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on the Medical Uses of Isotopes

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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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FALL 2018 MEETING

+ + + + +

THURSDAY,

SEPTEMBER 20, 2018

+ + + + +

The meeting was convened in the
Commissioner's Hearing Room, One White Flint North,
11545 Rockville Pike, Rockville, Maryland, at 11:00
a.m., Christopher J. Palestro, M.D., ACMUI Chairman,
presiding.

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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
- MEGAN L. SHOBER, Member
- JOHN H. SUH, M.D., Member
- LAURA M. WEIL, Member

NRC STAFF PRESENT:

- DOUGLAS BOLLOCK, NMSS/MSST/MSEB, Designated
Federal Official
- SABRINA ATACK, NMSS/MSST/SMPB
- MARYANN AYOADE, NMSS/MSST/MSEB/MRST
- LISA DIMMICK, NMSS/MSST/MSEB/MRST
- SOPHIE HOLIDAY, OE/EB
- KATIE TAPP, NMSS/MSST/MSEB
- DONNA-BETH HOWE, NMSS/MSST/MSEB/MRST

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

2 (11:01 a.m.)

3 CHAIRMAN PALESTRO: Good morning, this is
4 Dr. Palestro. I'm going to open this ACMUI meeting
5 and I'm going to turn it over to Mr. Bollock for
6 opening remarks.

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

12 My name is Doug Bollock, 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
16 with 10 CFR Part 7.11.

17 Present today as the alternate designated
18 federal officer, is Lisa Dimmick, the team leader of
19 the Medical Radiation Safety Team. This is an
20 announced meeting of the Committee, is being held in
21 accordance with the rules and regulations of the
22 Federal Advisory Committee Act and the Nuclear
23 Regulatory Commission (NRC).

24 This meeting is being transcribed by the
25 NRC, and it will also be transcribed and recorded by

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1 others.

2 This meeting was announced in the July
3 25th, 2018 addition of the Federal Register, Line 83,
4 Page 35287.

5 The function of the Committee is to advise
6 the NRC Staff on issues and questions that arise in
7 the medical use of byproduct material. The Committee
8 provides counsel to the Staff but does not determine
9 or direct the actual decisions of the Staff to the
10 Commission.

11 The NRC solicits the views of the Committee
12 and values their opinions. I request that whenever
13 possible we try to reach a consensus on the various
14 issues that we'll discuss today, but I recognize there
15 may be minority or dissenting opinions. If you have
16 such opinions, please allow them to be read into the
17 record.

18 At this point I'd like to perform roll call
19 of the ACMUI members participating today. Dr.
20 Christopher Palestro, our Chairman?

21 CHAIRMAN PALESTRO: Here.

22 MR. BOLLOCK: Thank you. Dr. Darlene
23 Metter, our Vice Chairman?

24 VICE CHAIRMAN METTER: Here.

25 MR. BOLLOCK: Thank you. Dr. Vasken

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1 Dilsizian?
2 MEMBER DILSIZIAN: Here.
3 MR. BOLLOCK: Thank you. Dr. Ronald Ennis?
4 MEMBER ENNIS: Here.
5 MR. BOLLOCK: Thank you. Mr. Richard
6 Green?
7 MEMBER GREEN: Here.
8 MR. BOLLOCK: Thank you. Dr. Melissa
9 Martin?
10 MEMBER MARTIN: Here.
11 MR. BOLLOCK: Thank you. Dr. Michael
12 O'Hara?
13 MEMBER O'HARA: Here.
14 MR. BOLLOCK: Thank you. Mr. Zoubir Ouhib?
15 MEMBER OUHIB: Here.
16 MR. BOLLOCK: Thank you. Dr. Robert
17 Schleipman?
18 MEMBER SCHLEIPMAN: Here.
19 MR. BOLLOCK: Thank you. Mr. Michael
20 Sheetz?
21 MEMBER SHEETZ: Here.
22 MR. BOLLOCK: Thank you. Ms. Megan Shober?
23 MEMBER SHOBER: Here.
24 MR. BOLLOCK: Thank you. D. John Suh?
25 MEMBER SUH: Here.

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1 MR. BOLLOCK: Thank you. And Ms. Laura
2 Weil?

3 MEMBER WEIL: Here.

4 MR. BOLLOCK: Thank you. I confirm we have
5 a quorum and for the first time, I think in about two
6 years, we have a full 13 Member Committee.

7 I'd like to add that this meeting is being
8 webcast, so other individuals may be watching online.
9 We have a bridge line available and the phone number
10 is 888-677-2595. The pass code to access the bridge
11 line is 95756#.

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

17 Dr. Palestro, at his option, may entertain
18 comments or questions from members of the public who
19 are participating with us today. Comments and
20 questions are usually addressed by the Committee near
21 the end of the presentation, after the Committee has
22 fully discussed the topic.

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

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

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

7 At this point I'd like to turn the meeting
8 over to Ms. Sabrina Atack, the Acting Deputy Director
9 of Division of Material Safety, Security, State and
10 Tribal Programs, for some opening remarks.

11 MS. ATACK: Thank you, Doug. I'd like to
12 open the meeting by welcoming everyone to the Fall
13 2018 meeting and echo Doug's remarks regarding
14 congratulating the Committee for having a full 13
15 members at this time. It should be a great meeting.

16 Again, my name is Sabrina Atack, I'm the
17 Acting Deputy Director of the Division of Material
18 Safety, Security, State and Tribal Programs. And our
19 current Deputy Director, Kevin Williams, who you may
20 know, is on rotation in the Office of the Executive
21 Director for Operations, so he's unable to join us
22 today.

23 Our current division director, Dan Collins,
24 is also on annual leave so I apologize. But you have
25 me today.

1 I'd like to highlight a few areas that may
2 be of interest to the Committee and to the meeting
3 participants in my opening remarks. As you're aware,
4 the Commission approved rule changes for the medical
5 use of byproduct material, a little more than a year
6 ago last August.

7 The final rule, 10 CFR Part 35, was
8 published on July 16th, 2018 and will be effective
9 this January. Again, thank you to the Committee for
10 working with the Staff on this major initiative, this
11 is a great accomplishment.

12 When the rule was voted on, the Commission
13 did direct the Staff to evaluate whether it makes
14 sense to establish tailored training and experience
15 requirements, for different categories of
16 radiopharmaceuticals.

17 Staff completed its initial evaluation and
18 provided the status and next steps to the Commission
19 in a recent SECY paper. That's SECY 18-0084.

20 We do anticipate further work in this
21 regard in the next year and we look forward to active
22 engagement with the Committee on this activity.

23 I'd like to take a couple of moments to
24 report out on some NRC organizational changes. Most
25 of them you may be aware of, and there are some that

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1 are coming up, so I'd like to take a moment to share
2 those with the Committee.

3 and foremost, the Commission also is at
4 full First staffing so we're excited about that. In
5 May of 2018 we were honored to have both Annie Caputo
6 and David Wright join the Commission as new
7 Commissioners.

8 And in July of 2018, Margaret Doane, or
9 Margie, became the NRC's executive director for
10 operations. She follows Vic McCree's position in
11 that regard.

12 At the more programmatic level, we do have
13 some changes that are coming up with respect to the
14 materials function in NMSS. First, Dan Collins, who
15 is not at this meeting today, has accepted a position
16 in NRC's Region I and will be leaving the division of
17 material safety, security, state and tribal programs
18 sometime this winter.

19 We are working to actively backfill for
20 Dan. Our office director and deputy, conducting
21 interviews in the next few weeks to identify Dan's
22 backfill, but we do anticipate having a period of
23 turnover such that the incoming division director
24 will be able to get up to speed on the activities of
25 the division during the November, December time

1 frame.

2 You may be aware that Doug Bollock has
3 accepted a position in our Office of Nuclear Reactor
4 Regulation and will be leaving the division as well.

5 Coming behind Doug will be Chris Einberg
6 who previously served in the medical branch many years
7 back. So, Chris Einberg will become the chief of the
8 medical safety and advance assessment branch in the
9 October time frame.

10 That's all we know of at the moment, and
11 hopefully we won't have many more organizational
12 changes to report, but we appreciate your patience as
13 we conduct transition activities in the organization.

14 With respect to ACMUI membership changes,
15 we'd like to recognize that this is Dr. Suh's last
16 meeting. His term on ACMUI ends in October.

17 Many thanks for the tremendous
18 contributions over the past eight years. And we
19 anticipate selecting his replacement and being able
20 to announce that within the next few weeks so that
21 ACMUI will retain its full membership status.

22 I would also like to recognize that this is
23 Dr. Schleipman's first meeting, so welcome.

24 With respect to the meeting items of
25 interest there are several. I know this will be a

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1 very engaging and active meeting. I'm excited to be
2 here with you today and tomorrow.

3 I acknowledge the Committees has been
4 working hard on a number of subcommittee reports and
5 the subcommittees will discuss those with the ACMUI
6 today.

7 First, Dr. Ennis will present the medical
8 event Subcommittee analysis of medical events for
9 Fiscal Year 2017.

10 Dr. Metter will provide an update of the
11 actions of the training and experience for all
12 modality subcommittee and the plan path forward. Dr.
13 Metter will also discuss the Subcommittee's final
14 report on the nursing mother guidelines for exposure
15 from diagnostic and therapeutic radiopharmaceuticals.

16 In addition, Dr. Suh will discuss the
17 Subcommittee's comments on the draft revision of the
18 Leksell Gamma Knife Perfection and Icon licensing
19 guidance.

20 This afternoon, Mr. Sheetz will discuss
21 non-medical events reported by medical use facilities
22 and commercial pharmacies.

23 And Mr. Ouhib will discuss the American
24 Brachytherapy Society's Medical Event case study
25 program.

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1 We will also hear a presentation on the
2 Staff's outreach plan for the continued evaluation of
3 training and experience for administering
4 radiopharmaceuticals.

5 Tomorrow morning, Marc Dapas, the Office
6 Director of the Office of Nuclear Material Safety and
7 Safeguards, will make special presentations to Dr.
8 Alderson and Dr. Suh to thank them for their service
9 on the Committee.

10 This will be followed by a staff
11 presentation on Yttrium-90 revised licensing guidance
12 and information provided by Mr. Green on the
13 compounding of radiopharmaceuticals. That concludes
14 my remarks, and thank you again to everyone for their
15 participation in the meeting.

16 MR. BOLLOCK: Okay, thanks for that. We'll
17 turn it back to Dr. Palestro.

18 CHAIRMAN PALESTRO: All right, thank you
19 for your presentations. Next item on the agenda is
20 old business, and Ms. Dimmick will review the past
21 ACMUI recommendations and provide NRC responses. And
22 also, will explain to us the meaning of open.

23 MS. DIMMICK: Okay. So, I'll work to
24 enlarge the screen a little bit, but we'll go ahead
25 and get started because you do have the handouts.

1 So, I'd like to offer that we, in the last
2 meeting, were able to close pages and pages of open
3 items from the charts going back to 2007. So this
4 should be a much shorter presentation of the old
5 business than maybe some past meetings.

6 But, so our first open items are from 2007.
7 So, there are two open items that remain, and these
8 are under our delayed opening.

9 So, an open item is one that the ACMUI, we
10 made a recommendation or an action item that the Full
11 Committee agreed on, and/or it could be a
12 recommendation, it was basically a recommendation
13 that the Committee agreed upon, so it's an open item.

14 So, there is an expectation that there will
15 be some action to that open item at some point in the
16 future. And along the way we will work to close
17 these open items. So, that's what I know about open
18 items.

19 So, from 2007 there are two open items that
20 remain that did not get captured in the expanded
21 rulemaking for Part 35. So these items would remain
22 open until a future rule where they could be
23 reconsidered or if the Committee wanted to discuss
24 these at another time in the future we could do that
25 as well.

1 But, so there is still two open items.
2 Items Number 33 and 34. And both of these do concern
3 optometric treatments under 35.490 and 35.491. Okay,
4 so they'll stay on as open.

5 Next chart. So the next chart is from
6 2008, and we only have two open items remaining from
7 2008 as the majority of the open items from 2008 did
8 get closed with the expanded rulemaking.

9 So here are, these are the two ones.
10 Again, they were not picked up specifically in the
11 Part 35 expanded rule but could be reconsidered in a
12 future rule. So they'll stay open.

13 So moving on, our next open item chart is
14 from 2016. So if we could talk about, we'll take a
15 look at these.

16 So, for Item 16, this was the, in the last
17 meeting the ACMUI wanted to leave this open because
18 this particular Subcommittee is still performing the
19 reviews. This is the T&E expanded for all modalities
20 Subcommittee. So this one would continue to stay
21 open as the work is ongoing and reviews are ongoing.

22 Item Number 24, this is one where the ACMUI
23 made the recommendation that they would contact their
24 respective professional organizations to encourage
25 interactions between NRC and the ACMUI. And this one

1 we have open as, the action item is, it's open
2 indefinitely. So this would be an ongoing activity.

3 Let's see. So, items, finding my notes,
4 Items 39, 42, and 43. So 39 through 43 concern
5 Yttrium-90 microspheres and the licensing guidance.

6 So these are open items, and they'll stay
7 open. You'll hear tomorrow from Dr. Tapp on the
8 current status of the Yttrium-90 licensing guidance.
9 So, basically, these items will stay open as that
10 licensing guidance is still in process and has not
11 yet been finalized by the working group.

12 Items 49 through, 49, 50, 51 and 52, these
13 items concern the Northstar Moly Tech generator.
14 This guidance was issued back in February, but what
15 has not yet been provided to the Committee, is the
16 dispositioning of the ACMUIs recommendations for this
17 guidance document.

18 So NRC will be providing that documentation
19 to the Committee. So, until we've provided you that
20 documentation to show the dispositioning of comments
21 that you had on that generator guidance document,
22 these will remain open as well.

23 Okay. And then that will take us to the
24 2017 chart. There are three open items for the 2017
25 chart.

1 The first one is where the Committee had
2 requested that all of the Committee's recommendations
3 concerning the Part 35 rule, going back from 2007
4 going forward, including reports that were done in
5 2013 and 2016, that the Staff present a detailed
6 description of showing where those recommendations
7 were correlated to the new rule.

8 So we don't have that presentation at this
9 point. The rule will become effective in January,
10 so what I would propose is that the status be changed
11 from pending to an open item and that the NRC Staff
12 would provide that information at the next meeting.

13 So, is there a motion to change the status
14 from pending to open?

15 VICE CHAIRMAN METTER: This is Darlene
16 Metter. I propose to change the status from pending
17 to open.

18 MS. DIMMICK: Somebody needs to second it.

19 MEMBER WEIL: Second.

20 MS. DIMMICK: Any discussion? I think I
21 heard a second from Laura Weil. Any discussion?

22 I will add that to further support this we
23 will also be doing training on the new rule for NRC
24 Staff, agreement state staff, NRC licensees,
25 agreement state licensees and the master material

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1 licensees between October and March.

2 So there will be opportunities to see how
3 the changes of the new rule, which definitely
4 incorporate recommendations that were made by ACMUI.

5 Okay, the next open item is Number 12, Item
6 12. And this was, in reviewing the past transcripts,
7 here it says the NRC Staff will engage discussions
8 with the OAS Staff to find ways to centralize event
9 reporting from the agreement states.

10 The basis for this recommendation was, came
11 from, I believe the 2016 or the 2017 report of medical
12 events where that Subcommittee identified a lot of
13 variation and inconsistencies in the type of data
14 that was retrieved from NMED. So, the recommendation
15 was made to engage discussions with the agreement
16 states on improving the quality of that information.

17 So, NRC Staff did engage the agreement
18 states in a monthly OAS CRCPD call and talked about
19 what the ACMUI had noted. And also, to remind them
20 of timeliness and the quality of the type of
21 information and reviewed the procedural requirements
22 under the NMED reporting procedure, SA-300.

23 So we did have those discussions with the
24 agreement states. So, at this point, this is an open
25 item. Other than engaging the Staff, I mean, the

1 Staff did engage the agreement states, is there a
2 motion to close this particular recommendation based
3 on the actions taken so far?

4 MEMBER ENNIS: A Comment.

5 MS. DIMMICK: Sure.

6 MEMBER ENNIS: I think we were looking for
7 really a communication of setting up common items
8 that would have to be reported always, like a little
9 bit more structured substance to what the agreement
10 states would have to submit to match what we get at
11 NRC. So I'm not sure what was described is exactly
12 the way I recall what our Committee was looking for.

13 MR. BOLLOCK: Okay, so we do have
14 procedures that the agreement states use, SA, I think
15 it's SA-300 that gives the guidance for the agreement
16 states for what to report, what to put in NMED and
17 that information sharing.

18 So it is, there is commonality in what's
19 required and what's reported, it's just sometimes,
20 and I think we discussed this about a year and a half
21 ago in 2017, sometimes you just get disparity and
22 what information is in there. So we brought this up
23 at least once, I think actually more than one, OAS
24 call, we have monthly calls with OAS and CRCPD, we
25 brought this topic up as a reminder, to put in all

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1 the information you have. The better the information
2 is, the better we can all use it.

3 There was also discussion. It was a very
4 small portion of discussion, but during the last CRCPD
5 meeting in May, we talked a little bit about this
6 with some of the states. So, it's been communicated.

7 There are the structures in the SA
8 procedures, and it's just a matter of keeping the
9 encouragement, keeping people to, the states in NRC
10 regions and updating the events as they come in with
11 the information they have.

12 There are some other mechanisms, informal
13 mechanisms. Our contractors have run the NMED
14 program, they will reach out to the states to update
15 information if they see that it's not, doesn't have
16 everything that's in the SA or required by NMED. They
17 will reach out to the states as well.

18 So there are multiple, there's a procedure,
19 there is us discussing with OAS, just reminders. And
20 then the NMED Staff also reaching out to the states
21 to remind them to keep that.

22 So those are kind of the mechanisms in place
23 to do that. But I think a year and a half ago we're
24 recognizing that we got to keep on it.

25 And that's what we did with that, to just

1 communicate again, make sure to update it with the
2 best information. The more information we have the
3 more helpful it is for us and then for the other
4 licensees to, if the information is shared, to be
5 able to learn from the operational experience from
6 the events.

7 MEMBER ENNIS: So, if we need to stay on
8 it, does that speak to, we should keep this as an
9 open item?

10 MS. DIMMICK: Yes. If the Committee wants
11 to keep it open so that it's, that we're aware of it
12 and we continue to work towards improving the quality
13 of information, sure, we can keep it open.

14 MR. BOLLOCK: Yes, we can continue to work
15 towards it.

16 MEMBER ENNIS: Yes. I think if it's going
17 to be an ongoing phase it will help just remind us.

18 Now, in terms of the items that are
19 required, has there been a recent review of those
20 elements and what would be the mechanism for reviewing
21 and/or changing those?

22 MR. BOLLOCK: I don't know for sure when
23 the last SA update was. It was two years ago maybe.
24 Lisa, do you know --

25 MS. DIMMICK: If I could offer a little bit

1 more background. So, for the agreement states, one
2 area or one way that they're evaluated for, their
3 reporting of events into NMED is through the
4 integrated materials performance evaluation program
5 (IMPEP) review of the agreement states as well as the
6 NRC materials programs in each region.

7 So, one of the responsibilities of the
8 IMPEP team is to evaluate incidents and allegations.
9 And they review the data from NMED.

10 So, one thing that they're looking for is,
11 do they have open or closed events in NMED and if
12 they've been closed timely. So there is another set
13 of eyes on the NMED data that is reported by each
14 agreement state in their log and how it's handled.

15 So, that would be if there were things that
16 were not aligned with the procedure, it would be
17 identified in the IMPEP reviews with regard to the
18 NMED reporting.

19 MEMBER BNNIS: I've never seen any of those
20 reports, is that something that would be valuable to
21 ACMUI to see, and if we think we're trying to improve,
22 would we expect to see a decrease in a number of
23 deficiencies in certain states over the next few
24 years?

25 MR. BOLLOCK: Well, the states are assessed

1 every three years.

2 MS. DIMMICK: Three years.

3 MR. BOLLOCK: Typically --

4 MS. DIMMICK: Four years.

5 MR. BOLLOCK: -- four, four to five years
6 in IMPEP reviews. And if there are deficiencies,
7 it's expected that they work on those, and that's
8 reviewed in the next IMPEP work as part of their, the
9 frequency increase or shorten the time frame that
10 they're reviewed.

11 So, it is expected that there is, in those
12 areas, that there is a deficiency that they are
13 improved or rectified. I don't know, I've got some
14 staff that may have a little bit more information.

15 DR. TAPP: Just a quick backtrack. The
16 information that's required to be reported is --

17 MS. DIMMICK: Excuse me, Katie, could you
18 announce your name for the court reporter?

19 DR. TAPP: Oh, this is Dr. Tapp. The
20 information that is required to be reported to be
21 reported into NMED goes back to our rule, so it would
22 take rulemaking to add additional items to the NMED
23 reporting.

24 MEMBER SHOBER: This is Megan Shober. I
25 thought that the required elements are specified in

1 SA-300?

2 Are you talking about what the licensees
3 would be required to report to NRC?

4 There's more, for event evaluation, the
5 elements that are in SA-300 are what the agreement
6 states are expected to follow.

7 MR. BOLLOCK: Yes. So the structures, the
8 minimum requirements are in the NRC regulations and
9 that's what the states have to report to us. But if
10 SA-300 expands, as Megan said, SA-300 expands on that,
11 what more is expected from the states to share with
12 us. So that's kind of the documentation.

13 And then through the process is IMPEP
14 process, I failed to mention, thank you for reminding
15 me, that's the major review, formal process of
16 reviewing the states programs. But then the other
17 informal things in the time phase in-between.

18 MEMBER SHOBER: And this is Megan Shober
19 again. Just to speak to your question about the
20 records, all of the IMPEP reports are available on
21 NRC's website.

22 And there's a nice page, you can just click
23 through any state you want and those are all
24 available. And there is a section in there that's
25 about the incident reporting.

1 MR. BOLLOCK: And Dr. Howe from my Staff
2 has something else to add.

3 DR. HOWE: One of the other points is that
4 medical event reporting is a health and safety
5 criteria between the agreement states and NRC, so
6 it's not at the level of a Compatibility B, where the
7 agreement states have to provide exactly what's in
8 our regulations. So that may cause some differences.

9 MS. DIMMICK: So, I guess I would ask at
10 this time, because of earlier comments about keeping
11 this open for a period of time, would there be a
12 motion to change this from open to open indefinitely?

13 MEMBER ENNIS: I guess I don't really know
14 what the distinction is. I'm not certain we're going
15 to need to review this forever, but I do have a
16 feeling right now that we need to review it more. So
17 you can advise me about whether you think that it
18 needs open indefinitely or open.

19 MR. BOLLOCK: Yes, I think the distinction
20 for us is when we look at the chart we say, this is
21 something we want to continually look at, similar to
22 some of the previous ones where they were ACMUI and
23 NRC reaching out to the professional societies to
24 continue dialogue.

