

Official Transcript of Proceedings
NUCLEAR REGULATORY COMMISSION

Title: Meeting of the Advisory Committee
on the Medical Uses of Isotopes

Docket Number: (n/a)

Location: Rockville, Maryland

Date: Wednesday, April 3, 2019

Work Order No.: NRC-0262

Pages 1-209

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UNITED STATES OF AMERICA
 NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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SPRING 2019 MEETING

+ + + + +

WEDNESDAY,

APRIL 3, 2019

+ + + + +

The meeting was convened in Room 1-C03/1-C05, Three White Flint North, 11601 Landsdown Street, Rockville, Maryland, at 8:30 a.m., Christopher J. Palestro, ACMUI Chairman, presiding.

MEMBERS PRESENT:

CHRISTOPHER J. PALESTRO, M.D., Chairman

DARLENE F. METTER, M.D., Vice Chairman

VASKEN DILSIZIAN, M.D., Member

RONALD D. ENNIS, M.D., Member

RICHARD L. GREEN, Member

MELISSA MARTIN, Member

MICHAEL D. O'HARA, Ph.D., Member

ZOUBIR OUHIB, Member

ARTHUR SCHLEIPMAN, Ph.D., Member

MICHAEL SHEETZ, Member

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MEGAN L. SHOBER, Member

LAURA M. WEIL, Member

NON-VOTING MEMBER PRESENT:

HARVEY B. WOLKOV, M.D.

NRC STAFF PRESENT:

CHRIS EINBERG, NMSS/MSST/MSEB, Designated
Federal Officer

MARYANN AYOADE, NMSS/MSST/MSEB/MRST

JENNIFER DALZELL, R-III/DNMS/MCIB

SAID DIABES-FIGUEROA, NMSS/MSST/MSEB/MRST

LISA DIMMICK, NMSS/MSST/MSEB/MRST, Team Leader

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KEVIN WILLIAMS, NMSS/MSST, Deputy Division
Director

IRENE WU, NMSS/MSST/MSEB/MRST

MEMBERS OF THE PUBLIC PRESENT:

JENNA ABBOTT, Illinois Emergency Management
Agency (IEMA)

DANNY ALLEN, NuTech, Inc.

ERIC ANDERSEN, Dana-Farber Cancer Institute

MICHAEL BAXTER, American Pharmacists Association

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

KENDALL BERRY, Fox Chase Cancer Center

JEFF BRUNETTE, Mayo Clinic

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ANDREW MCKUSICK, *Unknown*

ASHLEY MISHOE, University of California, San
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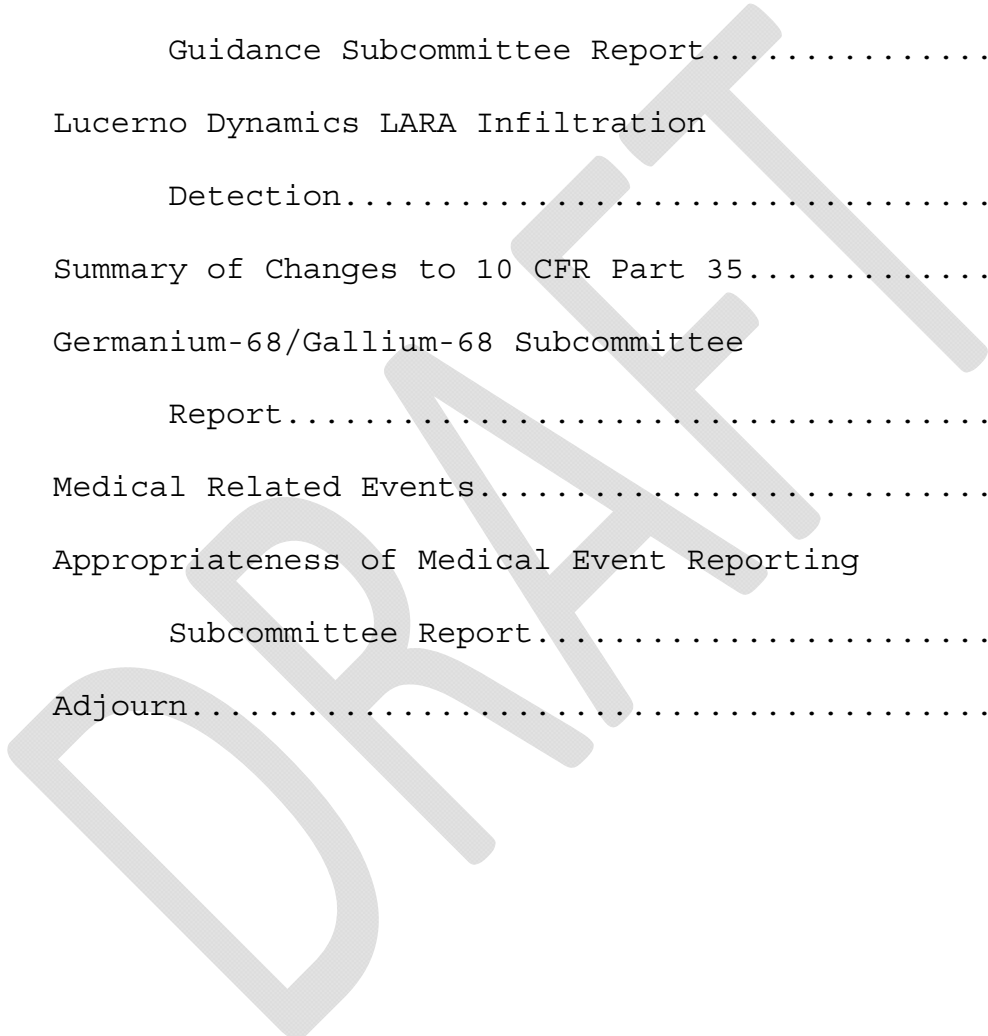
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P R O C E E D I N G S

8:36 a.m.

1
2
3 CHAIRMAN PALESTRO: Good morning, and
4 welcome to the spring meeting -- spring 2019 meeting
5 of the ACMUI. And at this point, I will turn the
6 meeting over to Mr. Einberg for opening remarks.

7 MR. EINBERG: Okay. Thank you, Dr.
8 Palestro. As the designated federal officer for this
9 meeting, I'm pleased to welcome you to this public
10 meeting of the Advisory Committee on the Medical Uses
11 of Isotopes.

12 My name is Chris Einberg. I'm the Branch
13 Chief of the Medical Safety and Events Assessment
14 Branch, and I have been designated as the federal
15 officer for this advisory committee in accordance with
16 10 CFR Part 7.11. Present today as the designated
17 federal officer is Sophie Holiday. Also as a
18 designated officer and ACMUI coordinator is Kellee
19 Jamerson.

20 This is an announced meeting of the
21 committee. It is being held in accordance with the
22 rules and regulations of the Federal Advisory
23 Committee Act and the Nuclear Regulatory Commission.
24 This meeting is being transcribed by the NRC and then
25 may also be transcribed or recorded by others. The

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1 meeting was announced in the February 19th, 2019
2 edition of the Federal Register, Volume 84, Page 4858.

3 The function of the committee is to advise
4 the staff on issues and questions that arise on the
5 medical use of byproduct material. The committee
6 provides counsel to the staff but does not determine
7 or direct the actual decisions of the staff or the
8 Commission.

9 The NRC solicits the views of the
10 committee and values their opinions. I request that
11 whenever possible, we try to reach consensus on the
12 various issues that we will discuss today. But I also
13 recognize there may be minority or dissenting
14 opinions. If you have such opinions, please allow
15 them to be read into the record.

16 At this point, I would like to perform a
17 roll call of the ACMUI members participating today.
18 Dr. Christopher Palestro, Chairman, Nuclear Medicine
19 Physician?

20 CHAIRMAN PALESTRO: Present

21 MR. EINBERG: Dr. Darlene Metter, Vice
22 Chairman, Diagnostic Radiologist?

23 VICE CHAIRMAN METTER: Present.

24 MR. EINBERG: Dr. Vasken Dilsizian,
25 Nuclear Cardiologist?

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1 MEMBER DILSIZIAN: Present.

2 MR. EINBERG: Dr. Ronald Ennis, Radiation
3 Oncologist?

4 MEMBER ENNIS: Here.

5 MR. EINBERG: Mr. Richard Green, Nuclear
6 Pharmacist?

7 MEMBER GREEN: Present.

8 MR. EINBERG: Ms. Melissa Martin, Nuclear
9 Medicine Physicist?

10 MEMBER MARTIN: Present.

11 MR. EINBERG: Dr. Michael O'Hara, FDA
12 Representative?

13 MEMBER O'HARA: Present.

14 MR. EINBERG: Mr. Zoubir Ouhib, Radiation
15 Therapy Physicist?

16 MEMBER OUHIB: Present.

17 MR. EINBERG: Dr. A. Robert Schleipman,
18 Healthcare Administrator?

19 MEMBER SCHLEIPMAN: Present.

20 MR. EINBERG: Mr. Michael Sheetz,
21 Radiation Safety Officer?

22 MEMBER SHEETZ: Present.

23 MR. EINBERG: Ms. Megan Shober, State
24 Government Representative?

25 MEMBER SHOBER: Present.

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1 MR. EINBERG: Ms. Laura Weil, Patients'
2 Rights Advocate?

3 MEMBER WEIL: Present.

4 MR. EINBERG: At the table today, we also
5 have Dr. Harvey Wolkov. Dr. Wolkov has been selected
6 as the ACMUI Radiation Oncologist. He is pending a
7 security clearance but may participate in the meeting.
8 However, he does not have voting rights at this time.

9 I would also like to add that this meeting
10 is being held via GoToWebinar so other individuals may
11 be listening through webinar. The webinar ID number
12 is 144-519-715. You must register for the webinar in
13 order to obtain the bridge line and unique pin
14 assigned per individual.

15 Individuals who would like to ask
16 questions or make comments regarding a specific issue
17 the committee has discussed should request permission
18 to be recognized by the ACMUI chairperson, Dr.
19 Christopher Palestro. Dr. Palestro, at his option,
20 may entertain comments or questions from members of
21 the public who are participating with us today.

22 Comments and questions are usually
23 addressed by the committee near the end of the
24 presentation after the committee has fully discussed
25 the topic. We ask that one person speak at a time as

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

4 At this point, I'd like to turn the
5 meeting over to Kevin Williams who's the Deputy
6 Director of the Division of Materials Safety,
7 Security, State, and Tribal Programs for some opening
8 remarks.

9 MR. WILLIAMS: Thank you, Chris. Good
10 morning and welcome today to the spring 2019 meeting.

11 As Chris stated, my name is Kevin Williams. I am the
12 Deputy Director in the Division of Materials Safety,
13 Security, State, and Tribal Programs in the Office of
14 Nuclear -- sorry about that -- Materials Safety and
15 Safeguards, or as we commonly call it, NMSS. I
16 started this position in May of 2017.

17 I want to first begin by thanking ACMUI
18 for all of your hard work and support to the NRC. We
19 greatly appreciate that. We truly value your
20 contributions, your knowledge, and your experience. I
21 would like to highlight a few areas that may be of
22 interest to ACMUI and the meeting attendees.

23 The final rule of 10 CFR Part 35, the
24 Medical Use of Byproduct Material-Medical Event
25 Definitions, Training and Experience, and Clarifying

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1 Amendments, was published on July 16th of 2018 and
2 became effective January 14th, 2019. I, again, would
3 like to thank the ACMUI on your work with the staff on
4 this major initiative.

5 In October of 2018, the staff published a
6 Federal Register notice requesting specific feedback
7 on our training and experience requirements, including
8 whether requirements should be tailored, and if so,
9 how. The comment period ended on January 29th of
10 2019. The staff is considering the comments received
11 as part of its evaluation and plans to provide for
12 Commission's consideration a notation vote by the fall
13 of 2019.

14 On May 14th, 2019, the NRC staff plans to
15 hold a public meeting to inform stakeholders of the
16 staff's proposed options for a limited scope AU
17 pathway. Once the date has been confirmed, a meeting
18 notice will be published in the Federal Register,
19 announced on the medical list server, and directly
20 communicated with ACMUI.

21 Shortly after the May 2019 public meeting,
22 the NRC staff will draft its Commission paper. The
23 paper will be provided to the ACMUI for its review.
24 We anticipate receiving the ACMUI's comments on the
25 staff's draft Commission paper during a public

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1 teleconference meeting in the summer of 2019.

2 On March 27th, 2019, the ACMUI Regulatory
3 Guide 8.39 subcommittee was provided with NRC's
4 staff's draft revision to Regulatory Guide 8.39. We
5 look forward to receiving the subcommittee's comments
6 and recommendations as part of a separate
7 teleconference meeting this summer.

8 We recognize that the ACMUI had a public
9 teleconference on February 26, 2019 to discuss the T&E
10 for all modalities subcommittee draft report for T&E
11 requirements for 35.300 uses. As stated in the
12 report, the subcommittee recommends maintaining the
13 current board certification pathway and the 700-hour
14 T&E alternative pathway under 10 CFR 30.390 which is
15 consistent with the full committee's position in 2016.

16 Thank you to the subcommittee for its efforts.

17 Now to talk about some NRC organizational
18 changes. The Office of Nuclear Material Safety and
19 Safeguards, or NMSS, Marc Dapas retired. He was the
20 Office Director. He retired in January of 2019. John
21 Lubinski is now going to be the NMSS Office Director,
22 and he began Monday, April 1st of 2019. John will be
23 stopping by to speak with us during the luncheon.

24 Andrea Kock was selected as the Division
25 Director of Material Safety, State, and Tribal

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1 Programs in November of 2018. Dan Collins previously
2 held that position, and he has taken a position at
3 Region I. Andrea is on travel today. Otherwise, she
4 would be the one speaking with you. But she really
5 wanted me to let you know that she appreciates ACMUI's
6 efforts and all that you do to help the NRC think
7 outside of the box and the things that you provide the
8 staff.

9 We recently just underwent a
10 reorganization. Specifically, we consolidated from a
11 five branch model to a four branch model. This
12 resulted in an additional staff member being added to
13 the medical group.

14 Additionally, NMSS is planning an office-
15 wide reorganization in which two divisions will merge,
16 our fuel cycle division and the division of spent
17 fuel. The Division of Rulemaking will expand to
18 include two new centers of expertise, one for
19 environmental review and one for financial assurance.

20 This reorganization is not expected to occur until
21 fiscal year 20 and will have no impact on our
22 division, MSST.

23 ACMUI membership changes. This is Ms.
24 Laura Weil's last in-person meeting as her second term
25 with ACMUI ends in August. Many thanks to you for

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1 your contributions over the past eight years. We
2 found those to be very valuable. Tomorrow morning,
3 our Deputy Office Director, Scott Moore, will be here
4 to present you with a special presentation thanking
5 you for your service.

6 Dr. Chris Palestro's second term will end
7 in September. The NRC posted a solicitation for both
8 the Patients' Rights Advocate and the Nuclear Medical
9 Physician representative positions in the Federal
10 Register as a call for nominations on February 20th,
11 2019. The nomination period closes April 22nd, 2019.

12 So that does leave us an opportunity to celebrate
13 your contributions, Dr. Palestro, at a later time.

14 The ACMUI subcommittees have been working
15 hard, and there are a number of subcommittee reports
16 that will be discussed and brought before the ACMUI
17 today.

18 Dr. O'Hara will discuss the subcommittee's
19 recommendations on NRC's draft revision 10 to the
20 Yttrium-90 Microsphere Brachytherapy Licensing
21 Guidance.

22 Ms. Shoher will discuss the subcommittee's
23 recommendations on the NRC's draft revision to the
24 Germanium Gallium Pharmacy Grade Generator Licensing
25 Guidance.

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1 Dr. Ennis will discuss the subcommittee's
2 interim report on the appropriateness of the required
3 elements of medical event reporting.

4 This morning, Lucerno Dynamics will
5 provide a presentation on their LARA Infiltration
6 Detection device which assists with detecting nuclear
7 medicine injection infiltrations.

8 The Commission meeting with the ACMUI will
9 be held tomorrow at 10:00 a.m. at the Commissioner's
10 hearing room.

11 I will now turn the meeting back over to
12 Dr. Palestro.

13 CHAIRMAN PALESTRO: Thank you, Mr.
14 Williams. Next item on the agenda is old business.
15 Ms. Holiday will review the past ACMUI recommendations
16 and provide NRC responses. Ms. Holiday?

17 MS. HOLIDAY: Give me just one minute as I
18 pull up the PDF, and excuse my hoarse voice.

19 (Pause.)

20 MS. HOLIDAY: Okay. Good morning. So
21 like I always like to say, this is your most favorite
22 presentation that you will hear at every single
23 meeting, and this is referred to as old business.
24 This is the part of the meeting where we review all of
25 the open or pending or open delayed recommendations or

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1 actions that have come forth from the committee.
2 Luckily at the last fall ACMUI meeting, a lot of the
3 recommendations were closed. So my voice is very
4 grateful for that.

5 On the screen, you see the 2007 chart. As
6 we always say, Items 33 and 34 are related to 35.491.

7 These are listed as open and delayed, and that means
8 that the NRC staff accepted these recommendations.
9 However, they were not included in the Part 35
10 rulemaking that we just completed and issued last
11 year. So that means it will be considered in the next
12 round of rulemaking.

13 Okay. Now what you see on the chart is
14 2008. Again, the same things for Items 19, 26, and
15 27. These all say open delayed because they were not
16 included in the current or the most recently issued
17 Part 35 rule. They will be considered in the next
18 round of rulemaking. So we leave those on the charts.

19 Okay. Item 6 in 2011 is the loan item for
20 the chart, and this is where the ACMUI created an item
21 to review its reporting structure on an annual basis.

22 It is open indefinitely as this is an item that the
23 committee has recommended that we discuss every single
24 year. You will hear that presentation from Ms. Kellee
25 Jamerson later on tomorrow -- or tomorrow morning,

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1 sorry.

2 So this brings us to the 2016 chart. The
3 first item is the formation of the training and
4 experience requirements for all modalities in 10 CFR
5 Part 35 subcommittee. This item is open indefinitely.

6 The idea is that this group of individuals or this
7 subcommittee body will review the training and
8 experience requirements for all authorized users under
9 Part 35 on a continual basis.

10 While it does not mean that it's evaluated
11 every year, it means that this subcommittee will
12 review these requirements on a frequent basis to
13 determine if those requirements need to change. As
14 you're aware, we had a teleconference just two months
15 ago where that subcommittee provided a report.

16 The second item, Item 24, is that the
17 ACMUI, as part of its efforts to partner with NRC to
18 do a better medical community outreach, the members on
19 the committee agreed to contact and interact with
20 their respective professional organizations to
21 encourage those interactions. So we've benefitted
22 quite greatly. We've had interactions and
23 presentations at SNMMI, AAPM, ACR. Later on this
24 summer, we will have one at HPS. So thank you for
25 those efforts.

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1 Item 39 is related to where the committee
2 requested that the NRC staff issue a generic
3 communication and information notice regarding tubing
4 issues during the administration of Yttrium-90
5 microspheres brachytherapy. That item is still
6 pending. We have not issued a generic communication.
7 So that's still on this chart.

8 Item 42 and 43 are related to
9 recommendations from the same Yttrium-90 microspheres
10 subcommittee for modifications to the Yttrium-90
11 microspheres licensing guidance. You will hear from
12 that subcommittee later on today as well.

13 Items 44 through 53 are related to the
14 NorthStar licensing guidance. While this licensing
15 guidance was issued a couple of years ago, we've left
16 these items on the chart until, as the ACMUI
17 requested, the NRC staff issue its memorandum to the
18 committee to inform you of how we dispositioned your
19 recommendations.

20 We had anticipated that this memorandum
21 would come this week. But since it has not, we will
22 leave these items on the chart until it does come
23 forth. So I suspect that we will request that there be
24 a motion at the fall meeting to close these items.
25 But until then, they will remain on these charts.

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1 Okay. So that brings me to the 2017
2 recommendations and actions chart. The first item is
3 that the committee requested the changes to the Part
4 35 rulemaking be reviewed and discussed at the ACMUI
5 meeting. At the time that the recommendation was
6 made, the rule had not been published yet. However,
7 it has been published and it went into effect in
8 January of this year for NRC licensees. So you will
9 hear a presentation from Ms. Lisa Dimmick today at
10 10:45 a.m. regarding the Part 35 rule.

11 Items 13 through 20 are related to the
12 medical event reporting and impact on medical licensee
13 patient safety culture subcommittee's report. Excuse
14 me. I have left these items as open on the chart
15 because, again, a memorandum has not come forth to the
16 committee to inform you of how NRC has dispositioned
17 your recommendations. My understanding is that I
18 think Mr. Doug Bollock perhaps gave a presentation a
19 year ago. But again, no formal recommendation, so
20 these items will stay on the chart.

21 Okay. This brings us to 2018. Item 1 and
22 Item 2 are related to the nursing mothers' guidelines
23 subcommittee report. These two items are also tied to
24 a couple of other items later on the chart. But the
25 subcommittee finalized that report. The ACMUI

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1 endorsed the report with a modification for some
2 language regarding FDA approved radiopharmaceuticals.
3 That was passed at the September meeting.

4 However, we have left these open because
5 my understanding is that, one, a memorandum has not
6 been issued to the ACMUI, and two, the intent is that
7 the NRC staff consider this as part of its changes to
8 Regulatory Guide 8.39. So until such time, this item
9 will also stay open on the chart.

10 Items 3, 4, and 5 are related to the
11 physical presence requirements subcommittee report.
12 They were also superseded by the subcommittee's report
13 that was presented at the fall 2018 meeting related to
14 the Leksell Gamma Knife Perfexion and Leksell Gamma
15 Knife Icon licensing guidance.

16 So for Items 3 through 5, and I'll have to
17 follow up with the other item that corresponds to
18 this, I have marked these as closed. And this is my
19 asking the committee if there is a motion to close
20 Items 3 through 5 because the NRC staff issued the
21 licensing guidance on January 29th of this year. And
22 the subcommittee report that came forth from the
23 committee stated that the committee endorsed the NRC
24 agreement state working group's draft guidance.

25 So at this time, is there a motion?

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1 MEMBER ENNIS: So moved.

2 MS. HOLIDAY: Dr. Ennis. Is there a
3 second?

4 MEMBER DILSIZIAN: Second.

5 MS. HOLIDAY: And do we have a vote to
6 close these items?

7 CHAIRMAN PALESTRO: All in favor?

8 MS. HOLIDAY: It's unanimous. Thank you.
9 Okay. Thank you.

10 Item 6 and Item 7 are both open
11 indefinitely. Items -- this is where NRC staff took
12 an action to create a recommendations web page.
13 Again, this is so that the ACMUI and future members
14 and members of the public are able to see historical
15 information as it relates to the recommendations and
16 actions that have come forth from this committee. So
17 last year, that website went live and we anticipate
18 updating it at least on an annual basis.

19 Item 7 is where we, NRC staff, agree to
20 send out a medical list server announcement to inform
21 the ACMUI -- to inform members of the public who are
22 subscribed to the list server every time that the
23 medical event slides are posted onto the medical tool
24 kit. These slides are for the PowerPoint
25 presentations that both the ACMUI gives and that the

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1 NRC staff gives.

2 As are you aware, in the springtime, the
3 NRC staff provides that presentation. And in the fall
4 time, the ACMUI subcommittee provides that
5 presentation. And all of the presentations have been
6 loaded, including the subcommittee's slides from the
7 most recent fall 2018 meeting.

8 Okay. Item number 9 is the other item
9 that was related to the physical presence requirements
10 for the Leksell Gamma Knife Icon subcommittee. So
11 similar to Items 3 through 5, I am asking if there is
12 a motion to close Item number 9. Dr. Ennis. Is there
13 a second?

14 VICE CHAIRMAN METTER: Second.

15 MS. HOLIDAY: Dr. Metter.

16 CHAIRMAN PALESTRO: All in favor?

17 MEMBER SCHLEIPMAN: I just had a quick
18 question.

19 MS. HOLIDAY: Yes.

20 MEMBER SCHLEIPMAN: I realize after I
21 voted. I think my security clearance is still --

22 MS. HOLIDAY: No, you have a full security
23 clearance, Dr. Schleipman.

24 MEMBER SCHLEIPMAN: Okay, thank you. They
25 were just in my office.

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1 (Simultaneous speaking.)

2 MS. HOLIDAY: No, you are perfect. Thank
3 you.

4 MEMBER SCHLEIPMAN: Thank you.

5 MS. HOLIDAY: Okay. Item 11 is, again,
6 tied to the nursing mother guidelines subcommittee
7 report. As I stated not too long ago, this item will
8 be left open until the NRC staff dispositions it and
9 considers it as part of the revision to Regulatory
10 Guide 8.39.

11 Oh, Item 12 is also related to the Leksell
12 Gamma Knife Perfexion Icon. Is there a motion to
13 close Item 12? Dr. Ennis and Dr. Metter. Is there a
14 vote? It is unanimous.

15 Okay. Item 13 is where NRC staff
16 committed to providing the ACMUI with a copy of the
17 briefing on the Agency Action Review Meeting, also
18 known as the AARM, specifically, the presentation
19 slides related to the Yttrium-90 microspheres. And I
20 believe Ms. Kellee Jamerson provided that to the ACMUI
21 last week.

22 So at this time, I'd like to ask if there
23 is a motion to close Item 13. Dr. Metter. Do we have
24 a second? Dr. O'Hara. And is there a vote? It is
25 unanimous. Thank you.

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1 Item 14, Dr. Palestro amended the
2 membership of the training and experience for all
3 modalities subcommittee. I've left this item on here
4 because, for obvious reasons, this subcommittee is
5 still active.

6 Okay. Item 15, Dr. Palestro formed a
7 subcommittee to review the germanium/gallium-68
8 pharmacy grade generator licensing guidance. We will
9 hear from that subcommittee later on today with their
10 subcommittee report.

11 Item 16, Dr. Palestro formed a
12 subcommittee to review the revisions to Regulatory
13 Guide 8.39, release of patients administered
14 radioactive material. Excuse me. The draft
15 Regulatory Guide 8.39 -- no, sir. Thank you. Pardon
16 the interruption. The draft Regulatory Guide 8.39 was
17 provided to the respective subcommittee members last
18 week. And we anticipate that there will be a
19 teleconference this summer to receive the
20 subcommittee's recommendations and to have a
21 discussion with the committee.

22 Item 17, Dr. Palestro formed a
23 subcommittee to review Yttrium-90 microspheres
24 brachytherapy sources and devices, TheraSphere and
25 SIR-Spheres licensing guidance. We will hear from

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1 that subcommittee later on today.

