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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

+ + + + +

FALL 2016 MEETING

+ + + + +

THURSDAY,

OCTOBER 6, 2016

+ + + + +

The meeting was convened in Room T-02B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:00 a.m., Philip O. Alderson, M.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

PHILIP O. ALDERSON, M.D., Chairman

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

FRANCIS M. COSTELLO*, Agreement State
 Representative

VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

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

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

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

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MICHAEL D. O'HARA, Ph.D., FDA Representative
CHRISTOPHER J. PALESTRO, M.D., Nuclear Medicine
Physician

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

LAURA M. WEIL, Patients' Rights Advocate

NON-VOTING: RICHARD GREEN

NON-VOTING: ZOUBIR OUHIB*

*via telephone

NRC STAFF PRESENT:

DANIEL COLLINS, Director, Division of Material
Safety, State, Tribal and Rulemaking Programs

PAMELA HENDERSON, Deputy Director, Division of
Material Safety, State, Tribal and Rulemaking
Programs (MSTR)

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

CLIFF DOUTT, NRR/DLR/RASB

MICHAEL FULLER, NMSS/MSTR/MSEB

VINCENT HOLAHAN, Ph.D., NMSS/MSTR

ESTHER HOUSEMAN, OGC/GCLR/RMR

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

ANGELA MCINTOSH, NMSS/MSTR/MSEB

GRETCHEN RIVERA-CAPELLA, NMSS/MSTR/MSEB

REANN SHANE, COMM/OCMJB

MICHELLE SMETHERS, NMSS/MSTR/MSEB

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

TORRE TAYLOR, NMSS/MSTR/RPMB

JENNY WEIL, OCA

MEMBERS OF THE PUBLIC PRESENT:

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

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

ASHLEY COCKERHAM, Sirtex

ROBERT DANSEREAU, New York State Department of
Health

WILLIAM DAVIDSON, University of Pennsylvania

ADAM DICKER, American Society for Radiation
Oncology (ASTRO)

JENNIFER ELEE, Conference of Radiation Control
Program Directors (CRCPD)

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

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SANDRA GABRIEL, International Atomic Energy
Agency

KSENIJA KAPETANOVIC, American Society for
Radiation Oncology (ASTRO)

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

JOSEPH MACE, Florida Cancer Specialists

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

SHAHIN NASSIR KHANI, Walter Reed National
Military Medical Center

ERIC PERRY, Kentucky Department for Public
Health

MICHAEL PETERS, American College of Radiology

KAREN SHEEHAN, Fox Chase Cancer Center

MICHAEL SHEETZ, University of Pittsburgh

DAVID SMITH, Medstar Georgetown University
Hospital

BRUCE THOMADSEN, Center for the Assessment of
Radiological Sciences (CARS)

CINDY TOMLINSON, American Society for Radiation
Oncology

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P R O C E E D I N G S

8:07 a.m.

1
2
3 MR. BOLLOCK: Good morning, everyone.
4 We'll begin now that we have everybody seated. As the
5 Designated Federal Officer for this meeting, I'm
6 pleased to welcome you to this fall meeting of the
7 Advisory Committee on Medical Uses of Isotopes. My
8 name is Doug Bollock. I'm the Branch Chief of the
9 Medical Safety and Events Assessment Branch and I've
10 been designated as the Federal Officer for this
11 Advisory Committee in accordance with 10 CFR Part 7.11.

12 Present today is the Alternate Designated
13 Federal Officer, Sophie Holiday, our ACMUI
14 coordinator.

15 This announced meeting of the committee is
16 being held in accordance with the rules and regulations
17 of the Federal Advisory Committee Act and the Nuclear
18 Regulatory Commission.

19 This meeting is being transcribed by the
20 NRC and it may also be transcribed and reported by
21 others. This meeting was announced in the August 3,
22 2016 edition of the Federal Register, Volume 81, page
23 51216 through 51217.

24 The purpose of the committee is to advise
25 the staff on issues and questions that arise in the

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1 medical use of by-product material. The committee
2 provides counsel to the staff, but does not determine
3 or direct the actual decisions of the staff or the
4 Commission. The NRC solicits the views of the
5 committee and values their opinions.

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

11 At this point, I'd like to perform roll
12 call of the ACMUI members participating today. Dr.
13 Phil Alderson, Chair.

14 CHAIRMAN ALDERSON: Here.

15 MR. BOLLOCK: Thank you. Dr. Pat
16 Zanzonico.

17 VICE CHAIR ZANZONICO: Here.

18 MR. BOLLOCK: Thank you. Mr. Frank
19 Costello, are you joining us via the phone?

20 MEMBER COSTELLO: I am here now.

21 MR. BOLLOCK: Thank you, Frank. Dr.
22 Vasken Dilsizian.

23 MEMBER DILSIZIAN: Here.

24 MR. BOLLOCK: Thank you. Dr. Ronald
25 Ennis.

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1 MEMBER ENNIS: Here.

2 MR. BOLLOCK: Thank you. Dr. Sue
3 Langhorst.

4 MEMBER LANGHORST: Here.

5 MR. BOLLOCK: Thank you. Dr. Darlene
6 Metter.

7 MEMBER METTER: Here.

8 MR. BOLLOCK: Thank you. Dr. Michael
9 O'Hara.

10 MEMBER O'HARA: Here.

11 MR. BOLLOCK: Thank you. Dr. Christopher
12 Palestro.

13 MEMBER PALESTRO: Here.

14 MR. BOLLOCK: Thank you. Dr. John Suh.

15 MEMBER SUH: Here.

16 MR. BOLLOCK: Thank you. And Ms. Laura
17 Weil.

18 MEMBER WEIL: Here.

19 MR. BOLLOCK: Thank you. Also at the
20 table we have Mr. Richard Green.

21 MR. GREEN: Here.

22 MR. BOLLOCK: Thank you. And on the phone
23 we may have Mr. Zoubir Ouhib joining us. Zoubir, have
24 you joined us on the phone? Unfortunately, Mr. Ouhib
25 is in Florida, so we may or may not hear from him given

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1 the current situation in Florida.

2 Mr. Zoubir Ouhib has been selected as the
3 ACMUI Therapy Medical Physicist and Mr. Richard Green
4 has been selected as ACMUI Nuclear Pharmacist. Both
5 Mr. Ouhib and Mr. Green are pending security
6 clearances, but may participate in the meeting.
7 However, they do not have voting rights.

8 I'd also like to add that this meeting is
9 being webcast, so other individuals may be watching on
10 line. We have a bridge line available and that phone
11 number is 888-831-8979. The pass code to access the
12 bridge line is 9959317 followed by the # sign.

13 Individuals who would like to ask a
14 question or make a comment regarding a specific issue
15 the committee has discussed, should request permission
16 to be recognized by the ACMUI Chairperson, Dr. Philip
17 Alderson. Dr. Alderson, at his option, may entertain
18 comments or questions from members of the public who
19 are participating with us today. Comments and
20 questions are usually addressed by the committee near
21 the end of the presentation after the committee has
22 fully discussed the topic.

23 We ask that one person speak at a time as
24 this meeting is being closed captioned. I would also
25 like to add that the handouts and agenda for this

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1 meeting are available on the NRC's public website.

2 At this time, I ask that everyone who is
3 on the call who is not speaking to place their phones
4 on mute. If you don't have the capability to mute your
5 phone, please press *6 to utilize the conference line,
6 mute, and un-mute functions.

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

11 MR. COLLINS: Thank you, Doug.
12 Hopefully, everybody can hear me. Thank you to all the
13 committee members for your time and for traveling out
14 here to attend this meeting. You've got a couple of
15 very important topics on the agenda today. I'll talk
16 a little bit more about it in a minute, but just by way
17 of some general information for you, since the last time
18 you met in the spring, the Office of NMSS has a new
19 Office Director. Mr. Marc Dapas reported to that
20 position in late July. Mr. Dapas has extensive
21 experience in power reactor regulation, security and
22 in nuclear materials. He was formerly -- his last job
23 he was the Regional Administrator for NRC Region IV out
24 of Dallas. Prior to that he was the Deputy Office
25 Director in the Office of Nuclear Security and

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1 Response. Prior to that he was the Deputy Regional
2 Administrator in Region I and prior to that he was the
3 Division Director for the Division of Nuclear Material
4 Safety in Region III. So he's brought experience,
5 familiar with both the medical and commercial and
6 industrial applications of nuclear materials from both
7 the safety and security viewpoint. So he's no stranger
8 to the topics that we're going to be discussing today.
9 And it's nice to have him. So I just wanted to let you
10 know that.

11 And then secondly, just kind of if you're
12 following the press, you may be aware that security of
13 radioactive materials is in the press again. There was
14 a GAO report issued in mid-July which covered another
15 undercover operation that they had conducted in 2015
16 in which they had posed as a fictitious company and
17 submitted applications to two Agreement States and one
18 NRC region for license to obtain a Category 3 well
19 logging source. In two of the attempts they were
20 unsuccessful in obtaining a license that was from one
21 Agreement State and from the NRC region that they
22 applied to. In the third case, another Agreement
23 State, they were successful in obtaining a license.
24 They then used that license and got a commitment from
25 a source supplier to provide a Category 3 well logging

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1 source. After they had that commitment, they modified
2 a copy of the license to change the source, make, and
3 model number that they were approved for and were able
4 to get a commitment from another supplier for another
5 Category 3 source.

6 In total, they never did take possession
7 of the material, but if they had, the two sources that
8 they would have obtained would have aggregated to a
9 Category 2 quantity of material. So NRC has been
10 working diligently over the past almost year now to take
11 a look at the vulnerabilities that were exposed by that
12 undercover operation, both in terms of our licensing
13 process, but also looking at ways to address the
14 accountability aspect of Category 3.

15 We're expecting to get some further
16 direction from the Commission to direct the staff to
17 do a further reassessment of our regulatory
18 infrastructure for accountability for Category 3
19 sources. So that's just going to continue to be
20 something that we're working on.

21 And we do have a Commission meeting coming
22 up on October 27th, that's going to be talking about
23 the staff's assessment of the adequacy of 10 CFR Part
24 37 which is security for Category 1 and 2 quantities
25 of material but there's some overlap with the security

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1 for Category 3 sources. So something that's still in
2 the works and that you should probably be aware of.

3 Moving on into the ACMUI specific topics,
4 we did send the Part 35 rule up to the Commission in
5 June. And so that's still under Commission
6 consideration. We don't have a direction or decision
7 from the Commission yet.

8 Towards the end of June, on June 24th,
9 ACMUI held a teleconference to discuss the draft ACMUI
10 Subcommittee report for revisions to the radioactive
11 seed localization guidance and the committee did
12 unanimously approve the report at the June meeting.
13 That guidance has not been issued yet. It's with OMB
14 right now for a Congressional Review Act review.

15 During that same teleconference, we also
16 heard a presentation from NRC staff regarding the
17 potential rulemaking to expand the financial assurance
18 requirements to include Category 1 and 2 radioactive
19 sealed sources tracked in the national source tracking
20 system. There's a staff recommendation that just went
21 up to the Commission last week related to that. So we
22 don't have a decision from the Commission yet.

23 ACMUI held a teleconference in August on
24 August 10th to discuss the subcommittee's report and
25 comments on the draft ACMUI germanium-68/gallium-68

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1 generator licensing guidance. The staff issued the
2 licensing guidance last week on September 28th and so
3 we thank the working group or actually the working group
4 thanks ACMUI rather for their review and comments on
5 the draft guidance. And Dr. Tapp will be discussing
6 this more tomorrow morning in her presentation.

7 On July 29th of this year, a memorandum was
8 provided to the U.S. Nuclear Regulatory Commission
9 Regional Administrators that delegate to them the
10 authority to grant specific license exemptions from the
11 decommissioning funding plan requirements for medical
12 germanium-68 and gallium-68 generators and we'll also
13 hear more on that tomorrow from Dr. Daibes.

14 Tomorrow, we'll also hear a presentation
15 from Dr. Palestro related to his subcommittee's efforts
16 and possible revisions to the training and experience
17 requirements for all modalities under 10 CFR Part 35.
18 And immediately following his presentation, we'll hear
19 a presentation from Spectrum Pharmaceuticals regarding
20 the training and experience requirements related to
21 authorized users of alpha and beta emitters.

22 Dr. Dilsizian will give a presentation on
23 ACMUI's comments on the draft RadioGenix, moly-99,
24 technetium-99 generator system, which I guess is the
25 NorthStar Medical Radioisotopes LLC, 10 CFR 35.1000

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1 licensing guidance.

2 And Dr. Metter, we're looking forward to
3 your presentation on ACMUI's comments on the draft
4 revision 10 of the NRC licensing guidance on yttrium-90
5 microsphere, brachytherapy sources and devices.

6 And lastly, I'd like to mention that while
7 Dr. Langhorst is not scheduled to rotate off of ACMUI
8 until September of next year, the solicitation for
9 nominations for the Radiation Safety Officer position
10 on ACMUI was published in the Federal Register on August
11 30, 2016 and any nominations are due by the end of
12 October, October 31st of this year. And with that, Dr.
13 Alderson, I'll turn the meeting back over to you.

14 CHAIRMAN ALDERSON: Thank you very much.
15 I think we're ready to move to old business and Michelle
16 Smethers who has joined the group will speak to us.

17 MS. SMETHERS: Good morning. It's nice
18 to be here with you today. I'm new to this, so I'm still
19 learning how to use the microphone, but I am Michelle
20 Smethers and it's good to be here with you today.

21 The next portion of our agenda that I will
22 go over is a familiar piece that we do at each meeting.
23 At every meeting we go over old business which recapped
24 all of the recommendations and actions put forth by the
25 committee and/or staff and noting any changes.

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1 With that said, much of what you heard
2 today will be very similar to our previous meeting in
3 March.

4 So getting started, for the 2007 chart, all
5 of the items that are listed as open are included in
6 the current Part 35 rulemaking and open and delayed
7 means they will be considered in future rulemaking.

8 Sophie is going to have to help me out with
9 moving these forward.

10 Moving on to 2008, again all of these items
11 that are listed as open are included in the current Part
12 35 rulemaking and again open and delayed means they will
13 be considered in future rulemaking.

14 For 2009, we have two items on the chart,
15 and again both of these items are also included in the
16 current Part 35 rulemaking.

17 Moving to 2010, oh, there is no 2010.
18 Please note then that in 2010 -- please note that 2010
19 is not included because all recommendations and actions
20 were closed previously.

21 Continuing on to 2011, items 11, 13, 14,
22 and 15 are included in the current Part 35 rulemaking.
23 Going back to item 1, item 1 and 16 had to do with the
24 patient release criteria. Both these are pending
25 because there are two patient release efforts going on

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1 at the NRC, one in the Office of Research and one in
2 the Office of Nuclear Material Safety and Safeguards.

3 Moving to the end for item 32, Dr. Oxenberg
4 will provide an update tomorrow morning on the proposed
5 revision to the Abnormal Occurrence Criteria Policy
6 Statement.

7 We did go over item 6, the last one is the
8 indefinite open action item for the committee to review
9 its reporting structure on an annual basis. The next
10 review of this item will be next spring meeting.

11 Moving on to 2012, all items for 2012 were
12 closed or addressed in the March 2016 spring meeting.

13 So moving on to 2013, items 1 through 13
14 are part of the current Part 35 rulemaking. Item 21
15 pertains to the Germanium-68/Gallium-68 generator
16 where the ACMUI recommended relief from the
17 decommissioning funding plan requirements. Staff
18 issued a memorandum to the NRC regions in July 2016 that
19 grants them the authority to issue licensing exemptions
20 from the decommissioning funding plan. Requirements
21 for Germanium-68 provided that certain conditions are
22 met. You will hear from Dr. Daibes regarding this
23 topic tomorrow.

24 I would like to make a motion to close this
25 item since staff issued the exemption memo in July 2016.

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1 CHAIRMAN ALDERSON: A motion has been
2 made. Is there further discussion?

3 MEMBER LANGHORST: Don't we have to make
4 a motion?

5 CHAIRMAN ALDERSON: Do we have to make the
6 motion?

7 MS. SMETHERS: I request that we make a
8 motion.

9 MEMBER LANGHORST: I'll so move. Sue
10 Langhorst.

11 CHAIRMAN ALDERSON: Is there a second?
12 All in favor. Opposed. Abstentions.

13 (Committee votes.)

14 That passes unanimously.

15 Back to you.

16 MS. SMETHERS: Thank you. Please note
17 that item 25 will be removed after this meeting, since
18 it was closed last meeting and NRC staff sent up the
19 rule to the Commission for votes.

20 We'll move on to 2014. Again, item 6
21 pertains to the same Germanium-68/Gallium-68 topic.
22 Again, I would like to request that we make a motion
23 to close this item since staff issued the
24 decommissioning funding plan exemption memo in July
25 2016.

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1 MEMBER LANGHORST: Sue Langhorst, I so
2 move.

3 CHAIRMAN ALDERSON: Second. Further
4 discussion? Hearing none, all in favor? Any opposed?
5 Any abstained?

6 (Committee votes.)

7 None, passes unanimously. Back to you.

8 MS. SMETHERS: Thank you. This now
9 closes the 2014 recommendation and action chart.

10 Moving on to 2015, item 7 is still listed
11 as open as we are waiting on staff's review and
12 evaluation to revise the NRC's Abnormal Occurrence
13 Criteria Policy Statement. You will hear more on this
14 from Dr. Oxenberg.

15 For items 12 through 15, we will hear a
16 presentation later today from Mr. Fuller in response
17 to the committee's remarks on the term "patient
18 intervention."

19 For item 18, item 18 deals with the
20 comments and recommendations provided by the
21 Radioactive Seed Localization Subcommittee. The
22 ACMUI recommended that the individual who implants the
23 source for radioactive seed localization procedures
24 can do so under the supervision of an authorized user.
25 Staff accepted this recommendation in its revision of

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1 the radioactive seed localization guidance. However,
2 this is not final yet and is pending congressional
3 review.

4 For item 22, like item 7, item 22 has to
5 do with the NRC's Abnormal Occurrence Criteria Policy
6 Statement. As I mentioned earlier, we will hear a
7 presentation from Dr. Oxenberg tomorrow regarding an
8 update on the Abnormal Occurrence Criteria Policy
9 Statement.

10 Yes?

11 MEMBER LANGHORST: You said on item 18 it
12 was awaiting congressional review and do you mean
13 Commission review?

14 MR. BOLLOCK: No, it's Congressional
15 Review Act review.

16 MEMBER LANGHORST: Oh, okay. I wondered
17 why Congress was going to review it. Okay.

18 MR. BOLLOCK: No, and Dan spoke on that
19 one. OMB is reviewing for Congressional Review Act.
20 So if they make a determination that it needs to be
21 reviewed by Congress, then it will go to Congress.

22 MEMBER LANGHORST: Got it. Thank you.

23 MR. BOLLOCK: We don't foresee that.

24 MEMBER LANGHORST: Thank you.

25 MS. SMETHERS: Thank you, Dr. Langhorst.

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1 Okay. Item 23, is that where we were? Okay. Item 23,
2 the ACMUI endorsed the NUREG-1556, Volume 9
3 Subcommittee Report. We have left this item open
4 because as you are aware, the NUREG-1556, Volume 9 has
5 not been finalized yet. I was notified by Dr. Tapp that
6 they will let the ACMUI know when it is issued for public
7 comment.

8 Moving on to 2016. Items 1 through 15 all
9 deal with the Part 35 Rulemaking Subcommittee Report
10 that had the recommendation related to the draft final
11 rule. Staff transmitted a response memorandum to the
12 ACMUI on August 2, 2016 which conveys staff's reasons
13 for partially accepting or not accepting the
14 committee's recommendation. The Part 35 rulemaking
15 package is sitting with the Commission for vote as Dan
16 mentioned. We'll hear an update later today from Ms.
17 Torre Taylor.

18 Item 16, for item 16, we will hear from Dr.
19 Palestro tomorrow for an update on the work done by the
20 new Training and Experience for All Modalities
21 Subcommittee.

22 Item 17 through 19 are closed, but remain
23 on the list pending recommendations from the Training
24 and Experience for All Modalities Subcommittee.

25 Item 20 is the commitment by the NRC to

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1 provide data to the ACMUI for medical events reported
2 over a five-year span for trending purposes. Ms.
3 Holiday provided this data to the ACMUI for the time
4 period of fiscal years 2010 through 2015 on October 3,
5 2016. Consequently, I would like to request that this
6 action be closed.

7 CHAIRMAN ALDERSON: Is there a motion to
8 close this out?

9 VICE CHAIR ZANZONICO: So moved.

10 CHAIRMAN ALDERSON: And second?

11 MEMBER LANGHORST: Second.

12 CHAIRMAN ALDERSON: Further discussion?
13 Hearing none, all in favor. Any abstaining? Any
14 opposed?

15 (Committee votes.)

16 Hearing none, unanimously approved.

17 MS. SMETHERS: Thank you. And please
18 note going forward, staff will continue adding to the
19 list provided by Ms. Holiday.

20 CHAIRMAN ALDERSON: I would just like to
21 make a comment that I thought the summary was excellent.
22 It was clear. It really summarized the trends very
23 well, so thank you to Ms. Holiday for providing this
24 information.

25 MS. SMETHERS: Thank you. Item 21

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1 pertains to the formation of the Medical Event
2 Reporting and Impact on Safety Culture Subcommittee.
3 The subcommittee will report at the Spring 2017
4 meeting.

5 For item 22, item 22 is an NRC action to
6 provide the draft final 35.1000 licensing guidance for
7 the Leksell Gamma Knife Perfexion and Leksell Gamma
8 Knife Icon to the committee. Ms. Holiday provided the
9 draft final guidance to the ACMUI on April 19, 2016.
10 The final guidance was issued on May 25, 2016. And
11 consequently, I would like to request that this action
12 item be closed.

13 CHAIRMAN ALDERSON: Would someone like to
14 move in that regard?

15 MEMBER LANGHORST: So moved.

16 CHAIRMAN ALDERSON: Second. Discussion?
17 Hearing none, all in favor. Opposed? Abstained?

18 (Committee votes.)

19 It unanimously passed. Thank you.

20 MS. SMETHERS: Thank you. Item 23 was an
21 NRC action to provide the ACMUI with the total number
22 of medical use licensees within the United States. Ms.
23 Holiday provided the requested information on March 18,
24 2016. Again, I would like to request that this item
25 be closed.

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1 VICE CHAIR ZANZONICO: So moved.

2 CHAIRMAN ALDERSON: And a second?

3 MEMBER DILSIZIAN: Second.

4 CHAIRMAN ALDERSON: Discussion? All in
5 favor? Opposed? Abstaining?

6 (Committee votes.)

7 It passes unanimously. Thank you.

8 MS. SMETHERS: Thank you. Item 24 was an
9 ACMUI recommendation to reach out to professional
10 organizations to encourage interactions and
11 communications between these organizations, the NRC,
12 and the ACMUI. We will hear a presentation from Dr.
13 Alderson tomorrow reporting on these outreach efforts
14 by the ACMUI.

15 Would you like to close this item at this
16 time or keep it on the list for now?

17 CHAIRMAN ALDERSON: I'd like to keep it on
18 the list.

19 MS. SMETHERS: Okay. Thank you. Item 25
20 was an ACMUI action to hold the Fall 2016 ACMUI meeting.
21 And since we are all here today and we are holding this
22 meeting today and tomorrow, October 6th and 7th, I would
23 like to request that we close this item.

24 CHAIRMAN ALDERSON: Yes, and I assume
25 since you're all here, one of you who is here can make

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1 such a motion.

2 MEMBER METTER: So moved.

3 MEMBER DILSIZIAN: Second.

4 CHAIRMAN ALDERSON: All in favor? None
5 opposed or abstaining.

6 (Committee votes.)

7 Please carry on.

8 MS. SMETHERS: Thank you. For items 26
9 through 30, management approved the radioactive seed
10 localization guidance in August 2016, but it is pending
11 a review against the Congressional Review Act. Once
12 OMB has made the determination that the guidance is not
13 considered a major rule, it will be distributed to the
14 regions, Agreement States, and ACMUI. Staff will also
15 post it on the medical tool kit and send an announcement
16 out on the medical list serve.

17 For items 31 through 37, staff issued the
18 Germanium-68/Gallium-68 Eckert & Ziegler GalliaPharm
19 guidance on September 28, 2016. Dr. Tapp will discuss
20 this further on Friday.

21 This concludes my portion of old business.
22 Are there any questions or comments?

23 CHAIRMAN ALDERSON: Dr. Langhorst?

24 MEMBER LANGHORST: Yes. Some things were
25 in red, some things in black and I was confused whether

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1 it had any meaning at all.

2 MS. SMETHERS: I asked about this as well
3 because I worked on this with Sophie Holiday and she
4 said that red items are things that have changed since
5 last meeting. Is that correct? Do you want to add
6 anything to that, Sophie?

7 MS. HOLIDAY: That is correct. So red
8 text indicates anything, any actions that may have
9 changed whether we accepted, did not accept, if an
10 action was closed or moved to open and delayed.

11 MEMBER LANGHORST: So the closed items
12 were closed last time, but they remain on the list
13 because they're black.

14 MS. HOLIDAY: They may have been closed
15 last time or an action may have occurred between the
16 March meeting and this meeting that would have resulted
17 in a closed action.

18 MEMBER LANGHORST: Okay. And I wanted to
19 make one comment. I really appreciate the size of the
20 font because it used to be so teeny tiny to read and
21 I really thank you.

22 MS. SMETHERS: That was all Sophie.

23 MS. HOLIDAY: If I may before we adjourn
24 from the old business portion, it did not make it as
25 a change on the old business chart at the time because

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1 these were printed September 16th, but as Ms. Smethers
2 indicated, the Germanium/Gallium-68 GalliaPharm
3 Eckert & Ziegler generator licensing guidance was
4 issued on September 28th. I would like to request if
5 the ACMUI would like to make a motion to close those
6 items on the list related to the Germanium/Gallium-68
7 Subcommittee's recommendation.

8 CHAIRMAN ALDERSON: Is there a motion to
9 that effect?

10 MEMBER LANGHORST: So moved.

11 CHAIRMAN ALDERSON: And second?

12 MEMBER COSTELLO: Second.

13 CHAIRMAN ALDERSON: Further discussion?
14 Hearing none, all in favor? Opposed? Abstaining?

15 (Committee votes.)

16 It passes. Thank you. Thank you, Ms.
17 Smethers for your report.

18 MS. SMETHERS: Thank you.

19 CHAIRMAN ALDERSON: This moves us to the
20 open forum where the floor is open for the ACMUI to
21 identify medical topics of interest for further
22 discussion. Is there any -- yes?

23 MEMBER LANGHORST: Sue Langhorst, yes,
24 thank you. I just wanted to echo Mr. Collins' comments
25 on the Category 3 sources. This is something that

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1 medical licensees have to keep a close eye on because
2 this will impact the need to track more sources. And
3 Senator Schumer has sent a letter to the Chairman
4 calling for a ban on licensing any new Category 3
5 sources. I mean so the Commission has a lot of pressure
6 on it in regard to this.

7 Right now, the discussion is tracking
8 those sources in the National Source Tracking System,
9 the NSTS. It hasn't been mentioned about putting it
10 into Part 37 where you have to have additional security.
11 What that impacts for medical licensees is primarily
12 the HDR sources in radiation oncology. It would be a
13 lot more effort in the security end of things.

14 Now all of the ploys to get licensing have
15 been for industrial gauges for those -- oh, gosh -- help
16 me with that, what's the licensees -- they're the --
17 yes, the well loggers and so on. There's a lot more
18 effort to get a medical clinic up and running and I don't
19 think a storefront would pass as a medical clinic. But
20 still, this has big impact. So I just -- I think that's
21 something that we need to pay close attention to and
22 know what's happening in the NRC world about this topic.

23 CHAIRMAN ALDERSON: Good. Other
24 comments on that? I think, yes, Ron Ennis.

25 MEMBER ENNIS: We may have addressed this

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1 a little bit the last time, but there are efforts in
2 other parts of the Federal Government, like the
3 Department of Energy.

4 I think we may have touched on this a little
5 last time, but there is an effort underway in the
6 Department of Energy to also introduce a variety of
7 regulations about radioactive sources for security
8 concerns, but I and other medical specialists are quite
9 concerned about the impact it might have particularly
10 in the area of oncology and Gamma Knife and HDR, but
11 depending on where the line is drawn and a concern that
12 it could not make it illegal to have such sources, but
13 create such barriers as to essentially de facto remove
14 those sources from medical practice. It's well-known
15 to this subcommittee that this committee that these are
16 providing really critical treatments for people and I
17 think we need to be aware of it and maybe we need to
18 express something as a committee about our concern on
19 the potential impact on cancer care.

