 and we made the suggestion that, if we found any
6 trends or thought there were any trends, then we could
7 ask about those confounding factors in those issues.

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

13 Would someone wish to make a motion to
14 that effect?

15 VICE CHAIRMAN ZANZONICO: Sure.

16 MEMBER COSTELLO: Moved.

17 CHAIRMAN ALDERSON: So moved, says Pat
18 and Mr. Costello.

19 Is there a second to that?

20 MEMBER COSTELLO: Second.

21 CHAIRMAN ALDERSON: Is there further
22 discussion?

23 Hearing none, those in favor?

24 (Chorus of aye.)

25 CHAIRMAN ALDERSON: Opposed or

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1 abstaining?

2 That is accepted unanimously.

3 Thank you, Mr. Fuller.

4 Yes, I believe Mr. Costello has a comment
5 before we adjourn.

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

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

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

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

25 But, I think that when that's adopted,

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1 they also affect, maybe even reduce, the number of
2 medical events if you take a broader view of what
3 patient intervention may be.

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

6 CHAIRMAN ALDERSON: Yes, excellent.

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

11 Hearing none, I assume that there are no
12 comments there.

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

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

19 CHAIRMAN ALDERSON: We're going to call
20 the meeting to order and get started on the next
21 section.

22 So, we're ready to hear the report on
23 Medical Event Reporting for All Modalities Except
24 Permanent Implant Brachytherapy and John Suh will be
25 reporting for the Subcommittee.

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1 MEMBER SUH: On October 9, 2015, Dr.
2 Ennis provided the ACMUI with the annual presentation
3 on the previous fiscal year's medical event
4 reporting, which still remains extremely low.

5 Dr. Bruce Thomadsen, the outgoing ACMUI
6 Chair, discussed the incident at his institution
7 where there was confusion as to whether or not it
8 constituted a medical event.

9 As a result, this led to the formation of
10 this Subcommittee to look at that report, medical
11 event reporting for this.

12 So, in terms of history of medical event
13 reporting, since the 1970s, there's not been much
14 change in how medical event reporting has been
15 performed.

16 In 1991, medical event criteria included
17 the difference between the prescribed and
18 administered dose of greater than 10 percent. So,
19 that's kind of been the backbone in terms of the
20 history of medical event reporting.

21 As a result, the current definitions may
22 not be appropriate given the advances and
23 technologies currently used, particularly in
24 radiation oncology. 10 CFR Part 35, Subpart M covers
25 these reports.

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1 In terms of the Subcommittee discussions,
2 the Subcommittee discussed the current medical event
3 reporting criteria under 10 CFR Part 35.3045.

4 The Subcommittee also reviewed different
5 scenarios in which the current medical event criteria
6 were ambiguous and, therefore, required possible
7 modifications.

8 And given the spatial precision of modern
9 therapies, a slight shift in significant dose in
10 nearby tissues or parts of organs can occur.

11 And, just to review the current report
12 notification of medical events from 35.3045, a
13 licensee shall report any event except for an event
14 that results from patient intervention in which the
15 administration of the byproduct irradiation from
16 byproduct material results in the following.

17 So, a dose that differs from the
18 prescribed dose or dose that would have resulted from
19 the prescribed dosage by more than 5 rem, effective
20 dose equivalent, 50 rem to the organ or tissue or 50
21 rem shallow dose equivalent to skin.

22 And, total dose differs by prescribed
23 dose by 20 percent or more. The total dose differs
24 -- delivered difference from the prescribed dose by
25 20 percent or more or falls outside the prescribe

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1 dosage range or the fractionated dose delivery
2 differs from the prescribed dose for a single fraction
3 by 50 percent or more.

4 Another possibility is where there is
5 administration of a wrong radioactive drug containing
6 the byproduct material, administration of a
7 radioactive drug containing byproduct material by the
8 wrong route of administration, an administration of
9 a dose or dosage to the wrong individual or human
10 research subject, an administration of a dose or
11 dosage delivered by the wrong mode of treatment or a
12 leaking sealed source.

13 And, in terms of other scenarios, the
14 licensee shall report any event resulting from
15 intervention of a patient or human research subject
16 in which the administration of a byproduct material
17 or radiation from byproduct material results or will
18 result in unintended permanent functional damage to
19 an organ or a physiologic system in the opinion of a
20 physician. I should note that's bolded in red and
21 I'll highlight that in a little bit.

22 The licensee shall notify by telephone
23 the NRC Operations Center no later than the next
24 calendar day of the discovery of the medical event.

25 That's just some background in terms of

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1 the current definition and the notification of a
2 medical event.

3 So, in terms of medical events that would
4 need to be covered for the variety of treatment
5 options, you can see what are listed here.

6 Treatment options such as selective
7 internal radiation therapy, and we heard a little bit
8 about the SIR-Sphere and TheraSphere, high dose
9 brachytherapy which is used for many different organs
10 right now, including breasts, Gyn, lung, prostate and
11 skin cancer, also for Gamma Knife radiosurgery or
12 ViewRay, or low dose rate implants that are non-
13 prostate related, low dose rate meshes which are
14 sometimes used for some thoracic malignancies,
15 instilled sources which could be intravenous or oral
16 and IPAC brachytherapy.

17 We had discussed whether or not defining
18 medical events by modalities was perhaps preferable
19 and the thinking was that it may be easier for the
20 licensee to determine if a medical event occurred.

21 It may be easier to inspect and regulate
22 and it may facilitate programs, procedures and
23 education to prevent future events.

24 Since the delivery systems at risk are
25 very different for each of these modalities, the

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1 specific medical event for each modality may provide
2 some advantages, but the Subcommittee did not favor
3 modality-specific medical events just because that
4 would require individualizing the definition of
5 medical events for each of the modalities which was
6 just shown previously.

7 In terms of recommendations from the
8 Subcommittee, the Subcommittee felt that medical
9 event reporting should allow identification of the
10 medical event and provide a forum to discuss how to
11 avoid and reduce the likelihood of such an event.

12 The definitions of a medical event
13 reporting need to be broad, simply and consistent so
14 reports are easily applicable by an authorized user,
15 applicable by regulators and process focused to
16 eliminate any ambiguity of what constitutes a medical
17 event.

18 The Subcommittee believes that the part
19 of the definition based on, quote, unintended
20 permanent functional damage to an organ or a
21 physiologic system as defined by a physician, end of
22 quotes, needs reconsideration, especially the word
23 unintended.

24 The Subcommittee also believes that the
25 creation of a subsection within the current

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1 definition of medical event reporting be considered
2 to address the newer oncology modalities that
3 prescribe doses to volumes.

4 And, finally, the Subcommittee believes
5 that any proposed changes must not encroach on the
6 practice of medicine.

7 Thank you.

8 CHAIRMAN ALDERSON: Thank you, Dr. Suh.

9 This report is now open for comment.

10 Mr. Costello?

11 MEMBER COSTELLO: Well, you gave a lot
12 of good arguments. You have a lot of events to the
13 regulator and then you said the Committee decided not
14 to go that direction.

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

17 MEMBER SUH: So, it's -- there's a lot of
18 different -- so, again, there are, I think, benefits
19 to try and do it per modality. I think the difficulty
20 is going to be to try to define medical events for
21 every single modality is going to be a very big
22 undertaking and it's probably going to a very long
23 time as well.

24 And, I think it's going to keep it simple
25 and also not create a lot of different what if

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1 scenarios.

2 The thinking was from the Subcommittee is
3 that it's going to be easier if we amended the current
4 definition of medical events rather than try and
5 create separate medical event definitions for every
6 single modality.

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

11 CHAIRMAN ALDERSON: Dr. Langhorst?

12 MEMBER LANGHORST: Sorry, I may be a
13 little dense these days, but did we have a written
14 report, a draft report? So, we didn't have anything
15 to read on this other than the slides?

16 MS. HOLIDAY: Dr. Langhorst, this is
17 Sophie.

18 I think the idea is that Dr. Suh's
19 Subcommittee would be presenting their discussion and
20 this would serve as more like a forum or a discussion
21 amongst the Committee members.

22 MEMBER LANGHORST: Okay, thank you.

23 Sorry, I was confused about what it was
24 supposed to be.

25 MEMBER SUH: Yes, it was a work

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1 discussion. So, actually, I had that discussion with
2 Sophie before this talk. So, you were not mistaken.

3 CHAIRMAN ALDERSON: Further comments
4 from the ACMUI?

5 MEMBER COSTELLO: I have one other.

6 CHAIRMAN ALDERSON: Yes, Frank?

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

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

13 MEMBER SUH: So, I think in terms of
14 what's next is I think we will need to start the
15 process of defining what constitutes a medical event
16 for non-permanent implant for any type of radiation
17 modality. So, we're going to need to start that
18 process defining what constitutes a medical event for
19 these.

20 And, just given the variety of different
21 modalities that are being used right now to treat
22 various conditions, it's going to be a big
23 undertaking. But, I think we need to start defining
24 what that is going to be.

25 MEMBER COSTELLO: So, this is a work in

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1 progress, then?

2 MEMBER SUH: This is a work in progress.

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

8 MEMBER SUH: Yes.

9 MEMBER COSTELLO: Okay.

10 MEMBER SUH: I think just to build on
11 what Dr. Donna-Beth Howe just presented, I think this
12 also gives us an opportunity in terms of, kind of,
13 you know, we're moving more toward, you know, looking
14 at the education composite piece. So, I think this
15 also will tie in very well as in terms of just what
16 constitutes these medical events.

17 And, I think one of the things I just
18 want to comment on just from the last part of the
19 meeting, I think having the information being made
20 more public I think is very useful I think for, you
21 know, someone who's been trained to actually look at
22 what they didn't identify as the right patient I think
23 it very important.