2 Item 18, Dr. Palestro formed a
3 subcommittee to review and update the ACMUI bylaws as
4 needed, including a review of the role of the ACMUI
5 chair in his or her participation on subcommittees.
6 We will hear from that subcommittee tomorrow.

7 Item 19, Dr. Palestro formed a
8 subcommittee to review the appropriateness of the
9 required elements of medical event reporting, the
10 adherence to these requirements, and recommend actions
11 to improve reporting. We will hear from that
12 subcommittee later on today. The subcommittee's
13 report for this particular topic is an interim report.

14 Item 20, the committee recommended that
15 the NRC draft an information notice on the best
16 practices that could help prevent medical events. The
17 NRC staff accepted this recommendation and will draft
18 such a generic communication pending resource
19 availability.

20 Item 21, the committee requested a list of
21 all of the current ACMUI members, their contact
22 information, information regarding each member's term,
23 and the subcommittees they serve on. The committee
24 also requested that the NRC staff create a web page
25 that lists the active subcommittees and subcommittees

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1 that have been sunset, their members, the term
2 expiration, NRC staff resource, and the specific
3 charge of the subcommittee.

4 I perhaps have jumped the gun putting
5 closed on this. However, the latter part of the
6 action, we did create ACMUI subcommittee's web page,
7 and that went live yesterday. And this information
8 was shared with the committee last night. And I do
9 have a contact sheet which will be circulated. So
10 perhaps we will review closing this item during the
11 administrative closing part tomorrow.

12 Item 22, the committee tentatively
13 scheduled the spring 2019 meeting for April 15th and
14 16th. And alternate meetings date are April 3rd and
15 4th subject to Commission availability. We're here
16 today. It's April 3rd. Is there a motion to close
17 this item? I saw Dr. Ennis and Dr. Metter. Is there
18 a vote to close this item? It is unanimous.

19 Okay. We're on our last chart. So as I
20 stated earlier, we had a teleconference meeting in
21 February, specifically February 26th, to receive the
22 subcommittee's report as it related to the training
23 and experience requirements for authorized users under
24 35.390.

25 Item 1, the committee recommended adding

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1 language into the report regarding the committee's
2 desire to work with the NRC staff to develop a
3 curriculum for limited scope authorized user pathway.

4 So that language was added into the final report.
5 And Item 2 is that the committee endorsed the training
6 and experience requirements for all modalities
7 subcommittee report and the recommendations included
8 therein.

9 So I guess my question to the committee
10 is, is there a motion to close either items? My
11 recommendation would be that the committee close Item
12 1 because that's an administrative item just to add
13 the language into the report. However, the committee
14 may consider leaving Item 2 open as the NRC staff has
15 not done anything in terms of issuing any revisions or
16 putting out an official statement on whether or not
17 there will be changes to 35.390

18 VICE CHAIRMAN METTER: I move that we
19 close Item 1.

20 MS. HOLIDAY: Did you hear that, court
21 reporter? Okay. So for the record, Dr. Metter made
22 the motion. Dr. Schleipman seconded. Is there a
23 vote? It is unanimous.

24 Okay. That concludes old business. Yes
25 ma'am?

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1 MEMBER WEIL: I had a question for you.
2 If you can just go back to 2016, Item 39. This
3 relates to the generic communication about tubing
4 issues.

5 MS. HOLIDAY: Yes.

6 MEMBER WEIL: So that's a 2016, and it's
7 2019. And it's still open. Can you explain that?

8 MS. HOLIDAY: Dr. Katie Tapp will come to
9 the microphone to address your question.

10 DR. TAPP: This is Dr. Tapp. That generic
11 communication was in regard to the Yttrium-90
12 microsphere brachytherapy and specifically it was in
13 regard to kinking, connection, hub, et cetera. When
14 the staff began evaluation of that, we realized that
15 the kinking and connection was related to the catheter
16 and the selection of the catheter. And we were really
17 delving into that and determined that was very much
18 practice of medicine. And we were concerned if we
19 issued guidance, we would be providing something that
20 would be interfering with the practice of medicine.

21 What the staff is considering now is
22 issuing a generic communication in a careful manner
23 that just alerts licensees that these are happening
24 and that they have to be diligent in their selection
25 with other medical events related to Y-90 and ways to

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1 prevent them. So we are working on that one now to
2 close it. But in 2016, we evaluated it and just
3 didn't release it at that time.

4 MEMBER WEIL: So when do you expect this
5 communication to be available? I mean, it's been
6 three years. Patients are endangered. And I'm not
7 sure I agree with you that it's a practice in medicine
8 issue but defer to NRC policy on that. It just seems
9 to me that this is not a complicated thing and that I
10 think the medical community would appreciate the
11 notification.

12 DR. TAPP: We do expect that to be out
13 this year.

14 CHAIRMAN PALESTRO: Any other comments or
15 questions from the committee?

16 MEMBER OUHIB: I'm just curious. If there
17 is such what I consider as a defect perhaps, should
18 that fall under the FDA?

19 MEMBER O'HARA: If it is a product defect,
20 it does fall under the FDA. It would be our
21 jurisdiction to look at it.

22 MEMBER OUHIB: Right. So would you
23 consider this as a defect, the kinking? If a catheter
24 is kinking which should not be?

25 MEMBER O'HARA: I can't talk about FDA's -

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1 - what we're currently doing. But we are looking at
2 that.

3 CHAIRMAN PALESTRO: Thank you. Any other
4 comments or questions? Mr. Sheetz?

5 MEMBER SHEETZ: The NRC may want to
6 consider including this recommendation on appropriate
7 catheter use for Y-90 microspheres and including it in
8 the guidance document that was requested from the
9 subcommittee on best practices to avoid a medical
10 event. Because that was one of the issues that was
11 brought up with respect to the Y-90 microspheres. So
12 you may be able to accomplish both items with one
13 guidance document.

14 CHAIRMAN PALESTRO: Any other comments,
15 questions? Right. Move on to the next item on the
16 agenda which is the open forum. Are there any topics,
17 medical topics of interest that anyone wishes to bring
18 up for discussion? Dr. Ennis?

19 MEMBER ENNIS: Actually, this really is
20 just kind of a continuation of the prior conversation.

21 I was going to ask the same thing as Ms. Weil, and
22 there's some things from 2017 that also are still
23 open. I'm wondering whether this committee needs to
24 look at timeliness of the responsiveness and perhaps
25 make some recommendations about improving that.

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1 CHAIRMAN PALESTRO: Actually, you raise an
2 interesting point, Dr. Ennis. One of the questions
3 that I have is some of these items are open because
4 the memorandum from staff has not been issued yet.
5 And I believe, and there were a lot of items, that
6 some of them go back perhaps two years; is that
7 correct? So is there a requirement or a definition of
8 timeliness for such a memorandum?

9 MS. HOLIDAY: NRC staff doesn't have a
10 defined date for when it should issue. We do try our
11 best to be timely in our responses to both ACMUI and
12 members of the public. However, as you guys are
13 aware, the medical team has suffered great resource
14 constraints. I, myself, was gone for roughly nine
15 months, and there have been some rotations and other
16 shifts on the team as well.

17 So we've had to prioritize our work based
18 on the direction that we received both from the
19 Commission and from our senior management. However,
20 the -- for example, the NorthStar guidance memorandum,
21 the staff member that was responsible for that has
22 been directed to other projects as well. And
23 understanding that, just like the ACMUI members here,
24 everybody is a subject matter expert for their
25 respective field. And so the individuals that are

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1 responsible for some of these items, they are one of
2 the few that can also respond to them.

3 However, we have tried our best to try to
4 go back and go through the charts and resolve any open
5 items to the best of our ability. The NorthStar
6 guidance memorandum should be coming out ideally by
7 the end of this week or next week. So for things like
8 that with the memorandums, some of it may be
9 oversight. Some of it may just be resource
10 constraints.

11 But ideally, we do our best to -- and this
12 is a Sophie fictitious time line. We try to issue a
13 memorandum reasonably within 60 days. But sometimes
14 that can't happen because of other higher priority
15 work issues.

16 MR. EINBERG: Dr. Palestro?

17 CHAIRMAN PALESTRO: Yes, Mr. Einberg?

18 MR. EINBERG: Yeah, Chris Einberg here.
19 Yeah, thank you, Sophie, for that explanation. We'll
20 take a look at the list and go through there and see
21 if we can prioritize these and make sure that they get
22 closed in a timely fashion.

23 CHAIRMAN PALESTRO: Thank you. Other
24 comments? Dr. Dilsizian?

25 MEMBER DILSIZIAN: Thank you, Dr.

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1 Palestro. Recently, we received an important drug
2 safety information from the FDA. It's relating to
3 CardioGen Rubidium-82 generator which is used quite
4 commonly for myocardial perfusion imaging. And the
5 subject matter is that there's been a recent shortage
6 in normal saline. And you need the normal saline to
7 do the generator.

8 And the pharmacies have been sending
9 instead of normal saline Lactated Ringer's solution.
10 The problem with the Lactated Ringer's solution is
11 that it has calcium in it and that's not good because
12 calcium exchanged with strontium results in strontium-
13 82 and strontium-85 with half-lives of 30 days or a
14 month, 25 days or two months. And that goes to bone
15 marrow and results in excess radiation exposure to
16 patients.

17 The memo says patients were exposed to
18 such high levels of radiation. I guess that's how
19 they found out about it. And the question is, is this
20 simply a medical event or should the NRC be addressing
21 this?

22 CHAIRMAN PALESTRO: Comments, responses to
23 Dr. Dilsizian?

24 MEMBER GREEN: This is Mr. Green. Not
25 having read the directions for use for the CardioGen

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1 or the Ruby-Fill, I'm fairly certain that the license
2 commitments when a licensee obtains one or permission
3 to have one, they commit to following the
4 manufacturer's directions for use. And apparently, if
5 they're substituting other solutions for elution
6 purposes, they're not following directions for use.

7 DR. HOWE: This is Dr. Howe. The events
8 have been happening in the state of Colorado which is
9 an agreement state. And we have been in contact with
10 Colorado, and there were medical events associated
11 with it.

12 My understanding is that a patient that
13 had a strontium rubidium procedure was at the hospital
14 for a different reason. And a survey was done, and
15 they were determined to be radioactive when they
16 weren't expected to be. And that's how the events
17 were identified, then they went back and saw that they
18 had about eight medical events -- six to eight with a
19 strontium breakthrough. It was too high. So we do
20 have medical events. Okay?

21 But we don't have all the information yet.
22 Colorado is still collecting information. And we're
23 anticipating putting out maybe a generic communication
24 to remind people about the issues associated not only
25 with this series of medical events which was a Lugol's

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1 solution with the calcium. But also the previous one
2 from Nevada and Florida where individuals were not
3 eluding the generators correctly or were overusing the
4 generators.

5 There was also an issue here with the
6 licensee not understanding that the generators had
7 breakthrough even though they were performing a
8 breakthrough measurement. So there are many issues
9 here.

10 CHAIRMAN PALESTRO: I think the question
11 is -- or certainly one question that arises is, can
12 the NRC do anything proactively to reduce the
13 likelihood of some of these events occurring?

14 DR. HOWE: We already have guidance and
15 requirements for licensees to perform the breakthrough
16 test. We have new requirements that went into effect
17 in January for licensees to report breakthrough when
18 they discover it to the NRC and to the distributor
19 within seven days. So we have regulatory elements
20 that would help discover these. But when you've got
21 individuals that are doing breakthrough and they don't
22 understand the results that they're getting and they
23 don't identify that they have breakthrough in a timely
24 matter. It is an issue.

25 So that is our biggest problem right now

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1 is people don't appreciate that they have breakthrough
2 and don't take quick action on it. It's set up so
3 that they -- if they recognize breakthrough, they
4 should not be using the material on patients. But
5 because they're not recognizing, patients are getting
6 overexposed.

7 CHAIRMAN PALESTRO: Thank you.

8 MS. KUBLER: Hi, good morning. Caitlin
9 Kubler with the Society of Nuclear Medicine. We were
10 also alerted to this and we have had a couple
11 different conference calls. And we are working with
12 ASNC. We are actually scheduled to send out a release
13 to our members to remind them that this is standard of
14 practice.

15 We did some informal surveying amongst our
16 members, and the feedback that we got was positive,
17 that most of our members are aware that this is
18 standard of practice. The Lactated Ringer's are not
19 supposed to be used. The feedback that we did get
20 where those situations occurred were incorrect or it
21 was an accident, the person that grabbed the
22 accidental Lactated Ringer and then did not notice
23 that they had done so.

24 So we are sending that alert out with ASNC
25 today just to remind our members that this is standard

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1 of practice and to be aware. And if there is a
2 situation that they have noticed a Lactated Ringer has
3 been attached, to immediately stop the infusion. And
4 of course, we work with Bracco to make sure that the
5 language that we are sending out is accurate and what
6 is required.

7 Thank you.

8 CHAIRMAN PALESTRO: Mr. Ouhib?

9 MEMBER OUHIB: Yeah. I guess my feeling
10 is listening to this, should the manufacturer send out
11 a notice that all users should respond to with some
12 sort of a form that they will have to sign and confirm
13 that they fully understand the process? This is
14 something that probably needs to be done in my
15 opinion.

16 CHAIRMAN PALESTRO: I'm not sure that
17 that's the responsibility of the NRC to send out that
18 sort of form. Mr. Einberg?

19 MR. EINBERG: I'm not sure. I was going
20 to ask if Dr. O'Hara wanted to comment and see if
21 that's an FDA responsibility.

22 MEMBER O'HARA: The FDA is looking -- has
23 been looking into this issue. The FDA sent out the
24 dear -- I call a dear doctor letter to inform people
25 of the issue. And they are working with the sponsor

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1 on various corrective actions.

2 CHAIRMAN PALESTRO: Thank you. Any other
3 comments or questions from the committee? Attendees
4 in the room? Bridge line? Dr. Dilsizian, does that
5 answer your question?

6 MEMBER DILSIZIAN: Yes. It seems to me
7 that FDA is addressing this issue and that the medical
8 events will be reported, the medical events. So
9 that's, I guess, all that NRC can do at this point.
10 Thank you.

11 CHAIRMAN PALESTRO: Dr. O'Hara?

12 MEMBER O'HARA: Also the medical events
13 end up in the medical event database. It's at FDA
14 too.

15 CHAIRMAN PALESTRO: Thank you. The next
16 item on the agenda is the Yttrium-90 microspheres
17 brachytherapy licensing guidance subcommittee report.
18 It'll be presented by Dr. O'Hara.

19 MEMBER O'HARA: Next slide, please. I'd
20 like to thank the subcommittee members, Dr. Dilsizian,
21 Ms. Martin, Dr. Metter, Dr. Ouhib, and Dr. Schleipman
22 for their efforts on this. And I would also like to
23 thank Katie Tapp for being the expert. It occurred
24 during a time when FDA was partially shut down, and I
25 was not officially allowed to work on any of this. So

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1 I do appreciate everybody's efforts.

2 For background, this is a manual intra-
3 arterial brachytherapy implant with unique properties
4 for primary and secondary hepatic malignancies. It's
5 regulated under 10 CFR 35.1000 and titled, other
6 medical uses of byproduct materials or radiation from
7 byproduct materials. Next slide, please.

8 The licensing guidance was published in
9 2002 and revised in 2004, '07, '08, '11, and '16.
10 October '16, the ACMUI provided comments on the
11 initial draft revision 10 of the licensing guidance.
12 Specific topics that were addressed included
13 consideration of the elimination of Pathway 2, a
14 manufacturer of the authorized user training, update
15 of waste and disposal section and review Y-90
16 radiation safety issues in autopsy and cremation.
17 Next slide, please.

18 November 2017, the NRC published a draft
19 on revision 10 of the licensing guidance in the
20 Federal Register for public comment. The comment
21 period ended in January 2018. In July of 2018, the
22 final Part 35 rule, Medical Use of Byproduct Material-
23 Medical Events, Definitions, Training, Experience, and
24 Clarifying Amendments, was issued. The rule went into
25 effect January 14th, 2019 for NRC licensees. Oh,

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1 sorry. I was waiting for you to change it.

2 The NRC agreement state working group
3 updated the draft revision to licensing guidance to
4 include the criteria for training and experience and
5 medical events reporting, inventory requirement
6 specifications, and waste disposal issues and align
7 the guidance with Part 35 rule. After addressing
8 public comments, the 2016 ACMUI comments, and the rule
9 changes, the working group provided the subcommittee
10 with revised draft guidance for its review and
11 comment.

12 Our charge for this subcommittee was to
13 review the staff's draft revision 10 of the Yttrium-90
14 microspheres brachytherapy source and devices,
15 TheraSpheres and SIR-Spheres licensing guidance and to
16 provide any comments or recommendations for change or
17 acceptance of the guidance.

18 The subcommittee believes that this is a
19 well-written and well-documented licensing guidance
20 document. The subcommittee endorsed the draft
21 revision 10 of the licensing guidance subject to the
22 following changes.

23 We believe that the manufacturer's
24 representative for training should be documented. We
25 also feel that three hands-on cases for each type of

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1 microsphere delivery device should be kept. The Y-90
2 spheres are slightly different, being glass or
3 polymeric, and the delivery systems of the two devices
4 are slightly different. We also feel the RSO
5 familiarity would require all device uses at the
6 facilities. So the RSO should be familiar with both
7 manufacturers' devices.

8 Evaluation of a possible medical event for
9 unexpected dose or activity to an organ or tissue
10 other than the treatment site that is caused by
11 catheter placement should be looked at as a medical
12 event. Next slide, please.

13 Delineating the site to be treated more
14 specifically is another recommendation, i.e., left
15 hepatic lobe or right hepatic lobe. Adding activity,
16 date of administration and route of administration
17 should also be looked at. We question whether the
18 term, intervention, should be defined in the licensing
19 guidance document. And last, the explicit labeling
20 should include patient's name, dose, date, and
21 treatment site, if feasible. Next slide.

22 That's it. I'd like to make one point to
23 our earlier discussion. The FDA is also under -- I
24 was going to use the word, difficulty. But it's not a
25 difficulty. The FDA does not -- we don't regulate the

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1 practice of medicine. So if an interventionalist, at
2 his or her own insistence, changes the catheter, we
3 usually don't have much to say about that. And I just
4 wanted to make that clear.

5 CHAIRMAN PALESTRO: Comments or question
6 from the committee? Excuse me, from the subcommittee
7 first. Comments or questions from the committee?

8 Dr. O'Hara, I have two questions regarding
9 the slides, specific comments on the licensing
10 guidance. Your first bullet says, defining the
11 manufacturer's representative. I'm not sure I
12 understood that. Does that mean stating the
13 individual's name, or does it mean listing the
14 qualifications of the individual or both?

15 MEMBER O'HARA: Listing the qualifications
16 of the individual.

17 CHAIRMAN PALESTRO: Okay. And then my
18 second question on that same slide, further down, it
19 says, RSO familiarity required with all devices used
20 at the facility. Is there a more precise or a more
21 structured term other than familiarity? Because that
22 could be taken in a lot of different ways.

23 MEMBER O'HARA: What I meant was that the
24 RSO should be experienced with both delivery devices
25 and on both manufacturers' devices.

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1 CHAIRMAN PALESTRO: Thank you. Any other
2 comments or questions from the committee? From
3 attendees in the room? Dr. Tapp?

4 DR. TAPP: Dr. O'Hara, I just had a quick
5 clarification. On this slide and the comment -- the
6 next slide, the delineation of the site to be treated
7 more specifically. You said, for example, left
8 hepatic lobe, right hepatic lobe. Are those just
9 examples for the staff to consider, or are those the
10 recommendation of the --

11 MEMBER O'HARA: Examples to consider.

12 DR. TAPP: Thank you.

13 CHAIRMAN PALESTRO: Any other comments or
14 questions from attendees here in the room? From the
15 bridge line?

16 MS. HOLIDAY: I'm not showing any.

17 CHAIRMAN PALESTRO: Ms. Holiday, at this
18 point, do we move to -- all right.

19 MS. HOLIDAY: Yes. Is there a motion to
20 approve the report and the recommendations as stated?
21 Sure. Dr. Dilsizian has a question.

22 MEMBER DILSIZIAN: I guess bullet number
23 three, how does the staff handle that? When we say,
24 question whether the term, intervention, should be
25 defined or not, how do we address that?

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1 MS. HOLIDAY: Dr. Tapp, I think that
2 question was directed for you.

3 DR. TAPP: Sure. I think in the written
4 report, it was clear that it was a recommendation if
5 the staff believed patient intervention was defined
6 and to provide more definition into the guidance to
7 make it clearer to the user. So the working group can
8 add the patient intervention and clearer for the user
9 to see.

10 CHAIRMAN PALESTRO: Dr. Metter?

11 VICE CHAIRMAN METTER: I have a question
12 regarding the last bullet point there about the
13 explicit labeling to include the patient name. Is
14 that part of what we need to do, or is that -- can you
15 just explain that whole bullet point there?

16 MEMBER O'HARA: There was discussion
17 amongst the subcommittee that if it was feasible, all
18 of that information should be provided from the person
19 doing the intervention. I forgot the exact
20 phraseology. But it wasn't clear that all of that
21 information could be found in a small label. That's
22 what I meant by feasible.

23 VICE CHAIRMAN METTER: Oh, the label?

24 MEMBER O'HARA: Yeah.

25 VICE CHAIRMAN METTER: You mean the

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1 labeling of the dose?

2 MEMBER O'HARA: Yes.

3 VICE CHAIRMAN METTER: I understand.

4 Thank you.

5 CHAIRMAN PALESTRO: Mr. Ouhib?

6 MEMBER OUHIB: Yes. This is actually just
7 a clarification because there was a medical event
8 where there were two different doses. And by
9 accident, the wrong dose was actually administered to
10 the wrong patient. And therefore, the vial should be
11 explicitly labeled so that way people will not make
12 those sorts of mistakes.

13 CHAIRMAN PALESTRO: Dr. Schleipman?

14 MEMBER SCHLEIPMAN: If I could just add,
15 the current sentence prior to that recommendation
16 read, label syringes and syringe radiation shields for
17 the radioactive drug. And we felt perhaps that wasn't
18 sufficient enough to promote patient safety as in that
19 event. Added that, where feasible, it should also be
20 identification of the patient receiving that dose.

21 CHAIRMAN PALESTRO: Thank you. Yes?

22 MS. FAIROBENT: Lynne Fairobent, member of
23 the public. Dr. O'Hara, if we could go back and just
24 revisit the bullet on the RSO familiarity again
25 because I got more confused listening to your

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1 clarification.

2 I'm not sure in all cases that the RSO
3 would have experience with the devices. They would
4 have familiarity with the rad protection and rad
5 safety aspects of the devices. But I'm not sure what
6 type of experience you are referring to with it
7 because the RSO would not be the one that would be
8 involved in the use, only simply in the rad safety and
9 the rad protection of it.

10 MEMBER O'HARA: I think that is what the
11 subcommittee members wanted was familiarity with both
12 types of devices.

13 MS. FAIROBENT: Thank you.

14 CHAIRMAN PALESTRO: Mr. Green?

15 MEMBER GREEN: To follow up on the -- on
16 Dr. Schleipman's comment. It's line 16 where they say
17 the patient label syringes and radiation syringe
18 release and labels with the radioactive drug.

19 I just want to point out that neither of
20 these Sieverts products are drugs. Their license is
21 medical devices. And that term should be device type
22 but not drug.

23 MEMBER O'HARA: Yes. That's correct.

24 CHAIRMAN PALESTRO: Thank you. Mr. Ouhib?

25 MEMBER OUHIB: Yeah. Just to comment on

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1 the RSO. I think it's not necessarily using it per
2 se. Because there are other people involved in that.

3 But the event -- in the event that there
4 is a malfunction or something that went wrong, the RSO
5 should understand the device itself. And be able to
6 sort of evaluate and make some recommendation or
7 intervene or what not.

8 CHAIRMAN PALESTRO: Thank you. Mr.
9 Sheetz, not to put you -- I was just going to ask you
10 if you would comment because you're the RSO
11 representative here.

12 MEMBER SHEETZ: Thank you. I think it's
13 very important for the RSO to understand the delivery
14 apparatus. Understand all the plumbing, the
15 connections, the limitations, catalysts that are
16 appropriate for use with that device and so forth.

17 While they are not typically involved in
18 the administration process, it's very important for
19 them to understand that device. And all the aspects
20 of it and how it works.

21 So, I support the Subcommittee's position
22 on that.

23 CHAIRMAN PALESTRO: Thank you.

24 MS. COCKERHAM: This is Ashley Cockerham
25 with Sirtex Medical. To add onto what Mr. Sheetz just

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1 said.

2 The -- for Sirtex, they would provide
3 manufacturer training specific to the RSO. And
4 provide certification and documentation of that
5 training specific to that device.

6 And they are very different devices with
7 different training. And it would be completely
8 different on the nuke med side and the administration
9 as a whole.

10 So, I would think for each device is very
11 specific. The training is different for both of them.

12 And that the manufacturers are able to support that
13 at least from the Sirtex side I can attest to that.

14 On the labeling, I wanted to make one
15 quick comment on the syringe shields. And so I guess
16 this would only apply on the SIR-Sphere side because
17 there's an actual dose draw.

18 I think the way that the guidance is
19 currently written, it's actually impractical to label.

20 You would be covering what you're trying to see
21 through the syringe shield. And that's not something
22 that would actually go to the patient anyway.

23 So, to back up a step, a shipping vial
24 would come in with SIR-Spheres in it. And they would
25 remove using the syringe and syringe shield, a portion

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1 of that specific to the patient.

2 And then they would inject that into
3 another vial. All of those are clear. And you need
4 to be able to see between one and three milliliters.

5 So these are small amounts. You need good
6 visual on this. And if you're putting labels over all
7 of that, it's not going into the patient room anyway.

8 You're drawing it up in the hot lab.
9 Using it there. And then you inject it into another
10 vial that's going to go actually into the patient
11 room.

12 That vial you also need to be able to see.

13 The physician is looking at it. And watching the
14 meniscus. So, if you're putting labels, or putting
15 things over this, that's going to be a significant
16 problem just to be able to see what the admin -- what
17 you're doing with the administration.

18 So, the shipping vial that comes in
19 complies with the labeling. And I think the intent.
20 But everything after that, I think we're kind of going
21 into a space where maybe more discussion could be had
22 around that labeling.

23 CHAIRMAN PALESTRO: Thank you. Mr. Ouhib?

24 MEMBER OUHIB: I guess my question is for
25 the -- how would you avoid using the wrong dose for

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1 the wrong patient?

2 If you have two cases that are sent back
3 to back. And you have two doses sitting there, how
4 would you -- what would the manufacturer recommend?

5 MS. COCKERHAM: I don't have a quick
6 answer for you. I was going to say, I feel like there
7 -- we need more discussion on it.