20 CHAIRMAN ALDERSON: Thank you, Dr. Ennis.
21 Would anyone like to follow up that comment or have
22 another comment in that regard?

23 John Suh.

24 MEMBER SUH: I also just want to echo what
25 Ron just mentioned. The modalities that we use for a

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1 high dose rate brachytherapy as well as gamma knife
2 radiosurgery are really important and proper treatment
3 of cancer patients for a lot of different diseases. So
4 I also think it's important as a subcommittee we follow
5 this very carefully because I believe it would be
6 detrimental to patient care if those modalities were
7 very difficult to utilize because of regulations.

8 CHAIRMAN ALDERSON: Those are excellent
9 comments. I'd like to keep those in mind. I don't
10 think we're going to stop right now and form a new ad
11 hoc subcommittee to look at this, but it is an issue
12 that we could consider in the future if this continues
13 to be out there.

14 I also appreciate Dr. Langhorst bringing
15 it forward because I think if you can go back to when
16 I started on the committee, I asked about the security
17 of various radiation sources used in medicine and with
18 the suggestion that this committee know more about
19 them, be informed, be talking about and engaged in that
20 issue. So I think with this further interest now that
21 we may wish to do so.

22 There's a comment here in the room, yes?

23 MS. FAIROBENT: Thank you, Dr. Alderson.
24 Lynne Fairobent with the American Association of
25 Physicists in Medicine. I just wanted to mention that

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1 the community at large is very much actively involved
2 in this issue and has created a new group on source
3 security working group with many organizations that are
4 members of that. There is a 12 member steering
5 committee and AAPM is one of the steering committee
6 members.

7 We have been on the Hill recently and we'll
8 continue to do so in an education and outreach to Hill
9 staffers. It was mentioned that there are or have been
10 pieces of legislation that have been promulgated and
11 we have been working actively to keep them from going
12 forward, but also should something go forward to have
13 it be appropriately reflected.

14 But I also did want to mention as a take-off
15 on the press articles that was written, I don't know
16 how many of you watch TV, and this goes to Sue's comments
17 that -- and I totally agree -- that we've been
18 fortunate, it's a little harder to stand up a storefront
19 hospital or medical facility than it is a storefront
20 licensee to receive industrial sources. But NCIS LA,
21 their opening season issue this year involved the theft
22 of several cesium chloride blood irradiators for dirty
23 bombs. If you have not seen that episode, you might
24 want to look at it. All of this publicity does not help
25 our case.

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1 I firmly believe, as does AAPM, that we are
2 using radioactive materials safely and securely in
3 medical applications and that they are actually
4 critical to patient care in the overall scheme of
5 things. But we cannot afford to lower our guard, shall
6 we say, on watching what is going on and being proactive
7 and not simply reactive every time an article appears
8 in the paper. Thank you, Dr. Alderson.

9 CHAIRMAN ALDERSON: Thank you, Ms.
10 Fairobent. I think that that was an excellent comment
11 and I think overall we've got to establish a balance
12 in the committee to look for that balance between
13 availability for medical needs and safety and security
14 for the nation. So we'll clearly be revisiting this
15 topic.

16 Any other comments at this time? All
17 right. We'll move on then, if there's no other
18 comments. This is still the open forum.

19 Yes, Pat Zanzonico.

20 VICE CHAIR ZANZONICO: Yes, there's two
21 issues I'd like to bring to the committee's attention
22 for those of you who may not be aware of it, but recently
23 the Nuclear Medicine Technology Certification Board,
24 which is the national board which professionally
25 certifies nuclear medicine technologists, are creating

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1 a special competency area in radiation safety and it
2 will have a certifying exam.

3 And I was recently at their meeting
4 formulating the curriculum and drafting questions for
5 that exam. And the intent is not to have any regulatory
6 significance attached to this new certification.
7 Their intention is not to create a subcategory of
8 technologists, RSOs, so to speak. That's what they're
9 saying publicly. I frankly find it hard to believe
10 that that's not the ultimate intent, but their public
11 stance is that that's not the intent.

12 What it is designed to do is recognize the
13 reality, frankly, that in small practices and in
14 private offices often it is the nuclear medicine
15 technologist who performs the radiation safety tasks,
16 wipe tests, so forth and so on. Of course, under the
17 direction of typically the AU RSO and the thinking is
18 that a technologist who had the certification would be
19 more employable by having demonstrated expertise in
20 this area, again, not to large hospitals, not to major
21 medical centers where there's a radiation safety staff,
22 but again, rather to private practices, small offices,
23 even small community hospitals where there may not be
24 that sort of support.

25 And as I said, it's the medical AU who is

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1 listed as the RSO and so they would have to document
2 this competency. And it would not just be for
3 radioactive materials. It extends into radiation
4 safety generally for radiographic sources, so forth and
5 so on. So that is moving forward.

6 There seems to be a lot of support and a
7 lot of interest among the nuclear medicine technology
8 community in this competency because again, it does
9 look like it would enhance and I imagine it will, their
10 employability. So that's where that stands.

11 CHAIRMAN ALDERSON: One clarification
12 point, Dr. Zanzonico, if I heard this correctly and this
13 is the issue to clarify, you just said that the nuclear
14 medicine technologists were going to be involved with
15 the safety of radiation sources that are not
16 radionuclide sources?

17 VICE CHAIR ZANZONICO: Well, they would --
18 in a practice, for example, where there might be PET/CT,
19 there might be radiation generating machines.

20 CHAIRMAN ALDERSON: Such as CT?

21 VICE CHAIR ZANZONICO: Right, not just
22 radioactive sources. The nuclear medicine
23 technologists who had this competency or were granted
24 this competency could do this while the certification
25 board would also have to demonstrate competency in

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1 those areas. So it's not strictly for radioactive
2 materials and the curriculum and the exam will include
3 material on non-radioactive source radiation safety
4 issues.

5 CHAIRMAN ALDERSON: Thank you. That
6 point is clarified. Thank you.

7 MEMBER DILSIZIAN: It's extremely
8 important and I'm actually surprised that this is not
9 even part of their training and certification to begin
10 with. I would think that any nuclear medicine
11 technologist should be aware of radiation safety
12 issues, wipe testing and all -- not the CT portion, but
13 all the others. So not only do I think this is
14 important, but I think that it should actually be
15 included in their training, not in separate
16 certification. I think everybody should have it.

17 VICE CHAIR ZANZONICO: Agreed. And I
18 think the notion is that this is to create a recognized
19 competency area. It's an issue of marketability and
20 employability.

21 There is a component in the general nuclear
22 medicine technologist certification on radiation
23 safety and related issues. I think this to formalize
24 it, to recognize it, to expand it, but certainly that
25 is part of their training.

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1 CHAIRMAN ALDERSON: Yes, Dr. Palestro.

2 MEMBER PALESTRO: I actually have two
3 comments. One is -- I think it's an excellent idea and
4 I think it's not only good for marketability, I think
5 it's good for radiation safety and patient safety.

6 My question is individuals who already are
7 certified, can they go back and take an examination that
8 will add this competency to their certification or an
9 additional certification?

10 VICE CHAIR ZANZONICO: I'm not speaking
11 for the NMTCB. I'm not part of that organization. I
12 was just enlisted to help draft a curriculum and
13 questions. But that is my understanding that in fact,
14 an individual would first have to be certified by a
15 nuclear medicine technology board before they become
16 eligible for this additional certification. And it
17 would include an in-residence requirement as well.

18 So in other words, they would have to have
19 an AU RSO or an equivalent individual attest to the fact
20 that they've been involved, I believe, for at least one
21 year in radiation safety related activities. So yes,
22 not only would existing certified techs be eligible,
23 that would be a requirement for this additional
24 competency.

25 MEMBER PALESTRO: So this is a separate

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1 examination?

2 VICE CHAIR ZANZONICO: It's a separate
3 examination.

4 MEMBER PALESTRO: Thank you.

5 CHAIRMAN ALDERSON: Yes, Mr. Green.

6 MR. GREEN: I think this is a worthwhile
7 endeavor. My concern is that the NMTCB takes
8 appropriate measures to make sure it's in the
9 educational materials, as candidates take this course
10 work, that they understand that they are becoming
11 skilled and knowledgeable in assisting the RSO in
12 health physics and radiation safety functions, but this
13 does not grant them an authorized user status where they
14 can independently make choices and decisions without
15 the guidance and direction of the RSO.

16 VICE CHAIR ZANZONICO: Right, and as I
17 have said, they've been very explicit in stating that
18 NMTCB be very explicit in stating this is not a pathway
19 to become recognized to act as an RSO. Again, that's
20 what they're stating and hopefully, they'll stick to
21 that. But I have a suspicion that as this moves forward
22 that may become an effort on their part, but that's not
23 the case at the moment. They would not be RSOs. They
24 would not be listed on -- or licensed as RSOs, and so
25 forth and so on.

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1 CHAIRMAN ALDERSON: Further comments on
2 this issue? Yes, Dr. Ennis.

3 MEMBER ENNIS: I guess, too, just kind of
4 for informational purposes, is there an effort then on
5 the board, whoever does their basic training, to
6 incorporate this level just into the initial training
7 so that this becomes maybe not necessary in the long
8 run?

9 VICE CHAIR ZANZONICO: Again, I'm not
10 speaking for the Board, but my impression is that at
11 least in the initial roll out of this certification,
12 and it's something brand new, that would not be the
13 case. Now that may just be a logistical issue because
14 they have obviously a large number of currently
15 certified techs in the field, so they're not going to
16 go back and retake the entire training. But I think
17 the intention is that that would not be the case. In
18 other words, they would take their normal training.
19 They would take the normal or general nuclear medicine
20 technology certification and then subsequently take
21 this exam.

22 Now being eligible for the exam, as I said,
23 has a residency requirement, one year working in the
24 field, but it doesn't have a didactic training
25 requirement so that once a tech is certified and working

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1 in the field, presumably there is an AU or AU RSO who
2 would attest their length of experience in that area.
3 Then they can just sit for the exam without any
4 additional didactic training.

5 MEMBER ENNIS: The question was the
6 inclusion of nonradioactive source training, I'm not
7 sure what's the rationale for that?

8 VICE CHAIR ZANZONICO: I think it's in the
9 spirit of recognizing that in certain types of
10 situations, like private offices, there may be multiple
11 modalities involving radiation. And again, the RSO
12 would be the position AU, but the individuals -- sort
13 of the boots on the ground who would be implementing
14 a lot of the regulatory compliance and that would
15 include, for example, CT, doing certain measurements
16 on that and so forth -- might be a technologist.

17 I think the nuclear medicine tech
18 certification board sort of wants to state their claim
19 that their constituency is often the individuals doing
20 those safety checks beyond those for radioactive
21 materials. I was a little surprised myself when I
22 first saw how the broad scope of what they were aiming
23 at, but that's their intent.

24 Again, since it doesn't have any legal
25 standing or regulatory standing at this point, rather,

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1 and you know, the Certification Board is a
2 self-governing body, they can do what they want. They
3 can make the rules and that's what they're doing at the
4 moment.

5 MEMBER ENNIS: Does that reflect the
6 reality on the ground that such technologists are doing
7 CT, QA, things like that?

8 VICE CHAIR ZANZONICO: You know, I raised
9 that question when I was at this recent meeting, because
10 that's not my experience at all. And my experience may
11 be skewed because I'm at a large academic medical
12 center.

13 We have a large radiation safety group and
14 medical physics group and there are sort of
15 subspecialists for the different modalities, but
16 according to the folks on the board, that is a reality
17 that in certain small community settings, private
18 offices and so forth, that is often a tech who -- a
19 nuclear medicine tech who is doing these sorts of things
20 beyond radioactive material.

21 CHAIRMAN ALDERSON: Dr. Langhorst.

22 MEMBER LANGHORST: Sue Langhorst. I think
23 it also recognizes the fusion technologies and forgive
24 me, Dr. Zanzonico, if you've already said that, but the
25 PET/CT, there's always a question well, it's PET/CT

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1 who's doing the CT and the CT measurements can be done
2 under the authority of a qualified expert, but the techs
3 may be doing those measurements and then it's reviewed
4 by that qualified expert, so kind of a similar situation
5 as rad material and RSOs.

6 VICE CHAIR ZANZONICO: That's a very good
7 point and that was my inference that the reason this
8 competency certification was extending beyond
9 radioactive materials was because of multi-modality,
10 not just PET/CT, but MR/CT also. But they're also
11 including fluoroscopy, interventional radiology and
12 even MRI and safety aspects of that. So it's a very
13 broadly aimed competency certification at this point.

14 CHAIRMAN ALDERSON: I would just state
15 that although it is of interest, obviously, to our
16 panelists that such an idea is out there. It relates
17 to safety which is something that we're engaged with.
18 The ACMUI is, in fact, engaged with radionuclide
19 safety, so the fact that this political action, it may
20 in fact be a political action, it's extending beyond
21 that realm, although of interest, it probably isn't in
22 the core interest of this particular committee.

23 There's someone at the microphone. Thank
24 you very much.

25 MS. BLANKENSHIP: Hi, Dr. Blankenship,

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1 Bette Blankenship, AAPM, a physicist also an RSO. And
2 I just wanted to comment to the group that we do have
3 nuclear medicine technologists that work in a hybrid
4 setting whether it's PET/CT or SPECT/CT and they are
5 currently doing the CT testing, the quality assurance
6 for those pieces of equipment, although they don't
7 routinely do stand alone CT. They do get -- can be
8 granted by their state -- to be a CT technologist on
9 a hybrid device, so they have expanded their role. So
10 I could see the importance of them wanting to have an
11 understanding of the safety implications of working
12 with that device, so they have just by nature of their
13 work experience have been kind of thrust into a new
14 environment for themselves. So I think it's a great
15 idea, too. So thank you so much.

16 CHAIRMAN ALDERSON: Thanks very much.
17 Good comment. Thank you. Are there further comments
18 on this subject?

19 VICE CHAIR ZANZONICO: Again, I think what
20 the board is thinking of and appropriately so, as a
21 number of people have said, is that often the nuclear
22 medicine technologists in reality are addressing and
23 to some extent responsible for some of these
24 safety-related issues. And this is a mechanism for
25 formalizing that and recognizing it. But I think

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1 that's the motivation for this at the moment.

2 CHAIRMAN ALDERSON: Good. The floor is
3 open for other items. Dr. Zanzonico.

4 VICE CHAIR ZANZONICO: So this is a
5 completely separate item and very recently at Sloan
6 Kettering one of the new nursing leaders at the
7 institution is a real advocate for breast feeding and
8 has asked us to review and, if necessary, revise
9 guidance on breast feeding, cessation of breast
10 feeding, so forth and so on among patients receiving
11 radioactive materials. There's all sorts of guidance
12 included in the regulatory guides on cessation of
13 breast feeding with administration of different
14 radioactive materials.

15 And the issue has come up is should a
16 recommendation be created for discontinuing breast
17 feeding in advance of receiving a radioactive material.
18 Apparently, because of the stimulation of lactation,
19 there can be an increase deposition of radioactive
20 materials in breast milk in women who are actively
21 breast feeding. And so to reduce that uptake and
22 presumably reduce any radiogenic risk associated with
23 that uptake, there's now a question of whether there
24 should be a recommendation to discontinue breast
25 feeding for some period of time prior to the

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1 administration of radioactive materials -- of the order
2 of several weeks perhaps.

3 So that's not included at the moment in any
4 of our institutional guidance and I don't see it in any
5 regulatory guidance and I wonder if that's an issue that
6 we should perhaps address.

7 CHAIRMAN ALDERSON: I think that is a very
8 interesting subject to raise. We're in the open forum
9 which is a relatively limited time period and this is
10 not a subject that you just raised that can be discussed
11 effectively in a very limited amount of time. So I'm
12 going to ask you to set that aside and we'll think about
13 bringing that back on to a future agenda or later in
14 the meeting.

15 And I think at this time if there's no other
16 questions we should move on to the medical event forum
17 which is a major portion of our morning meeting. And
18 Dr. Langhorst has agreed to introduce this segment.
19 She helped organize to introduce this segment and give
20 us a lead as we get started. Dr. Langhorst.

21 MEMBER LANGHORST: Thank you. As our
22 panelists come up to the front, I just wanted to remind
23 the committee that at last meeting, Dr. Alderson formed
24 a subcommittee, the Medical Event Reporting and Safety
25 Culture Impact Subcommittee. We haven't come up with

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1 a catchy title yet on that, but that's what it is. And
2 just to remind you, our charge is to explore the impact
3 of medical event reporting and its impact on
4 self-reporting safety culture, identify potential ways
5 to improve the effectiveness of self-reporting in
6 support of a culture of safety, and suggest ways to
7 share medical event reports and lessons learned with
8 the medical community to promote safety.

9 And so our subcommittee felt like it would
10 be nice to have in attendance the groups that had
11 reported to the committee, it's been a couple years now,
12 who have event reporting systems that they have people
13 reporting on.

14 And we've asked our panels to address these
15 questions. How has your event reporting system grown?
16 How do you share your results and with whom? Do you
17 include near-miss reports? What do you think is the
18 most important thing you have learned to date? What
19 do your participants think of the feedback they
20 receive? And what can ACMUI and NRC learn from your
21 event reporting system?

22 Well, I want to thank the panelists that
23 we have to help talk about this. Dr. Adam Dicker is
24 here to present the ASTRO system. Ms. Jennifer Elee
25 is here to talk about the CRCPD system. Dr. Bruce

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1 Thomadsen is on the phone. He'll be talking about his
2 system known as CARS. And Dr. Sandy Gabriel is on the
3 phone. I hope those both are on the phone. She'll be
4 speaking about the IAEA system.

5 And I will -- let's see, I guess Dr. Dicker
6 will be the first one to present and so I'll let you
7 take it away. Thank you.

8 DR. DICKER: Thank you, good morning.
9 Just for those who are present with the help of Ms.
10 Holiday, we are using the revised document. So it's
11 my pleasure to present what we've learned from the
12 RO-ILS system. I'm going to talk about where we've
13 been, where we are, and where we're going.

14 I just want to first start out by what makes
15 a smarter team. It's not intelligence. It's not IQ.
16 I would contend in the RO-ILS system, there's been a
17 lot of research by groups at MIT, Carnegie-Mellon
18 talking about the subject and it boils down to three
19 things. If you have three components for a team,
20 you'll outperform other teams in problem solving. So
21 it's about emotional intelligence of the team. It's
22 about making sure that someone does not overtake the
23 others and dominate the conversation. And the last
24 part is having women. If you don't have women on your
25 team, you're dead.

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1 (Laughter.)

2 So this is incontrovertible. There's an
3 updated paper in Science about this. There's a book,
4 Smarter, Faster, Better. This is incontrovertible.
5 And I'm contending the RO-ILS system is not the
6 smartest, but is trying to get smarter.

7 Okay, this is the only medical specialty
8 sponsored instant learning system for radiation
9 oncology. It's a joint partnership with ASTRO and
10 AAPM. It does receive some industry support. So the
11 goal is really to have an environment which is safe,
12 where people can share information in a non-punitive
13 way, and that we can then bring it back to the community.
14 I mean the community in the greatest collective sense
15 of the word.

16 So as you know, this works under AAHRQ.
17 There's a specific Patient Safety Act that prevents
18 medical litigation and other types of lawyers from
19 finding out about this stuff. We've been in existence
20 for two years. We have over 224 institutions. We have
21 2300 submitted reports. We've issued seven quarterly
22 reports and in the remaining time, I'm going to show
23 you a little bit of our data mining and the examples
24 that we've observed through this data mining and
25 thematically what we've disseminated and I'll tell you

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1 futuristically or what we're doing right now to prepare
2 for the future.

3 So we're building on the important work of
4 the NRC. So I'm going to show you two examples of a
5 number of examples that relate to over reliance on
6 technology. In this particular case, it's using cone
7 beam CT, an over reliance on cone beam CT. So in the
8 first case, it's a hypofractionated treatment for
9 vertebral body. Unfortunately, the wrong vertebral
10 body was treated for two out of five fractions because
11 the cone being locked on to the wrong vertebral body.
12 It was appreciated on the third fraction.

13 In another, as part of our data mining, we
14 look for other examples of this and this is a situation
15 where there was a large field size or there was a large
16 shift of five centimeters and it was appreciated by the
17 physicist who was doing the weekly check that the cone
18 beam was too small for this type of field that was used
19 and it wouldn't be accurate enough and suggested
20 complementary approaches.

21 So we came out with a recommendation from
22 these two examples and a number of other ones, the
23 policies and procedures, when there are large shifts,
24 how do we -- what can people learn from these examples,
25 how to use cone beam CT maybe more appropriately, maybe

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1 need to be larger when there are opportunities for
2 making mistakes, especially when vertebral bodies can
3 look alike, and having complementary types of imaging
4 such as kilo voltage imaging or megavoltage imaging
5 where it's appropriate.

6 I'm going to show you just again,
7 everything that we're going to show you is the public
8 domain regarding these quarterly reports. And the
9 quarterly reports really reflect our evolution as we've
10 learned and as we've gotten better and as we've
11 reflected on what we've observed.

12 We initially talked about severe or almost
13 severe medical events. We give case examples of time
14 out procedures. We then talked about near misses,
15 unsafe conditions, miscommunications, what happens
16 when staff is rushed. And again, I've got to credit
17 all the facilities for sharing all this information and
18 not holding back on what they shared with the RO-ILS
19 system.

20 As we got a little more evolved, we
21 discussed issues about communication, electronic
22 versus verbal because there were numerous instances we
23 observed where we were seeing thematically the same
24 thing again and again. I'll give you a couple of
25 examples in a moment.

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1 We got into near misses. In trying to
2 categorize the near misses, we talk about -- there were
3 some equipment issues. We got into a priority-scale
4 issue because we appreciated the taxonomy had to
5 evolve. For now, for near misses, we have a scale that
6 goes from one to five in terms of severity just for near
7 misses alone.

8 We talk about mistreatments and
9 prescriptions, a number of issues that relate to HDR
10 and IGRT, pacemaker policies and procedures, other
11 things like that. And then finally, we came across
12 equipment -- vendor/vendor issues and particularly
13 with HDR and we shared this in our quarterly reports.

14 We have a categorization system about
15 since it reached it patient there are near misses or
16 we perceived as our unsafe conditions. And I mentioned
17 for the near misses we've expanded that to a five point
18 scale.

19 For a number of cases, what was planned and what was
20 treated didn't exactly match and I'm just going to show
21 you a couple of examples, but this is just from the data
22 mining. These are repeat things that we find
23 repeatedly that we're trying to disseminate to the
24 community.

25 So the physician gave incorrect

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1 instruction. The physician wrote 5 gray times 6
2 instead of 6 gray times 5. Sometimes in a hierarchical
3 system this gets -- this doesn't get questioned,
4 sometimes it does get questioned in trying to show that
5 everyone makes mistakes and to empower and create a safe
6 environment for reporting within a facility.

7 Sometimes the plan did not match the
8 prescription and it was unappreciated at the time of
9 approval and sometimes it's the last component of a
10 safety chain. It's the therapist who is at the linear
11 accelerator which picks up on this. Sometimes the
12 planner wrote the prescription, so the written
13 directive was not written by the physician. We've seen
14 this in a number of cases and it creates all sorts of
15 opportunities. For example, 12 and 2, so the
16 dosimetrist receives a verbal order from the radiation
17 oncologist to treat a shoulder 12 and 2. The
18 dosimetrist wrote a written directive for 6 treatments
19 of 2 gray each for a total of 12 gray. It was approved
20 and it should have been 2 fractions of 6 gray for a total
21 of 12 gray. It was picked up at chart rounds and then
22 it was ultimately rectified. But it just highlights
23 a number of things that we've observed as we've data
24 mined the system.

25 Wrong hepatic lesion treated, especially

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1 in the hypofractionated area with SBRT. We're seeing
2 this more and more. So this isn't a teaching facility,
3 and a physician resident reviewed the case. The
4 resident ultimately contoured the wrong lesion. So
5 the QA was completed and hemangioma was treated for five
6 fractions. Only after the patient was followed up and
7 showed progression in the liver, that they went back
8 and looked at what had happened and they appreciated
9 there was a geographical miss because they treated the
10 wrong area and this eventually was treated. These are
11 not isolated cases.

12 So the facility in this case appreciated
13 there were a number of contributing factors. We've
14 incorporated the facilities' observations and how
15 they've changed practices and in our quarterly reports
16 we emphasize a number of issues so this shouldn't happen
17 at any facility.

18 So how do we further build on Subpart M?
19 So as the RO-ILS system started taking hold and more
20 and more facilities started reporting, we recognized
21 that we needed to modify our forms. People are
22 reporting -- the richness of the story is in the
23 vignette. It's not in any particular field in the
24 relational database. We also appreciated we were
25 getting overwhelmed with data and we needed a better

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1 way to try to evaluate things.

2 So we appreciated that there are different
3 types of triggers that will allow one to bin data, data
4 that reached the patient, data that was a near miss,
5 data that represents an unsafe condition and then
6 within these bins have different levels of significance
7 so we can really spend our time more effectively in
8 trying to figure out where can we connect the dots, how
9 can we disseminate this, and what are the teaching parts
10 from the database. So we've just implemented this and
11 we're now starting to see -- we haven't yet seen the
12 fruits of this labor.

13 The RO-ILS system is only two years old and
14 I think it's a credit to the people at ASTRO and AAPM,
15 as well as the volunteers, as well as the member
16 institutions who through this labor of love, who are
17 submitting information. At some places, it's the
18 therapist, it's the physicians, it's the dosimetrists.
19 At some places, it's mostly the physicists.

20 The way the system is designed at the
21 initial level, anyone can submit-- it could be nursing.
22 It doesn't really make a difference. Anyone should be
23 able to submit to the RO-ILS system and then there's
24 a second layer where you can provide the richness of
25 the incident that happened.

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1 At the Society meetings, we have various
2 informational opportunities. We conduct educational
3 webinars. We have tips of the month. We provide
4 specific reports to each institution. We have safety
5 alerts. We provide to the vendors reports in a
6 de-identified way that explains what we found. Again,
7 everything that we do is in the public domain and we
8 certainly receive a lot of advice and suggestions from
9 the community as to how we can make it better.

10 I'll just point out that Cindy Tomlinson,
11 who's from ASTRO, who's in the audience can answer some
12 specific questions regarding the RO-ILS system and with
13 that, I thank you.

14 CHAIRMAN ALDERSON: Thank you. Thank
15 you, Dr. Dicker. Because we have speakers on the phone
16 who may be in their home institutions and have other
17 scheduling issues, I'm going to ask us to hold the
18 questions on the individual reports until we go through
19 all of the presentations and then everything will be
20 open and at that time we will ask the people on the phone
21 if any of them are going to need to leave the session
22 early or at some particular point and would direct the
23 initial questions, if any, to them. So we'll carry on
24 now with Dr. Elee.

25 MS. ELEE: Hi, I'm Jennifer Elee. I'm here

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1 representing the CRCPD, Conference for Radiation
2 Control Program Directors. It's been a while since
3 I've talked to you in the past and I think there's some
4 new faces. So is everybody familiar with who CRCPD is?
5 Okay, if I needed to go into that.

6 I still chair the H38 Committee on Medical
7 Events and I'm also the Healing Arts Council Chair now
8 for the conference for two more years. I'm serving a
9 three-year term as that.

10 So just a little background. In 2011, we
11 did conduct a pilot and collected machining events for
12 the first time. Since then, we've been collecting
13 events from all states who have requirements. It's
14 important to note that some states have no reporting
15 requirements and some have therapy only, not
16 diagnostic. And we only collect our events from the
17 states themselves. We do not take them from
18 facilities. So these are events that have been
19 reported to a state and the state reports them into our
20 system.

21 In 2013, we entered into an MOU with AAPM
22 to further analyze the information that we get, the
23 specific information on the event. We redact the
24 facility and state information so they don't know where
25 the events come from and they provide that back as an

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1 annual report to CRCPD and the AAPM Boards and we both
2 present a summary at the CRCPD annual meeting.

3 Why we collect information, we want to
4 share lessons learned, prevent errors, look for trends
5 and of course, improve patient care and safety. Our
6 event definitions, we currently have event definitions
7 for both therapy and diagnostic. We're very excited.
8 Our definition of diagnostic was included in our latest
9 version of the suggested state regulations for
10 diagnostic x-ray. And as states adopt those, we hope
11 to see more states have reporting of diagnostic events
12 since that is the first time that's actually been
13 included in the SSRs for diagnostics.