24 I think it's something that, if you look
25 at some of these various modalities that are being

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1 used, I think there's definitely best practices that
2 can be learned.

3 CHAIRMAN ALDERSON: Dr. Langhorst?

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

7 I encourage you to look specifically at
8 the 35.1000 guidance documents because sometimes they
9 have some specific guidance about medical event
10 reporting.

11 I know we'll probably be doing that on
12 the training and experience piece of just what you
13 were suggesting.

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

17 Thank you.

18 CHAIRMAN ALDERSON: Yes, Dr. Zanzonico?

19 VICE CHAIRMAN ZANZONICO: I just have a
20 more or less a procedural question. I mean, I think
21 we've all learned that when regulations or for, in
22 this instance, medical events are defined in the
23 prescriptive manner and then trying to update them
24 wasn't even possible.

25 So, I wondering if maybe a middle ground

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1 with non-modality specific definitions for MEs are in
2 the red. But, as Sue just pointed out, supplement
3 those with modality specific guidance documents.
4 Because that seems like it would give you the
5 flexibility as new modalities are introduced, so
6 forth and so on, that you can provide concrete
7 guidance to users for those.

8 But, I mean, I agree putting modality
9 specific definitions of MEs is like after the work
10 will work well.

11 So, that's just a comment.

12 CHAIRMAN ALDERSON: Yes?

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

17 MEMBER SUH: So, we talked about as a
18 Subcommittee, we really didn't come up with a better
19 word than unintended, but we just felt that the
20 connotation of unintended was probably not what is
21 best suited in terms of what constitutes a medical
22 event.

23 CHAIRMAN ALDERSON: Yes, Dr. Dilsizian?

24 MEMBER DILSIZIAN: For example, it's you
25 know, the attention on unintended, for example, you

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1 know, I proposed ``unexpected.'' It's not something
2 anybody was intending, it's some -- those kind of
3 things, more of a bad definition than it seems to
4 connote with unintended.

5 MEMBER WEIL: I can imagine, you know,
6 that in treating a tumor of some sort that you might
7 damage, you might cause functional damage
8 intentionally, though. I mean, it would be part of
9 the therapeutic goal, no?

10 MEMBER DILSIZIAN: Well, absolutely.
11 But, this is --

12 MEMBER WEIL: Different?

13 MEMBER DILSIZIAN: -- unintended events.
14 In essence, if some, you know, we talked about
15 microsphere therapies, it's going in the wrong
16 [location] unintentionally, but it's unexpectedly.
17 So, those are the couple of things I think we're
18 talking about, right?

19 MEMBER SUH: Yes, yes. You wanted
20 something else for the word unintended, and it's
21 something you felt that unintended was perhaps not
22 the best verbiage.

23 CHAIRMAN ALDERSON: So, Dr. Suh, is it
24 true then, to follow up on Ms. Weil's question, that
25 when you came back in slide 14 and, as a

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1 recommendation, you again brought up this phrase and
2 said that it needs reconsideration, is it primarily
3 the word unintended that is the thing that is the
4 problem in that phrase?

5 MEMBER SUH: I think that was the
6 concern. I wouldn't say it was necessarily a
7 problem, but I think some people in the Subcommittee
8 felt that that word was not the best word for that.

9 CHAIRMAN ALDERSON: Right, okay. So,
10 that's what brought it here? Thank you for that
11 clarification.

12 Other comments or questions from the
13 ACMUI on this report?

14 Anyone else in the audience that wishes
15 to comment on this report? Anyone here in the room?

16 MS. HOLIDAY: Dr. Alderson, this is
17 Sophie.

18 CHAIRMAN ALDERSON: Yes, Sophie?

19 MS. HOLIDAY: If I may, I guess I just
20 want to remind the Committee of why this Subcommittee
21 was formed.

22 If you guys will recall during the
23 October meeting, Dr. Thomadsen, during his farewell
24 presentation had brought up multiple things. And,
25 one of the things that he brought up was that there

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1 was an event that occurred at his institution and
2 they thought that it was a medical event.

3 So, they reported it and their regulatory
4 authority came back and said, no, it's not a medical
5 event.

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

14 And, that way, it could help facilitate
15 the Subcommittee's work.

16 CHAIRMAN ALDERSON: Well, thank you, Ms.
17 Holiday.

18 So, would anyone on the Committee like to
19 help us resolve the ambiguity in medical events by
20 giving us some examples from their own experience?
21 Redacted for the appropriate details, of course.

22 Yes, Dr. Zanzonico?

23 VICE CHAIRMAN ZANZONICO: Yes, well,
24 actually, it was the I-124 incident that was reported
25 as an ME and there was a lot of disagreement at

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1 Memorial over whether this was reportable or not.

2 I did not think it was reportable. And,
3 what had happened was, the catheter was put in place
4 and the infusion, since it's directly into the brain,
5 has to be done very slowly, microliters per minute to
6 avoid brain swelling.

7 And so, the amount of activity that was
8 injected into the body that was injected in the slow
9 rate of injection meant that the patient was awake
10 with the catheter in place and these are children.

11 And, in the past, when a small body of
12 activities were used, it was done completely in the
13 OR while they were under anesthesia.

14 And, the children, people doing what they
15 do, move and the catheter didn't come out, but the
16 connector was loosened.

17 I think that can be interpreted as
18 patient intervention. Nothing was done incorrectly
19 by the surgeon or anyone else involved with the
20 procedure and so, in that respect, it was a -- I
21 thought it was not a medical event even though the
22 activity delivered was easily 50 percent from that
23 that was prescribed.

24 I mean, I think that's the kind of thing
25 where there's sort of a grey area as to whether

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1 patient intervention resulted in the under dosing or
2 over dosing or something incorrectly was done that
3 resulted in that and so forth.

4 CHAIRMAN ALDERSON: So, given, just to
5 follow up on your comment, given, then, that you
6 clearly as an expert, didn't feel it was a medical
7 event. How did this event get reported? How was
8 that decided that it should be reported?

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

11 CHAIRMAN ALDERSON: I see. So, it's the
12 RSO?

13 VICE CHAIRMAN ZANZONICO: It's the RSO's
14 fault. It was.

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

21 CHAIRMAN ALDERSON: I got it.

22 Ms. Weil will be next.

23 MEMBER WEIL: If you go back to the
24 purpose of reporting medical events, and to see it in
25 a positive opportunities for making a public

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1 situation -- these are opportunities for public
2 discussion or public perusal of events that have
3 happened.

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

10 CHAIRMAN ALDERSON: Okay.

11 Yes, Mr. Zanzonico would like to respond
12 to that.

13 VICE CHAIRMAN ZANZONICO: Yes, right.

14 CHAIRMAN ALDERSON: And then, we have a
15 couple of others.

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

23 The other point is, these events, even if
24 they're not reported to a regulator of a medical
25 event, are reported. They're reported in the peer

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1 review literature as case reports and so forth.

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

8 CHAIRMAN ALDERSON: We have many -- many
9 hands are up. Ouhib?

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

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

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

25 CHAIRMAN ALDERSON: Thank you.

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1 I think Dr. Ennis was next.

2 MEMBER ENNIS: Thank you.

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

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

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

22 And now, what we do is much smaller,
23 précised and less homogeneous. So, there are
24 scenarios that can come up, I'll give you a couple of
25 examples, that just don't fit.

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

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

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

13 Their colon is getting -- you get the
14 idea. And, it's not wrong body sites, it's the same
15 body site, it's a little off, volume wise. How much
16 off to what 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
20 double dose and I'm treating some other spots, but
21 half of that dose.

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

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

4 So, I think from a radiation oncology
5 perspective, this whole volume issue in particular
6 and 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
11 is going to talk a little bit about the OIG report.
12 And, one of the recommendations was to clearly define
13 the 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
22 that the Committee should consider taking up.

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

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1 therapy has changed a lot since 1980. Okay?

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

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

11 And, reasonable people can differ what
12 the purpose of the rule because it was put out in
13 1980, it could be clearer now in 2016.

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

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

23 That's all.

24 CHAIRMAN ALDERSON: Thank you, Mr.
25 Costello, for that comment.

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1 Dr. Langhorst?

2 MEMBER LANGHORST: Another aspect to what
3 Frank was bringing up is, what is the regulatory
4 measure? What do you measure?

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

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

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

20 But, you want to be able to bring that
21 forward without fear of repercussion.

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

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1 violation?

2 I mean, I hate to say it that way, but
3 that's the way it happens.

4 So, I think we'll be discussing it more
5 as we talk about the OIG report tomorrow. But, how
6 do you have a regulatory environment with regulations
7 that you have to enforce and also be supportive of a
8 safety culture in bringing those things forward.
9 And, it's not an easy balance.

10 CHAIRMAN ALDERSON: I think that's an
11 excellent comment.

12 Dr. Metter?

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

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

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

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1 I got reprimanded for bringing it up by
2 my department chair. And, I was not supposed to
3 anything like that unless I get it cleared by the
4 department chair who didn't understand what a medical
5 event was.

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

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

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

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

25 And so, at some point, as part of these

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1 discussions on medical events, we, as a Committee,
2 should consider whether, you know, you've got to start
3 somewhere. We should be speaking up and making it
4 clear that we think that the regulatory culture on
5 this should not be punitive.

6 So, I just put that out there as an
7 observation. And now, I believe the next comment was
8 Mr. Costello.

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

15 For many cases, I simply rely and trust
16 our licensees to calculate doses properly and
17 calculate -- and figure out which activities put there
18 properly. And, then that's what I identify.