8 Because you've got a clear acrylic, you
9 know, you've got 360 view on it. And you've got to be
10 able to see it.

11 I don't know where you realistically put a
12 label. Because you're watching the spheres as you're
13 administering.

14 That visual feedback is -- is critically
15 important. On the cart?

16 MEMBER OUHIB: I fully understand that.
17 But I think whatever we introduce, we have to make
18 sure that it does not introduce additional errors per
19 se.

20 CHAIRMAN PALESTRO: Dr. Schleipman?

21 MEMBER SCHLEIPMAN: I would just agree
22 that you do need to have that visual observation.
23 But, there are transports --

24 MS. HOLIDAY: Dr. Schleipman, can you make
25 sure your microphone is on?

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1 MEMBER SCHLEIPMAN: I'm pushing the -- oh,
2 there we go.

3 MS. HOLIDAY: Thank you.

4 MEMBER SCHLEIPMAN: Oh, totally agree that
5 you need that visual monitoring. But, if we could
6 make a -- perhaps make this less specific to vial.

7 But, at least that there is some patient
8 identification with the transports shield or what have
9 you.

10 MEMBER OUHIB: Perhaps further discussion
11 is needed.

12 MS. HOLIDAY: Mr. Ouhib, for everyone's
13 awareness, I do have someone on the webinar who is
14 responding to this comment. His name is Matthew
15 Williams.

16 And his response is that, they label the
17 top of the vial shield. Thank you.

18 MS. COCKERHAM: Okay. You could do that
19 with a sharpie on top.

20 CHAIRMAN PALESTRO: Okay. Any other? Dr.
21 Ennis?

22 MEMBER ENNIS: I would imagine if we or
23 NRC made a requirement, that the company would be
24 imaginative and come up with another design for the
25 device that would allow the important visualization.

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1 But also, for reporting patient name and
2 other things for safety purposes.

3 MS. COCKERHAM: That's a big ask to
4 redesign it and get an FDA approved new device.

5 CHAIRMAN PALESTRO: Mr. Sheetz?

6 MEMBER SHEETZ: It's not clear to me if
7 the Subcommittee endorses retaining the alternate
8 pathway with the vendor training for the AUs. While
9 they're implying the three cases should be retained,
10 I'm not sure if there's -- I don't see a specific
11 statement to that.

12 And if you could comment?

13 CHAIRMAN PALESTRO: Dr. O'Hara?

14 MEMBER O'HARA: I think, and I don't want
15 to speak for the Subcommittee here, but I think we
16 are.

17 CHAIRMAN PALESTRO: Comments from the
18 Subcommittee? Mr. Sheetz?

19 MEMBER SHEETZ: I would like to make the
20 recommendation that does the draft guidance imply or
21 suggest removing the alternate pathway for vendor
22 training of AUs. And so I would recommend that that
23 AU pathway, alternate pathway remain.

24 And make this a very important pathway for
25 the authorized users. I think they do a very thorough

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1 job of training its equivalent or superior to being
2 supervised by another authorized user.

3 So, I strongly endorse retention of the
4 alternate pathway for Y-90 microsphere authorized
5 users.

6 CHAIRMAN PALESTRO: Yes. Ms. Shober?

7 MEMBER SHOBER: Just a clarification on
8 that, on Mr. Sheetz' comment. With the alternate
9 pathway in number two that we're talking about, the
10 previous versions of the guidance had allowed a
11 physician to be named on a license before receiving
12 the three cases.

13 And at this point, could those -- do the
14 cases from the manufacturer need to happen -- does the
15 authorized user need to get named on the license
16 before those three cases happen?

17 Or are there sufficient preceptors around
18 to -- we could allow that second pathway through the
19 manufacturer. But, they would have to get those cases
20 before being named on the license.

21 Is that -- so, it's a question about
22 timing. It's very difficult from the regulator side
23 to put someone on a license when they're not fully
24 qualified, and then track whether or not someone is
25 allowed to preceptor another position.

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1 And so I guess my comment on that is that
2 if we're talking about the second pathway, can that be
3 structured so that manufacturers' training happens
4 before the physician is named on the license? If the
5 licensee chooses to use the manufacturer as the
6 preceptoring cases.

7 CHAIRMAN PALESTRO: Dr. Tapp?

8 DR. TAPP: The draft guidance did not
9 remove the manufacturers -- the pathway right now of
10 the working group. It just added a little bit more
11 requirements to that.

12 But they could still, the current draft is
13 still allowing the license to occur. And then the
14 three cases to happen.

15 They just had to be -- the three patient
16 cases would have to be supervised by a physician.
17 That was still in the draft.

18 CHAIRMAN PALESTRO: Any other comments?
19 Questions?

20 MS. COCKERHAM: This is Ashley Cockerham
21 again with Sirtex. I get to answer your question.
22 Unequivocally yes.

23 They need the ability to be able to --
24 their AUs are not going to voluntarily on their own
25 dime, visit other people's sites to train other

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1 physicians. That's just not the reality of how it's
2 going to happen.

3 And it's not imbedded in every fellowship
4 program where every IR coming out is going to have the
5 hands-on cases, especially with both products.
6 Because their fellowship could be one product or the
7 other.

8 And so your pool is going to be
9 significantly limited of your fellows coming out with
10 specific hands-on training.

11 So, really the only way to open a new site
12 now where you're in the community hospitals and where
13 you're out further, not in the major academic centers,
14 that pathway has to exist. And the manufacturers
15 support that by providing someone to supervise.

16 CHAIRMAN PALESTRO: Ms. Shober?

17 MEMBER SHOBER: Yes. I mean, that's what
18 we expect from every other radiopharmaceutical
19 therapy. So I'm not sure why the microsphere is a
20 special case.

21 MS. COCKERHAM: I guess the difference is,
22 if you're doing iodine, and I'm not a physician. I
23 don't know if there are any physicians that could
24 attest to the fellowship if you're coming through
25 doing iodine therapy or another therapy.

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1 But that's built into every fellowship.
2 It's standardized across the programs. How would that
3 look for Y-90 if you could explain how that was
4 different?

5 I understand it's different.

6 CHAIRMAN PALESTRO: Dr. Metter?

7 VICE CHAIRMAN METTER: Well thyroid for
8 thyroid therapy, which is originally 392 and 394,
9 these are imbedded within the training experience for
10 the radiologists and nuclear radiologists in nuclear
11 medicine, the radiation oncologists.

12 So it's embedded within their training at
13 the time of graduation. And so they have completed
14 the required therapies before graduations.

15 And then they apply to be on licenses
16 where they are -- they proceed to their practice.

17 So, I think Megan's question is, when are
18 they put on the license? Is that it?

19 MEMBER SHOBER: Yes. And I -- I mean, we
20 see this all the time with some of these other drugs
21 that are parenteral administrations.

22 So the same situation where you have
23 radiologists that want to do this at a community
24 hospital, but we require those physicians to have the
25 three cases somewhere. And then get on the license.

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1 So, I just don't see this as a different
2 situation.

3 MS. COCKERHAM: So, I guess the getting it
4 somewhere is the issue from the physician perspective.

5 You can't go to someone else's hospital.

6 You can't treat someone else's patient.
7 You can't practice medicine in a hospital where you're
8 not credentialed and where -- or in a state where you
9 aren't authorized to practice medicine.

10 And so you have to treat your patient at
11 your hospital with your radioactive materials license.

12 And if you can't get the material on your license to
13 get the experience, you're stuck in a situation of you
14 can't go elsewhere and get it, and it can't be brought
15 to you.

16 And so this was the whole between 2007,
17 '08, '09, and then 2011, the major revision happened
18 for -- to basically bridge that gap. To not have a
19 regulatory barrier.

20 CHAIRMAN PALESTRO: Mr. Sheetz?

21 MEMBER SHEETZ: Yes. Maybe I was not
22 clear previously. But that's the point I was trying
23 to make. For a new device, you're at a brand-new
24 facility, no one is an authorized user approved.

25 The only practical pathway is for the

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1 vendor to come in and train that authorized user or
2 that position to become an authorized user. They
3 actually do need to be named on the license so that
4 they can perform the procedure prior to being
5 supervised of doing their actual first live patient
6 case.

7 The same thing happens with gamma knife,
8 with the new model of the gamma knife that comes out,
9 the Gamma Part 1000. The vendor does the training for
10 the AU and the AMP.

11 They will do their first case with the
12 vendor representatives there with no previous
13 authorized user or AMP approved for that model of the
14 gamma knife. So this is a very similar situation.

15 And that was my point on having the vendor
16 training daily going into a new site and training the
17 AU, have them named on the license from the Mock Three
18 trials. They've been doing the patient cases then,
19 again, supervised by the vendor, because they're not
20 going to get another authorized user from another
21 facility to come in.

22 And as I pointed out, they're not going to
23 be able to go to another facility. They will not have
24 medical privileges to do that case at another
25 institution.

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1 CHAIRMAN PALESTRO: Thank you Mr. Sheetz.
2 Ms. Shober, does that clarify things for you?

3 MEMBER SHOBER: I mean, I hear what people
4 are saying. I just don't agree with it.

5 CHAIRMAN PALESTRO: Thank you. Dr. Ennis?

6 MEMBER ENNIS: Just to help. I think the
7 difference Megan, is that one is just an intravenous
8 administration, which you can watch someone do, or
9 have someone watch you do.

10 And then you can have an authorized user
11 doing that for you. As opposed to actually
12 technically doing the procedure.

13 There's just no way to get that experience
14 unless you're actually doing it. And having a
15 physician there doesn't really gain you anything,
16 because you actually have to do it.

17 So, I think there is a distinction to be
18 made between procedure type of training necessary
19 versus an intravenous administration.

20 CHAIRMAN PALESTRO: Ms. Martin?

21 MEMBER MARTIN: What type of experience
22 are you looking for to add that physician, if any, to
23 a license? Because it is sort of the cart before the
24 horse.

25 You have to add the physician with no

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1 experience to the license with some provision (audio
2 interruption) --

3 CHAIRMAN PALESTRO: Could you repeat that,
4 Ms. Martin? It was cut off at the end.

5 MEMBER MARTIN: I was just wondering what
6 type of provision, or how is the process approved to
7 add a license, following up on Megan's question.

8 To add a physician with zero experience to
9 a license to perform these procedures? Because that's
10 what you're doing.

11 If they're waiting for a manufacturer to
12 train them, you're having to add them to your license
13 with no experience in sort of good faith that they're
14 going to have a manufacturer's representative come in
15 there and train them.

16 Is that --

17 CHAIRMAN PALESTRO: Dr. Tapp?

18 DR. TAPP: Yeah. This is Dr. Tapp. And
19 this alternate pathway is both in the draft and in the
20 current guidance.

21 There is training requirements before
22 these three cases. All those training requirements
23 have to be completed before they're issued on the
24 license.

25 Those are the T&E hours, similar to other

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1 modalities. There are manufacture or other AU
2 training on the device itself.

3 And if they do not have the three patient
4 cases prior to the license, they have to have three
5 mock cases. So, after the license, is only the three
6 actual real live patient cases.

7 To actually run through the full thing
8 with a patient. So that's what's proposed after the
9 license.

10 And it's currently in guidance. And
11 that's what's in the draft.

12 CHAIRMAN PALESTRO: Ms. Martin, does that
13 answer your question?

14 MEMBER MARTIN: Yes.

15 CHAIRMAN PALESTRO: Thank you. Mr. Ouhib?

16 MEMBER OUHIB: I just want to switch gears
17 to another area that was of concern to me. And that
18 is the cremation component of these patients.

19 When I first thought about it, I thought
20 perhaps that took practice guidelines. But the more I
21 think about it, the more I feel like maybe not.

22 And looking at patient instructions, for
23 instance, prior to the procedure, if, you know, with -
24 - and patient instructions are the rules. You have to
25 provide patient instructions.

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1 That's when you submit your -- and I
2 think, and I really feel like that perhaps in the
3 patient instructions, that should be in there.

4 That you cannot be cremated for such a
5 procedure. Because all, you know, the items can be
6 listed there.

7 And then therefore the patient would know
8 up front, prior to the procedure, that that is an
9 absolute no no. If their wish is to be cremated,
10 therefore they can make a decision prior to the
11 procedure, and it's not to go forward with it.

12 I really wrestled with that. But, I think
13 I came to a conclusion that perhaps that should be
14 part of the patient instructions.

15 CHAIRMAN PALESTRO: Any comments on that?
16 Ms. Martin?

17 MEMBER MARTIN: I would support Mr. -- the
18 comments made already about cremation. Because
19 serving as an RSO, it -- in an active hospital in Los
20 Angeles, we've had a number of our encounters with the
21 various crematoriums and funeral services of disposal
22 of the bodies.

23 And it would have been so much more clear
24 if the patient had already -- if the family had made
25 that decision up front before the patient was treated.

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1 CHAIRMAN PALESTRO: Mr. Green?

2 MEMBER GREEN: Just to echo this, the
3 comments. Very supportive of these comments regarding
4 pre-need patient counseling.

5 We've seen a published article recently
6 out of Scottsdale, Arizona Mayo Clinic regarding
7 lutetium-177 and 117m in a patient that was treated at
8 hospital A, but then demised at hospital B.

9 And went on and was cremated. And
10 actually had, you know, contamination of the crematory
11 unit as well as the individual who performed the
12 cremation.

13 So, it should be advised a part -- it
14 should be part of the counseling to the patient that
15 with a certain period of time for this half-life of
16 this isotope, that other means of -- other than
17 cremation should be considered.

18 CHAIRMAN PALESTRO: Thank you. Any other
19 comments? Questions? Dr. Diabes, Figueroa?

20 DR. DIABES: Dr. Said Diabes. And Reg
21 Guide 8.39, we added a section that addresses this
22 specific issue on cremation of bodies. That -- of
23 patients have been treated and bodies that are
24 radioactive.

25 And it adds more information,

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1 instructions, a very vast amount of data on this
2 issue, which the Subcommittee will see soon, or is
3 seeing. It's reviewing at this moment.

4 CHAIRMAN PALESTRO: Thank you. Any other
5 comments or questions? Just as an aside before we
6 move on, the issue of cremation has also come up with
7 another radiopharmaceutical, lutetium-177.

8 And it's my plan to address the issue of
9 cremation and disposal of the seeds at some point
10 later on in this meeting. I don't want to get
11 sidetracked now.

12 But I think it's an important issue. And
13 it's not just limited to yttrium-90 microspheres. All
14 right.

15 Any other comments or questions from the
16 Committee? Attendees in the room? Bridge line?

17 (No response)

18 CHAIRMAN PALESTRO: At this point Ms.
19 Holiday, we're ready to vote on the Subcommittee's
20 report.

21 MS. HOLIDAY: We are ready for the vote.

22 CHAIRMAN PALESTRO: All right. May I have
23 a motion to approve the report?

24 MEMBER GREEN: I move the report be
25 approved with the change of the word drug to device.

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1 CHAIRMAN PALESTRO: All right. Second?

2 MEMBER O'HARA: I'll second.

3 CHAIRMAN PALESTRO: All right. All in
4 favor?

5 (Voting)

6 CHAIRMAN PALESTRO: Any opposed?

7 (Voting)

8 CHAIRMAN PALESTRO: Any abstentions?

9 (Voting)

10 CHAIRMAN PALESTRO: Thank you.

11 MS. HOLIDAY: Okay. So for the record,
12 Mr. Green made the motion to approve the Subcommittee
13 report with the changing of the word drug to device.
14 The motion was seconded by Dr. O'Hara.

15 And it was unanimously approved by the
16 Committee. Thank you.

17 CHAIRMAN PALESTRO: Thank you Ms. Holiday.

18 Next item on the agenda is the Lucerno Dynamics LARA
19 infiltration detection.

20 And Mr. Lattanze will provide an overview
21 about a product that can assist with detecting nuclear
22 medicine injection infiltrations. Mr. Lattanze?

23 MR. LATTANZE: Good morning. And thank
24 you for the opportunity to present. I'm Ron Lattanze.
25 I'm the CEO of Lucerno Dynamics.

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1 At Lucerno, we've developed the device
2 called LARA that provides insight into nuclear
3 medicine injection infiltrations, which are sometimes
4 referred to as extravasations.

5 I'll be covering a lot of material in a
6 short amount of time. So, I've prepared comments that
7 describe infiltrations, their incidents, and patient
8 impact.

9 I'll also share evidence that
10 infiltrations can nearly be eliminated. And will
11 conclude with a request that the NRC and the ACMUI
12 reconsider a 1980 decision regarding infiltrations.

13 In anticipation of questions after my
14 comments, I'd like to introduce Dr. David Townsend,
15 who is attending this meeting by phone. David is
16 Lucerno's scientific advisor, and receives no
17 compensation.

18 He's the co-inventor of the PET CT scanner
19 and a fellow of IEEE. He's received many awards
20 including the IEEE healthcare medal, and the SNMMI
21 Paul C. Aebersold Award.

22 Also in attendance is Dr. Dan Sullivan,
23 the former NCI Associate Director, Division of Cancer
24 Treatment and Diagnosis, and the former Director of
25 the NCI Cancer Imaging Program. He's a science

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1 advisor for the RSNA, and a founder of the
2 Quantitative Imaging Biomarkers Alliance.

3 Dan does consult with Lucerno to review
4 our scientific paper submissions. David and Dan are
5 here to answer any questions related to infiltration
6 effects on nuclear medicine imaging studies and on
7 patients in this era of precision medicine.

8 Most nuclear medicine studies are based on
9 the assumption that the radiopharmaceutical is
10 injected as a bolus, where the entire dose is
11 delivered in just a few seconds. The injection is
12 usually followed by a saline flush, and an uptake
13 period prior to imaging.

14 This process tends to ensure that by the
15 time the patient is imaged, the low background noise
16 and high counts in organs or lesions of interest
17 results in a high sensitive study.

18 An infiltration results when some or all
19 of the dose intended for a patient's vein is injected
20 into the tissue near the vein. This not only exposes
21 this tissue to unintended radioactivity, it increases
22 noise, reduces effective counts, and reduces image
23 sensitivity. And the image quantification is
24 incorrect and understated.

25 Because the injected dose is an input to

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1 the image quantification formula, quality control
2 measures are in place to ensure dose accuracy. Clocks
3 are synchronized in nuclear medicine departments to
4 account for radioactivity decay.

5 And technologists after injecting and
6 flushing the delivery syringe, measure the dose left
7 in the syringe, and subtract this amount for a net
8 injected dose. These QC measures increase accuracy of
9 the net dose approximately 1 to 2 percent.

10 Despite the accuracy that QC provides for
11 the net dose, there remains the assumption that the
12 net dose is actually delivered into the patient's
13 circulation.

14 Until recently there's never been a
15 routine monitoring to confirm the delivery into the
16 circulation. This is important, because an
17 infiltration can dwarf the effects of any errors
18 resulting from the residual or unsynchronized clocks.

19 To better understand the NRC position on
20 infiltration, I've reviewed the historical records.
21 And thank you for the folks who put the ACMUI
22 information on the website. That was very helpful.

23 In 1980, the NRC published a final rule on
24 misadministration reporting requirements. From a
25 review of the supplementary information supporting

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1 this rule, here are my interpretations of the NRC
2 conclusions regarding this administration.

3 The NRC emphasized their role in
4 protecting patients from unintended radiation
5 exposure, and from compromised diagnostic procedures
6 that could impact care.

7 They emphasized reporting is needed to
8 identify root cause. And then prevent recurrence.
9 And stated that referring physicians and patients
10 should be notified.

11 Interestingly, and in apparent to these
12 conclusions, the NRC reached their decision that an
13 infiltration should not be considered a
14 misadministration. Their decision was supported by
15 the following justification: infiltrations frequently
16 occur in otherwise normal intravenous and intra-
17 arterial injections. And are virtually impossible to
18 avoid.

19 In 2002 the term misadministration was
20 replaced with the term medical event in the
21 regulations. Additionally, reporting and notification
22 conditions and limits for these events were
23 established in Subpart M.

24 In 2008, a Boston VA patient was
25 infiltrated, aware of Subpart M, the VA reported the

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1 medical event to the NRC, based on their estimate that
2 the infiltration may have exceeded the effective dose
3 equivalent limit to the tissue.

4 The NRC requested that the VA retract the
5 report, referencing the 1980 decision that
6 infiltration should not be considered a
7 misadministration.

8 NRC shared this decision with the ACMUI.
9 And according to the December 2008 meeting minutes,
10 the ACMUI supported the NRC decision and rationale,
11 and passed a motion that "at this time, NRC should
12 continue its policy of not requiring infiltrations of
13 diagnostic dosages to be reported as medical events."

14 Few centers have ever shared their
15 infiltration rates. But the limited available global
16 data support the idea that nuclear medicine
17 infiltrations can occur frequently.

18 In the last decade, St. Louis University,
19 Ohio State University, and the University of Santiago
20 in Spain, have conducted six retrospective studies of
21 PET CT injection infiltration rates, by reviewing
22 images for infiltration evidence.

23 As states in one of these studies, rates
24 are likely under-reported, because as you can see
25 here, the injection site, like this infiltrated site

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1 shown by the arrow, are often outside of the routine
2 PET CT imaging field of view.

3 These six studies retrospectively reviewed
4 2,804 patient images, and found a 15.2 percent
5 infiltration rate. The studies ranged from 3 percent
6 to 23 percent.

7 In Alberta, nine centers each
8 retrospectively reviewed 25 consecutive nuclear
9 medicine bone scans for infiltrations on two separate
10 occasions.

11 In the first review of 225 patients, the
12 centers had an average infiltration rate of 15
13 percent. The centers ranged -- rates ranged from zero
14 to 28 percent.

15 The review of another 225 patient
16 injections had an average rate of 20 percent. And the
17 rates ranged from 8 to 44 percent.

18 From 2016 to 2018, Lucerno worked with
19 seven prestigious U.S. PET CT centers, including MD
20 Anderson, UCLA, Wake Forest Baptist, and UT Knoxville
21 on a project called LARA QI.

22 This quality improvement project used
23 LARA, our new monitoring device, to help clinicians
24 determine infiltration rates by prospectively
25 comparing the injection arm to the other arm for

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1 excess radiotracer, rather than retrospectively
2 reviewing images.

3 While this ensures infiltrations are not
4 missed due to the field of view detection issues, the
5 QI project results also likely under-represent real
6 infiltration rates. That's because of the observer or
7 trial effect.

8 Before beginning the infiltration rate
9 measurement in LARA QI, all technologists were trained
10 on the importance of high quality injections. They
11 knew that their injections were going to be monitored
12 for infiltrated radioactivity.

13 In the LARA QI measurement phase, 2,431
14 patients were monitored. Investigators found a 6.2
15 percent infiltration rate. Centers' rates ranged from
16 2 to 16 percent. Interestingly, technologists' rates
17 ranged from zero to 24 percent.

18 These results were presented at the SNMMI
19 annual meeting last June. During the closing session,
20 a distinguished subject matter expert summarizes in
21 what is known as the highlights lecture, selected
22 significant general nuclear medicine presentations
23 from the hundreds shared at that meeting.

24 The LARA QI findings were one of the 12
25 presentations highlighted last year. The highlight's

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1 lecture was published in the October issue of the
2 Journal of Nuclear Medicine.

3 Without an easy to use detection process,
4 technologists do not receive injection quality
5 feedback, are not aware of infiltrations, and thus
6 can't improve their technique. And when infiltrations
7 are identified, there are no reporting requirements in
8 place that lead to root cause investigation, quality
9 improvement, and reduction in occurrence.

10 In summary of this slide, the data we've
11 gathered support the NRC position that nuclear
12 medicine injection infiltration rates appear to be
13 high. But, do infiltrations matter?

14 We do not believe that all diagnostic
15 infiltrations matter acutely or to the ensuing patient
16 care. But some do matter. And they can matter in
17 many ways.

18 In 1980, the NRC stated that a
19 misadministration of a diagnostic radiopharmaceutical
20 could compromise the effectiveness of the diagnostic
21 procedure. They were right.

22 A literature review since then has
23 identified over 50 references that show how
24 infiltrations can harm or have harmed patients. These
25 references are cited in a letter that I sent to the

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1 NRC yesterday.

2 Examples of how infiltrations may
3 negatively affect patient care include missed disease
4 that impacts staging and treatment, wrong
5 quantification that adversely affects longitudinal
6 assessment scans and treatment planning, false
7 positive results that lead to unnecessary invasive
8 procedures, and repeated imaging that increases
9 patient radiation exposure.

10 I could show you many cases, patient
11 cases, but due to time limits, I'll only share two.
12 Here is a published report of a lung lesion patient
13 with an infiltrated PET CT study, the left image with
14 the infiltration circled in red.

15 That when repeated three days later with
16 study parameters kept as constant as possible, the
17 image on the right revealed a missed metastatic lesion
18 shown by the arrow. In the infiltrated image on the
19 left, only the lung lesion in the circle was
20 identified.

21 To eliminate the impact of the streaking
22 artifacts that you see emanating from the infiltration
23 and obscuring the torso, the patient was reimaged with
24 his arms over his head just 30 minutes after this
25 infiltrated image was produced. With a clear torso

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1 view, the reading physician did not identify any other
2 lesions.

3 The day three non-infiltrated image on the
4 right revealed that the standardized uptake value of
5 the in -- or the SUV of the infiltrated image lesion,
6 had been understated by 44 percent. More importantly,
7 it revealed right adrenal metastatic disease.

8 With the infiltrated image guiding
9 treatment, as is commonly done in many centers today,
10 the patient would have received local regional
11 treatment rather than treatment for metastatic
12 disease.

13 Informed of the day three scan results,
14 the patient chose to spend his last five months in
15 hospice.

16 The next patient had two PET CT scans
17 performed five days apart in a controlled test/retest
18 study. Imaging parameters were controlled. Four
19 metastatic lesions were quantified. And the results
20 from the two scans were compared.

21 This example is also important. The first
22 reason is the dramatic effect an infiltration can have
23 on quantification.

24 As you can see form the far right column,
25 the infiltration caused the SUVs of the four lesions

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1 to be understated between 33 and 54 percent. And the
2 infiltrated image metabolic tumor volume value
3 calculations were understated between 32 and 70
4 percent.

5 Another reason this case is important is
6 because without the device, no one would have known to
7 order a repeat scan. The injection site was in the
8 left hand, outside the imaging field of view.

9 In such a scenario, an infiltrated scan
10 would provide the wrong information in assessing
11 disease progression, or in developing treatment plans.

12 This latest example is not unusual.

13 From our monitoring of over 14 thousand
14 injections to date, we know injection site locations,
15 and estimate that about 50 percent of injection sites
16 are out of the routine imaging field of view.

17 A meaningful infiltration outside of the
18 field of view like the example I just shared, or an
19 infiltration that is seen, but not included in the
20 radiology report, may result in compromised care. And
21 patients and treating physicians would be unaware.