14 Our annual summary is a fiscal year
15 summary, just so you know, 10/1 to 9/30. In total, for
16 the period, we've had 187 therapy events reported and
17 9 diagnostic events. And that just kind of gives you
18 an idea of over the years. It's been fairly
19 consistent. We had a spike in 2014 on the number of
20 events and states reporting, but overall our numbers
21 are pretty consistent in the amount that we get.

22 Over the period, we have 20 states that
23 have actually input events into the system, so we have
24 20 states that have actually put events in, some of them
25 multiple years, but at least in one of those years.

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1 The highest number of states responding in
2 any one year was 37. Once we have our events in the
3 system, we polled the rest of the states to see if --
4 just to verify either they did not have events or they
5 do not have a reporting requirement. So we try to get
6 a little more information on what's going on in the rest
7 of the states. For those of you who do surveys, 37 out
8 of 50 is a pretty good response. That's the best we've
9 been able to do.

10 Types of events reported and in order to
11 your font, these are pretty typical of what we see each
12 year. It's pretty consistent, the types of events we
13 see, wrong patient, wrong site, you know the weekly dose
14 exceeds or the total dose or the single fraction. We
15 do have a fair number of events that go into the other
16 category and these are generally, we have a text field
17 where they can explain what the issue is.

18 It is somewhat concerning that we still see
19 wrong patient every year and two to three wrong patient
20 cases every year which is astounding.

21 Severity of effects, we've only had two in
22 the time frame that had severe effects that required
23 some type of follow up. Minor effects are generally
24 the response that we received or when we asked that
25 question.

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1 Events are discovered primarily by
2 technologists which I don't think would be a surprise
3 here and then physicists and physicians are primarily.
4 We've had some dosimetrists and other people in the
5 field.

6 Their chart check, quarter imagining
7 clinical review, and again, we have 25 percent that
8 indicate there was some other form of how their events
9 were discovered.

10 Causes and contributing factors,
11 therapist error. Again, this is a question where they
12 can answer multiple things, so most of our events have
13 multiple reasons. And usually it's therapist error
14 and something else. There's a lot of -- several
15 different boxes checked on those, but therapist error
16 does come out a good bit.

17 On our diagnostic side, we've had nine
18 events, four CT, three fluoroscopy, and one general
19 radiography, four of the nine were wrong patients on
20 the diagnostic side.

21 We had two which were exams done by
22 unlicensed or untrained operators, exceedance to the
23 lens of an eye, an unintended dose, and an equipment
24 failure.

25 I think it's important that we note in

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1 medical use of radiation we expose people on purpose
2 for a potential benefit which is unlike a lot of the
3 other radiation issues especially that NRC deals with
4 on the industrial side. There's millions of
5 procedures done every year. On our side, what we know
6 we can do better is better disseminate our information
7 outside of CRCPD and AAPM. We do a really good job of
8 sharing it with each other. We go to our own meetings.
9 We present it to our people. We put it in our
10 newsletter, but I don't know how well we're doing
11 getting that information to other people.

12 We continue to promote reporting of events
13 to states by facilities and states to report to CRCPD
14 so that we get more data. We try to follow up.
15 Between now and the 15th, we'll make calls to all the
16 states or emails to all the states who didn't report
17 to the system to try to find out if there's anything
18 they have.

19 I was asked to talk about safety culture
20 a little bit and so I just picked a few points off the
21 safety culture list and said for leadership knowing
22 when and who to report to, I think is very important.
23 And we're working on that. We realize that not
24 everybody knows who they need to send their information
25 to at the state level. So we're developing a list of

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1 state reporting contacts. We're going to put it on our
2 website. We'll share it with AAPM and ASTRO so that
3 they can disseminate it to their members as well. It
4 will include whether the state has diagnostic
5 reporting, therapy reporting, and then who to contact
6 at that state would be to send your events to so it's
7 readily available for the people who need to report.

8 Problem identification and resolution and
9 follow-up actions. This is something we're working
10 with our inspectors on. Identifying a problem in the
11 field is not as easy as it sounds when you're working
12 with a facility that may or may not want to tell you
13 that something has happened.

14 Personal accountability on the facilities
15 part, owning up to mistakes, raising concerns, and
16 respectful work environment, respect between us as the
17 inspectors from the state and the facility has a long
18 way to receiving more events and to finding out that
19 these things are happening. I put this on it. I also
20 applied this to the inspector or the regular. We need
21 to be able to identify the problem. We need to be able
22 to communicate with the facilities in a respectful
23 manner.

24 We need to be able to continuously learn
25 about new equipment and procedures. This is very

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1 difficult a lot of times for our state inspectors and
2 people in that area. We don't get the manufacturer
3 training that the facilities get when units are
4 installed. So a lot of times we're asking a lot of
5 questions because we're just not familiar with a new
6 piece of equipment or a new software system that you
7 have or whatever.

8 We want to help facilities find
9 resolutions and improve situations rather than just
10 cite violations and encourage and give credit to
11 facilities for reporting. I think that's a big thing.
12 If facilities know it's okay to report, they'll have
13 more that do.

14 What are we going to do in the future? We
15 are looking at doing some topic training at our CRCPD
16 meeting on safety culture and root cause analysis. So
17 taking some events that actually happen at facilities
18 and walking through them for our members so that we see
19 what it looks like on your side. So what it looks like
20 on your side, so we know when we go in what better to
21 look for.

22 We're looking at never events. Our
23 radiation therapy is looking into doing a handout on
24 this, you know, basically, events that should never
25 occur, wrong patient, for example. And this is a

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1 problem. And we're also planning to do a journal
2 article on our first five years of event reporting.

3 This is just the link to our reporting
4 forms. They're on the website. And we email them in
5 to our office.

6 This is my information if you need to
7 contact me at any time.

8 I will say our interaction with AAPM has
9 been very well received and very good. We have found
10 at least one incident of a software issue that occurred
11 in two different years in two different states which
12 we were able to report to FDA, so that's our goal with
13 this is to see things that we might not have seen
14 otherwise if we were looking at them individually, but
15 when we look at them all together, it's like oh yeah,
16 that happened here and it happened there and they may
17 not have even realized.

18 And as I said, we hope to see the diagnostic
19 side pick-up with Part F and people adopting that. And
20 our committee was initially set up to look at radiation
21 medical events. We focused on the machine side because
22 NRC was already -- had reporting on the materials side.
23 And at the time that was where we felt we needed to put
24 our efforts. But I think now we've got some water under
25 the bridge and we're certainly open. We've talked

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1 about it in the past to working with having a system
2 where all medical events to be both material and machine
3 into one system which would be nice for a facility.
4 That's it.

5 CHAIRMAN ALDERSON: Thank you. So we're
6 midway through these reports now. I would remind
7 people that the reason for this session is that we're
8 trying to learn how other organizations collect and
9 report data related to medical events and we are
10 considering the idea of how we move to an improvement
11 culture, away from a punitive culture and excellent
12 examples given just now by Dr. Elee from the CRCPD which
13 is the Conference of Radiation Control Program
14 Directorate. Thank you very much.

15 We'll move on now to the next speaker who
16 is on the phone and he is Bruce Thomadsen, our former
17 colleague and the immediate past chair of the ACMUI.

18 Dr. Thomadsen, are you ready to report?

19 DR. THOMADSEN: Yes, I am.

20 CHAIRMAN ALDERSON: Please, carry on.

21 DR. THOMADSEN: Thank you much. Thank
22 you very much, Dr. Alderson. And it's really good to
23 see all of you on the video and hear your voices.
24 Missed you all, but you seem to be carrying on quite
25 well.

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1 Can I have the slides, please? And there
2 is about a 20 second delay between the video, so I hope
3 I don't get out of phase too much. I am the president
4 of CARS. I'm also a professor at the University of
5 Wisconsin.

6 Next slide, please.

7 And just information about the Center for
8 the Assessment of Radiological Sciences or CARS. We
9 are a 501(c)(3) non-profit Patient Safety Organization
10 listed with the Agency for Healthcare Research and
11 Quality and we're the same software that's used in the
12 reporting system in the VA system, although because of
13 regulations, their data and our data cannot mix.

14 Next slide, please.

15 The charge that all the PSOs have from AHRQ
16 is to improve clients' quality and safety. And we take
17 that to heart by working with our clients to remediate
18 causes of any reported incidents. And we work with the
19 clients to develop prospective quality management for
20 their facilities also.

21 Next slide, please.

22 In our reporting system, the organization
23 is that a facility that has an incident goes online and
24 fills out a very short notice that they've had something
25 happen with few details. And most of the details we

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1 ask them for are only to get them -- to give them a
2 feeling that they're actually involved in this
3 reporting system. Because as soon as they submit the
4 report, we get a notice that a new report is online and
5 one of our staff calls the facility and talks with our
6 contact there.

7 And we'll go through all of the questions
8 in the questionnaire which we follow the AAPM-generated
9 taxonomy. And we go through it to make sure that we
10 understand exactly what's happened in the incident and
11 that the data being entered on the form is correct.

12 We also then after we get all the
13 information on the form, we'll go off and we'll do a
14 causal analysis of the event. We'll then put the form
15 back on line with all of our analysis and our proposed
16 solutions for what to do to improve the quality at the
17 facility.

18 We'll then talk with the contact at the
19 facility, go over our analysis to make sure that we have
20 understood what's happened and they agree. And go over
21 our proposed solutions because we understand that we
22 might make proposals that would be infeasible at the
23 given facility and so we'll work back and forth with
24 the facility until we can come up with what would be
25 a useful set of recommendations.

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1 And we do the analysis because from a study
2 we did back in the '90s of causal analysis of
3 radiotherapy events, we found that there's a very long
4 learning curve and that persons who do not have a lot
5 of experience doing causal analysis usually come up
6 with very superficial ideas of what the causes were and
7 generate very simplistic proposed correctives that
8 would have prevented the given event, but don't really
9 delve deeply into the system at the facility that
10 actually led to the weakness that manifested itself in
11 the event.

12 Next slide, please.

13 The data, as soon as the initial report is
14 submitted, goes into our database. And let's see, I'm
15 on -- okay. All the fields -- I think I'm on -- I'm
16 seeing -- no, this is the right slide. The delay sort
17 of makes it a little difficult to check where I am. But
18 all the incidents do go into the database which is
19 important to trigger the protection that the facilities
20 would have against the legal discovery. All fields are
21 completed in our reports and we make sure that they're
22 all correct.

23 The root cause analysis is done by
24 professionals who have expertise in both radiotherapy
25 and in systems analysis and we make a point of trying

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1 to support our clients as they're trying to improve
2 their system. We work with them directly.

3 Next slide, please.

4 The system does serve as the local database
5 for our clients, but it also is automatically part of
6 a national database when any researcher can register
7 and view and anonymous data from the system. We also
8 accept anonymous reports. If the anonymous report
9 identifies that the incidents happening at one of our
10 clients, we can then go back and work with our client
11 to try to improve the situation.

12 Next slide, please.

13 We do send out information through emails
14 to clients, messages to list servers, and letters to
15 professional organizations.

16 Next slide, please.

17 Just some of the findings that we found are
18 that it's very important not to get too hung up with
19 evaluating the severity of incidents that are reported.
20 When we're trying to help a facility prevent having a
21 major event, and analyzing each of the small incidents.
22 Even those that had no effect, no severity on the
23 patient are very important because they do identify
24 weaknesses in the system. And by following incidents
25 that happen at a given institution over time, we have

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1 been able to identify definite problems in facilities.

2 Just two examples are listed here. One
3 facility had a number of number of incidents reported
4 and what we were able to identify is that the problem
5 behind it -- well, each one, if you looked at them
6 individually, had causes that looked apparent.
7 Underneath those were a problem with the scheduling,
8 where the scheduling would end up with many patients
9 being started at the same time and then many lulls by
10 the time of lulls between patients. And they were
11 staffed for the average between these two and they
12 weren't really prepared for the higher patient load.
13 And this was periodic almost in the swells about a
14 monthly or bimonthly basis. Their events were
15 occurring during the busy periods and almost all of the
16 events tended to be omissions. That is, they got busy
17 and just missed some step that they were doing.

18 Another problem that we identified across
19 events occurring at a given facility was that they had
20 no systematic approach to communication and while each
21 event again had causes that something happened that
22 looked like it was a simple case, underlying everything
23 we could see was a constant communication failure that
24 they just didn't have a systematic way of dealing with
25 communications.

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1 Next slide, please.

2 Another one of the problems that we noted
3 that we were dealing with was a problem where there was
4 an omission of a device in a treatment set up. The
5 slide is showing the order form that had been used. The
6 top red arrow is pointing to a box where they would enter
7 comments about this set up. The lower arrow is a
8 checklist where they check off things like the
9 immobilization devices.

10 In this particular case, there was a long
11 comment on how to set up the patient and the therapist
12 and the simulator followed the comments, but as they
13 were following the comments, they thought that that was
14 pretty much describing all of the set up and they didn't
15 notice the immobilization device checked off at the
16 bottom.

17 Next slide, please.

18 And one recommendation we gave was to
19 reorder the information on the order form, moving the
20 check boxes up above the comments because when the
21 comments is filled out, the therapist is unlikely to
22 notice -- to miss the comment that's written in there.
23 And this brings the eyes down following human factors
24 analysis, brings the eyes down through the checklist
25 that is giving them the first indication of how the

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1 patient be set up and then leading them to the comments.
2 And this type of a change should help improve the
3 communication on how to set up the patient.

4 Next slide, please.

5 CARS also has a section for reporting
6 equipment failures and we accept reports both from our
7 clients and from just anybody if they have an equipment
8 failure. If there is an incident from a client that's
9 reported, we will automatically go in and enter the
10 equipment failure.

11 We then will go to the vendor and discuss
12 the problem with the vendor and come up with what their
13 solution would be and we try to assess whether that
14 would fix the problem and we would disseminate this
15 information not just to the people reporting it, but
16 on our website and if it's relevant through an
17 information release. If it's appropriate, we also
18 will take these reports and with the client's
19 permission, we will enter them on the FDA website.

20 We feel it's very important to actually
21 work with the patient -- with the client, rather, on
22 dealing with their problems because we have the
23 expertise in causal analysis and probably very few of
24 the facilities have had enough events where they've
25 gotten past the learning curve and can reliably

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1 identify what the true causes of the problems are.

2 We also have found it's very valuable to
3 work with the clients across their incidents to gather
4 more information about what may be underlying the
5 problems. So we were the first PSO taking events from
6 the radiotherapy community.

7 We have found that the approach we have
8 does help give better data and thorough data in the
9 report and we can support our clients and get more
10 information about them by getting to know them and
11 following them across incidents.

12 Thank you.

13 CHAIRMAN ALDERSON: Thank you, Dr.
14 Thomadsen.

15 We'll move on now to Sandy Gabriel from the
16 International Atomic Energy Agency who will tell us
17 about the radiation oncology safety system known by the
18 acronym SAFRON. Ms. Gabriel?

19 DR. GABRIEL: Yes, thank you. It's good
20 to be back with my old colleagues again. And I'll wait
21 for my title slide to show up. Again, we have a
22 20-second delay that may interrupt the presentation a
23 bit.

24 So thank you for inviting the IAEA to
25 provide an update on our radiotherapy incident learning

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1 system called SAFRON. Debbie Gilley is the SAFRON
2 project manager and she's traveling on IAEA business
3 today, so she asked me to make her presentation for her.

4 Could you please move ahead two slides,
5 Sophie?

6 So in the name SAFRON, SAF stands for
7 safety and RON stands for radiation oncology. SAFRON
8 is an international incident learning system developed
9 by the IAEA to improve and promote safe planning and
10 delivery of radiotherapy. Its purpose is to share
11 information, promote safety and clinical facilities
12 around the world, and provide resources for prevention
13 of future incidents. Thank you.

14 SAFRON includes data from a variety of
15 sources. It contains reports submitted directly by
16 individual radiotherapy facilities as well as data
17 shared by other reporting systems and organizations.
18 These include ROSIS, the Radiation Oncology Safety
19 Information System, which is based in Europe; ASN, the
20 French regulator of nuclear safety radiation
21 protection; and CRCPD, who we've heard from a few
22 minutes ago.

23 SAFRON is a web based voluntary reporting
24 system of incidents and near misses. It became
25 operational in December 2012 and is initially limited

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1 to external beam radiotherapy. As of mid-September of
2 this year, SAFRON contains 1334 reports. There are
3 currently 75 registered contributing institutions from
4 6 continents. Reporting to SAFRON is anonymous and
5 therefore non-punitive.

6 Next slide, please.

7 So SAFRON was designed to perform several
8 functions. It serves as both a local and international
9 incident learning system. For individual
10 participating facilities, SAFRON can be used as a local
11 database of incidents and near misses with analytical
12 tools such as statistical data and charts. By
13 anonymously sharing events, including detailed
14 narrative descriptions, SAFRON participants can
15 enhance the knowledge of staff and other facilities.

16 On an international level, SAFRON offers
17 a resource for the radiation oncology community to
18 improve quality and safety. In addition to the
19 analytical tools in SAFRON, IAEA staff provide
20 information in the form of reports and peer-reviewed
21 publications.

22 Direct access to the contents of the SAFRON
23 database is available over the Internet to anyone
24 worldwide who completes a simple registration process
25 in the centralized IAEA access point called NUCLEUS.

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1 An additional level of registration is required to
2 become a participating facility that can enter data
3 into SAFRON.

4 Next slide, please.

5 The next few slides will show examples of
6 different pages in the SAFRON website. We'll wait just
7 a minute until the first one shows up.

8 So the first image that I hope will display
9 -- there it is, is the current version of the first page
10 that is displayed after you login to SAFRON. It has
11 links to various functions within the system as well
12 as summaries of featured recent incident reports and
13 recent related publications.

14 There isn't enough time today to
15 demonstrate all of SAFRON's functions so I'll focus on
16 a few that were not covered in Debbie's presentation
17 to this committee in 2014.

18 Next slide, please

19 SAFRON provides a variety of search
20 parameters and report types. Participating
21 facilities can choose to view either their local data
22 or data from the full database. Everyone else is
23 limited to viewing anonymized data from the full
24 database. Let's wait for next image.

25 This slide provides an example of the

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1 screen that is displayed if you wish to search for
2 incident reports. You can search on a variety of
3 different parameters or on the text of the narrative
4 description. The search field demonstrated on this
5 slide is clinical incident severity. So the search is
6 done using a pull-down menu in that circled area on the
7 left of the slide to select one of the seven categories
8 of incident severity.

9 You got a little bit ahead of me, Sophie.
10 Okay, we'll switch to this one.

11 This slide is an example of one of the
12 statistical reports in SAFRON. It shows incidents
13 that reach the patient in blue, versus near misses in
14 red by year. You can see that right now there's a
15 relatively small number near miss reports that have
16 been submitted or captured, although the IAEA does
17 recognize the importance of near miss reports and
18 encourages participants to submit them. IAEA staff
19 have noted that the majority of reports are events that
20 reach the patient, but may not meet criteria for making
21 the reports a regulatory body.

22 You went back to the previous one. Let's
23 move ahead to, please, to the slide that has lots of
24 colors. Next one after this.

25 So one parameter included in SAFRON

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1 incident submissions is the way in which the incident
2 was discovered. SAFRON device is delivery of external
3 beam radiotherapy into 92 process steps divided into
4 three phases: nonclinical, pre-treatment, and
5 treatment.

6 This slide shows the results of the summary
7 report illustrating the ways in which incidents in each
8 phase were discovered. You can see from the green bar
9 in the center portion of the graph that the most
10 frequent discovery of incidents was by chart check
11 before the initiation of treatment.

12 Next slide, please.

13 This slide shows the total number of
14 incidents reported for each phase of the radiotherapy
15 process. To see a breakdown of the number of incidents
16 for each process step within a phase, you can click on
17 that bar in the graph to produce the more detailed
18 report shown on the next slide which I hope we can get
19 to fairly quickly.

20 Okay, the slide with quite a few bars
21 displayed that I'm not seeing quite yet shows the result
22 -- if you click on the bar for treatment phase in the
23 previous slide, the graph shows the number of reports
24 associated with each process step in the treatment
25 phase. Note that there are more than 30 process steps

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1 in this phase, so you would need to scroll to the right
2 to see the full graph. If the user identifies the
3 process step that they would like to improve or
4 research, SAFRON provides links to related
5 professional publications and other educational
6 resources.

7 Next slide, please.

8 Another important concept used in the
9 SAFRON database is safety barriers which are steps in
10 the process intended to catch errors. Incident
11 reports include three fields related to safety
12 barriers: what safety barriers fail to identify the
13 incident; what safety barrier identified the incident;
14 and what safety barrier might have identified the
15 incident if it was in place.

16 This slide shows a summary report of the
17 safety barriers that failed in each phase of the
18 radiotherapy process. You can see that some of the
19 reviews and checks intended to service safety barriers
20 were not always effective. For example, in the
21 treatment phase, the bright pink bar represents 25
22 reports of incidents in which image based position
23 verification failed to identify an incident. Several
24 of these involved online image match to the incorrect
25 vertebral level, similar to incident Dr. Dicker

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1 discussed today in his presentation.

2 Next. Let's skip the next slide and move
3 on to the one that is titled SAFRON Learning which I
4 presume you can already see, although I can't quite yet.

5 The final group of slides discusses the way
6 in which the IAEA has been using SAFRON as a learning
7 tool to improve safety and quality in radiotherapy.
8 Our staff has made numerous presentations to
9 international regulatory authorities and medical
10 groups on incident learning in radiotherapy of the
11 benefits of using SAFRON. The IAEA produces SAFRON
12 newsletters, usually twice a year, addressing issues
13 or trends that have identified reports of incidents
14 entered into the database. Topics addressed in the
15 three most recent newsletters are safety culture and
16 radiotherapy, learning from near misses, and a quality
17 process called check review and report that can be used
18 to resolve errors before they reach the patient.

19 Next slide, please.

20 Based on analysis of events in SAFRON, the
21 IAEA recently published a brochure on the check review
22 and report process. This brochure reviews the kinds
23 of checks that can be used to safety barriers,
24 strategies to perform effective checks, the importance
25 of resolving any identified discrepancies, and

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1 benefits of reporting incidents and near misses.

2 Next slide, please.

3 Another learning opportunity stemming
4 from SAFRON is a new IAEA e-learning course on safety
5 and quality in radiotherapy that will be available
6 online by the end of this year. This free course 12
7 modules covering topics such as failure mode effects
8 analysis, root cause analysis, incident learning and
9 safety culture. Three radiotherapy errors are used as
10 case studies to illustrate these topics.

11 Would you move ahead two, please, to the
12 slide called SAFRON Next Steps?

13 The IAEA plans a series of updates to
14 expand SAFRON's capabilities. Within the next year,
15 we intend to add a perspective risk analysis feature
16 and the ability to address brachytherapy events using
17 process steps designed specifically for this modality.
18 I hope you can see the slide called SAFRON Next Steps.
19 There we go.

20 In the future, we also plan to add
21 translation capabilities so SAFRON can be used by
22 speakers of languages other than English and the
23 ability to address nuclear medicine events.

24 Next slide, please.

25 As a final point, we like to be sure you

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1 are aware of the series of international conferences
2 on radiation protection in medicine that relate to the
3 topic of today's discussion. In 2012, the IAEA and the
4 World Health Organization co-sponsored a conference in
5 Bonn, Germany to identify and address issues related
6 to radiation protection in medicine. This was
7 attended by 536 individuals from 77 countries and 16
8 organizations. The conference prioritized ten
9 actions to approve radiation protection in medicine
10 during the next decade and published these as the Bonn
11 Call for Action.

12 Action 7 says improve prevention of
13 medical radiation incidents and accidents. There are
14 five sub-actions, the first of which is implement and
15 support voluntary educational safety reporting systems
16 for the purpose of learning from the experience of
17 safety-related events in medical uses of radiation. A
18 follow-up conference will be held in December 2017 at
19 IAEA headquarters in Vienna to assess progress on
20 implementing these ten actions. We hope you will all
21 consider participating.

22 And I think I am going to stop here on the
23 last slide. You can see contact information at our
24 website, rpop.iaea.org. And if you would like to learn
25 more about the IAEA's activities in the radiation

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1 protection of patients, you can also send a message to
2 Debbie or me at the email addresses shown on the last
3 slide.

4 So I'll end here and try to answer any
5 questions. Thank you.

6 CHAIRMAN ALDERSON: Thank you very much.
7 So we're now going to open up these four discussions.
8 Two comments, we've heard from four respected
9 organizations that collect data from a broad
10 participant basis in non-punitive ways in an attempt
11 to improve patient safety. And we listened to them so
12 that they may inform how the NRC might wish to consider
13 some of these similar approaches.

14 We'll begin with comments from the ACMUI
15 members and then move to our in-house audience and then
16 to listeners on the phone who might wish to comment and
17 we have approximately 20 minutes for this Q & A session.

18 So the floor is open to the ACMUI. Dr.
19 Zanzonico.

20 VICE CHAIR ZANZONICO: Well, thank you
21 all. I mean very, very informative. One thing that
22 strikes me when I'm listening to these reports from
23 diverse groups, diverse organizations is, is there any
24 effort, any value in collating reports from multiple
25 groups?

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1 I'm wondering is there redundancy of
2 reports among the groups or does each group have its
3 own constituency? So when you hear these
4 presentations collectively, it makes it kind of
5 difficult for one listening to it, at least for me, to
6 get a sense of what is the prevalence of these different
7 kinds of events in the field without some collective
8 collation of the data.

9 So whoever would like to sort of comment
10 or address that point?

11 CHAIRMAN ALDERSON: Dr. Dicker.

12 DR. DICKER: So, three points. One, I'm
13 going to use a lifeline to Ms. Tomlinson. Two, we have
14 about ten percent penetrance in the radiation oncology
15 community in the past two years. I don't know if it's
16 going to be linear, logarithmic, geometric in terms of
17 our penetrance. And Ms. Tomlinson will talk about
18 working with other societies.

19 And then the other comment I think you
20 relate to is if we have a de-identified relational
21 database, is there a way to merge databases, right?
22 That's kind of a technical thing.

23 So Ms. Tomlinson from ASTRO.

24 MS. TOMLINSON: Cindy Tomlinson from
25 ASTRO. So part of the problem with merging things is

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1 that under the Patient Safety Act and the way that
2 RO-ILS and CARS also operate, is that there's legal
3 issues. And so the Patient Safety Act gives legal
4 protections to the data. And so when you start
5 bringing in other things and moving that data out, you
6 have to be super careful with how you are making sure
7 that it's anonymous and de-identified and all these
8 other things

9 So it's not as simple as just merging the
10 data. I mean we're all looking sort of at the same data
11 points, but trying to merge them, brings in some
12 technical, but mostly some of the old issues as well.

13 Is it not on? Can you not hear me? Do you
14 want me to repeat that?

15 CHAIRMAN ALDERSON: Could people who were
16 on the phone, could they hear these last comments?

17 DR. THOMADSEN: No.

18 CHAIRMAN ALDERSON: No. So please repeat
19 the comments.

20 MS. TOMLINSON: I'm really sorry. It's
21 Cindy Tomlinson with ASTRO. Hopefully, I can repeat
22 it the same way that I did before. But basically,
23 trying to merge a lot of these databases especially with
24 RO-ILS and CARS who operate under the Patient Safety
25 Act is difficult.

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1 There are protections that the Patient
2 Safety Act gives to that data, and so taking that data
3 out requires a lot of work and there's some technical
4 issues as well, but mostly it's the legal issues with
5 merging all of that stuff together.

6 The CRCPD database, again, it's the states
7 that require reporting who then send that stuff off to
8 CRCPD. That stuff is in the public domain anyway, but
9 our data, especially since we're looking at near misses
10 and sort of other things that are -- I want to say not
11 major because that's not the right word, but that don't
12 rise to the level of state or even federal reporting,
13 it would be really difficult, I think to do that and
14 maintain the protections. Because that's the reason
15 why people participate in RO-ILS, one of them, is that
16 there is protection of their data.

17 CHAIRMAN ALDERSON: Do we have further
18 comments?

19 MS. ELEE: I was just going to say with
20 CRCPD, Cindy is right. We collect information from the
21 states that is reported to the states. Any of those
22 events are available through a FOIA request to that
23 specific state. CRCPD does not release any states'
24 information. We collect the data. We aggregate it,
25 we look at it. We do provide our information to IAEA

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1 and it is put into the SAFRON system. We are registered
2 users, CRCPD is, so they're put in as, I guess, CRCPD
3 events, not individual states events, but they are
4 included in that system.