19 As far as the punitive, you know, that
20 varies probably from regulator to regulator and I'd
21 say that I think we try not to, sometimes it may feel
22 that way. But, I don't think it's ever our intention
23 to do that.

24 And, the other observation I had is,
25 often times, we find that it is the better programs

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1 that are reporting the medical events. The better -
2 - it's not the, you know, marginal programs who's
3 reporting or anything, they don't report anything
4 because, if I may say bluntly, they wouldn't know a
5 medical event if it fell on their head. Okay?

6 But, it's the prestigious organizations
7 that have good quality programs that have internal
8 debates whether this is -- they're the ones reporting
9 it.

10 There are programs, I know, are not the
11 best that we never hear from. I don't have an answer
12 for that. Your institutions rule bound and those are
13 the ones that we get reports from.

14 So, if we, as regulators, are making you
15 feel -- being punished for doing the right thing,
16 following the safety culture, then we've got to a
17 better job.

18 CHAIRMAN ALDERSON: Dr. Metter?

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

23 Now, I believe the new culture is quality
24 improvement. And so, it's more of a just culture
25 where you're not individually penalized as

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1 individuals but more the systems and I think the
2 systems cause this sort of problem. And, I think
3 that's kind of what you're reflecting.

4 CHAIRMAN ALDERSON: Thank you.

5 Mr. Ouhib?

6 MR. OUHIB: Yes, I think you brought a
7 very good point. And, there are some sort of a
8 disconnect. There is a perception and there are
9 facts.

10 And, I think there was one -- somebody
11 had one slide earlier where it is time to have the
12 ACMUI, NRC and professional organizations sort of get
13 together and discuss this together, basically, to
14 come up with a better, you know, a culture of safety,
15 you know, and everybody is online.

16 CHAIRMAN ALDERSON: Very good.

17 Other comments?

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

21 MEMBER SUH: No, no.

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

25 Any final comments, Dr. Suh?

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

6 And, I fully agree that there are some
7 institutions where a mistake has happened, there's
8 repercussions. And, as a physician and as an
9 authorized user, you don't want to go there.

10 But, I mean, it's okay John. Not
11 necessarily like that, you know, depending where you
12 are at what institution. So, I think we're getting
13 better at that, but --

14 You know, and I think the other thing,
15 too, is I think, well, for a lot of physicians, making
16 -- admitting to -- a mistake is very hard for them to
17 do.

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

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

24 And, I do like the fact that there's going
25 to be greater transparency. And, I think one of the

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1 things that I can personally do is that, you know,
2 for the trainees that we have, I think it's good for
3 them to read about these events.

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

8 I mean, just simply just asking for your
9 name and your birth date and which part of the body
10 are you treating? And, if the patients says you're
11 supposed to be treating here with radiosurgery and
12 I'm going to treat here, I'd better think long and
13 hard before I sit the patient in the machine and push
14 the button.

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

19 So, I want to thank everybody who
20 contributed to this very good discussion and to the
21 great Committee report for their work and we'll move
22 forward with this.

23 Thank you.

24 So, I think we're ready, if Katie Tapp is
25 ready to start, we're ready to move on to the next

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1 presentation which is on NUREG-1556, Volume 9 Update.

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

4 NUREG-1556 is the consolidated guidance
5 about material licenses. Volume 9 is specific to
6 medical use licenses.

7 Currently, there are two updates going on
8 with Volume 9. The first update is associated with
9 the rulemaking. This update is on the bottom here
10 in this chart and its current has just received
11 comments from ACMUI and Agreement States.

12 As we discussed before, the NRC is
13 looking at these comments and going through the
14 resolutions and initiating to send up the final rule
15 to the Commission.

16 In addition, there is an update to the
17 sections that are not associated with the rulemaking.
18 That is the top part of this chart.

19 We have received comments from the
20 steering committee that's involved with updates to
21 all the 1556 volumes and from NRC staff and from the
22 ACMUI members.

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

25 This revision will not include the

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1 updates that are associated with the rulemaking.
2 This will be sent out without those updates.

3 As you can see from this table, it will
4 be after we get direction from our Commission for
5 that and as well as receiving the public comments for
6 the updates that are not associated with the
7 rulemaking, we'll bring those two together and then
8 we'll issue it for final publication.

9 The updates not associated with the
10 rulemaking are associated with comments that were
11 received but not addressed during Revision 2 to this
12 document.

13 Revision 2 was associated with the NARM
14 rule where we included naturally occurring and
15 accelerated produced isotopes.

16 In addition, we have new comments from
17 the public and from NRC and Agreement States staff
18 including both inspectors and licensing staff.

19 We received ACMUI recommendations and
20 we're incorporating those into the documents as well
21 as updates to references that have occurred and get
22 other guidance documents since the last revision.

23 We're going to reflect the movement of
24 going more electronic-based. This new document will
25 include hyperlinks so we can move throughout the

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1 document. It's a very large document, so this will
2 allow movement easily throughout the document as well
3 as to regulations and other guidance documents.

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

8 For example, reciprocity, when an
9 Agreement State licensee comes across and goes into
10 an NRC space, they have to send in a letter for
11 reciprocity. We want to make sure that it's
12 consistent between the volumes of what they have to
13 do to do this.

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

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

19 As was said this morning from Sophie
20 Holiday, we will issue a memo explaining if there are
21 any differences that the staff incorporates that are
22 not fully incorporated or not incorporated the same
23 way that it has been recommended or if no action was
24 taken on that recommendation. We're going to explain
25 why the staff made that determination.

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1 One recommendation that was made was the
2 comment period extension. The ACMUI recommended that
3 NUREG-1556, Volume 9 have a longer public comment
4 period than the other 1556 volumes because of the
5 complication with medical use licenses.

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

9 This is double the amount of time that is
10 allowed to other volumes. It was recognized this is
11 a complicated volume.

12 The ACMUI has provided, as I said, nine
13 other recommendations and we are going through those
14 with our working group and incorporating those.

15 And moving on to any questions?

16 VICE CHAIRMAN ZANZONICO: Pat Zanzonico.

17 I'm a little confused, I'm a little
18 confused by this approach because, if I understand
19 correctly, there will only be two reg guides
20 published, one without the rulemaking section and
21 with within a year of one another.

22 Because it says draft Volume 9 Guidance
23 published and then it says below that then there's an
24 arrow connecting the two lines where you'll publish
25 a final version with the rulemaking changes

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1 incorporated.

2 DR. TAPP: So, the draft Volume 9
3 Guidance published will be published for public
4 comment. It is not going to be published final.

5 VICE CHAIRMAN ZANZONICO: No,
6 understood. But, even with that, it still seems
7 confusing to, you know, perspective stakeholders to
8 comment on what is essentially an incomplete version
9 and then, within a year, comment on the final complete
10 version.

11 DR. TAPP: The public has already had an
12 opportunity to comment on the rulemaking version. We
13 did not want to confuse people by putting it back
14 out.

15 As we're going the parallel paths, we
16 wouldn't have to wait for all that to be finalized,
17 wait for the Commission. It would add a large delay
18 to our publication. So, we were doing it in parallel
19 paths so we can issue the final publication as soon
20 as after the final rulemaking is done.

21 The public has to have -- or we want to
22 give the public a chance to comment on all changes.
23 So, this was a pathway that would allow the public to
24 see both the rulemaking changes as well as the non-
25 rulemaking changes.

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1 But, the public will have a chance to see
2 both.

3 VICE CHAIRMAN ZANZONICO: I guess we
4 agree to disagree --

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

6 VICE CHAIRMAN ZANZONICO: -- in terms of
7 this approach.

8 CHAIRMAN ALDERSON: Other questions or
9 comments?

10 Dr. Langhorst?

11 MEMBER LANGHORST: Pat, you're right, it
12 is very confusing.

13 And, I have been trying to think of how
14 to help in this effort, especially as you put out a
15 draft of the non-rulemaking changes.

16 And, I wonder if maybe you can designate
17 those parts that are involved in the rulemaking in
18 some way to say, this was reviewed, this was updated
19 in the rulemaking and point them in that direction so
20 that they're not giving you feedback on stuff that
21 isn't up to date with the rulemaking.

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

25 I will say, and I think my licensing

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1 people at Region III know this, I love the NUREG-1556
2 series. And, it is very helpful to me as a radiation
3 safety officer in developing licensing -- license
4 amendments, license applications and so on.

5 And, I commend you for making things
6 consistent and trying to make sure that if you have
7 regulatory guidance that you keep it in one location
8 so you only have to update that one and you reference
9 it, and especially by hyperlinks is great. I know
10 it's not the greatest for those who still have to
11 look at paper, but at least I think that is the way
12 to go.

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

15 DR. TAPP: Thank you.

16 MEMBER LANGHORST: Thank you.

17 CHAIRMAN ALDERSON: Yes, Dr. Zanzonico?

18 VICE CHAIRMAN ZANZONICO: Not to beat
19 this horse to death, but my concern is that you're
20 going to get a segment of users who are going to see
21 the draft guidance and say, okay, this is the law of
22 the land, this is what I'm going to follow and almost
23 be completely unaware of the subsequent final
24 publication.

25 I mean, this two-step approach, and I

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1 understand the rationale for doing it from a
2 logistical point of view, but it seems almost destined
3 to create problems among, you know, a segment, perhaps
4 most of, you know, the user base.

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

6 The staff is well aware that this could
7 create confusion. We want to be as clear as possible
8 when we issue this for public comment and we take the
9 suggestions here as how to do that.

10 CHAIRMAN ALDERSON: Yes, Dr. Howe?

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

15 So, you won't have a draft that says, oh,
16 your training experience, you don't need an
17 attestation anymore. It will still say you need an
18 attestation.