22 Not only can infiltrations negatively
23 affect care, many exceed the NRC reporting limits
24 similar to the Boston VA case.

25 One medical event reporting limit is 0.15

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1 Sievert effective dose equivalent to the tissue.
2 We've worked with physicists, measured visible
3 infiltrations, and used Monte Carlo simulations to
4 show how diagnostic infiltrations can exceed Subpart M
5 reporting and notification limits.

6 In the letter that I sent to the NRC
7 yesterday, I've also provided engineering reports to
8 support these findings.

9 Example A is the actual case I just
10 presented, where the hand was out of the imaging field
11 of view. By knowing the injected dose and the tumor
12 quantification changes, by estimating the reabsorption
13 process, we can calculate how much infiltrated
14 radioactivity was in the hand at the time of imaging.

15 And that conservatively, the infiltration
16 resulted in an effective dose equivalent to the tissue
17 that exceeded the reporting limit by approximately 23
18 times.

19 Example B uses actual infiltration data
20 and is very interesting. It shows how the effective
21 dose equivalent of an infiltration can be easily
22 underestimated if one is just using static PET images.

23 In this example, at the time of imaging,
24 107 minutes post injection, there was a relatively low
25 amount of activity left at the injection site.

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1 Approximately 100 micro curies.

2 However, by using the infiltration
3 resolution data with known infiltration volume data,
4 we can estimate that an infiltration that may appear
5 minor on imaging, can actually exceed reporting
6 limits. Again, not all diagnostic radiopharmaceutical
7 infiltrations will matter to patients, but some will.

8 Some infiltrations will exceed medical
9 event reporting limits, and should be reported. And
10 the referring physicians and the patients should be
11 notified.

12 There is good news. Infiltrations are no
13 longer virtually impossible to avoid. And
14 infiltration rates can be dramatically improved.

15 Other healthcare injection processes
16 monitor and report infiltrations. Over the last 40
17 plus years, quality improvement projects have
18 monitored more than one million chemotherapy
19 injections and infiltration rates have continued to
20 decline.

21 A 2017 QI project involved nearly 740
22 thousand patients. And found a 0.18 percent
23 infiltration rate for the peripheral IV chemotherapy
24 injection. So that's an apples to apples comparison
25 of PET CT.

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1 Hundreds of thousands of contrast CT
2 injections have also been studied. And because of
3 monitoring and reporting, infiltration rates have
4 continued to decline.

5 Another recent QI project monitored over
6 450 thousand CT injections, and found a 0.24 percent
7 infiltration rate. The 1980 belief which was
8 reaffirmed in 2008, is no longer accurate in 2019.

9 Infiltrations are not virtually impossible
10 to avoid today. Now a device that uses sensors placed
11 on the arms, and that adds just 20 seconds to the
12 patient experience, can routinely help clinicians
13 detect infiltrations before imaging.

14 As a result, centers can provide
15 individual quality control for each injection with
16 time activity curves, or TACs like this one,
17 indicating no presence of excess radiotracers at the
18 injection site after about 30 seconds post-injection.

19 Here you can see the injection arm
20 sensor's black curve showing the bolus raise. And
21 then quickly drop to the level of activity represented
22 by the red arm, the referenced arm's red curve.

23 But not all TACs look ideal like this one.
24 Unfortunately, many look like this. Where the
25 objection arm's curve -- the objection arm's curve

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1 never drops to the level of the reference arm,
2 indicating the presence of excess radiotracers at the
3 injection site.

4 Just as importantly, by using the device's
5 quality assurance functions, centers can identify
6 factors associated with their infiltrations. And then
7 put improvement plans in place to correct them.

8 Following a QI -- following a QI process
9 can lead to very low infiltration rates, as we've seen
10 in other healthcare settings. In fact, four of the
11 seven LARA QI centers tried to improve their
12 infiltration rates.

13 As you can see by the columns highlighted
14 in red font, each center improved. Their aggregated
15 rate had a statistically significant decrease from 8.9
16 percent to 4.6 percent, with the p-value of less than
17 0.0001.

18 And even better news, measuring and
19 improving results can be accomplished in approximately
20 six to eight months. In fact now, some of these
21 centers are in sight of 1 percent infiltration rates.

22 These results were also presented at the
23 annual meeting last year. Their presentation was also
24 one of the 12 that were selected for the highlights
25 lecture.

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1 It appears to us that addressing the
2 infiltration issue is consistent with the goals of all
3 interested parties. Minimizing infiltration seems
4 consistent with the previously stated NRC goals of
5 protecting patients from unnecessary radiation
6 exposure.

7 As well as from compromised diagnostic
8 studies of reporting determining causes and preventing
9 recurrence. And of ensuring referring physicians and
10 patients are notified of medical events that exceed
11 reportable limits. Limits that I will add, that
12 should be agnostic to whether the source is a
13 diagnostic or therapeutic radiopharmaceutical.

14 Identifying and reporting infiltrations
15 are also in the best interest of nuclear medicine and
16 molecular imaging societies. As the NRC knows, the
17 importance of patient safety was a consistent message
18 throughout recent public comments received by the NRC
19 with respect to the training and experience
20 requirements for authorized users.

21 The societies are also focused on
22 precision medicine. Infiltrations lead to imprecise
23 medicine.

24 Societies are also aware that in the
25 future alpha and beta therapeutic injections, with

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1 their longer half-lives, will play an increasingly
2 important role in medicine. And they know that the
3 same personnel delivering diagnostic
4 radiopharmaceuticals today, will be delivering radio
5 therapeutics tomorrow.

6 And the SNMMI knows that infiltrations
7 have no place in their quality of practice initiative.

8 The goal of which is to ensure that members are known
9 for high quality, value driven performance, and
10 delivery of patient-centered nuclear medicine
11 practice.

12 And when we deal with individual centers,
13 the vast majority of technologists actually want
14 feedback that they are doing injections properly.
15 Physicists want reproducible imaging.

16 Safety officers want radioactive material
17 used optimally and safely. And most interpreting and
18 treating physicians we've spoken to, want the highest
19 quality imaging to help treat their patients.

20 Finally, and most importantly, are the
21 patients. It's their life and their care. We've met
22 with them, their families, their friends, and patient
23 advocacy groups. Their message is clear, and they all
24 want the highest quality nuclear medicine injections.

25 On that point, let me share my last slide.

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1 Now that there is awareness that infiltrations are
2 avoidable, that they can harm some patients, and that
3 they can exceed reporting limits, we are asking the
4 NRC and the ACMUI to review the information I sent to
5 the NRC yesterday, and reevaluate the 1980
6 infiltration policy.

7 Infiltrations that meet Subpart M
8 reporting and notification criteria should be
9 reported. This will lead to a reduction in
10 infiltrations and to an improvement in patient care.

11 Thank you for your attention. And we
12 welcome any questions you have.

13 CHAIRMAN PALESTRO: Thank you Mr.
14 Lattanze. Any questions from the ACMUI? Dr.
15 Dilsizian?

16 MEMBER DILSIZIAN: Thank you very much for
17 the nice presentation. I guess I have several
18 comments about your presentation.

19 But I'm going to start from agreeing with
20 you. That QA/QC requires that you properly inject the
21 dose.

22 And for the two examples that you gave,
23 chemotherapy, and I'm going to talk about cardiology,
24 when we're injecting radiotracers with exercise, we
25 make sure that there's a blood return when you have an

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1 IV line. Because you don't want to inject the
2 radiotracer and you'll probably get peak exercise.

3 Also for absolute blood flow measurement,
4 it's critical that when we're giving a bolus injection
5 that it's going to the patient.

6 MR. LATTANZE: Absolutely.

7 MEMBER DILSIZIAN: So, but I would like to
8 make the distinction between the type of examples that
9 you gave. To routine imaging for bone scan that's a,
10 where you direct inject the radiotracer to the vein,
11 there's no IV line.

12 And so those are the type of things I
13 think we're mixing the two information. But
14 infiltration from radio diagnostic studies, whether
15 it's common or infrequent to really reporting them as
16 -- from the regulatory body, I'm just questioning
17 that.

18 Now, let me address two of the things you
19 have presented. The arm down patient that you made a
20 big picture out of, --

21 MR. LATTANZE: Yes.

22 MEMBER DILSIZIAN: It would never happen
23 in a radio institution. The arm should never be next
24 to it to miss that adrenal gland. It should have been
25 up anyway.

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1 Number two, so that's not really a good
2 example. It's misleading. I mean, no one would
3 accept that. If I saw that image, I'd say repeat the
4 image with the arm up.

5 MR. LATTANZE: They did repeat the image
6 with the arm up 30 minutes later.

7 MEMBER DILSIZIAN: Yes.

8 MR. LATTANZE: They had extended uptake in
9 the SUV. And there was no evidence of that
10 metastatically.

11 MEMBER DILSIZIAN: No, what I was saying,
12 the first image, if they --

13 MR. LATTANZE: Yes. That -- that -- no --

14 MEMBER DILSIZIAN: They improperly
15 identified it. And the other thing you made a big
16 deal about the SUVs and all.

17 You know, I read nuclear medicine studies
18 every day. You gave a difference between seven versus
19 11, 28 versus 41, six versus 11. Clinically
20 irrelevant. They're all hot.

21 It doesn't matter if I say to you it's
22 seven versus 11, that doesn't change anything but
23 therapy. So yes, it does affect SUVs. It doesn't
24 change patient address. We're making a bigger deal
25 than it is.

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1 And the other thing, I'd like to caution
2 you using the word can harm or have harmed patients.
3 It's under some dramatic and exaggerated statements.

4 I agree with you that QA/QC we should do
5 our best to give the dose that's necessary to the
6 patient. I doubt it that it really has harmed or have
7 harmed patients.

8 I mean, the examples that you gave are
9 maybe rare, not common. And the percentages that you
10 give as an SNMMI incoming President, I agree with you.
11 We should not do those.

12 But, I don't think that these are
13 significant enough events that should be reported
14 routinely, except when the whole dose for example, if
15 I'm giving a thallium dose, --

16 MR. LATTANZE: Um-hum.

17 MEMBER DILSIZIAN: And everything went to
18 the arm, I know that there's going to be skin issues.
19 Those are reportable. But not the routine ones that
20 we do every day.

21 MR. LATTANZE: So, is that done? Okay.
22 So, the question about harm, when I sent the letter
23 yesterday, I cited the 50 references that are peer
24 reviewed. That they're the ones that state how
25 patients have been harmed or can be harmed. So

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1 that's, I'm just using what the references state.

2 The SUV use, and I hear this frequently,
3 because I talk to oncologists as well as the nuclear
4 medicine physicians. When oncologists are using the
5 SUV, and it maybe not what nuclear medicine physicians
6 want, in longitudinal assessment scans, they're making
7 decisions often whether they're seeing a change in
8 response.

9 And so according to the PERCIST criteria,
10 a lot of these changes would actually be more than the
11 PERCIST criteria. And they would make a decision that
12 the patients have responded or not.

13 And so I think that while I understand
14 very well the variability in the SUV measurements, the
15 fact that the quality of the injection is not being
16 reported to the physician, doesn't give them the
17 opportunity to understand that they might have even
18 more variability than they would normally expect.

19 So, the oncologist, and I do talk to a lot
20 of oncologists, they are completely unaware that
21 patients are being infiltrated.

22 Your comment about the -- the arms up, and
23 getting and IV, getting blood drawn, all the centers
24 that we go into, very few -- nobody does a straight
25 stick anymore that we've seen.

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1 They use the butterfly or the IV access.
2 And every technologist will tell you, I look for blood
3 in my return.

4 And we've been in cardiology centers as
5 well, and have seen very similar infiltration rates in
6 both stress and rest exams. That they will actually
7 draw blood back in.

8 And they will tell you, I am sure that
9 this is a good injection. And then when they look at
10 the image, they'll see that they've infiltrated.

11 So, I understand what you're saying. I
12 think it's actually my experience, we've been in some
13 other centers as well, the occurrence is far more
14 frequently than you think.

15 That's our experience.

16 CHAIRMAN PALESTRO: Any other comments or
17 questions? Mr. Ouhib?

18 MEMBER OUHIB: Yeah. I have to apologize,
19 this is certainly not my expertise. But listening to
20 this presentation, it sounds to me like this is a
21 practice of medicine more than anything else.

22 And society should be addressing that.
23 Not a regulatory item.

24 MR. LATTANZE: Yes. I agree that the --
25 what we found is that the main difference between

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1 chemotherapy injections for example, which is a very
2 similar patient population to oncology PET CT
3 patients, is that it's a practice of -- that you have
4 trained clinical nurses that do chemotherapy
5 injections for a living, and technologists don't.

6 But once they get the feedback, the
7 technologists can get as good as those patients, or as
8 those nurses. However, it's not a regulatory issue
9 unless the dose that is affecting the tissue is so
10 high that you're exceeding that Subpart M reporting
11 limits.

12 So, by not reporting those doses that are
13 very high to the NRC, you don't know when patients are
14 being affected and when they're not.

15 Does that make sense? That's the
16 regulatory piece. Not the -- not the training piece
17 that can be fixed very quickly. Well, within six or
18 eight months.

19 CHAIRMAN PALESTRO: Dr. O'Hara?

20 MEMBER O'HARA: There could be a
21 regulatory piece as well, depending on how the firm
22 advertises this product.

23 MR. LATTANZE: Absolutely. And I think we
24 met back in December, Dr. O'Hara at the FDA.

25 And we're very conscious of, you know,

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1 what the device does is it tells a clinician, it helps
2 the clinician detect whether they have an infiltration
3 or not. It does not tell them they have an
4 infiltration.

5 CHAIRMAN PALESTRO: Any other comments or
6 questions Mr. Ouhib? Dr. Ennis?

7 MEMBER ENNIS: My question isn't really
8 directly related to your request, regulatory request.
9 But, more of a, I guess curiosity about your product,
10 if you'll indulge me.

11 MR. LATTANZE: Sure.

12 MEMBER ENNIS: So if you could explain why
13 CT infiltration rates and chemotherapy -- you alluded
14 to the chemotherapy one, are so low compared to what
15 you seem to be seeing with nuclear medicine
16 infiltration rates, A.

17 And B, why would a nuclear medicine
18 department need your device if CT and chemo have
19 figured out how to decrease infiltration rates without
20 a chemo detection device, or a --

21 MR. LATTANZE: That's great.

22 MEMBER ENNIS: Contra-detection device?

23 MR. LATTANZE: That's great. The
24 different -- the reason that chemotherapy and contrast
25 CT rates are so much better than nuclear medicine

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1 rates that we've seen so far is, for a lot of reasons.

2 One is -- the primary reason is the
3 detection issue. So, when a chemotherapy patient is
4 infiltrated, they know they've been infiltrated,
5 because it's a vesicant and does an extravasation.

6 There's immediate feedback to the nurse
7 that that patient has been infiltrated. In a contrast
8 CT, the volumes are so large you actually see a
9 swelling in the arm. So, there's feedback.

10 Unfortunately for nuclear medicine, there
11 has been -- the technologists have never gotten the
12 feedback, because they're injecting such small doses
13 that they do not see that.

14 We have had one patient say that they felt
15 a burning sensation. And it was a large dose
16 infiltration. Larger than the one that I showed
17 earlier.

18 But that's the only case we've ever heard
19 of where a patient complained about a burning
20 sensation. So, the patients don't know. The
21 technologists don't know.

22 The injection sites are often out of the
23 imaging field of view. And the other thing we've
24 known is that infiltrations resolve during the time --
25 you know, during the 60 to 70 minutes of uptake time.

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1 So when physicians do see them on the
2 static pad image, they actually are seeing something
3 that's much smaller than what it was during the uptake
4 period. And so the detection issue is the main
5 difference.

6 Your second question was well, once they
7 can detect it and can solve their problem, do they
8 need to continue to use the product? You know, is
9 there a need for the product?

10 And that's an issue that the market will
11 solve later. But what we've experienced in all the
12 centers that have gone on to use the device, is
13 because this is a human to human interaction, you
14 know, you have this sophisticated PET CT technology
15 that's so amazing, but it still relies on the human
16 to human interaction between a technologist and the
17 patient's arm, sometimes with very bad veins.

18 Is that if one of those humans, the
19 technologist is not having a good day, they're --
20 we've seen actually where some of the best
21 technologists at a center for over a year, will all of
22 a sudden go and infiltrate 27 percent of their
23 patients over the next nine working days. We've seen
24 that example.

25 Some things happen because they're human.

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1 And so, the centers have chosen to continue to use it
2 as an ongoing monitoring process.

3 Also, because nuclear medicine is growing.

4 And new technologists are coming in. And there is no
5 training for this process.

6 The technologists are two year physicist
7 students. They receive their training on the job from
8 other technologists.

9 And so all the centers that have used the
10 device continue to use the device, because they
11 realize that there's a need to keep making sure that
12 as people move around, that they're doing great
13 injections.

14 CHAIRMAN PALESTRO: Any other comments or
15 questions? Dr. Metter?

16 VICE CHAIRMAN METTER: Thank you for your
17 presentation. It was very -- very informative.

18 One thing I would like to caution, is that
19 the volume of CT studies are clearly far more, and
20 performed 24 hours a day, usually in an institution,
21 versus nuclear medicine, which is generally performed
22 during the working hours of 8:00 to 5:00.

23 And so you're looking at perhaps like at a
24 good day for example at our institution, maybe there
25 are 30 studies in nuclear medicine, versus three

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1 hundred or more for CT.

2 So if you looked at that, and if you look
3 at a 25 percent infiltration rate, so you have, let's
4 say, seven out of 30, versus 75 out of 300.

5 So, I caution you regarding that. Because
6 the numbers, the smaller the numbers, an error in one
7 area can raise that percentage.

8 MR. LATTANZE: Yes.

9 CHAIRMAN PALESTRO: Mr. Sheetz?

10 MEMBER SHEETZ: Thank you for an
11 interesting presentation. I have -- was surprised by
12 the infiltration rates that you presented on slide
13 five. You don't have to go back to it.

14 But, it looks like you took a -- pulled
15 the data and took a number of studies for different
16 centers, took their infiltration rates, and then took
17 the median value as your, you know, the reported rate
18 as an average for those centers.

19 Did you look to normalize that for the end
20 number for the actual number of patients? Because
21 some centers may have had ten patients and had an
22 infiltration rate of say 44 percent.

23 Another center may have had a thousand
24 patients and an infiltration rate of two.

25 MR. LATTANZE: Yes.

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1 MEMBER SHEETZ: And so by just taking the
2 median value of those rates per centers, it could skew
3 the percentage rates.

4 MR. LATTANZE: Yes. So, I like to often
5 report, you know, that -- the -- both values. And so
6 the -- we have seen that some centers are at the 2 to
7 3 percent rate. And they are usually the higher
8 volume centers.

9 We've also seen some high volume centers
10 have a 13 percent rate. And so, all that information
11 will be in our -- once that LARA QI paper publishes,
12 you'll be able to see all that data.

13 And you know, also sorry, one last
14 comment. The other interesting thing is, oftentimes
15 at a center, many of the technologists can be very,
16 very low at the infiltration rate. But then you can
17 have one that is a 25 or 24 percent infiltration rate
18 technique, so.

19 CHAIRMAN PALESTRO: Ms. Martin?

20 MEMBER MARTIN: I would just comment
21 following up sort of on what Dr. Metter said. Most
22 facilities do not have anyone around that can make
23 these calculations routinely to decide whether that
24 infiltrate is at a dose of .5 Sieverts.

25 I was just wondering, who would make those

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1 calculations routinely in a facility if it were
2 required? Because that is not something that is
3 routinely done by either nuclear medicine physicists,
4 which are not necessarily on staff, unless you're a
5 very large facility.

6 I don't see how that could routinely be
7 happening.

8 MR. LATTANZE: So, I'm not sure how to
9 answer that question. In the centers where we've had
10 those calculations performed, the physicist involved
11 actually has done the calculation.

12 MEMBER MARTIN: Um-hum.

13 MR. LATTANZE: But, you know, I get this
14 question a lot when I go into centers that say well,
15 you know, first they say I don't think I have an
16 infiltration problem.

17 And then when they finally say, well maybe
18 I do. And we start looking at it, their real concern
19 is, well, if I'm infiltrating at 15 or 20 percent of
20 the time and I have to reschedule these patients, then
21 it's a problem.

22 And what I try to emphasize is that it's
23 only a problem for a very short period of time. Once
24 you start, like any quality improvement project, any
25 time you want to improve something, if you start to

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1 measure it, the improvements can happen very quickly.

2 And so, I would suspect that while the
3 rates are high today, based on our experience in the
4 centers that we've been in, the rates could be
5 dramatically better very quickly if you begin to
6 actually start detecting and reporting them.

7 Any time you put that process in place, it
8 causes improvement. So then I don't think it's a big
9 problem, because very few of the -- if you can reduce
10 the infiltrations dramatically, then even fewer will
11 be moderate or significant infiltrations what would
12 require reporting.

13 CHAIRMAN PALESTRO: Any other comments or
14 questions from the Committee? Mr. Green?

15 MEMBER GREEN: I think it was a very
16 interesting presentation. You know, it's been, you
17 pointed out and it's been --

18 MS. HOLIDAY: Rich, can you bring the
19 microphone closer?

20 MEMBER GREEN: You pointed out, and it's
21 been repeated by members of the Committee that not all
22 nuclear procedures are quantitative. But PET with SUV
23 are.

24 And I just wanted to point out that not
25 all nuclear medicine and radiopharmaceuticals are

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1 injected intravenously. There are now in the last
2 five years, a drug which is indicative for intradermal
3 administration, has also subcutaneous administration,
4 and one that's intrathecal.

5 So, if we consider things that would
6 require reporting, you know, not all drugs are
7 intravenous. You know there are five that are oral,
8 and two that are inhaled. But I'm excluding those.

9 But, via needle, not everything goes in a
10 vein.

11 CHAIRMAN PALESTRO: Mr. Ouhib?

12 MEMBER OUHIB: Yeah. Just looking at your
13 request here. So, moving forward with required
14 reporting of infiltrations.

15 I guess I'm trying to understand, what do
16 you think that will eventually achieve? People paying
17 more attention?

18 And if so, wouldn't that be more like
19 education and training and understanding that? Versus
20 --

21 MR. LATTANZE: So the current NRC policy
22 is that if a patient is injected and they're
23 infiltrated, and the dose exceeds the reporting
24 limits, is that that is not considered a
25 misadministration, even though it could, you know, it

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1 is a misadministration.

2 It's not considered one because there was
3 the belief back in 1980 that they're virtually
4 impossible to avoid. So, my request is, to the NRC,
5 to say, well, we know now that they are not virtually
6 possible to avoid.

7 They may have been back then. And when
8 you go back and look at chemotherapy rates and
9 contrast CT rates from the 1980s, they were
10 significantly higher than they are today, too.

11 So my request is, if you change your
12 policy and say that if you misadminister an injection,
13 and you expose a patient to above the reporting limits
14 in Subpart M, that that should be a reportable event.

15 Whether it's a therapeutic infiltration,
16 or a diagnostic infiltration, if it's receiving -- if
17 a hand -- if tissue in a hand is receiving 11 Sieverts
18 over a period of, you know, during a two-hour
19 reabsorption process that should likely be a
20 reportable event.

21 And if you do that, then people will start
22 to monitor their injections. And they will actually
23 improve their injections. Just like we've seen in
24 every center that we've been in.

25 You know, until it -- you know, we've had

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1 a lot of physicians tell me that, you know, we know we
2 should be doing this, but we're not going to do it
3 until we're told to do it. Until it's required to do.

4 And I think when you begin to monitor
5 process, you'll see the results come down. And that
6 will be better for patients.

7 CHAIRMAN PALESTRO: Mr. Sheetz?

8 MEMBER SHEETZ: I'm going to go back to my
9 surprise on the infiltration rates. And I do want to
10 point out that the gamma cameras and the PET scanners
11 are very, very sensitive, so and a 15 millicurie
12 injection, if only 1 microcurie or fraction of that
13 leaks or infiltrates, you will visualize that.

14 So, I'm not sure, did you try to quantify
15 any of your infiltrations? Or if you visualize it,
16 it's an infiltration.

17 And I will say, it would probably not be
18 uncommon to be able to visualize something. But, the
19 actual amount of activity in a dose related to that
20 would be inconsequential, of no real risk or harm.

21 Certainly if you extravasated the entire
22 dose, that would be of concern. And you would want to
23 be able to monitor, detect, or know that.

24 So, I'm not sure how you would try to
25 quantify or evaluate whether this was a slight leakage

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1 of a microcurie or so. Or we extravasated multiple
2 millicuries.

3 MR. LATTANZE: Yeah. That's a great
4 question. So, as Dr. O'Hara pointed out, you know,
5 again we're not -- all our device can tell you is
6 whether there is excess radiotracer. And then we
7 leave it to the clinicians to determine how much is
8 there.

9 Often times to your point, they'll see
10 like a trace of a, you know, what appears to be a
11 little bit of radiotracer. Our device would pick that
12 up. But the time activity curve would be very, very
13 low above the reference arm.

14 It's the ones that are like the ones that
15 I've shown you before that were considered to be in
16 sitting down with the physicians at the site. And
17 when often times they had physicists, get involved and
18 try to image the injection site if it was available,
19 if the injection site was in the field of view. And
20 in those cases, the clinicians determined that that
21 was the infiltration.

22 But, I think the University of Santiago in
23 Spain example, they had an 18 percent infiltration
24 rate. And of those they found that they had a very
25 small percent that were moderate or significant.

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1 And you know, my point is, if you're only
2 looking at a static image, all you're seeing is what
3 was taken at 70 minutes. You don't know whether it
4 was, you know, dramatically worse than that
5 beforehand.

6 So you'd need to have some idea of what
7 happened during the uptake period. If that makes
8 sense.

9 CHAIRMAN PALESTRO: All right. Thank you.
10 Any comments or questions from attendees in the room?

11 (No response)

12 CHAIRMAN PALESTRO: On the bridge line?

13 (No response)

14 CHAIRMAN PALESTRO: All right. At this
15 point we're already running behind. And I'd like to
16 end the discussion for the moment on this topic.

17 However, it's an interesting issue that's
18 been raised. And it was last addressed by the NRC in
19 1980, which is almost 40 years ago.

20 And at that time I don't -- don't know if
21 there were any intravenously administered therapeutic
22 agents. There certainly are several since then.

23 And the vast majority, if not all of the
24 intravenously administered diagnostic agents were
25 technetium based. And now we've got indium-based

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1 agents, iodine-based agents, and so forth.

2 So, with that in mind, I'm going to form a
3 Subcommittee to reevaluate the 1980 NRC decision. And
4 you may come away with the same conclusion.