25 I think we have been doing that the past

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1 couple of years but we'd like to continue, so we just
2 put indefinitely to continue on. So that would just,
3 it's just to help us with recognizing when we look
4 through the chart that, yes, this is something we
5 want to keep doing and remind us to interact and
6 engage OAS and informally along with the formal
7 processes we have in place.

8 MEMBER SHOBER: And this is Megan Shober
9 again. From what I'm hearing in this discussion, the
10 item, what you want isn't really defined a way to
11 centralize reporting because reporting is already
12 centralized through the Ops center.

13 What you're looking for is consistent,
14 information that's consistent between like different
15 states. So I'm not sure if that bears mention here.

16 MEMBER WEIL: So if I might add, so what
17 you could consider is looking, based on the outreach
18 that was done closing the recommendation and then
19 discussing a new option in the open forum that we'll
20 be getting to in a moment if you want to consider a
21 different way to describe what was really, what is
22 intended or what the current need might be.

23 CHAIRMAN PALESTRO: Any comments on that?

24 MEMBER ENNIS: I'd be okay with closing
25 this, but then in the open forum having a discussion

1 about, if we, as a committee, want to investigate
2 this further and how we want to articulate that.

3 CHAIRMAN PALESTRO: Can we have a motion
4 to that effect please?

5 MEMBER ENNIS: I move that we close this
6 item.

7 CHAIRMAN PALESTRO: Second?

8 MEMBER SUH: John Suh, second.

9 CHAIRMAN PALESTRO: All in favor?

10 (Chorus of ayes)

11 CHAIRMAN PALESTRO: Any opposed?

12 MS. DIMMICK: Okay, great, thank you.
13 Okay, the Items 13, 19 and 20 are related to the
14 recommendations that came out of the medical event
15 reporting and its impacts on medical licensee patient
16 safety culture, the NRC did speak about this at the
17 last ACMUI meeting, and also, this is one of the
18 topics in the commission brief last spring as well.

19 These items currently are shown as open and
20 the NRC will need to close them, provide our response
21 to those recommendations to you in a memo and we need
22 to do that. So, they should stay open until we
23 provide that memo to the NRC. I mean, to the ACMUI
24 members.

25 Okay, we'll go ahead and move on to the

1 2018 recommendations. So Recommendation 1 and 2 are
2 open items. And we will be hearing from Dr. Metter
3 on the nursing mother's guideline final report, I
4 think it's later today.

5 And so that will provide additional
6 information in these areas. So these would stay open
7 until after the Committee has approved that final
8 report.

9 And the first one is an NRC action because
10 it will be based on the final report, what NRC Staff
11 might do with that information with regard to
12 regulatory guide 8.39. Okay, Dr. Metter, you have a
13 --

14 VICE CHAIRMAN METTER: Yes, this is Darlene
15 Metter. I do see that some of the recommendations
16 here are listed, have been revised with different
17 calculations. So, after my final report if you could
18 update this action item.

19 MS. DIMMICK: Which number?

20 VICE CHAIRMAN METTER: Number 1.

21 MS. DIMMICK: Okay. Okay, so Items 3 to
22 5, these concern the physical presence requirements
23 for the Leksell Gamma Knife Icon updated licensing
24 guidance.

25 So we'll be hearing from Dr. Suh on that

1 Committee's draft report. Or I'm sorry, that
2 Committee's report on the licensing guidance so these
3 could stay open until after the Committee has an
4 opportunity to deliberate that report.

5 Okay. So, Item 6 was a recommendation from
6 the Committee for NRC to update the ACMUI, or to post
7 the recommendations that showed all of the
8 recommendations and their status on the web page.
9 And NRC did take action on that and did post a
10 recommendations on the ACMUI web page.

11 So, instead of it saying open indefinitely,
12 is there a motion that, to close this recommendation?
13 Or any discussion.

14 CHAIRMAN PALESTRO: Question?

15 MR. BOLLOCK: This is Doug Bollock. This
16 is one of those things that we're going to have to
17 continually update, so we can keep that as open
18 indefinitely as the, right, so we carry on.

19 After this meeting when we've updated the
20 recommendations we'll put the new, we can put the new
21 one with any new recommendations coming out of this
22 meeting on the website. So I, NRC, I feel we should
23 leave that on there.

24 MS. DIMMICK: Okay, we can leave it open
25 indefinitely. And that's how its currently

1 reflected. Unless, right.

2 Okay. So, Item 7. This concerns sending
3 out a medical Listserv announcement after the ACMUI
4 has met and then issue and provide in those Listserv
5 announcements the recommendations or actions of the
6 ACMUI.

7 We did that after the last meeting. And,
8 again, this is another one reflected as being open
9 indefinitely. Since this is something new we're
10 doing, we would continue to keep it open indefinitely,
11 till it becomes part of our process.

12 Okay, so I'll move on to Item Number 8.
13 This one basically indicates the date for the fall
14 meeting. So I would propose, is there a motion to
15 close this item since we are in fact convening this
16 meeting?

17 MEMBER SCHLEIPMAN: Robert Schleipman, I
18 move that we close.

19 (Laughter)

20 PARTICIPANT: Second.

21 MS. DIMMICK: Second, okay. Okay. And
22 all those in favor?

23 (Chorus of ayes)

24 MS. DIMMICK: Okay. Just going through
25 formalities.

1 Okay, so the next item, Number 9, is where
2 Dr. Palestro had appointed Megan and Zoubir to serve
3 on the physical presence requirements for the Gamma
4 Knife Subcommittee meeting.

5 This is currently open and it does link to
6 two, three other recommendations in 2018.
7 Recommendations 3, 4 and 5, which are the physical
8 presences ones.

9 So we could either, this is just showing as
10 that it's open because it's a current committee. So
11 we could keep it open until we address the physical
12 presence report.

13 CHAIRMAN PALESTRO: Any discussion or
14 comments on that?

15 MS. DIMMICK: Dr. Suh will talk about the
16 report and so I don't, unless you have discussion,
17 you want to talk about this.

18 CHAIRMAN PALESTRO: No, I meant about the,
19 whether or not we should keep it open, that's what
20 I'm referring to.

21 MS. DIMMICK: Oh, it could be closed
22 because the Committee is formed and reviewing it or
23 it could stay open until the Committee has presented
24 its report. I've seen it done both ways.

25 (Off microphone comments)

1 MR. BOLLOCK: -- there may be other items
2 to close. So there is no right or wrong there.

3 CHAIRMAN PALESTRO: Okay.

4 MS. DIMMICK: Yes.

5 CHAIRMAN PALESTRO: So, is there a
6 consensus among the Committee? Leave it open until
7 such time?

8 MR. BOLLOCK: Yes.

9 CHAIRMAN PALESTRO: All right. Okay,
10 fine.

11 MS. DIMMICK: Okay. And the last one for
12 2018 is the ACMUI endorsed T&E SECY Subcommittee
13 report. The T&E SECY paper, this was the
14 Subcommittee report.

15 So, the T&E SECY paper, SECY 18-0084, was
16 sent to the commission. It is currently publicly
17 available under, in ADAMS, under Session Number
18 ML18135A276.

19 The ACMUI's final report and comments on
20 that draft, on the draft SECY report, are appended to
21 that commission paper. So you're feedback on that
22 report are part of the record for that SECY paper.

23 And you're also going to hear about NRCs
24 outreach plan by Maryann Ayoade later in this meeting.

25 So I, so could there be a motion to close this

1 recommendation based on the publication of the SECY
2 paper and NRCs planned outreach? Continued outreach.

3 CHAIRMAN PALESTRO: Do we have a motion to
4 that effect?

5 VICE CHAIRMAN METTER: This is Darlene
6 Metter. I move to close the item.

7 CHAIRMAN PALESTRO: Second?

8 MEMBER SCHLEIPMAN: I'll second that.
9 Robert Schleipman.

10 CHAIRMAN PALESTRO: Any discussion? All
11 in favor?

12 (Chorus of ayes)

13 CHAIRMAN PALESTRO: Any opposed?

14 MS. DIMMICK: Okay, so that item is closed.
15 And that was the last old business item for this
16 meeting.

17 So now Dr. Palestro, I'll turn it back to
18 you for any open forum discussion. There are no
19 handouts for the open forum so this is where the
20 Committee can bring up any topics.

21 CHAIRMAN PALESTRO: All right, so we'll
22 move on to the next item which as Lisa said is the
23 open forum. Any topics for discussion?

24 MEMBER ENNIS: I guess we already had a
25 lead in to whether or not we want to look in more

1 depth at what gets reported in NMED and the
2 differences between agreement states and not and
3 possibly also this report that I guess is available,
4 but ACMUI has never, as Committee, like looked at it
5 and see what kind of information is there about
6 individual states and their performance.

7 So, I guess it's an open question whether
8 we want to have a Subcommittee to look at that. I
9 think I would be in favor of it.

10 I feel like it's an open, it's a loose
11 thread that I don't have a good handle on and I guess
12 with being the medical events subcommittee chair and
13 having seen NMED and raised some of the issues, it
14 feels like this might be part of that loop that we
15 ought to investigate. But, I only want to do that
16 if other people do.

17 CHAIRMAN PALESTRO: This is Dr. Palestro.
18 Dr. Ennis, could you state what exactly would be the
19 charge of the Subcommittee?

20 MEMBER ENNIS: I'll try. The Subcommittee
21 will review the requirements, NRC requirements, in,
22 that are a part of the regulation it's in as well as
23 in the SA-300 document for, to evaluate the -- well,
24 I'm having a little trouble articulating it.

25 A consistency in the quality of the data

1 relative to the charge of medical event analysis. It
2 probably could be articulated better, so feel free to
3 chime in.

4 CHAIRMAN PALESTRO: Any other comments or
5 suggestions? Mr. Ouhib.

6 MEMBER OUHIB: Yes, I think this item was
7 discussed multiple times if I recall correctly. And
8 the issues were there were some inconsistencies in
9 reporting medical event.

10 And that means details were not sufficient
11 to actually improve or provide corrective action and
12 all that. That sometimes even the event simply does
13 not make any sense when you read it. And there are
14 some corrections that come up later and so on and so
15 forth.

16 I know for a fact that, I think Bruce
17 Thomadsen, when he was the chair, we discussed this
18 and there is a task group within the AAPM, actually
19 was looking at this also at the same time. I can't
20 remember the task group number, it might have been
21 188, I can't remember.

22 But any rate, I think there's a great need,
23 in my opinion, to have some consistency, what should
24 be reported and what format should be reported sort
25 of becomes fairly easy to understand for everybody.

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1 But it also, you force the user to provide you that
2 information that we think it's really critical in
3 evaluating the event and perhaps providing some
4 corrective actions and so on.

5 MEMBER WEIL: This is Laura Weil. If I can
6 try to perhaps interpret some of the sub-text of
7 what's going on. We, in the item, agenda item that
8 we just closed, we closed it because we felt the
9 language did not reflect the ACMUI's interest in
10 getting, assuring that more complete information was
11 being received for all medical events, correct?
12 Okay.

13 So, perhaps what, because the stuff that
14 gets collected is determined by rule, it's not
15 something that we can change easily, it's rulemaking,
16 maybe what we need to do is simply have a sub-charge
17 to the Committee that looks at medical events to
18 monitor whether there is increasing compliance based
19 on NRC Staff's activities to engage with OAS and other
20 entities that are reporting.

21 Is that what we're after, just seeing if
22 things are improving whether we're getting more
23 complete information?

24 MEMBER ENNIS: I don't know, I think, at
25 least in my mind we're actually after two things.

1 One is that, but two is, since there is, beyond
2 rulemaking, a possible mechanism for modifying. At
3 least what's strongly recommended.

4 I think it would be of value to the ACMUI
5 to look at that document, see what's required, see if
6 that makes sense to us, if it ought to be modified
7 and then make some recommendations about that
8 document. And maybe some rulemaking recommendations
9 too, although we understand the challenges in doing
10 that.

11 So I think it's both we need the elements
12 that are being asked of people and also how well that
13 is being done.

14 CHAIRMAN PALESTRO: So, this is Dr.
15 Palestro again. Dr. Ennis, then would you favor the
16 creation of a separate and distinct subcommittee to
17 do that?

18 MEMBER ENNIS: I'm really open to either
19 way. The NRC Subcommittee Members here could speak
20 to whether they want to do it as part of our medical
21 event Subcommittee or if there's interest for people
22 not on the Committee, maybe we form a separate
23 Subcommittee. I think either mechanism would be
24 fine.

25 CHAIRMAN PALESTRO: It is open for

1 discussion. Any comments from the Subcommittee
2 Members in particular? Mr. Green.

3 MEMBER GREEN: I thought I heard Mr.
4 Bollock say that there was a subcontractor who
5 monitors the input of data into this database and can
6 go back to a state, an agreement state, and say, hey,
7 you're a little shy on the data here can you fill in
8 these fields? I'm not sure it's the ACMUI's role to
9 be the monitor of completeness, I think that
10 contractor will do that though.

11 I think we could look at the list of data
12 we request on the form that the agreement states work
13 with, to see if that has all the data elements that
14 we would like to see.

15 MEMBER ENNIS: I guess I'm feeling, just
16 having seen the data for a while, that maybe the
17 monitor needs a monitor. Or at least notice that
18 someone else is looking from time-to-time.

19 MEMBER SHEETZ: This is Mike Sheetz. Does
20 the NRC have a template on what information they are
21 requesting to report a medical event or some other
22 event on the other parts in the regulations?

23 MEMBER ENNIS: Yes.

24 MEMBER SHOBER: This is Megan Shober. It's
25 called a state agreements procedure. It's SA-300.

1 Which, again, it's, I don't know which branch is
2 responsible for it but that has a list of all the
3 elements that are required for a complete NMED record.

4 And so if a state submits information to
5 NMED and it doesn't include all those elements, then
6 the NMED contractor sends an email to the state and
7 says, please provide this information within the next
8 60 days.

9 So, they're pretty on top of that. And the
10 state doesn't necessarily respond I guess, but NMED
11 is cross-checking the NMED report against the SA-300
12 elements and requesting more information when it's
13 not initially provided.

14 MEMBER SHEETZ: And this is Mike Sheetz
15 again, is there a mechanism to monitor whether the
16 state ever responds back with a request of additional
17 information?

18 MEMBER SHOBER: This is Megan again. NMED
19 doesn't follow-up after that initial round, but the
20 place where it would be noticed, again, is through
21 the integrated materials performance evaluation
22 program.

23 They do look at records that are open and
24 closed in making sure that records are getting closed.
25 I don't know if it would trickle down to that extreme

1 level of detail to look at those elements, but if
2 there is a problem with reporting of course, more
3 attention is paid in that area.

4 But as far as a routine basis, probably
5 not. Not that detailed.

6 MR. BOLLOCK: Right. So the IMPEP process
7 they may, if they see a programmatic issue, states
8 are lacking in information on every report they have,
9 it will probably be noticed.

10 Here, there missing information may not be
11 just based on, it's all sampling and looking at it
12 for, you know, a coder could not be identified. So,
13 I mean, there are, like I said, there are mechanisms
14 but we recognize the concern the Committee has brought
15 is that we want to make sure the information is as
16 best as possible, consistent as possible, can be as
17 useful as possible.

18 So, yes, the only other way I think it would
19 be identified is if the event was an AO, and then we
20 get all the information on it. So that's the only
21 other way, if the event is significant. And that's,
22 a structure is looking at what's most significant.

23 So I'm hearing, I just want to clarify, I'm
24 hearing two things. One, the consistency in the
25 reporting, that they're reporting what they're

1 supposed to be reporting on their SA-300 and it's
2 consistent to get the best information.

3 And then also, consideration for a
4 Subcommittee to review the SAs and seeing what is out
5 there. So I just want to, I think that's what I'm
6 hearing, I just want to make sure that we understand
7 so we can capture that, that's what it is.

8 CHAIRMAN PALESTRO: So I'd like to bring
9 that back to my original question. As Dr. Ennis
10 discussed, there are one or two options.

11 One is to incorporate this into the current
12 Subcommittee on medical events work or to establish
13 a separate subcommittee to carry out this task. And
14 so I'd like to get some discussion on that. Dr. Suh.

15 MEMBER SUH: Yes. So, I've had a chance
16 to review the medical event reporting for, I guess
17 it's now seven years.

18 And one thing that I have noticed is that
19 there are, the reports are not consistent and/or
20 sometimes not fully accurate. So I do believe there
21 is a need, as Dr. Ennis has pointed out, to have a
22 subcommittee or to really look at what can be done
23 differently so that there is greater consistency and
24 accuracy of these medical events.

25 Because by evaluating these medical events

1 hopefully you'll get more information, which will
2 help drive changes, which will help patients and
3 healthcare providers as well.

4 So, whether or not it's part of the current,
5 what I say for, is because the current medical events
6 committee, subcommittee is familiar with how to
7 interoperate these NMED reports, that it should be,
8 that should be the charge of that particular
9 subcommittee rather than forming another
10 subcommittee. I'd still have to replace the
11 radiation oncology and that's whoever my replacement
12 will be.

13 CHAIRMAN PALESTRO: Other opinions?

14 MEMBER ENNIS: Well, I guess I have a
15 little opinion because both Megan and Zoubir have
16 seem to be interested in this topic and they're not
17 currently on the Committee, so I'm wondering, for
18 that reason, maybe, maybe we should have a different
19 Committee. But maybe they want to speak to that.

20 MEMBER OUHIB: This is Zoubir. Just a
21 comment. I guess my question would be is, when was
22 the last time that list, that required list that needs
23 to be submitted, was actually looked at to revise?

24 And let me just follow-up with one more
25 thing is that, the reason I'm asking this, is it

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1 possible that there is information that's lacking in
2 that list that is really critical or perhaps important
3 in reporting a medical event.

4 And there might be others that perhaps are
5 not really needed and is there time to look at that
6 and see, how can we best make that more efficient and
7 useful.

8 CHAIRMAN PALESTRO: I understand what
9 you're saying, this is Dr. Palestro, but I want to
10 come back to the question that really needs to be
11 answered, I think. And that's, do we incorporate
12 this new charge into the responsibilities of the
13 existing Subcommittee or do we want to create a
14 separate subcommittee? And that's what I would
15 really like to focus on at the moment.

16 MEMBER ENNIS: All right, so our current
17 members of the NRC Medical Event Subcommittee are --
18 sorry guys, I know you worked hard on our Committee
19 report that we're about to see, but I don't want to
20 miss anyone.

21 Richard Green, Dr. Metter, Dr. O'Hara, Dr.
22 Suh and Mr. Sheetz. Did you guys want to work on
23 this or should we have a separate Committee?

24 CHAIRMAN PALESTRO: How many members do you
25 have, six?

1 MEMBER ENNIS: Six.

2 CHAIRMAN PALESTRO: Okay. At this point
3 you can't add any more members.

4 (Off microphone comment)

5 MEMBER ENNIS: Well, Dr. Suh is leaving but
6 does he have to be replaced by another --

7 CHAIRMAN PALESTRO: That would be replaced,
8 but you can have a maximum of six members on the
9 Committee.

10 MEMBER ENNIS: Okay.

11 CHAIRMAN PALESTRO: So the Committee can
12 choose --

13 MEMBER ENNIS: So I'd like to suggest we
14 have a separate Committee because I see some valuable
15 members around the table that are not able to be on
16 this Committee.

17 CHAIRMAN PALESTRO: All right. Well, as
18 Chair I believe I have the prerogative to establish
19 a separate, or to establish a subcommittee, which I
20 will now do. But I will rely on Dr. Ennis to create
21 the specific charge for that subcommittee.

22 MEMBER ENNIS: I'm going to ask Ms. Weil
23 to articulate it for me.

24 CHAIRMAN PALESTRO: Unless I'm violating
25 some rule, we don't need to have that specific charge

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1 at this minute. I'd like to have it before the close
2 of business today so that we can formalize it.

3 MEMBER WEIL: Yes, that's fine.

4 MR. BOLLOCK: Yes, that's fine, as long as
5 you close --

6 CHAIRMAN PALESTRO: Rather than being vague
7 and trying to knock it out in five minutes before
8 lunch. So, Dr. Ennis, and again, while the Chair
9 appoints the Subcommittee Members, I think it makes
10 sense to ask for your input, who you feel should be
11 on the Committee. Subcommittee.

12 MEMBER ENNIS: Okay. Dr. Ouhib, would you
13 be willing to serve?

14 MEMBER OUHIB: I'd be happy to.

15 MEMBER ENNIS: Megan?

16 MEMBER SHOBER: Yes.

17 MEMBER ENNIS: Okay. Laura, are you going
18 to be around on the Committee for long enough to --

19 MEMBER WEIL: Only about a year though.

20 MEMBER ENNIS: Oh, a year is good enough.

21 Will you be willing to serve?

22 (Laughter)

23 MEMBER WEIL: Yes.

24 MEMBER ENNIS: All right. One more
25 volunteer. Oh, sorry.

1 DR. HOWE: I just wanted to make a point,
2 Dr. Suh, this is his last day so he will be coming
3 off of the medical event committee, so you may want,
4 if you have more than him, you might keep it in the
5 same committee or you might come in with a new
6 subcommittee.

7 MEMBER ENNIS: Great. No, I think we felt
8 there was an interest in people who could not be,
9 because of size requirements that subcommittees fit,
10 so we're going to do a separate committee.

11 We probably would want to ask the new
12 radiation oncologist to join this Subcommittee but we
13 don't know who it is or when it's going to be, so for
14 now I think we've got a good Committee, but maybe
15 there be one more person to volunteer?

16 MEMBER MARTIN: I'll volunteer.

17 MEMBER ENNIS: Excellent.

18 MEMBER OUHIB: Yes. This is Zoubir. I
19 think that would be perfect because we definitely
20 need a variety of therapy, diagnostic and so on and
21 so forth.

22 MEMBER ENNIS: Do we have enough nuclear
23 medicine expertise though? There are nuclear
24 medicine events and I think actually we need some
25 nuclear medical expertise, sorry, but --

1 MEMBER DILSIZIAN: I'll volunteer.

2 MEMBER ENNIS: Okay. Dr. Dilsizian has
3 volunteered, thank you.

4 CHAIRMAN PALESTRO: All right, so then just
5 to review very quickly. Dr. Ennis is the Chair of
6 the Subcommittee and the Members are Dr. Dilsizian,
7 Mr. Ouhib, Ms. Shober and Mr. Sheetz, is that correct?
8 I'm sorry, and Ms. Weil.

9 PARTICIPANT: That would be six.

10 (Off microphone comment)

11 PARTICIPANT: That's six, we don't need,
12 okay.

13 (Off microphone comment)

14 CHAIRMAN PALESTRO: All right, so that's
15 the Subcommittee. But again, I would ask that before
16 the close of business, at some point, you come back
17 with the specific formal charge.