19 Now, as soon as the rule is final, we'll
20 have guidance to say you don't need the attestation
21 anymore. That will come back together on the final
22 NUREG and you will have to absolutely follow in Part
23 35.

24 But, on the draft, that'll be out before
25 the final rule comes out. So, you won't be confusing

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1 people between what's in the existing regulations
2 because it doesn't have any regulatory changes. It
3 just has consistency.

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

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

17 Well, we were faced with Revision 3
18 coming out and then within a very short period of
19 time, maybe a month or two, Revision 4 coming at us.

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

24 So, we're bringing these things up
25 parallel with the idea, they will come together and

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1 will be one huge revision to Volume 9. Because, we
2 think that's going to be, in the end, the clearest
3 that -- what Volume 9 are you dealing with? I'm
4 dealing with Revision 3. Okay, it's all in Revision
5 3. You don't confuse 3 and 4 because they're two or
6 three months apart.

7 CHAIRMAN ALDERSON: Yes, Mr. Fuller:

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

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

13 Staff has struggled with this for several
14 years. You know we've been in rulemaking for many
15 years.

16 We have requirements that when we propose
17 a rule, we publish a proposed rule. We must publish
18 the draft guidance, which we did. And we got comments
19 on that. That's part of the rulemaking process.

20 Then, and we keep talking about parallel
21 paths, we have an obligation to revise this guidance
22 irrespective of the rulemaking. That's a fact of
23 life. That's just we have to do that. It's not an
24 option for us.

25 So, we have -- the staff has been put in

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1 a position of having to do two different things at
2 the same time that involve NUREG-1556, Volume 9.
3 Again, it's a fact of life.

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

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

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

22 But, it's, as I said, we are where we are
23 and we are obligated to do both of these things which
24 are different things. And, that's the best way I can
25 describe it.

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1 CHAIRMAN ALDERSON: Further comments?

2 Yes, Mr. Mattmuller?

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

11 So, just to help them keep the two
12 processes separate.

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

15 CHAIRMAN ALDERSON: We'll ask if anyone
16 is on the line right now who's a member of the public
17 who wants to comment about this issue? Is there
18 anyone on the line that wishes to comment?

19 There are no such comments.

20 More comments from within the room here?
21 Members of the ACMUI? I'm sorry, I missed somebody.

22 Yes, sir?

23 MR. MCMURTRAY: Hello. I'm Tony
24 McMurtray. I'm the overall Senior Project Manager
25 for the NUREG-1556 project. So, I've got all 21

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1 volumes that I'm trying to work with Katie and others
2 to move through.

3 I appreciate all the comments that we
4 have here. As we've said, we'll work with our admin.
5 We'll probably put up in the draft a comment section,
6 maybe this time line or something specific for this.

7 We also have this issue with the Volume
8 13, Radiopharmaceuticals, because there's going to be
9 language also in that volume that's going to come
10 from the rulemaking that's going to come in.

11 Just as some background, some of the key
12 things that we're trying to do with the overall NUREG-
13 1556 series, we're putting security information in
14 there to address the Part 35 rulemaking that happened
15 for security and we're doing a lot of things with
16 consistency and bringing all the volumes into a
17 consistent standpoint.

18 We just -- if you want to look and see
19 what some of this information looked like, we just
20 issued for final report Industrial Radiography,
21 Volume 2 last week. So, you can go on our public
22 website and look at that. You can see some of that
23 standard information that's in there.

24 But, as Katie mentioned, things like
25 Agreement State information, an update on the

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1 Agreement State map, reciprocity, all those sort of
2 things, we've updated that, some of the things as far
3 as electronic submittals. There's a lot of new
4 information like that that we've added in.

5 So, we appreciate the comments and we'll
6 work to try to clarify this both for Volume 9 and
7 Volume 13 when we put those out.

8 CHAIRMAN ALDERSON: Thank you, Mr.
9 McMurtray.

10 Are there questions for Mr. McMurtray?

11 MEMBER MATTMULLER: Just one quick
12 comment.

13 I think if you could put this out there,
14 then put a little red arrow to tell the public, you
15 are here.

16 CHAIRMAN ALDERSON: Okay, that's a nice
17 sound suggestion.

18 Thank you very much.

19 Other questions or comments about this
20 topic?

21 Hearing none, thank you --

22 DR. TAPP: Thank you.

23 CHAIRMAN ALDERSON: -- Dr. Tapp.

24 I think that we're ready to go on to the
25 next item on the agenda which is Sophie Holiday

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1 talking about the Committee Reporting Structure.

2 MS. HOLIDAY: Hello, again.

3 And, I think I'm going to up Donna-Beth
4 and say, *this* is the most important presentation that
5 you'll hear --

6 CHAIRMAN ALDERSON: We all say that.

7 MS. HOLIDAY: All year long.

8 So, today, I'm going to speak to you about
9 what is the current reporting structure, talk about
10 or give you your annual review. As I said earlier
11 this afternoon, this is a recommendation from the
12 Committee put forward for us to review your structure
13 on an annual basis, talk about your meeting frequency
14 and then open it up for discussion.

15 So, many of you are very familiar with
16 this chart. You just saw it this morning in Dr.
17 Alderson's presentation. This is simply just to say
18 that you, the Committee, reports to Dan Collins who
19 is the Director of the Division of Materials Safety,
20 States, Tribal and Rulemaking Programs, which is
21 within the Office of Nuclear Material Safety and
22 Safeguards.

23 And, of course, our office, NMSS, falls
24 under the purview of the Executive Director for
25 Operations, Victor McCree, which some of you also got

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1 to meet after the meeting.

2 And then, the EDO relays staff's
3 positions and things of that nature to the Commission.

4 The dotted line simply represents that
5 each of these individuals, and I did not have a dotted
6 line for the Director of MSTR, but this is not to say
7 that the dotted line does not exist, it's simply to
8 say that all of these individuals have an Open Door
9 Policy, which simply means that, at any time you guys
10 wish to come in and speak to them, you have that
11 opportunity. You just have to arrange it with their
12 secretaries.

13 And, lastly, that box at the bottom,
14 MSEB, represents our branch, which Doug is the Branch
15 Chief of - the Medical Safety and Events Assessment
16 Branch.

17 Like I said last year, while it may seem
18 like you report to me, you do not. Our branch just
19 oversees and supports the day-to-day activities of
20 the Committee.

21 So, in an annual review in September of
22 2012, the ACMUI reiterated their recommendation to
23 have an annual review of your reporting structure.
24 This is the sixth annual review that we have conducted
25 since then.

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1 I think my best quote that I like to say
2 comes from the ACMUI Bylaw Subcommittee Report in
3 which Dr. Zanzonico presented the Committee with the
4 option to continue reporting to our office, NMSS, or
5 directly to the Commission.

6 And, in that report, it stated, verbatim,
7 ``the working relationship between the NRC and ACMUI
8 remains excellent. The reporting structure through
9 NRC staff continues to function effectively and the
10 associated logistical overhead associated with direct
11 reporting to the Commission, e.g. the need for more
12 frequent meetings, did not and does not now justify
13 any change in the ACMUI's reporting structure.''

14 Comparatively, we have another federal
15 advisory committee, the ACRS, Advisory Committee on
16 Reactor Safeguards, this is actually one of their
17 meeting rooms. And, they report directly to the
18 Commission.

19 So, on an annual basis, this Committee
20 reviews if you would like to be similar to ACRS and
21 report directly to the Commission or continue
22 reporting to staff or rather the management in NMSS.

23 So, we meet here at Headquarters twice a
24 year in the spring and in the fall. Your spring
25 meetings are usually between March and April and your

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1 fall meetings are usually between September and
2 October.

3 We hold ad hoc teleconferences on an as
4 needed basis. That means approximately each year,
5 we have between two to three teleconferences,
6 although some years, you know, you may have less or
7 you may have more. It just depends on what the need
8 is.

9 So, at this time, I would like to open it
10 up for discussion.

11 Is the Committee satisfied with
12 continuing to report to NMSS or would you prefer to
13 report directly to the Commission?

14 Are you agreeable to two in-person
15 meetings or would you like more or would you like
16 less?

17 What other changes would you like to see?

18 Thank you.

19 CHAIRMAN ALDERSON: Thank you, Ms.
20 Holiday.

21 Now, those are three separate questions.
22 I hope we can discuss them separately.

23 So, the first question was, does this --
24 is the ACMUI happy with its current reporting
25 structure or would we prefer to report directly to

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1 the Commission?

2 So, let's try to address that single
3 question.

4 Mr. Costello?

5 MEMBER COSTELLO: I have a question about
6 something the Chairman said today. And, the
7 impression I got was, if we were working and reporting
8 directly to the Commission, I'm sorry --

9 That the Chairman said if we were
10 reporting to the Commission like ACRS is, you couldn't
11 have people who are actively engaged as members
12 appear, you'd wind up having people who are retired.

13 I don't know -- understand why that is,
14 but if that is the case, then clearly we benefit by
15 not reporting directly to the Commission because look
16 at all the practical experience you're getting now.

17 But, is that true?

18 MS. HOLIDAY: I will paint the picture
19 like this, ACMUI meets here twice a year. ACRS meets
20 here ten times a year in-person.

21 And, your meetings are usually -- they're
22 here for in-person full committee meetings as well as
23 subcommittee meetings.

24 MEMBER COSTELLO: So, I gather that means
25 that it's not required by law that they be retired,

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1 but no one here could give up that much time to come
2 here ten times a year for meetings. And so,
3 practically, it has the effect of not being able to
4 have people who are currently practitioners be able
5 to do the work.