5 I have no idea. And this has nothing to
6 do with the device that Mr. Lattanze is talking about.
7 That's not part of this.

8 And so I'd like the Subcommittee to charge
9 -- the Subcommittee is to reevaluate the NRC's 1980
10 infiltration position. And to report back to us at
11 the September meeting.

12 I'm going to ask that Ms. Martin chair
13 this Committee, Subcommittee, excuse me. And members
14 will include Mr. Green, Ms. Shober, Mr. Sheetz, and
15 Dr. Dilsizian.

16 MR. LATTANZE: Thank you very much.

17 CHAIR PALESTRO: Thank you. And at this
18 time we will take a short break and resume -- let's
19 try to resume at five to 11:00 so we can get ourselves
20 back on schedule. Than you.

21 MR. EINBERG: But excuse me, before we
22 break, Dr. Palestro, would you like to have a
23 patients' rights advocate on the subcommittee also?
24 Because I think this has impacts for patients as well.

25 MS. HOLIDAY: Mr. Einberg, Ms. Weil's term

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1 ends in August. So she will not be here for the
2 September meeting.

3 However, I do recognize that the
4 Subcommittee would start their work prior to the
5 September meeting. Just to throw that out there for
6 consideration.

7 MR. EINBERG: To the extent that she can
8 participate while the deliberations are going on, I
9 would recommend that.

10 CHAIRMAN PALESTRO: I think that's an
11 excellent suggestion. I appreciate that. Ms. Weil?

12 MEMBER WEIL: Yes.

13 CHAIRMAN PALESTRO: You will?

14 MEMBER WEIL: I will.

15 (Laughter)

16 CHAIRMAN PALESTRO: Thank you. Okay.
17 We're adjourned for ten minutes.

18 (Whereupon, the above-entitled matter
19 went off the record at 10:44 a.m. and
20 resumed at 10:56 a.m.)

21 CHAIRMAN PALESTRO: I'm going to call the
22 session to order, please, to resume, so we can try to
23 get back on schedule.

24 MS. HOLIDAY: Dr. Palestro just requested
25 that ACMUI members return to your respective seats.

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1 We're getting ready to restart.

2 CHAIRMAN PALESTRO: All right, and we're
3 going to resume with item number six on the agenda for
4 today, a summary of the changes to 10 CFR Part 35, and
5 it will be presented by Ms. Lisa Dimmick from the NRC.
6 Thank you.

7 MS. DIMMICK: Thank you, and good morning,
8 everyone. So I guess I can thank the meeting planners
9 for not putting this talk after the lunch break
10 because I know, the regulation changes, how exciting
11 is that? So anyway, we'll go ahead and get started.

12 So this presentation will kind of quickly
13 step through the final rule changes, largely for 10
14 CFR Part 35, and there were some changes impacting
15 Parts 30 and 32, but largely Part 35.

16 So the objective today is to present to
17 you a summary of the rule changes that became
18 effective January 14, 2019. Just to note that Part 35
19 was last amended in its entirety back in 2002, so this
20 rule change or set of changes really encompasses a
21 number of clarifications that needed to be made for
22 that 2002 rule.

23 So this was really a long term rule in the
24 making. There's a lot of history with this rule.
25 There's a lot of involvement with ACMUI on this rule

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1 change, especially in the area of permanent implant
2 brachytherapy and the medical event definitions.

3 The major changes to the rule do address
4 impacts for permanent implant brachytherapy, medical
5 event reporting, and notification. The rule also now
6 names an associate radiation safety officer or
7 officers on a medical license.

8 There are generic changes to training and
9 experience requirements for all individuals, and there
10 is now a new frequency for reporting of, well, a new
11 frequency for testing the Moly breakthrough in your
12 Moly/Tech generators, as well as the reporting of
13 failed generators.

14 So those are the major changes that most
15 people are aware about. However, there are changes
16 throughout the rule, and so in that sense, the rule
17 changes were substantive because there were a lot of
18 changes.

19 So we can kind of break down our talk this
20 morning on the rule changes in 11 broad areas of the
21 Part 35 regulation, so we're going to touch on the
22 generator changes, the changes or the new associate
23 RSO, as well as the ophthalmic physicist.

24 There were some changes impacting emerging
25 technologies, changes in notifications, and some of

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1 the rule changes or areas of interest are actually
2 found in the notification section of the regulation.
3 We have changes to manual brachytherapy, training and
4 experience.

5 There are some changes in diagnostic
6 medical uses, also in the 10 CFR 35.300,
7 radiopharmaceutical requiring a written directive,
8 sealed source and device registry, vendor training,
9 and Gamma Knife.

10 So we're going to talk just basically
11 about some of these rule changes, and in some areas,
12 I'll try to give a little bit more perspective or
13 insight as to why that rule was changed.

14 Okay, so for generators, the breakthrough
15 for the Moly/Tech generator is now to be required for
16 each generator elution. Before, the rule required
17 just the first elution of the day with that generator,
18 but now it's for each generator elution the
19 Moly/Technetium ratio needs to be checked.

20 Also, if the breakthrough limits for the
21 Moly/Tech generators, as well as the strontium
22 rubidium generators, and we also carry this into the
23 35.1000 guidance for the germanium/gallium generators,
24 if you have a breakthrough in excess of the limits,
25 there is a requirement now to report that as a failed

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1 generator to both the NRC and the distributor.

2 So the rule change basically changes the
3 frequency for testing the Moly/Tech breakthrough, and
4 then there is the reporting requirement for failed
5 generators.

6 So the reporting requirement for the
7 failed generators is a telephone report within seven
8 calendar days, and that telephone report needs to
9 include the manufacturer, model number, and serial
10 number or lot number of the generator, the results of
11 the measurement, the date of the measurement, and
12 whether the dosages were administered to patients or
13 human research subjects when the distributor was
14 notified and the action taken.

15 A follow up 30-day report is also required
16 to note any actions taken by the licensee, also the
17 patient dose assessment and the methodology used to
18 make that dose assessment if the eluate was
19 administered to the patient.

20 So when we were talking earlier about the
21 strontium rubidium generator and the breakthrough, so
22 now we have a new regulation that will help filter or
23 provide a path to report those situations that wasn't
24 maybe previously present in the regulations.

25 The regulations now define an Associate

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1 Radiation Safety Officer. Here, it will be ARSO, and
2 we also identify an ophthalmic physicist. So these
3 terms are defined in the regulation. These are new
4 definitions in the regulations.

5 There are some changes to preceptors for
6 the ARSO, and also some other requirements for the
7 ARSO that I'll mention here in a moment, and it
8 provides some clarifications for the licensee, the
9 radiation safety officer, and the ARSO.

10 So the changes in the regulations are
11 found, some of the changes here are found in 35.50, 10
12 CFR 35.50. It now includes training requirements for
13 the radiation safety officer and associate radiation
14 safety officer.

15 The changes made clarify the basic
16 training and experience requirements are basically the
17 same for the RSO and the ARSO. The regulations also
18 permit the ARSO to provide written attestation.

19 So for example, the ARSO authorized for
20 maybe 10 CFR 35.100 uses on a license and that license
21 is authorized for 35.100 and 35.200 uses. That ARSO
22 could provide the attestation for another ARSO or a
23 radiation safety officer for the 35.100 uses because
24 that's the uses for which that ARSO is authorized. So
25 the message here is that the ARSO can provide written

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1 attestation for another RSO or ARSO.

2 This regulation also fixed a few issues in
3 the previous regulation. It does now permit -- so if
4 an individual is seeking to be a new authorized user
5 and a radiation safety officer on a new license, that
6 can occur.

7 Previously, when a new license was issued,
8 you could not make the individual both an AU and an
9 RSO at the same time. Now with the rule, that can
10 happen for those new licenses where the AU will also
11 be the RSO.

12 The regulation, the new regulation also
13 fixes and permits authorized individuals to use
14 authorized status to be an RSO on a different license
15 for the same use for which the individual is
16 authorized.

17 Previously, the authorized individuals had
18 to be listed on the same license for which they are
19 seeking RSO status. So the rule made some
20 clarifications and provided some flexibilities that
21 weren't previously found in the rule.

22 The ophthalmic physicist, this is a new
23 role, and there are specified tasks for the ophthalmic
24 physicist, as well as certain training criteria that
25 needs to be met for the ophthalmic physicist. The

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1 rule also clarifies the expected duties for the
2 authorized medical physicist and that of the
3 ophthalmic physicist.

4 Emerging technologies, so with regard to
5 10 CFR 35.1000, which is the other uses of byproduct
6 material, we often refer to this as emerging medical
7 technologies, there is a link to 35.1000 to 35.12. So
8 35.12 clarified information for the 35.1000 medical
9 use applications.

10 So now, in addition to the regulations in
11 35.12, an application for a license or amendment for
12 medical use of byproduct material as described in
13 35.1000 must include any additional aspects of the
14 medical use of the material that are not addressed in
15 or are different from other parts, the other subparts
16 of 10 CFR, including general information,
17 administrative requirements, technical requirements,
18 records, and reports, also the identification and
19 commitment to follow the applicable radiation safety
20 program requirements that are appropriate for that new
21 technology that are found in the other medical
22 modalities, in addition, if there is specific
23 information that should be included regarding
24 radiation safety precautions and instructions for
25 those uses under 35.1000 or the methodology for dose

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1 measurement for doses to be administered to patients
2 or human research subjects, as well as calibration,
3 maintenance, and repair of instruments. So the
4 regulation makes the link between 35.1000 and 35.12
5 more clear.

6 So notifications is an interesting section
7 of the regulations because this is where it describes
8 what amendments or notifications are required, so in
9 this section are some of the areas that we've already
10 mentioned regarding, for example, the ophthalmic
11 physicist.

12 So for the ophthalmic physicists was added
13 to the amendment section in 35.13. The section of the
14 regulation now allows the licensee to allow an
15 ophthalmic physicist, in addition to an AU, AMP, or
16 ANP to work without an amendment request provided the
17 individual is already listed as an ophthalmic
18 physicist on a license.

19 Also in the notification, the ARSO was
20 added to the amendment section. This section of the
21 regulation requires the licensee to submit and receive
22 approval for an amendment before it permits anyone to
23 work as an ARSO or before the RSO assigns duties and
24 tasks to that ARSO that differ from those tasks for
25 which the individual is authorized on the license.

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1 The notifications also permit the licensee
2 to receive a sealed source from a different
3 manufacturer or to receive a different model number
4 than authorized by its license. So if the sealed
5 source is used in manual brachytherapy, it's listed in
6 the SS&D and is in a quantity for an isotope already
7 listed by the license.

8 So this rule uses the provisions of the
9 notification process to give manual brachytherapy
10 licensees the flexibility to change manufacturers or
11 models of a source for which they're authorized, or a
12 radionuclide for which they're authorized without
13 having to wait for an approval of an amendment.

14 The notifications, there's also, in this
15 section, the regulations were revised to remove the
16 requirement for preceptor attestation for board
17 certified individuals. The regulation continues to
18 require submission of a copy of the board
19 certification and documentation of additional training
20 of clinical case work for authorized users under 10
21 CFR 35.300 or the additional training for an AU or ANP
22 under 35.600.

23 And then last, I wanted to note that with
24 regard to exemptions regarding Type A specific
25 licensee of broad scope, the broad scope licensee is

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1 exempted from certain notification processes such that
2 it can name its own users and an ophthalmic physicist
3 as a new user under that broad scope licensee, that
4 the broad scope licensee can name them without
5 notification.

6 Manual brachytherapy, so the ACMUI had
7 raised concerns that the NRC's regulations that were
8 issued in 2002 did not properly address the needs of
9 the manual brachytherapy authorized users and
10 patients. Physicians were beginning to perform manual
11 brachytherapy procedures in real time in the operating
12 room and using image guided techniques, and as such,
13 they were finding they might need to adjust the doses
14 or the dose that was going to be delivered to the
15 patient, and they were not able to calculate the
16 radiation dose to the patients. So they believed the
17 written directive requirements and medical event
18 reporting requirements prevented them from providing
19 the best care to patients.

20 So as a result, and a long process, 35.40
21 was amended to clarify some components of the written
22 directive.

23 With the written directive, it still
24 includes an authorized user's signature and dating
25 before the administration, but instead of requiring a

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1 dose, it now requires the total source strength in the
2 pre-implantation portion of the written directive to
3 be recorded, and what it does do is it does delete the
4 dose, so again, it's only using source strength.

5 So in the pre-implantation portion of the
6 written directive, the source strength to be
7 administered or delivered is recorded, and then upon
8 completion of the procedure, the actual source
9 strength that was delivered is what gets recorded.

10 And it does require and it introduces a
11 new term that the source strength that was delivered
12 is to be reported on the post-implantation of the
13 written directive before the patient leave the post-
14 treatment recovery area.

15 And what we mean by that, and it's got a
16 specific meaning in the regulations, the term post-
17 treatment recovery area in 35.40 means the area or
18 place where a patient recovers immediately following
19 the brachytherapy procedure before being released to a
20 hospital intensive care unit or patient room, or in
21 the case of an outpatient treatment, released from the
22 licensee's facility.

23 So the other change in the manual
24 brachytherapy, it revises the definition of a medical
25 event for permanent implant brachytherapy. So the new

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1 requirements or the new criteria for reporting a
2 medical event in permanent implant brachytherapy says
3 that licensees shall report any event as a medical
4 event except for an event that results from patient
5 intervention in which the permanent implant
6 brachytherapy, for the permanent implant
7 brachytherapy, the administration of byproduct
8 material or radiation from byproduct material results
9 in a total source strength administered differing by
10 20 percent or more from the total source strength
11 documented in the post-implantation portion of the
12 written directive, or the other, going on, the total
13 source strength administered outside of the treatment
14 site exceeding 20 percent of the total source strength
15 documented in the post-implantation portion of the
16 written directive, or the administration that includes
17 any of the following, the wrong radionuclide, the
18 wrong individual or human research subject, a sealed
19 source implanted directly into a location
20 discontinuous from the treatment site as documented in
21 the post-implantation portion of the written
22 directive, or a leaking source resulting in a dose
23 that exceeds 0.5 Sv or 50 Rem to an organ or a tissue.

24 And another term was introduced in the
25 regulations being discontinuous, and what does that

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1 mean with regard to 10 CFR 35.40? Discontiguous in
2 general terms is used to describe things that are not
3 contiguous in space, things that are not adjacent or
4 touching, and things that have a gap between, or
5 disconnected, or separate.

6 As it relates to medical event criteria in
7 35.30.45 for permanent implant brachytherapy,
8 discontiguous means a location that is not physically
9 adjacent to or touching the treatment site.

10 The other component to manual
11 brachytherapy is requiring licensees to have
12 procedures to determine if medical events have
13 occurred, and the procedures must have determined
14 within 60 days.

15 So the requirement now has that the
16 procedures need to determine for permanent implant
17 brachytherapy within 60 calendar days from the date
18 that the implant was performed, the total source
19 strength administered outside of the treatment site
20 compared to the total source strength documented in
21 the post-implantation portion of the written directive
22 unless a written justification of patient
23 unavailability is documented, and that's what I just
24 referred to.

25 So concerning training and experience,

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1 this rule did address some generic training and
2 experience changes. Primarily this rule removed the
3 written attestation and board certification pathway
4 requirements.

5 It revised the written attestation when
6 one is required to say in one portion of it that the
7 person who is being attested to is able to
8 independently fulfill the radiation safety-related
9 duties as, for instance, an authorized user, as an
10 authorized medical physicist, or authorized nuclear
11 pharmacist.

12 This regulation change also permits
13 residency program directors to provide written
14 attestation under certain conditions.

15 So one area I wanted to note was that in
16 35.51, this is for the training for the authorized
17 medical physicist. This section was amended to
18 clarify that the AMP who provides supervision for
19 meeting the requirement of this section must be
20 certified in medical physics by a specialty board
21 whose certification process has been recognized by the
22 NRC or an agreement state.

23 Under the T&E, there were some
24 grandfathering conditions that were incorporated into
25 the rule as a result of some previous petitions in

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1 this area. The rule grandfathered -- so grandfathered
2 RSOs and AMPs must meet the requirements in 10 CFR
3 30.50 and 30.51 for materials or uses that they were
4 not previously authorized for.

5 The grandfathered individuals who were
6 board certified on or before October 24, 2005 by
7 boards listed in the regulation for materials and uses
8 performed before this date. So there was some
9 grandfathering as a result of what we know as the
10 Ritenour petition. For those of you, that petition
11 came in several years ago.

12 There were a few clarifications made under
13 diagnostic medical uses. There was concern that the
14 sources authorized under 35.65 for calibration,
15 transmission, and reference sources were being used on
16 patients without licensees recognizing these uses
17 required by an authorized user.

18 There was also some concern that the
19 sources that have an individual maximum activity were
20 being bundled to produce a source that exceeded the
21 maximum value in the regulation, so clarifications
22 were made in that regard, and so the regulations also
23 clarify when these sources do not have to be listed in
24 the license.

25 Continuing with diagnostic medical uses

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1 for the T&E, for use of sealed sources and medical
2 devices for diagnosis, this section was restructured
3 and expanded to clarify that both diagnostic sealed
4 sources and devices authorized under 35.500 for use of
5 sealed sources for a diagnosis are included in the T&E
6 requirements of the section.

7 A new paragraph was also added that
8 recognizes the individuals who are authorized for uses
9 listed in 35.200 or equivalent agreement state
10 regulations are also authorized for use of diagnostic
11 sealed sources or devices under 35.500.

12 So there were amendments made under
13 35.300, radiopharmaceuticals requiring a written
14 directive, and so the points I wanted to make here was
15 that under 35.300, there was a change that clarifies
16 that a licensee's authorization of the
17 radiopharmaceuticals requiring a written directive is
18 only for those types of radiopharmaceuticals for which
19 the authorized user has documented training and
20 experience.

21 This section was also amended for the
22 35.390, training for unsealed byproduct material for
23 which a written directive is required. This section
24 of the regulation was revised to identify a single
25 category of parenteral administrations of a

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1 radionuclide.

2 Parenteral administration of any -- and
3 that changes parenteral administration of any
4 radioactive drug that contains a radionuclide that is
5 primarily used for electron emission, beta radiation
6 characteristics, alpha radiation characteristics, or
7 photon energy of less than 150 keV for which a written
8 directive is required.

9 And just to note, in 35.300 and under
10 35.396, training for parenteral administration of
11 unsealed byproduct material requiring a written
12 directive, the change concerning the parenteral
13 radiation characteristics was carried over in this
14 section to be the same as 35.390.

15 And I also wanted to note that under
16 35.396, that this is a training and experience section
17 that does still require an attestation for board
18 certified individuals.

19 I have several slides that, after looking
20 at them, are probably a little bit confusing. So
21 they're included. It's not advancing, so -- that talk
22 about the previous rule, the current rule through
23 35.300, but I believe they're a little bit confusing
24 and they kind of restate what I just said in regard to
25 the 35.300 and 35.390 and 396 descriptions in the

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1 regulations that were amended, so we're going to skip
2 ahead through these for clarification purposes.

3 35.400, use of sealed sources for manual
4 brachytherapy, so this section is expanded to allow
5 for sources that are listed in the sealed source and
6 device registry for manual brachytherapy to be used
7 for other manual brachytherapy uses that may not be
8 explicitly listed in the sealed source and device
9 registry.

10 The paragraph in the regulation was
11 amended to allow sources that are listed in the sealed
12 source and device registry for manual brachytherapy
13 medical uses to be used for manual brachytherapy
14 medical uses that are not explicitly stated in the
15 sealed source and device registry provided that these
16 sources are used in accordance with the radiation
17 safety conditions and limitations described in the
18 sealed source and device registry.

19 These radiation safety conditions and
20 limitations described in the sealed source and device
21 registry may apply to storage, handling,
22 sterilization, conditions of use, or leak testing of
23 the radiation sources.

24 The NRC recognizes that the medical uses
25 specified in the sealed source and device registry may

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1 not be all inclusive, so the final rule permits
2 physicians to use manual brachytherapy sources to
3 treat sites or diseases not listed in the sealed
4 source and device registry.

5 For example, the sealed source and device
6 registry may specify that the sources are for
7 interstitial use, but the final rule change allows
8 physicians to use sources for a topical use. It does
9 not have to be explicitly stated in the SS&D that
10 topical use is a condition of use.

11 So the NRC determined that flexibility
12 should be afforded to physicians to use at their
13 discretion in the practice of medicine brachytherapy
14 sources in this way.

15 Coming down the pipe, vendor training, so
16 there was an amendment to 35.610, safety procedures
17 for instructions for remote afterloader units,
18 teletherapy units, and gamma stereotactic radiosurgery
19 units. This section was revised and restructured to
20 add a new training requirement for the use of
21 afterloaders, teletherapy units, and gamma
22 stereotactic radiosurgery units.

23 This amendment requires all individuals
24 who operate these units to receive vendor operational
25 and safety training prior to their first use for

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1 patient treatment of a new unit or an existing unit
2 with a manufacturer upgrade that effects the operation
3 and safety of the unit. Again, this is a new
4 requirement in these regulations.

5 This training must be provided by the
6 device manufacturer or by an individual certified by
7 the device manufacturer to provide that training.
8 This training is also required when software upgrades
9 are made by the vendor or the manufacturer that effect
10 the operation or safety of the unit.

11 This section was also revised to clarify
12 that the training required by this paragraph on the
13 operation and safety of the unit applies to any new
14 staff who will operate the unit or the units at the
15 facility.

16 And the last regulation change I wanted to
17 mention is in the area for 35.655 for Gamma Knives
18 specifically, and this is now the full inspection
19 servicing for teletherapy and gamma stereotactic
20 radiosurgery units.

21 The section title was revised to delete
22 the five-year inspection and insert full inspection
23 servicing to more accurately reflect the requirements
24 in this section for inspection and servicing of
25 teletherapy units and gamma stereotactic radiosurgery

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1 units.

2 The regulation was revised to extend the
3 full inspection and servicing interval between full
4 inspection servicing for gamma stereotactic
5 radiosurgery units from five to seven years to assure
6 proper functioning of the source exposure mechanism.

7 The interval between the full inspection
8 and servicing for teletherapy units remains the same,
9 so it's not to exceed five years. So it was changed
10 for GSRs to seven years and remain the same for
11 teletherapy units at five years.

12 And that, real quick, were the changes to
13 Part 35, and if you have any questions, my colleague,
14 Donna-Beth Howe -- yeah, I don't know if you want to
15 hold questions now, or if there are any questions, or
16 --

17 CHAIRMAN PALESTRO: Thank you, Ms.
18 Dimmick, for a very concise review of a very
19 comprehensive document. We have time for one or two
20 brief questions or comments from the committee.

21 MS. DIMMICK: Let me -- I'll take
22 questions, but just, we are having -- we've had
23 several public meetings on the Part 35 changes and
24 they last anywhere from about four hours, then with a
25 lunch break, almost five hours.

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1 So they are fairly comprehensive and take
2 a deeper dive into why the rule areas were changed.
3 We also talk about inspection changes that were made
4 to look at various areas of the regulations and
5 inspection.

6 Our next public meeting will be on April
7 24. It will be on our public meeting notice website,
8 so, and Donna-Beth Howe and Maryann Ayoade have been
9 the presenters of those webinars and they've been very
10 well received.

11 So if anyone wants to spend a couple of
12 hours listening more about Part 35, you are more than
13 welcome to call into that webinar.

14 CHAIRMAN PALESTRO: Thank you very much.
15 Mr. Sheetz?

16 MEMBER SHEETZ: I actually participated in
17 the last webinar and I thought it was absolutely
18 excellent, and I think it's a must for any medical
19 RSO.

20 MS. DIMMICK: Yeah.

21 CHAIRMAN PALESTRO: Thank you. Any other
22 comments or questions? Comments or questions from
23 attendees here in the room or on the line?

24 All right, if not, then we will move onto
25 the final topic of this morning's session, the

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1 Germanium-68/Gallium-68 Subcommittee Report which will
2 be presented by Ms. Shober.

3 MEMBER SHOBER: Good morning. I will wait
4 for the slides to come up, I guess. Okay, yes, my
5 name is Megan Shober and I'm going to be presenting
6 the discussion from the ACMUI subcommittee on the
7 Germanium-68/Gallium-68 generator licensing guidance.

8 Next slide.

9 The subcommittee members, as we heard
10 earlier this morning, most of them are Dr. Metter,
11 Mike Sheetz, and myself, and our NRC staff resource
12 who is very helpful is Dr. Diabes. Next slide,
13 please.

14 Okay, so just to kind of go through some
15 of the features of the existing guidance that was
16 published in 2017 -- you can click. The current
17 guidance expressly names the Eckert and Ziegler brand
18 of the generator. It also includes a specific
19 breakthrough limit that's particular to that
20 generator.

21 It has some instructions for what to do if
22 the generator hasn't been eluded within 48 hours. It
23 requires notification to the NRC operations center if
24 the eluate exceeds the breakthrough levels, and it
25 requires wipe tests on each day of use. So that's

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1 what has been, that is functionally in place now, and
2 if you can go to the next slide?

3 So when the proposed guidance was
4 published, there were several things the NRC was
5 trying to move forward with in these future versions
6 of the guidance, and one of those is to make the
7 guidance brand neutral as there's already one
8 additional generator and several others that are
9 coming down the pipeline.

10 So the proposed revision removes the
11 reconditioning requirements for generators that are
12 not eluded within 48 hours, and there were some
13 revised breakthrough reporting requirements in the
14 proposed guidance that talked about multiple failures,
15 and so those are just some of the higher level changes
16 with the proposed licensing guidance changes. Next
17 slide.

18 Okay, so the subcommittee had a few
19 recommendations that I would like to highlight today.

20 So the guidance in its draft form had an alternative
21 pathway training option for an authorized user, but
22 not for an authorized nuclear pharmacist. So to make
23 it consistent, we suggested adding an alternate
24 pathway training option for the authorized nuclear
25 pharmacist.

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1 As I mentioned earlier, the breakthrough
2 limit that is in the proposed guidance revision does
3 have a brand-specific breakthrough limit, and it's my
4 understanding that some of the other generators that
5 are developed or being developed may have different
6 breakthrough limits for those products, and so our
7 recommendation was to remove the brand-specific
8 breakthrough limit from the licensing guidance.

9 And then we, as the subcommittee, wanted
10 to reject the proposed breakthrough failure reporting
11 requirement, and in lieu of that, we recommend
12 conformance with the recently published 10 CFR 35 that
13 we just heard about. Okay, next slide.

14 Okay, so one of the things that we had a
15 lot of discussion about in the subcommittee is at what
16 point the breakthrough is considered a generator
17 failure, and this is because unlike with other
18 generators that are commonly in use in nuclear
19 medicine, the breakthrough testing for these
20 germanium/gallium generators, it does take a couple of
21 days to actually get to the point where you can
22 determine whether the generator has breakthrough.