18 And now that we have this Subcommittee I
19 would also ask that Staff appoint a liaison.

20 MR. BOLLOCK: Yes, I'll work on that. Lisa
21 and I have to discuss and we'll absolutely supply a
22 staff liaison.

23 CHAIRMAN PALESTRO: Any other matters for
24 the open forum? All right then, we will adjourn and
25 we resume at 12:45.

1 (Whereupon, the above-entitled matter went
2 off the record at 11:58 a.m. and resumed at 12:45
3 p.m.)

4 CHAIRMAN PALESTRO: I call the afternoon
5 session to order. First presentation this afternoon
6 is the Medical Events Subcommittee and it will be
7 presented by Dr. Ennis.

8 MEMBER ENNIS: Thank you Dr. Palestro, good
9 afternoon, everyone, I'm happy to report the Medical
10 Events Subcommittee report for this meeting. The
11 report is the work of all members of the subcommittee,
12 it is very much a joint effort with each of us pretty
13 much owning one part of the report and I invite all
14 the subcommittee members to speak to their point at
15 the end if I haven't touched on all key elements.
16 Next slide, please.

17 MR. BOLLOCK: This is Doug Bollock with NRC.
18 I apologize, we're having some technical difficulties
19 so it seems like we're getting them resolved quickly.

20 MEMBER ENNIS: Okay, back one slide please.
21 So our subcommittee members in addition to myself,
22 Mr. Green, Dr. Metter, Dr. O'Hara, Dr. Suh and Mr.
23 Sheetz. Thank you.

24 The subcommittee decided to change the way
25 it had been reporting for the last several years,

1 with encouragement from NRC staff, particularly Dr.
2 Howe with the support of Dr. Palestro, that rather
3 than go through NMED ourselves for the last fiscal
4 year and review all the events and report on them in
5 a way similar to what Dr. Howe had done in the spring,
6 instead we decided to review the last three-year
7 reports of this committee plus Dr. Howe's spring
8 report, so this is covering three and a half fiscal
9 years to take a wider angle or high level looking for
10 themes that might be recurring within Part 35 or
11 perhaps even across different parts and see if we can
12 come up with some recommendations for improvements.

13 So in the end as you'll see is the data but
14 just to give you a summary now, we saw two overarching
15 themes. One, there's good examples to suggest that a
16 performance of a "time-out" type procedure
17 immediately prior to the administration of
18 radioactive byproduct material has been done in
19 surgery and other settings in medicine, currently
20 with great success, could have prevented some others.

21 And there seems to be a second theme, that
22 lack of a recent or frequent performance of a specific
23 administration appears to be a contributing factor in
24 a number of cases. Next slide.

25 So, now going through the data for the three

1 and a half years by section. In Part 200, Unsealed
2 Byproduct Material for Imaging and Localization not
3 meeting written directives, these are the types of
4 events that have occurred over the last four years,
5 21 events in total, wrong drug, wrong dosage, wrong
6 patient. Next slide.

7 "Time out" likely would have been able to
8 deal with several of these, confirm the order compared
9 to the prescription, wrong patient also a time out
10 ought to have been an effective mechanism for
11 minimizing that. A rough estimate is about half of
12 the cases might have been prevented if a "time out"
13 had been used.

14 The wrong dosage is a little trickier in
15 that dose calibrators are not necessarily required
16 and not everyone has them, so that those errors may
17 be a little bit more difficult to overcome and
18 probably not effectively changed by implementing a
19 "time out." Next slide.

20 In 300, Unsealed Byproduct Material
21 Requirement Directive, these are the issues and
22 again, a few every year, pretty consistent, you know,
23 a handful, half dozen or so different types of things
24 cover the vast majority of events, and again at least
25 half to three-quarters may have been able to be

1 prevented by a "time out."

2 Written directive not done or incorrectly
3 done would be likely, error in the number of capsules
4 is a common theme, and again something about "time
5 out," how many capsules as a check, dose, equipment
6 things obviously are different, unauthorized clinic
7 is obviously a totally separate issue. Again, wrong
8 patient ought to be able to be caught by a "time
9 out". Thank you. Next slide.

10 Manual brachytherapy, both prostate and
11 non-prostate, these are obviously a little bit more
12 technical in nature. Applicator issues, the
13 applicator moved during the implant, wrong site
14 implanted and activity, being prescribed,
15 prescription error and air kerma versus millicuries.
16 Then in the prostate there's dose group, which has
17 been a large group. Next slide.

18 Looking at these, let's go back actually if
19 you don't mind, just to be able to talk about it. The
20 applicator issue sort of had a "time out" issue
21 potentially for some not familiar, not doing the
22 procedure often issue, although most of the ones
23 actually described here did not appear to be that
24 either, but you could imagine sometimes that might be
25 a role.

1 Wrong site implanted, in this setting we're
2 talking penile bulb implantation which is a
3 significant number of those. It is certainly an
4 infrequency of the procedure that is playing a
5 significant role. And activity prescription error is
6 a "time out", potentially caught by "time out".
7 The prostate dose, of course, with the new definition
8 of medical events, this is going to change
9 dramatically. Many of these events are by the new
10 definition not events, so it will be very interesting
11 to see what emerges afterwards.

12 But some of the prostate dose events are
13 the type that could be caught by a "time out",
14 because there were errors in prescription for, just
15 one example, someone getting external beam and a seed
16 implant ought to get a certain dose and there was at
17 least one or two events where they prescribed the
18 wrong dose, confusing that the patient also got
19 external beam. So a "time out" could have caught
20 that. Next slide.

21 So in summary, sense is about ten percent
22 of these types of events might be affected by a "time
23 out", and another maybe 15 are impacted by a lack of
24 experience. Next slide. Let's see, I think we've
25 covered this here. Next slide.

1 In 600, HDR and the gamma knife are
2 regulated under 600. These are the types of events.
3 Wrong position, reference Linux plans, software
4 failure. 37 events over four years and again, if
5 there's a half a dozen things that pretty much cover
6 all of them. Next slide.

7 This is just broken down by disease site.
8 Again, all related to wherever brachytherapy or gamma
9 knife played a role in the diseases. Next slide.

10 Again, looking in review, "time outs"
11 likely impact, could have an impact in about 15
12 percent. Next slide.

13 The infrequent user phenomena may be
14 playing a role in about 30 percent. So it seems like
15 so far at least the technical anatomic procedures,
16 it's a little bit more about frequency of the
17 procedure and the comfort or experience of the person,
18 and that plays a lesser role in the radioactive
19 intravenous administrations for diagnostic or
20 therapeutic purposes. Next slide.

21 Okay, and radioactive seed localization, we
22 have a few obviously different parts to 1,000, so
23 just a few events but potentially could be an impact
24 of a "time out", at least the wrong site implant.
25 Next slide.

1 For Perfexion, Gamma Knife Perfexion, these
2 are the number of events and the causes, the most
3 common being positioning alignment, but that was a
4 very specific vendor and site. Other ones pretty
5 uncommon but a few events, some of them potentially
6 addressed by "time out", wrong site for example.
7 Perhaps patients had maybe some experience playing a
8 role there as well. Next slide.

9 Then Y-90, so as we have seen before, more
10 events in this category. We have talked about this
11 before. Complicated procedure, tubings, etc., so
12 here's a nice summary of events over time, and a lot
13 of it has to do with activity remaining in the device
14 or problems with the catheter, the shunting issue,
15 setting up properly, but some of the more kind of
16 dose calculation issues as well. Next slide.

17 This is for SirSpheres, the prior slide was
18 for Theraspheres, not demonstrably different, pretty
19 similar patterns of what's common and what are the
20 issues. Next slide.

21 So again, nice way to review this is in a
22 pie chart. A big one is residual activity, but then
23 we have the other problems as well. Next slide.

24 Things that might be able to be done within
25 the Y-90 area to prevent medical events, reviewing

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1 the mechanics of delivery device and setup procedure,
2 again speaking particularly, I think, to the setting
3 of infrequent users or not having used it in a while
4 or just getting started, ''time out'' type thing to
5 report all the, ~~reveal~~ review the elements that are
6 in the written directive would be helpful as well, as
7 we have mentioned. Next slide.

8 Just trying to categorize, ball park if you
9 will, what kind of impact the ''time out'' might be
10 able to have on the three different areas within 1000
11 that we just talked about so for the RSL, maybe one
12 of them, so maybe 25 percent. Obviously it's a small
13 number. Within the gamma knife sphere,
14 Perfexion/Icon, maybe also about 25 percent could
15 have been prevented if a ''time out'' had been done
16 and the Microspheres, about 12 percent. So again,
17 kind of consistent with the idea when doing technical
18 procedures, anatomic ones, the ''time out'' has a
19 modest impact, potentially ten to 20 percent. Next
20 slide.

21 In terms of just infrequent user type
22 problems, none of the RSLs seem to be that. Maybe 15
23 to 20 percent of the Perfexion/Icon events that may
24 have played a role and Microspheres best guess is a
25 small percentage as well. Next slide.

1 So if we were to try and distill this idea
2 of a "time out" across all parts of Part 35, what
3 could we think about as being something that might be
4 suggested as elements of a "time out" for all of
5 them? A pretty basic stuff of what's a "time out"
6 in surgery and in other settings that it's already
7 being used, identifying the patient with two
8 identifiers is a generally accepted element of a
9 "time out", reviewing the exact procedure that's
10 going to be performed, the isotope, its activity, the
11 dosage, then there may be consideration for adding
12 additional elements depending on the acuity of the
13 procedure, the whole treatment being done.

14 For example, an LDR prostate would be wise
15 to include a recalculating based on air kerma or
16 millicuries, anatomical location for the anatomic
17 type procedures would make sense, is the patient's
18 name on a treatment plan if there is such a thing, so
19 like in brachytherapy is there a treatment plan, or
20 in Y-90, is that this patient's plan, independent
21 second check, has that been performed in a way that's
22 required in many quality programs but you are
23 verifying that it's actually been done prior to
24 proceeding.

25 And so again, some very specific things

1 about HDR related to catheter lengths, that is a
2 consistent source of occasional error. Almost every
3 year there's one of those, and --- like for a cell
4 implant site location. Next slide.

5 For the issue of the infrequent or user
6 hasn't used it for a while or program, rather than
7 not just a specific user, but it could be the
8 department, the program, things that might be
9 recommended at this point, just in terms of taking
10 advantage of what's out there, requiring or
11 recommending, requiring is probably too strong a
12 word, recommending a review course be done. There's,
13 also, all professional societies now have video or
14 slide review courses that can be taken on line,
15 there's review articles all over the place for all
16 these procedures for people to review.

17 There's obviously the opportunity but
18 encouragement to speak to a colleague with
19 experience, and I think particularly important might
20 be a recommendation that a dry run be done if you
21 haven't done this procedure or you're not feeling
22 totally comfortable or confident, go through all the
23 steps with your entire team. I think that could go a
24 long way.

25 And then when you're dealing with a

1 particular device, particularly a Y-90, and the
2 tubing, just perform a dry run essentially so you
3 know exactly how what to push when and when you flip
4 the catheters or the, you know, to make the flow go
5 in the right direction. Next slide.

6 So what could NRC do to affect this or
7 promulgate this? We thought that, and our
8 subcommittee recommends, that NRC consider issuing an
9 information notice alerting authorized users to these
10 things and to the recommendations of the subcommittee
11 about ways to prevent them in the future. Thank you.

12 Committee members, anyone want to add to, if I left
13 out any important things or just any other comments?

14 CHAIRMAN PALESTRO: Any comments from
15 members of the ACMUI? Dr. Martin?

16 MEMBER MARTIN: Learn how to do the buttons.
17 Just a question. We obviously have an idea that
18 everything would be perfect and we would never have
19 any of these medical events. I think it would be
20 interesting to know how many total procedures were
21 done that were done correctly. In other words, if
22 we've got 21 events, it's 21 out of how many thousand
23 did we do correctly? Just to put it into perspective
24 that this is not a hazardous, I mean, not that we
25 like to have 21 events, but it's 21 out of, I don't

1 know, 2,000, 20,000, how many procedures were
2 actually done of those type of procedures? I think it
3 would just be interesting, maybe put it into
4 perspective as to, quote, really how big a hazard
5 this is.

6 MEMBER BNNIS: So yes, in prior reports that
7 kind of information has been shared, and it's a tiny
8 fraction of each one of these reports. Certainly one
9 perspective can be well, there's hardly any events,
10 but that being the case we don't need a subcommittee
11 to look at it, frankly. And I think we would all agree
12 that if there's relatively straightforward easy
13 things to do to do better, then why not do that.

14 MEMBER MARTIN: I completely agree. I was
15 just putting it into perspective so it didn't come
16 across that this was a real hazardous process that
17 we're doing.

18 CHAIRMAN PALESTRO: Other comments? Dr.
19 O'Hara?

20 MEMBER O'HARA: Yeah, Mike O'Hara. One
21 follow up on this is that a few years ago we started
22 having two review scientists from the FDA be able to
23 review the NMED data base, and that and Dr. Howe's
24 report has added a lot of strength to our review of
25 medical device failures.

1 What I mean, there's a couple of examples
2 here. Machine malfunction could be a medical device
3 failure and software failures. Those are, software
4 failures are definitely something that we're
5 interested in. And just for everybody's knowledge, in
6 radiation oncology, right now 74 percent of all of
7 the recalls that involve radiation therapy devices
8 are due to software failures. So we actually are
9 putting a lot of effort into approve, or clearing,
10 new devices with new procedures, new ways of testing
11 for the software failures. And NRC has really helped
12 us to that, with better communication.

13 CHAIRMAN PALESTRO: Dr. Dilsizian?

14 DR. DILSIZIAN: Great presentation, Ron.
15 When I looked at your summary, you had two main
16 themes. One was the "time out" and the other one
17 was the lack of training or experience. Both of those,
18 unfortunately are not regulations. It's the practice
19 of medicine.

20 The reason this comes up every time is
21 because I'm the chairman of radiation safety
22 committee and our radiation oncology colleagues on
23 the committee want to have us as a safety committee
24 to decide what type of a period you would need of
25 lack of let's say doing Y-90s, where you should not

1 either teach or do, which I thought was the order of
2 medicine, not radiation safety.

3 So what's interesting is that as a
4 committee we're trying to deal with these, which you
5 summarized beautifully, but it's really the practice
6 of medicine. You even mentioned that the Society
7 should be recommending this, not NRC. So what is then
8 our role? It's very interesting.

9 MEMBER ENNIS: That's a great comment and
10 something we struggle with here all the time. It's on
11 that line and I guess maybe in part we're not really
12 joined to any kind of regulatory work. This is just
13 more of informational, hey, as a body that reviews
14 medical events, so that's kind of working it into the
15 regulatory space. As regulators, if you will, we want
16 to help you minimize that and these are some things
17 we're recommending.

18 I agree I wouldn't want NRC to start to
19 stipulate the definition of what's frequent, what's
20 not frequent for this particular procedure. That's
21 definitely out of their purview, but I think it's
22 okay for NRC to say, hey, we're regulating you, we
23 see a pattern here, and we want to highlight that for
24 you and you guys now think about what's the
25 appropriate time, what's the appropriate things in

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1 the "time out", I mean we're not really mandating
2 the specific things, just think about time, I'd like
3 to hear some suggestions.

4 I think that comes close to the practice of
5 medicine but is still as a practitioner I think that
6 would be okay for NRC to kind of let me know, here's
7 some advice.

8 CHAIRMAN PALESTRO: Other comments or
9 questions?

10 MEMBER OUHIB: Two minor items, probably.
11 One regarding the education and training, sort of
12 like get people -- you know, perhaps medical events
13 should be part of that training, to be aware of what
14 actually has happened using that device or doing that
15 procedure, and they need to know how things can go
16 wrong. Unless you know, you might very well make the
17 same mistake. I think that would be valuable.

18 The other one is on the "time out".
19 Looking at other medical events that took place,
20 perhaps, is that asking a simple question as, is there
21 anything that is different that we're doing in this
22 procedure that we have done before? Modification of
23 the applicator, anything, a very recent upgrade of
24 the software was done last night, something regarding
25 the device itself. Something, there was a repair that

1 was done, the engineer was, I don't think it would
2 affect you but just look at. Things like that I think
3 would be valuable to sort of, so anybody can speak up
4 and talk about it.

5 CHAIRMAN PALESTRO: Mr. Sheetz?

6 MEMBER SHEETZ: I would like to follow up on
7 Zoubir's comment about licensees understanding what
8 the occurrence was for other medical events,
9 especially with the Y-90 microspheres. If you look
10 at the main cause for the events, it's greater than
11 20 percent of the residual activity remaining in the
12 delivery apparatus, not due to stasis. So it was not
13 all an elective termination of the procedure.

14 These can be caused by trying to infuse too
15 many microspheres, kinking of a catheter, or
16 inadequate flushing of the device. If we looked at
17 the cause of lack of experience or infrequent use for
18 the Y-90 microspheres, we only attributed those for
19 the device setup errors, and it was around eight
20 percent, so it wasn't significant.

21 But if you add the residual activity,
22 greater than 20 percent, to the infrequent use because
23 they weren't quite sure how the device worked or they
24 weren't sure combinations of flushing and infusing
25 microspheres, that comes up to over 70 percent as the

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1 reason for the medical event.

2 So I'm not sure of the answer on how to
3 correct that but maybe licensees could reach out back
4 to the manufacturer for a refresher if it's been a
5 period of time for them using the device. The
6 manufacturers are very willing to come out and provide
7 additional instruction after they've already been
8 approved. Thank you.

9 MEMBER CUHIB: And just to follow up on this,
10 during that refresher I would love to see the
11 manufacturers actually creating events during the
12 training and showing them how the system can actually
13 go wrong. I'm going to do this, watch this and see
14 what's going to happen, and go over every single event
15 that is known, basically with the users so they are
16 prepared and they can avoid it.

17 MEMBER GREEN: This is Richard Green.
18 Playing off Dr. Martin's comments that there are very
19 few events for the millions that occur. Many
20 practitioners, knock on wood, will go through a career
21 and not have a medical event. But it's not until we
22 aggregate this data to the level that we have, this
23 30,000 foot view that we have of all the data for
24 multiple years, where we come up with this very
25 salient, you know, this "time out". This review of

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1 a skillset that you may have had but that may have
2 gotten rusty because of unuse.

3 I think it's, this level of our viewpoint,
4 we can suggest, and that's all it is, a suggestion,
5 that the NRC puts out an informational notice that
6 says, this is good advice. It's not a regulation,
7 it's not all things are infringing on the practice of
8 medicine, but it's something that we can identify
9 that you may not see, may have gone a whole career
10 and not had a problem, but this could help prevent a
11 problem.

12 CHAIRMAN PALESTRO: Other comments or
13 questions from the committee?

14 MEMBER SCHLEIPMAN: One quick one. The
15 possible elements of a "time out" or use of a "time
16 out", is there a possibility that could be put into
17 model procedures at the NRC post, and/or appendant to
18 the written directive 35.3 regulations to say, this
19 is strongly suggested or this is an element of safety
20 that could be incorporated into the written
21 directives?

22 MEMBER ENNIS: Well, I think that's a
23 question for NRC, whether they can and can't. Is there
24 a way of going into and changing the regulations
25 themselves, it's not a big enough problem to do that.

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1 I think the information notice was the mechanism we
2 thought, but again, I would open it up to Doug or
3 anyone else to say --

4 MR. BOLLOCK: Yes, from the NRC. So to answer
5 a direct question, we could but is it necessary, like
6 Dr. Ennis said, is it necessary with this low number
7 of cases, probably not. That would be getting another
8 step further. We would have to really evaluate if
9 it's a problem, and right now we don't see it as a
10 problem.

11 But that doesn't mean there are other
12 things that can be done, like the stuff in these
13 recommendations for information for us to share. You
14 know, here are, here's our personal experience for
15 seeing here the events, here are some of the causes,
16 here are some things that could prevent it. You know,
17 that is absolutely something that we can do very
18 easily.

19 CHAIRMAN PALESTRO: Mr. Green?

20 MEMBER GREEN: I think the information
21 notice that that does occur would then go to the
22 professional medical societies for them to
23 incorporate into their procedure guidelines and model
24 procedures for them to work with their peer group to
25 perfect and improve the processes within each

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1 professional society.

2 CHAIRMAN PALESTRO: Mr. Ouhib?

3 MEMBER OUHIB: And I think just to answer
4 that one, I think that's already part of an accredited
5 program by ASTRO, for instance. That is a must. The
6 "time out" is a must. But let me just add one more
7 thing is, we talk about a "time out" button prior
8 to the procedure I'd like to suggest that perhaps a
9 "time out" at the end of the procedure to make sure
10 that the treatment was actually delivered according
11 to the written directives and there is nothing out
12 there that perhaps went incorrectly, and not wait for
13 the fifth fraction to discover that all these five
14 previous fractions were treated incorrectly.

15 And I think, and I hate to call it a "time
16 out", but it probably will fit just fine, to have a
17 good review at the end of the procedure and say, okay,
18 let's take a look. Did we do anything incorrect here,
19 and can we confirm it, and how?

20 CHAIRMAN PALESTRO: Dr. Ennis?

21 MEMBER ENNIS: I'm not sure how I feel about
22 that. I guess the hesitation is I feel like if
23 anything did happen, that generally does get
24 discussed and the need to add a layer to every single
25 procedure of yet one more, I'm not sure the value

1 added. In theory, I get it but in practice I'm not
2 really sure.

3 MEMBER OUHIB: Well, there are certain
4 procedures that you're required to review your case
5 and make sure that nothing has happened and there
6 wasn't a medical event. Then you're supposed to
7 document that. I think what I'm saying is that perhaps
8 that should be applicable to all procedures to make
9 sure that there wasn't a medical event and not wait
10 for the fifth fraction, perhaps.

11 CHAIRMAN PALESTRO: Any other comments or
12 questions from the committee? Dr. Ennis, I have one
13 question for you. This indeed is a change in the focus
14 of the subcommittee, and I think a change for the
15 better. We've talked about this at the ACMUI meetings
16 for several years and I think you certainly have
17 provided useful information. However, you looked at
18 a time span of three and a half years.

19 My question is, and you and I have talked
20 about this via email, is this report, should this
21 report continue to be an annual report or should it
22 be less frequently, at some specified interval, so
23 that you look at new accrual of data?

24 MEMBER ENNIS: It doesn't really seem to
25 make sense to do this every year, very few, relatively

1 few events per year and there's going to be
2 significant overlap to next year this year. We'd be
3 looking at the same data.

4 I guess my gut feeling would be maybe every
5 two years would be appropriate. Whether this
6 committee should not really report anything except
7 every two years or it should do something else on the
8 intervening years, I'm open to thoughts. But in terms
9 of this task, at least, seems like it probably makes
10 more sense to do it every two years.