6 Thank you.

7 CHAIRMAN ALDERSON: Additional comments?

8 Yes, Dr. Zanzonico?

9 VICE CHAIRMAN ZANZONICO: I think we will
10 recognize that the medical component of the NRC
11 overall is a relatively small component and the
12 concerns and knowledge of the Commission is -- that's
13 a small portion of the overall concerns.

14 And so, if we, for whatever reason,
15 decided it was advantageous to report directly to the
16 Commission, we frankly would be dealing with
17 individuals who have much less familiarity, much less
18 knowledge, et cetera, et cetera, of all of the issues
19 used in medical applications of byproduct materials.

20 And, I think we would spend a lot of our
21 time explaining and re-explaining things and much
22 less time productively in, frankly, discussing real
23 issues.

24 So, I think given how the -- what the NRC
25 does overall and how it's configured, I think we're

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1 far better off working through the staff than working
2 directly with the Commission.

3 CHAIRMAN ALDERSON: Other comments on
4 this particular question?

5 The first two comments both favor
6 continuing our current reporting structure. Are
7 there any people who would speak against that
8 particular idea?

9 Hearing none, I think we have resolved
10 that question. We would like to continue with the
11 current structure.

12 I believe the second question had to do
13 with two meetings a year at the Headquarters. So,
14 that issue is, we currently meet twice a year and is
15 the ACMUI pleased with that? Is that a good frequency
16 of meetings or do we feel that we should meet at some
17 other frequency?

18 So, those who might wish to comment on
19 that, please do so.

20 MEMBER COSTELLO: I think two is the
21 right number.

22 CHAIRMAN ALDERSON: Mr. Costello thinks
23 two is the right number.

24 Several people are nodding their heads in
25 agreement at this point.

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1 Dr. Zanzonico, would you like to comment?

2 VICE CHAIRMAN ZANZONICO: Our meeting is
3 ending at 1:00, so we don't even need two full days
4 for this meeting. So, two is enough and three we'd
5 just be sitting around staring at each other. I
6 think it's the right number of meetings.

7 CHAIRMAN ALDERSON: So, it seems that the
8 consensus of the Committee is that the two meetings
9 a year is the correct amount.

10 Am I hearing anyone speak against that?
11 No, so we agree that two meetings a year would be
12 fine.

13 And, remind me of what the third point
14 was?

15 MS. HOLIDAY: Are there any other changes
16 that you would like to see?

17 CHAIRMAN ALDERSON: Right, a more open
18 question. Are there any other changes you would like
19 to see?

20 So, if anyone would like to see any,
21 please -- Dr. Ennis?

22 MEMBER ENNIS: We talked, I guess,
23 earlier this morning about that we need to get more
24 feedback from -- I apologize.

25 We talked this morning, there were

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1 comments that the Commission made this morning, I
2 believe, that getting more feedback from NRC staff to
3 ACMUI with why, what was the thinking in adopting or
4 not adopting particular recommendations.

5 And, along those lines, and consistent
6 with kind of the overarching theme here, is there --
7 ought there be a time and place for NRC to give
8 feedback to ACMUI in general about their performance,
9 if you will, I think we're doing a great job, but
10 what would you like to see better or worse or
11 strengths and weaknesses, is that something that is
12 done? Should be done?

13 MS. HOLIDAY: So, actually, you may be
14 familiar, Dr. Ennis, and many of the members are,
15 every two years, staff writes a paper to the
16 Commission which is our biennial evaluation of the
17 Committee.

18 So, when I had you guys complete forms,
19 there were questions that you had to answer about the
20 Committee's interactions, staffs interaction with the
21 Committee, things of that nature.

22 On the other side, staff also has to
23 evaluate the Committee.

24 So, both the staff's position and the
25 Committee's position or evaluation is included in

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1 that Commission paper. And, we, too, agree with you
2 that we are very satisfied with the Committee.

3 CHAIRMAN ALDERSON: Mr. Costello?

4 MEMBER COSTELLO: I have one issue maybe
5 to refer to the table. I believe that years ago,
6 that there was no cardiologist on the ACMUI because
7 back then, that was all done by nuclear medicine
8 physicians and now we have the benefit of nuclear
9 cardiologists.

10 We've had recent discussions, a lot of
11 recent discussions, about alpha and beta emitters and
12 the role of medical oncologists.

13 Were there any reason to consider
14 including the oncologist, someone who's not a
15 radiation oncologist, but a medical oncologist as a
16 member of the Committee? Is that someone who can
17 contribute to our discussion we have about the, you
18 know, the alpha and beta emitters, is that a viewpoint
19 that we're missing with our current membership?

20 CHAIRMAN ALDERSON: So, I think it's
21 appropriate for the ACMUI to comment on that question
22 before we go to Dr. Langhorst and her next question.

23 So, would people like to comment on that
24 issue? Should we have a medical oncologist on the
25 ACMUI?

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1 Dr. Ennis?

2 MEMBER ENNIS: A lot of what we're doing
3 is not oncological related. So, a lot of their
4 expertise would not be particular helpful and they
5 may not be interested. But, also not necessarily
6 needed.

7 I think that having radiation oncologists
8 who bring the oncology background and the radiation
9 background really suffices, I think, unless people
10 feel otherwise, for that knowledge.

11 And, obviously, we can always have guests
12 come as we and just see, to bear -- give us their
13 expertise for those certain things where needed.

14 CHAIRMAN ALDERSON: Yes.

15 Yes, Dr. Dilsizian?

16 MEMBER DILSIZIAN: This is nuclear
17 cardiology, but nuclear cardiology I think they do
18 nine million procedures per year in this country.
19 So, it's not just a cardiology specialty, it's
20 actually works with ionizing radiation and they have
21 expertise in it.

22 And, wherein, oncology, ionizing
23 radiation is really not part of their training and
24 there's a subspecialty, certification board of ASNC
25 which is NRC recognized. So, it's not the same.

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1 CHAIRMAN ALDERSON: Other comments to
2 this particular question?

3 Dr. Suh and then Dr. Palestro?

4 MEMBER SUH: So, I also concur with the
5 two previous individuals. I think the value-added
6 for having medical oncology as part of the ACMUI would
7 be very limited because I think their scope and
8 knowledge would be very limited.

9 And also, on the current Committee, it's
10 radiation oncology. I think the oncology perspective
11 would be reserved.

12 CHAIRMAN ALDERSON: Dr. Palestro?

13 MEMBER PALESTRO: I would agree with Dr.
14 Suh and the previous comments.

15 In addition to that, I think that with
16 the open forums that we have, there's also the
17 opportunity for oncologists and whoever else wanted
18 to contribute and offer information or even use
19 radiopharmaceuticals, that's more than ample.

20 But, I would also point that we don't
21 have any physician on the Board, nor do I think it's
22 necessary, to have an endocrinologist on the Board to
23 address issues of radiation pertaining matters and
24 they even have a certification board for that.

25 CHAIRMAN ALDERSON: Would anyone else

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1 like to comment on this question?

2 Mr. Costello, I think the consensus of
3 those commenting is that we do not need a medical
4 oncologist on this Committee, but could call one if
5 we needed their expertise.

6 MEMBER COSTELLO: Thank you.

7 CHAIRMAN ALDERSON: Good.

8 Are there any other comments on this
9 question of other things the Committee -- oh, yes,
10 Dr. Langhorst was going to make a comment.

11 MEMBER LANGHORST: Thank you very much.

12 I know one of the things that we have
13 discussed during this kind of annual review and so on
14 is the level of medical use or medical team support
15 and the challenges that they face as far as funding
16 and being able to do their jobs.

17 That's always a concern. We've already
18 heard a few instances where they've not been able to
19 work on things we presented to them because they don't
20 have the resources to do so.

21 I think the extensive time of getting
22 Part 35 rulemaking through is hard to believe. And,
23 there's no -- you saw on what Sophie went through
24 this morning that there are things that are pending
25 the next Part 35 rulemaking.

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1 Well, I'm pretty sure most of us won't
2 even be alive when that starts.

3 So, I just want -- I'm sorry, I'm talking
4 about the Committee here.

5 I just want to say that the funding for
6 the medical team and, if we go back to last fall and
7 the report on abnormal occurrences, they're all
8 medical. I mean, there's very few, but that's not
9 the focus that NRC puts on things.

10 So, I just wanted to make mention of that.
11 And, we think that there should be a little more
12 funding for the medical team.

13 CHAIRMAN ALDERSON: Thank you.

14 Other -- yes, Dr. Ennis?

15 MEMBER ENNIS: I think that's very
16 interested, I hadn't thought of that, but if there
17 were more staff like to Part 35, would that -- is it
18 realistic to think that if there had been more staff
19 that could have been done in significantly less time?

20 MR. BOLLOCK: In regards to that, the
21 current Part 35 rule, I don't know that that would
22 necessarily have sped it up that much. I'm sure
23 every, you know, every bit of resource helps.

24 And, we have a lot of our staff helped
25 with the Part 35 working group. But, there are a lot

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1 of other factors that, internal, external factors,
2 and changing factors over the past ten years that
3 delayed the rule, not so much our staff resource.

4 And, I think my staff can attest that
5 when it came down for the time for that working group
6 to get back together and go over the comments and
7 work on it, we put -- we shift effort and we've been
8 able to do it fairly well. We've been flexible
9 enough.

10 You know, but as anything, any
11 organization, we have our challenges with resources.
12 As just look around the room, you may see that Ashley
13 Cockerham is no longer with us. So, right now, we're
14 looking at filling her position. So, right now,
15 we're one staff down.

16 Actually, for a number of months, we're
17 two staff down because we also fill other roles in
18 the Agency and I have another member of the medical
19 team helping out the division. And, that just
20 happens.