23 And so the question that we have that we
24 weren't really able to resolve with the current
25 licensing guidance is when does that failure happen?

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1 Is it when you elute the generator to take the test?

2 Is it when you measure that after all of
3 the gallium has decayed? Is it later, some day later
4 when you actually calculate what that breakthrough
5 number is? And so we just were wanting some
6 clarification on that point at which that breakthrough
7 is considered failed.

8 And then with the last recommendation to
9 highlight today, we recommended revising the survey
10 requirements to allow increased flexibility in how
11 those are performed.

12 So the guidance currently specifies wipe
13 testing, but, for example, kit preparation areas, they
14 could be adequately monitoring with meter surveys.

15 And then the other comment about that is
16 that the guidance currently requires generator storage
17 areas to be surveyed quarterly, and that conflicts
18 with the existing guidance in NUREG-1556 Volume 13 for
19 radiopharmacies, which requires weekly contamination
20 surveys of storage areas.

21 So those are the recommended changes from
22 the subcommittee and that's all I had for this part of
23 the presentation.

24 CHAIRMAN PALESTRO: Okay, thank you for
25 your presentation, Ms. Shoher. Any comments from

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1 other members of the subcommittee? Mr. Green?

2 MEMBER GREEN: I think this is a very nice
3 report, a very thorough report, and it does nail down
4 some of the unique characteristics of germanium
5 generators.

6 One artifact of the germanium generator is
7 it does not have a United States Pharmacopeia
8 breakthrough percentage. The analog, the Moly/Tech
9 generator has a USP limit of 0.15 microcuries of Moly
10 per millicurie of Tech at the time of patient
11 administration.

12 There is no USP analog for that for
13 germanium/gallium because the raw trichloride is not
14 FDA approved for human use in raw form. You use that
15 as an API to label a kit that's FDA approved. So
16 there's no USP limit for the breakthrough percentage.

17 The manufacturer, Eckert and Ziegler, has
18 a 0.001 percent breakthrough limit that they've
19 adopted and that's the European Pharmacopoeia
20 breakthrough limit because in the European
21 Pharmacopoeia, they do have a standard for it, and so
22 generator manufacturer number one has that European
23 limit, so does generator number two. The Galli Eo has
24 the same 0.01 percent.

25 There's another manufacturer coming out

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1 that's got a unit that's in the pipeline that has a
2 0.05 percent, so it's a value five times higher than
3 the other two manufacturers.

4 There is no U.S. limit to point to. We're
5 kind of hugging and holding the European limit for
6 those two manufacturers. Is the NRC, is the committee
7 comfortable with saying don't exceed the
8 manufacturer's limit, but two manufacturers have a
9 value that is one-fifth of the other? Just a
10 question.

11 CHAIRMAN PALESTRO: Any other comments or
12 questions? Mr. Sheetz?

13 MEMBER SHEETZ: I actually have a question
14 or a clarification from the NRC related to the
15 licensing guidance document which was not addressed by
16 our subcommittee.

17 There was a memorandum issued on July 13,
18 2017 creating a technical basis for the exemption from
19 the decommissioning funding plan for licensing of a
20 germanium/gallium generator, but I was curious and
21 I've had questions from several licensees to me on
22 what the rationale was for still requiring the
23 financial assurance element?

24 If the requirement is for the licensee to
25 have to return the generator to the vendor or to the

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1 manufacturer, what was the need or rationale for still
2 requiring the financial assurance?

3 Because the decommissioning funding plan
4 requires manpower to develop the plan, but the
5 financial element actually costs the licensee money,
6 and so if we could provide clarification on that, I
7 know that would because I know I have gotten questions
8 on that. Thank you.

9 MR. EINBERG: Lisa, can you address that
10 question, or Said?

11 DR. DIABES: Said Diabes. Thank you for
12 the question. So before I answer any of your
13 questions, let me clarify something. So a licensee
14 has the option of pursuing a DFP or pursuing the
15 medical exemption, so they have either one, or, you
16 know, whatever is in their best interest.

17 The whole point of providing the medical
18 exemption was to relieve a licensee from the actual
19 DFP because early on, the same rationale of being
20 expensive, too onerous, too complicated was brought up
21 to the committee and to staff as well, so the whole
22 point of initiating discussions of the medical
23 exemption were under that basis.

24 So going back to your question on what's
25 the point of financial assurance. When we initiated

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1 discussions as we exempted the DFP, there had to be a
2 mechanism that provided a pocket of money or basically
3 finances to assure that in a case of bankruptcy or a
4 case of an emergency, there was funding somewhere to
5 work with decommissioning, and that was the basis.

6 I don't know if Lisa would like to provide
7 further information or our legal side. Okay, thank
8 you.

9 CHAIRMAN PALESTRO: Mr. Sheetz?

10 MEMBER SHEETZ: Thank you, and I
11 understand that rationale should the licensee go
12 bankrupt, but in the guidance, in that memorandum, it
13 left it open to agreement states because it's a health
14 and safety compatibility level.

15 And so the agreement states would have the
16 option of not requiring financial assurance, and
17 that's exactly what's happening across the country.
18 Some agreement states are requiring it, other ones are
19 not, and so it makes it difficult for the licensees
20 having a double standard.

21 CHAIRMAN PALESTRO: Mr. Einberg, could I
22 ask you to respond to that?

23 MR. EINBERG: Yes, so the agreement states
24 are co-regulators, and as such, they have the latitude
25 to establish the financial assurance requirements for

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1 their particular state.

2 As such, again, what we find acceptable,
3 the agreement states may have more stringent
4 requirements, and as such, it seems like what you're
5 calling out is happening across the country or in
6 certain states, that they have additional requirements
7 that they want to impose, and so that's a part of the
8 compatibility that we have agreed with the agreement
9 states.

10 Our agreement state representative, Megan
11 Shober, do you have anything to add regarding that?

12 MEMBER SHOBER: So the thresholds at which
13 financial assurance is required, those are uniform
14 across the country, and I think the difference is that
15 what you're mentioning is with the amount of financial
16 assurance or whether or not there's an exemption.

17 So agreement states or the NRC can exempt
18 licensees from any rule or requirements on a case by
19 case basis, and so I don't have a lot of -- I know
20 that there was a lot of question originally when this
21 first version of the guidance came out as far as what
22 actually is being exempted.

23 And so, and we were receiving requests
24 from licensees to use these products before they
25 showed up at a lot of NRC facilities, and so straight

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1 out the gates, agreement states often have -- we
2 encounter these products first.

3 We have to make these decisions early on,
4 and it took quite a while to get the memo out
5 originally about what NRC's position about financial
6 assurance was.

7 And so I think in the period of months to
8 a year, or however long it took between when these
9 products first show up versus when the NRC policy
10 statement came out, that's the time period where the
11 various states are making the best decisions they can
12 with the information that we have, and I think that's
13 where some of those gaps tend to show up, and then
14 once those exemptions have been granted, it's
15 difficult to go back and then require the financial
16 assurance from a licensee.

17 CHAIRMAN PALESTRO: Mr. Green?

18 MEMBER GREEN: I understand the confusion
19 at first when the products first came on the market,
20 and so there was the document to allow an exemption
21 for the decommissioning funding plan and that's great,
22 but it still left open for debate in different
23 agreement states the financial assurance's warranty
24 bond.

25 I can assure you that the roughly \$100

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1 cost to Federal Express a generator back to the
2 manufacturer or distributor is far outweighed by the
3 annual cost of the quarter-million dollar financial
4 assurances' warranty bond. For the generator, it's
5 just overkill.

6 For under 100 bucks, I can FedEx a package
7 and make it go away, and have a proof of delivery
8 receipt that that generator is back at the
9 manufacturer, but a quarter-million dollar financial
10 assurances' warranty bond with an annual payment of
11 one or two percent of that bond to keep that bond
12 there far exceeds \$100 for FedEx.

13 CHAIRMAN PALESTRO: Other comments or
14 questions? Ms. Shober, I'd like to go back for a
15 moment. It was an issue, I think, raised by Mr.
16 Green, and then we got off on the financial assurance,
17 regarding the difference in the breakthrough levels.

18 Does the subcommittee have any concerns
19 about the fact that one company is allowing a
20 breakthrough about five times as much as two other
21 vendors?

22 MEMBER SHOBER: We, I think absent a value
23 that's in the regulations, I'm not sure that as a
24 subcommittee, I'm not sure that we want to recommend a
25 particular number, and then just looking, especially

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1 as we look forward, I don't know what those future
2 products are going to look like. I'm not sure that
3 it's appropriate for us to specify a number.

4 CHAIRMAN PALESTRO: Thank you. That
5 answers my question. Other comments or questions?
6 Mr. Ouhib?

7 MEMBER OUHIB: Yeah, I think it only makes
8 sense to have some sort of a number that any company
9 should be below that. They don't have to meet that,
10 but they have to be somewhere below a certain number.

11 MEMBER SHOBER: So are you suggesting a
12 maximum that may not agree with any of the vendor
13 recommendations?

14 MEMBER OUHIB: Correct, but something
15 that's meaningful, you know, based on some data.

16 CHAIRMAN PALESTRO: The question to that
17 is are those data available? And absent those data,
18 it would seem at least for the moment to be the more
19 appropriate course is what the subcommittee had
20 adopted. Mr. Green?

21 MEMBER GREEN: I'm aware of one published
22 study that shows the actual effective dose equivalent
23 from, you know, minuscule micro, submicrocurie
24 quantities of germanium in gallium, and the argument
25 could be made that even the manufacturer's level of

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1 0.001 percent is gross overkill, but that's votes.

2 We have the European Pharmacopoeia, which
3 two manufacturers have adopted, but it really doesn't
4 bear any semblance to reality as far as level of
5 patient harm.

6 CHAIRMAN PALESTRO: Thank you. Any other
7 comments or questions from the subcommittee or the
8 committee? Comments or questions from attendees in
9 the room? Comments or questions from the bridge line?

10 MS. JAMERSON: Yes, we have two
11 individuals. Mr. Mattmuller, I will unmute your line.

12 MR. MATTMULLER: Yes, hi, this is Steve
13 Mattmuller. As they often say, long time listener,
14 first time caller on the radio.

15 But I certainly appreciate the comments on
16 the financial assurances because I really think while
17 they're needed, I think at the current level, they're
18 inappropriate, inappropriately high.

19 And as an example, we recently are in the
20 process of replacing our cyclotron, so we've had to
21 figure out how much it would cost to remove and have
22 our old cyclotron disposed of, and the costs and the
23 effort are in sharp contrast to what would be needed
24 for a gallium generator.

25 I mean, for a cyclotron, you have a high

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1 energy accelerator that serves as a source of protons
2 for the radionuclide production versus a gallium
3 generator. It's a final product. It produces -- the
4 generator itself is produced under an FDA GMP and it
5 serves as a source of gallium-68 or
6 radiopharmaceutical used in a patient.

7 The math of the two items, the cyclotron,
8 its utility cabinets, its water recirculation system,
9 its shielding all adds up to a total of 66 tons versus
10 31 pounds for the EZ generator.

11 If you consider the radionuclides, the
12 cyclotron components and concrete floor underneath the
13 cyclotron contain activation products from its
14 operation, and the exact level and quantities are
15 really unknown at this time versus the generator where
16 you know exactly how much is in it from the
17 calibration label.

18 When it comes to disposal sites, our
19 cyclotron will go to two different sites in the U.S.,
20 one in Idaho and a second one in Texas for the
21 cyclotron itself and the shields, whereas for the
22 generator, it gets returned to the manufacturer.

23 So what are the current costs for all of
24 these activities? To decommission and remove our
25 cyclotron, it will cost less than \$400,000 versus

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1 what's currently recommended by the NRC is if you have
2 less than or equal to 100 millicuries, \$225,000, and
3 if you have more than 100 millicuries of germanium,
4 \$1.125 million.

5 So I think as highlighted or was hinted in
6 some of the previous comments by other members, the FA
7 amounts are really inappropriate for a gallium
8 generator.

9 And I would say when the NRC staff first
10 considered the FA amounts for the licensing guidance,
11 one really couldn't fault them for erring on the
12 conservative side, but we've now had several years of
13 experience with the generator in the field with no
14 incidents.

15 And as compared to other radionuclides
16 that require financial assurances, it should be
17 emphasized that this is a final product. It is a
18 completely known entity. Its product, gallium-68, is
19 used in patients, and its disposal is very, very
20 simple.

21 So I think it would be wonderful if the
22 same subcommittee could make a recommendation to
23 assign more reasonable levels of financial assurances
24 for the generators. I think \$10,000 per generator
25 would be more than sufficient and appropriate. Thank

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1 you.

2 CHAIRMAN PALESTRO: Thank you, Mr.
3 Mattmuller. Any other comments or questions from the
4 bridge line?

5 MS. JAMERSON: Yes, we have Mr. Rubin.
6 Mr. Rubin, I have unmuted your line. Mr. Rubin?

7 CHAIRMAN PALESTRO: All right, while
8 you're trying to connect with Mr. Rubin, I see that
9 Ms. Weil had a comment or a question.

10 MEMBER WEIL: I do have a comment just in
11 support of Mr. Green and Mr. Mattmuller's comments.
12 This is one of those instances where -- you can't hear
13 me -- one of those instances where an unnecessarily
14 stringent regulation may be creating a barrier for
15 patient access to a necessary piece of treatment and
16 diagnosis.

17 And I would strongly suggest that we
18 revisit this financial assurance question because
19 there are, you know, smaller institutions who don't
20 have broad scope licenses that make adding this
21 generator easy, financially easy, and it's an
22 unnecessary barrier in my opinion.

23 CHAIRMAN PALESTRO: Other comments or
24 questions? Mr. Sheetz?

25 MEMBER SHEETZ: Another point to consider

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1 is that the Appendix B Part 30 limits are based on the
2 Appendix B Part 20 limits, and so as one looks at the
3 rationale on how those limits are established from
4 inhalation and exposure rate at 10 centimeters, the
5 limit for germanium-68 would be 10 microcuries, and
6 then it would be exempt from the financial assurance.

7 CHAIRMAN PALESTRO: Other comments or
8 questions? Dr. Diabes?

9 DR. DIABES: Said Diabes. I want to add
10 that we're currently working on a petition for
11 rulemaking that is addressing financial assurance all
12 across, not only for germanium/gallium, but how we
13 implement financial assurance for every single case,
14 and that is currently under review and we're working
15 on it, and it will address many of the issues that
16 we're discussing here today.

17 CHAIRMAN PALESTRO: Thank you. Any other
18 comments or questions? Sorry, Ms. Martin?

19 MEMBER MARTIN: I was just wondering if he
20 could elaborate on what they were looking at for the
21 germanium-68 because obviously these are significant
22 costs now, or to follow Mr. Sheetz's recommendation to
23 allow them to be exempt by changing the limits.

24 CHAIRMAN PALESTRO: Dr. Diabes?

25 DR. DIABES: Said Diabes. So let me see

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1 what I can say here since we're currently working on
2 this petition, but with respect to germanium and
3 gallium, we're trying to find a way that we don't even
4 have to apply the exemption anymore.

5 So it's going to be based more on a risk
6 assessment approach per isotope and it will be applied
7 in the same manner all across, but it's still -- we're
8 working on it. I cannot expand more, but I'm going to
9 pass it to our colleague here from the legal side.

10 MS. HOUSEMAN: Hi, my name is Esther
11 Houseman. I'm an attorney in the Office of the
12 General Counsel and I just want to make a quick point
13 about the process.

14 So the staff is currently in the
15 deliberative process of reviewing the petition for
16 rulemaking. They're going to develop a paper to send
17 to the commission to make a recommendation on how to
18 disposition that petition, and the commission will of
19 course vote on it.

20 So what Dr. Diabes is explaining now is
21 that process that we're going through, but do keep in
22 mind that commission approval is necessary to move
23 forward with that proposed rulemaking.

24 CHAIRMAN PALESTRO: I have a question. In
25 terms of that proposal, can we get a sense, and I know

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1 it may be difficult, of a timeline?

2 MS. HOUSEMAN: The paper to the commission
3 should go up to the commission in the next several
4 weeks to a few months. Again, that depends on upper
5 level management review, so that's the point we're at
6 in the process. How long it will take the commission
7 to vote on that paper is highly variable and we can't
8 commit to a timeline on that.

9 CHAIRMAN PALESTRO: Thank you. Any other
10 comments or questions? Mr. Green?

11 MEMBER GREEN: As we get limited
12 opportunities to meet with the commissioners directly,
13 I think it would be worth the committee's time to
14 plant the seed that they will be hearing about the
15 decommissioning funding plan, financial assurance
16 warranty bond changes.

17 And they met with us one or two years ago
18 when we first showed them a generator and they
19 developed this exemption process. They will be
20 getting a document from the staff as we just
21 described, either we have the opportunity to meet with
22 the commissioners very soon.

23 And I think it would be worth the time to
24 plant the seed that we're very supportive of the
25 forthcoming financial assurance's revisions to

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1 facilitate generator use in the medical community.

2 CHAIRMAN PALESTRO: We are on the agenda
3 for a meeting tomorrow with the commission, but that
4 program is already set and it's not going to include
5 the Geranium-68/Gallium-68 generator, nor is there,
6 and correct me if I'm wrong, Mr. Einberg, nor is there
7 leeway to make alterations in these programs.

8 MR. EINBERG: Yes, Dr. Palestro, you're
9 correct. There is no leeway to make alterations in
10 the agenda right now.

11 So, but having said that, and in listening
12 to the dialogue here, maybe, Esther, will the ACMUI
13 have an opportunity to review the SECY paper at some
14 point or would that be appropriate for them to be able
15 to review the SECY paper that's going up to the
16 commission on decommission funding?

17 MS. HOUSEMAN: I don't believe that
18 process is built into the schedule because this
19 rulemaking, this proposed, would affect far more than
20 just medical uses.

21 If the commission were to see the paper
22 and if the paper recommends that we undertake this
23 rulemaking and they agree, and they vote to initiate
24 the rulemaking process, perhaps at the draft proposed
25 rule stage and the final, the draft final rulemaking

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1 stage, there might be an opportunity for ACMUI review
2 at that point.

3 Again, I say might because I'd have to go
4 back to the project manager and management in the
5 rulemaking division and the lead office on such a
6 rulemaking to confirm that.

7 CHAIRMAN PALESTRO: Any other comments or
8 questions? Bridge line?

9 MS. JAMERSON: Mr. Rubin, I'm going to
10 unmute your line.

11 CHAIRMAN PALESTRO: Is he on mute?

12 MS. JAMERSON: Is your phone on mute?

13 MR. RUBIN: Hey, it's Joe Rubin. Can you
14 hear me?

15 MS. JAMERSON: Yes, we can.

16 MR. RUBIN: Oh, good, sorry about that.
17 I'm clearly having audio problems. Mr. Joe Rubin on
18 behalf of the United Pharmacy Partners. We're a group
19 of 80 nuclear pharmacies. I just wanted to echo the
20 concerns about the financial assurance --

21 MS. JAMERSON: Mr. Rubin?

22 MR. RUBIN: -- for the gallium generators.
23 We'll be submitting more formal comments, but I
24 wanted to echo the concern and thank the ACMUI and the
25 commission for taking steps to try and address this

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1 problem, so thank you for your consideration.

2 CHAIRMAN PALESTRO: Thank you, Mr. Rubin.

3 All right, at this time, I'll entertain a motion for
4 approval of the --

5 MS. JAMERSON: One more.

6 CHAIRMAN PALESTRO: One more?

7 MS. JAMERSON: Mr. MacDougall, I'm
8 unmuting your line.

9 MR. MacDOUGALL: Yes, can you hear me?

10 MS. JAMERSON: Yes.

11 MR. MacDOUGALL: This is Rob MacDougall
12 and I'm the project manager for the petition for
13 rulemaking that Esther just spoke of, and I can at
14 least attest that if the commission does approve the
15 staff's recommendation and the rulemaking goes
16 forward, we have already built in additional time for
17 review, both during the proposed rule stage and the
18 final rule stage.

19 CHAIRMAN PALESTRO: Thank you. All right,
20 at this -- Mr. Einberg?

21 MS. DIMMICK: Hi, it's Lisa Dimmick,
22 medical team leader. I just wanted to add that UPPI
23 did send in a letter to the ACMUI to discuss their
24 issues and concerns with the financial assurance for
25 germanium/gallium generators, so you will have a

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1 letter appended to the meeting for their concerns.

2 CHAIRMAN PALESTRO: Any other comments or
3 questions? All right, at this point, I'll entertain a
4 motion for approval of the subcommittee's report. Dr.
5 O'Hara is second, Mr. Sheetz. Any discussion? All in
6 favor? Any opposed? Any abstentions? All right,
7 thank you.

8 All right, that ends this morning's
9 session and we will resume promptly at 1:00.

10 (Whereupon, the above-entitled matter went
11 off the record at 12:03 p.m. and resumed at 1:03 p.m.)

12 CHAIRMAN PALESTRO: All right, we're going
13 to call the afternoon session to order.

14 But before we begin with presentation on
15 medical related events, my haste to assemble a
16 subcommittee to review the NRC's viewpoint on
17 infiltrated doses, I neglected to add a staff
18 resource.

19 And that staff resource will be Maryann
20 Ayode. And I appreciate her willingness to
21 participate.

22 So now we're going to move on to the first
23 item on this afternoon's agenda, Medical Related
24 Events. And this will be presented by Dr. Howe. Dr.
25 Howe.

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1 DR. HOWE: Okay, welcome everybody back
2 from lunch. And this will be such an exciting one
3 that nobody is going to be napping. I know that.

4 So, I'm going to be talking about the
5 medical events that happened in the Fiscal Year 2018.

6 Which would have been October 1st, 2017 through the
7 end of September in 2018.

8 And medical events, we always put this
9 disclaimer. The number that's presented on this slide
10 at 150,000 therapeutic procedures is a ballpark. I
11 don't really have a reference for it but it's about a
12 right number.

13 So, the message here is that, as you see,
14 we will have very few medical events for the fiscal
15 year compared to the number of patients and treatments
16 that are being provided.

17 And previously, the ACMUI has asked for a
18 perspective on how the medical events for this year
19 compare with last year. So, I'm going to just run
20 very quickly through the, I got about the previous
21 five years and then this years.

22 So, you will see that the total medical
23 events for 2013 to 2015 range from 43 to 57. If you
24 look at the table, you'll see most of the medical
25 events are down in 35.1000.

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1 And as in all of those years and in this
2 year, most of those medical events are going to be
3 with the TheraSpheres and the SIR-Spheres.

4 And to be more up to date, I've got 2016
5 through 2018. And I've got a couple typos on there so
6 that should be '16, '17, '18.

7 And in this slide, I've got 50 medical
8 events reported in 2018. In fact, I went back and
9 counted, and I really only have 48.

10 And as you can see, we have very few
11 diagnostic medical events. We've had zero for the
12 last few years.

13 We didn't have very many
14 radiopharmaceutical therapy events. We have a fair
15 number of manual brachytherapy. That number is
16 incorrect, it should be 11 and 13.

17 And the parenthesis is the total number of
18 patients that were affected by medical events in that
19 particular category.

20 And once again, most of the medical
21 events, over half of them are occurring in 35.1000.
22 And most of those are in the Yttrium microspheres.

23 So now I'm going to start looking at
24 medical events by modality. And as you saw before,
25 there were no medical events in the diagnostic

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1 radiopharmaceuticals.

2 And we had two in the radiopharmaceuticals
3 requiring written directives. We had one for I-131
4 MIBG and we had one for Radium-223.

5 The MIBG case was an interesting one. In
6 this case, part way through the administration of the
7 MIBG, the patient needed to use the restroom facility,
8 so they disconnected the patient from the pump, and
9 when they came back and they reconnected it, they
10 didn't realize that they had not connected it
11 correctly at the Spiros connector.

12 And so, at the end of the procedure, they
13 ended up with a high activity of I-131 on the
14 patient's clothing and the bed linen.

15 And even at this point, they didn't do any
16 additional testing to see if they had a medical event.

17 And so, it wasn't until two days later that the
18 patient reported discomfort and reddening of skin on
19 the upper right thigh and erythema lesion that went to
20 spot formation the next day. So that was a fairly
21 hefty dose that they had not expected.

22 And why did it happen? Well, for one
23 thing, the activity levels for the I-131 were quite
24 high. They did not decontaminate the patient until
25 signs of the erythema.

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1 And it's clear that they could have done
2 some surveys to see that they had an I-131 skin
3 contamination. Even though they thought it would be
4 difficult to measure because of so much I-131 in the
5 patient.

6 And what did they do for corrective
7 measures? Well, for corrective measures they decided
8 that they will no longer disconnect the patient,
9 unless it's a medical emergency. So that they don't
10 have the issues with connecting and reconnecting.

11 That they will always use absorbent pads
12 underneath the administration line, so if there is a
13 leak on the administration line it will be absorbed
14 into the pad and not onto the patient.

15 And they will develop patient specific
16 decontamination procedures. Because with the I-131
17 MIBG, they would have had to use a different type of
18 decontamination than you would use from a water-
19 soluble isotope.

20 And so, the other case was a radium
21 dichloride. And in this case, we have one of our
22 medical events where the, a medical event is when you
23 depart from the written directive. In this case, the
24 written directive asks for something.

25 It asks for an oral administration of

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1 radium-223, which Radium-223 is never given orally.
2 And the technologist just must have been in autopilot
3 because she administered it intravenously, which is
4 the way it should have been administered. So the
5 patient got what they were supposed to get, but the
6 treatment was not in accordance with the written
7 directive.

8 And so, as a corrective measure, the
9 licensee is going to implement new written directive
10 procedures so that it is clear what mode of
11 administration you're going to have. I think they
12 looked at the, I guess they normally did sodium iodide
13 oral administration and they just clicked the wrong
14 boxes. And they're going to do a current review of
15 their policy and procedures.

16 So that takes us to the manual
17 brachytherapy procedures in 35.400. And this is where
18 I have some mistakes on my slide.

19 We had a total of 11 medical events
20 involving 13 patients. We had an eye plaque medical
21 event and then we have an unknown procedure.

22 And then for the prostate we had non-
23 medical events with 11 patients.

24 So, what happened with the eye plaque, the
25 licensee was using a new eye plaque and they hadn't

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1 really focused on, was there a difference between
2 their old plaque and their new eye plaque. And it
3 ended up there was a difference.

4 And so, the isodose curves differed in the
5 brachytherapy plan and the dose, because of how the
6 new eye plaque was made, put the dose deeper into the
7 tissue. So they had prescribed 8,000 centigray and
8 they only received 6,500. So that was their
9 corrective action.