11 CHAIRMAN PALESTRO: Dr. Metter?

12 VICE CHAIRMAN METTER: This is Darlene
13 Metter, and I think that's a good idea but I think it
14 still should be monitored in case any event does come
15 up that I don't want to wait two years or three years
16 before we realize that two years ago these events
17 occurred. So perhaps the subcommittee can at least
18 monitor it and we can maybe report that there was
19 nothing unusual that occurred this year and not give
20 such a detailed report, but somebody needs to monitor
21 it on an annual basis.

22 CHAIRMAN PALESTRO: Any other comments or
23 questions from the committee? Dr. Suh?

24 MEMBER SUH: I commend the fact that we have
25 actually started to look at 30,000 foot views for

1 medical events, and think one of the things that this
2 report really underscores is the importance of very
3 simple practices to make a difference in the quality
4 and safety of patient care.

5 So I would really encourage the
6 subcommittee and committee to continue to promote
7 things like universal "time out". I mean, it's very
8 simple to do, it should be part of the universal
9 practice in terms of how we treat patients, and yet
10 it's not being done. And if you look at the
11 percentages, it ranges from the various reports from
12 between 15 percent to maybe as high as 85 percent,
13 medical events could have been prevented with a "time
14 out".

15 Which to me, that's why even though it's a
16 very small number of patients the fact that the 35.300
17 upwards of 85 percent may have been prevented at the
18 time I think is a very powerful statement.

19 CHAIRMAN PALESTRO: I certainly agree with
20 you, Dr. Suh. Any other comments, questions from the
21 committee? Ms. Weill?

22 MEMBER WEILL: This is Laura Weill. Just a
23 question. You cite infrequency of use as a significant
24 factor. How did you determine that, and is it related
25 to the kind of facility or the location of the

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1 facility?

2 MEMBER ENNIS: So, it's a very soft
3 judgment. That's why we, part of why we divided it up
4 by expert. The expert was reviewing what was reported
5 and it's like, that sounds to me like someone who
6 probably hasn't had, but we didn't have like a nice
7 group of criteria and so it's just a rough estimate
8 based on expertise and we did not delve into type of
9 institution, so there's no doubt those things play a
10 role but we don't have enough data to really look at
11 it in that kind of a way.

12 CHAIRMAN PALESTRO: Any other comments,
13 questions, from the committee?

14 MEMBER ENNIS: So I just want to hear a
15 little bit more clearly what the charge for my
16 subcommittee should be for next year. Should we report
17 the way we did in the past, and go through all the
18 events and just say, you know, in that kind of
19 detailed kind of thing to make sure the numbers are
20 not high, like our old reporting similar to Dr. Howe,
21 or in what way do you want us to make sure, I just
22 kind of want to know what the greater committee would
23 like our subcommittee to do.

24 MR. BOLLOCK: This is Doug Bollock, NRC. I
25 don't know if you want some of our perspective eye

1 and say that your current, the report you just did is
2 more helpful than a rehash of the annual reports, and
3 then perhaps like Dr. Metter said, each year if
4 something came up that is noticeable, that is
5 identified that hey, this could be a problem, to bring
6 that, to review that.

7 MEMBER BNNIS: Okay, so we will just kind of
8 review them all and if we think there's a theme we
9 want to report on or otherwise say, basically, no
10 change, subcommittee's comfortable without a bit
11 report or anything.

12 MR. BOLLOCK: Right. I can see that we do
13 that, you know, if you feed us that. I can see the
14 value in that but your report looking back at the
15 last three and a half years, this is very helpful to
16 us. I mean, I'd like to thank the subcommittee. This
17 is good information, these are things we find useful.

18 We may not say, in information notes we may
19 not say exactly what you said but it, this, this is
20 right along the lines of what we would offer in
21 information notices. This is extremely helpful to us.
22 We do appreciate that. So that's our perspective, and
23 I've got some staff I think may have some other
24 perspectives. Dr. Howe?

25 DR. HOWE: My perspective is that your

1 presentation this year was exactly what we need to
2 hear, because we go through in the spring time and
3 give you the details of each medical event.

4 One of the things I did want to bring in is
5 the regulatory perspective. We do have NRC
6 requirements that get to some of your issues. They're
7 peripheral. One would be that the licensee is required
8 to provide training for the supervised individuals on
9 what is a medical event, and on the regulations which
10 would also be the written directives and in the
11 program to ensure that administrations are in
12 accordance with the written directive.

13 Probably one of the things that we are
14 missing is we don't have that same requirement for
15 periodic training of the supervising individual,
16 because as you come into the medical practice in your
17 30s and then you get into your 60s, things have
18 changed and so it's probably still important to know
19 what is a medical event for your specialty this year.

20 Another point is that we have in our new
21 rule which will be effective in January, there is a
22 requirement under 35.40 which is your written program
23 to assure that administrations are given in
24 accordance with the written directive, that you
25 determine if there's a medical event.

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1 We've assumed that would happen in the
2 past, but now every time there is an administration,
3 the licensee is supposed to determine if there was a
4 medical event. So there should be more focus now on
5 what is a medical event for each of the modalities
6 and did this particular treatment meet that standard.

7 So we do have certain parts of the
8 regulation, one on supervision, one on written
9 directive, one on your written program to assure
10 administrations are in accordance with the written
11 directive, and then the medical event reporting that
12 get to some of these issues. Not exactly the issues,
13 but they do get to some of them.

14 So we could probably write an information
15 notice from that regulatory perspective. Thank you.

16 CHAIRMAN PALESTRO: Any other comments or
17 questions from attendees in the room? Questions or
18 comments from anyone on the telephone lines? Hearing
19 none, I presume it's time for the committee to accept
20 the report, is that correct?

21 MR. BOLLOCK: Yes, that's correct.

22 CHAIRMAN PALESTRO: All right. And the
23 motion is the report itself, if I'm not mistaken. We
24 need a second. Do we have a second, on acceptance of
25 this report? Seconded by Dr. Schleipman. Any

1 discussion? All in favor? Any opposed? Thank you.

2 All right, the next presentation is
3 entitled Non-Medical Events, and it will be presented
4 by Mr. Sheetz.

5 MEMBER SHEETZ: This presentation will cover
6 the non-medical-related events reported by medical
7 licensees for fiscal year '17. Next slide, please.

8 This data comes from the nuclear material
9 events database for non-medical events reported by
10 licensees in both NRC and agreement states. It does
11 not include the medical events reported under Section
12 35.3045 involving patient administration errors,
13 Section 35.3047 involving unintended exposures to a
14 embryo fetus or nursing infant or other events
15 involving patient safety or harm.

16 What is included are the events reported
17 under various sections of 10 CFR parts 20,30, 35 and
18 49 CFR 171 involving leaking sealed sources, lost or
19 stolen radioactive material, personnel overexposures,
20 contamination incidents and transportation incidents
21 involving radioactive material. Next slide, please.

22 If we look at the different categories and
23 number of non-medical events occurring in fiscal year
24 '17, there were eight leaking sources, seven lost,
25 abandoned or stolen sources, four personnel

1 overexposures, four incidents with the shipment of
2 radioactive material and three radioactive
3 contaminations incidents. There are no equipment
4 malfunctions. Next slide, please.

5 This chart shows the relative number of
6 non-medical events reported by medical licensees
7 compared to the total number of NMED events for all
8 categories. You can see that they are a relatively
9 small fraction of approximately five percent. Next
10 slide, please.

11 If we look a little closer at the
12 circumstances of the events in the different
13 categories, for lost sources there were three
14 involving I-125 seeds used for radioactive seed
15 localization of non-palpable breast lesions. Two were
16 lost in the process of trying to remove the seed from
17 the tissue specimen after it had been explanted from
18 the patient, and one involved transferring a specimen
19 not knowing that it contained a radioactive seed to
20 another hospital.

21 Two involved the loss of 200 microcuries
22 Cesium-137 sealed sources used for calibration of
23 dose calibrators in nuclear cardiology. One involved
24 the loss of a 400 microCurie I-125 calibration seed
25 that was shipped in a separate lead pig from the other

1 brachytherapy seeds and so was discarded with the
2 shipping box.

3 Then there was an incident with a return
4 shipment of a 4 Curie Iridium-192 source where the
5 common carrier tracking system could not account for
6 the location of the package but it was ultimately
7 delivered back to the manufacturer. Next slide,
8 please.

9 For leaking sources, five involved the
10 Cesium-137 dose calibrator sealed sources, found to
11 have removable contamination during the routine six-
12 monthly test. An Iridium-192 source had removable
13 contamination discovered during source replacement,
14 and I-125 seed was cut during removal of the seed
15 from the tissue specimen, and a P-32 flex film used
16 for brachytherapy treatment of an eye tumor was found
17 to have removable contamination at the completion of
18 the treatment. None of these resulted in the spread
19 of significant contamination. Next slide, please.

20 For shipments of radioactive materials,
21 there were three incidents where the outer surface of
22 the package containing radiopharmaceuticals coming
23 from a commercial vendor had removable contamination.
24 Interestingly, the surface contamination was not the
25 same isotope as that being shipped, so it is assumed

1 that the contamination occurred during packaging at
2 the vendor facility. There was no noted contamination
3 of the common carriers.

4 And there was one incident where the
5 container of an Iridium-192 source was cracked during
6 transit. However, there was no loss of contents,
7 contamination or exposure to personnel. Next slide,
8 please.

9 For radioactive contamination, one incident
10 involved contamination of a hospital room from a
11 patient who was admitted and had been administered
12 200 millicuries of I-131 sodium iodide two days
13 earlier, and they did not know the patient had been
14 administered this iodine.

15 There was extensive contamination of
16 several rooms in a nuclear medicine department from
17 a child who, after being administered a capsule
18 containing 30 millicuries of iodine 131 sodium
19 iodide, removed it and held it in their hand. There
20 was also extensive contamination on the child. What
21 a mess.

22 And there was an incident resulting in
23 contamination of an interventional radiology suite
24 from the improper setup of the Y-90 microsphere
25 delivery device. Next slide, please.

1 For personnel overexposures, there were two
2 overexposures to personnel from PET isotope radio-
3 pharmaceutical production. These were in commercial
4 radiopharmacies, one resulting in an extremity dose
5 of 510 millisieverts and the other with a whole-body
6 dose of 110 millisieverts.

7 There was an overexposure to an engineer
8 from cyclotron repair and maintenance activities with
9 an extremity dose of 941 millisieverts and there was
10 an exposure to three non-radiation workers from the
11 release of fluorine-18 from a V vial event at a
12 commercial radioactive pharmacy cyclotron, resulting
13 in a calculated whole-body dose of approximately 112
14 millisieverts. Next slide, please.

15 There are always a number of miscellaneous
16 events that get reported to NMED which do not fit
17 into one of their defining categories. One of these
18 related to medical licensees is the detection of
19 short-lived medical isotopes at municipal waste
20 landfills or transfer stations. The radioactivity
21 gets into the waste from the body fluids of patients
22 who have been administered radiopharmaceuticals,
23 treated diagnostic or therapeutic
24 radiopharmaceuticals procedures.

25 There is no standard reporting requirement

1 for these events. The NRC does not require them to be
2 reported and so the requirement varies from state to
3 state. In the past there have been a relatively large
4 number of events, coming primarily from four
5 different states. Up until the past year, there have
6 been averaging around a hundred reported events
7 annually. I can't explain the reason for the small
8 number in fiscal year '17.

9 I'm sure many of these events are still
10 occurring across the country. The response to these
11 events often results in either the waste being held
12 in the garbage truck for a day or two until the
13 radioactivity has decayed away or the contents of the
14 truck are unloaded and an attempt is made to locate
15 the hot waste bag.

16 If the bag is located, there may be attempts
17 to identify the originator of the hot waste, which
18 can then result in a fine or request to retrieve the
19 waste.

20 I take the time to point this out as I feel
21 these reported events are only the tip of the iceberg
22 and that a significant response effort is being
23 undertaken for something that does not present a
24 public safety hazard or risk.

25 I think Pennsylvania has a model landfill

1 monitoring program to address this problem, where it
2 requires all waste to be monitored for radioactive
3 sources. It allows waste identified to only contain
4 short-lived medical isotopes to immediately be
5 buried. This eliminates the response efforts for
6 something that does not pose any risk to the public.
7 Next slide, please.

8 So, in conclusion I think there are a
9 relatively small number of non-medical events
10 reported by medical licensees. Types of events
11 occurring have had minimal health and safety impact,
12 and standardization of landfill radiation alarm
13 response to allow for short-lived medical isotopes to
14 be immediately buried will reduce the burden on both
15 regulators, licensees and landfill operators. Thank
16 you.

17 CHAIRMAN PALESTRO: Thank you for a very
18 interesting presentation, Mr. Sheetz. Comments or
19 questions from the committee? Mr. Sheetz, I have a
20 question for you. You may have answered it and I
21 simply didn't hear it, or you may have already
22 mentioned it.

23 In terms of the decrease in the large,
24 relatively large number of events down by more than
25 a 100 in 2014 to fewer than 20 in 2017, explanation

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1 for that? Have the alarms been readjusted in terms of
2 sensitivity? Or have individuals received more
3 detailed instructions about storing radioactive waste
4 or potentially radioactive waste?

5 MEMBER SHEETZ: I do not know the answer to
6 that. I just have the data from the NMED.

7 CHAIRMAN PALESTRO: Any other questions or
8 comments from the committee? Comments or questions
9 from the attendees in the room? Comments or questions
10 from anybody on the phone lines? Thank you, Mr.
11 Sheetz. I do have a question for Mr. Bollock,
12 procedural. This is not a formal subcommittee report,
13 does it need to be formally approved by the committee?

14 MR. BOLLOCK: No, there's nothing that was
15 reviewed, nothing given to us other than the
16 presentation itself, so no further action.

17 CHAIRMAN PALESTRO: Thank you. All right,
18 next presentation is the American Brachytherapy
19 Society's effort to reach out to the brachytherapy
20 community for creative corrective actions regarding
21 events that have taken place, and it will be presented
22 by Mr. Ouhib.

23 MEMBER OUHIB: Thank you, Dr. Palestro. This
24 idea came about when Dr. Howe, actually we were
25 talking about medical events, and we said maybe we

1 could do something with all these medical events and
2 improve patient safety. Next slide, please.

3 So in general, basically it's a lesson
4 learned from medical events. Understand how to use
5 medical events in improving patient safety, identify
6 possible corrective actions for a known medical
7 event. What I mean by known, known with a lot of good
8 and accurate details. Look for possible preventive
9 actions to avoid such medical events, and lastly,
10 engage the brachytherapy community in improving
11 patient safety. Next slide, please.

12 I have no disclosure. Next? So, facts on
13 medical event, they're here to stay and we know that
14 no one is immune. Similar events are occurring at
15 different facilities. New events will also eventually
16 replace the old ones. You have new technologies, some
17 upgrades and things like that, or even if you
18 implement something as a corrective action, you might
19 have just introduced another possibility of a medical
20 event. So the question is, how can we prevent some,
21 and hopefully reduce others? Next slide, please.

22 Importance of information when reporting
23 events. This is addressed to the users. Need of
24 accurate information and details about the event
25 define effective solutions. Without those, we can't

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1 do a whole lot.

2 Details on an event before, that means
3 preconditions, during the event and certainly after
4 the event are very, very essential. When reporting
5 events, provide facts only and not personal
6 interpretation because that could be misleading
7 information. Information on the software, which
8 version's being used, the hardware, the devices,
9 application, modality, etc.

10 And certainly involve all individuals with
11 knowledge about the event. You'd be surprised when a
12 therapist can provide you some valuable information
13 that nobody thought about. Next slide, please.

14 Again, report event to regulatory agency
15 but also notify the vendor as soon as possible. And
16 there's a reason for that as far as the vendor. The
17 vendor can help you really understand what actually
18 took place. But more important, if there is a need
19 for a recall or notifying FDA, so on and so forth,
20 they are prepared to.

21 Manufacturer to alert as soon as possible
22 other users. Once a year users confirm and provide
23 some clear guidance because the user might not be
24 able to provide that. Manufacturers should resist
25 user evaluating the possible source of event, try to

1 sort of guide them. Corrective action to be shared
2 with others. Next slide, please.

3 Regulators. Written and very clear
4 statements should be provided. Preliminary reports
5 should perhaps be reviewed by the user before going
6 public for accuracy. And I should add, perhaps, should
7 be viewed by the manufacturer, because perhaps the
8 user did not provide full information. Next slide,
9 please.

10 So, for both solutions there have to be
11 reasonable specific, practical, proven and have been
12 evaluated to avoid new errors. Next slide, please.

13 The medical event project basically was to
14 simply select the medical event based on its impact
15 and frequency, share the event with users for input
16 on corrective and preventive actions, tabulate the
17 solutions and share them with the brachytherapy
18 community. Solutions are reviewed by an ABS select
19 team. Next slide, please.

20 To ensure the final recommendation is
21 shared among all users so the whole peer is to really
22 have the ABS and the ABS website and available to
23 AAPM, ASTRO, IAEA, manufacturers and so on, so forth.
24 But really, our hope is to bring in all these
25 organizations into this and then work like a team,

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1 track these specific errors and evaluate effect on
2 information sharing. Are we seeing this error again
3 or not, or was this institution aware of these
4 corrective actions?

5 Encourage users to share similar near-
6 misses errors, very similar to what just took place.
7 Maybe they almost had the same error, but maybe with
8 the information they had they were able to avoid it.
9 Next slide, please.

10 So, here's the first case, Incorrect Source
11 Transfer Tube Length. This was actually selected by
12 two of our graduate students at Florida Atlantic
13 University, and you will see their names later on. We
14 provided them with a case description basically to
15 the users, specific feedback requested from the users
16 and provided them with an email where they can send
17 the feedback. Next slide, please.

18 The intent of the project, the number one
19 was to improve patient safety. Involve as many users
20 as possible for best possible solutions, involve the
21 manufacturer for better solution improvement and
22 share solution with the community. Next?

23 Here's how the question that was proposed
24 as far as for case number one. "When you are
25 considering corrective action, try answering the

1 following questions. What safety barrier failed to
2 identify the incident? What possible safety barriers
3 identify the incident? What safety barriers might
4 have identified the incident? What possible factor
5 contributed to the incident? Next slide, please.

6 That basically will lead the users to look
7 at what preventive action could stop reoccurrence of
8 a similar event Next slide, please.

9 The users' feedback was to be sent at this
10 email address, which was very creative by these
11 graduate students, PreventMedEvent@gmail.com. And
12 that was by Sarah Price and Panagiota Galanakou.
13 Excellent work. Next slide, please.

14 There's always a motivation line in jumping
15 in on something, and I recall at the most recent ABS
16 meeting there was a keynote speaker, Tom Kelly, and
17 his statement was, "Noticing that something is broken
18 is an essential prerequisite for coming up with a
19 creative solution to fix." That never left my mind.
20 It was like, you know what, this is something that
21 maybe I should embark on and take a look because
22 there's something broken out there. Next slide,
23 please.

24 I'm not going to ask you to read all this
25 but this is the information that was sent to the

1 users, basically. What the project is all about, and
2 so on and so forth. Next slide, please.

3 Here's a summary of the case. This was for
4 11 patients. HDR unit was commissioned with a click-
5 fit A. The institution received later Miami
6 applicator with a click-fit B for all three catheters,
7 tandem and ovoid. The click-fit B is ten centimeter
8 longer than a click-fit A. One of the click-fit A
9 broke, so new plan was generated using a click-fit B.
10 The therapists were instructed to use click-fit B for
11 tandem only. There was a miscommunication and that
12 led to the use of click-fit B for all three catheters,
13 not just the tandem.

14 What was the result of such action? Those
15 from ovoids were inferior then designed by ten
16 centimeters, less goes to target and more goes to
17 normal tissue. You can see a picture down below there.
18 You can see the click-fit A being shorter than the
19 click-fit B, which is with the green marker. Next
20 slide, please.

21 Summary of case number two. This is
22 additional 57 patients that were involved. While
23 investigating the previous event, additional was
24 discovered and it led me back to the "time out" on
25 the very first case. If that was done, perhaps these

1 77 patients would have not been affected by that.

2 The actual total meant for click-fit B was
3 133.5. For planning purpose, this is just detail,
4 length of tandem should be 133.5 minus 1.4, that's
5 132.1. What is that 1.4 cm? That accounts for the
6 quick-connect part for the HDR unit.

7 For planning, there's a default value of
8 130 cm that was used, versus 132 for one that has
9 been measured. So the result is that the previous, in
10 addition to the previous 11 patients, actually
11 received treatment at 2.1 cm further lower than the
12 previous ten centimeters, which is about 12.1 cm. So
13 that means the dose is even lower, lower in terms of
14 anatomy-wise. Next slide, please.

15 This is the case that was sent out to all
16 users to evaluate. Next slide, please.

17 And the information regarding the error
18 tube. Next slide, please.

19 So, the same thing here, basically. I'll
20 just read you the bottom here is that, "We are eager
21 to receive your reply on how you would have dealt
22 with this situation if it had occurred in your
23 institution and what you have in place that would
24 have prevented similar events." Next slide, please.

25 The summary of feedback is here for the

1 user, oh, this is what was sent to the users. "As
2 promised in our case 001, posted on brachytherapy
3 Brachyblast on July 31, 2018, we are eager to present
4 the feedback corrective and preventive measures that
5 we have collected from several colleagues, medical
6 physicians and radiation oncologists. At the same
7 time, it was a reminder to reader this is a case of
8 a HDR procedure where the use on an incorrect length
9 has led to a medical event." Next slide, please.

10 This is the summary, more or less, and it's
11 unfortunate that we can't see it very clear from here.
12 The feedback from you said there was corrective action
13 and there was a preventive. This is for the immediate,
14 that means short term, independent manual measurement
15 check to verify treatment length matches planning
16 length. And you'll have to forgive me, I'll have to
17 get my hard copy here. I can't read that either.

18 Okay. Policy and procedures that required
19 the medical physicist to be directly involved with
20 the treatment setup when there are any alterations to
21 the plan, HDR equipment or treatment devices. So they
22 should be directly involved in service for the
23 brachytherapy team, regarding the use of click-fit
24 with all applicators and the clinical impact when
25 using the non-planned one. What could actually

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1 happen?

2 The preventive was when a different click-
3 fit than manufacturer recommended click-fit is to be
4 used as a substitute with any applicator, a
5 commissioning should be performed in advance using
6 manufacturer-recommended length, confirmed of course
7 with measurement by the users.

8 All members of the brachytherapy team
9 should be directly informed regarding any
10 modification to the use of device or treatment plan.
11 In addition, the verbal instructions, written ones
12 with photos of selected click-fit set used for
13 planning should be provided for treatment setup
14 verification and delivery. That means they will have
15 some sort of a hard copy to take for the setup.

16 The physicist involved in the modification
17 of any treatment plan should directly be involved in
18 the patient setup prior to treatment. The resulting
19 setup should be independently verified by a treatment
20 team.