5 CHAIRMAN ALDERSON: Dr. Thomadsen or Ms.
6 Gilley, do you have comments on this question?

7 DR. THOMADSEN: Yes. I would just say
8 that CARS and RO-ILS data do not overlap that I know
9 of. I don't think that we have any clients who are in
10 both systems. We have talked with the RO-ILS advisory
11 and analysis group about trying to combine data. AHRQ
12 does try to combine data from all of its PSOs.
13 Unfortunately, its database that we could upload into
14 is not made for any of the information that's really
15 relevant in radiation oncology. So we would be trying
16 to work between the RO-ILS system and the CARS system
17 to try to combine data and make sure that there is not
18 overlap. The taxonomies are pretty much the same, so
19 that is not a barrier.

20 As far as events, we've actually not had
21 an event in our database which would rise to the level
22 to go into the CRCPD's or the NRC's, but we do have a
23 data field that tells if the event is reportable in
24 which case it would be identified as an event which
25 could be in either of those databases.

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1 We are going to be talking, actually just
2 next month, with Debbie Gilley to see what, if any,
3 combination of data we could have with SAFRON.

4 CHAIRMAN ALDERSON: Ms. Gabriel, any
5 further comments on this?

6 DR. GABRIEL: I think the focus of SAFRON
7 is a bit different in that we're worldwide and the IAEA
8 does quite a bit of work with developing countries who
9 are starting new radiation oncology services or trying
10 to expand the ones that they have. So our focus is
11 somewhat different.

12 As we've already discussed, we do
13 cooperate with other systems and organizations in
14 trying to service a clearinghouse to collect lots of
15 different reports.

16 CHAIRMAN ALDERSON: Thank you. The next
17 ACMUI question comes from Mr. Richard Green.

18 MR. GREEN: There's a great deal of value
19 in getting an aggregation of the data so we can see the
20 whole picture, but with anonymized data, it just seems
21 you've got your clients and they've got their clients
22 and how do we know we're not double counting? That's
23 the challenge I see.

24 CHAIRMAN ALDERSON: Other comments?

25 DR. THOMADSEN: This is Bruce Thomadsen

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1 again. At the moment, between the RO-ILS and CARS you
2 wouldn't be double counting the data because the
3 clients are separate. Although it's totally possible
4 that somebody who is a client of RO-ILS could be a client
5 of CARS, too, because we do offer different services.
6 That would be one reason why it would be very good for
7 RO-ILS and CARS to be able to cooperate in trying to
8 combine data in some way that would prevent that.

9 CHAIRMAN ALDERSON: The next ACMUI
10 comment is from Dr. Dilsizian.

11 MEMBER DILSIZIAN: Thank you very much,
12 Dr. Alderson.

13 I want to congratulate to all the
14 presenters. It's a wonderful start and I think that
15 the reason we're having this discussion is because we
16 really feel that the number of programs or number of
17 incidents is just the tip of the iceberg. And I think
18 that the SAFRON presentation of the clearinghouse of
19 multiple reporting systems of 4 organizations and
20 individual clinics that represent only 75 programs in
21 6 continents tells us that we can't do anything about
22 prevalence of anything here because we're talking about
23 very small number of those who are reporting.

24 I guess the challenge that our committee
25 is going to be dealing with is how do we expand that.

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1 CHAIRMAN ALDERSON: Dr. Langhorst?

2 MEMBER LANGHORST: Yes, I wanted to bring
3 it back to what -- not necessarily that we gather all
4 this data and learn -- I want to know what you think
5 ACMUI and NRC can learn from your experiences to help
6 us in advising the NRC as medical event reporting.

7 One of the things that I wanted to ask Ms.
8 Elee was the fullness of information that your states
9 gather from their facilities. And you speak about
10 giving credit to the facilities and I wanted to learn
11 a little bit more about what that meant.

12 MS. ELEE: Well, I think and I think just
13 to address another question or maybe make a point is
14 that we're a little different in that we are -- we don't
15 collect from facilities and that was discussed at the
16 beginning. And the reason is we don't want to make
17 double work on the facilities. So if they're already
18 submitting it to the state, we don't want them to have
19 to submit it to us, plus there's the issue of if one
20 group gets the certain amount of information and
21 another group gets different information, that kind of
22 thing.

23 The other thing that we discussed early on
24 was near misses. We don't collect that because we are
25 representing regulators. And if you have a near miss,

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1 and you caught it, your system worked. We like that.
2 So we didn't want to put those in our database because
3 they really aren't relevant for us. They're very
4 relevant for the facilities to learn from, but on the
5 state side it would clog the system with things that
6 could happen.

7 MEMBER LANGHORST: Also I wanted to add
8 the inspectors being able to identify it.

9 MS. ELEE: Right, and that's where we
10 think we need to do better. We think we need to help
11 our inspectors learn how to look for events. Or maybe
12 what the right questions, open-ended questions are to
13 ask facilities. For example, and it's more on the
14 diagnostic side than the nuclear side, but maybe
15 relevant. It's not do you have events, but do you ever
16 x-ray the wrong patient? What happens when you x-ray
17 the wrong patient? How do you deal with that? And I
18 think those are questions we need to learn to ask better
19 and maybe there's a better way to do that. A lot of
20 facilities handle those a lot of different ways and we
21 need to figure -- they may, I dare say, some write orders
22 for patients that they x-ray incorrectly, therefore,
23 it's not a reportable event, because now there's an
24 order. So there's things like that that we need to
25 figure out how to talk to facilities about. And that's

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1 something Lynne and I have discussed of having training
2 at our annual meeting for inspectors.

3 CHAIRMAN ALDERSON: Thank you. Before we
4 go on, there's some other hands up in the room. I'd
5 like to ask people, not our invited panelists, but
6 others who might be on the phone listening to this
7 discussion, are there any questions out there from the
8 public? Would anyone like to speak who is on the phone?

9 MEMBER COSTELLO: This is Frank.

10 CHAIRMAN ALDERSON: Yes, Frank, please.
11 Frank Costello, one of our members in absentia today.
12 Frank, please speak up.

13 MEMBER COSTELLO: Thank you, and sorry I
14 can't be there today, but I'll try my best to be there
15 in the spring.

16 A question for any of the panelists. Many
17 of you mentioned that these are data made anonymous and
18 the NRC system, when a report comes in and it goes to
19 the WHO, it's put on the website. It's not made
20 anonymous.

21 How important -- what advice do you have
22 for the NRC as far as making these reports anonymous
23 or keeping it as it is where it's identified with a
24 particular licensee?

25 CHAIRMAN ALDERSON: That goes to any of

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1 our invited panelists.

2 DR. DICKER: Yes, I'll just say --

3 CHAIRMAN ALDERSON: Please identify.

4 DR. DICKER: I'm sorry, Adam Dicker,
5 representing RO-ILS.

6 Our system is designed to scale and we've
7 seen a flood of reports as institutions have come on
8 board. And it's the protection that AHRQ through a
9 patient safety organization in the de-identified way.
10 In fact, none of us who participate on the advisory
11 capacity of RO-ILS can be a surveyor for the
12 AAPM/ASTRO/APEX accreditation. So we take this pretty
13 seriously and we see incredible volunteerism,
14 especially for things that did not for near misses and
15 other things, for unsafe environments, stuff that you
16 would never pick up at the level of the NRC. So we think
17 the de-identified is incredibly important.

18 DR. THOMADSEN: This is Bruce Thomadsen
19 for CARS. Likewise, I think if the information is
20 going out to the public, if it were not de-identified,
21 the likelihood of reporting would drop to zero for the
22 most part, I would say.

23 So the anonymous reporting and the
24 anonymous data that goes out to the public is essential
25 for trying to get the information to the community so

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1 that they can learn as well as those of us who are
2 actually working for the PSO and have to work with the
3 facility, so we have to know who it is. But for the
4 public, it would have to be anonymous for that data to
5 even be here in the first place.

6 MS. ELEE: And I would just point that
7 although CRCPD does not give out any state or facility
8 information, the state that the event was reported to
9 does have that information, very similar to NRC, so it's
10 not really anonymous.

11 CHAIRMAN ALDERSON: Comments from the
12 audience here in-house at the NRC? No, but Dr. Ennis
13 has a question.

14 MEMBER ENNIS: This will be for any of the
15 presenters. The protection and anonymity seem to be
16 key, but I'd like you to put on the NRC hat for a moment
17 and view it from the perspective of a requirement to
18 protect the public from excessive exposures. And do
19 you think that the current system and its lack of
20 anonymity, if you will, actually interferes with the
21 ability to protect the public or are these just
22 complementary ways to get different layers of
23 information so the highest level it's appropriate, but
24 lower levels, near misses, the protected environment
25 works? Are these complementary styles or are these

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1 really conflicting styles that we need to grapple with
2 throughout the entire event process?

3 DR. THOMADSEN: Can I take that one? This
4 is Bruce Thomadsen again.

5 CHAIRMAN ALDERSON: Yes.

6 DR. THOMADSEN: I think that we could take
7 a lesson from the aviation industry which started
8 making not only reports of problems -- it wasn't a
9 matter of anonymity, although it was, but lack of
10 punitive efforts in enforcing problems that happened,
11 even if there was a violation that may have occurred,
12 not by something like being drunk while flying or
13 sabotage, but by an accident.

14 People who have those problems could
15 report and in the reporting are protected from
16 punishment. We could learn from that -- and what
17 happened was, you don't then have the ability to punish
18 the people who committed an error, but in the long run,
19 they found that their reliability and safety and
20 quality improved remarkably with this system.

21 And part of the problem with a database
22 that's based on a regulatory framework where the names
23 are public and it's based on potential punishment is
24 that the information that's given to the inspectors may
25 be reserved. They may not -- the inspectors may not

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1 get all of the information that the facility might think
2 relevant to the event just because they would be afraid
3 of that information being used against them. And so
4 all that information which might be very relevant to
5 an event and could be helpful in preventing events that
6 were similar in the future becomes lost.

7 CHAIRMAN ALDERSON: Yes, Dr. Dicker.

8 DR. DICKER: I'd like to connect to make
9 an arc to something you talked about a little earlier
10 before this session. How can the NRC help? Well, if
11 you look at training programs for therapy, for
12 dosimetry, medical physics, radiation oncology, and
13 then you look at the certification process, what is the
14 -- how much emphasis is on patient reporting? Do
15 people know at the dosimetry or therapy level about
16 patient safety organizations?

17 So it's not so much that RO-ILS is the best
18 or CARS or something, but they should belong to
19 something, right? And what is that awareness within
20 different communities that are involved in the chain
21 of safety that touch a patient?

22 So I think the NRC can make in its own
23 regulatory manner whether it's suggestions or
24 encourage or having it as a badge of honor that you
25 participate in some type of PSO like -- or incident

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1 reporting event. So I think that's where the
2 organization at the training level can have influence,
3 if not making it a reg.

4 CHAIRMAN ALDERSON: All right, other
5 questions or comments from within the room? There's
6 one here in the room. Please identify yourself.

7 MS. FAIROBENT: Thank you, Dr. Alderson.
8 Lynne Fairobent with AAPM. I just want to make a couple
9 of points. I agree with what Dr. Thomadsen just
10 expressed, but I think it's important that we remember
11 that what is reported to NRC to get to the issue of
12 identification or not are regulatory, reportable
13 events. They're not as with the CRCPD database,
14 they're not necessarily collecting near misses.
15 Although something that may be reported, the licensee
16 is unsure if it's reported or not, errs on the
17 conservative end and will report something that may
18 turn out then not to be reportable event.

19 My biggest concern and problem is that the
20 NRC database is not publicly available for us to do
21 trending analysis on what is officially reported into
22 NRC. So although we can do, collectively we can do
23 trending analysis on what is in RO-ILS, what is in
24 SAFRON, we do trending analysis with CRCPD and what's
25 reported in their database. CARS is doing trending

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1 analysis.

2 We do not have access as the public, to do
3 trending analysis on the NRC's nuclear medical event
4 reporting system. And that to me is problematic
5 because yes, we learn from what we may see on near
6 misses, but I don't know that we have had a system of
7 where you can step back and take a look at are there
8 trends on actual reportable events that we should be
9 picking up earlier? Are there trends on perhaps
10 differences in inspection and compliance analysis?
11 And this may be, I don't know, may be able to be
12 determined if we can access the database to see what
13 is actually being reported in.

14 Yes, we can piecemeal all this together
15 because the initial reports come in to the emergency
16 ops center and you could then track them and track them
17 through ADAMS, but it is a cumbersome way to go about
18 that.

19 MS. ELEE: To your point, we might could,
20 and I'm making some notes, at least CRCPD could and
21 maybe it would be interesting to know how many of the
22 events that are put in actually result in a punitive
23 fine. I mean I think probably most of them at the state
24 level are going to result in some violation letter or
25 that kind of thing, but how many of those are actually

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1 punitive I would guess a small portion which we could
2 survey and find that out for you.

3 CHAIRMAN ALDERSON: Thank you. We only
4 have a few more minutes. I'm actually going to let the
5 session run about three minutes longer because the
6 previous open session ran over time, but we will be
7 closing this session down in just a few minutes.

8 Sophie, do you have a comment?

9 MS. HOLIDAY: Yes, I know that you asked
10 for people on the phone if they had comments.

11 CHAIRMAN ALDERSON: I did.

12 MS. HOLIDAY: So at this time I would like
13 to ask the operator if you can check to see if there
14 are any members on the phone that would like to make
15 a comment or ask a question.

16 CHAIRMAN ALDERSON: Thank you. Did the
17 operator hear that?

18 OPERATOR: The line is open for questions.
19 If you'd like to ask a question, please press *1 and
20 record your name. Thank you.

21 CHAIRMAN ALDERSON: Hearing none, I will
22 assume that there are no people out there who wish to
23 comment who have not commented up until now. We'll
24 take a last comment here.

25 Dr. Langhorst, do you wish? And then

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1 we'll go to Dr. Collins.

2 MEMBER LANGHORST: Okay, I just wanted to
3 say thank you to all the panelists. One thing I wanted
4 to ask Ms. Elee is when you start going into the NRC
5 required reporting data, will your states have to put
6 that in NMED and then your database?

7 MS. ELEE: That's why we haven't done it.

8 MEMBER LANGHORST: Okay, thank you.
9 Thank you.

10 CHAIRMAN ALDERSON: Dr. Collins.

11 MR. COLLINS: Thank you, Dr. Alderson. I
12 just wanted to for context share with everybody here
13 that the NRC's enforcement policy or process does
14 consider actions by the licensees. So when there is
15 a violation, when we're reviewing it, and making
16 determinations about what, if any, enforcement is
17 taken, we do look at whether or not the issue was
18 self-identified by the licensee and what corrective
19 actions are taken by the licensee and whether or not
20 they're prompt and comprehensive. So it's not like
21 we're flying in the blind on that. So I just wanted
22 to make sure that that context is out there.

23 CHAIRMAN ALDERSON: And I'll just take the
24 chair's prerogative to make two closing statements and
25 then we'll bring this session to an end.

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1 Things that I heard that might not be
2 controversial and that might be able to be achieved
3 would be if issues came up through the NRC system with
4 a licensee to check whether that licensee is, in fact,
5 in some sort of quality improvement organization and
6 if they aren't, well then that perhaps should be part
7 of the advice that that particular site receives.

8 And regarding the comment about the lack
9 of accessibility of the NRC database, I would suggest
10 that that's not easily resolved, but in fact, one of
11 our current initiatives here in the ACMUI is to improve
12 communication with our outside partner organizations.
13 So in fact, if we could internally decide what triggers
14 communication, if there is a trend, and then make that
15 trending available to some of these outside QI
16 organizations that might fulfill some of that need.

17 But I would like again thank everyone and
18 Dr. Langhorst for organizing this excellent session and
19 that will bring us to a close. We're now on break until
20 10:30.

21 (Whereupon, the above-entitled matter
22 went off the record at 10:17 a.m. and resumed at 10:33
23 a.m.)

24 CHAIRMAN ALDERSON: We'd like to reconvene
25 now for the next portion of the meeting. This is the

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1 Medical Event Subcommittee Report. Dr. Ron Ennis is
2 ready to give us that report.

3 So, Dr. Ennis, you are on.

4 DR. ENNIS: Thank you, Dr. Alderson, and
5 good morning everyone.

6 This will be the annual report of medical
7 events for Fiscal Year 2015. I want to start by
8 thanking my Subcommittee members, Dr. Langhorst, Dr.
9 O'Hara, Dr. Palestro, Dr. Suh, and Dr. Zanzonico, who
10 helped in various ways in putting this together, and
11 if there's discussion, may even speak to some of the
12 events as needed.

13 And, I also want to thank Dr. Donna-Beth
14 Howe for her comments on our report as it was being
15 developed.

16 So, we will start with 35.200, unsealed
17 byproducts for imaging and localization. So, in the
18 current fiscal year, there were four such events.
19 Three of them involved technetium, two from myocardial
20 perfusion studies, and one for lymphoscintigraphy, and
21 one thyroid I-123 event.

22 In a little more detail, the technetium
23 events, one of them was technetium pertechnetate,
24 instead of technetium-sestamibi was used. Another
25 one, again a different technetium product was confused,

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1 the one for the other, failed to follow proper
2 procedures in detail were felt to be the causes of
3 those.

4 The lymphoscintigraphy events, I think
5 again, not again, was a technologist not identifying
6 the proper patient, and dosage.

7 And, the other event was the wrong activity
8 delivered by ten-fold, and was attributed to "human
9 error." Someone, presumably, put a decimal point in
10 the wrong place, or misread the decimal point.

11 Moving on to unsealed materials that
12 require written directive, there were seven events.
13 Five of them involved I-131. One involved radium, and
14 one involved this monoclonal antibody.

15 And similar themes again, the first event
16 was a overdose, almost 45 percent, again, technologists
17 failing to confirm the activity.

18 Second event, ten-fold, so a decimal point
19 issue it would seem in that the written directive was
20 written incorrectly.

21 The third one involved a significant
22 overdose as well, with the technologist selecting the
23 wrong vial and not confirming with the written
24 directive.

25 And, the last one involves double -- half

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1 a dose, excuse me, technologist was supposed to have
2 delivered two capsules but only gave one.

3 And, the last of this group was not really
4 very well described, so it's hard to know exactly what
5 happened. This was a 21 percent under dose, and it is
6 described as "failure to follow procedures."

7 So, certainly, these are all fairly
8 similar in their issues, I would say.

9 The radium events, again, a similar thing.
10 The dose was almost double, and it was attributed
11 misreading a prescription and administration of the
12 incorrect dose because of that.

13 And, iodine monoclonal antibody, this was
14 a different issue, which we will see later on. In other
15 settings, this also occurs, as you'll see later on, but
16 here a leakage of a catheter connector that they hadn't
17 noticed on visual inspection.

18 So, that's the events of unsealed sources
19 for the year that have been reported.

20 And then, for 35,400 events, so HDR events,
21 so these are the trends over the last few years, then
22 comments from the last session about trending analysis.
23 So the number events is small, so trending analysis was,
24 obviously, kind of limited. And, I would say that
25 there's no clear trend here. The relatively small

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1 numbers is the only consistent trend.

2 In terms of the specifics of the events of
3 this year, so this is something we haven't seen to my
4 recollection recently, but head and neck implants with
5 iridium wires, these are placed and left in the patient
6 while the patient remains in the hospital for a period
7 of hours to a day or two.

8 And, in this event the patient was checked
9 in the morning by the MD; everything looked good. And
10 the MD did rounds on the patient midday. One of the
11 sources of the iridium wires was missing.

12 They searched, whatever, and they found it
13 in the linens that had been changed around 10:00 a.m.
14 So, the presumption is that it fell out or was pulled
15 out in some manner between the morning check and the
16 bed linen check, maybe involving the bed linen check
17 around 10:00 a.m.

18 So, it was found at noon, and it was
19 reinserted; the treatment was completed from a dose
20 delivery point of view. The facility and the
21 regulators agreed later that there was no event there,
22 but the regulators on the site visits thought there may
23 have been an unintended skin dose. If that source had
24 been lying in the bed linens along the patient's side,
25 for example, for those several hours, it could have

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1 yielded a dose that would qualify as a medical event
2 through the skin.

3 So, it was then reported to the NMED there.
4 According to the licensee there was, actually, no
5 patient toxicity related to this and that they dealt
6 with this by writing a new policy, presumably, about
7 how bed linen is changed or something along those lines.
8 It was a little vague in the specifics.

9 Another -- there were seven events in
10 prostate brachytherapy. In one, the physician mistook
11 the penile bulb for the prostate. So, this is
12 something we saw last year, from our recollection as
13 well, a couple of times. It doesn't seem to happen
14 commonly. There's one or two a year, but the prostate
15 bulb is a structure that's at the base of the penis below
16 the prostate. It is round, and can confuse someone to
17 think it's the prostate if they're too quick to make
18 that assumption.

19 The licensee, actually, attributed it to
20 calibration changes on their ultrasound unit that had
21 been done just prior to that procedure. That is my own
22 editorial comment that I'm surprised there was no
23 attribution to the MD in this error, but I wasn't there
24 to say for sure.

25 So, they implemented a procedure to be sure

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1 their ultrasound is double-checked prior to using it
2 after any service, which does seem to be a good policy
3 to have in place.

4 Other events related to prostate
5 brachytherapy, some of these are going to reflect
6 things that in the new rulemaking may not be events,
7 and maybe are examples of why the rulemaking is needed,
8 but they are reported as of now, so we'll review them.

9 In one case, this does not fall into that
10 comment that I just made I would say, the source ordered
11 based on air kerma rather than millicuries, so there
12 was some confusion there between what was prescribed
13 and what was ordered. So, they ended up delivering 20
14 percent more dose because of that error, and they just
15 implemented new procedures and labeling to make sure
16 everyone is talking the same language throughout their
17 process.

18 In another case, which again does not fall
19 into the category of things that would not -- this would
20 still be an event. It's my understanding it should be.
21 The dose delivered was more than intended in a
22 significant way. The error, essentially, is that
23 prostate brachytherapy can be done in combination with
24 external beam, and then it's called a boost, if you
25 will, and the dose is discounted to a degree because

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1 of the external beam that's delivered, or it can be done
2 as sole treatment.

3 And, essentially, this patient was
4 supposed to receive boost implant to be combined with
5 external beam, but instead they did a full dose implant,
6 which was not their intention. And, the decision
7 between those two is a medical one, but once they made
8 the decision to do one, they didn't follow through on
9 the one that they did. They dealt with that medically
10 by just not doing the external beam part of the
11 treatment to not further overdose the patient, but
12 clearly that wasn't really their medical intent to
13 begin with, so it was an event.

14 And, they corrected -- tried to modify
15 their procedures in confirming documentation so they
16 are clear through their process what type of implant
17 is planned, boost versus full-dose implant.

18 This event is one where the dose delivered
19 was 27 percent less. It's a little vague in the details
20 to really be able to comment to you on what exactly
21 happened, other than to say that there seems to be a
22 lot of procedural problems at this site, because the
23 licensee was cited for several failures, not developing
24 proper written procedures, not doing proper
25 exceptions, testing some computers, not properly

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1 documenting post-procedure written directives, not
2 doing an annual review of quality safety programs. It
3 doesn't sound like they had much of a safety culture,
4 but, again, details of the specific cases are not
5 forthcoming, and they were requested to hire a medical
6 physicist to audit their program in the future.

7 Another one, which is listed, again, in
8 somewhat vague terms, but said that it was due to,
9 "irregularities found in the licensee's practice." I
10 don't know if it's related to my prior case presented,
11 because they are from the same corporate entity but seem
12 to be different sites within the same corporate entity.
13 So, I don't know if the regulators said, all right, now
14 that we saw a problem in one division of this entity,
15 we are going to go visit the others, and then in another
16 one they found a problem. That's a bit of
17 interpretation on my part, but that may be the case;
18 it's hard to say for sure.

19 In that event, they did find two specific
20 medical events where the dose delivered was 37 percent
21 of prescription and 67 percent of prescription. Both
22 used palladium. But again, really can't comment much
23 on the events themselves with this little data provided
24 about the specifics of the events.

25 Here's one with D90. This again is a dose

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1 parameter that is often used, but I'm not clear if
2 that's really a regulatory thing, because although
3 some -- many papers show D90 to be important, not every
4 research study has. But in any event that was used in
5 their report and was reported to NMED as 34 percent less
6 of prescription, although it was later retracted.
7 That with further investigation, I guess the regulator
8 felt it was not an event. Anyway, this highlights the
9 need for the rulemaking that we've been talking about
10 for a while.

11 And again, one case where misplaced seeds
12 resulted in a higher dose in the rectum by 61 percent.
13 This is also a little vague, because that could be
14 trivial, or it could be significant. 61 percent is
15 only a percentage. If it was 61 percent of 1 cc of the
16 rectum got 160 Gy instead of 100 Gy, maybe that doesn't
17 matter. But, if it was 5 ccs, et cetera, you
18 understand. So, it's a little hard to know whether
19 this is really something that ought to be a medical
20 event or not, but it was reported, and the licensee,
21 essentially, said they could find no cause other than
22 it's not an easy procedure to do, and there's some
23 inherent uncertainties in there.

24 Moving on to Gamma Knife, and other .600.
25 So, here we'll do the HDR, I apologize. And, so again,

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1 not much of a trend really. I would say, perhaps, a
2 slight uptick in HDR, but very -- I wouldn't really make
3 anything of it. We'll go over the specifics of the
4 HDRs.

5 One was a bust; nine were GYNs; one was a
6 skin too long. And, conceptually or categorizing
7 them, five had to do with wrong positioning of the
8 sources, or the applicator in which the sources went,
9 and three had to do with wrong reference length entered
10 in the planning. Two were, it was, actually, the wrong
11 patient's plan, presumably, two patients with the same
12 disease getting fairly similar treatment, but still
13 it's the wrong patient. And one was "a deficient
14 treatment plan", again, what the deficiencies were was
15 a little vague, and two machine problems due to some
16 type of malfunction. I don't think we have more data
17 on those two to know whether they are a common thread,
18 unfortunately.

19 And, generally, the way these were dealt
20 with were increased training or fixing the units or
21 upgrading of units, implementing a proper timeout,
22 verification of the site cylinder placement. This
23 would be for, presumably, a vaginal case, that it's
24 place correctly, and making sure that it's in the same
25 position when you complete the treatment. And,

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1 manufacturer notification, presumably, having to do
2 presumably with one of the cases that we alluded to
3 before.

4 In terms of Gamma Knife, so there were no
5 regular Gamma Knives, but there was one perfection
6 event, fairly significant it seems. Systematic
7 problem that occurred for eight patients, where the
8 target was off by 1.8 millimeters. So again, depending
9 on exactly what was being treated, that could be pretty
10 significant. Those exceeded the prescription by 100
11 percent, and they implemented a new set of tests to
12 verify patient positioning to prevent that from
13 happening again.

14 Moving on to 35.1000 events. So these
15 are, essentially, all microspheres this year. They
16 are all microspheres this year. Radioactive seed
17 localization, there were no events reported this year
18 for that modality.

19 In terms of the microsphere events, so
20 three of them were situations where microspheres were
21 retained in the catheter, the tubing, the hub, the vial,
22 and it resulted in under doses in the 70 to 60 percent
23 range. Five of them were situations where small
24 catheters were used, which led to microspheres being
25 retained in the hub, and all these occurred at one

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1 particular institution. We'll get into more detail in
2 the next few slides on these.

3 One was just an incorrect set up of tubing,
4 and really about tubing and catheter issues. One was
5 incorrect tightening of the tubing, leading to a leak.
6 And, one was kinking of the tubing. So, a lot of
7 those -- all those, obviously, they are falling into
8 the tubing and catheters, et cetera.

9 There were some other categories as well.
10 There was a low flow to some small arteries leading to
11 a decrease in dose from intended. There was one
12 case -- well, I'll give you some more detail in a moment,
13 where the stomach actually received a low dose, but
14 still an unintended dose, and the infusion itself was
15 discontinued because the shunting was going on, and the
16 catheter, apparently, moved during a procedure when the
17 fluoroscopy table was moved, and this wasn't detected.
18 And this led to infusion of a significant percentage
19 of the dose to the wrong vessel, which then went to the
20 small bowel, rather than to the liver. And,
21 presumably, they did not re-image after moving the
22 table, and the corrective action was to do that in the
23 future.