21 So, as far as more people on the -- I
22 think as long as we are fully staffed to what we're
23 supposed to have, we can get a lot of work done.
24 Unfortunately, that's not always the case and we
25 weren't able to get to the patient intervention, we

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1 weren't able to get to that in the past year with the
2 rule and with patient release project and five or six
3 working groups for 35.1000 guidance.

4 So, but, you know, we appreciate the
5 endorsement to get more resources. I wish, you know,
6 I wish we had more resources. I wish I had more
7 money for -- to get out to the -- more societies and
8 send more staff out to the processional societies
9 and, you know, train everybody as much as possible.

10 Unfortunately, you know, we are in an --
11 our current budgetary environment is we are
12 shrinking. I think we'll still be able to do
13 everything we need to do, I'm confident of that. But,
14 we're not going to be able to expand on that,
15 unfortunately, not in the near future.

16 CHAIRMAN ALDERSON: Ms. Weil?

17 MEMBER WEIL: Lest I put myself in the
18 unenviable place of trying to make more work for the
19 team, it would be useful for us, I think, as a
20 Committee, to hear more reports from the working
21 groups.

22 We have only half a day tomorrow and we
23 would do our work better if we understood the context
24 in which it all fits into place.

25 I know that you do stuff that we don't

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1 hear about much or certainly not every time. And,
2 while I'm sure you don't want us meddling in
3 everything you do, I think we could be more productive
4 if we had the bigger picture.

5 CHAIRMAN ALDERSON: Mr. Costello?

6 MEMBER COSTELLO: Kind of in support of
7 what Sue had to say, and the reason why I think it's
8 important is you provide as many resources as they
9 can to the medical side of the program.

10 While medical -- the NRC program is a
11 relative small part of what they do. If you think
12 of the number of people in America who are actually
13 affected by what we do, it's probably almost anyone
14 you know knows someone who's either having a
15 diagnostic test, having a treatment or knows someone
16 who is.

17 Probably, you're talking hundreds of
18 millions of people who are affected one way or another
19 by what we do.

20 And, all due respect to the other side of
21 the house here, I think the routine impact that they
22 may have on those hundreds of millions of people may
23 not be so immediate as what we do here.

24 So, I'm just tooting our own horn here.
25 What we do here is very important. What your team

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1 does is very important. And, I rather hate the idea
2 of having to have cuts at all.

3 CHAIRMAN ALDERSON: Are there any other
4 comments on this topic?

5 Well, thank you, and I believe that
6 terminates our discussion of new issues.

7 And, we'll now move on to Katie Tapp,
8 again, who will talk to us about the update on
9 Yttrium-90 Microspheres Brachytherapy Licensing
10 Guidance.

11 DR. TAPP: Thank you.

12 I'm now going to discuss the update to
13 the Yttrium-90 Microsphere Brachytherapy Licensing
14 Guidance.

15 What I'm going to go over today is an
16 outline of what was changed in the Revision 9 that
17 was recently issued. It was issued on February 12,
18 2016 as final.

19 In addition, I'm going to discuss the NRC
20 and Agreement State working groups consideration for
21 a potential future updates of what we're actually
22 going to be looking at for the possibly Revision 10.

23 First, with the Revision 9 changes, the
24 first change, large change to this licensing
25 guidance, was to specifically exclude reporting of

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1 medical events that are due to static or emergent
2 patient conditions.

3 In addition, we're also excluding events
4 that are caused by shunting when shunting was
5 evaluated prior to treatment in accordance with
6 manufacturers' procedures.

7 This was a -- these both were
8 recommendations from the ACMUI and they were
9 incorporated into this revision.

10 With the removal of the reporting of the
11 events with shunting, the shunting dose and activity
12 is no longer required to be documented on the written
13 directive.

14 Additional training or additional changes
15 is to the training experience section where we are
16 allowing interventional radiologists certified by the
17 American Osteopathic Board of Radiology to be deemed
18 status for authorized user as well as this guidance
19 is an updated format which includes a Table of
20 Contents and easier to use to be able to use.

21 And this is something that's going to be
22 done for all of our Part 35.1000 licensing guidances
23 in the future.

24 Now, I'm going to shift gears to future
25 considerations.

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1 We wanted to get that last revision out
2 quickly because we knew those were important updates.
3 I believe all the updates are important, but those
4 were some that the ACMUI recommended that we get out
5 and to review and issue as soon as we possibly could.

6 Now, we are going on and doing future
7 considerations to look as see if there's more
8 revisions necessary for this document.

9 I'll go over each of these considerations
10 separately.

11 The first one is on long-lived
12 impurities. In 2007, the NRC was notified that there
13 were long-lived impurities in the Yttrium-90
14 microspheres, both in TheraSpheres and SIR-Spheres.
15 These impurities are created by the manufacturing
16 process themselves.

17 The working group is considering
18 potential updates to this section because we're
19 hearing that there might not be impurities in the
20 TheraSpheres -- in some of the microspheres.

21 The working group is considering this
22 update to either the section of the guidance document
23 itself or to the IN document, the Information Notice
24 that was issued in 2007.

25 The next consideration is to the autopsy

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1 and cremation. This was a topic that was discussed
2 by Dr. Zanzonico at a previous ACMUI meeting.

3 The microspheres, when they're injected
4 into a patient, they become trapped in the patient in
5 the capillary beds. These are permanent.

6 As you know, the Yttrium-90 has a short
7 half-life and will probably decay away. But, there
8 are considerations to the long-lived impurities.
9 These are something to be considered then during
10 autopsy and cremation upon the death of a patient.

11 The working group is considering if
12 information needs to be added to the licensing
13 guidance to provide guidance to individuals in
14 regards to autopsy and cremation.

15 Finally, we're considering the training
16 and experience section. This was not open in the
17 last revision, but we are opening this now to look at
18 it closer.

19 In particular, to the pathways that we
20 allow -- that we grant authorized users.

21 What we're looking at, specifically, is
22 the two pathways by which interventional
23 radiologists become authorized users.

24 The first pathway is to receive their
25 three clinical hands on cases under the supervision

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1 of an authorized user.

2 The second pathway is to have a
3 representative from the manufacturer come out and to
4 complete their three clinical hands on experience
5 with the manufacturer there.

6 The working group is evaluating as if
7 that manufacturer pathway is still necessary. That
8 pathway was added because there was not as many
9 authorized users for Yttrium-90 when it first
10 started.

11 As we are aware that this procedure is
12 growing, there are becoming more authorized users, so
13 we're evaluating if that pathway is still necessary.

14 The schedule of this, the working group
15 is working currently on looking at these
16 considerations and if we decide that a new revision
17 is necessary, the draft is expected here in the
18 spring.

19 This would then allow for the ACMUI to
20 look at the draft and provide a comment period as
21 well as an Agreement State review. And then, we
22 expect to issue this in the summer.

23 Leave that open to the now discussion.

24 CHAIRMAN ALDERSON: Questions on this
25 update?

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1 Dr. Langhorst?

2 MEMBER LANGHORST: I have a little more
3 generic question. On licensing guidance, typically
4 you don't open that up for any public comment, is
5 that correct?

6 DR. TAPP: That is correct.

7 MEMBER LANGHORST: I feel that's a lost
8 opportunity. I mean, it wouldn't necessarily need a
9 long public comment period, but in making these
10 various revisions, well, I think that would be
11 helpful. Just my opinion.

12 CHAIRMAN ALDERSON: Is anyone else on the
13 ACMUI like to extend that discussion with a further
14 opinion?

15 It appears not.

16 MS. HOLIDAY: Dr. Alderson?

17 CHAIRMAN ALDERSON: Yes, Sophie?

18 MS. HOLIDAY: This is Sophie.

19 If I could, Dr. Langhorst, while we don't
20 necessarily post licensing guidance documents for
21 public comment, on our NRC's medical use licensee
22 toolkit, where these licensing guidance documents are
23 housed, there is a statement there that says, at any
24 time, the medical community or members of the public,
25 something along those lines, have the option or the

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1 ability to inform NRC if changes are necessary for
2 guidance.

3 That is the reason why Revision 9 for the
4 Y-90 guidance has been issued. And, it's also the
5 reason why the ACMUI had a Radioactive Seed
6 Localization Subcommittee formed because staff
7 received comments from a few members of the public
8 regarding the recentness or the outdatedness, rather,
9 of the RSL guidance.

10 So, there are opportunities for that to
11 happen at any time members of the public can do so.

12 Thank you.

13 CHAIRMAN ALDERSON: Thank you for that
14 clarification.

15 Yes, Dr. Langhorst?

16 MEMBER LANGHORST: And, I appreciate
17 that. But, it's a little bit different if you're
18 saying, okay, here's what we're planning to update
19 and if you can get some feedback on that immediately
20 rather than trying to develop the justification for
21 redoing a licensing guidance, that's much more
22 onerous for an RSO to propose or others in a licensee
23 than it is to at least have some opportunity of input,
24 at least to see it and maybe even go through their
25 ACMUI representative, I don't know.

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1 But, it is a little frustrating in that
2 way, from my perspective.

3 CHAIRMAN ALDERSON: Dr. Palestro?

4 MEMBER PALESTRO: I have a question, I
5 guess, it's really directed toward the staff. Why
6 aren't they posted for public comment?

7 DR. TAPP: Sure. These are licensing
8 guidances for the license reviewers for evaluating
9 modalities that are regulated under 10 CFR 35.1000.

10 35.1000 modalities are emergent
11 technologies that we're trying -- that we use under
12 this pathway under licensing guidance for the review
13 because they are coming out faster than our rulemaking
14 process can adapt the medical use.