21 When there's any doubt about proper setup
22 and use of brachytherapy device, time out should be
23 performed and a manufacturer should be contacted for
24 clarification and recommendation prior to treatment.

25 And last, when having two different sets of

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1 click-fits, A and B, consider retiring one set to
2 eliminate the use of the wrong one. The resulting
3 total length when connected to the selected click-fit
4 set remains a variable, and one should consider a
5 cable of thorough length for all applicators as a
6 reference for treatment planning so they will have
7 the values in front of them by the treatment planning
8 and they will know which total length should actually
9 be used. Next slide, please.

10 Long terms. Manufacturers should consider
11 redesigning the afterloader to measure in a dummy
12 sequence each treatment length and stop treatment if
13 the measured value is not within one millimeter of
14 the planning length, and I know manufacturers are
15 actually currently working on that. It has not been
16 released yet.

17 Manufacturers should move the legacy magic
18 number, the 1.4 cm difference between the actual
19 measurement of the treatment length with a quick-
20 connect for Varisource IX and the actual treatment
21 length.

22 Manufacturers should remove the default
23 treatment length from the BrachyVision TPS system.
24 The user should be forced to enter the length and
25 there should be an authorization popup requiring

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1 initial or password to proceed. This will ensure
2 measurements were actually performed.

3 Click-fit should be designed and sold such
4 that they have the same length for all applicators.
5 Manufacturers should provide illustration or
6 demonstration of the possible ramification of
7 improper use in various click-fit sets. For this
8 specific example, demonstrate how using an incorrect
9 click-fit set will result in a medical event.

10 During training. Emphasis should not only
11 be on how things will work well, but also things can
12 lead to medical events. Reported event should be part
13 of the education, with demonstration. Manufacturers
14 should provide detailed demonstration or
15 demonstration of the procedure the staff should
16 follow for proper treatment.

17 And last is treatment summary. Generated by
18 the plan that will include all critical parameters
19 for treatment setup and delivery will be very useful.
20 Parameters such as patient name, applicator model,
21 click-fit set, planning length, fraction and so on,
22 and perhaps even a diagram of the setup itself. That
23 could be taken for setting up the patient and
24 verifying what's in the treatment console to make
25 sure that everything is good. I think that would be

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1 very helpful. Next slide, please.

2 This is what was sent to the users. "We
3 encourage our readers to continue to submit their
4 ideas to this email address, as there might have been
5 other preventive and corrective actions that we did
6 not identify. Be sure to check out our next month's
7 Brachyblast where we will present case number two."
8 We already working on case number two as we speak.
9 Next slide, please.

10 These are the acronym, and last slide,
11 please. I would like to acknowledge Dr. Howe, IAEA,
12 Debbie Gilley was very helpful in providing us the
13 medical events, Sarah Price and Panagiota, the
14 graduate students, have done a wonderful job. These
15 are the names of the users that made a huge
16 contribution to this project. Thank you.

17 CHAIRMAN PALESTRO: Thank you for your
18 presentation, Mr. Ouhib. Comments or questions from
19 the committee? I have a question for you. How often
20 are these cases sent out? Is it on a monthly basis,
21 one case per month, or ---

22 MEMBER OUHIB: The intent right now is to
23 send it on a monthly basis and that the, by the second
24 month will provide the answers. We'd like to sort of
25 delay it. So we'll provide the solutions that we came

1 up with, and in the meantime we send out the second
2 case so that way people can start working on case
3 number two.

4 CHAIRMAN PALESTRO: My second question is,
5 do you have, I assume this is just starting up, but
6 do you have a way of determining or will you have a
7 way of determining how many individuals will be
8 participating in this?

9 MEMBER OUHIB: Yes. We're tracking that,
10 actually, because we asked them to write us their
11 names, their institution, their profession, medical
12 physicist, radiation oncologist. The institution name
13 is actually optional, they don't have to, they can
14 just simply, so we're keeping that information.

15 CHAIRMAN PALESTRO: Thank you. Any other
16 comments or questions from the committee? Comments or
17 questions from attendees in the room? Comments or
18 questions from anyone on the phone lines? Dr. Ennis
19 has a comment or question.

20 MEMBER ENNIS: I just think it's great. It
21 will be really interesting to see what the feedback
22 is. It looks quite valuable. I'd be interested to see
23 how it plays out and if it really has an impact. I
24 guess the next thing would be maybe other societies,
25 particularly ones involved with technical procedures,

1 I'm thinking Y-90 maybe, might want to mimic this in
2 some way.

3 MEMBER OUHIB: Yes, we actually, I had
4 personally approached the AAPM and we've been talking
5 about this, and there is an interest in that. We're
6 hoping to sort of join forces and hopefully maybe
7 we'll get ASTRO and ISTRO, who knows? Because keep in
8 mind, this is not just going to the US, this is going
9 worldwide because the IAEA will put this on their
10 website also. So there are people who are going to be
11 seeing it in, you name it, so this information
12 hopefully will help a lot of people.

13 CHAIRMAN PALESTRO: Dr. Suh?

14 MEMBER SUH: Excellent presentation. How
15 receptive do you feel the vendors will be with your
16 short term and long term action plans? Obviously the
17 vendors can help out a lot. We had heard from Mike
18 O'Hara that software failure being reached in therapy
19 treatments.

20 MEMBER OUHIB: They have been very
21 receptive, let me just tell you this. They were
22 willing to assist us and provide us information that
23 we're looking for. I can tell for case number two,
24 for instance, the vendor has already done a
25 presentation for us on the case itself and said,

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1 here's actually what took place, and we intend to
2 talk to them some more.

3 I think, at least from my point of view,
4 this will only help the manufacturer, basically.
5 Because we're here to say okay, here's what's going
6 on, here's what we think happened, what do you think
7 you could do to prevent this or whatever? And they
8 might have some suggestion, recommendations or
9 whatnot, but this is helping everybody. Really,
10 everybody for one and only one cause, improving the
11 patient safety. Nothing more, nothing less.

12 It is not by making a manufacturer look
13 bad, it is not by making an institution look bad, or
14 a physicist or a radiation oncologist because we don't
15 even touch those names at all. We focus on the process
16 itself. How did it happen and can we prevent this?
17 What can we do to avoid such error, and how can we
18 inform somebody else from not doing it, and what's
19 the best way to do this?

20 So we're hoping that this information will
21 go to all website, hopefully, and then people, medical
22 organizations and people will learn from them. I don't
23 know how we're going to keep up with this, because
24 eventually these graduate students will move on with
25 their lives and we have to figure out a way.

1 But let me just tell you another thing, is
2 that we also hoping to capture experts for different
3 manufacturers and identify them like the expert team,
4 and then that we we'll go to them and say okay, here
5 are all the solutions that we have gathered. What are
6 your thoughts? And they might say, well, yeah, this
7 is good but guess what? This isn't going to work and
8 here's why, and so on, so on.

9 So we don't just make a decision and put
10 that information there. We run it by all these experts
11 and see what they think, and then we finally tabulate
12 that and then provide it to users.

13 CHAIRMAN PALESTRO: Any other comments,
14 questions? Again, thank you, Mr. Ouhib. At this point
15 we are ready to go into break unless, Mr. Bullock,
16 are there any loose ends that need to be tied up
17 before we recess?

18 MR. BOLLOCK: No.

19 CHAIRMAN PALESTRO: All right then, we will
20 reconvene at 2:45. Thank you.

21 (Whereupon the above-entitled matter went
22 off the record at 2:03 p.m. and resumed at
23 2:45 p.m.)

24 CHAIRMAN PALESTRO: All right. It's 2:45,
25 and we're going to resume. The first presentation

1 will be given by Dr. Metter, and it's entitled
2 "Training and Experience for All Modalities: The
3 Update of the Subcommittee." Dr. Metter?

4 VICE CHAIRMAN METTER: Thank you, Dr.
5 Palestro. I'm Darlene Metter, and I'm giving the
6 report on the Subcommittee on Training and Experience
7 for All Modalities. Now, I'd like to thank the
8 members of my subcommittee: Dr. Philip Alderson, Mr.
9 Michael Sheetz, Megan Shober, Dr. John Suh, and Ms.
10 Laura Weil.

11 Now, the Training and Experience
12 Subcommittee, or the T&E Subcommittee, created a
13 standardized approach and template for T&E review.
14 They completed the review of 10 CFR 35.100. However,
15 a concern was raised about patient access, so 10 CFR
16 35.300 and specifically 10 CFR 35.390 was expedited
17 for review.

18 During our March 2018 ACMUI conference,
19 public teleconference, there was a new concern that
20 was raised by the subcommittee and that was the
21 potential for future shortages of AU for therapy, and
22 this resulted in two recent developments at the time,
23 the first being the FDA approval for 177 Lutetium
24 dotatate which has a wide broad-spectrum of therapy
25 indications and, thus, may increase the therapeutic

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1 procedures; and, number two, there was a concern for
2 decrease of the number of candidates sitting for the
3 initial American Board of Nuclear Medicine
4 certification exam.

5 So the T&E Subcommittee's concern with the
6 idea of potential increase in procedures with a
7 concurrent decrease in authorized user had a
8 potential future AU shortage. So their
9 recommendation at this time was to reconsider an
10 alternate authorized user pathway for therapy.

11 So what is the current status? Well, as
12 you know, in August of 2017, there was a revision of
13 10 CFR Part 35, and the Commission tasked the NRC
14 staff to investigate the feasibility of a limited
15 authorized user pathway specifically for
16 radiopharmaceutical therapy. The Commission
17 requested that there be an update every six months
18 with the first report to be given this past August in
19 2018.

20 So what were the tasks for a limited AU
21 pathway? Well, the first one was is it feasible
22 to have a limited AU pathway for certain
23 categories of radiopharmaceuticals? And if so,
24 how were we to develop these categories? And
25 with these categories, what would be the

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1 appropriate training and experience
2 requirements? And lastly and very importantly,
3 how could you assess competency that the
4 knowledge and skills obtained would be able to
5 be used in a competent fashion on patients and
6 would this be based on the number of training
7 and experience hours or by an objective measure
8 such as an examination?

9 So the NRC staff started to assess the
10 feasibility of a limited AU pathway with tailored
11 training and experience and documentation of
12 competency. And at this point in time, they are
13 continuing their broad stakeholder input.

14 Next slide. So the staff, NRC staff
15 developed a draft of the potential knowledge topics
16 needed for an authorized user for therapy, and they
17 started with 10 CFR 35.390 and there was subcommittee
18 input.

19 As I mentioned, the proposed curriculum
20 incorporated, it started off with the knowledge
21 topics of 10 CFR 35.390 as a starting point, and these
22 could potentially be tailored to the specific
23 radiopharmaceutical that was going to be looked at
24 for therapy with potential need for additional
25 knowledge topics, depending on what the agent was.

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1 Next slide. However, due to time
2 constraints, there was an initial stakeholder
3 outreach which was limited.

4 So what were the results? With the initial
5 stakeholder response, pretty much the majority agreed
6 that there needs to be a fundamental and specific
7 radiopharmaceutical knowledge in 10 CFR 390 to safely
8 administer radiopharmaceuticals. That was pretty
9 much the majority of stakeholder input.

10 How to obtain this knowledge? There were
11 many varied responses. How to evaluate the
12 independent application of this knowledge, and this
13 was also very varied in the responses obtained.

14 Next slide. There were many stakeholder
15 concerns, and some of these included how to categorize
16 a radiopharmaceutical. How were these training and
17 experience requirements going to be administered, and
18 how many hours would it take to have adequate training
19 and experience? And, lastly, how to assess
20 competency? Were they going to develop an exam,
21 perhaps by the medical community or medical specialty
22 boards, or was a preceptor attestation needed, and
23 perhaps maybe there may be new certification boards
24 that would need to be created.

25 Next slide. The NRC staff conclusion after

1 this initial stakeholder input came to the conclusion
2 that it may be feasible to develop a limited AU status
3 for certain radiopharmaceuticals with tailored
4 training and experience and a competency-based
5 assessment of the knowledge and skills obtained. So
6 the ACMUI subcommittee reviewed this, and we agreed
7 with the broadest stakeholder outreach was needed for
8 the potential limited AU status. And with this, they
9 needed to define the radiopharmaceutical categories.
10 What were going to be the limited training and
11 experience requirements? And the competency
12 assessment for knowledge and skills obtained would
13 need to be very carefully looked at.

14 The subcommittee review agreed that you
15 need collaboration with the medical community in
16 developing competency-based assessment tools and that
17 the subcommittee also warned that minimizing training
18 and experience may jeopardize patient, staff, and
19 public safety.

20 Next slide. The subcommittee also looked
21 at the issue of an AU shortage, and it looked at it
22 and said that the initial, there was initial
23 underestimation of available AUs for 10 CFR 35.390.
24 According to the ACGME website, there are
25 approximately 900 potential authorized users in

1 training, and this included radiation oncology,
2 nuclear medicine, nuclear radiology and the
3 redesigned American Board of Radiology pathway. The
4 American Board of Osteopathic, for Osteopathic
5 Radiology has about 150 to 200 trainees at this point
6 in time with about 30 to 40 authorized users
7 graduating every year. So you're looking at over a
8 thousand authorized users in training.

9 Next slide. So the subcommittee reviewed
10 that the feasibility of an alternate pathway, despite
11 the number of authorized users that are currently in
12 training, should still be explored. There was a
13 concern about estimating the number of hours of
14 training and experience required, and the training
15 and experience requirements should be based on the
16 necessary knowledge and skills and not on hours and,
17 therefore, should be based on competency.

18 Next slide. So the subcommittee
19 recommended that we review the existing authorized
20 user pathways to maintain safety, maximize patient
21 access, and clearly define the authorized users'
22 scope of practice. The training and experience must
23 be inclusive. It must have a comprehensive coverage
24 of radiation physics, radiation biology, radiation
25 instrumentation and mathematics, radiation protection

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1 and safety, patient release, and applicable
2 regulations at the federal and state level and
3 information on medical events. Authorized user
4 competency must be determined objectively for not
5 only initial assessment but ongoing maintenance of
6 competency, and we strongly agreed that a greater
7 stakeholder input is needed.

8 So what are the subcommittee
9 recommendations? Recommend the NRC staff should
10 monitor potential AU shortage for 10 CFR 35.300 to
11 include geographic data and perhaps practice patterns
12 as part of the monitoring process.

13 Next slide. So the current plans for the
14 subcommittee is to work with the NRC staff to expand
15 the stakeholder outreach and to explore the
16 feasibility of a limited AU pathway or pathways.

17 Next slide. The subcommittee's future
18 work. We plan to work with the NRC staff if the NRC
19 plans to propose changes to the current training and
20 experience requirements as a result of this broad
21 reassessment.

22 Next slide. Future work. We need to look
23 at the training and experience. What are the core
24 requirements? What is going to be the adequate
25 acquisition and application of the knowledge and

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1 skills obtained for the appropriate
2 radiopharmaceutical use and administration of the
3 radiopharmaceutical while ensuring patient, staff,
4 and public safety? The subcommittee plans to
5 continue to work with the NRC staff to determine how
6 best to assess competency.

7 And these are the acronyms we used. Thank
8 you.

9 CHAIRMAN PALESTRO: Thank you, Dr. Metter.
10 Members of the subcommittee have any comments,
11 questions? Members of the ACMUI, any comments or
12 questions? Dr. Dilsizian?

13 MEMBER DILSIZIAN: A very nice
14 presentation. So I'm thinking about this, and it
15 seems to me that you've all agreed, the subcommittee,
16 that an alternate pathway is a reasonable thing to
17 do. So, therefore, the whole training of whether
18 there's enough physicians out there, radiologists or
19 radiation oncologists, nuclear medicine physicians,
20 is really not the issue. You've kind of accepted the
21 philosophy in several slides that it's reasonable to
22 explore an alternate pathway. Is that a fair
23 beginning? Because then I would like to continue if
24 that's the --

25 VICE CHAIRMAN METTER: Okay. So first of

1 all, as far as the question of AU shortage, there is
2 not, I mean, that we'd foresee as a shortage now or
3 in the future. And as far as the feasibility, we
4 still thought that perhaps we should still look at
5 the feasibility of a limited authorized user
6 pathway, which is looking at the feasibility of it.

7 MEMBER DILSIZIAN: Exactly. So if that's
8 where we're going to start, the next question is that,
9 in several places, we're talking about hours and
10 competency to administer this safely, the words are
11 safely, and that we shouldn't be limited on hours
12 alone but plus some type of an examination. I think
13 the way I'm seeing this is that the oncologist or
14 whoever it's going to be going through this alternate
15 pathway, I don't think they've asked us to change the
16 requirements of the training. The whole radiation
17 biology, radiation physics, all of those things are
18 there.

19 I think the question that's always come up
20 is that do those educational pathways translate to
21 700 hours or less? And all that they're, I think,
22 asking us is to say please define is it 600, is it
23 500 or 400? I don't think they're asking us to kind
24 of give a crash course so that they be less safe to
25 patients. I think that we should be respectful that

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1 these are physicians that have had medical school
2 degrees, three years for medicine, three years of
3 oncology. I don't think they're going to be
4 irresponsible physicians, shall we say. They're
5 simply saying please define what is a reasonable
6 number of hours, and they're not even saying that it
7 should be 80. They're simply saying define the
8 hours.

9 So from my perspective, I'm simply looking
10 at this and saying why don't we just take the
11 curriculum because nobody has defined 700 hours, how
12 we came to that number, but in a reasonable way come
13 up what is the number and simply provide that. Am I
14 missing something?

15 VICE CHAIRMAN METTER: The subcommittee is
16 looking at that, you know, as far as the core
17 knowledge, like you said, that has to be obtained.
18 And then we're looking at that other issue you spoke
19 about. But it's very difficult. Again, the bottom
20 line is going to be, with that basic knowledge and
21 skills that you need for therapy, how are you going
22 to assess competency? It's going to be based on
23 hours, which is very difficult, versus another type
24 of assessment.

25 MEMBER DILSIZIAN: In general, the way we

1 define anybody's competency is the number of years of
2 training as a cardiologist or as a surgeon or a
3 radiation oncologist and then you pass board
4 certification. Why don't we just simply apply what
5 we always do? Give certain number of minimum hours
6 for the trainees to be educated and then give them a
7 competency test like we always do? I don't think it
8 should be that complicated. I don't think it's one
9 or the other. I think it should be both.

10 CHAIRMAN PALESTRO: Dr. Dilsizian, just to
11 comment. In point of fact, the stakeholders who are
12 looking and seeking the so-called limited alternative
13 pathway were quite clear about the number of hours
14 and they suggested that 80 hours was more than
15 sufficient. So there was an hour issue.

16 Any other comments or questions? Mr.
17 Green?

18 MEMBER GREEN: I appreciate the very
19 thorough review of the proposal and it's just the
20 beginning of the process to, you know, figure it out.
21 I'm excited by drugs. I'm a drug dealer. I
22 shouldn't have said that, huh?

23 MEMBER ENNIS: Unusual to acknowledge it
24 in a federal facility.

25 MEMBER GREEN: I'm licensed. I have a

1 license to sell drugs. But Lutetium 177 was remarked
2 in your presentation. Since our last meeting in
3 April, the FDA has approved a new therapeutic I-131,
4 iobenguane. Azedra is the brand name. So we have
5 another therapeutic 35.300 drug. I don't know if
6 it's going to go crazy, but it's another drug in the
7 armamentarium of physicians to treat patients, and
8 there will be more following those footsteps.

9 CHAIRMAN PALESTRO: Mr. Ouhib?

10 MEMBER OUHIB: Yes. I think we need to be
11 careful about, you know, new procedures are coming
12 along the line to justify or to jeopardize the safety
13 of treatment, in my opinion. I think we need to
14 separate them completely.

15 I think when you go to training and
16 education, it's only getting, I would say, better. I
17 wouldn't say worse. It's getting better. I mean, I
18 look back, as a medical physicist looking back, that
19 I used to spend two years or whatever and I can get
20 my master's degree and I can jump and -- you can't
21 get that anymore. You get your degree and you have
22 to go and do a residency program. That's a two-year
23 program to actually be qualified and, of course, pass
24 the board to actually be a qualified medical physicist
25 out there in the field.

1 So I think we need to be careful. I'm
2 almost like, you know, is 700 hours enough really?
3 Is it enough? You know, I'm thinking the other side.
4 I'm not looking on the lower side, I'm looking on the
5 higher side probably. So I think we need to pay
6 attention to that.

7 CHAIRMAN PALESTRO: Any other comments?
8 Dr. Ennis?

9 MEMBER ENNIS: Just echoing the things
10 here. I think thinking about competencies and
11 defining a curriculum, you know, is a very reasonable
12 response and way to move forward. I doubt that will
13 translate into something that's easily achievable,
14 but potentially a specialist who really wants to
15 genuinely do this and become their niche? Maybe.
16 But I do think we're being asked to kind of really
17 define a real curriculum.

18 But I want to echo what Zoubir said.
19 There's no doubt it's not enough to have book
20 knowledge, and any alternative pathway is going to
21 have to require some significant apprenticeship. You
22 know, three cases, let's say, which is kind of a
23 common kind of, like, thing in some of the regulations
24 to have a specific new authorization, is clearly not
25 enough. You're never going to see all the mistakes,

1 all the errors, all the problems. So we're going to
2 have to think about that aspect, but I think that
3 that's going to be a crucial element to this, some
4 substantial apprenticeship.

5 CHAIRMAN PALESTRO: Other comments,
6 questions, from the committee? Dr. Suh?

7 MEMBER SUH: So first of all, thanks, Dr.
8 Metter, for that excellent presentation. So this is
9 a question of what's going to be considered safe,
10 also by quality, protecting the public, protecting
11 the patients, etcetera. And, obviously, the
12 stakeholders kind of have different interests in
13 terms of what qualifies for a sufficient number of
14 hours.

15 I guess my commentary would be that, in
16 terms of the minimum amount, I think we all agree
17 that the minimum amount should include all the
18 knowledge of radiation biology, physics etcetera.
19 And then the big question becomes how much experience
20 does one need?

21 What I would advocate for is the fact that
22 a radiation oncologist lives and breathes x-ray
23 treatment day-in and day-out, a nuclear medicine
24 physician lives and breathes x-ray treatment day-in
25 and day-out, I think there is a particular value to

1 that when you're delivering therapy. My concern
2 would be that if you have a urologist or a medical
3 oncologist whose primary instrument, urology is
4 surgery, medical oncology is chemotherapy, are they
5 going to have the same insight, knowledge, that one
6 would glean from a four or five-year residency program
7 compared to someone who has a, I'll just use a number,
8 400 hours' worth of experience? I don't know, and I
9 think that -- and then I would just ask the committee
10 to really think about that long and hard because if
11 we do decide to make a change and quality and safety
12 become worse, then we're going to kick ourselves, you
13 know, we did the wrong thing.