24 And, two others went to the wrong arteries.
25 One was in the liver, but to the wrong artery, so it

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1 was, therefore, the wrong lobe. And, the corrective
2 action was to have an angiogram present, so you remember
3 which side of the liver you are going to.

4 And one was there was an infusion into the
5 kidney, to the artery feeding the kidney, the renal
6 artery, instead of to the liver, and this delivered a
7 very significant dose to the kidney.

8 This had been the first procedure done by
9 the licensee, which as we all know, the first time you
10 do something, typically, it's a set up for potential
11 errors. They caused no damage to the kidney, but the
12 "yet" is my editorial comment. That was a lot of dose
13 to the kidney.

14 And, corrective action is to have a formal
15 checklist, mapping of the images prior to procedure,
16 analogous to the prior case, and making sure a second
17 MD confirms the positioning of the kidney. That seems
18 like a wise idea.

19 And so, two reported, actually, as
20 underdoses, but then were later retracted with further
21 investigation which revealed the correct dose. Again,
22 more detail about like what was the -- why did one person
23 think it was one, or what was the correction, not enough
24 detail to be able to comment on that.

25 So, those were the TheraSphere and the

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1 other brand. I'm blanking on the name right now. But
2 that's the events for the year.

3 The last part is about other medical events
4 that are more to do with transport and things like that,
5 and there are a variety of these, and we've got the
6 current year's events and then in parentheses last
7 year's number of events, and similar to everything
8 else, I would say there's no clear trends, just bouncing
9 around in relatively low numbers, but considering the
10 scope of these things.

11 So, there's some leaking sources.
12 There's some lost sources in shipping. Thankfully, no
13 category 1 or category 2 sources. Some shipping
14 issues. And, what we've talk about here a couple years
15 ago, landfill alarm issues.

16 Some occupational over exposures, no
17 public exposures this year. No airborne issues this
18 year. A couple equipment failures, some
19 contaminations, record-keeping, no "suspicious"
20 activities.

21 Cesium-137 is just isotopes that are used;
22 you can see them here.

23 Lost source after procedure 10,
24 lost/found, you see there a few of those, lost during
25 shipment. The package was thrown away we didn't have

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1 any this year. Theft, none this year as well, and a
2 buried pacemaker. Okay. That should be our worst
3 problem.

4 And, delivery to the wrong address, there
5 were four, stored in unsecured area, one; accidents on
6 the roads, none this year; shipping package issues; and
7 there were no sources delivered to someone who is not
8 approved. That's good.

9 And, landfill issues, you know they have
10 been one in the past, and there are, again, a decent
11 number of them, but I guess in the big picture, it's
12 still not a huge number. And again, not very much from
13 years past.

14 But, I guess only a few Agreement States
15 actually report these, so, presumably, there are a lot
16 more out there. And, why some states report these and
17 some states don't I guess is worth a conversation. I
18 don't know.

19 So again, pretty stable trends I would say.
20 Nothing jumps out. There are a few patterns there, for
21 example, in the microsphere arena there seems to be
22 tubing issues as, you know, a significant reporting of
23 these events are tubing issues, I don't know if that
24 means we can send out an alert, or someone ought to tell
25 people to be really careful about your tubing issues,

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1 whether there's a mechanism for that, I don't know.
2 But, that is one thing that stands out a little bit,
3 and was a fair number, you know, that were within that
4 space.

5 All the rest seems to be pretty much
6 reading the written directive properly, following the
7 proper procedure, being clearly documented, putting
8 the decimal point in the right place. These are, you
9 know, not really things I think that we can, it's part
10 of being human beings and being flawed.

11 So, that really concludes my report. I'm
12 happy to answer any questions.

13 CHAIRMAN ALDERSON: Thank you, Dr. Ennis.
14 Yes, I have two questions, they are just
15 clarifications. One is just a clarification.

16 On the slide that was about two slides ago,
17 it's your page number -- it's this table, it's your
18 slide number 36.

19 DR. ENNIS: Is that this one?

20 CHAIRMAN ALDERSON: Yes, that one.

21 DR. ENNIS: Okay.

22 CHAIRMAN ALDERSON: The other events,
23 landfill. Down at the bottom it has these percentage
24 numbers on each one of those reports from agreement
25 states. Is that a misprint, or does that mean there were

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1 18 such problems this year in Alabama, and 12 last year,
2 or what's the percentage?

3 DR. ENNIS: I think it's the percentage of
4 events reported by that particular state for the entire
5 group. So, California presents 81 or 85, depending on
6 the year presented, of all the events reported to NMED
7 of a landfill type.

8 CHAIRMAN ALDERSON: I see. Okay.

9 DR. ENNIS: So, California seems to care
10 about landfill events more, or has a lot more of them.

11 CHAIRMAN ALDERSON: Yes. All right.

12 MEMBER LANGHORST: Dr. Alderson, I'll say
13 these are the ones that I could tease out that looked
14 like could be from a medical type of issue.

15 CHAIRMAN ALDERSON: I see. Okay. Thank
16 you.

17 And, I guess that we commented earlier on
18 that very nice set of slides that just appeared about
19 two days ago, and are these all -- those are all going
20 to be updated by this year's report?

21 DR. ENNIS: Yes.

22 MEMBER LANGHORST: So, let me talk a little
23 bit about that, because last year was supposed to be
24 the first time I reported on that, and I apologize, I
25 wasn't here. I really apologize that I wasn't here.

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1 But, that spring meeting before that, the
2 issue was raised that one of our former members, Ralph
3 Lieto, used to do this presentation, and everyone
4 looked at me like, why haven't you been doing this. I
5 didn't know I was supposed to.

6 So, I think in the past, when Ralph gave
7 those reports, he, typically, gave them when Dr. Howe
8 did her updates. And so, what I'd like to propose is
9 that I put together this new set of data and report it
10 at the spring meeting with Dr. Howe, kind of get it out
11 of the medical look at medical events, to just kind of
12 update that.

13 And, hopefully, that I could work with
14 Zoubir Ouhib to get him up to speed on it, so he can
15 carry it forward after I'm off of the committee.

16 So, that's what I'm going to propose, and,
17 hopefully, we can work that out.

18 CHAIRMAN ALDERSON: Sounds like a good
19 plan. Does anyone else have a comment on that?

20 Thanks very much, that will be excellent.

21 DR. TAPP: Dr. Alderson, this is Katie Tapp.
22 And, to respond to Dr. Ennis' comment about issuing a
23 notice regarding tubing with the yttrium-90 event.

24 The NRC does have options to issue generic
25 communications, such as information notices, to share

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1 operating experience and events. If that is something
2 we are going to identify here, we can look that and share
3 that with industry.

4 DR. ENNIS: We think there are enough events
5 that that would be worthwhile.

6 CHAIRMAN ALDERSON: Mr. Green.

7 MR. GREEN: Not, specifically, on the
8 TheraSpheres, but for the Part 100 -- sorry, Part 200
9 and Part 300, radiopharmaceutical event that you
10 mentioned in the beginning of your presentation.

11 Almost every other medication in the
12 hospital, except radiopharmaceuticals, is now tending
13 towards bar code bedside verification of accuracy of
14 drug. And, nuclear medicine has always been a gap.

15 The Institute for Safe Medication
16 Practices, ISMP, is propagating pushing this to be a
17 standard of care. And, radiopharmaceuticals, at least
18 through certain providers, are now barcoded for bedside
19 verification. So, knock on wood, we might see a decrease
20 in events related to radiopharmaceuticals if barcoding
21 does catch on.

22 DR. ENNIS: Just for a licensee, what is
23 required on their end? Do they have to buy equipment?

24 MR. GREEN: No, it's printed on the
25 prescription.

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1 DR. ENNIS: What's that?

2 MR. GREEN: It's printed on the
3 prescription. So, it should interface with the
4 barcoding technology you already use to give the
5 patient a Tylenol.

6 But, nuclear medicine was a gap. Now it
7 may come with, doses of sestamibi or medrinatate would
8 come with a barcode on the prescription.

9 DR. ENNIS: But, I think those barcoding
10 things are for in patient.

11 MR. GREEN: Yes.

12 DR. ENNIS: So, what -- but, on the
13 outpatient side such a system isn't in place. So, if
14 someone was an outpatient in nuclear medicine?

15 MR. GREEN: Then they'd have to outfit
16 themselves with barcode readers.

17 CHAIRMAN ALDERSON: A clarification, Mr.
18 Green.

19 Is this only if certain suppliers are
20 providing those doses from certain central pharmacies?

21 MR. GREEN: That's correct.

22 CHAIRMAN ALDERSON: So, if you are an
23 academic medical center you have your own in-house
24 group, this does not exist.

25 Dr. Langhorst.

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1 MEMBER LANGHORST: And also, if you get a
2 bulk dose, if you are proportioning it out to give to
3 patients, you wouldn't have that patient's specific
4 barcode. So, it would mean you would have to have
5 barcoding, not only just barcode reading.

6 MR. GREEN: Right. So, it is related to the
7 patient-specific unit dose.

8 CHAIRMAN ALDERSON: So, this may be a trend
9 that's coming, but it's coming only in one part of the
10 industry right now.

11 Other comments or questions about the
12 medical events report?

13 Anyone from the audience who would like to
14 comment?

15 MEMBER COSTELLO: This is Frank.

16 CHAIRMAN ALDERSON: Yes, Frank.

17 MEMBER COSTELLO: Dr. Ennis, I have a
18 question for you to think about. Reflecting on what
19 we heard in the previous presentations about their
20 reporting systems, and noting that you noted some of
21 our reports were lacking detail or maybe lacking depth
22 on root cause.

23 Should we consider any recommendation on
24 how the NMED reports are prepared, prepared and the
25 level of detail that are in them. So, it makes our

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1 analysis more meaningful.

2 DR. ENNIS: I think, certainly, that would
3 be helpful. I guess I don't know like how you would
4 create a language in the regulation that would,
5 specifically, illicit enough detail, if it's not being
6 provided, because this really comes out of the
7 anecdote, the story as one of the speakers said before,
8 really, what you get in the information is the narrative
9 part.

10 I don't know that we could -- but maybe
11 someone has an idea how to mandate a narrative that is
12 rich enough for us to really interpret it.

13 MR. GREEN: I'd like to comment on that.

14 CHAIRMAN ALDERSON: Mr. Green.

15 MR. GREEN: Yes, I'm thinking of, you can
16 either write your own procedure to do dose calibrator
17 testing, or you can say I'll follow the guidance
18 provided in, I believe it's, Appendix O. So, you can
19 either take the easy path, or do it yourself.

20 There may be an opportunity here to write
21 a couple of examples of ways to do it, so folks will
22 have a good example of how to provide all the details
23 we are looking for, so we can, actually, make sense of
24 an event.

25 CHAIRMAN ALDERSON: Yes, Dr. Langhorst.

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1 MEMBER LANGHORST: On the NMED reporting,
2 this is either NRC putting in that data or agreement
3 states putting in that data. So, it's the same kind
4 of issues that Ms. Elee had brought up about CRCPD
5 reporting.

6 And, I have a question probably for NRC
7 staff, I know in looking at NMED data, which is very
8 nice that our committee has access to that, but the
9 public does not, that there seems to be agreement states
10 that never put anything in there.

11 And so, I don't know what the requirement
12 is to report NMED incidents and have it be in there by
13 the various agreement states.

14 CHAIRMAN ALDERSON: Dr. Howe has a comment.

15 DR. HOWE: The matter of compatibility for
16 NMED is a C, which you discussed in length with the
17 medical reporting part of it, and that means you have
18 to meet the essential objectives, but they don't have
19 to be identical.

20 I did want to say that the requirements of
21 what needs to be reported are included in 35.3045, and
22 it's a brief description of the event, why it occurred,
23 the effect, if any, on the individual, and what actions,
24 if any, have been taken.

25 You will find that in many cases if it's

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1 an NRC report, you will see a lot more information,
2 because our inspectors will go out and give an
3 inspection report, put more of their information in.

4 The agreement states had a more mixed
5 response on the richness of the information that is
6 provided, but they have to provide this minimum
7 information.

8 CHAIRMAN ALDERSON: Yes, Doug.

9 MR. BOLLOCK: I can address that a little
10 bit more. So, the states, by agreement with us, there
11 are state agreement procedures, they will, in a certain
12 amount of time, when it's in an agreement state, the
13 event happens in an agreement state, they will report
14 to us, and then put in NMED at least those -- or what's
15 required in our regulations, or pretty close to that.

16 And then, as Dr. Howe was saying, NMED
17 reports then get updated after inspectors who are
18 filing inspections occur, they -- that's where they may
19 get the probably causes or root causes. And so, it does
20 vary on how much follow through is done, at what point
21 that was, and then there will be updates periodically
22 in NMED.

23 You know, our inspectors are good about
24 updating it after their inspection, after they have
25 completed the report and their evaluation. And, the

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1 states, some of them are very good about that, others,
2 as you alluded to, are not as good.

3 So, yes, there are some disparities in the
4 data in NMED.

5 CHAIRMAN ALDERSON: Yes, Dr. Langhorst.

6 MEMBER LANGHORST: I want to follow up on
7 one thing that Ms. Fairobent brought up, in that on the
8 NRC's event reporting website, the agreement states do
9 put in their events. And so, there's not anonymity,
10 necessarily, if the facility is named. But, some
11 agreement states don't name the facility.

12 And, as Ms. Fairobent brought up, you can,
13 for NRC inspections, look at inspection reports and
14 kind of tease out the information. But, those reports
15 for agreement states aren't available. And so, again,
16 there's just very little follow up information you can
17 get publicly.

18 MR. COLLINS: So, this is Dan Collins.
19 Just wanted to respond on that.

20 The few states that do provide some level
21 of anonymity to their licensees, it's because they have
22 state laws in place that are associated with that. The
23 remainder of the states, most of them have some form
24 of a Sunshine Act that requires the information to be
25 public, similar to Federal regulations.

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1 CHAIRMAN ALDERSON: Frank Costello, you
2 are, obviously, our states' representative. Did you
3 hear this discussion? Do you want to make any
4 comments?

5 MEMBER COSTELLO: Yes, thank you.

6 There is variety among the states, and this
7 reporting system, you know, the medical event reporting
8 system, has a huge purpose, which is to, you know,
9 identify cause of medical events and share it with
10 community. Ultimately, the goal is for the patient's
11 safety.

12 The more, the richer the data is the
13 better. Something that, perhaps, could be considered
14 would be that if the states provide information and the
15 NRC reviews it, there could be a dialogue between the
16 NRC and the states maybe to tease out a little more
17 information that the state didn't include the first
18 time.

19 You know, there is, certainly, variety
20 among the states on this and on every other issue. But,
21 I think if there was continued dialogue between the NRC
22 and the state when the reports comes in, that variety
23 could be reduced a little bit.

24 CHAIRMAN ALDERSON: Thank you, and Dr.
25 Langhorst and Dr. Ennis then will comment.

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1 MEMBER LANGHORST: Sorry, and I want to
2 follow up, too, that in the NMED data there are, is it
3 quarterly reports that are published, or annual
4 reports.

5 DR. ENNIS: Annual reports.

6 MEMBER LANGHORST: Yes. But, that few -- I
7 can't remember now if they are anonymous or they do name
8 facilities.

9 DR. ENNIS: They do not.

10 MEMBER LANGHORST: They do not. So, that
11 is publicly available, but again, any details, there
12 are, I'm going off of memory, there are details on some
13 of the events, but those are mainly NRC type events.

14 CHAIRMAN ALDERSON: Dr. Howe wants to
15 respond to that one.

16 DR. HOWE: Well, also in response to a
17 similar question earlier, we are starting to --

18 MEMBER LANGHORST: We cannot hear you at all
19 back here.

20 DR. HOWE: Okay. In response to that
21 comment made earlier in previous ACMUI meetings, we are
22 beginning to put together our slides that we present
23 in the spring to give the public an idea of what the
24 medical events are. We are not giving names of
25 licensees at that point, but we are giving a short

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1 description of what the events were.

2 And, the other pointed I wanted to make is,
3 when you do your NMED reports, there is a short report,
4 and it's the short report I provide to you at the spring.
5 And, one of the reasons I developed that one was at the
6 bottom there are references. And so, if you believe
7 you need to see those references, we can go back and
8 ask for the inspection reports and enforcement reports
9 and those things that are referenced there, although
10 many of them are very limited.

11 MEMBER LANGHORST: And, just one more point
12 for our new committee members. NMED does not mean it's
13 on medical events. It stands for nuclear material
14 event database. So, it isn't just medical, it's all
15 nuclear materials. So, don't be fooled by the NMED
16 acronym. I was for many years.

17 CHAIRMAN ALDERSON: I think Ron Ennis has
18 the next comment.

19 DR. ENNIS: Two comments. So one regarding
20 this, and again I don't know the mechanisms, but I would
21 endorse what Mr. Costello said, that NRC would
22 encourage a more interactive process and a review as
23 NMED reports come in, and a determination of their
24 adequacy. And, if not, really reach out and get that
25 information, so when we do this it's more meaningful.

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1 I would say 10 to 20 percent of these cases really were
2 not meaningful. And, if that becomes an operating
3 procedure, then they can improve the quality of what
4 we do.

5 Along the same lines, even if it's Category
6 C, the disparity which states are reporting I think
7 needs to be addressed. I think ongoing dialogues with
8 the states that are not reporting, they can't not have
9 the same proportion of events as the other states with
10 the number of, you know, radioactive fields being used.
11 It's extremely unlikely.

12 So, there's an issue there that I think
13 needs, you know, some kind of dialogue between the
14 specific agreement states and the NRC.

15 Then, I would like to ask that what Dr. Tapp
16 suggests should be done, but I don't know if all of us
17 feel the same, to, actually, send that with some kind
18 of alert or whatever it would be called to users of the
19 microspheres about tubing issues, because I think we
20 see, I don't know if it's about half of the events, or
21 about tubing issues. So, we might as well let people
22 know, pay a little more attention to the various tubing
23 issues in some non-punitive but educational manner.

24 CHAIRMAN ALDERSON: Right, and I think that
25 does go along with the earlier session. The trending,

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1 if we and the NRC find trending, it would be very useful
2 to communicate that trending to the user community so
3 they could be on alert.

4 Dr. Metter, did you want to comment?

5 MEMBER METTER: No, no, I totally agree with
6 what he was saying.

7 CHAIRMAN ALDERSON: She did not. I'm
8 sorry. I misinterpreted yes.

9 Dr. Bollock, did you want to comment?

10 MR. BOLLOCK: I was just going to say, if
11 we let Dr. Palestro say, then Mr. Collins and I can
12 address some of these and speak a little bit more.

13 CHAIRMAN ALDERSON: All right. Chris?

14 MEMBER PALESTRO: Yes. Whenever I listen
15 to these reports, and look at the slides, I always try
16 to figure out what I can learn from them from the nuclear
17 medicine standpoint to take back to my own division,
18 to try to improve things or make sure that we have things
19 in place.

20 And, in thinking about this, particularly,
21 the nuclear medicine section today, it seems that
22 although the data is somewhat limited a lot of the
23 errors can be attributed to procedural failures.

24 CHAIRMAN ALDERSON: Yes.

25 MEMBER PALESTRO: And, I think that this is

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1 the type of information that we can bring back to our
2 Society meetings, without going into specifics, and
3 merely identify these are the types of things that we
4 see, and when you go back into your practice you can
5 review them and see whether or not everything is in
6 order, or you feel that you can make improvements.

7 CHAIRMAN ALDERSON: Not only review, but,
8 perhaps, preemptively teach about these procedures,
9 and make people sort of relearn them periodically, to
10 make sure that they know what they are doing, for
11 example. That's great advice, Dr. Palestro.

12 MR. BOLLOCK: And so, we can address some
13 of those. The first thing I'd start with, if ACMUI has
14 a recommendation to us to do some sort of generic
15 communication on the tubing issues, we can do that,
16 actually put a note as that being a possibility. You
17 know, it's fairly easy for us to write an information
18 notice or some sort of generic communication and get
19 that out to licensees, and also to the states.

20 CHAIRMAN ALDERSON: Good.

21 MR. BOLLOCK: So, that's something we can
22 do.

23 MS. HOLIDAY: Doug, before you continue,
24 this is Sophie, may I ask if that is an official
25 recommendation or motion put forth by the committee so

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1 that it may be captured on the record?

2 CHAIRMAN ALDERSON: Okay, so let's make
3 this -- is there a motion to that effect?

4 So moved.

5 Is there a second?

6 MEMBER COSTELLO: Second.

7 CHAIRMAN ALDERSON: Fine, there's a second,
8 and then is there any further discussion of this motion?

9 Yes, Dr. Dilsizian.

10 DR. DILSIZIAN: Ron, were the tubing
11 issues, do you think, manufacturer problems, or is it
12 kinking, they are not tightened right? We don't get
13 that data, right?

14 DR. ENNIS: Right.

15 DR. DILSIZIAN: So, it's tough for us to
16 really say there's tubing problems without having
17 details data.

18 DR. ENNIS: Well, I guess you could -- I
19 think you could say, you know, just pay attention to
20 tubing, it could be human, it could be manufacturer,
21 but just a heightened awareness to make sure everything
22 is fitting together, and then you'll figure out, oh,
23 I haven't been doing this right, or, oh, this tubing
24 stinks, I need a new company.

25 CHAIRMAN ALDERSON: Mr. Green.

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1 MR. GREEN: And, there are two
2 manufacturers, is it fairly equal between the two, that
3 it could be globally for the procedure?

4 DR. ENNIS: That's my impression. We could
5 jump back if we have the time, but my impression was
6 fairly mixed between the two. So, there were six SIR
7 and eight TheraSphere, let's see, there was about 12
8 patients overall. It might take a little work to go
9 through, I don't know if you want to do that. But, my
10 impression was that it was pretty split.

11 CHAIRMAN ALDERSON: Other comments? There
12 is a motion on the floor.

13 Dr. Langhorst.

14 MEMBER LANGHORST: Would it be more
15 meaningful if the ACMUI encourages the manufacturers
16 to look at this, because I don't think we have enough
17 data to put together an information notice. And, I'd
18 hate to put out many information notices, because that
19 dilutes the importance of those, when we don't have the
20 full information, but to encourage the manufacturers
21 to look into this, and maybe even provide us with
22 something to say that this is their view on that
23 problem.

24 CHAIRMAN ALDERSON: Mr. O'Hara wants to
25 comment on that.

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1 MEMBER O'HARA: Yes. The manufacturers
2 are regulated by the FDA. And, we are encouraging the
3 manufacturers to look at these issues, these kinking
4 issues. In some cases, kinking or a physician uses a
5 different catheter.

6 I think at least one of the -- actually,
7 I think both of the providers, actually, have their own
8 catheter. So, the FDA is talking to the manufacturers
9 about the catheters.

10 MR. BOLLOCK: If I can address this. Just
11 a few things, but my staff, if we were going to develop
12 an information notice we would look and try to get as
13 much detail as we could in certain cases.

14 And, it could be just as generic and simple
15 as, there have been a number of cases, you know, and
16 give a couple of examples.

17 So, yes, just be mindful of that. And, a
18 lot of times that is -- it can be as simple as that.
19 It's just an information notice, just awareness to
20 licensees and the public and the other regulators. So,
21 it could be that simple.

22 So, yes, we don't, necessarily, have
23 to -- I mean those are other options, you know, we
24 wouldn't have to do that in order for us to develop and
25 send out an information notice.

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1 CHAIRMAN ALDERSON: And, the very knowledge
2 and exchange of information, such as we just had between
3 the representative, Dr. O'Hara from the FDA, and
4 between the NRC, it allows the two agencies to see that
5 this is happening on both sides, and that facilitates,
6 you know, getting information out.

7 MR. BOLLOCK: Yes, if it was a device issue
8 with the tubing itself, deficiency there, yes, it would
9 likely fall under FDA, or, you know, we have Part 31
10 or something else, if it was a radiological safety issue
11 with that.

12 But, we can do it independently. It can,
13 like I said, we would -- my staff would look into these
14 cases and get as much information as we have.

15 CHAIRMAN ALDERSON: And, the idea of
16 providing an alert is the key issue.

17 Now, we do have a comment from the audience
18 here.

19 MS. BLANKENSHIP: Bette Blankenship, AAPM.
20 Thank you, Dr. Alderson.

21 We also find, because we are very active
22 in administering MicroSpheres.

23 We also, not just the tubing, we also at
24 times have residual MicroSpheres remaining in the hub
25 of the administration device. So, I think a generic

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1 message of we are having, you know, a number of reported
2 cases where the spheres are not delivered for whatever
3 reason.

4 So, I think if it is generic, that it would
5 count for both of those.

6 So, thank you. I think that's very good.

7 MR. BOLLOCK: Yes, and we could cover both
8 of these issues in one generic way.

9 CHAIRMAN ALDERSON: So, are there further
10 comments on the motion, as I will say as amended by the
11 information that's been provided by the interim
12 speakers here?

13 Further comments? Hearing none, let's
14 vote on the motion.

15 All in favor?

16 ON THE PHONE: Hello, aye.

17 CHAIRMAN ALDERSON: Opposed?

18 Abstaining?

19 MEMBER LANGHORST: I'll abstain.

20 CHAIRMAN ALDERSON: One abstention, but it
21 carries. Two abstentions, I'm sorry.

22 DR. ENNIS: No, no.

23 CHAIRMAN ALDERSON: No, you'll support it.
24 You are opposed.

25 DR. ENNIS: No, no.

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1 CHAIRMAN ALDERSON: I'm sorry. This is Dr.
2 Alderson, I'm sorry I didn't go in the right direction.

3 So, everyone is in favor except there is
4 one abstention. Thank you very much. And so, the
5 motion carries. Thank you.

6 MR. BOLLOCK: Also, to continue on, some of
7 the other things you were discussing with agreement
8 state information, or, you know, put into NMED, we do
9 have regional state agreement officers who, if there
10 are events reported from the state, they will -- there
11 are primary -- NRC is the primary point of contact with
12 our counterparts in each state, and they, typically,
13 do, and they will follow up with each -- with the state
14 if there was an event there to try to get that
15 information.

16 So, there's that kind of on the day-to-day
17 basis, that encouragement, and that communication, to
18 get the feedback. Again, they are independent
19 regulators, there's only, you know, we can encourage
20 each other to get as much information and, you know,
21 especially, getting more information is better for
22 learning those -- you know, the root causes or what can
23 we get out of that based on the information they've put
24 into NMED.

25 So, we do, you know, on a day-to-day basis

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1 we do that.

2 MEMBER COSTELLO: This is Frank. Can I
3 comment on that?

4 CHAIRMAN ALDERSON: Please.

5 MEMBER COSTELLO: As you heard from another
6 speaker, an earlier speaker from the panel, root cause
7 analysis is a skill that's not always easily acquired.
8 And some states, small, some states are well developed
9 doing root cause analysis, and some states not too much.

10 Perhaps, the NRC, when they get the report
11 from the state, look at the root cause analysis and
12 consider whether the state could be given a little more
13 help in doing this, because remember the presentation
14 we had before, sometimes those reporting people are
15 assisted and they can get into the real root cause.
16 Otherwise, often it's done by your operator, or
17 something like that, where you are not really getting
18 the root cause, which could be a training issue, or it
19 could be an issue where there are too many people -- too
20 much is trying to be done in a short period of time
21 because of peak workloads and that kind of thing.

22 So, perhaps, they, actually, consider
23 giving assistance to the states as needed to get the
24 real root cause, because not every state is willing for
25 them to get the root cause.

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1 CHAIRMAN ALDERSON: I think, perhaps, one
2 of the issues you may want to clarify, Frank, is what
3 assistance means. That could be the NRC providing some
4 advice, or it could be something much more than that.
5 What are you, actually, aiming at?

6 MEMBER COSTELLO: Yes, I think most of the
7 time it would be advice, have you considered this, have
8 you considered that? I don't think many states would
9 want the NRC to take it over, but I think if they gave
10 them assistance by advice on how to do the root cause,
11 I think that might help.

12 CHAIRMAN ALDERSON: Would the NRC like to
13 comment?

14 MR. COLLINS: Yes, so this is Dan Collins.
15 Thanks, Frank.

16 So, we do have protocol in place where if
17 a state feels like they need assistance that they can
18 request it and we'll provide it. There's also, you
19 know, root cause training that we could, perhaps,
20 provide to the various states. So, there are a number
21 of avenues with respect to how we might be able to
22 provide some assistance to the states.