10 Now, I've got an unknown procedure. And
11 you should expect that if the licensee doesn't provide
12 enough information in the NMED report, we're not going
13 to know much about this procedure. And I hope this is
14 one of the areas that will be talked about in the next
15 talk.

16 So, about all we got from this particular
17 NMED report was that it was only 70 percent of the
18 intended dose. I think I could guess that it's
19 probably going to be a prostate brachytherapy one, but
20 I don't have any information to confirm that.

21 So we'll have to go back to the regulator
22 and get additional information, okay?

23 So now we move on to the largest category
24 under manual brachytherapy, and those are the prostate
25 dose administrations.

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1 And it was pretty interesting here because
2 we had one licensee that had three different reports
3 of medical events with prostate brachytherapy. The
4 inspectors went out and inspected the licensee and
5 found a medical event in 2018.

6 And as part of that inspection process,
7 the licensee went back and did a historical review.
8 And during that historical review, they identified two
9 more medical events.

10 So the first report has three separate
11 patients within it, and then we're going to have two
12 more events that were reported later. So they did not
13 determine a root cause, but they attributed it to
14 human error.

15 They did not expand on what human error
16 was involved. It appears that some seeds may have
17 migrated post-implant.

18 So the first patient received 63 percent
19 of the prescribed dose, the second patient received
20 132 percent of the prescribed dose, the third patient
21 received 130 percent of the prescribed dose for the
22 prostate.

23 So that was the first report for that
24 particular licensee. And then subsequent to the 2018
25 medical event that was reported, they discovered two

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1 more medical events in 2018.

2 And so, in Report Number 2 it was an
3 underdose to the patient. And in Report Number 3, it
4 was also an underdose to the patient. And not a lot
5 of additional information was provided at this point.

6 So moving on to other prostate implant
7 brachytherapy therapy. We had a patient that received
8 roughly 53 percent of the dose.

9 This was a stranded implant. And part of
10 the seeds in the strand were implanted into the
11 bladder. And so when the licensee removed those
12 seeds, immediately then the dose to the treatment site
13 was much less.

14 And they attributed it to human error.
15 And for a corrective action, they're now going to have
16 a new written directive procedure.

17 They're going to use more needles and more
18 independent seeds and they're going to do less
19 aggressive sparing of the urethra. And they're going
20 to stop using pre-loaded strand seeds so that
21 improperly planted seeds can be individually placed.

22 And the next licensee, let's see, 15,
23 okay. They received 50 percent of the prostate,
24 received no dose at all.

25 They were using the ultrasound volume of

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1 the prostate. And it was smaller on the ultrasound
2 pre-implant scan, than the CT post-implant scan. So
3 the prostate appeared to be much larger in the CT
4 post-implant.

5 And the real-time implementation didn't
6 allow them to really get a good idea of how big the
7 prostate was. And so, it didn't permit visual
8 identification of visual errors that they had during
9 the procedure.

10 They attributed the medical event to human
11 error. For additional corrective actions they're
12 going to have additional training to personnel and
13 improved supervision.

14 And they're going to terminate the seed
15 implant program due to low patient volume. So they
16 have essentially given up their manual brachytherapy
17 program.

18 And now we've got two different reports on
19 this slide. And the first one the patient received 56
20 percent of the dose they attributed to human error.
21 And they use, the corrective actions they're going to
22 improve their imaging techniques.

23 In the next one, they received 73 percent
24 of the dose. And they attributed it to the lack of
25 dose being given to the prostate as an 18 percent

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1 increase in the prostate size when compared to the
2 pre-plan.

3 And the plan, they also planned and
4 intentionally cooler coverage near the rectum. So
5 they're going to provide additional training to their
6 personnel.

7 Okay. So now we've got a pretty
8 interesting medical event. In this case, they
9 intended to give 12,500 centigray, but they only gave
10 about 1,000 centigray.

11 They were using a Foley catheter, and they
12 should have inflated the balloon in the urethra, but
13 they inflated the balloon in the prostate. So, 32 of
14 the 54 seeds were placed outside the prostate and
15 three seeds couldn't be seen at all.

16 And they expect the risk of radiation
17 damage to the, they expect risk of the radiation
18 damage to the rectum and to the surrounding tissue
19 because of where the seeds ended up.

20 So they, part of the problem was they
21 failed to locate the Foley catheter, and that
22 compounded, was compounded by using a magnification
23 factor that didn't allow them to get a full view of
24 the treatment and relevant anatomy.

25 So, this licensee, for this particular

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1 case, the physician and the medical physicist will now
2 audibly concur on image quality before procedure.
3 This on their corrective actions.

4 Their manufacturer was asked to re-set the
5 default magnification value so that the initial view
6 would be of the relevant prostate anatomy. And then
7 once the first seed is implanted, they're going to use
8 the fluoroscopic image to make sure that they have the
9 relative location of the seed and the Foley catheter
10 where it's expected to be.

11 Okay. So now we've got a patient that
12 was, received about 77 percent of the prescribed dose.

13 They had three seeds in one needle but the seeds
14 didn't remain in place.

15 They considered the contributing factors
16 to be the AU's preference for peripheral loading. The
17 potential rotation of the prostate during the needle
18 insertion and pressure effects when using a hydrogel
19 to separate the prostate from the rectum.

20 So, as a result of the medical event,
21 they're no longer going to implant the needle between
22 the urethra and the rectum, they're going to use two
23 needles offset on an axis. And they're also going to
24 use stabilizing needles during surgery so that the
25 prostate doesn't move as much.

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1 And that brings us to the end of the
2 manual brachytherapy medical events.

3 And moving on to the 35.600, which are the
4 therapy devices. We had ten medical events. And they
5 were all with the HDR unit.

6 We had one skin, two breast and seven
7 gynecological. And as you'll see, we had a device
8 malfunction. We had a wrong site in the human error.

9 So, let's look at the first one, and that
10 was the skin. In this case, the patient was
11 prescribed to get eight fractions of 500 centigray for
12 each fraction to the temple area, but they only
13 received 350 centigray on the first two fractions.

14 So, the problem here was, the first
15 physicist used an incorrect setup. There is an
16 accuform that should have been in place to give the
17 proper distance from the sources to the temple area.
18 But they didn't use it.

19 And then the second physicist used the
20 correct setup. So, the first physicist did the first
21 two fractures and then the second physicist came back
22 on the third fracture, used the correct setup and then
23 they proceeded from there.

24 So, there was a gap between the treatment
25 device and the patient's skin.

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1 So, what did they do for corrective
2 action? They lacked a policy for custom and
3 mobilization devices for skin treatment. They're
4 going to develop that now.

5 And the therapist present at the first
6 treatment, and anytime, will be present at the first
7 treatment anytime there is a new physicist. So there
8 will be a continuation of information going from one
9 treatment to the next.

10 And another thing that contributed to it
11 is, when they had the patient setup and they were
12 running the HDR sources out, the patient orientation
13 was such that they could not really see where the
14 sources were and they couldn't see whether the
15 accuform was in place or not.

16 And so they're going to now take a
17 photograph at setup. With and without the patient to
18 show how the accuform should be used. And then
19 they're also going to check that when they do have a
20 patient.

21 And they're going to use a barcode
22 scanning system to track custom setups using their
23 devices.

24 So now we have a breast medical event.
25 And in this case, we had 1,200 centigray to the

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1 lateral breast skin.

2 This is similar to other medical events
3 that we've seen with the HDR in the breast implants,
4 in which the physicist used the tip end instead of the
5 connector end in the treatment plan. And so, the dose
6 was not delivered to the treatment site but out close
7 to the skin and created problems.

8 So, corrective actions are going to be
9 additional training to personnel.

10 We had a second breast medical event,
11 wrong site. In this case, the first one we didn't
12 identify whether there was a, what applicator was
13 being used, but in the second case it's a Savi
14 applicator.

15 And in this case, there are six struts and
16 two and six were mislabeled. So that changed the
17 orientation of the applicator and the direction of the
18 radiation field.

19 So, the corrective actions are that the
20 second physicist will independently verify that the
21 catheter struts are in the treatment plan and there
22 will be an HDR review checklist and they'll verify
23 digitization of the struts in the treatment plan.

24 And they're going to add an HDR review,
25 plan review, to their monthly audit so that they can

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1 pick these things up. And they're going to provide
2 additional training to their personnel.

3 So now we move into the largest category
4 for 600 medical events, and that is the gynecological
5 treatments.

6 In the first one we have a device
7 malfunction. The patient was to receive 1,500
8 centigray during three fractions in 13 dwell positions
9 but the HDR malfunctioned at Dwell point nine and the
10 treatment stopped at that point. And then after the
11 device was repaired, then they continued with the
12 treatment.

13 We had another one that was device
14 malfunction. The device failed to fully retract at
15 completion of the treatment fraction, so that you had
16 a dose of 100 centigray to the patient thigh.

17 The source was five centimeters from the
18 cylinder guide to connector. And the source wire was
19 bent at the source.

20 And then was a delay in removing the
21 source from the vicinity of the patient and reporting
22 the event to the RSO. So they compounded the issues
23 that they had.

24 If they had been a little faster on
25 identifying the sources outside of where it was, they

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1 might not have had a medical event.

2 Then we have catheter movement. And in
3 this case, the connector locking nut was too loose and
4 that allowed the catheter to slide out. And the event
5 was discovered by skin reaction progressing to moist
6 desquamation.

7 The dose to the skin was between 5,000 and
8 8,500 centigray. The corrective action was to retrain
9 the medical staff and the AU.

10 The AU will now double check all
11 connections and placements before and after each
12 treatment to make sure they were intact during the
13 treatment. And they've purchased a new cylinder with
14 a new design that they believe won't have this
15 connection problem.

16 The next medical event there were six
17 fractions of 350 centigray each. But the first
18 fraction received 2,100 centigray.

19 So the total treatment time was
20 incorrectly entered into the treatment planning
21 system. It was human error and poor decision making.

22 They started the first treatment after
23 hours. And there should have been two physicists
24 checking, but the second physicist wasn't available.
25 So the second physicist put the information in and it

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1 wasn't correct.

2 So, their corrective actions are now to
3 have the second physicist independently verify the
4 treatment plan and the physicist to check if the plan
5 was exported correctly to the treatment console.

6 Okay. The next one is a pretty
7 interesting one. It was a wrong site. The patient's
8 pelvis had extensive damage due to uterine cancer, not
9 cancel.

10 There were two dwell positions that
11 shifted to deliver the dose to the non-target small
12 intestine bowel in the first three fractions. So the
13 treatment plan was modified for the next two fractions
14 so they could give treatment to the treatment site.

15 And the licensee originally thought it was
16 not reportable because, in the process they gave the
17 dose to the treatment site that was asked for.

18 But NRC determined that it is reportable
19 because the licensee did not take into account that
20 the fact that the fractional dose was greater than 50
21 percent. And that the dose was delivered to the wrong
22 treatment site. They were focusing only on the
23 treatment site.

24 So, we have another wrong site. In this
25 case, the dose was delivered 5.5 centimeters outside

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1 the treatment site. It received 500 centigray in a
2 half centimeter volume.

3 And this was a digitization issue. We had
4 digitization issues earlier. In this case, Channel 12
5 was digitized twice with no digitization of Channel
6 13.

7 And so, there were no dwell positions in
8 13. The treatment plan was displayed. There was
9 plenty of opportunity for the physicist and the AU to
10 see that there was no dwell positions in Channel 13,
11 and no one picked it up.

12 So, the physician approved the plan and
13 the physicist, neither one of them picked up that
14 there was a problem here. So, they attributed the
15 fact that they were rushing.

16 The patient was in discomfort with a full
17 bladder. They had tried to start the procedure. They
18 had the patient on the table and they tried to do the
19 procedure, while the patient was there, and the
20 patient was discomfort so they rushed to get the plan
21 and export it into the treatment console and they
22 overlooked their errors.

23 The corrective action is there will be a
24 second check by the physicist that did not prepare the
25 plan. And then each channel will be carefully

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1 reviewed, and the patient won't be brought to the
2 treatment area until the plan has been checked and
3 exported to the console.

4 Another wrong treatment. So, in the first
5 three fractions they digitized the catheter as linear
6 instead of a single curve catheter.

7 So, the physicist failed to recognize the
8 incorrectly reconstructive catheter shape in the
9 planning software. And treatment length was 15.7
10 centimeters instead of the nine centimeters.

11 Okay. And they didn't discover the
12 problem until the second fraction. So, one of the
13 things they attributed it to was that the treatment
14 plan was not enlarged enough, so the physicist
15 couldn't see the dwell points that were overlapping in
16 that incorrectly digitized Channel 12.

17 And the corrective actions are to enlarge
18 each treatment plan in which the physicist signs off
19 and to use a formalized checklist. And that concludes
20 our 35.600 medical events.

21 And now we move into the emerging
22 technology or the other medical uses. We had 25
23 medical events. We had one for the Perfexion, one for
24 intravascular brachytherapy, one for radioactive seed
25 localization and then we had 22 for the Yttrium-90

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1 microspheres.

2 For the Perfexion, the device
3 malfunctioned. The device recorded an error, the
4 backup power was low, so the sources were returned to
5 the shielded position and they had to get the device
6 repaired. So, only one-third of the prescribed dose
7 was delivered.

8 For intravascular brachytherapy, they were
9 using an extra-long delivery catheter and the source
10 would not go out to the treatment site. So they
11 retracted the source safely, they exchanged the long
12 treatment catheter for another extra-long treatment
13 catheter and the source still wouldn't go out to the
14 treatment site, but the source could not be returned
15 to the intravascular brachytherapy unit. And all the
16 catheters were removed.

17 The hydraulic return mechanism failed to
18 return the source, and no dose was given to the
19 treatment site and 39 centigray was given to the
20 surrounding tissue. And they looked at it and
21 determined there was a deformation of the delivery
22 catheter that was the root cause.

23 Okay. We had one radioactive seed
24 localization. In this case, the patient was given a
25 seed and was scheduled to come back for surgery six

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1 days later.

2 And in the middle of this process, after
3 the seed was implanted, but before the seed could be
4 removed, the insurance company rescinded the approval.

5 And it required about, it required three medical
6 opinions before they would continue to okay the
7 surgical removal of the seed.

8 So the surgery wasn't performed until
9 approximately 64 days after the implant. So the
10 surrounding tissue from the implant was supposed to
11 get 12 centigray and the patient received 99
12 centigray.

13 And now we're going to move into the
14 Yttrium-90 microspheres. We have 25 of them. And the
15 first two, they did not identify the manufacturer.

16 So you can imagine if they didn't identify
17 the manufacturer, you're not going to see a lot of
18 information on the first two.

19 So they got, in the first one they got 77
20 percent of the intended dose. No other information.

21 The second one the patient received 60
22 percent of the prescribed dose. And no other
23 information.

24 And now we'll move on. I'll always divide
25 these up to TheraSpheres and SIR-Spheres because the

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1 devices are not exactly the same and some of the root
2 causes are not the same.

3 So this year I'm doing the TheraSpheres
4 first. We had 13 medical events involving 14
5 patients. We had an overdose, catheter obstruction,
6 bubbles, backflow to contrast and a human mistake.

7 So, let's take a look first at the
8 overdose. They prescribed 13,670 centigray, but they
9 received 29,400 centigray.

10 They picked up the wrong dosage. They
11 measured it, they compared what they saw with what was
12 on the shipping box and not what was in the written
13 directive. So they had a shipping box that was for
14 next week's patient, and they picked that up and they
15 administered that to this week's patient.

16 So, the post-administration calculations
17 identified the medical event. And so, as a corrective
18 action, they're going to add a dose verification step
19 in the interventional radiology department.

20 And now we're going to see a lot of cases
21 where the dose didn't end up in the patient, it ended
22 up in the waste jar. Or in the catheters or in some
23 other place, but not in the patient.

24 So they prescribed 12,000 centigray, but
25 they only administered 1,700 centigray. Fourteen

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1 percent of the intended dose.

2 They thought the equipment didn't function
3 as designed, and most of the dosage was found in the
4 waste jar. The manufacturer was unable to determine a
5 root cause.

6 On the next medical event we had two
7 patients. And both of them received less dose than
8 prescribed.

9 So the first patient was prescribed 72.6
10 millicuries, but they received 15 millicuries. And
11 the inspector that went out and looked at this case
12 thought the expansion tubing resulted in turbulent
13 flow triggering suspension issues.

14 The second patient was also prescribed 72
15 millicuries but received 36.7 millicuries. And the
16 inspector thought the lack of adequate agitation prior
17 to administration, or that the issues were with a
18 quality sizing of the microspheres.

19 So, as a result, the licensee is no longer
20 using extension tubing, and the manufacturer supported
21 the inspector's findings.

22 The next case, they were prescribed 122
23 millicuries but received 46 millicuries, 38 percent of
24 intended dose. The device components were sent to the
25 manufacturer, and no cause of the blockage was

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1 determined.

2 There was an obstruction blockage located
3 in the micro-catheter in the outlet tubing to the E
4 junction. The manufacturer recommended handling
5 micro-catheters with extra care in looking for kinks.

6 So, we have another 12,000 centigray but
7 only received 2,000 centigray. The licensee
8 attributed it to a malfunction in the administrative
9 set.

10 Significantly less pressure was noted than
11 usual when pressing the syringe. Saline accumulated
12 in the overflow valve.

13 And only, they were supposed to return the
14 whole unit to the manufacturer. All the tubing and
15 everything but they only returned a portion of the
16 administration set that infused the dose into the
17 patient, to the manufacturer. So they didn't get to
18 see what the real problem was.

19 It could have been a kink or obstruction
20 in the treatment catheter, but it wasn't conclusive.
21 So their corrective actions, next time they have one
22 these, they're going to send everything back to the
23 manufacturer.

24 So we've got now one licensee with two
25 reported medical events. In Report Number 1, they

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1 were scheduled 64 millicuries, they only got 41, 65
2 percent of the activity.

3 Air bubbles were noted in the overflow
4 tube. So they connected a three-way stopcock between
5 the overflow tube and the micro-catheter, aspirated
6 bubbles to the syringe with a stopcock close to the
7 patient. And I believe they decided to stop the
8 treatment at that point.

9 And they re-surveyed the delivery kit,
10 showed residual activity.

11 And Report Number 2, they prescribed 46
12 millicuries but only received 27. Or 59 percent of
13 the activity.

14 They used the left radial artery with a 5-
15 French Sarah Radial catheter with a coaxial micro-
16 catheter. They didn't see anything unusual. They
17 didn't have any radioactive contamination. But then
18 they found the dose was in the catheter, the gauze,
19 the dose vial and the other waste.

20 This one received about 64 percent of the
21 dose. There was a backflow of microspheres into the
22 contrast line and syringe. There was significant
23 contamination in the contrast syringe, the flushing
24 syringe, the contrast tubing and the associated y-
25 adaptor.

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1 Though, they thought that the contrast
2 syringe and tubing were made of materials that bind
3 the microspheres more than the administration kit.
4 And so they're going to look for things that are, have
5 the same materials as the manufacturer's recommended
6 administration kit. And they are now going to use a
7 clamp and a one-way valve.

8 This one was, received about 32 percent of
9 the activity. There was a blockage in the delivery
10 apparatus. They imaged the administrative set and saw
11 most of the undelivered activity near where the
12 plunger connects to the dose file.

13 So they, in this case, they're going to
14 send the administration kit and procedure waste to the
15 contract. To the manufacturer.

16 And this one received 16 percent of the
17 activity. The microspheres were coagulated in the
18 tubing. There was unexpected activity remaining near
19 the Touhy-Borst connector.

20 And the manufacturer thought the cause, by
21 issues with the micro-catheter. Their remedy will be
22 to flush the micro-catheter immediately prior to
23 connecting it to the administration kit. They think
24 that might help in getting the micro-catheters through
25 the, getting the microspheres through the micro-

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1 catheter.

2 This patient received 65 percent of the
3 dose. The first vial was administered without
4 incident.

5 They primed the second vial and they
6 prepared it, but they saw a train of bubbles in the
7 line between the dose vial and the patient. So the AU
8 stopped the procedure.

9 They didn't want the bubbles to cause the
10 flow to reflux to the gastric artery and cause
11 permanent damage to the stomach. And they couldn't
12 pinpoint a cause for the bubble, so they limited, they
13 now limit the number of staff trained to prime and do
14 the setup, to ensure enough are available on treatment
15 day.

16 The next patient received 53 percent of
17 the dose. They did a CT scan to verify the dose was
18 administered to the correct location, but the
19 remainder of the dose hung up in the catheter despite
20 flushing, and the catheter tube met the manufacturer's
21 specification. So no root cause was identified.

22 In this case, the patient received 71
23 percent of the dose. And this particular licensee
24 used three different written directives to fractionate
25 the delivery.

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1 So they thought the small activity
2 prescribed in one of those fractionated doses
3 contributed to the underdose because of the typical
4 loss of microspheres in the valve and the tubing.

5 They are now going to order higher dosages
6 for any administration below ten millicuries, and
7 they're going to amend the license to go to a
8 different manufacturer. So they're switching
9 manufacturers.

10 That brings us to the end of the
11 TheraSpheres and we're now moving into the SIR-
12 Spheres. We had seven medical events with SIR-
13 Spheres.

14 You'll see that we have wrong site,
15 measurement unit error, written directive error, high
16 activity clogging, and low activity clogging.

17 So the first one was a wrong treatment
18 site. And the post-treatment scan appeared normal
19 with the small uptake in the bowel, but the patient
20 experienced pain in the abdomen and erythema on the
21 abdomen.

22 They thought the dose was above 55
23 centigray but less than 1,000 centigray. And they
24 thought one-third of the dose migrated up a venous
25 ligament and lodged in the abdominal wall.

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1 I think this is one of the first ones that
2 we've seen with erythema on the abdomen. Or
3 microspheres.

4 So, they attributed their issues to
5 difficulty visualizing the arterial access to the
6 tumor. That the micro-catheter was not advanced far
7 enough into the correct artery.

8 And this particular patient had a
9 preexisting kidney impairment that precluded use of
10 more contrast, so that was attributed to why they
11 didn't get a good visualization.

12 And they're going to add a second monitor
13 to refer to the original arteriogram without switching
14 task and to improve the confidence and correct
15 location. And they're going to take prophylactic
16 measures for future patients with impaired kidney
17 function.

18 This is another wrong site. They
19 prescribed it to the left lobe of the liver, but they
20 delivered twice as much to, they prescribed it to the
21 right lobe of the liver but they received about two to
22 three times more dose to the left liver.

23 They attributed it to human error, and
24 they placed the catheter in the left hepatic artery
25 instead of the right hepatic artery.

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1 This was an interesting one. This was a
2 measurement unit error. They prescribed .91
3 gigabecquerels but they received 8.9 millicuries.

4 They ordered it, even though it's
5 prescribed in gigabecquerels, they ordered it in
6 millicuries. They marked the wrong box in the
7 computer. And when they went to measure it, they
8 didn't multiply the measurement dose value by a
9 correcting factor of ten.

10 So they didn't identify it until the post-
11 procedure check, so they are going to revise their
12 worksheets to be all in SI units. And the written
13 directives will also be in SI units, and the dose
14 preparation and post-procedure forms will be in SI
15 units.

16 So they had issues going back and forth
17 between SI units and other units. So they're going to
18 make uniformity. Uniformed changes there.

19 Okay. This is a written directive error.

20 They prescribed 1,500 centigray to the right lobe of
21 the liver, but they delivered about 1,500 centigray to
22 the left lobe.

23 The written directive was prepared
24 incorrectly. The AU wanted to treat the left lobe.
25 And it was identified after completion of the

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1 procedure.

2 It also indicates that the AU didn't
3 indicate the correct treatment site on the written
4 directive, and the AU didn't fall with the pre-
5 treatment information to the RSO. So the clinical
6 staff failed to identify the discrepancy between,
7 during their patient time-out just before the
8 implementation.

9 So, we've had a number of licensees that
10 use time-out as a corrective measure, but time-out
11 doesn't always work.

12 So now we have a high activity clog where
13 19 percent of the dose was received. The micro-
14 catheter clogged due to an unusually large number of
15 microspheres being used, according to the licensee.

16 The prescribed activity was at the high
17 end of the treatment range and the patient was
18 administered, the administration was delayed a day,
19 and because it was delayed a day and it decayed, then
20 they had to increase the number of microsphere volume
21 roughly by 25 percent.

22 And so, in the future they're going to use
23 smaller aliquots and do a slower infusion rate.

24 And we have a device malfunction. In many
25 of the things, licensees are now attributing most of

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1 their problems to device malfunction.

2 So they received 25 percent of the
3 activity. They say the device malfunctioned and
4 ceased to deliver the microspheres. I think this is
5 another way of saying clogging.

6 The manufacturer's representative was
7 present, but the cause of the malfunction was unknown.

8 They'll return the delivery device to the
9 manufacturer for technical analysis and root cause
10 determination.

11 This patient received 51 percent of the
12 activity. They had planned to deliver the activity in
13 two split dosages. The written directive was not
14 properly reviewed.

15 So they split one dose into two, instead
16 of providing two separate doses. The radiation
17 oncologist failed to check the drawn dosages prior to
18 injecting them. And the identification was after the
19 injection, when the remainder of the doses was
20 delivered. Discovered.

21 So, they attributed this to lack of
22 comprehension of the dose draw worksheet, a
23 miscommunication failure to review the written
24 directive and a failure to perform a safety pause and
25 properly review the dosage to be administered against

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1 the written directive prior to administration.

2 And that concludes my list of 48 medical
3 events for FY 2018. Are there any questions?

4 CHAIRMAN PALESTRO: Thank you, Dr. Howe.
5 Comments or questions from the ACMUI?

6 MEMBER SCHLEIPMAN: I have a question.
7 It's more just a process.

8 Who adjudicates, some of the corrective
9 actions seem quite appropriate, some seem, perhaps,
10 not enough. Who adjudicates whether those corrective
11 actions are sufficient and how are they followed up
12 and by whom?

13 DR. HOWE: What normally happens is, if
14 you have a medical event there's normally an
15 inspection. These medical events happen throughout
16 the agreement states in NRC.

17 And then on inspection time and reviewing
18 their reports, they give corrective actions. And it's
19 up to the regulator to say, yes, that appears to be
20 reasonable. And we generally will sign off on
21 retraining of people.

22 The licensee comes up with their own
23 corrective actions.

24 CHAIRMAN PALESTRO: Any other comments or
25 questions?

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1 Comments or questions from attendees here
2 in the room?

3 On the bridge line? Mr. Ouhib?

4 MEMBER OUHIB: Yes, I just have a
5 question. I know this has been brought up in the past
6 regarding the units, which the SI units many times.
7 Any hope, any chance, any plan for that down the road?

8 DR. HOWE: Normally our SI unit problem,
9 that's been brought to our attention is, the problem
10 with the manual brachytherapy seeds being air kerma or
11 some other unit.