14 So I would just ask everyone to think about
15 that in terms of if we do make the change, and, again,
16 maybe there's a number that we can come up with, but
17 is that going to be the right number? Therapy is
18 very different than diagnostics, and I think that's
19 very -- and that's been said multiple times in the
20 eight years I've been on this committee is therapy
21 and diagnostics is very different, and now we've been
22 asked to make some comments about can we change the
23 limited scope? I would just be very careful about
24 that moving forward.

25 CHAIRMAN PALESTRO: Dr. Suh, question for

1 you. Are you suggesting that perhaps individuals,
2 assuming there were a limited AU pathway, that
3 individuals who go down that path would be required
4 to have more clinical experience in therapeutic
5 administration than someone who's gone through the
6 deemed board pathway?

7 MEMBER SUH: That may be one implication.
8 I'm not saying I'm right or wrong about that, but I
9 think the fact that someone grows up with radiation
10 and knows what's involved with it versus someone who
11 takes it as secondhand -- and I'm not saying anything
12 negative about what other specialists can do. Again,
13 that's just a concern I'm bringing up. I'm not saying
14 I'm completely against an alternative pathway. I'm
15 just mentioning this is something we need to think
16 about as a subcommittee and also as a committee, as
17 well, moving forward.

18 CHAIRMAN PALESTRO: No, I wasn't suggesting
19 that it was negative. Going through in my mind to
20 think if there's a parallel or analogous occurrence
21 in other areas of medicine. And I apologize that I
22 don't remember the numbers exactly, but when PET-CT
23 first exploded onto the scene, the various societies,
24 nuclear medicine societies, the radiological
25 societies, tried to put together or did, in fact, put

1 together white papers describing the amount of
2 experience that would be required or recommended for
3 an individual to be proficient at reading these
4 studies. And if I remember correctly, and if anyone
5 knows different please correct me, but, if I remember
6 correctly, there were a substantially larger number
7 of studies that should have been read by the nuclear
8 physician, non-radiologist nuclear physician, in
9 order to gain proficiency in the cross-sectional
10 imaging comparable to what the radiologist would
11 have.

12 So there was a discrepancy or discordance
13 in a number of cases with a logical explanation. So
14 if, in fact, that's what you are suggesting or raising
15 as a possibility, I think there's precedent for that.

16 CHAIRMAN PALESTRO: Other comments or
17 questions?

18 VICE CHAIRMAN METTER: This is Darlene
19 Metter again, and thank you for your comments, Dr.
20 Suh. The committee is looking into the idea of the
21 clinical aspect because with a list of agents that
22 are coming up in the pathway, as far as for therapy,
23 they have multiple complex entities that need to be
24 involved, a lot of teamwork, a lot of different things
25 you have to be careful about. And so the committee

1 is looking at that and is concerned about the clinical
2 experience, too.

3 CHAIRMAN PALESTRO: Mr. Sheetz?

4 MEMBER SHEETZ: I just wanted to express
5 one of the radiation safety concerns with this limited
6 scope alternative pathway for radiopharmaceutical
7 administration. Currently, they're being
8 administered within a nuclear medicine department or
9 a radiation oncology department, and there's other
10 support staff, nuclear medicine technologists,
11 medical physicists, medical health physicists, even
12 RSOs. And so it's really a team approach on these
13 administrations. Everybody has their role.

14 With the current medical specialties that
15 are interested in doing this, they don't normally
16 practice with these other specialties. And so I'm
17 not sure how they would accomplish a lot of the duties
18 that normally are delegated from the AU to the
19 technologist or to a medical physicist or medical
20 health physicist.

21 And so there's just an unknown there on how
22 that would be accomplished. It's not just, you know,
23 brushing the plunger and administering the
24 radioactive drug. It's the whole thing from the
25 receipt, the essay, setting up the administration,

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1 responding to spills potentially, and so forth. So
2 it's a much bigger picture than just a quick
3 administration of a unit dose.

4 CHAIRMAN PALESTRO: Dr. Martin?

5 MEMBER MARTIN: I would just reiterate what
6 Mr. Sheetz has been saying. We cover, my physics
7 group covers several hospitals that do these
8 treatments, and in every one of them it involves the
9 physicist being there, as well as the nuclear medicine
10 technologist being there, and all of that staff work
11 has to be in place.

12 I haven't read them and I don't know all
13 the details, obviously, being new. But what I have
14 read is the proposals I don't hear being made for
15 working with the staff. I hear, like, an independent
16 physician wanting to provide these services in
17 smaller community hospitals without that support
18 staff, and I would just reiterate I think it could
19 very well be a hazard because that support staff is
20 not going to be there. And from what I've seen, we
21 find it absolutely crucial to have the nuclear
22 medicine's technology staff and the physicist
23 involved.

24 CHAIRMAN PALESTRO: Mr. Ouhib?

25 MEMBER OUHIB: Yes. And I think the other

1 item that we should not forget is it is not just a
2 matter of doing an injection or anything like that.
3 There's a patient management after that for patients
4 that have had radioactive material. It's another
5 critical component that require another education and
6 so on and so forth.

7 CHAIRMAN PALESTRO: Any other comments?

8 MEMBER DILSIZIAN: Just was wondering, you
9 know, at a site of nuclear medicine, you know, we're
10 talking about even radiation oncologists, thinking
11 about that, given that the therapy choices are going
12 to be increasing, that, even within our training that
13 we may have, an additional year just dedicated for
14 therapy.

15 So would the subcommittee consider then --
16 again, I'm not saying to do 80 hours. Just consider
17 that if you are coming in as an oncologist with
18 having, again, three years of internal medicine,
19 three years of oncology experience of managing sick
20 patients, what if they would like to have the
21 alternate pathway to be one year of fellowship in
22 therapy? Would you, as a committee, consider it?
23 It's not shortening the pathway. It's actually
24 spending a year learning and they want to be good
25 citizens treating their patients.

1 So I'm just trying to understand what the
2 alternate pathway is, which is why I started saying
3 if you accepted that then you have to define what is
4 that alternative pathway.

5 VICE CHAIRMAN METTER: Thank you for your
6 comments. This is Darlene Metter. There is an
7 alternate pathway already. It's the 700 hours with
8 the 200 hours of knowledge in didactics and laboratory
9 and the 500 of clinical. So that is the alternate
10 pathway. So as far as what you're saying, I think
11 this already exists.

12 I think the other thing, too, is, you know,
13 as far as I know, issues have been brought up in
14 regards to patient-ready doses and you don't, you
15 know, that sort of issues. But the thing is that is
16 what? It's the what if. What if this happened? You
17 really have to have the ability to handle the what
18 ifs, and that's why I think it's very important to
19 have the knowledge and the skills and the experience
20 to handle these. These therapies are going to get
21 more complicated, so, at this point in time, you know,
22 I'd be a little bit concerned in shortening the
23 clinical experience because of the other entities
24 that are coming up the pathway, which are a fair
25 number.

1 CHAIRMAN PALESTRO: Any other comments,
2 questions, from the committee? Comments or questions
3 from the attendees?

4 MS. TOMLINSON: Good afternoon. I'm Cindy
5 Tomlinson with ASTRO. So, Chairman Palestro, ACMUI,
6 NRC staff, thank you for allowing me to provide this
7 statement on behalf of ASTRO.

8 I'm responding to the staff paper entitled
9 "Staff Evaluation of Training and Experience
10 Requirements for Administering
11 Radiopharmaceuticals." As we've commented in the
12 past, in past statements to the ACMUI, we strongly
13 oppose any reduction in the training and experience
14 requirements found in 10 CFR 35.390. ASTRO believes
15 that the requirements found in this section are
16 appropriate, protect the safety of patients, the
17 public, and practitioners, and should not be changed.

18 Radiopharmaceuticals are highly effective
19 in treating cancer with possible harmful effects to
20 both the patient and the public if not used correctly
21 and under the supervision of a highly-trained
22 physician. We are pleased that in its report the NRC
23 staff determined that the current requirements of 200
24 hours of classroom and laboratory training hours
25 prescribed under the alternate pathway is reasonable

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1 to acquire the fundamental knowledge that an AU would
2 need to administer any radiopharmaceutical.

3 However, we are concerned that tailoring
4 the number of hours to work experience, of work
5 experience required based on categories of
6 radiopharmaceuticals will lead to confusion and
7 complexity for both licensees, as well as the NRC and
8 agreement states. We are concerned, we are also
9 concerned that if new radiopharmaceuticals are
10 approved for use that do not fit into one of these
11 categories the NRC will have to promulgate additional
12 regulations to include these new agents, a process
13 that could take time to finalize, delaying patient
14 access to potentially life-saving
15 radiopharmaceuticals.

16 The rigorous T&E requirements contribute to
17 the excellent safety record of radiopharmaceuticals.
18 We believe that it is important that the person
19 administering the radiopharmaceutical is
20 appropriately trained in the safe handling, exposure
21 risks, and the management of side effects of
22 radiation.

23 We continue to believe that a thorough and
24 comprehensive review of current T&E requirements is
25 reasonable. Additionally, we fully support a

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1 thorough examination of geographic distribution and
2 practice patterns of current AUs under both 35.300
3 and 35.390, as well as seeking greater stakeholder
4 input.

5 As we've mentioned in previous statements,
6 the American Board of Radiology estimates that
7 between 2007 and 2017 approximately 650 radiation
8 oncologists were certified by the ABR with an AU
9 eligibility designation and may become AUs. In
10 addition, we estimate that there are approximately
11 2200 radiation oncology facilities in the United
12 States. Together with current radiation oncology
13 AUs, the 773 radiation oncology residents currently
14 in residency programs and nuclear medicine-trained
15 AUs nationwide, there are likely enough AUs to
16 administer radiopharmaceutical. We caution that
17 changing the current requirements without a
18 comprehensive investigation could result in
19 unintended harm to patients, personnel, and the
20 public.

21 We look forward to working with both the
22 ACMUI and the NRC as you continue your deliberation
23 and review. And I will submit these written comments
24 to staff.

25 CHAIRMAN PALESTRO: Thank you. Any other

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1 comments from attendees?

2 DR. GHESANI: Yes. This is Munir Ghesani?

3 Can you hear me? Hello?

4 CHAIRMAN PALESTRO: Yes, we're taking
5 comments at the moment from attendees here in the
6 room, so we will just hold on for a few minutes.

7 DR. GHESANI: Okay.

8 DR. RAZMARIA: Hi, Mr. Chairman, members
9 of NRC and ACMUI. My name is Aria Razmaria. I'm a
10 senior resident in nuclear medicine and in my final
11 year of training at UCLA Medical Center in California.
12 I'm also the recipient of the Robert Henkin Fellowship
13 of Government Relations with Society of Nuclear
14 Medicine and Molecular Imaging. I speak here on
15 behalf of myself and also on behalf of trainees in
16 nuclear medicine and combined programs in nuclear
17 medicine and radiology as a board member of a nuclear
18 medicine resident organization and fellows
19 organization.

20 I am a graduate of a medical school in
21 Vienna, and I'm trained in family medicine and urology
22 in addition to nuclear medicine. I came to U.S.
23 inspired by the cutting-edge science and excellence
24 in patient care. However, what we are witnessing in
25 nuclear medicine in U.S. is that U.S. is falling

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1 behind at the global level behind many other countries
2 in Europe and Australia. Many new advancements in
3 the field of nuclear medicine, for example in
4 diagnostics, are coming from outside the U.S. The
5 vast majority of research published in U.S.
6 scientific journals are from countries other than
7 U.S.

8 In many instances, patients travel across
9 the Atlantic to receive life-saving or life-
10 prolonging therapeutics which are not available in
11 U.S. This is despite the fact that nuclear medicine
12 was invented and first developed in U.S.

13 Losing training requirements will not solve
14 these problems. The reason these countries are ahead
15 of the game are because of a clearly-defined pathway
16 to nuclear medicine and the scope of practice. We
17 in the U.S. are in dear need of dedicated people in
18 nuclear medicine who are thoroughly trained and are
19 eager to push the field of nuclear medicine forward,
20 not people that practice nuclear medicine as a side
21 trade.

22 We, as nuclear medicine and nuclear
23 medicine radiology trainees, are ready and determined
24 to face this challenge and this calling in this
25 country. We oppose any attempts of minimizing

1 training or pathways to nuclear practice of nuclear
2 medicine on limited authorized user pathways or
3 alternate user pathways based off hypothetical
4 concerns of shortage of workforce. This would be
5 similar to equating a specialty training of three
6 years to 700 hours, which is not more than four months
7 of training or less.

8 We would dare to ask if any of our loved
9 ones would be need of receiving radiopharmaceuticals.
10 We rather would consult with an expert who has three
11 years of training versus four months of training.

12 Even in Code of Federal Regulations, 10 CFR
13 Part 35 pertaining to administering of sealed
14 sources, we see as requirement three years and that's
15 rightfully and appropriately three years of training
16 in radiation oncology. Why are we applying different
17 standards in terms of usage of unsealed sources,
18 whereas these agents are distributed to the whole
19 body.

20 Regular considerations of this scope
21 infringe upon autonomy of medical specialties and are
22 in contradiction to evidence-based practice of
23 medicine. In an era of increasing sub-
24 specialization, diminishing sub-specialization
25 training and experience requirements appears

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1 irrational.

2 In this regard, we point to recent
3 guideline recommendations by International Atomic
4 Energy Agency as put forward in the most recent
5 meeting in Vienna in June of 2018 which requires as
6 a standard international requirement three to four
7 years of training in nuclear medicine, 3,000 cases of
8 300 or 100 therapies that have been administered.

9 As nuclear medicine and nuclear medicine
10 radiology trainees, we see this regulatory
11 concentration as undermining existence of nuclear
12 medicine as a viable specialty in the U.S., our future
13 as a new generation of nuclear medicine physicians
14 and, above all, endangering highest level of care for
15 our patients.

16 During my fellowship in government
17 relations, I have visited institutions like NIH, NCI,
18 FDA, the Capitol and I met with patient advocates
19 organizations. I've learned about fascinating new
20 groundbreaking research pertaining to nuclear
21 medicine and molecular imaging at a national level
22 and the readiness of institutions like FDA to provide
23 guidance to take these new discoveries through the
24 regulatory process. I've learned about the support
25 of legislation, representatives, and alliance of

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1 patient advocates.

2 Nuclear medicine and nuclear imaging is not
3 about shipping one unit dose across the country to be
4 injected or a pill to be swallowed, rather a new age
5 of targeted and individualized paradigm in
6 radionuclide therapies with exact personalized
7 calculations of radiopharmaceutical therapy with
8 evaluation of indication, sequence of therapies,
9 dosimetry calculation, follow-up of treatment which
10 requires in-depth understanding, and intricacies of
11 the new novel treatments.

12 Thank you for your attention.

13 CHAIRMAN PALESTRO: Thank you. Any other
14 comments from attendees in the room?

15 MR. GUASTELLA: Thank you, Dr. Palestro.
16 I don't have any written comments. I did make some
17 notes. I thought I'd just offer them for the ACMUI
18 to consider.

19 I'm Michael Guastella. I'm the Executive
20 Director of the Council on Radionuclides and
21 Radiopharmaceuticals. And as many of you may know,
22 CORAR does support an alternative to the current 700
23 hours. We were actually one of the stakeholders in
24 the limited outreach that Dr. Metter had mentioned a
25 few minutes ago.

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1 And we did, to your point, Dr. Palestro,
2 did provide an overview and kind of scoped out an 80-
3 hour program for AU certification. And in doing
4 that, we kind of had several considerations. One,
5 the limited role in handling patient-ready doses that
6 are provided from nuclear pharmacies. Dr. Metter,
7 you had actually mentioned that as one of the things
8 that had been considered and have been commented on.
9 The safety profiles of the radiopharmaceuticals,
10 mostly that these alpha and beta emitters that are,
11 if not already approved, certainly in the pipeline
12 and, importantly we certainly believe is the
13 physician experience for like a hem-onc, for example,
14 in handling chemotherapy drugs, toxic chemotherapy
15 agents.

16 And we've had conversations and have
17 presented to the ACMUI over the last several years.
18 I think one thing to consider, and I'm very sensitive
19 to the safety issues that have been raised by a number
20 of you here today in this meeting, but prior to 2005
21 there were some med-oncs, chem-oncs, that actually
22 were grandfathered in, and we had a couple of
23 presentations made a few years back. And as part of
24 the consideration and the evaluation, it might be
25 helpful to go back and see how those professionals

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1 are doing relative to administering to their
2 patients, if they are depending on local nuclear
3 medicine departments, for example. I can't answer
4 that question today, but I think, in trying to be as
5 comprehensive as possible in your evaluation, these
6 are the types of things that you may want to consider.

7 So I appreciate your time. Thank you.

8 CHAIRMAN PALESTRO: Thank you. Any other
9 comments, questions, from anybody here in the room?
10 Comments, questions, from anyone on the telephone
11 lines?

12 DR. GHESANI: Hi, Dr. Palestro. This is
13 Munir Ghesani. Can you hear me?

14 CHAIRMAN PALESTRO: Yes, we can. Thank
15 you.

16 DR. GHESANI: Okay. So good afternoon.
17 I'm a physician from NYU and board certified in both
18 radiology and nuclear medicine. And today I'm
19 speaking on behalf of the Government Relation
20 Committee and the SNMMI in general. And we in SNMMI,
21 along with the American College of Nuclear Medicine
22 and the American Society of Radiation Oncology --
23 you've heard already from Cindy Tomlinson -- we have
24 formed an ad hoc committee to offer the collective
25 recommendations for the potential updates to the

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1 Nuclear Regulatory Commission's requirements.

2 We identified some clinical knowledge and
3 skills needed by individuals seeking authorized user
4 status with the alternate pathway, and, as Dr. Metter
5 already described, there's already one in existence
6 with the 700 hours.

7 With regards to the training and experience
8 in the initial determination of competency, it is our
9 opinion that the mastery of the curriculum listed
10 below will ensure high-quality practice of
11 radionuclide therapy. This didactic instruction is
12 important for safe and effective therapies and should
13 not be minimized.

14 The use of unsealed sources for the
15 therapeutic applications is complex and has serious
16 medical and safety risks associated with it, not only
17 for the patients but also their family and public at
18 large. As such, we feel that it is important to
19 maintain this high quality of training and
20 experience.

21 We heard a few comments about how stringent
22 some of these training requirements are, spanning for
23 several years. So if we know that that has ensured
24 the safety, why take a risk in minimizing the
25 requirement and have the aftermath of some of the

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1 complications?

2 Now, my colleague, Michael Razmaria,
3 mentioned about the possibility of exploring the
4 experience of the previous grandfathered medical
5 oncologists, but I would caution that, on that end,
6 it may be a small sample and it was in a different
7 scenario at that time. Some of the complex
8 therapeutic radiopharmaceuticals that are approved
9 now were not in existence at that time. And I think
10 that, on one hand, it would be interesting to get the
11 data, but I would be a little cautious about using
12 the data in any meaningful way.

13 So we have heard from several speakers
14 about being cautious in releasing these requirements,
15 and I would really emphasize that on behalf of the
16 SNMMI, as well as on behalf of the ad hoc committee
17 that we have formed amongst various societies of
18 oncologists to explore this issue. Thank you for
19 your time.

20 CHAIRMAN PALESTRO: Thank you, Dr. Ghesani.
21 Any other questions or comments from anyone on the
22 telephone lines? Comments or questions from anyone
23 here on the committee or attendees in the room? Dr.
24 Ennis?

25 MEMBER ENNIS: I just want to thank --

1 where is he? The trainee, the fellow. What was your
2 name again?

3 DR. RAZMARIA: Aria.

4 MEMBER ENNIS: Dr. Aria. I don't know.
5 His comments really struck me in two ways. One of
6 them I thought about before, but I think he really
7 articulated it and we haven't here. And I guess it's
8 best, I think, to think of this as an analogy. I
9 can't imagine, like, going to an urologist who only
10 has had to do a TURP, a simple urologic procedure,
11 even if that's all that I needed, because so many
12 times in medicine things are way more complicated
13 than that. And if he doesn't have the broad expertise
14 of all of urology at least, I can't imagine going to
15 him. I can't imagine going to a cardiologist who
16 only knows about high blood pressure, doesn't know
17 about cholesterol, doesn't know about angina. And
18 it's kind of what we're kind of saying here. Well,
19 maybe we can do alphas with a certain half-life in a
20 single-dose vial. Is it really going to be that
21 simple? I think it's really an apt analogy for us
22 to think carefully about do we want to go down that
23 kind of a pathway? It certainly goes against the
24 current of the entire rest of medicine, how medicine
25 is done.

1 And number two, I think his public policy
2 issues that he raised I had not thought of before but
3 I think is quite valid. There's a lot that can be
4 done in all areas of medicine, and the safety to
5 quality of nuclear medicine going forward is somewhat
6 in the purview of NRC and can be affected by NRC
7 policy. And thinking about safety, not case-by-case
8 safety, and thinking downstream ten years and
9 thinking of a lot of agents, I couldn't agree more
10 with his comments that to empower the specialists who
11 really make this their lives is going to lead to
12 significantly more safety at that high-level view of
13 imparting it to people for whom it's just a side show.

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

16 VICE CHAIRMAN METTER: This is Darlene
17 Metter. Thank you, Dr. Ennis, for that comment. It
18 made me think about another analogy that you bring
19 up. If I go to a driving school and let's say I want
20 to learn how to drive, so I go to a driving school
21 and I take the courses and everything, as opposed to
22 my friend who goes and their father teaches them, we
23 get the end result. We both get a driver's license.
24 So that's kind of what I think we're looking at here.

25 Another thing would be let's say I learn

1 how to drive. I know how to go forward, I know how
2 to go backwards, I know how to turn right, I know how
3 to turn left, I know how to park, and I know how to
4 drive on the highway and on other roads. Now, if I
5 were just going to go ahead and drive forward, because
6 I know how to drive forward, maybe I could do that.
7 I could just learn just a limited thing just learning
8 how to drive forward. But if I have to stop, well,
9 maybe they can teach me that, too. But if I can't
10 go backwards, I might have to just go around the
11 block. So it's a limited pathway. I can go forward,
12 but that's all I can do.

13 My car has an automatic start, and I'm ready
14 to go when I hit that button and the car starts. You
15 know, I kind of see that as an analogy. Let's just
16 think about that. I think you really have to have a
17 broad basis because if I want to drive forward, what
18 happens if a car comes right in front of me or there's
19 a big detour sign or I have to reverse? I can't do
20 that.

21 CHAIRMAN PALESTRO: Any other comments or
22 questions? All right. Thank you all for your
23 participation and your input. And, Dr. Metter, thank
24 you and your subcommittee for all your hard work.

25 We're going to continue now with the

1 training and experience. Maryann Ayoade will discuss
2 stakeholder outreach plan.