15 In the regulations, when we do
16 regulations, we have to have a public comment period.
17 As you guys are well aware, once we do public comment
18 period, that does add extra time. So, that would add
19 extra time to these modalities when we're trying to
20 get out guidance that can be used quickly for emerging
21 technologies that are moving very quickly.

22 CHAIRMAN ALDERSON: Dr. Zanzonico?

23 VICE CHAIRMAN ZANZONICO: Yes, I fully
24 second what Sue was suggesting. I mean, these are
25 very complicated procedures and to generate a

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1 licensing guidance for any purpose without the input
2 of the practitioners, the people doing them, is almost
3 certain to generate an inadequate document.

4 I mean, you really need the input of
5 people who do these procedures. There are so many
6 points and steps where something can go wrong and
7 interpret or misinterpret it as a medical event.

8 I mean, as Sue said, it's a real missed
9 opportunity not to solicit the input of the
10 practitioners in this area.

11 CHAIRMAN ALDERSON: Dr. Langhorst?

12 MEMBER LANGHORST: I can certainly
13 understand the hesitation to just open it up for
14 public comment and then you get all these comments
15 and you have address each of them.

16 What is, and I don't know how you do this
17 because I know there's rules and requirements that
18 don't allow you to, but to have a few people who do
19 these things on your working group would be wonderful
20 and would have an opportunity of bringing the medical
21 community into the regulatory development of these
22 things and give you that valuable perspective.

23 Because, you guys don't have physicians
24 working at Agreement States or at the NRC.

25 And so, I don't know if there's any

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1 possibility of being able to do that. I'm sure there
2 probably isn't and I'm not saying that you have to
3 then have an ACMUI member on there, because heaven
4 knows, you guys don't want to have a third meeting at
5 all.

6 So, that's our frustration because these
7 are being done in what appears to be a vacuum.

8 CHAIRMAN ALDERSON: So, these
9 interesting comments are on the spectrum of
10 communications which we talked this morning to the
11 Commission about.

12 I'm not saying by making that comment
13 that means this is one beyond the top of the priority
14 list, maybe it would be , maybe it wouldn't, but it's
15 on that communication spectrum.

16 And, you're right, that if you had an
17 open website, well, there'd be a lot of comments that
18 would be perhaps hard to field and it might take, you
19 know, somebody assigned to that area.

20 But, in this day of social media and
21 people communicating with each other so quickly all
22 the time, a number of organizations are literally
23 developing groups who communicate this way, as one of
24 the things they do to communicate with their
25 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
4 eventually 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
8 going to be working on is based on what and who's
9 feedback exactly?

10 DR. TAPP: The original revision,
11 Revision 9, was actually based on recommendations
12 from a Subcommittee from the ACMUI which was then the
13 ACMUI's recommendations.

14 The changes there were all ACMUI
15 recommendations. There was no additional ones.

16 But, with the other ones, some of these
17 are 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,
23 we don't have standard process to make them open for
24 public comment in draft form. We do discuss changes
25 and things 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
5 like ASTRO, AAPM and so on and so forth instead of,
6 if you cannot go to the public, perhaps you can go to
7 these professional organizations and they will be
8 able to 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
14 first 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
17 as members of the public. If you are not an NRC
18 employee, you're considered the public, or another
19 federal agency, you're grouped under as a member of
20 the public.

21 As far as getting feedback from the
22 medical community and who participates on these
23 working groups, these working groups really, in the
24 most recent years, or for the past five, six years,
25 maybe more than that, these 35.1000 guidance

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1 documents have been developed by a joint working
2 group.

3 By joint, I mean members from both NRC
4 staff and from the Agreement States.

5 As we've heard over and over again, we
6 have 37 Agreement States which make up over 87 percent
7 of the medical use licensees in the country.

8 So, the beauty of our working groups is
9 that we get both NRC's perspective as well as the
10 Agreement States' license reviewers. And, I will
11 pick on my co-chair who's here from my Icon Working
12 Group, Mr. Eric Perry works for the Kentucky
13 Department for Public Health. So, he's also on my
14 working group as a non-NRC staff person.

15 The working groups also have the ability
16 to reach into our resources, and that is the ACMUI.
17 The ACMUI serves as both an advisory committee, but
18 you can also serve as medical consultants.

19 Our working groups have been able to use
20 members on the ACMUI when we need that expertise.

21 For example, when the ViewRay Licensing
22 Guidance was developed, my working group did reach
23 out to Dr. Suh as a gamma stereotactic radiosurgery
24 radiation oncologist for his expertise.

25 Likewise, the Y-90 Microspheres Working

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1 Group was able to rely on the Y-90 ACMUI Subcommittee
2 and their recommendations. And, that Subcommittee
3 was comprised of many of the physicians that represent
4 the medical community that administers this
5 procedure.

6 So, we always have that ability to
7 incorporate the advice and the expertise and the
8 knowledge from the medical community.

9 While we don't post it for public
10 comment, these documents are considered pre-
11 decisional, but because the ACMUI members are NRC
12 special government employees, that's why we are able
13 to give them to you for your review and your comment
14 before we move it forward.

15 Likewise, we also send the guidance in
16 the draft form to the NRC regions where our license
17 reviewers are, as well as the Agreement States for
18 their review and comments as well.

19 So, not only are we getting comments from
20 NRC staff, we're getting them from Agreement States
21 staff and the ACMUI.

22 Thank you.

23 CHAIRMAN ALDERSON: Thank you.

24 Yes, Dr. Howe?

25 DR. HOWE: I think one of the things to

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1 remember is that we're talking about emerging
2 technologies. And so, while some of them that you
3 were talking about now, Yttrium microspheres have
4 been here for a number of years.

5 We also have others coming down the pike
6 that have not been used yet. So, we don't have the
7 professional societies out there with the experience
8 for it. We don't have the medical use licensees out
9 there with experience for it.

10 But, there's a tremendous push to get
11 them out so they can have these. So, many cases
12 where these emerging technologies, we have to come up
13 with a regulatory framework. If they can get out and
14 get into the medical community where they can be used,
15 we try to go with the fastest route we can and that
16 is guidance on our website versus a much more
17 structured guidance document like the 1556 series
18 where we really have to go through the full rulemaking
19 kind of a process.

20 So, that's one reason you don't see
21 things necessarily in the beginning. But, as Sophie
22 has indicated, once we put them up on the website,
23 and you guys do get a chance to look at it, but once
24 we put them up on the website, they're not in
25 concrete. They are considered now working documents

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1 that anyone can respond to and you guys can look at
2 again.

3 So, that's one reason we try to get them
4 up quickly. The idea that maybe we aren't all
5 inclusive but we're trying to get them up as fast as
6 we can so that the medical community really has access
7 to it.

8 CHAIRMAN ALDERSON: So, Dr. Howe, when
9 you put guidance up on the website, is there something
10 on the website that says if you, you being the person
11 who's looking at the site, have comments on this
12 guidance and then some sort of hotlink where they can
13 click and then send a message or is it just out there
14 for them to read?

15 DR. HOWE: We do have, I think Sophie
16 talked about it earlier, we have a statement up on
17 the website that they can make comments at any time
18 and submit them to us.

19 CHAIRMAN ALDERSON: Okay.

20 DR. HOWE: I think, do we have -- Sophie,
21 do we have like an email that we bring them to medical
22 questions?

23 Yes, so we have a system set up so they
24 can bring them in to us and then we constantly monitor
25 this email system --

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1 CHAIRMAN ALDERSON: That's good.

2 DR. HOWE: -- to try and answer
3 questions.

4 CHAIRMAN ALDERSON: Good, okay.

5 Mr. Fuller?

6 MR. FULLER: Yes, just one more thought
7 about this.

8 I'm reminded that the Yttrium-90
9 microsphere update Revision 9 as it is that Katie's
10 been talking to us about, I just think back, you know,
11 what kind of prompted this.

12 You know, it was the ACMUI as the result
13 of reviewing, and I kind of thought of this as a real
14 success story, they ACMUI was reviewing the medical
15 event information that Dr. Howe had reported out on
16 and there was some good discussion about is this, you
17 know, do we have the right medical event definition
18 and so forth for Yttrium-90 microspheres?

19 This Committee formed a Subcommittee.
20 Dr. Guiberteau headed that up. And, I remember when
21 he made his presentation on what changes were needed
22 to this guidance.

23 He said, you know, I'm not an expert so
24 I reached out to my colleagues who are. And, he
25 brought a very, very strong compelling argument with

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1 lots and lots of information that the staff was able
2 to then use as our basis for why we realized that
3 changes were appropriate.

4 And, that's what we got. I mean, we got
5 what we felt like and this Committee felt like was
6 excellent information from the medical community and
7 from the actual experts in the field.

8 And so, I kind of see this as a, again,
9 sort of a success story.

10 We are challenged when we realize that,
11 as regulatory agency, we have certain tools in our
12 toolboxes to actually develop these regulatory tools
13 or these regulatory -- or these ways in this new
14 framework for emerging medical technologies.

15 We are very, very interested in doing
16 this quickly and in a very agile and nimble way. We
17 are able to update things without going into
18 rulemaking and so forth.

19 So, adding another layer, and I know it
20 doesn't sound like much, but if you really think about
21 what we would have to, we would have to do everything
22 that we're doing now and then we would add another
23 step of publishing it for public comment, receiving
24 those comments, forming a working group, looking at
25 each and every one of those comments, deciding which

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1 ones were reasonable and which ones were maybe outside
2 of the scope.

3 And then, bringing that back to the ACMUI
4 for your review of our responses to those comments.

5 I mean, it goes against the original
6 objective of 35.1000, in my opinion, of being very,
7 very responsive to the needs of the medical community.