12 And in this case, it was a licensee that
13 appeared to have multiple different kinds of units
14 from one document to the next and didn't have
15 uniformity. So they were just kind of, it was really
16 something that was kind of asking to have an accident
17 between ordering in SI units and ordering in
18 millicuries and then making measurements.

19 So, it wasn't the normal type of unit
20 problem we have, it seemed to be kind of unique to
21 this particular licensee.

22 CHAIRMAN PALESTRO: Any other comments,
23 questions? Ms. Weil.

24 MEMBER WEIL: I have a question. Not
25 necessarily for Dr. Howe but maybe for the group.

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1 If the NRC were to take the suggestion
2 that these high level infiltrations, where the dose to
3 an unintended tissue reached the regulatory limit, how
4 much would that increase, do you think, the number of
5 medical events that are reported?

6 Is there any way of thinking about that?

7 DR. HOWE: I don't think we know at this
8 point. I would suspect we would get, we do have cases
9 where they report infiltrations with therapy drugs and
10 we don't call them medical events because of our
11 prior.

12 And so we have ones and twos of those.
13 But I think if there was more focus on it, we might
14 see more, I'm not sure.

15 It would also depend on whether we kept
16 the same, if we were to go to calling them medical
17 events, whether we kept the same criteria in place or
18 we developed a different criteria that might be a
19 little bit higher to take account for capturing things
20 that might have a significance for the patient. But
21 we have an able team that's going to look at that.

22 CHAIRMAN PALESTRO: Any other comments or
23 questions? Thank you very much, Dr. Howe. I'm sorry.

24 DR. HOWE: No, you get the --

25 PARTICIPANT: Oh, it's working now?

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1 DR. HOWE: No.

2 MS. BLANKENSHIP: Hi. Bette Blankenship,
3 AAPM. I had a question on the SIR-Sphere medical
4 event.

5 Typically, you can only order three
6 gigabecquerel and receive three gigabecquerel from the
7 SIR-Sphere's folks. So I was curious as to why they
8 would indicate that they had received 8.9 millicuries
9 because you can only order in gigabecquerel, receive a
10 gigabecquerel, that amount, and then draw from that
11 what your physician orders or prescribes.

12 So I was just curious on, they're
13 reporting is even further confusing because they
14 didn't receive 8.9 millicuries because Sirtex can't
15 ship anything other than three gigabecquerel. So they
16 only work in SI units.

17 DR. HOWE: And that's the one where they
18 confused all the SI units and --

19 MS. BLANKENSHIP: Yes. It basically says
20 prescribed .91 gigabecquerels but received 8.9. So
21 that, just that language there kind of confused me,
22 because they can only ship in one --

23 DR. HOWE: So, they were supposed to get
24 .91 gigabecquerel, they wrote it out for .91
25 millicuries.

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1 MS. BLANKENSHIP: Okay.

2 DR. HOWE: And then when they made the
3 measurement, they didn't multiply by ten, so they
4 stopped, thought they were still down in the level
5 they were supposed to, and it wasn't until later that
6 they discovered that they were --

7 MS. BLANKENSHIP: Yes.

8 DR. HOWE: -- way off.

9 MS. BLANKENSHIP: Yes, I just, thank you.

10 DR. HOWE: Yes. I can't explain any more
11 than that.

12 CHAIRMAN PALESTRO: Mr. Sheetz.

13 MEMBER SHEETZ: In response to that, some
14 licensees will receive SIR-Spheres from a
15 radiopharmacy and they'll get a unit dose, so the
16 three gig vial will be sent to the radiopharmacy, the
17 radiopharmacy will then follow-up and then dispense
18 into the dose vial what the licensee has required. Or
19 requested.

20 MS. BLANKENSHIP: Okay.

21 CHAIRMAN PALESTRO: Any other comments or
22 questions? All right, thank you very much. Dr. Howe.

23 Next topic on the agenda is the
24 Appropriateness of Medical Event Reporting
25 Subcommittee Report, will be presented by Dr. Ennis.

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1 MEMBER ENNIS: Good afternoon, everyone.
2 Thank you, Chairman Palestro.

3 And I couldn't have asked for a better
4 introduction. Especially the case where we didn't
5 know what site was implemented.

6 Okay. So, we formed a subcommittee
7 looking at the appropriateness of medical event
8 reporting that came out of the growth of Donna-Beth's
9 presentations over the last few years, as well as
10 mine.

11 And just take a look at the pictures on
12 the bottom, and you'll see a better representation of
13 what we're doing here, than we saw this morning.

14 Next slide. Okay. So, our charge was to
15 review the appropriateness of required elements of
16 medical event reporting, the adherence to these
17 requirements and recommendations to improve reporting.

18 Next slide. So I want to thank the
19 subcommittee members, this was really an excellent
20 subcommittee. A lot of involvement of all, and
21 activity of all the members, including Dr. Dilsizian,
22 Ms. Martin, Mr. Ouhib, Ms. Shober and Ms. Weil and
23 myself.

24 Next slide. So starting, it's worth
25 reflecting on what is the purpose of reporting. And

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1 using some of the NRC documents that describe the
2 event reporting requirements and schedules for them.

3 I will highlight for you what are relevant
4 aspects of the requirements for a higher subcommittee.

5 And that this information of medical events should be
6 used to assess trends and patterns, recognizing
7 inadequacies of unreliability of specific equipment or
8 procedures, and will significantly aid in
9 understanding why events, an event occurred and then
10 find any actions necessary to improve the
11 effectiveness of NRC and agreement state regulatory
12 programs.

13 Next slide. These are the documents that
14 we reviewed in helping us make our determination of
15 what is required. Currently in the medical event
16 reporting and what is available to the public.

17 Next slide. In the end, the events that
18 are reported are collected into a database. The
19 nuclear materials event database, otherwise known as
20 NMED.

21 It does include information for both
22 agreement states and the NRC. It's managed by an
23 office within the NRC, the Office of Nuclear Materials
24 Safety and Safeguards.

25 And there is a contractor that is

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1 responsible for coding and quality control of the
2 information under the oversight of the NRC NMED
3 project coordinator.

4 Of note, access to NMED is limited. And
5 the general public does not have access to that.
6 Rather they have access only to an annual report that
7 is available publicly.

8 Next slide. Issues that our subcommittee
9 identified in NMED are as follows. We felt that
10 frequently the narrative was inadequate for an ACMUI
11 reviewer to understand the event, its cause and
12 contributing factors, and the adequacy of the
13 corrective action.

14 At times, there appear to be a disconnect
15 between the narrative and the chosen cause from the
16 cause pick list.

17 Just a point of clarification, there is a
18 drop-down menu within NMED for causes and for
19 corrective actions that lists many of the most common
20 causes and corrective actions with a word or phrase.

21 But that chosen corrective action or
22 cause, from the drop-down menu, often does not appear
23 to connect well to the description within the
24 corrective action or cause parts of the NMED database.

25 Next slide. In addition, NMED lacks

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1 information from some inspections that have been
2 conducted by NRC or agreement states, like the example
3 we talked about a minute ago.

4 We did a brief audit of a couple of issues
5 and, for example, of all the medical events in Fiscal
6 Year 2017/18, 23 percent of them, there was either no
7 cause or no corrective action identified in NMED as of
8 a month ago.

9 In addition, of all medical events
10 reported in 2017, 11 percent are still incomplete and
11 an additional 11 percent are listed as pending
12 additional information, and, again, this is as of a
13 month ago.

14 And as alluded to before the public,
15 including authorized users, RSOs, physicists,
16 authorized physicists, only have access to an annual
17 report, not to the actual data that we can see in
18 NMED.

19 Next slide. As such, our subcommittee is
20 in the process of finalizing recommendations to
21 improve and address the issues laid out in the first
22 part of this presentation.

23 Those that we are moving towards a full
24 recommendation on include the following, that the root
25 cause and corrective action sections in NMED, in

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1 addition to the pick list, there should be a required
2 narrative and searchable section.

3 Currently there is the narrative section
4 itself of the NMED is searchable, but there's only one
5 place for a narrative section. It's not specifically
6 asked that there be a narrative part for the root
7 cause and corrective action aspects.

8 Currently, whoever is entering the data
9 can just do a drop down menu for those aspects, which
10 really are the crucial ones to really understanding an
11 event and helping the ultimate goals of these that we
12 discussed on the first couple of slides.

13 We also are leaning towards a
14 recommendation that the root cause and corrective
15 action sections always need to be completed. (Sound
16 system interference.)

17 PARTICIPANT: Sorry.

18 MEMBER ENNIS: We are looking at requiring
19 that information gathered from any investigations be
20 added to NMED as that is not necessarily the case at
21 this point.

22 We are looking to require that a report
23 may be fully completed within 12 months. We are
24 looking to require ACMUI and NRC staff annually
25 promulgate the findings of the ACMUI subcommittee on

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1 medical events to the medical community and the
2 medical physics community.

3 Currently, while that report does go up on
4 the website, we might recommend that additional ways
5 of promulgating that be done on an annual basis in
6 order to educate the medical community about what can
7 be learned.

8 Next slide. Further things we are
9 considering but haven't totally come to a conclusion
10 on include requiring that the report use additional
11 guidelines that we might develop to assure more
12 complete and useful information is provided.

13 So, more specifically, what is required of
14 a root cause analysis, how can we structure the
15 requirements of causes and root cause analyses and the
16 connections between them, can we come up with ways of
17 structuring those and advising licensees that when
18 they are reporting what is required in more detail so
19 that we get better reports.

20 Another aspect we were looking at is
21 requiring that the report eventually gets submitted
22 and reported within NMED be initially written by the
23 authorized user and their physicists and then reviewed
24 by the inspector as opposed to being written by an
25 inspector, having in mind that the authorized user and

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1 medical physicists tend to have a deeper understanding
2 particularly of the medical aspects of what is going
3 on.

4 Require that the inspector interview all
5 involved in a medical event, to do a more in depth
6 evaluation of each medical event, require the report
7 from a manufacturer be included in the report if the
8 event reported involved the device to assure adequate
9 responsiveness from the manufacturers and input from
10 them, and then, again that gets reported within NMED
11 so that we can all learn from those individual events
12 and the manufacturer's thoughts about it.

13 We are also looking at a notion that a
14 corrective action be explicitly defined to include
15 medical aspects as well as technical aspects because
16 some of these solutions or the improvements of that
17 nature and could be helpful to other authorized users
18 to be aware of these, but would be missed if not
19 specifically required, and to require that the final
20 report, even if drafted by the physicist and the
21 authorized user, be signed off by all involved,
22 meaning the authorized user, the physicist, and the
23 inspector.

24 I think that's the end. Next slide. Ah.
25 So in conclusion we believe, our subcommittee

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1 believes there are significant opportunities to
2 enhance the utility of the medical event reporting,
3 the NMED database specifically, and promulgation of
4 the information to user community.

5 The subcommittee asks that it be able to
6 continue evaluating these issues in more detail with
7 the goal of creating a set of specific
8 recommendations. Thank you.

9 CHAIRMAN PALESTRO: Thank you, Dr. Ennis.
10 Comments or questions from the subcommittee?

11 (No audible response)

12 CHAIRMAN PALESTRO: From the ACMUI?

13 (No audible response)

14 CHAIRMAN PALESTRO: Dr. Ennis, I have two
15 questions. One, in your recommendations you say that
16 you recommend that a report in NMED be completed
17 within 12 months. That seems like an awfully long
18 time.

19 MEMBER ENNIS: This is trying to be
20 strict. The point is as a previous slide shows that
21 about a quarter were opened two years or so. If you
22 could go back a couple slides. There we go.

23 So 2017 we reviewed all the events of
24 2017, 11 are still incomplete, 11 percent, and another
25 11 percent are still pending additional information,

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1 so we are trying to make it a little bit stricter by
2 requiring a year.

3 I certainly wouldn't disagree that that
4 might be generous, but for a starting point at least
5 we thought that would be a good place to start.

6 CHAIRMAN PALESTRO: Are there time
7 requirements in place now?

8 (Off microphone comment)

9 CHAIRMAN PALESTRO: All right. Yes, I'm
10 sorry, Mr. Einberg.

11 (Off microphone comment)

12 PARTICIPANT: Your mic is the one that
13 died.

14 (Off microphone comment)

15 MR. EINBERG: Dr. Palestro, yes, there are
16 no time requirements. However, the agreement states
17 and licensees report these to the agreement states and
18 the agreement states have to report into NMED and NRC
19 licensees report to us and we put it into NMED.

20 And then during the IMPEPs, which are the
21 Integrated Materials Performance Evaluation Program,
22 where we go out and evaluate agreement states, we look
23 at whether they have been entering their NMED reports
24 in a timely fashion.

25 CHAIRMAN PALESTRO: Thank you. But

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1 without any time requirement how do you define timely?

2 MR. EINBERG: Well whether they have been
3 entering the reports at all.

4 CHAIRMAN PALESTRO: Okay. Thank you.

5 MS. HOLIDAY: Dr. Palestro, this is
6 Sophie. I would also like to follow up to say that
7 there have been times where medical events come in and
8 members on the medical team specifically reach out to
9 a staff member actually in our branch who is called
10 the regional coordinator and we ask that she reach out
11 to the NRC regions or to the respective RSAOs, which
12 are the Regional State Agreement Officers, to ask them
13 for additional information.

14 Yet at the same time we are asking for the
15 information doesn't mean that we the medical team can
16 force them to provide us that information, but we as a
17 medical team often do reach out and ask for additional
18 information.

19 CHAIRMAN PALESTRO: I have another question
20 for you, Dr. Ennis. Excuse me. Where you said that
21 you require the final report must be signed off by the
22 AU, physicist, and inspector, what about the RSO?

23 MEMBER ENNIS: I wouldn't disagree with
24 that. That may have been an oversight on our
25 committee.

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1 CHAIRMAN PALESTRO: Mr. Sheetz?

2 MEMBER SHEETZ: That was going to be one
3 of my comments, yes.

4 CHAIRMAN PALESTRO: Any other comments or
5 questions from the ACMUI?

6 (No audible response)

7 CHAIRMAN PALESTRO: From attendees in the
8 room?

9 (No audible response)

10 CHAIRMAN PALESTRO: Bridge line?

11 (No audible response)

12 CHAIRMAN PALESTRO: All right. Now this
13 is an interim report so we don't have to take any
14 action on that, am I correct, Ms. Holiday?

15 MS. HOLIDAY: Correct. That was going to
16 be my next comment. While what you guys see on the
17 slide says recommendations under consideration, as I
18 think I have alluded to previously these are not the
19 formal recommendations being put forth by the
20 subcommittee at this time.

21 These are just things that they have
22 thought about and that they are considering. When
23 they have finished their deliberations they will come
24 forth with a draft final report for vote.

25 CHAIRMAN PALESTRO: All right. Well, I'm

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1 certainly happy to extend the term of the
2 subcommittee, Dr. Ennis, and we look forward to
3 another report from your group at the fall meeting.

4 MEMBER ENNIS: Thank you very much.

5 CHAIRMAN PALESTRO: Thank you.

6 MEMBER ENNIS: If anyone has any other
7 ideas to add we're open to hearing suggestions.

8 MR. EINBERG: And, Dr. Palestro, is there
9 a staff resource for this subcommittee?

10 MEMBER ENNIS: Yes, Lisa Dimmick.

11 MR. EINBERG: Lisa, okay. Thank you.

12 MEMBER ENNIS: I apologize for not
13 mentioning that, Lisa.

14 CHAIRMAN PALESTRO: Actually, you know, Mr.
15 Einberg, you made a good point. I think we tend to be
16 negligent when we put up the members of the
17 subcommittee that we should acknowledge the staff
18 resource, because not only because they are important
19 contributors but we should know who they are as well.

20 MR. EINBERG: Yes. And that was not my
21 intent to call out Lisa, but Lisa does great work and
22 I just wanted to make sure that you were getting the
23 support that you needed.

24 CHAIRMAN PALESTRO: Thank you. I wasn't
25 suggesting it was, but I think it really should be

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1 done.

2 MR. EINBERG: All right.

3 CHAIRMAN PALESTRO: Any other comments or
4 questions?

5 MEMBER GREEN: Dr. Palestro?

6 CHAIRMAN PALESTRO: Any other business --
7 I'm sorry. Mr. Green?

8 MEMBER GREEN: Going back to the timeframe
9 of completing the medical event report, it's a long
10 time to write regulations and do rulemaking, but could
11 we recommend that, could the subcommittee recommend
12 that that get written into the regulations and then,
13 you know, some years later it will be adopted by the
14 agreement states, but right now it's just open-ended?

15 CHAIRMAN PALESTRO: The answer is, number
16 one, this an interim report so we are not approving
17 or, not approving or rejecting any recommendations
18 today.

19 And while I am not initially thrilled with
20 the idea of a one year lag time, given the fact that
21 there is no time limit at the present time I think
22 that's a step in the right direction and then assuming
23 that eventually gets written into the records that it
24 could potentially be shortened. Any other comments or
25 questions?

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1 (No audible response)

2 CHAIRMAN PALESTRO: All right. I have an
3 item that I had hoped to bring up earlier this
4 morning, but we ran out of time in the open forum and
5 rather than waiting until tomorrow I would like to
6 bring it up now if I may.

7 It's an issue that came up regarding
8 cremation of a patient or patients who had received
9 lutetium-177 dotatate for treatment of neuroendocrine
10 tumors.

11 Apparently, and I actually went back and I
12 very quickly checked through the NRC website and
13 looked under cremation, deaths, tried to come up with
14 a variety of terms, and maybe I wasn't looking using
15 the right terms or looking thoroughly enough, but the
16 only thing that I could find was a statement in NUREG-
17 1556 about the explanation of plutonium-powered
18 pacemakers prior to cremation.

19 And so the issue arises is there a policy,
20 is there recommendations or are there recommendations
21 by the NRC for the handling of decedents, particularly
22 with respect to cremation when they have radioactivity
23 on board?

24 DR. DIABES: Said Diabes. We are
25 currently working on patient instructions and part of

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1 those patient instructions is instructions for family
2 members, caregivers, on cremation and what should that
3 entail.

4 That was directed by the Commission on a
5 patient release project and we are currently working
6 on that data and that was part of the updated data on
7 Reg Guide 8.39.

8 There is a whole section on cremation and
9 instructions related to cremation and what information
10 shall be provided. We are currently working on other
11 initiatives, a brochure, and more information that
12 will come available later.

13 CHAIRMAN PALESTRO: So let me ask you a
14 question and, Mr. Einberg and Ms. Holiday, is this an
15 appropriate time to form a subcommittee to work with
16 you on that or for you to consult?

17 MR. EINBERG: This would be, but I think
18 Katie, Dr. Tapp, here, wants to add some additional
19 information as far as what we require at this time.

20 DR. TAPP: Yes. Just adding on to Dr.
21 Diabes, so patient release regulations in 10 CFR 35.75
22 do have the limits for release of patients and then
23 you have -- the release should have instructions if
24 it's likely to exceed 100 millirem.

25 So we do right now require licensees to

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1 consider situations where the release of that patient
2 could possibly expose members of the public to over
3 100 millirem.

4 That's how we go back to Reg Guide 8.39
5 and adding in some instructions for licensees to
6 follow that will help them for cremation in the
7 future.

8 We also are adding to NUREG-1556, Volume
9 9, in the Draft Revision 3 that is going out final
10 hopefully here in the summer, a reference to NCRP-155,
11 and NCRP-155 right now has guidance for cremation.

12 But you can form a subcommittee to address
13 more of Reg Guide 8.39, I wasn't trying to stop that.

14 But I am saying right now we are going to reference
15 NCRP-155 in the near term soon to kind of have a stop
16 gap.

17 CHAIRMAN PALESTRO: Thank you. Do you
18 want to --

19 VICE CHAIRMAN METTER: Thank you. Also,
20 you know, usually when you talk about cremation you
21 also talk about autopsies and I really think that
22 should also be included in this investigation.

23 DR. TAPP: Yes. NCRP-155 discusses
24 cremation and autopsy. One other thing to mention is
25 Dr. Zanzonico, a former nuclear medicine physicist,

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1 did have a talk with the ACMUI I believe in 2015 on
2 cremation, so there was a presentation from him where
3 he looked at gaseous plumes and had some follow-up
4 items just for consideration as you go forward.

5 CHAIRMAN PALESTRO: Mr. Green?

6 MEMBER GREEN: A question for Dr. O'Hara.

7 Would it be conceivable that the NRC, the FDA, can
8 ask the manufacturers when they revise PIs or submit
9 PIs for new NDAs that they include information on
10 graded pharmaceuticals on autopsy and cremation?

11 MEMBER O'HARA: The labeling that the FDA
12 looks at is by definition draft labeling, so we can
13 ask for that in the labeling and the manufacturer can
14 change that.

15 And then where it becomes, when it becomes
16 an issue is when an inspector goes to a manufacturer
17 and sees that that has been changed, but it can be a
18 long drawn out process, yes, but that is a safety
19 consideration that I think that we can at least
20 propose.

21 MEMBER GREEN: With the number of new
22 therapies, you know, we're changing nuclear medicines,
23 changing from a primarily diagnostic modality to a
24 much more robust therapeutic modality with the
25 theranostics that are coming our way, you'll have many

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1 coming across the FDA desk where maybe that's an ask
2 you make for these new therapies and we'll catch up
3 the other ones later.

4 But I think it would be great to have a
5 resource to the prescriber and to other practitioners
6 that is actually in the labeling for the product on
7 autopsy and cremation.

8 MEMBER O'HARA: I will pass that on to the
9 drug side of FDA as well because the theranostics they
10 usually get the call on those.

11 CHAIRMAN PALESTRO: Any other comments or
12 questions? Ms. Holiday?

13 MS. HOLIDAY: Dr. Palestro, as Dr. Diabes
14 was mentioning, and Dr. Tapp as well, you do have an
15 existing subcommittee that is looking at the draft
16 Regulatory Guide 8.39, which they both mentioned.

17 Just to remind you guys of who the members
18 are on that subcommittee as they, those subcommittee
19 members, were provided with the draft Reg Guide last
20 week.

21 The members are Dr. Dilsizian, Ms. Martin,
22 Dr. Schleipman, Ms. Shober, Ms. Weil, and Mr. Sheetz
23 is the Chair of that subcommittee. The NRC staff
24 resource is Dr. Diabes and in particular there is, as
25 Dr. Diabes mentioned, a section in the Reg Guide that

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1 is related to patients who are deceased after
2 undergoing radioactive administration.

3 So I don't think that you have to amend
4 the charge of the subcommittee as their charge is to
5 review the Reg Guide in its totality and provide
6 comments to the NRC staff.

7 CHAIRMAN PALESTRO: Thank you. Mr. Sheetz?

8 MEMBER SHEETZ: As the Chair of that
9 subcommittee and actually I was wondering if this
10 topic was going to come up, I was going to bring it up
11 also later, because the JAMA article did get a lot of
12 media attention, I do think it's an issue that needs
13 to be evaluated further.

14 While there are NCRP-155 guidelines I am
15 not sure how practical they are. It's a very
16 difficult and sensitive situation when someone dies,
17 you know, whether they are to be cremated or not, they
18 may have pre-arrangements. It's very difficult to
19 stop that process to go with alternative plans.

20 So I think it does warrant for the study,
21 you know, is there a potential risk to workers and the
22 general public from the radiation, what's the
23 magnitude of the risk, how prevalent is the event,
24 although cremation is now over 50 percent of all
25 burials in the United States, what guidance can be

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1 provided to reduce or mitigate that, and so these are
2 the questions we will certainly look at.

3 CHAIRMAN PALESTRO: Thank you. Is the --
4 Is Ms. Weil on that subcommittee? I'm sorry, okay.
5 Yes, I would think that would be appropriate,
6 especially appropriate for the patient rights
7 advocate.

8 MEMBER SHEETZ: Thank you.

9 CHAIRMAN PALESTRO: Mr. Ouhib?

10 MEMBER OUHIB: Yes. I just have -- I
11 think, and maybe Ms. Shober can answer this question,
12 this is not just addressing like the concern with the
13 authorized uses and all that, but this goes to the
14 cremation centers and all that that if in the event
15 there is a -- How would you determine that a patient
16 has radioactive material or not, you know, when they
17 come from cremation?

18 I guess the question is does the state get
19 involved with these cremation centers at all, is there
20 any communication?

21 MEMBER SHOBER: This is Megan Shober. So
22 I can only speak for my experience. We have been
23 involved with cremation centers in the past. Usually
24 we find out about that from the licensee where the
25 decedent had been previously treated.

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1 And so it's not clear how that information
2 comes. You know, like there is not a process for
3 that. But as soon as our licensee found out about it
4 they followed up with us.

5 And I am not sure how else you can
6 regulate that, but it is a huge -- By the time you
7 find out about it it's happened and it's happened a
8 while ago usually.

9 CHAIRMAN PALESTRO: Thank you. Any other
10 comments, questions?

11 (No audible response)

12 CHAIRMAN PALESTRO: Mr. Sheetz, are you
13 comfortable with the subcommittee that is already
14 formed?

15 MEMBER SHEETZ: Yes. Yes, I am.

16 CHAIRMAN PALESTRO: All right. Thank you.
17 All right, then the afternoon session, the open
18 session is adjourned and Ms. Holiday --

19 MR. EINBERG: Wait.

20 CHAIRMAN PALESTRO: I'm sorry, Mr. Einberg.

21 MS. HOLIDAY: And we'll resume at 8:30 in
22 the morning tomorrow. Mr. Einberg?

23 MR. EINBERG: Yes. Actually before we
24 close this with the creation of a new subcommittee for
25 cremation does this possibly merit a separate

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1 subcommittee because of the extensiveness of the
2 issue?

3 For 8.39 we are looking for a fairly rapid
4 turnaround on the review of that Reg Guide. We are
5 asking for a 60-day turnaround on that. Would
6 additional time and a separate subcommittee give you
7 the opportunity to explore this issue in more detail
8 or --

9 CHAIRMAN PALESTRO: I will defer to Mr.
10 Sheetz on that.

11 MEMBER SHEETZ: Why don't you allow our
12 subcommittee to look at that and if we need further
13 time on that particular topic we could come back and
14 do that.

15 MR. EINBERG: Okay.

16 MEMBER SHEETZ: I would like to stay
17 involved in that. I have an interest. I grew up in
18 that business from my father and so I am interested in
19 seeing this through.

20 MR. EINBERG: Okay. Thank you.

21 CHAIRMAN PALESTRO: Any other comments,
22 questions?

23 (No audible response)

24 CHAIRMAN PALESTRO: This session is
25 adjourned. Thank you all.

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1 MS. HOLIDAY: Thank you.

2 (Whereupon, the above-entitled matter went

3 off the record at 2:27 p.m.)

DRAFT