3 MS. AYOADE: All right. Good afternoon,
4 everyone. My name is Maryann Ayoade, and I'm a member
5 of the Medical Radiation Safety Team at NMSS. And
6 today I'm going to be presenting to you the Part 35
7 medical training and experience stakeholder outreach
8 plan that is going to be coming up, hopefully, right
9 now.

10 So the purpose is to conduct a more
11 extensive outreach with the medical community focused
12 on assessing the options to tailor the training and
13 experience requirements for medical uses authorized
14 under 10 CFR Part 35.300, which is for
15 radiopharmaceuticals that require a written
16 directive.

17 So just to give you a little bit of
18 background, and Dr. Metter talked about the
19 Commission direction. So in August 2017, the
20 Commission directed the NRC staff to evaluate whether
21 it made sense to establish tailored training and
22 experience requirements for different categories of
23 radiopharmaceuticals, to evaluate how those
24 categories should be determined, to evaluate what the
25 appropriate T&E requirements would be for each

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1 category, and to evaluate whether those requirements
2 should be based on hours of training and experience
3 or competency.

4 Next slide, please. So the evaluation
5 included a limited outreach in April - May time frame
6 of 2018, and that outreach we did in the form of a
7 questionnaire that was sent out to some medical
8 stakeholders, including some medical licensees, some
9 medical professional societies, a regulator, an
10 industry trade organization which we had CORAR
11 speaking here today. And so we sent the
12 questionnaire out to them. We also shared and worked
13 with the T&E Subcommittee on the questionnaire, as
14 well. And the results of that evaluation were
15 documented in an information SECY paper which is SECY-
16 18-0084 that was recently made publicly available.

17 And so the evaluation concluded that it may
18 be feasible to establish tailored training and
19 experience requirements for different categories of
20 radiopharmaceuticals and to create a means of
21 authorizing the administration of certain categories
22 of radiopharmaceuticals, which is a limited
23 authorized user status. It also concluded that there
24 are viable options for creating a competency-based
25 approach to demonstrating acceptable training and

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1 experience requirements for limited authorized users
2 and that also the staff plans to do a more extensive
3 outreach, which is what I'm going to talk about today.

4 And the results of that limited outreach
5 were discussed during a teleconference on July 16th
6 with the ACMUI, and we also have a summary of the
7 responses from that limited outreach in the SECY
8 paper, as well, if you want to look at that.

9 Next slide. Okay. So what is the staff
10 planning to do for the outreach? This is just a list
11 of some of the outreach activities that we were
12 planning to have. We plan to publish in the Federal
13 Register a notice with questions that are going to be
14 related to training and experience requirements, and
15 I will go over an overview of some of the questions
16 in an upcoming slide.

17 We also plan to conduct public meetings and
18 webinars that will discuss the Federal Register
19 notice questions, as well as this initiative. We
20 plan to have a website dedicated to training and
21 experience with this information, information on the
22 initiative, as well as information about the Federal
23 Register notice questions, as well.

24 We also plan to send out letters and emails
25 to the stakeholders, which I will go over in the next

1 slide, as well as do poster presentations, posters
2 and presentations at the upcoming professional
3 society meetings. We also plan on writing articles
4 in the newsletters for these professional societies.

5 Next slide, please. So in addition to the
6 Federal Register notice and the public meetings and
7 all of the activities that I mentioned in the previous
8 slide, we plan to do some additional information
9 gathering. And this was a result of feedback that
10 we received from the ACMUI, as well as feedback that
11 we received from the, the comments that we received
12 from the first outreach. And so we want to look at
13 the evaluation of the authorized user shortage
14 regarding patient access, also to include patient
15 access as it relates to geography as well.

16 We also plan on reviewing medical and
17 radiation safety events to look to see if there are
18 any trends in these events and to see if any of the
19 trends indicate a need for a change in our training
20 and experience requirements. And we also want to
21 look at what's being done in the international scene
22 to see what are they doing for their
23 radiopharmaceutical training and experience
24 requirements right now and to see if they have any
25 kind of tailored training and experience requirements

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1 that may be similar to what we're trying to look at
2 now.

3 And so this is a list of the stakeholders
4 that we plan on reaching out to. We collaborated
5 with the Training and Experience Subcommittee
6 recently to make sure that we have a comprehensive
7 list of stakeholders, so we plan on reaching out to
8 more medical licensees, more regulators, medical
9 specialty boards, some patient health organizations
10 and advocacy groups, some trade organizations and
11 industry groups, more medical professional societies,
12 the medical specialty training and fellowship
13 organizations, and the medical oncology community.

14 Next slide, please. And so this just gives
15 an overview of the Federal Register notice questions
16 that we're going to be putting out. We also have
17 worked with the T&E Subcommittee to make sure that we
18 have questions that will give us information that
19 would be useful as we move along with this project.

20 And so we have some questions regarding
21 establishing tailored training and experience
22 requirements for the radiopharmaceuticals that
23 require a written directive. We have questions
24 regarding competency, so the assessment of knowledge,
25 skills, and abilities, and questions regarding

1 patient access.

2 Next slide, please. And so one of the next
3 steps following outreach. So we plan to analyze the
4 public comments and information that we receive from
5 the outreach that we conduct, and then we also plan
6 to continue to engage the ACMUI in our efforts, as
7 we've been doing. We also plan to keep the Commission
8 informed of the outreach efforts. And as a result
9 of everything that we've done, we will determine
10 whether the changes to the current T&E requirements
11 are warranted.

12 That's it for my presentation. I will take
13 any questions you may have.

14 CHAIRMAN PALESTRO: Any questions or
15 comments from the committee? Attendees here in the
16 room?

17 MR. BOLLOCK: So the question was about the
18 time lines. Yes, we are still working to finalize
19 that through our management chain, roughly it will
20 end in 12 to 14 months but I can't say for sure. But
21 the FRN, then those questions, that is being developed
22 right now, so that would be in the next two months.

23 VICE CHAIRMAN METTER: Yes, that's correct.
24 We just wanted to give you guys a sense of where we
25 are in the plan that we have to do outreach to move

1 forward.

2 MR. GUASTELLA: Maybe Mr. Bollock can
3 repeat my next question. So if there is --

4 CHAIRMAN PALESTRO: Excuse me. Would you
5 identify yourself for the transcriptionist, please?

6 MR. GUASTELLA: Oh, hi. Michael Guastella
7 from CORAR.

8 MR. BOLLOCK: Okay. So Mr. Guastella from
9 CORAR as the second question.

10 MR. GUASTELLA: Assuming an alternate
11 pathway is recommended, is that, are we talking about
12 expedited rulemaking or are we talking going through
13 the general rulemaking process? Just kind of
14 curious.

15 MR. BOLLOCK: So the question regards if a
16 change to the training and experience authorized user
17 requirements is determined to be warranted by the
18 staff, what would the rulemaking process go? Right
19 now, I mean, by default, it's the normal rulemaking
20 process, so it would have to go through, you know, we
21 would develop a rulemaking plan, present that to the
22 Commission. The Commission would approve and then
23 go on with development of a draft rule, public
24 comment. So, yes, the normal process is the default
25 there.

1 MR. GUASTELLA: This is Michael Guestella
2 to say thank you.

3 MR. BOLLOCK: And Mr. Guastella thanked us.

4 CHAIRMAN PALESTRO: Dr. Martin, I believe
5 you had a question.

6 MS. AYOADE: And just to add to that. If
7 no changes are needed, we will still be relaying that
8 to the Commission in another SECY paper, so we'll
9 share that with you guys, as well.

10 CHAIRMAN PALESTRO: Dr. Martin?

11 MEMBER MARTIN: This is Melissa Martin. I
12 was just noticing your list of societies that you
13 were going out to, and I'd try to encourage you to
14 actually engage the AAPM because we're the medical
15 physicists that are going to be working with the users
16 of this material, regardless of what their profession
17 is.

18 MS. AYOADE: Yes, that's correct. We have
19 the AAPM on our list, along with some other medical
20 professional societies. Thank you.

21 CHAIRMAN PALESTRO: Any comments or
22 questions from anyone on the telephone lines? Any
23 other comments or questions from anyone? All right.
24 Thank you, Ms. Ayoad.

25 Now we'll move on to some lighter fare.

1 And I'd just like to briefly review with you the
2 results of our, really my opinion of the joint ACMUI-
3 Society of Nuclear Medicine and Molecular Image
4 session, what's up for you and your patients that we
5 ran at the annual meeting of the society this past
6 June.

7 As you may recall, my predecessor as chair,
8 Dr. Phil Alderson, had sought to establish improved
9 communications and outreach with various professional
10 organizations and societies and these are our efforts
11 with the Society of Nuclear Medicine and Molecular
12 Imaging. Dr. Metter, myself, and Dr. Daibes-Figueroa
13 all took part in the session.

14 Dr. Metter gave an introduction and
15 overview, and she provided information on guidelines
16 for the nursing mothers. I talked about training and
17 experience for authorized users and a patient release
18 project for I-131 and question and answer period all
19 three of us participated in.

20 So how did we arrive or how did we identify
21 topics that would be of interest? And they were
22 really selected based on feedback from the Society of
23 Nuclear Medicine and Molecular Imaging. And we were
24 fortunate that we were able to run this not only as
25 a continuing medical education session but also a

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1 self-assessment module session. And, interestingly,
2 there were only two rooms, if I understood correctly,
3 available at that meeting for SAMs, so we were
4 delighted that we had the opportunity to present it
5 as a SAM.

6 Overall, it was well attended and I
7 personally was particularly impressed with the
8 audience who were clearly engaged. And there was an
9 excellent dialogue between the audience and the
10 speakers, and I want to highlight Dr. Daibes-Figueroa
11 because I think that the best way to describe it is
12 he put a face on the name of the NRC. I thought he
13 did an excellent job interacting with the attendees
14 coming across as a peer, rather than coming across a
15 regulator or a person of authority, if you will. So
16 I think he really did an excellent job, and we would
17 certainly, I would certainly recommend that these
18 sessions should be held on an ongoing basis and we
19 intend to try to repeat it again this coming year.

20 Comments or questions from the committee?

21 Mr. Green?

22 MEMBER GREEN: Just to back up your
23 comments, you were a presenter. I was in the
24 audience, and I think your assessment is 100-percent
25 spot-on. It was very well received, a lot of

1 interaction with the audience beyond the point that
2 the meeting was over and it continued in the hallway,
3 it continued in the aisles. Very productive session
4 and a very good face for the NRC.

5 CHAIRMAN PALESTRO: Any other comments or
6 questions? Dr. Metter, your impression?

7 VICE CHAIRMAN METTER: Yes, I think it was
8 a very good session and there were lots of questions
9 and really the NRC has a very good face. It was a
10 very interactive session. They had a lot of
11 questions about the regulators and I actually think
12 that was a very good outreach, and they invited us
13 back so we plan on doing that again next year.

14 CHAIRMAN PALESTRO: Dr. Dilsizian.

15 MEMBER DILSIZIAN: I was in the audience,
16 as well. I have to say, you know, when you're
17 designing these scientific sessions, this would be
18 the last one I would think that people would show up
19 to, never mind making it a SAM session. I was really
20 surprised. I mean, I have to say, in the past, in
21 order to make sure there were enough people, we would
22 combine the FDA with NRC because, you know, the new
23 things, a food fast. So the combination actually was
24 even better.

25 But I think there were so many questions.

1 I was surprised and I do encourage to continue this.
2 This is great. Congratulations.

3 CHAIRMAN PALESTRO: Any other comments or
4 questions from the committee? Questions or comments
5 from any of the attendees in the room? Questions or
6 comments from anyone on the phone lines?

7 All right. Mr. Bollock?

8 MR. BOLLOCK: Doug Bollock, NRC. So Dr.
9 Palestro and Dr. Metter, you know, worked with us to
10 try to support these meetings. We, the NRC, continue
11 to try to support the meetings as best we can. I've
12 brought this up many times. You know, unfortunately,
13 sometimes there are budgetary constraints, so we
14 can't send people to the meetings. We've been very
15 successful, I think, over the past year or so at least
16 sending one person, one representative from a medical
17 team at most of the major society meetings. I believe
18 we have been able to go to AAPM annual meeting this
19 year, SNMMI, ASTRO last year. I think right now
20 we'll be sending staff to ask for this year, and we'll
21 continue to try to support this as best we can.

22 We believe, as you say, this is important
23 to keep the lines of communication.

24 CHAIRMAN PALESTRO: Dr. Metter?

25 VICE CHAIRMAN METTER: Yes, and thank you

1 for supporting this. This was our second year that
2 we had done the session, and the first year was on a
3 short notice and it was an odd time but we still had
4 a fair number of people that attended. Clearly, a
5 lot more this year. It was publicized and it was at
6 a good time and people are aware of it. And people
7 have told me they are looking forward to this as a
8 regular session.

9 CHAIRMAN PALESTRO: Any other comments or
10 questions? Mr. Ouhib?

11 MEMBER OUHIB: Yes, I'd just add that we
12 had a representative, actually, to the ABS also that
13 went very well talking about the approve rules, and
14 I think that went very well also.

15 CHAIRMAN PALESTRO: All right. Thank you.
16 All right. The next presentation, Dr. Metter will
17 discuss the Nursing Mothers Guidelines Subcommittee's
18 final report for exposure from diagnostic and
19 therapeutic radiopharmaceuticals. Dr. Metter?

20 VICE CHAIRMAN METTER: Thank you, Dr.
21 Palestro. So I'll be presenting the report of the
22 Subcommittee on the Nursing Mother Guidelines for the
23 Medical Administration of Radioactive Materials.
24 This is a revised report. It was based on stakeholder
25 input that has been incorporated into the final

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1 document from an ACMUI public conference call earlier
2 this year in February. And in it, the final document,
3 it includes acknowledgments of the benefits of
4 breastfeeding and also additional calculations and
5 the table modifications regarding changing the units
6 to the SI units, incorporating gamma constants, and
7 correcting certain references. And I'll be
8 presenting one of the tables later on in this
9 presentation.

10 I'd like to first start by thanking the
11 members of my subcommittee: Dr. Vaskin Dilzisian, Dr.
12 Christopher Palestro, and Dr. Pat Zanzonico.

13 Now, breastfeeding is the feeding of an
14 infant from the female breast. Lactation is a
15 process of milk production, and lactation will cease
16 approximately six weeks after the last breastfeeding.
17 So the nursing mother guidelines charge was to review
18 the radiation exposure from diagnostic and
19 therapeutic radiopharmaceuticals, including
20 brachytherapy, to the nursing mother and child.

21 Now, we know that radiation safety
22 principles is we rely on the ALARA principle as our
23 guidance for radiation safety. Fortunately, we know
24 that many nuclear medicine procedures are elective,
25 thereby allowing a temporary or, at times, complete

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1 cessation of nursing or breastfeeding.

2 Patient release. Now, a patient may be
3 released, and in this particular instance nursing
4 mother, if the total effective dose to any individual,
5 and in this case the nursing child, will be less than
6 5 millisieverts. If, however, the exposure could
7 exceed 1 millisievert, written instructions and
8 information regarding adverse consequences to include
9 the written instructions if nursing is not stopped
10 and guidance on the discontinuation of breastfeeding.

11 Radiopharmaceuticals. Many drugs and
12 radiopharmaceuticals we know enter the breast milk.
13 It is estimated that less than ten percent of any
14 administered drug or radiopharmaceutical will enter
15 the breast milk with an average of about 0.3 to 5
16 percent. We also know by our physics is that after
17 ten physical half-lives a radionuclide will decay by
18 99.99 percent.

19 Most radiopharmaceuticals administered
20 will require a temporary cessation of breastfeeding.
21 Now, if you have pumped radioactive breast milk, it
22 can be held for ten physical half-lives before
23 feeding the milk to the nursing infant.
24 Alternatively, the mother can breast pump prior to
25 the administration of the radioactive agent and use

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1 this non-radioactive milk to feed her infant during
2 the cessation of breastfeeding.

3 A few radiopharmaceuticals, however, if
4 administered, may require complete cessation of
5 breast feeding. This one exception, and this section
6 really refers to modification of the agent to decrease
7 the maternal breast dose, and this is I-131. To
8 decrease the maternal breast dose because it gives a
9 very, very high dose to the lactating breast, for
10 example 150 millicuries of sodium iodide, 131,
11 approximates about 200 rads to the maternal breast.
12 Therefore, if I-131 is administered, it requires
13 cessation of breastfeeding six weeks prior to
14 radiopharmaceutical administration, thereby allowing
15 for the cessation of lactation, and the cessation of
16 breastfeeding needs to continue for that child. The
17 mother, however, may breastfeed future children.

18 Next slide. So let's look at the radiation
19 exposure during nursing, and you have two
20 individuals: the mother which is obvious to exposure
21 from the administration of the radioactive material
22 and the child comes from two sources, the external
23 source which is the mother and an internal source
24 which is the ingested radioactive milk.

25 So let's look at this external exposure.

1 The mother is a very significant source of exposure
2 to the child. And if we look at the ALARA principle,
3 which is as low as reasonably achievable, we know
4 that time and distance is going to be a factor.
5 During routine childcare, there's an increased time
6 with the radioactive source, the external source, to
7 the infant, and the distance is decreased and, hence,
8 the mother can be a significant radiation source to
9 exposure to the nursing child.

10 Next slide. Radiation exposure to the
11 nursing child by internal source is ingestion of
12 radioactive milk, and what is the dose? Well, it
13 depends on the radiopharmaceutical, and, as I
14 mentioned, it approximates about 0.3 to about 5
15 percent if the initial administered activity enters
16 the milk, again, except for sodium iodine, where the
17 mother needs to cease breastfeeding for six weeks
18 before administration and then for the remainder of
19 that child. However, she may breastfeed for future
20 children.

21 Next slide. So the subcommittee came up
22 with recommendations in regards to if a nursing mother
23 is administered radioactive material. There must be
24 an interruption of nursing in the sense of she needs
25 to stop nursing for the following agents: as we

1 mentioned, I-131, sodium iodide, beginning six weeks
2 prior to the administration, for I-124 sodium iodide,
3 any alpha emitters, and any diagnostic or therapeutic
4 doses of 177 Lutetium octreotate. There's no
5 cessation required for O-15 or rubidium-82, about one
6 hour for C-13 and N-13, four hours for fluorine-18,
7 and, actually, this chart, Ga-68 was in the initial
8 chart but, after recalculation, you really do not
9 need to cease breastfeeding for gallium-68.

10 Next slide. So for technetium-99m, one
11 time frame was used which was the 24 hours, and it's
12 because there are various different agents that we
13 use for technetium and there are very different times
14 of temporal cessation. So the subcommittee chose a
15 one-time period to simplify the guidance and avoid
16 error. So we chose 24 hours of nursing cessation.

17 For I-123, sodium iodide, the initial
18 recommendation was seven days. It currently is three
19 days. This is a newer chart in the sense of we did
20 actual recalculations with the initial ones being
21 placed on extrapolation. Thallium-201 four days,
22 indium labeled white cell and octreotate six days,
23 and gallium-67, 89 zirconium 28 days.

24 Now, this is the revised chart from our
25 teleconference call, and, actually, it does include

1 what was recommended at that time, the 100 and 500
2 millirem dose limit to the newborn tissue. It is
3 listed as 0.1 rad, but in the submitted document it
4 has been revised to the millirem dose limits.

5 I also would like to point out that under
6 indium labeled white cells, the dose is listed as 5
7 millicuries. That needs to be corrected to 0.5
8 millicuries.

9 The other corrections I have made, as I
10 mentioned, regarding the calculation was the initial
11 one for fluorine-18 was 12 hours. It is currently
12 four hours. For gallium-68, it was 12 hours. It's
13 currently no interruption is needed. And I mentioned
14 before, I-123, it was initially seven days. It's now
15 three days.

16 Sealed sources. Y-90 microspheres,
17 there's no need to interrupt breastfeeding for this.
18 Breasts and sentinel lymph node sources, no
19 interruption is needed as long as the source is not
20 within the mother.

21 And, lastly, it's important to inform the
22 nursing mother or mothers planning to nurse in the
23 near future who are scheduled for a nuclear medicine
24 procedure. And they must be informed that certain
25 radiopharmaceuticals, if they're received during this

1 procedure, may require radiation safety precautions
2 and such patients are advised to notify the nuclear
3 medicine staff or nuclear medicine physician prior to
4 their procedure.

5 Next slide. So in summary, the
6 subcommittee presented its draft report during the
7 February 1st, 2018 public ACMUI teleconference call.
8 The report at that time was endorsed by the full
9 committee with some caveats, which I have reviewed on
10 this presentation. One was a wording addition of the
11 benefits of breastfeeding which was incorporated into
12 the final written document and then the revisions on
13 the calculations and the modifications of the table
14 which is in the final document.

15 So I'm asking the committee to recommend
16 that this final report be approved as presented.

17 CHAIRMAN PALESTRO: Any questions or
18 comments from members of the subcommittee? Questions
19 or comments from members of the committee? Dr.
20 Ennis?

21 MEMBER ENNIS: Just for my own personal
22 clarification, so for sodium iodide we're talking
23 about six weeks before administration as the
24 requirement?

25 VICE CHAIRMAN METTER: I-131. That would

1 be for therapeutic or diagnostic, correct.

2 MEMBER ENNIS: But all the others, the
3 hours we're talking about are hours after
4 administration until you can breastfeed again?

5 VICE CHAIRMAN METTER: Correct, correct.

6 MEMBER ENNIS: Okay. So for someone who's
7 not, like, familiar with that, that wasn't clear.

8 VICE CHAIRMAN METTER: Okay. I'm sorry.

9 MEMBER ENNIS: No, it's okay. Maybe you
10 just make sure everyone else is clear.

11 VICE CHAIRMAN METTER: Right. The
12 breastfeeding interrupt time frame was the time
13 that's listed, correct. Thank you for the
14 clarification.

15 CHAIRMAN PALESTRO: Any
16 other questions or comments from the committee? Mr.
17 Green?

18 MEMBER GREEN: Beyond the report, will this
19 document go and be submitted by the NRC or become
20 license guidance? I mean, does it stop here? Does
21 it go beyond this?

22 CHAIRMAN PALESTRO: Mr. Bollock?

23 MR. BOLLOCK: So the committee can
24 recommend to us how -- I mean, once the report is
25 given to us, it's going to go on our, the ACMUI public
website for all to see and then use as they wish. If

1 the committee has a recommendation they'd like to see
2 us try to make in some other guidance, a regulatory
3 guide incorporate, we are currently working on
4 updating Reg Guide 839, which is the patient release.
5 You know, that could be something where we incorporate
6 it as an enclosure in that. There are options.

7 If there's an option that, if you'd like to
8 hear other options, I can share that. If you have
9 any thoughts that you have, you can share that with
10 us and the committee can give a recommendation what
11 they recommend the staff does, and then we will
12 respond. We will, you know, we may do exactly what
13 you recommend, we may do something slightly
14 different. We will respond to you all and tell you
15 what we do. At the very least, it will be on our
16 public website.