23 Also, we have had an effort ongoing for a
24 couple years now for doing training for the agreement
25 states relative to the NMED reporting, and that's

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1 something that our staff, in concert with the
2 contractor that administers the database has been
3 performing. But again, that's at the state's request,
4 it's not mandatory.

5 CHAIRMAN ALDERSON: Dr. Langhorst.

6 MEMBER LANGHORST: Mr. Collins, is there
7 any group in NRC that focuses on root cause analysis
8 specific to medical events?

9 MR. COLLINS: Well, that would be Doug's
10 team.

11 MEMBER LANGHORST: Okay.

12 MR. BOLLOCK: Yes, it would be us. That
13 would really fall on us, and we do have -- you know,
14 there are -- there is, for NRC inspections we do have
15 root cause training classes available for the state,
16 being available to the state. They are available to
17 state personnel as well.

18 I'd have to look at their specific
19 qualifications if that's available. I know I have seen
20 state represented when I took it years ago.

21 MS. ELEE: I've been there.

22 MEMBER LANGHORST: I'd just like to point
23 out that medical use is different.

24 MR. BOLLOCK: Yes, and I've taken the
25 classes, as Jennifer has, yes. It is, a lot of times,

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1 the focus is, primarily, on reactors, a lot of --

2 CHAIRMAN ALDERSON: Jen, microphone.

3 MS. ELEE: Yes. My comment was just that
4 I have attended the root cause analysis class. I,
5 actually, think it's a very good class of the many NRC
6 classes. But, it is not a lot of medical information
7 and medical is very, very different.

8 So, it may be that like we talk about
9 training, it's medical training on root cause analysis
10 that we need to consider.

11 MR. BOLLOCK: Yes, the class, they use
12 different examples, not, necessarily, even nuclear in
13 some cases. So, they do try to broaden it when they
14 give the examples. But, it's more how do you figure
15 out a root cause, or something -- in some cases we have
16 a class on how to review root causes, and they give
17 examples that are not, necessarily, just reactor, you
18 know, they use different types, and even other -- I've
19 seen them from other, like DOT, and examples like that.

20 So, they do try to broaden it. It is more
21 focused on root cause. But, specifically, did they
22 have any specific examples of medical in the class that
23 I took, they did not. And, maybe there are some
24 contractors that do it, but again, they do broaden it,
25 and the focus is root cause, not, necessarily, the

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1 technical part.

2 CHAIRMAN ALDERSON: Are there any other
3 comments people would like to have or questions for Dr.
4 Ennis on his report?

5 Dr. Suh.

6 MEMBER SUH: Just a question. I see part
7 of this reporting structure is to learn, and also to
8 come up with best practices. So, is there a
9 possibility for -- right now all these reports are
10 divided up into Part 200, Part 300, 500, or 600, 1000.

11 What I would find meaningful is that if
12 there's a way of trying to figure out, is there a common
13 theme through all of these reports? And, what I mean
14 by that is, when I look at the -- listening to Ron's
15 presentation, many of the errors are just because time
16 out wasn't done. And, I think we see a trend that time
17 outs are not being done on a routine basis. That's
18 something that, perhaps, the committee, NRC, could say
19 it's something that we should really take seriously,
20 I mean because part of this is the right patient here
21 from the right location, and, you know, many of the
22 reports are because just simple base procedures weren't
23 done. I think sometimes you just forget, you get in
24 a hurry and you forget, yes, you have to always identify
25 they are treating the right location, right patient on

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1 the table, et cetera.

2 And, I think when we go through these
3 reports year after year, but I'm not sure if we're
4 focusing on what is the true root cause. At least for
5 me, the Section 700 there's some patient identification
6 which just wasn't done properly. I don't know if there's
7 a way to categorize the incident. At least you get the
8 trend, shows a trend that we are not doing time out as
9 well as we should, or is training not as robust as it
10 should be.

11 CHAIRMAN ALDERSON: Thank you.

12 Other questions or comments?

13 Hearing none, I believe that we are ready
14 to --

15 MR. OUHIB: This is Zoubir, can you hear me?

16 CHAIRMAN ALDERSON: Who is this, yes?

17 MR. OUHIB: Zoubir.

18 CHAIRMAN ALDERSON: Please. Please, speak
19 up.

20 MR. OUHIB: My apology for joining a little
21 bit late, but I've been listening to some of the
22 conversation.

23 Now, on the SIR-sphere and the
24 TheraSphere, I just have a comment on that, that I think
25 somebody made a statement on that, is that it would be

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1 extremely valuable to have more data from both
2 manufacturers, and find out exactly how many of
3 the -- how many people, you know, how many users,
4 actually, experienced the issues. And, what's the
5 total number of users that we have.

6 The point I'm making here is that, I know
7 for a fact that there are some institutions that did
8 not experience these tubing issues and all that. So,
9 therefore, is it a training issue or is it a user issue,
10 or what is it exactly?

11 And, I think that will help us probably get
12 a little bit more understanding about that. And,
13 perhaps, provide some valuable lessons, or, you know,
14 remedies, or what not.

15 CHAIRMAN ALDERSON: Thank you. Thank you,
16 Mr. Ouhib.

17 Any other questions or comments?

18 Hearing none, I think we are ready to
19 bring -- we have one more comment. Yes, Mike Fuller.

20 MR. FULLER: Just a real quick question
21 before we break.

22 Sophie, could you read back what the actual
23 recommendation is that just -- or the motion, what the
24 motion was, because at one point I heard that staff
25 should look into this and see if generic communication

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1 is appropriate. And then I think I also heard that we
2 were, actually, receiving a recommendation that we
3 issue some generic communication.

4 So, could you just clarify that for me,
5 please.

6 MS. HOLIDAY: Sure. So, the
7 recommendation that I have written is that ACMUI
8 recommended that staff issue a generic communication
9 regarding tubing issues (kinking, connection, et
10 cetera) during the administration of Y90 MicroSpheres
11 brachytherapy.

12 Is that appropriate as captured by the
13 committee?

14 CHAIRMAN ALDERSON: Yes. We are all
15 nodding our heads, yes.

16 But, there are people now that want to
17 comment.

18 MR. BOLLOCK: Well, the tubing and hub
19 issue.

20 CHAIRMAN ALDERSON: The hub was in the et
21 cetera, but, yes, you can add that specific, yes.

22 So, Mike, does that answer your question?

23 MR. FULLER: Yes, thank you.

24 CHAIRMAN ALDERSON: It does.

25 Are there further questions before we draw

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1 this session to a close?

2 Seeing none, I think we'll close this
3 session, and we are adjourned for lunch. And, we'll
4 be back at 1:00.

5 (Whereupon, the above-entitled matter was
6 recessed at 11:30 a.m., and will reconvene this same
7 day at 1:00 p.m.)

8 DR. ALDERSON: Well, we're ready to start
9 the afternoon session. We're going to continue our
10 discussion of medical event reporting, and be led by
11 Dr. John Suh.

12 MEMBER SUH: All right, good afternoon.
13 So I'll be reporting on medical events reporting for
14 all modalities except permanent implant brachytherapy.
15 I want to acknowledge the Subcommittee members, Ron
16 Ennis, Vasken Dilsizian, Chris Palestro, Pat Zanzonico
17 and Zoubir Ouhib.

18 So the Subcommittee's charge was to
19 propose the appropriate criteria for medical event by
20 reporting other than permanent implant brachytherapy,
21 and on March 17th of this year, the Subcommittee's
22 initial thoughts of the definition of medical event
23 reporting for all modalities except permanent implant
24 brachytherapy were presented.

25 Recommendations from the March 2016

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1 meeting were that the medical bench reporting shall
2 offer identification of a medical event and provide a
3 mechanism to discuss how to avoid and reduce the
4 likelihood of such an event, and also that the
5 definition of a medical event needs to be broad, simple
6 and consistent, so reports can easily be prepared by
7 authorized users, evaluated by regulators and process
8 focused in order to limit ambiguity.

9 In addition, the part of the definition
10 based on "unintended permanent functional damage from
11 an organ or physiologic system as determined by a
12 physician" needs reconsideration. Also, we felt that
13 the creation of a subsection within the current
14 framework of medical bench reporting be considered to
15 allow for new radiation oncology modalities or
16 prescribed dosage rate and volume routed to a point.
17 Now any proposed change should not overly be
18 prescriptive and encroach on the practice of medicine.

19 So in terms of the ongoing discussions that
20 we've had, we discussed current any reporting criteria
21 under 10 C.F.R. Part 35.3045, and we've discussed
22 various scenarios where the medical event criteria may
23 be somewhat ambiguous and maybe require additional
24 modifications.

25 Given the advances in radiation oncology

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1 in particular, that site shifts can actually result in
2 significant dose of nearby tissues and/or organs, so
3 that prescribing to a point is really not relevant to
4 how we prescribe in radiation oncology in particular.

5 So one of the discussion items that we had
6 was that current radiation oncology plans are not
7 prescribed to the point but usually to a treatment site.
8 So the Subcommittee felt that the current ME
9 definitions for radiopharmaceuticals are sufficient.
10 So that should not be a part of the subcommittee, but
11 that we should devise a definition for 2-D and three
12 dimensional conformal radiotherapy,
13 intensity-modulated radiation therapy, which is IMRT,
14 SRS, which is stereotactic radiosurgery, SBRT, which
15 is stereotactic body radiation therapy, low dose rate,
16 high dose rate brachytherapy and intraoperative
17 modalities.

18 During our discussions, we also felt that
19 this language "unintended permanent functional damage
20 to the organ or physiologic system, as determined by
21 (reading)" in Section 3(b) of 35.3045 and not be
22 revised.

23 So the medical event criteria would need
24 to cover these modalities, high dose rate for all body
25 sites, Gamma Knife, low dose rate, temporary brachy

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1 implants and intraoperative modalities. So in terms
2 of the main modification that we focused on was really
3 the -- if you look at 1, Part 1 and Part 2, is that the
4 original definition was total dose to -- differs from
5 a prescribed dose by 20 percent or more.

6 So what we discussed was adding the phrase
7 "treatment site." We actually went back and forth on
8 whether or not we should do the definition of a target
9 versus a treatment volume versus treatment area. We
10 ultimately decided that treatment site would best
11 fulfill what we wanted.

12 Also we also talked about having 80 percent
13 of that treatment site, because of the way radiation
14 planning is done today with the various modalities, be
15 part of the definition. So the recommendation was that
16 the total dose of 80 percent of the treatment site
17 differs from the prescribed dose by 20 percent or more.

18 So again, the main difference is that 80
19 percent of the treatment site is the big difference.
20 Then for single fraction treatment, it's 80 percent of
21 the treatment site differs from the prescribed single
22 fraction dose for a single fraction by 50 percent or
23 more. The treatment site would be defined by physician
24 and could be referenced by the signed treatment plan.
25 Just trying to minimize ambiguity from the regular

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1 standpoint.

2 So again, the big part of our discussion
3 was how to word that section of treatments, and we
4 ultimately decided on treatment site. The hope is by
5 defining medical event by use of treatment site that
6 it will be easier for the licensee to determine if an
7 ME occurred.

8 Also, hopefully it will be easier to
9 inspect and regulate, will better protect the public,
10 and facilitate programs, procedures and education to
11 prevent future events. Since the delivery systems and
12 risk are different for each of the modalities, we felt
13 that a specific medical event for each modality may
14 provide some advantages, but we felt that overall that
15 a modality-specific ME was not advisable, and that
16 their classification of non-selective internal
17 radiotherapy, non-Viewray and
18 non-radiopharmaceuticals using the definition of
19 treatment site as part of a medical event reporting
20 structure.

21 So the current recommendations are that we
22 use the current definitions for the permanent implant,
23 that we use the current 35.3045 definition for
24 radiopharmaceuticals, and for treatment sites that
25 utilize 2D, three dimensional conformal radiation

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1 therapy, IMRT, SRS, SBRT, low dose rate and high dose
2 rate brachytherapy interactive modalities, that we
3 utilize the definition of treatment site to help
4 clarify what would be encompassed for it being a medical
5 event.

6 The subcommittee believed that the
7 creation of a treatment site within the current
8 definition be considered to address the new radiation
9 oncology modalities that prescribe dose to a volume.
10 But I think historically what we've thought of as a
11 point to take into account the newer modalities that
12 we have available today.

13 DR. ALDERSON: Okay, thank you Dr. Suh.
14 Next, we're clearly going to hear from the radiation
15 oncology segments of our team. So Dr. Ennis, would you
16 like to comment on this?

17 MEMBER ENNIS: John described well the
18 thinking on the Subcommittee. We participated in the
19 discussions and the key, you know, to step forward is
20 to start talking in volumes rather than just dose, which
21 is not really so meaningful anymore in terms of how we
22 do it.

23 We have this ambiguity of occasionally
24 licensees thinking they have an event and the
25 regulation saying they don't and vice-versa, and

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1 wanting to kind of follow the general rubric that's
2 already been established about criteria levels seemed
3 that this was a good way to do it in terms of defining,
4 just defining as a treatment site the volume that we're
5 talking about, and then having a high proportion of that
6 as if a dose variation to that treatment site in a high
7 proportion of that volume of that site, and that would
8 rise to the level of a medical event.

9 So I support, and that was the
10 recommendation we put out here and I think that's it.

11 DR. ALDERSON: Okay, Laura.

12 MEMBER WEIL: (off mic)

13 MEMBER SUH: Yes. We went back and forth
14 with that a little bit. Let me just go back that
15 definition. So there is -- when we do any type of
16 radiation procedure, there are some unintended things
17 that can happen as a result of actual treatment. So
18 this phrase we felt encompassed that in some situations
19 you may have unintended damage to the organ or the
20 physiologic system as determined by the physicians.

21 So we wanted to just give that leeway in
22 terms of what constituted an unintended event. So we
23 actually played with the verbiage a little bit, trying
24 to change some of the words around. But we felt that
25 this actually best encompassed what we wanted as part

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1 of this definition.

2 MEMBER WEIL: So you -- the group as a
3 whole did not feel that permanent functional damage was
4 problematic in terms of there can be serious temporary
5 functional damage as well. I mean the patient might
6 recover some function in a limb or in skin or in
7 something, but it would still be an unintended event
8 and still be significantly harmful to the patient.

9 MEMBER SUH: I mean that's a possibility.
10 Again, for this, in terms of calling it a medical event,
11 we decided to keep the word "permanent" in there.

12 DR. ALDERSON: Dr. Dilsizian.

13 MEMBER DILSIZIAN: Laura, if you
14 remember, we had this discussion previously on the
15 committee, and if I want to read back to you, what we
16 decided at that time was -- it's in Item 12.

17 This is in October 2015, that we said
18 unintentional treatment outcome due to an anatomic or
19 physiologic anomaly falls into the category of the art
20 of medicine practice. Remember that statement,
21 provided that the standards of medical practice was
22 met.

23 So I think if you think about this, it's
24 the same thing. It's unintended permanent functional
25 damage is unintended, meaning it could be anatomical

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1 variation, some physiological variation, something
2 that the physician didn't, you know, perceive or
3 couldn't prevent and didn't practice outside the
4 medical practice to create that damage. I think --

5 MEMBER SUH: And that's how we interpreted
6 it.

7 MEMBER DILSIZIAN: Yes.

8 DR. ALDERSON: Just for clarification, as
9 I understood these last comments, the issue is the word
10 "permanent" up here. So if the patient gets a dose to
11 the bowel that's outside the treatment area and the
12 patient has serious, you know, you can imagine
13 complications, and that goes on for an extended time,
14 could interrupt their work, could change their
15 lifestyle.

16 But eventually, it clears up she's asking,
17 I think, that would not be a medical event. Is that
18 right?

19 MEMBER SUH: I mean there are some
20 situations. Even in the best planned out therapies,
21 you can get complications as a result of the treatment.
22 So I think the use of permanent is to rise to the
23 occasion of being called a medical event.

24 DR. ALDERSON: Dr. Ennis.

25 MEMBER ENNIS: I guess -- first of all I'm

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1 saying it did not meet any of the dosimetric criteria,
2 right. So it was not that 80 percent of the volume did
3 not get the dose. So that didn't happen. So kind of
4 execution-wise, it's not at the level of a medical
5 event. But we want to have this other catch-all,
6 should I stop? Yeah. Donna-Beth seems to want to --

7 DR. HOWE: So this is just a point of
8 clarification. The document says Section 3B. It is
9 not Section 3B. It is Section B. It happens to come
10 under 3, but Section B is only referring to when you
11 have patient intervention. So in your discussion,
12 you're kind of applying it to a medical criteria in
13 normal practice.

14 But this section B only addresses patient
15 intervention. So I just want to make sure that as
16 you're discussing this, you are understanding that in
17 our regulations.

18 DR. ALDERSON: I'm sure that the committee
19 wants it to be in the correct section, whatever that
20 section is. If Dr. Howe is correct, I'm sure the
21 committee would agree that you put it in Section D as
22 in Dog. That was - if that was where it belongs.

23 DR. HOWE: I think that the confusion is
24 that B comes right after 3, and so people thought it
25 was 3B, and in fact it's B because A in the beginning

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1 talks about regular medical events and B only talks
2 about patient intervention.

3 DR. ALDERSON: Okay, very good. Well,
4 we'll see that it's repositioned in the correct place.
5 Yes.

6 MEMBER LANGHORST: I wanted to come back
7 to the volume versus point. In order for inspectors
8 to identify, it seems like this might require new
9 regulations and what you document for a written
10 directive, to require that this information be put down
11 some place with assurance that the circumstances of the
12 planning are the same as the circumstances of the
13 evaluation post-treatment, to show that 80 percent of
14 the target area is not different than 20 percent.

15 I can't even say it in the correct way, but
16 you understand? As an inspector, I mean as I have to
17 look at these things, I'm not sure I'd know how to look
18 at it. I know that's one of your intents, to make sure
19 that the inspectors can recognize it too. So did you
20 talk about that aspect of how this would be done?

21 MEMBER SUH: So I think a lot of it -- so
22 some of this is going to be actually on the treatment
23 team, on the physician. So if, for instance, I am doing
24 a stereotactic treatment or vertebral body that's
25 supposed to be a T-12 and I treat T-11, then that's a

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1 medical event. I have mistreated that patient.
2 Clearly, 80 percent of that volume did not get the dose
3 that I intended to receive.

4 That's something where I would voluntarily
5 say that was a medical event. So I think part of it
6 also needs to be on the physician and the physicist to
7 report that as well. I mean in terms of treating, you
8 know, the other definition of terms of like wrong site,
9 wrong patient, wrong -- I mean all those statements say
10 it.

11 So this is really trying to -- because
12 depending on where, and if you're treating a volume and
13 if there's a point that's more peripheral versus more
14 central, you can have a definition be somewhat more
15 ambiguous, and we want to try to make it more clear now.
16 You could argue is 80 percent the right number, you
17 know. Is there a paper that says sort of 80 percent,
18 90 percent.

19 But we felt it needed to be -- the majority
20 of the body needed to be treated with whatever technique
21 that you're using. It really more applies to the
22 radiation technologies, which actually have this very
23 sharp dose gradient. We want to make sure it's
24 encompassed within the treatment area.

25 MEMBER LANGHORST: But where would I find

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1 that as the inspector? Am I only able to be told it's
2 a medical event and I would never have an opportunity
3 to identify it if you chose not to report it? I mean
4 how does it work?

5 MEMBER ENNIS: So I guess right now, how
6 do you know what part of the written directive of the
7 prescription is your source of information about what
8 I was intended to treat?

9 MEMBER LANGHORST: I agree. Sometimes an
10 inspector can't without the licensee, and that
11 is -- that's --

12 MEMBER ENNIS: So is the question how is
13 this changing? I mean what's required right now? I
14 mean in the normal practice of most practitioners, we
15 write in the prescription what it is that we're trying
16 to see, and that's what we have in mind when we say the
17 treatment site. But regulatory-wise, tell me what
18 right now happens that allows you to decide whether the
19 dose was okay or not?

20 MEMBER LANGHORST: And so I'm just trying
21 to get to your point that you're trying to make this
22 better, and so I'm not sure I understand how it's
23 better. I'm not arguing that we have a perfect system
24 now. But yeah, that's my question. I'm not certain
25 what needs to be done in order to document this so you

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1 can show we did this evaluation and this is what it was,
2 and here it is on this piece of paper or this database
3 or whatever.

4 MEMBER ENNIS: I think the words it's in
5 the treatment plan, but maybe that wouldn't -- can you
6 go back John to the slide?

7 DR. ALDERSON: So we have a comment from
8 NRC then here.

9 DR. TAPP: Dr. Suh if I may --

10 DR. ALDERSON: You need a mic.

11 DR. TAPP: Okay, thank you. I'm an NRC
12 staff member on the subcommittee. One of the things
13 when you give this total dose to 80 percent, you're
14 allowing the inspectors in this review to start using
15 the standard dose volume histogram curves that are used
16 generally in practice of medicine.

17 You're talking about we could actually
18 start using these and you could show that to inspectors
19 and we could actually use this as a line you draw. It's
20 an easy shift, then, to see that 20 percent. So it's
21 actually a little bit easier to actually identify
22 medical events.

23 MEMBER SUH: It's more quantitative than
24 we have now. So yes, so I agree. It is more
25 quantitative, because you look at the graph and say well

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1 I'm off by whatever, 20 percent, 30 percent.

2 DR. TAPP: So you can actually use -- you
3 can actually use graphs, that we could start to show
4 inspectors on how to read one, and like today, where
5 different people can prescribe it different ways and
6 evaluate it in different ways, okay. If that helps.

7 MEMBER LANGHORST: So I'll ask Dr. Tapp.
8 Do you then think that there needs to be changes in not
9 only the medical event reporting criteria, but what
10 needs to be documented on the written directive, to say
11 this is the data that -- to make it consistent, so that
12 you can show that? That was my question, of how do we
13 do it?

14 DR. TAPP: Yeah. If that would be the
15 recommendation. We'd have to look at it as a whole if
16 we actually went forward with this, yes.

17 MEMBER SUH: And I agree. This is not
18 a -- I mean we've had a lot of discussions about how
19 to define a medical event and it's a little bit of a
20 moving target, and we wanted to at least just to present
21 to the Committee that there's always one thought
22 of -- again, we want to use treatment site.

23 MEMBER LANGHORST: Right.

24 MEMBER SUH: You know, because I think
25 that's a big move trying to going through. Right when

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1 we were going between do you call it a target, a
2 treatment volume and ultimately we decided target site
3 was best for the patient. The last sentence on this
4 particular site, the treatment site's defined by the
5 physician. The physician has to define what that
6 treatment site is going to be.

7 So that's really going to be on the
8 physician to decide that, and then the treatment plan
9 would be something you can refer to, to say that you
10 actually treated the patient. So obviously if I were
11 to treat, I'm going to use Gamma Knife as an example,
12 I'm supposed to treat a right-sided brain lesion, but
13 the plan clearly shows I treated the left side. I mean
14 that's an ME.

15 MEMBER LANGHORST: Right.

16 MEMBER SUH: And the purpose of using this
17 80 percent definition is that if the treatment plan
18 shows that I am off by more than 20 percent for that
19 one treatment site, at least that's a cut-off, that we
20 at least are proposing to call it a medical event for
21 that treatment.

22 MEMBER LANGHORST: And I am fully
23 supportive of that. I just wanted to know how you do
24 it so that the inspector can see it, that --. Then I
25 had one other question.

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1 DR. ALDERSON: Sure.

2 MEMBER LANGHORST: Did you review, also
3 consider all of the 35.1000 uses? You said Gamma
4 Knife, but Perfexion is under 1000. So I assumed
5 that's kind of included, and then let me think if
6 there's anything else. I guess there's no --

7 MEMBER SUH: Right. So this, so as part
8 of the definition --

9 MEMBER LANGHORST: You said not Viewray.
10 I know you cut --

11 MEMBER SUH: Right, not Viewray, and also
12 again, right now the Perfexion, as you know, is under
13 35.1000. So it's really meant for the non-Viewray,
14 non-SRTs, because we felt that the current definition,
15 KSRT that we've talked about as a group was sufficient,
16 and we also felt that the radiopharmaceutical
17 definition, the current definition as it stands now is
18 also sufficient as well.

19 So it's really to address more than
20 radiation oncology-specific brachytherapy,
21 non-permanent implant brachytherapy modalities with
22 this.

23 MEMBER LANGHORST: And so then that would
24 leave out the microspheres, which are brachytherapy?
25 But they're permanent. Okay, thank you.

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1 MR. OUHIB: Hello, this is Zoubir.

2 DR. ALDERSON: Yes, please Zoubir.

3 MR. OUHIB: You know, I think we forgot the
4 purpose of a quality management program, which is
5 really -- I mean the intent there is to review
6 post-treatment, if there was any possibility of a
7 medical event, and if so, that's when you document that.
8 So the answer to your question as far as the state
9 inspector or the NRC, whatever, the first question is
10 okay, well can you share with me your quality management
11 program, and have you had any medical event and what
12 is the outcome that's documented when you do a
13 post-implant review basically, to determine whether
14 there was a medical event. But that documentation is
15 available from the management program.

16 DR. ALDERSON: Understood.

17 MEMBER LANGHORST: Yes, this is Sue
18 Langhorst. But sometimes you can't evaluate those
19 without your medical physicist walking you through it.
20 And so is that -- is that a very good measurable
21 regulatory control, or should that be more practice of
22 medicine? That's my point.

23 DR. ALDERSON: Someone should comment on
24 that, from either Mr. Zoubir or one of our two radiation
25 oncologists.

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1 MEMBER SUH: I mean ultimately from, you
2 know in terms of regulation, again I think a lot is going
3 to be on the onus of the post treatment review, as Zoubir
4 mentioned. If the post-plan shows that you're clearly
5 off, then ultimately it's going to be up to the health
6 provider to say a medical event has occurred, because
7 again, I think we've had this discussion before.

8 How many medical events in the U.S. are
9 there each year, and how many are actually reported by
10 every physician? Does every medical center out there
11 being truly honest with every medical event that
12 occurs? I don't know. I don't know what that
13 numerator is and denominator is.

14 So again, if by this definition if we're
15 off by -- if that 80 percent is not covered by the
16 treatment site, then on the pulse planner unless
17 something happened with the treatment, then it would
18 be on me to say this is a medical event and I'm reporting
19 it, and when the inspector and there's a deviation, we
20 were clearly off and it constitutes a medical event.

21 So I think part of it's going to be
22 communication with the inspector. So I don't -- with
23 the definition as it currently has, can someone just
24 flip through a bunch of charts and find this? No,
25 that's not going to help. That's not going to happen.

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1 MEMBER LANGHORST: But I think if you're
2 required to have these histograms and this is one of
3 the things you're showing, this is how this shows more
4 than 80 percent was within 20 percent, however it
5 showed, then you can -- that's something an inspector
6 can look at and it shows that you've done that
7 evaluation, and that there's assurance that what you're
8 pre-planning circumstances were are the same as what
9 your post-administration circumstances that you've
10 shown you've documented, that you were within that
11 criteria and so there was no medical event.

12 So I think anything you can do to push it
13 towards something that you can really document that's
14 easy to show the inspector, that's a good, measurable
15 regulatory control. So I'd just encourage you to think
16 about how the rubber meets the road, I guess, is what
17 it comes down to. Thank you.

18 DR. ALDERSON: Dr. Zanzonico.

19 VICE CHAIR ZANZONICO: Correct me if I'm
20 wrong Dr. Suh or Dr. Ennis, but this is a -- that
21 criteria, an 80 percent deviating from the prescribed
22 dose, is a pretty bad result. If you were for example
23 flipping through dose volume histograms, that would be,
24 I think, very obvious.

25 I mean I think with modern radiation

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1 therapy, the dose volume histograms look almost perfect
2 in terms of coverage of the tumor site, and if you were
3 really under dosing up to 80 percent by 20 percent, I
4 think it would be fairly obvious just visually looking
5 at the histograms.

6 DR. ALDERSON: So -- we're coming wearing
7 our hat as a regulator and we don't talk the same
8 language. So we need to come to a middle place where
9 we're meaning the same things. I think some of the
10 terms and things that we use aren't completely clear,
11 like in fact what that really means.

12 So I'm hearing Sue saying I need you to tell
13 me what is a treatment site more specifically somehow,
14 and maybe we do have to somehow put into the written
15 directive and again, I haven't really read over
16 recently the requirements in detail to know how it's
17 revised. But maybe there has to be something more
18 specific.