8 So, I'll just leave it at that.

9 CHAIRMAN ALDERSON: Thank you, Mr.
10 Fuller.

11 We have a comment from the audience.

12 MS. FAIROBENT: Yes, Lynne Fairobent with
13 the American Association of Physicists in Medicine.

14 While I appreciate the concept of what
15 was started with 35.1000 way back in 2002 when the
16 rule was originally drafted, the intent was never
17 that we would regulate forever by guidance under
18 35.1000.

19 Nothing has been moved out of 35.1000
20 and, remember, it is guidance and the Agreement States
21 do not have to comply with it.

22 And, while I recognize it was an attempt
23 to expeditiously address emerging technologies, I'm
24 not so sure it's been the success that we all thought
25 it might be.

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1 And, I agree with Dr. Langhorst, I
2 believe it was who said, with just posting of the
3 guidance, there is not opportunity for the public
4 input.

5 And, yes, there is a link and there is
6 discussion, but if one looks at doing rulemaking in
7 a timely fashion in accordance with NRC
8 documentation, I would argue that over ten years to
9 do a Part 35 rulemaking is not timely regulation.

10 CHAIRMAN ALDERSON: Thank you, Ms.
11 Fairobent.

12 Do we have other comments from the
13 Committee?

14 MEMBER COSTELLO: I have a question.

15 CHAIRMAN ALDERSON: Oh, you have a
16 question? Frank Costello has a question.

17 MEMBER COSTELLO: I appreciate what you
18 did with the Subcommittee's recommendations. I think
19 you're very proud of what you did, actually.

20 I do have a question, though. When you
21 talked about shunting, you're excluding shunting when
22 shunting's evaluated as part of treatment, I think,
23 then you say in accordance with the manufacturer's
24 procedure. Well, there are only two manufacturers.
25 Right?

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1 Are those, as an inspection regulator,
2 are those procedures unambiguous and easy to come by?

3 DR. TAPP: They are. The procedures do
4 have -- the manufacturers do have their procedures on
5 their website. So, if you're talking about like
6 package inserts, they are publically available
7 documents. They describe the shunting evaluation
8 procedures that they recommend that be followed.

9 So, inspectors can see those on
10 publically available websites and we can provide
11 those, too.

12 MEMBER COSTELLO: So, they're expecting
13 them, the licensees, to follow what the manufacturers
14 recommend for evaluating shunting to lung or
15 whatever.

16 And, if they're not doing that, if
17 they're not doing that and they have shunting to the
18 lung or they have shunting to the GI tract, then that
19 might be a problem.

20 DR. TAPP: Yes. And, the procedures are
21 generalized for this procedure for the pre-treatment
22 shunting evaluation. I think we've heard of it
23 before is the pre-treatment where they inject the
24 tech-99m MAA and evaluate that by imaging or the
25 angiograms with the contrast.

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1 They are in both manufacturer procedures,
2 they are only about a paragraph long discussing that.

3 MEMBER COSTELLO: But, there is something
4 there?

5 DR. TAPP: Yes.

6 MEMBER COSTELLO: That if anything
7 happens, I can go on the manufacturer's website and
8 look up that procedure and then say, Mr. Licensee,
9 did you follow this?

10 DR. TAPP: Yes.

11 MEMBER COSTELLO: Okay, thank you.

12 CHAIRMAN ALDERSON: Do have other
13 questions or comments?

14 VICE CHAIRMAN ZANZONICO: I just have a
15 couple of specific questions that I might be
16 misunderstanding some things.

17 But, we said training and experience
18 allowed interventional radiologists certified, but I
19 mean that's in addition to allow training and
20 experience for ABR certified individuals who have the
21 AU designation. This is in addition to that?

22 DR. TAPP: This is in addition to what
23 was there before for ABR. It is the interventional
24 radiologists subspecialty as well.

25 VICE CHAIRMAN ZANZONICO: And, further

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1 on when you discussed training and experience, you
2 said current license guidance, et cetera, et cetera,
3 provided by either an AU Pathway 1 or the
4 manufacturer.

5 But, isn't the manufacturer -- does that
6 mean a non-AU who received -- I mean, because an 'or'
7 implies that a non-AU who receives a manufacturer
8 training could be effectively an AU for this
9 procedure. Is that the intent?

10 DR. TAPP: This is the current guidance
11 that's out there right now is it is an AU or a
12 manufacturer representative. It is not specified
13 that that manufacturer representative had to be an AU
14 in the current guidance.

15 That is what we are looking at
16 evaluating.

17 VICE CHAIRMAN ZANZONICO: Somehow that
18 doesn't seem right.

19 MEMBER COSTELLO: I remember that the
20 manufacturer's representative doesn't -- isn't even
21 a physician.

22 DR. TAPP: That is correct. That is how
23 it's currently --

24 VICE CHAIRMAN ZANZONICO: So that means
25 a non-AU who went through the manufacturer's training

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1 could administer these?

2 DR. TAPP: They do have to have training
3 beforehand and they do have to, for this pathway,
4 they do have to be an interventional radiologist in
5 training or certified. But, yes, that is correct,
6 the three cases would be under supervision from a
7 manufacturer representative, it is not specified they
8 have to be a physician.

9 VICE CHAIRMAN ZANZONICO: Something just
10 doesn't seem right.

11 MEMBER COSTELLO: In fact, they're often
12 not a physician, they're an evaluator.

13 DR. TAPP: Yes. That's what --

14 MEMBER COSTELLO: I mean, know who these
15 people are and they're often not physicians.

16 DR. TAPP: This is why the working group
17 has received comments and we are evaluating this
18 pathway to see if it's still necessary because there
19 are a lot more authorized users.

20 This is something the staff is
21 evaluating. It was not yet a recommendation from the
22 ACMUI.

23 CHAIRMAN ALDERSON: Dr. Metter?

24 MEMBER METTER: I have a question.

25 So, let's say you have an authorized user

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1 who's -- sorry.

2 So, let's say you have a nuclear medicine
3 physician who's an authorized user for Y-90
4 microspheres and you have an interventional
5 radiologist who does the arteriogram and then
6 administers the Y-90 but is not an authorized user,
7 but it's under the licensee of the nuclear medicine
8 physician. Can that interventional radiologist be
9 the prompter for the three therapies for their
10 training?

11 DR. TAPP: They're not an AU?

12 MEMBER METTER: Correct.

13 DR. TAPP: Under current guidance, if
14 they're following this guidance, that does not sound
15 like they could be the AU doing -- or they could be
16 the supervisor for these three cases.

17 MEMBER METTER: Okay.

18 DR. TAPP: It would have be a nuclear
19 medicine AU.

20 MEMBER METTER: Okay, thank you.

21 CHAIRMAN ALDERSON: Are there other
22 questions about this report?

23 Hearing none, Mr. Bollock, I think that
24 we've reached the end of today's sessions. Did you
25 have anything you'd like to say in closing?

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1 MR. BOLLOCK: No, just thank you all and
2 I guess Sophie has something before we all leave.

3 CHAIRMAN ALDERSON: We have a couple of
4 logistical issues, too that I'd like to --

5 MS. HOLIDAY: A couple of logistical
6 issues.

7 CHAIRMAN ALDERSON: -- bring out, but
8 they're not, you know -- pardon me.

9 MS. HOLIDAY: I'd just like to remind
10 everybody, I know it's a little bit confusing on the
11 agenda, we are returning for our open session at 8:00
12 a.m. tomorrow, not 8:30 a.m. So, I'm asking staff
13 and ACMUI members to arrive by 7:45 so we can start
14 on time.

15 Make sure to take your name badges off as
16 you don't run off with them and forget them tomorrow.

17 CHAIRMAN ALDERSON: So, we begin at 8:00
18 a.m. tomorrow?

19 MS. HOLIDAY: 8:00 a.m. tomorrow.

20 CHAIRMAN ALDERSON: Yes.

21 And, so I just -- I turned the microphone
22 off because we're --

23 So, just a couple of issues that I -- the
24 more serious one that I want to bring up is I'm
25 personally very interested in and hope all of you

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1 are, too, in what Ms. Houseman's going to, you know,
2 talk to us about tomorrow.

3 And, as Ms. Houseman -- and she's worked
4 hard in preparing some slides. It should be a great
5 discussion.

6 Now, when -- so, I'm a little concerned
7 that it's at 1:00 to 2:00 p.m. Has that been moved
8 up?

9 MS. HOLIDAY: It should be 12:00 to 1:00.

10 CHAIRMAN ALDERSON: Good, it is 12:00 to
11 1:00. Pat and I were both confused about it, but
12 it's 12:00 to 1:00, that's very good because I think
13 a lot of people, not me in this case, but a lot of
14 people plan to get away and their air transportation
15 on the basis of a 1:00 p.m. close or approximately
16 that.

17 And, this is an important session. This
18 may well engender a number of questions and
19 discussion. So, I just wanted to make sure, so we're
20 starting that at noon, that's excellent.

21 MS. HOLIDAY: Yes, I think you were
22 looking at an old version.

23 CHAIRMAN ALDERSON: Well, it may be,
24 there's several versions laying around here on the
25 table.

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1 The other issue is, you know, very
2 logistical and more social than anything else and
3 that is, that usually, this evening after we part, we
4 usually congregate downstairs at the hotel for an
5 hour or so.

6 And, if people -- pardon me? Or more,
7 or many more, so, for those, so it's now ten minutes
8 to five, so what do you say, 5:30 downstairs? Does
9 that seem reasonable?

10 So, to get there and grab a big table and
11 save some chairs and then we'll all sort of gather
12 around.

13 Okay, well, that's great.

14 Thanks everybody, I think it's been a
15 great day.

16 (Whereupon, the above-entitled matter
17 went off the record at 4:49 p.m.)

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