19 What is the treatment site so the regulator
20 can say okay, I see here your documentation on this
21 patient. This is a treatment site and now show me that,
22 you know, the dose was delivered. The other part of
23 this, to Pat's point and to clarify for everyone on the
24 subcommittee. So a dose volume histogram will be based
25 on an imaging, usually CT but it could be MRI, done in

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1 the planning process.

2 Whether that was executed every day is not
3 based right now in general on reproducing dose volume
4 histogram based on a today imaging, but rather based
5 on the imaging done today that is then matched to the
6 idealized image of what it ought to look like today,
7 and making sure that everything is lining up perfectly.

8 So we'll do imaging right before treatment
9 on some basis, sometimes it's daily, sometimes it's
10 weekly, to make sure things are lining up properly.
11 That is the moment where we can all of the sudden
12 recognize there's a misalignment of a significant
13 degree, and then go ahead and say well, how much of a
14 degree? What did 80 percent of our treatment site did
15 not get and get the dose?

16 So it wouldn't be that we would have,
17 immediately at least, a new dose volume histogram that
18 we would comparing side by side, but it would be the
19 imaging that was used to verify the positioning to be
20 correct, show that it was dramatically off and
21 therefore we determined that we had done something
22 incorrectly.

23 So that's kind of the process. Now I guess
24 we have to talk regulator language of how you translate
25 it into regulator ease that is easy. But that's kind

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1 of what happens, and what we're trying to get at is okay,
2 if you're off by that much, we know what that means.
3 But Sue wants to know how are you going to tell me what
4 that means and I can do that independently.

5 Which I kind of hear but there's a gap in
6 our language. Mike Fuller would like to comment.

7 MR. FULLER: Well, and again I don't want
8 to take this down a path that's too far from where we
9 are right now.

10 But I wanted to -- because it seems to me,
11 listening to this discussion, that there is an interest
12 in having criteria that an inspector could come in
13 during an inspection and independently look at whatever
14 documentation and so forth that's available, and then
15 come to an independent conclusion about whether or not
16 something was a medical event and whether or not it was
17 reported.

18 What I would like to share and remind
19 people of is that while there may still be some
20 inspectors that do that, and there may be a need for
21 someone like Dr. Langhorst, as the radiation safety
22 officer who's doing more internal audits to be able to
23 do something like, as an inspector we train folks over
24 and over and over again that identifying independently
25 medical events or independently identifying medical

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1 events that weren't reported is not and should not be
2 the focus of an inspection.

3 The focus of the inspection is to come in,
4 through discussions and observations and interactions
5 with the licensees, to come to a determination about
6 whether or not the licensee has a strong, rigorous
7 program in place that enables them, the licensee, to
8 identify and ensure -- well first of all, I'm sorry,
9 to ensure that any procedure that requires a written
10 directive is done in such a way that the licensee knows
11 when they have departed from what they had intended.

12 So if you start your inspection from the
13 perspective of tell me about your program that you have
14 written and in place and have trained your folks on,
15 that ensures that when you write a written directive,
16 that that actual procedure is carried out in accordance
17 with that directive and that when it's not you know it.

18 If you start your inspection there, you
19 really don't need and you make a determination that in
20 fact this licensee has a strong program and has a
21 program with rigor in that regard, you never really get
22 to the point to where you need to count medical events,
23 because once you know or once you determine as an
24 inspector that that program does not exist or that
25 program does not have rigor, then you don't really need

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1 to go even at that point in time counting up how many
2 medical events weren't reported because that's really
3 the regulator's role.

4 The regulator's role is to focus more on
5 35.41, as it is to understanding and being able to
6 independently identify those cases where 35.3045
7 happened and it wasn't reported. So anyway again, just
8 to kind of bring people back to what the regulator's
9 role should be. It's not counting, it's not
10 independently counting medical events.

11 It is assessing the strength and the rigor
12 that that licensee has in its program for ensuring that
13 treatments and other procedures are carried out in
14 accordance with the written directive. So sorry, I
15 didn't mean to preach too much but --

16 MEMBER COSTELLO: Okay. This is Frank.
17 Can I make a comment?

18 DR. ALDERSON: Someone's on the phone?

19 VOICES: Frank.

20 DR. ALDERSON: Frank, Frank, speak up.

21 MEMBER COSTELLO: Right. Can you hear me
22 now?

23 DR. ALDERSON: Yes.

24 MEMBER COSTELLO: Okay. I'd like to
25 comment a little bit on what Mike had to say, mostly

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1 to agree but to go beyond it a little bit. We try to
2 be a performance-based inspecting organization, as
3 does the NRC and the other Agreement States, and we do
4 begin the way Mike described. A question I'll often
5 ask a licensee is how will they know whether or not
6 they've had a medical event, for whatever modality
7 we're talking about?

8 Then they will describe it to me and that's
9 how I think, if we do change the definition, I would
10 expect them to explain to me how they reviewed each
11 individual treatment to determine whether it was a
12 medical event or not. However, we are a
13 performance-based organization, and it's to trust and
14 verify.

15 So I might select a few individual
16 treatment plans and look to see if the program they
17 described to me is actually the program that they're
18 implementing. So it's not just enough to have them
19 tell you what they're going to be doing. At some point
20 you have to verify using a performance-based approach,
21 to see whether or not what they're doing, what they say
22 they're doing is what they're really doing.

23 I have one other comment, kind of separate
24 from that, and that is I notice what modalities is this
25 new definition of medical event supposed to apply to?

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1 So IMRTs discuss intraoperative treatment. Many of
2 those are machine-produced. You've got to remember
3 that we're not talking about medical events from
4 machine-produced radiation. So if you have -- coming
5 from the subcommittee, how much of this discussion we
6 have applies mostly to machine-produced radiation?
7 Thank you.

8 DR. ALDERSON: Comments on that?

9 MEMBER SUH: Well, I think this applies to
10 the high dose rate brachytherapy. So it's, you know,
11 if your dose is off from treatment site for more than
12 20 percent or 50 percent for a single event, then that
13 would be, at least from this definition, would be
14 considered a medical event.

15 Also in terms of Gamma Knife for the
16 non-Perflexion unit, if you're off, you're not
17 encompassing the target, that also constitutes a
18 medical event as well. So yes Frank, some of these
19 definitions are more related to what we think of as a
20 linear accelerator. But again, there are some
21 situations where I think we want to be more encompassing
22 in terms of this definition.

23 So that's why we tried to make an attempt
24 at trying to find what should constitute a medical
25 event, and again, we came up with treatment site as

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1 being kind of the first step and then can argue about
2 what percent of coverage of the target would be -- the
3 treatment site would be considered a medical event or
4 not.

5 But let me just get back to one point.
6 Again, I think just go back to some of the comments,
7 at the, you know if -- you know again, there is a balance
8 between regulations and delivering the best treatment,
9 and again there's going to be a little bit of going back
10 and forth. You want to try to make it as easy as
11 possible for everyone involved.

12 But at the end of the day, if you have a
13 high quality program, you're going to fall well
14 within -- you're going to treat the right site. You're
15 going to treat the right patient, you're going to treat
16 the right location. If you look at what Ron presented
17 earlier today, some of those medical events are
18 reported, are you know, are -- were clearly medical
19 events. I mean I don't think anyone would have any
20 question about that.

21 So again, now we're saying okay, let's take
22 a much more select scenario for giving as high dose
23 radiation, and again just going back to brain and spine,
24 which is what I do. I'm treating a T-12 vertebral body,
25 and I'm treating just half of the vertebral body. To

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1 me, that's a clear medical event. I've missed, and
2 right now the definition the way it is, it doesn't
3 really clearly specify.

4 So that's really what the attempt is, of
5 saying if it's part -- well, if it's treatment site,
6 does not cover by at least 80 percent of what I intended
7 to treat, that would constitute a medical event. So
8 that's --

9 DR. ALDERSON: Yes.

10 MEMBER LANGHORST: Sue Langhorst. So I
11 wanted to come back to Dr. Zanzonico's point about oh,
12 that would be not very good and yeah, I agree. But you
13 can't get to perfection on a regulatory control. This
14 is, you know, major health, public health and safety,
15 patient safety. So you have to have -- it's not ideal
16 from a physicist's point of view obviously, but what
17 is that end point that really you need to report it as
18 a regulatory issue.

19 So yeah, you wouldn't want to treat that
20 way every time. But I know I did, our institution if
21 we're outside of ten percent or five percent, that's
22 when we're going oh, that's not how we want to treat
23 or that's not how we want to do our diagnostic
24 procedures. But that keeps you well. I think Dr. Suh
25 was saying that it keeps you well within the regulatory

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1 framework.

2 So yeah, you wouldn't want to do that every
3 time, but that really tells you something went wrong
4 there.

5 DR. ALDERSON: So by just listening to
6 this, I think that the committee's done an excellent
7 job of modernizing the criterion, and giving us some
8 new standards. I guess the real question is, given
9 that they're a little bit more complicated, are they
10 understandable enough that the Committee would want to
11 recommend that they be adopted?

12 I mean that seems to be the crux of what
13 I'm hearing the discussion be. I think that among
14 radiation oncologists, you would say the answer to that
15 is clearly yes, and the question is, is that -- is that
16 sufficient and that it -- in fact, it may well be.
17 Perhaps you'd like to argue or support that point, given
18 that these instruments are all, you know, done in using
19 radiotherapy.

20 I think if that's true, then you know,
21 there would be a feeling that we would want to support
22 it. I think that's the only question. It's a question
23 of can anyone else, you know, understand it and if they
24 can't, then it's not useful at all, because no one else
25 can understand it. Please comment.

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1 MEMBER ENNIS: Well, my feeling is we
2 need to have some more discussion, to figure out how
3 we achieve that goal. So how does the regulator in
4 particular, you know, how does this fit into the
5 well-articulated framework that Mike laid forth about
6 what we're really trying to accomplish, and what do we
7 need to be saying needs to be in place for a regulator
8 to go in and yes, verify that there are proper
9 procedures and perhaps to independently review some
10 cases, as Frank said, and verify all that, again without
11 creating a tremendous amount of work for that
12 institution, without burden, that translates this into
13 reality.

14 And I think we do feel like every radiation
15 oncologist who is worth his salt would understand what
16 this means, does do this and would agree yes, those are
17 medical events and this is a good step. This is
18 reasonable. We'll see, now that it's public, what
19 response we get from the radiation oncology community.

20 But yeah, I think, you know, that part is.
21 But you know again, I think we need to kind of look a
22 little bit broader and figure out like what do we need
23 to make this real.

24 DR. ALDERSON: John.

25 MEMBER SUH: So I appreciate everyone's

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1 comments. This is -- I sense this is going to be
2 contentious. It's medical event reporting and we're
3 spending a lot of time on the importance of safety and
4 to protect the public, protect the patients. I see
5 there is other stakeholders that we need to also involve
6 as well.

7 So one of the things that I would ask that
8 if it's okay, if I prepare a formal report at the next
9 meeting, get other stakeholders, try to refine the
10 definitions so that the regulator and the licensee
11 would say well, this makes sense for us. Again, it may
12 not be an easy process but we should at least try and
13 present it again formally at the next meeting.

14 DR. ALDERSON: I think that's aiming in
15 the direction that everyone's been sort of trying to
16 go. Dr. Ennis.

17 MEMBER ENNIS: Do we have a regulator on
18 our subcommittee? If not, maybe one should be added.

19 DR. ALDERSON: Dr. Tapp.

20 MEMBER LANGHORST: Yeah, Dr. Tapp.

21 DR. ALDERSON: Would you like to add Dr.
22 Tapp to your subcommittee?

23 DR. TAPP: I cannot be added to the
24 subcommittee, but I can be a resource at any time you
25 contact me and I'll be a resource.

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1 DR. ALDERSON: Yes. Would you like to be
2 a resource?

3 MEMBER SUH: Yes please.

4 MEMBER COSTELLO: This is Frank.
5 Actually, I'm a regulator.

6 (Off mic comments.)

7 MEMBER SUH: Yeah, Frank is a regulator.

8 DR. ALDERSON: So Frank, would you like --

9 MEMBER COSTELLO: I'd be happy if you
10 reach out to me if you want to.

11 DR. ALDERSON: Frank, would you like to
12 join this committee also? Would you like to join this
13 committee?

14 MEMBER COSTELLO: Yes, I would.

15 DR. ALDERSON: Okay, and you're --

16 (Simultaneous speaking.)

17 DR. ALDERSON: -- a resource.

18 MEMBER SUH: Yes, okay. That's great.

19 MR. OUHIB: This is Zoubir again. If I
20 may, this is just a comment for Frank. Wouldn't a
21 procedure for post-implant evaluation for a possible
22 medical event be helpful for regulators?

23 In other words for any modality, there is
24 a clear procedure of how this is being evaluated to,
25 you know, at the time of the event he says okay, what

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1 exactly did you do? He says well here's my procedure.
2 This is how I evaluate all cases post-implant, because
3 they're different. We know that.

4 MEMBER COSTELLO: My reference
5 regulation, Section 35.41, states that you need a
6 procedure to make sure that the right patient gets the
7 right dose. I would think a good procedure like that
8 would include post-treatment analysis.

9 MR. OUHIB: Right, right.

10 MEMBER COSTELLO: So I think that a good
11 35.41 procedure would include evaluating the treatment
12 to see whether or not there's a medical event or not.
13 So I'm agreeing with you.

14 MR. OUHIB: Right, right, and that's
15 exactly what we do. In other words, if we do safe
16 procedure we have a -- or a modality, we have a certain
17 procedure to follow, okay. Some, you might may use DVH
18 imaging and all that, but others maybe just be imaging
19 or what-not because you can't do a DVH on (phone
20 interruption) or something like that.

21 So really, that's how we relied on.
22 Basically it says okay, this is this type of procedure.
23 All right, here's how we're going to evaluate it. This
24 is good, this is good, this is questionable. Let's
25 look further and so on and so forth. Okay. I've just

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1 thought I'd make a comment.

2 DR. ALDERSON: Okay. So let's summarize,
3 because our time is up for this discussion. We're
4 going to add Frank Costello --

5 MS. HOLIDAY: Dr. Alderson. This is
6 Sophie. I just want to remind you guys that we're
7 limited to 50 percent of ACMUI membership to serve on
8 the subcommittee. Currently, there are five members
9 and you have Zoubir Ouhib as your sixth member once he
10 becomes a full member.

11 So at the time, we only have 11 full
12 members. So the subcommittee cannot have more than
13 five members at this time. So we can't add Frank or
14 alternatively, when Zoubir and Mr. Green join the
15 committee, you'd have to pick between Frank or Zoubir.
16 Sorry.

17 (Off mic comments.)

18 DR. ALDERSON: I think in this particular
19 case, it seems like an important issue that we should
20 continue, and we should get a report back the next time.
21 Let me go on to the second half of this and then I'll
22 come back to your question. I think we're going to vet
23 the clarity of the final statements with a number of
24 other stakeholders, and the idea would be that we'll
25 report back in the spring, and Dr. Tapp will be a

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1 resource to you.

2 So the issue is Frank Costello, who has an
3 interest in being on and does have a vote, and Zoubir
4 who was appointed but doesn't have a vote at this time.
5 So I think that if you'll accept the chair's
6 prerogative, I think Frank needs to be on the committee,
7 someone that can vote and take an action, and Zoubir
8 needs to be a resource to the committee. Do you accept
9 that Zoubir?

10 MR. BOLLOCK: But you can only do
11 that -- so Zoubir is actually, he was on the
12 subcommittee. If he's not officially on the
13 subcommittee, he's not officially --

14 DR. ALDERSON: Oh, he's not on the
15 subcommittee.

16 MR. BOLLOCK: Officially, because he's
17 not officially part of this committee --

18 DR. ALDERSON: So we don't have to invite
19 him to step off, right.

20 MR. BOLLOCK: Right. So we'd still -- so
21 officially the subcommittee has five members. So
22 right now one member would have to step off in order
23 to add --

24 DR. ALDERSON: Oh, I see. That wasn't so
25 good. There already are five other members.

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1 MR. BOLLOCK: Right, yeah. So that's why
2 his name is italicized. He's not officially on the
3 Subcommittee because he doesn't officially work for the
4 committee.

5 DR. ALDERSON: All right. So please,
6 Frank, will you be a resource to the committee also?
7 Frank?

8 MEMBER COSTELLO: I'd happily be a
9 resource.

10 DR. ALDERSON: Yes, very good. So we've
11 got another resource. So you can reach out to Frank.
12 He's not officially a member of the committee, and thus
13 not able to do --

14 MR. BOLLOCK: Right, because
15 he's -- because he is part of the Committee, you can
16 use my staff as a resource to help and not so like Dr.
17 Tapp is not part of the subcommittee, but she is a
18 resource if you need to check for that, you know, for
19 regulatory definitions and that understanding of
20 questions. That's what you use Dr. Tapp for.

21 Because Frank is on the Committee, we're
22 circumventing FACA rules if we were trying to do that.
23 So we can't really do that. So right now, there are
24 five official members on the subcommittee. It has to
25 remain five. So in order to add Frank, we would have

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1 to remove one of the five.

2 DR. ALDERSON: Who are the official
3 members of the committee?

4 MR. BOLLOCK: Dr. Ennis, Dr. Dilsizian,
5 Dr. Palestro, Dr. Suh and Dr. Zanzonico.

6 VICE CHAIR ZANZONICO: I mean I'd be happy
7 to step off the committee.

8 (Laughter.)

9 DR. ALDERSON: Dr. Zanzonico is willing to
10 take one for the team, all right, and resign from this
11 committee. Thank you Dr. Zanzonico.

12 VICE CHAIR ZANZONICO: (off mic)

13 (Laughter.)

14 DR. ALDERSON: I didn't even ask you this
15 time. And then Frank will step onto the committee.
16 Frank, is that all right with you? Is that acceptable
17 to the rules and regulations? It is. So done. So
18 we'll look forward to a report from this group at the
19 spring meeting. Thank you very much.

20 MEMBER SUH: Okay, thank you.

21 VICE CHAIR ZANZONICO: All right. On we
22 go. So we're into a report from the NRC, Dr. Taylor,
23 on 10 C.F.R. Part 35 rulemaking update.

24 10 C.F.R. Part 35 Rulemaking Update

25 MS. TAYLOR: Good afternoon. I think

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1 you called me doctor. I'd like to clarify. I do not
2 have my Ph.D.

3 DR. ALDERSON: All right.

4 MS. TAYLOR: I admire those that get
5 through that program.

6 (Off mic comments.)

7 MS. TAYLOR: Okay. I am the new project
8 manager. It seems like every time you turn around we
9 have a new project manager, right. For this rule, my
10 name is Torre Taylor. I'm in the rulemaking branch in
11 MSTR. So I'm here to provide you an update on the rule.
12 I wish I could tell you we have an SRM and official
13 decision but we don't.

14 Let's see. Okay. So now on to my
15 presentation. Well let me start, back up. I started
16 to work on the rule in January 2016, so my work started
17 with ACMUI recommendations and then comments from the
18 Agreement States, and then we took it forward from there
19 with the final recommendation just to the Commission.

20 So I'm going to focus on the background and
21 the current status, highlight high level ACMUI review
22 unless you want to get into more details and our staff
23 response, the major changes in the final rule, which
24 to me is the more important discussion, the final
25 process for publication. I'll have a slide for

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1 contacts so people can write that down with phone
2 numbers and emails for questions, and then any
3 questions the Committee has.

4 As a reminder, the proposed rule was
5 published in the Federal Register on July 21st, 2014.
6 I have that citation if anyone wants it. The comment
7 period closed November 2014, and we received 69 comment
8 letters. Some of those arrived after the end of the
9 comment period, but we were able to consider all of them
10 but two in the time period we were finalizing the rule.

11 The comments can be seen in ADAMS or in
12 regulations.gov. For ADAMS, if you want to get some
13 information about how to get to those specifically, I
14 don't have a single ML number for you, but I can step
15 you through how to find them.

16 I can even send you a list of the MLs, or
17 you can go to regulations.gov and you would just go to
18 that site and the docket ID is NRC-2008-0175. That's
19 often for the benefit of the public. They may not be
20 aware of the comments we received.

21 ACMUI did have early opportunities to
22 review and provide comments on the draft proposed rule,
23 and also on the final rule. The final rule was sent
24 to the Commission via SECY 16-0080. The ADAMS number
25 is written there, ML 16123A342. It has all the

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1 enclosures to the rule, the Federal Register, the ACMUI
2 report, our response, the state comments and our
3 response and all the particulars of the rulemaking
4 process that have to be with that.

5 It is public, and it's also on the website
6 if you want to go to the SECY papers that way. The
7 Commission is currently reviewing the rule. We do have
8 two votes. I can't discuss those votes obviously.
9 We're waiting on the last vote. So my discussion is
10 based on what we sent to the Commission, and obviously
11 the Commission may make changes.

12 Let's see. You all provided the report on
13 your recommendations in January of 2016, and that's
14 Enclosure 4 to the SECY, and then we provided a response
15 back. That's Enclosure 5 to the SECY, and you have a
16 public teleconference on it in let's say, when was that?
17 It was January 6th as well.

18 Essentially, the high level is that you all
19 endorsed six provisions of the final rule. There were
20 two recommendations that the staff accepted. There
21 was one that -- I've got that written wrong. There were
22 two recommendations accepted. One was accepted in
23 part and we had four recommendations that were not
24 accepted.

25 The major changes is where I want to focus

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1 the discussion. But in the reporting criteria for
2 permanent implant brachytherapy, the proposed rule
3 included dose base criteria for permanent implant
4 brachytherapy. That provision has been eliminated and
5 for within and outside the treatment site, and we now
6 had it as source strength-based.

7 The medical community expressed concerns
8 about a dose-based criteria that we're not practical,
9 they might create confusion, they could discourage
10 licensees from using the treatment modality, and this
11 is a recommendation or change that the ACMUI endorsed.
12 We did revise the language to be clear that it was based
13 on the post-implantation portion of the written
14 directive.

15 An Agreement State pointed out to us that
16 it wasn't clear if it was pre- or post or what. So to
17 be consistent, everything is the post-implant portion
18 of the rule. The ME criteria for wrong location, this
19 is in Section 35.3045(a)(2)(iii)(C). So we've revised
20 that to state that sealed sources implanted directly
21 into a location discontinuous from the treatment site
22 as defined in the written directive. This was a
23 recommendation by ACMUI.

24 The proposed rule would not contribute
25 dose to the treatment site, and the Committee expressed

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1 some concerns about that and we agreed with the
2 Committee on that.

3 The other change is the reporting of failed
4 technetium and rubidium generators. So the proposed
5 rule and the final rule has this new requirement to
6 report a generator eluate that exceeds permissible
7 concentrations of their respective radionuclides.

8 After reviewing the public comments on the
9 proposed rule, we changed the notification and
10 reporting deadlines. So the notification deadline is
11 going to be within seven calendar days. The proposed
12 rule had that as 30, and the deadline for submitting
13 a written report is within 30 calendar days, and the
14 proposed rule had that as 45.

15 We deleted the separate category for
16 training experience for alpha emitting
17 radiopharmaceuticals for parenteral administration.
18 So that's all been included in 35.390(b)(1)(ii)(G)(3).
19 So that provision is now everything related to electron
20 emission, beta radiation characteristics, alpha
21 radiation characteristics or photon energy of less than
22 150 keV for which a written directive is required. So
23 there's no longer a separate category there if
24 obviously the Commission approves that.

25 A big issue in the proposed rule stage and

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1 comments was the compatibility category for medical
2 events for 35.3045. After reviewing all the public
3 comments and the comments from the ACMUI and the
4 Agreement States, the staff's recommending to the
5 Commission that this be designated as a Category C.

6 The essential objections have to be met by
7 the Agreement States to avoid conflicts, duplications
8 or gaps in the regulation. It doesn't have to be
9 exactly the same as NRC requirements, but they have to
10 meet the essential objectives. They can require
11 reporting of MEs with more restrictive criteria than
12 those required by the NRC, but we did make clear that
13 we do not consider a dose-based criteria as part of the
14 essential objective for this section of the
15 regulations.

16 The main reason for essential objectives
17 is we want a consistent national program. We
18 determined that the dose-based criteria could conflict
19 with and create inconsistencies with a national
20 program, and we could end up with reports of
21 non-significant events.

22 It allows the NRC to identify trends or
23 patterns, identify generic issues, recognize the
24 inadequacies or unreliability of certain equipment or
25 procedures and why an event occurred, and whether any

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1 actions are necessary. So that's where that fell out
2 and we'll see if the Commission agrees, because if you
3 remember, they came back and told us to notice it as
4 a B and then asked for comments, and we got a lot of
5 comments.

6 Okay. The final process. It's with the
7 Commission. We're waiting for a staff requirements
8 memorandum. At that point, once we get that direction
9 we'll make any changes that they direct and then we will
10 send the package over to the Office of Management and
11 Budget for their review and approval. That can be a
12 90 day process. Hopefully it will be shorter rather
13 than longer, but we don't know.

14 If we get an SRM in October, I'm estimating
15 the earliest we could publish this rule would be in the
16 spring of 2017. The rule will be effective 180 days
17 from its publication date. So that's six months, and
18 then the Agreement States will have three years from
19 the effective date to adopt the provisions.

20 Now often it's the publication date; in
21 this rule we're doing the effective date. The medical
22 team is going to finalize guidance for this rule, and
23 they will be the one to address any questions anyone
24 has on that along the way.

25 Here are the contacts. I am the person for

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1 the rulemaking process, Torre Taylor for those on
2 the -- well I guess everyone signed up for GotoMeeting,
3 right? So there's my email and phone number, and then
4 Mike Fuller and Doug Bollock can address any specific
5 technical questions, and I think that's all I have,
6 except for any questions y'all have.

7 DR. ALDERSON: All right. Questions for
8 Ms. Taylor.

9 VICE CHAIR ZANZONICO: I have a question.
10 I was always under the impression that the Commission
11 was sort of the omnipotent adjudicator of all the rules
12 and regulations and so forth. But I see it goes
13 back -- it goes to OMB after Commission approval?

14 MS. TAYLOR: Well, the Commission
15 approves it for the agency. OMB is a government-wide
16 review. They make the final, final say. They won't
17 change anything technical, but they look at resources,
18 budget from a government perspective and say is this
19 a major rule, is it not a major rule and they make that
20 kind of determination.

21 So if they reject it, we wouldn't be
22 able -- we wouldn't be able to publish it.

23 VICE CHAIR ZANZONICO: Well that's the
24 question. I mean --

25 MS. TAYLOR: I don't think that would

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1 happen.

2 VICE CHAIR ZANZONICO: Is the OMB review
3 ever involve sort of in the sense restarting the
4 process?

5 MS. TAYLOR: I don't think so.

6 VICE CHAIR ZANZONICO: In other words, can
7 they find schematic issues with it that --

8 MS. TAYLOR: No.

9 VICE CHAIR ZANZONICO: Not that to have to
10 start from scratch, but there were major issues to
11 revisit and --

12 MS. TAYLOR: No, not from a technical
13 perspective, yes.

14 DR. ALDERSON: Other questions? Yes.

15 MS. HOUSEMAN: Torre, please -- is this
16 on? Please -- oh, this is Esther Houseman, OGC and NRC.
17 Torre, please correct me if I'm wrong on this, but the
18 OMB review, because we're an independent agency and
19 don't have to send rules through OIRA, the OMB review
20 is just for Congressional Review Act purposes; correct?
21 Because it is a major rule.

22 MS. TAYLOR: Yeah. Actually yeah, so --

23 MS. HOUSEMAN: And that's for OMB to
24 review the rule and determine whether it needs to go
25 to Congress under the Congressional Review Act?

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1 MS. TAYLOR: Oh okay.

2 MS. HOUSEMAN: The Congress almost never
3 takes up rules for Congressional review.

4 MS. TAYLOR: Oh okay, that's good to
5 know.

6 MS. HOUSEMAN: Just so you're aware.
7 It's for a very narrow purpose that OMB looks at the
8 rule.

9 MS. TAYLOR: Okay, thank you.

10 DR. ALDERSON: Other questions?

11 (No response.)

12 DR. ALDERSON: So there are none.

13 MS. TAYLOR: Okay, great. Thank you.

14 DR. ALDERSON: Thank you for your report.

15 MS. TAYLOR: We should have a final rule.

16 DR. ALDERSON: So now we're going
17 to -- Mike Fuller is going to speak with us on NRC
18 comments on patient intervention.

19 (Pause.)

20 NRC Comments on Patient Intervention

21 MR. FULLER: Thank you Dr. Alderson.
22 Yes, I'm Mike Fuller, the team leader of the Medical
23 Radiation Safety Team here at the NRC. I appreciate
24 the opportunity to speak to everyone today about
25 patient intervention, and the title of my presentation

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1 should give you a hint.

2 So it's entitled, the document I want to
3 talk about, because it's patient intervention and how
4 do we proceed. So the purpose of my presentation today
5 is to review the ACMUI recommendations related to the
6 definition for patient intervention, and discuss the
7 challenges that are facing NRC staff as a result of
8 those.

9 First, to give you just a little bit of
10 background and I guess short history, it wasn't that
11 long ago, back in March of 2015, Dr. Gabriel, who we
12 heard from this morning from Vienna, who at that time
13 was a member of the Medical Radiation Safety Team here
14 and Mr. Frank Costello of the ACMUI, made a couple of
15 presentations to the ACMUI.

16 Sandy's presentation was really focused
17 sort of on the background and the history of the term
18 patient intervention, and how the NRC came up with the
19 definition and when and so forth and so on. And then
20 Frank provided a presentation that was a little bit more
21 focused on apparent misalignment between the meaning
22 of patient intervention between the NRC staff and the
23 ACMUI, or at least according to Mr. Costello.

24 So as a result of that, of those two
25 presentations, the chairman at that time formed a

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1 subcommittee and charged that subcommittee with
2 clarifying the meaning of patient intervention, to make
3 sure that the Nuclear Regulatory Commission and the
4 advisory committee or the ACMUI are aligned in their
5 interpretation of the term patient intervention.

6 So then last fall, in October of 2015, we
7 heard a presentation by Dr. Dilsizian of the ACMUI. He
8 presented the subcommittee. So that subcommittee was
9 formed. Dr. Dilsizian I believe chaired that
10 subcommittee, and he presented the subcommittee's
11 recommendations to the full committee.

12 So with some changes to those
13 recommendations, the full ACMUI provided staff with the
14 following recommendations, and these recommendations
15 are really on two separate issues. So Issue 1 in the
16 first recommendation states that "an
17 intentional/unintentional patient action would
18 represent a reportable medical event, even if it
19 results or will result in" -- I'm sorry, "a reportable
20 medical event if it results or will result in unintended
21 permanent functional damage to an organ or
22 physiological system as determined by a physician."

23 And of course the overall goal would be to
24 prevent or mitigate patient action that may impact
25 treatment. In reviewing the presentation from Dr.

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1 Dilsizian and looking at what the current rule says,
2 we've taken this to mean that, with maybe some minor
3 modification in the wording although it's not clear,
4 that they were endorsing what we currently have.

5 The second issue and the second
6 recommendation I think is really where we need to focus,
7 and that's where I'm focusing my talk today. The
8 second issue had to do with anatomic and physiological
9 anomalies, and the recommendations that the staff
10 captured from that presentation is provided here.

11 So unintentional treatment outcome due to
12 anatomic or physiological anomaly and/or imaging
13 uncertainty falls into the category the art of medical
14 practice, provided that the standards of medical
15 practice are met. Reporting such unpredictable and
16 unavoidable patient-specific medical events will not
17 help to prevent such events in the future and therefore
18 cannot be regulated.

19 So at this point, NRC staff or we on the
20 medical team are assuming that the ACMUI wishes the
21 staff to state or conclude that the current definition
22 encompasses this new criteria. So here's what the
23 regulations currently say, or this is how the
24 regulations currently define patient intervention.

25 Patient intervention means actions by the

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1 patient or human research subject, whether intentional
2 or unintentional, such as dislodging or removing
3 treatment devices or prematurely terminating the
4 administration.

5 So before I get into the discussion or my
6 part of the presentation about possibly making changes,
7 I want to explore further a little bit about what, just
8 what problem it is that we're trying to solve. I say
9 that because in Mr. Costello's presentation in March
10 of 2015, the primary concern was focused on yttrium-90
11 microspheres.

12 So I've taken these two quotes directly
13 from Mr. Costello's slides, where he states and I think
14 he's -- well, based upon the presentation, it's clear
15 that he's speculating or assuming. So he said the
16 patient's artery contracts and the spheres flow
17 retrograde into the gastrointestinal artery. In
18 another place he says if the patient's lung shunt
19 fraction was one value during the workup and changed
20 for the treatment.

21 So I want to remind folks that this past
22 February, in fact on February 12th, the NRC issued Rev
23 9 or Revision 9 to the yttrium-90 microsphere
24 brachytherapy sources and devices, TheraSphere and
25 SIR-Sphere licensing guidance. In that revision, we

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1 made changes such that there's an exemption made for
2 shunting when shunting was evaluated prior to the
3 treatment in accordance with the manufacturer's
4 procedures.

5 Back in June of 2012, the NRC issued Rev
6 8, and in that revision there was an exception made for
7 emergent patient conditions that prevent
8 administration in accordance with the written
9 directive, and we actually stated and used specific
10 examples that related to artery spasm or sudden change
11 in blood pressure.

12 So that's why I say I want to explore a
13 little bit more at this point in time about what is the
14 problem that we're trying to solve. So if you'll
15 recall back to the then-chairman, ACMUI chairman's
16 charge, it was to evaluate or to take a look at the
17 definition of patient intervention and two, and let me
18 read it again.

19 So to clarify the meaning of patient
20 intervention, to make sure that the Nuclear Regulatory
21 Commission and the ACMUI are aligned in their
22 interpretation of this term. I can say today that it's
23 clear that we're not aligned, and that the NRC staff
24 cannot implement the ACMUI recommendations as
25 currently written.

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1 So the first recommendation, what we
2 called Issue 1, it's not clear what the difference is.
3 I mean we could go back and look at that and evaluate
4 that more closely. But reading the words that were
5 presented and reading the words that are currently in
6 the rule, it's not clear what the real difference is.

7 But for Issue 2, at this point in time it's
8 not implementable, and so other than yttrium-90
9 microspheres, which I think we have addressed, I'm not
10 certain what the concerns are. Perhaps some of you are
11 aware of instances where maybe a licensee determined
12 that a situation was not a reportable medical event due
13 to patient intervention, and then the regulator, say
14 an inspector or someone, disagreed and determined that
15 the circumstances surrounding a certain case did not
16 constitute patient intervention.

17 I'm not aware of any such instances or
18 cases, and so -- but it is possible that that has
19 occurred. So and here's the other part that I think
20 is the real crux of the situation. Based upon my
21 evaluation of the recommendations that we received and
22 where we are with the current regulations, I believe
23 that this really is more of a legal issue rather than
24 a technical one.

25 So according to 10 C.F.R. 1.23, the NRC's

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1 Office of General Counsel provides interpretations of
2 laws, regulations and other sources of authority, and
3 patient intervention is defined in 10 C.F.R. 35.2. Now
4 the -- I think there are a couple of different ways we
5 might could proceed.

6 If the ACMUI wishes, we could go to our
7 Office of General Counsel and ask them if the additional
8 language that was recommended, and that really has to
9 do with Issue 2, the unintentional treatment outcome
10 due to an anatomic or physiological anomaly and/or
11 imaging uncertainty falls into the category of the art
12 of the practice of medicine, provided that the
13 standards of medical practice are met.

14 Again, I'm not an attorney, but I read the
15 definition, the current definition of patient
16 intervention and I don't see how we can get there. But
17 if the ACMUI would like for us to, we could go to our
18 Office of General Counsel and ask them if in fact that
19 definition could be interpreted such. But in order for
20 us to do that, frankly we're going to need a little bit
21 more from the ACMUI.

22 We're going to need some -- I mean I can't,
23 I can't assume and take the slides that we received with
24 those recommendations, and then try to fill in the
25 blanks and assume what the basis is for that. So at

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1 a minimum, I think if the ACMUI wants to proceed to do
2 that and go to OGC for an interpretation, we would need
3 a report, I believe, that fully fleshes out these issues
4 and provides us with the basis for these -- for these
5 recommendations.

6 And the other thing that of course we could
7 do, but it would require some of the same sort of efforts
8 on the part of the subcommittee, is we could go to
9 rulemaking. That's always an option. But we all know
10 what that entails. In other words, you would have
11 to -- we would have to develop a rulemaking plan. We
12 would have to get the Commission to agree to go forward
13 with rulemaking, and then we would do the public, the
14 full-blown multi-year process of changing the
15 regulations to change this definition.

16 So that's kind of where we are, and I would
17 welcome your comments and your thoughts on this.

18 DR. ALDERSON: Yes. Laura Weil.

19 MEMBER COSTELLO: This is Frank. Can I
20 make a comment?

21 DR. ALDERSON: Okay. Just Laura's going
22 to speak first, Frank, and then you'll come.

23 MEMBER COSTELLO: Okay.

24 MEMBER WEIL: If I'm hearing you
25 correctly, and correct me if I'm wrong, you're saying

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1 that the current 10 C.F.R. Part 35 definition, as
2 outlined on Slide No. 6, is adequate?

3 MR. FULLER: Well, what I'm saying is that
4 that is the current definition. That is in our
5 regulations and that is -- and if we wanted, if the ACMUI
6 wanted us to state or communicate out that it
7 encompasses the recommendation that we talked about in
8 Issue 2, staff does not have the authority to do that.

9 We would have to go to our Office of General
10 Counsel and get them to agree that that -- and
11 specifically what I'm talking about is that anatomic
12 or physiologic anomalies and/or imaging uncertainty
13 thought would need to be incorporated or they would have
14 to agree that that's already there, that that could
15 be -- that this definition could be interpreted to
16 encompass those things, because the staff doesn't have
17 the authority to do that interpretation.

18 And what I've said further was in order for
19 us to go to OGC, we're going to need some help, because
20 looking at the presentation, we don't see -- in other
21 words, I wouldn't want to try to assume what the basis
22 was without getting it from the ACMUI. We would have
23 to -- this would be a formal process that we would have
24 to go through, that we would have to develop the
25 documents and send them to OGC for them to evaluate and

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1 get back to us.

2 DR. ALDERSON: Okay Frank, you're next.

3 MEMBER COSTELLO: Okay. Basically, I
4 raise this issue because in my experience with the NRC
5 I was very familiar with this definition, how we
6 interpreted it in the past, and in discussions on a
7 number of issues, it became clear to me that patient
8 anomalies were being thought of as being patient
9 intervention. If the patient's physical anomalies
10 result in a dose not being delivered as intended, that
11 was being thought of by any number of people as being
12 a patient intervention.

13 I used microspheres as an example because
14 we hadn't changed the definition of a medical event yet.
15 That comes from the six months or whatever it was.
16 However, I think -- as I think about it, there might
17 be other situations and other modalities where patient
18 anomalies may result in the dose, through no fault of
19 the medical treatment staff, not being delivered just
20 because of the way the patient was built.

21 However, at the time I came up with those
22 because that was on my mind. There may be others, and
23 maybe someone else can think of some. Thank you.

24 DR. ALDERSON: Yes, Sue.

25 MEMBER LANGHORST: Again, I apologize. I

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1 wasn't here last year to talk about this during that
2 presentation. But there is -- I'll give you an
3 example, Mike. I brought -- I had one ready for that
4 meeting and couldn't do it. So in 1980, the NRC had
5 the final rule for misadministration, and in there,
6 they said, in the final rule documentation,
7 extravasation is the infiltration of injected fluid
8 into the tissue surrounding a vein or artery.

9 Extravasation frequently occurs in
10 otherwise normal intravenous or intra-arterial
11 injections. It is virtually impossible to avoid.
12 Therefore, the Commission does not consider
13 extravasation to be a misadministration. The NRC
14 asked ACMUI to review this again in, oh gosh when was
15 that, that was 2009, and there was a teleconference on
16 the diagnostic point of that and also then they asked
17 could you talk about this in regard to therapeutic
18 administrations.

19 And so that was presented in the spring
20 meeting of the ACMUI, and at that point in time the NRC
21 stated that it was determined that extravasation does
22 not require reporting as a medical event. They asked
23 the ACMUI on the therapy part and ACMUI said yes, you
24 should continue to have that policy.

25 I'm not sure it was clear that the NRC staff

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1 accepted that, but there's been no other change in
2 policy in that regard. So that's kind of buried in
3 historical information that isn't necessarily clear,
4 that it's never related to patient intervention.

5 And so patient intervention having that
6 definition and knowing what it means has a big impact
7 on licensees because of medical event reporting and if
8 you say it's patient intervention then you have that
9 Item B on permanent impact to a tissue or organ. So
10 that's the problem we're trying to solve, to make sure
11 we're all talking the same thing.

12 MR. FULLER: Right, and so -- and I think
13 it might mean -- and I'm sorry. I don't have what you
14 have in front of you, right in front of you. But I would
15 appreciate if you'd read that again, because when I
16 heard you talk about extravasation, it's not -- nowhere
17 in there do we say that that is patient intervention.

18 MEMBER LANGHORST: Right.

19 MR. FULLER: So that's the point I'm
20 trying to make, and that is what we were asked -- the
21 recommendation, or what we took from the presentation
22 was it looked like we were being asked to declare or
23 state that anatomic or physiologic anomalies are
24 considered, and again I'm having to fill in the blanks
25 and make assumptions, but they all would be considered

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1 maybe involuntary actions.

2 That's the part I'm trying to get to, and
3 we just can't do that right now. Yeah, unintentional.
4 So when we -- when I read, and we have it up here,
5 "patient intervention means actions by the patient or
6 human research subject, whether intentional or
7 unintentional, such as," and then we give the examples.
8 "Dislodging or removing devices, or prematurely
9 terminating the administration."

10 So I'm not arguing the merits of
11 this, of these recommendations. I'm just simply
12 pointing out that we have a process that we have to
13 follow, that only certain folks can interpret our
14 regulations. If we want to change the regulations, we
15 have a way to do that and so forth and so on. That's
16 the purpose of my presentation. It's not that we're
17 taking a stance one way or the other on the merits of
18 the argument.

19 DR. ALDERSON: So the question that I
20 heard articulated is, and I know we discussed anatomic
21 anomalies in some depth, that you're saying is do we
22 believe that anatomic anomalies are captured within
23 that statement, and I think the answer is no, they are
24 not. So that if anatomic anomalies are going to be part
25 of this, and I believe the Committee feels that they

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1 should be based on previous discussions, then you need
2 to have some rewording done.

3 MEMBER LANGHORST: No, no.

4 DR. ALDERSON: Let me finish. You need to
5 have -- I think you need to have some rewording done.
6 I don't think it's a legal issue. I think it's a
7 medical issue at this point. Now Sue.

8 MEMBER LANGHORST: Sorry. I say no
9 because you don't want it necessarily in patient
10 intervention, because that drags it into the medical
11 event arena. It's where you put that or where that's
12 considered, and it, you know, again it comes to that
13 definition of what's practice of medicine versus what
14 can be regulated.

15 DR. ALDERSON: Right, okay. Dr.
16 Dilsizian.

17 MEMBER DILSIZIAN: So we did struggle with
18 this and I think again, just to summarize quickly, the
19 dislodging of device was an easy one. Patient
20 accidentally or unintentionally, you know, the device
21 comes out and that's why Rule 1 wasn't changed really.
22 I really do. So we agreed with that.

23 MR. FULLER: Okay.

24 MEMBER DILSIZIAN: The discussion was
25 about physiological or anatomical anomalies. In

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1 essence, the patient didn't do anything wrong or take
2 the Y-90 example.

3 MR. FULLER: Uh-huh.

4 MEMBER DILSIZIAN: You're trying to treat
5 the liver, the gastric artery's adjacent even though
6 they may coin it or not. Then maybe some Y-90 goes
7 backwards and now you have a stomach ulcer, which is
8 what Frank was seeing in his regulatory stage, as he
9 was reviewing these cases.

10 So he brought up the case well, what are
11 we doing? We have these patients having ulcers.
12 Well, how can we prevent it? Well, this is where the
13 discussion started. So even with your best efforts
14 sometimes, you're going to have some reflux. Now there
15 may be permanent damage or temporary long ulceration.
16 Is that something that is reportable or not, and the
17 question ultimately we said these things happen. It's
18 anomalous or physiological that regulators cannot
19 really regulate that, and therefore the conclusion was
20 not to be regulated.

21 So I agree with you. It doesn't fit into
22 this definition, but the question is does it belong
23 anywhere and we should be talking about this.

24 MR. FULLER: And that's why I asked the
25 question the way I did, because if you look at the time

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1 line of, you know, when this information was brought
2 to us, we had a separate recommendation from the ACMUI
3 to change the yttrium-90 microspheres licensing
4 guidance. In that, because it's 35.1000, we can define
5 what is a medical event or what needs to be reported
6 as a medical event.

7 So we made those changes. In those types
8 of situations that Frank described and the ones that
9 you just described are repeated are no longer required
10 to be reported, assuming that folks did the diagnostic
11 studies appropriately prior to the administration. We
12 had already previous to that, and I thank Frank for his
13 clarification.

14 Again, where the arterial spasm is
15 something that we recognize should not have to be
16 reported as a medical event. It's far beyond the
17 control of the licensee. So we changed that licensing
18 guidance and made it clear to the community that those
19 are not medical events. We didn't change the
20 definition of patient intervention to get there, and
21 that's the point of this presentation today.

22 And so that's why I kind of asked, okay,
23 do we still have other instances that we can think of,
24 where the general definition in Part 35 needs to be
25 changed, such that -- and of course we don't know what

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1 the future holds always. But my point, the whole point
2 of this presentation is to let folks know that, you
3 know, we're not taking a stance one way or the other
4 about whether or not the definition ought to be changed.

5 That's why it's more of a legal question
6 rather than a technical question, and again I think you
7 and I are saying the same thing, Dr. Alderson, maybe
8 just coming at it from a different perspective. If in
9 fact the ACMUI wants us to say that anatomic or
10 physiologic anomalies is captured in this definition,
11 that's where I say the legal -- that's where the legal
12 question comes in because again, I don't think any of
13 us believe that.

14 But if that's the stance of the ACMUI, then
15 the lawyers or our Office of General Counsel would have
16 to do that evaluation and analysis and get back to us
17 I think. Anyway, so I'm repeating myself now.

18 DR. ALDERSON: Yes. So I think my sense
19 is the medical community is, you know, I believe that
20 normal variations in human biology, physiology and its
21 interaction with the world can't be, should not -- lead
22 to a medical event. I hear you saying that essentially
23 in the practical sphere, we've kind of dealt with it
24 right now through rulemaking, because it's in the 1000
25 category, which I think is actually true. I don't feel

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1 like there's another issue pushing.

2 But it would seem likely that some other
3 intervention, some new modality will come down the
4 road, and we'll be back to square one with it again,
5 and it might not -- I think it would be wise if it was
6 practical to get it dealt with now. I guess what you're
7 saying is the only real way to do that, there are only
8 two ways to do that.

9 One, ask the lawyers can they read into
10 unintentional in the way we would like it to be, that
11 definition expanded to mean not just unintentional
12 mechanical category but unintentional like I didn't
13 know I was made that way; I didn't mean to be made that
14 way, that made a shunt, right? That would be what we
15 were talking about.

16 And I mean if it's not incredibly
17 burdensome, I think asking the lawyers to try to make
18 that interpretation would be valuable going forward so
19 that issue would be settled. If that's not doable and
20 you say it's rulemaking, and I think we would all
21 probably agree it is not such a pressing issue in a
22 practical sense to go through rulemaking.

23 DR. ALDERSON: Yes, we had a comment.
24 Microphone.

25 MS. COCKERHAM: This is Ashley Cockerham

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1 with Sirtex Medical. Just a comment for -- while I
2 appreciate that it was added to the guidance to allow
3 for these anatomic variations, not all of the Agreement
4 States implement the guidance as written, nor are they
5 required to because Part 35.1000 is Compatibility D.

6 So if something like this was to be added
7 to the definition in Part 35 as 35.2, the Agreement
8 States would be more consistent with I think what the
9 Committee is intending here.

10 DR. ALDERSON: Yes Laura.

11 MEMBER WEIL: Looking at your definition,
12 the existing definition, we were discussing at some
13 meeting, I don't remember which one, patients who have
14 radioactive seed implantation for breast cancer
15 localization, don't return for removal. That's
16 patient intervention, but it's not caught in that
17 definition.

18 I don't know that it rises to the level of
19 medical event, but it's definitely not caught in there.

20 MR. FULLER: Well, I would argue that if
21 someone fails to return, that that is an action.

22 MEMBER WEIL: It's an action, yes.

23 MR. FULLER: And that that action was
24 intentional, and that it resulted in prematurely
25 terminating the administration.

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1 MEMBER WEIL: I don't see prematurely
2 terminating the administration.

3 MR. FULLER: Maybe not prematurely
4 terminating, but prolonging. In other words --

5 MEMBER WEIL: It's interfering with the
6 plan.

7 MR. FULLER: Yeah. Well, here's again.
8 If that question, if that question came to us and we've
9 dealt with that in a different way obviously --

10 MEMBER WEIL: Yeah, several times, yeah.

11 MR. FULLER: Because we could, because
12 it's 35.1000. But if that question came to us --

13 MEMBER WEIL: Oh, it's 1000, okay.

14 MR. FULLER: --then we would have to -- we
15 would have to ask for an interpretation. We would have
16 to -- we would do what's called a technical assistance
17 request and we would say this is what the staff's
18 position is. We believe that this is correct, and then
19 we would ask the attorneys to tell us if we were correct
20 or not.

21 DR. ALDERSON: Dr. Langhorst is next.

22 MEMBER LANGHORST: I would just propose
23 the thought that these types of things may not be
24 appropriate to put in patient intervention, but that
25 there be some other term defined that covers these types

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1 of things, so that licensees and regulators understand
2 this is -- this cannot contribute to a medical event,
3 such as the extravasation, that you don't have to go
4 to your law library to look up all the details on it
5 to get to it.

6 DR. ALDERSON: Mr. Green, you had the next
7 comment.

8 MR. GREEN: Looking at the existing
9 definition, if the last word "administration" was to
10 change to "procedure," would that encompass the
11 patient's localization brachytherapy seed, breast
12 cancer?

13 MS. HOLIDAY: Dr. Alderson, if I can just
14 clarify. Ms. Weil made a comment about the radioactive
15 seed localization guidance and the fact that we called
16 out patients who do not return for their ex-plantation
17 surgery. That's not captured in the medical event
18 reporting portion of that guidance as patient
19 intervention.

20 What that section actually says is that for
21 whatever we say it's a medical event, except for those
22 that result from the intervention of a patient or human
23 research subject, or a patient not returning for their
24 scheduled surgery or the physician determination. I
25 just wanted to clarify that.

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1 DR. ALDERSON: Yes, Mr. Fuller.

2 MR. FULLER: I noticed that our legal
3 counsel, Esther Houseman, has moved to the microphone
4 a while back, and I've probably taken all sorts of
5 liberties. I would just like for you to recognize. I
6 know she had some comments.

7 DR. ALDERSON: Certainly. Ms. Houseman.

8 MS. HOUSEMAN: Yes. I wanted to add just
9 clarification on the service that OGC would provide to
10 help resolve this issue. So first of all, and I'm not
11 incredibly familiar with this particular provision of
12 10 C.F.R. 1.23, but I believe that the paragraph you're
13 referring is typically -- what they're referring to is
14 a public interpretation of law, policy, etcetera.

15 OGC rarely uses that tool. So often if we
16 provide a legal interpretation, it is -- it is advice
17 that OGC provides to its client, the NRC staff. So you
18 won't necessarily see a legal memo authored by me or
19 someone else in OGC. But we do provide assistance on
20 that front. It's just often not public, and I do want
21 to make sure that you understand that.

22 The other thing I want to clarify is OGC's
23 role in helping to resolve an issue like this. What
24 I can assist in doing is helping the staff and taking
25 ACMUI's recommendations into consideration, and

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1 looking at this definition and figuring out is the
2 ACMUI's recommended reinterpretation a reasonable
3 interpretation of the definition that's in 10 C.F.R.
4 right now.

5 If it's not a reasonable interpretation,
6 then the difficulty that you run into is that the agency
7 could unreasonably interpret some regulations, and
8 that would come with litigative risk, and OGC would
9 advise the staff on that.

10 In terms of what the definition should be,
11 that's very much more of a technical question than a
12 legal question. So just so you know on what the
13 definition should be and as Dr. Langhorst mentioned,
14 you know, whether there should be a separate definition
15 and separate term entirely is more of a technical
16 question for you all to discuss, and how to go about
17 revising 10 C.F.R. or reinterpreting the meaning of
18 this definition of patient intervention is something
19 that OGC can assist with.

20 DR. ALDERSON: Okay, thank you. I'd like
21 to -- that's a very good comment, thank you. What we
22 appear to be trying to do here, I don't think we can
23 accomplish it. That's in Part 35 definition, and what
24 I hear you all doing, well-intentioned, is trying to
25 wordsmith that definition. Let's add a word here,

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1 let's take a word out there.

2 That isn't going to go anywhere.
3 Certainly not today and not anywhere when you consider
4 what rulemaking is. So I believe that if we think that
5 this is not an adequate inclusion of all the various
6 things we've talked about, and that that needs to be
7 out there in a more permanent way or a better way than
8 35.1000, then we probably should put a subcommittee
9 together to start working on that, and then create some
10 advice that's more inclusive than this is.

11 But I don't think that sitting here today,
12 you know, we can take it much further by the sort of
13 discussion we're having right now. If someone
14 disagrees with that point, then speak up. You disagree
15 with that point?

16 MEMBER LANGHORST: No. I just --

17 DR. ALDERSON: No?

18 MEMBER LANGHORST: --suggest that maybe
19 the subcommittee that worked on the original thing
20 could take it up.

21 DR. ALDERSON: That would be fine. That
22 would be fine. If that subcommittee would be willing
23 to continue to work on this issue, that would be fine.
24 But right now we're at a point where they can't work
25 with what's up there and what we think. So we've got

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1 to resolve that dilemma. So I will -- Sophie, do you
2 know right now who was on that subcommittee?

3 It should take two minutes. I would
4 suggest that we do that after we take a break. We're
5 ten minutes into the break period, and perhaps Sophie
6 you can come and tell us that when we reconvene at three
7 o'clock.

8 MS. HOLIDAY: I can tell you who the
9 subcommittee members are.

10 DR. ALDERSON: Oh now you can do it. You
11 are very fast.

12 MR. FULLER: And we need to do it before
13 we go to closed session.

14 MS. HOLIDAY: The previous subcommittee
15 members, and I'm going to exclude you Dr. Alderson.

16 DR. ALDERSON: Yes, have to exclude me,
17 right.

18 MS. HOLIDAY: Include Mr. Frank Costello,
19 Dr. Dilsizian as the chair, Dr. Ennis, Dr. Suh and Ms.
20 Laura Weil.

21 DR. ALDERSON: So is that group of five
22 people, are you all willing to take this up further?
23 Yes. Very good.

24 MEMBER COSTELLO: Sure.

25 DR. ALDERSON: Then excellent, good.

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1 Well then that subcommittee will take up this issue,
2 and then report back to us at the spring meeting, yes.

3 MR. FULLER: And can I ask just one
4 housekeeping question, and perhaps Sophie or Michelle
5 can help me with this? So we've had a recommendation.
6 I think it's clear we are unable to implement and follow
7 that recommendation fully. So with this presentation
8 and this new charge to the subcommittee, will we be able
9 to close out that recommendation, that has been sitting
10 out there now -- or actually there's two
11 recommendations that were presented to us last fall.
12 Can we close those?

13 MS. HOLIDAY: We cannot close them until
14 the Patient Intervention Subcommittee presents and the
15 ACMUI votes on the action at the next meeting.

16 MR. FULLER: Okay.

17 DR. ALDERSON: Good. Thank you.
18 Vasken.

19 MEMBER DILSIZIAN: Could we have a staff
20 member to at least direct us what all we can --

21 (Simultaneous speaking.)

22 MEMBER DILSIZIAN: We know what we want to
23 say.

24 MS. HOLIDAY: Your previously
25 appointed --

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1 MEMBER DILSIZIAN: But the question is how
2 we resource.

3 MS. HOLIDAY: I'm sorry. Your previously
4 appointed resource staff person is Ms. Maryann
5 Abogunde.

6 MS. ABOGUNDE: Over here.

7 DR. ALDERSON: Okay, very good. So you
8 have a staff person.

9 MEMBER DILSIZIAN: Okay, good.

10 DR. ALDERSON: Good, thank you. I think
11 at this point let's call this discussion to a close,
12 and we'll now take a shorter break and we will reconvene
13 at three o'clock.

14 (Whereupon, the above-entitled matter
15 went off the record at 2:40 p.m.)

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