17 And we have, you know, we've internally
18 discussed possibilities of what to do. We just
19 haven't made a final decision yet.

20 CHAIRMAN PALESTRO: Ms. Shober?

21 MEMBER SHOBER: Yes, this is Megan Shober.
22 I would recommend that the cessation times be included
23 in NUREG-1556, Volume 9 in Appendix U, which provides
24 instructions to licensees.

25 MR. BOLLOCK: And NUREG-1556, Volume 9,

1 Appendix U, that now references Reg Guide 839. So
2 if we put into Reg Guide 839, that will --

3 MEMBER SHOBER: It will take care of that?

4 MR. BOLLOCK: Yes. For clarification.

5 CHAIRMAN PALESTRO: Any other comments or
6 questions from the committee? Mr. Ouhib?

7 MEMBER OUHIB: Yes, just a minor question
8 here is that is there a statement in the document
9 somewhere that state that this is applicable only to
10 these particular isotopes or any new isotope should
11 now be considered as being part of -- you know what
12 I'm saying? Let's just say next year there's another
13 one that pops up in the market now and then it's sort
14 of similar use for this same treatment or something
15 like that. How are you going to deal with that?

16 VICE CHAIRMAN METTER: I'm not
17 understanding your question. You mean the same
18 radionuclide?

19 MEMBER OUHIB: Right.

20 VICE CHAIRMAN METTER: These were based on
21 radionuclides, like, for example, the technetium one
22 day, gallium-68 really no interruption, and those are
23 based on that.

24 MEMBER OUHIB: Right. It's only
25 applicable to the listed nuclide --

1 VICE CHAIRMAN METTER: Correct.

2 MEMBER OUHIB: Is there a statement there
3 that this is applicable only to these listed nuclides
4 in here?

5 VICE CHAIRMAN METTER: It's in the final
6 report. This is just a summary of that.

7 MEMBER OUHIB: Okay.

8 CHAIRMAN PALESTRO: Ms. Weil?

9 MEMBER WEIL: Am I understanding you
10 correctly -- this is Laura Weil, I'm sorry -- that
11 you're asking what if tomorrow there's a new approved
12 radionuclide, is there a statement in this report
13 that says these are the radionuclides FDA approved in
14 use as of this date, other -- this does not include
15 anything that may have come on the market after this
16 date? I mean, Lutetium is new, right? And the
17 application is new, so you wouldn't have included it
18 had you written this report two years ago. So two
19 years from now there may be another drug that will
20 not be included in this report but which is relevant.

21 MEMBER OUHIB: Right. That's what I'm
22 getting at.

23 VICE CHAIRMAN METTER: They're not included
24 in this report. This is the current one, and these
25 are listed as -- and there's actually a little

1 explanation as to the rationale of how these interrupt
2 time frames were obtained.

3 MEMBER WEIL: If I may just respond, I
4 think what we're getting at here is that there should
5 be a statement perhaps in the report stating that, as
6 of this date, this is comprehensive but that if you're
7 reading it three years from now you should know that
8 there may be additional information that you need to
9 access.

10 VICE CHAIRMAN METTER: Okay. I
11 understand. Yes, we can add that.

12 CHAIRMAN PALESTRO: Any other questions or
13 comments from the committee? Questions or comments
14 from attendees in the room? Questions or comments
15 from anyone on the telephone lines?

16 All right. Then I believe it's time to act
17 on subcommittee's recommendation to accept the final
18 report. That's a motion, so can I have a second? Go
19 ahead.

20 MEMBER ENNIS: Is the subcommittee going
21 to ask NRC to do something with the report? We left
22 that hanging.

23 MR. BOLLOCK: So you have a report. The
24 subcommittee has a report, so you can vote on the
25 report and then you can separately give us a

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1 recommendation, vote on a recommendation to staff on
2 what you want us to do with it, as an option.

3 CHAIRMAN PALESTRO: Mr. Green?

4 MEMBER GREEN: I would move to approve the
5 report with the addition of a paragraph describing
6 that this is all the drugs approved at the time of
7 this authorship, that practitioners should evaluate
8 other resources for other nuclides and drugs that are
9 not currently listed. If there's that included, I
10 would be able to approving.

11 CHAIRMAN PALESTRO: I'm not going to object
12 to that, but I just find it confusing that if I don't
13 see something -- why do I need a statement to tell me
14 that what's in these pages is all that it's applicable
15 to? I mean, if there's another drug that's out there
16 and it's not on those pages, how would I presume to
17 extrapolate something from what's there? Do you
18 follow what I'm saying? If you got a list of drugs,
19 list of radiopharmaceuticals, and it gives you the
20 prescribed times of stopping breastfeeding, so why do
21 I need a statement to say that this is valid only for
22 the agents that are listed here?

23 MEMBER GREEN: Yes, it may be confusing.
24 I think some of the references are nuclide-specific,
25 but some are drug-specific. I-131 sodium iodide,

1 which is a different animal from I-131 iodohippurate
2 or I-131 MIBG. So there are references to nuclides
3 and others are chemical compounds associated with
4 that isotope, so there may be current isotopes with
5 new flavors, new drug compounds attached to that.

6 So I think there's some statement, and I'm
7 not sure what that statement should be, but I agree
8 with the two comments we've heard previously.

9 CHAIRMAN PALESTRO: Okay. Any other
10 comments? Well, we have a motion to approve the
11 report as written, presented I should say. Do we
12 have a second?

13 MEMBER SHEETZ: Second.

14 CHAIRMAN PALESTRO: Mr. Sheetz. All in
15 favor? Any opposed? And now Mr. Green or perhaps
16 it was Dr. Metter, I don't recall, suggested, once
17 the report was approved, to make a recommendation on
18 behalf of the committee to add a statement. All
19 right. So we can proceed with that, if we can develop
20 a formal statement. I'd like to do that now.

21 MEMBER GREEN: On the spot.

22 MR. BOLLOCK: It's a committee
23 deliberation, so this is, you know, we're in a public
24 setting right now. If we don't do it now and then
25 you'd have to come back and have another vote on it

1 later in a public setting.

2 MEMBER GREEN: Just off the top of my head?

3 MR. BOLLOCK: So we can give you time. You
4 can do it tomorrow.

5 MEMBER GREEN: Thank you.

6 MR. BOLLOCK: We'll give you a little bit
7 of time.

8 CHAIRMAN PALESTRO: Yes, I just don't want
9 to leave it hanging after the end of the meeting
10 because things like that disappear, so we can just
11 add that to the open forum tomorrow.

12 All right. Last item on today's agenda,
13 Dr. Suh is going to discuss the ACMUI comments on the
14 draft revision of the Leksell Gamma Knife Perfexion
15 and the Leksell Gamma Knife Icon licensing guidance.

16 MEMBER SUH: Thank you, Dr. Palestro. I
17 want to start out by thanking the subcommittee
18 members: Dr. Ron Ennis, Mr. Zoubir Ouhib, Ms. Megan
19 Shober, and Ms. Laura Weil. I also want to thank the
20 NRC staff resource, Ms. Sophie Holiday.

21 So the original subcommittee charge was to
22 propose the appropriate physical presence
23 requirements for the Leksell Gamma Knife Icon
24 radiosurgery unit. And just as an introduction for
25 the new committee members in the ACMUI, so there are

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1 different types of Leksell gamma knives, so there's
2 the Leksell Model B, C, and 4C. And for purposes of
3 this discussion, I'm going to group them altogether.
4 The gamma knife is a unit that allows high-dose, high-
5 precision radiation to be delivered to an
6 intracranial target, mostly used for malignant brain
7 tumors. It can also be used for benign brain tumors,
8 as well as vascular conditions and some functional
9 disorders such as trigeminal neuralgia.

10 The Model B, C, and 4C has 201 cobalt-60
11 sources which are stationary. There's external
12 helmets which are attached to the machine. These are
13 eight 14 to 18 millimeter commandeer helmets. The
14 Model B unit has manual trunions which are set by a
15 physician or medical physicist, whereas the Model C
16 and 4C is an automatic positioning system that does
17 not require manual manipulation of the X, Y, and Z
18 coordinates.

19 Next slide, please. The Gamma Knife
20 Perfexion (2006) uses, rather than 201 cobalt-60
21 sources, uses 192 cobalt-60 sources which move within
22 eight permanently-installed independent movable
23 sectors which are 4, 8, and 16 millimeter beams.
24 There's one body with different diameter of holes
25 which correspond to different positions of the

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1 sectors, and there's an automatic movement of the
2 robotic treatment table. So this is a different
3 design compared to the Model B, C, and 4C, and the
4 picture is shown there.

5 Next slide, please. In 2016, the Gamma
6 Knife Icon was developed. This also has 192 cobalt-
7 60 sources which move within the eight permanently-
8 installed independent moveable sectors which have the
9 4, 8, and 16 millimeter beams. Again, there's one
10 body with different size holes corresponding to
11 different positions of the sectors. They also have
12 an automated movement of the robotic treatment chart
13 table.

14 What's different about the Icon versus
15 Perfexion is outlined in blue. It has an integrated
16 stereotactic home beam CT image, which is shown there
17 in the lower right-hand picture. It also has an
18 online adaptive dose control and also allows for a
19 frameless mass base treatment. So I just wanted to
20 give you direction in terms of the various gamma
21 knives.

22 Next slide, please. So in terms of the
23 background of the current regulation, all Leksell
24 Gamma Knife procedures follow the physical presence
25 requirements outlined in 10 CFR Part 35.615(f)(3)

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1 that, "An authorized user," which was AU, " and an
2 authorized medical physicist," which is referred as
3 AMP, "are physically present throughout all
4 treatments involving the unit."

5 The NRC defines "physical presence" as a
6 distance "such that each can communicate with the
7 other within hearing distance of normal voice." So
8 Model B, C, and 4C are licensed under 10 CFR 35.600,
9 whereas the Perfexion and Icon are licensed under 10
10 CFR 35.1000.

11 In 2018, the subcommittee was asked to make
12 recommendations. And looking at the very low number
13 of reported medical events with the Perfexion which
14 total 12 from 2006 to 2012 and advances with the Icon
15 unit the subcommittee recommended that an authorized
16 user and authorized medical physicist be physically
17 present during all, during the initiation involving
18 all treatments involving the units, and this is for
19 the Icon system; the authorized medical physicist be
20 physically present throughout all patient treatments
21 involving the unit.

22 Next slide, please. In addition, one of
23 the modifications we suggested was that, in terms of
24 the physical presence requirements, that the current
25 physical presence for the requirements for the AU be

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1 modified by allowing the AU to be present within a
2 two-minute walk to the console area and immediately
3 available to come to the treatment room. In addition
4 to AU and AMP, we recommended as good medical practice
5 that appropriately-trained nursing or auxiliary staff
6 be present at the end of treatment to respond to any
7 immediate medical needs. And then, finally, at the
8 conclusion of treatment, the AU must be present at
9 the console to discuss any treatment or patient issues
10 with patient, physicist, and nurse.

11 So those are the recommendations of the
12 subcommittee report which was endorsed by the ACMUI
13 committee in February 2018.

14 The working group reviewed the
15 subcommittee's recommendations and reports and also
16 reviewed the comments submitted from Elekta, as well
17 as Michael Sheetz our current ACMUI radiation safety
18 officer. And the workgroup proposed revisions to the
19 recommendations that the subcommittee put forward on
20 February 2018.

21 So the working group and management were
22 not supportive of the two-minute walk as they felt
23 that this was very ambiguous. And they proposed that
24 the physical presence requirements be similar to that
25 of high-dose rate brachytherapy. In addition, they

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1 proposed the requirements include both the Perfexion
2 and Icon units. Since I outlined earlier, many
3 components of the Icon and Perfexion unit are similar.

4 Next slide, please. So the working group's
5 recommendations were the following: Number one, AU
6 and AMP be physically present during the initiation
7 of all patient treatments involving the Perfexion or
8 Icon unit. In addition the AMP and either an
9 authorized user or a physician under the supervision
10 of an authorized user who has been trained in the
11 operation and emergency response for the unit will be
12 physically present during continuation of all patient
13 treatment involving the Perfexion or Icon unit and
14 the authorized user will return to the Perfexion or
15 Icon unit console if there's an interruption of
16 treatment to evaluate the patient, to review any
17 information related to an abnormal situation, and to
18 ensure that the treatment is being delivered in
19 accordance with the treatment plan and written
20 directive prior to the re-initiation of the
21 treatment.

22 So the subcommittee reviewed the working
23 group's recommendations and these are our current
24 recommendations based on the review of the working
25 group's recommendations. We agree that an AU and AMP

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1 will be physically present during the initiation of
2 all patient treatments involving the Perfexion or
3 Icon unit.

4 In addition, we believe that the proposed
5 physical presence requirements is similar to that of
6 HDR brachytherapy. The subcommittee believes that
7 this definition is not ambiguous and will be easier
8 to enforce than the two-minute walk that was
9 originally proposed by the subcommittee in February
10 2018.

11 In addition, we agreed that the AU will
12 return to the Perfexion or Icon unit console if
13 there's an interruption of treatment. And one of the
14 changes with the workgroup recommendations versus
15 what we originally proposed to the subcommittee was
16 to incorporate both the Perfexion and Icon in this
17 recommendation. So since the Perfexion and Icon are
18 licensed under 10 CFR Part 35, Subpart K, 10 CFR
19 35.1000, and are mechanically similar to each other,
20 the subcommittee endorses a draft revision to the
21 Leksell Gamma Perfexion and Leksell Gamma Icon to
22 include both the physical presence requirements for
23 both units.

24 So last slide. Although the scope and
25 recommendations are different than the original ACMUI

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1 report from February 2018, we endorse the Leksell
2 Gamma Perfexion and Leksell Gamma Knife Icon
3 licensing guidance. We encourage licensees to
4 continue to audit and monitor their programs, to adopt
5 best practice including a high-liability system
6 approach to ensure quality and safety, and, finally,
7 the ACMUI and NRC review any negative trends that may
8 occur as a result of change in guidance.

9 I'll take any questions. And the next
10 slide is just the acronyms that were used as part of
11 this report. Thank you.

12 CHAIRMAN PALESTRO: Any questions or
13 comments from the subcommittee? Questions or
14 comments from the ACMUI? Mr. Sheetz?

15 MEMBER SHEETZ: I would like to thank the
16 ACMUI subcommittee and the NRC working group for
17 working together on this effort and arriving at this
18 final version for the physical presence requirements.
19 I think it will provide significant relief to
20 licensees for the authorized user, not having to be
21 there for very long treatments and also be, at the
22 same time provide, you know, equivalent patient
23 safety. Thank you.

24 CHAIRMAN PALESTRO: Any other comments or
25 questions from the committee? Comments or questions

1 from the attendees here in the room?

2 MS. TOMLINSON: Cindy Tomlinson with ASTRO.
3 Again, thank you, Chairman Palestro for allowing me
4 to provide this statement on behalf of ASTRO. We are
5 responding to the ACMUI's or I guess the
6 subcommittee's report. Because the NRC's working
7 group, their draft guidance is not public, our
8 comments reflect only the ACMUI subcommittee's review
9 and comments.

10 The safety records for both the Gamma Knife
11 Perfexion and Icon are excellent. Because of the
12 required training for physicians, physicists, and
13 therapists, the safety features embedded within the
14 machines, and, most importantly, because of
15 authorized user presence during the procedure.

16 Given that both the Perfexion and Icon use
17 high doses of radiation to treat cancer, the presence
18 of the AU is essential to ensure patient safety.
19 According to the subcommittee report the NRC's,
20 working group is proposed the following requirements
21 for both Perfexion and Icon. An authorized user and
22 an authorized user medical physicist will be
23 physically present during the initiation of all
24 patient treatments involving the Perfexion or Icon
25 unit.

1 An authorized user medical physicist and
2 either an authorized user or a physician under the
3 supervision of an authorized user who has been trained
4 in the operation emergency response for the unit will
5 physically, will be physically present during
6 continuation of all patient treatments involving the
7 Perfexion or Icon and an authorized user will return
8 to the Perfexion or Icon unit console, and an
9 authorized user will return to the Perfexion or Icon
10 unit console if there's an interruption of treatment
11 to evaluate the patient , to review any information
12 related to an abnormal situation, and to ensure that
13 the treatment is being delivered in accordance with
14 the treatment plan and written directive prior to re-
15 initiation of the treatment.

16 ASTRO is pleased with the direction of the
17 working group's proposed requirements. We think that
18 it has the potential to strike the appropriate balance
19 between safety and efficient medical practice and is
20 in line with ASTRO's position on physical presence
21 requirements for Gamma Knife.

22 We look forward to continuing to with the
23 ACMUI and the NRC on this issue. And, again, I will
24 send our written statement to your staff.

25 CHAIRMAN PALESTRO: Thank you. Any other

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1 comments or questions from the attendees in the room?

2 MS. LOHMAN: Yes. I'm Susan Lohman,
3 clinical applications manager for Elekta. And on
4 behalf of Elekta, we'd like to thank the opportunity
5 to engage both ACMUI and the NRC on this issue.

6 We believe the revised guidance is a step
7 in the right direction. However, we are wary about
8 the fact that HDR and Gamma Knife procedures are being
9 considered substantially similar for physical
10 presence requirements.

11 Once the revised guidance is issued, Elekta
12 would like to continue dialogue with the ACMUI and
13 NRC for further revision of the guidance. In the
14 meantime, thank you for your attention to this issue
15 and we appreciate and look forward to further
16 collaboration.

17 CHAIRMAN PALESTRO: Thank you. Any other
18 comments or questions from attendees here in the room?

19 MR. BOLLOCK: Hi, Dr. Palestro. This is
20 Doug Bollock, NRC. So a few of us in the NRC have
21 reviewed the workgroup's report and we just have, you
22 know, we have another final concurrence on the working
23 group's guidance. So there's not a question but more
24 of a philosophical thing that we're considering.

25 Icon and Perfexion is 35.1000 guidance.

1 The intent of anything that goes in 35.1000 guidance
2 will eventually go into the rule. So if these Gamma
3 Knives go into 35.600, what would that do for the
4 physical presence part of the rule? I'm not saying
5 it can't happen. So what are the differences? And
6 this is, I think there is, there are answers to this.
7 One of the differences with these units that make
8 them safer so that the, basically, the equivalent
9 level of safety is there with, essentially, a lowering
10 of physical presence requirements. I believe the
11 answer is there. I believe there is an answer. We
12 just need to, when we develop the guidance.

13 And I don't know if Sophie is going to
14 respond to me, but she just heard this from me
15 recently. And it's a question maybe Sophie can
16 consider answering. I just want a perspective from
17 the ACMUI on that because that is, that's going to be
18 important going forward, right? If this was brought
19 back into the rule, to keep a consistency amongst the
20 rule for other, you know, what about these units are
21 safer than the 35.600 units that you can have that
22 difference? I believe it's there. I'm just
23 wondering what your thoughts are, and I'll let Sophie
24 Holiday from my staff speak to this first.

25 MS. HOLIDAY: Hi, everybody. This is

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1 Sophie Holiday. Technically, from Doug Bollock's
2 branch, we're currently on detail to the Office of
3 Enforcement, but I was the NRC co-chair for the
4 working group that developed this draft revised
5 guidance.

6 So just one thing I want to clarify to start
7 off with is that, you know, you've heard comments in
8 here where the subcommittee supported the working
9 group's recommendations. ASTRO also came to the
10 microphone and said that they supported it. We heard
11 from Lohman.

12 Just to clarify, as Doug said, we have not
13 issued the final guidance yet. I'm actually still
14 in the process of resolving all of the comments that
15 I've received from the agreement states and NRC
16 regions relating to this guidance, so this is not to
17 say that this will be the final physical presence
18 requirements that come out from this guidance
19 document.

20 Second, to address what Doug said related
21 to possibly how this will affect if it's rolled into
22 rulemaking. During the spring 2018 meeting, one of
23 the items that we closed from the agenda was a very
24 longstanding item where the committee had asked NRC
25 to move the Perfexion from 1000 into 35.600.

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1 Comparatively, they also asked to move yttrium-90
2 microspheres brachytherapy to somewhere in the Part
3 35 regulations.

4 There was a lot of discussion between the
5 committee and staff related to the benefits of
6 pursuing those recommendations from the ACMUI. And
7 what ultimately came from the committee was that you
8 would close those items, as you guys were supportive
9 of keeping both the yttrium-90 microspheres
10 brachytherapy and the Perfexion and now Perfexion
11 Icon guidance in 35.1000 space because it allowed us
12 to be nimble to make these types of changes.

13 As you know, the yttrium-90 is on revision
14 9 currently, pursuing revision 10. But what Doug is
15 asking you to do is think about in the future if we
16 do move this to incorporate Perfexion and Icon unit
17 into the regulations under 35.600, which, as you know,
18 include all gamma stereotactic radiosurgery units.
19 We are aware of other gamma stereotactic radiosurgery
20 units that are on the horizon or currently approved
21 by the U.S. Food and Drug Administration. What is
22 it that we would be able to caveat in our regulations
23 or what would be the conditions that we could do in
24 order to allow such physical presence?

25 Ms. Lohman, I just want to address that we

1 are not saying that Gamma Knife treatment or Gamma
2 stereotactic radiosurgery treatment is similar to HDR
3 in any sense. We're just trying to draw the parallel
4 that there are physical presence requirements such as
5 this for the HDR unit. Currently, all Gamma
6 stereotactic radiosurgery units have to have both AU
7 and AMP, so, in order to draw that parallelism, that's
8 why we say this is what it is for HDR.

9 Okay. So I just wanted to offer those
10 comments. Thank you.

11 CHAIRMAN PALESTRO: Thank you. Any other
12 comments from attendees in the room? Comments or
13 questions from anyone on the telephone lines?

14 DR. TAPP: I guess I'll go back to Mr.
15 Bollock's question. This is Dr. Tapp with the NRC.
16 Sophie pointed out there are new emerging Gamma
17 stereotactic radiosurgery units coming out right now,
18 and the NRC has formed a working group with the
19 agreement states to start developing guidance for
20 these documents. And going back to Mr. Bollock's
21 comments was if the committee could comment on what
22 were some things that you see with the Perfexion Icon
23 that you thought were important that allowed to change
24 in the physical presence? Was it the imaging? I'd
25 get some comments on that.

1 So when I'm forming my physical presence or
2 the working group is forming the physical presence
3 requirements for these new units, we have some
4 guidance there.

5 CHAIRMAN PALESTRO: Mr. Sheetz?

6 MEMBER SHEETZ: I'd like to comment on Mr.
7 Bollock's question about the safety of the Icon and
8 Perfexion in relation to the other Gamma Knives. In
9 my experience, and we were the first licensee of a
10 Gamma Knife, the U unit, 1987. We've had every Gamma
11 Knife model, and we currently have an Icon and a
12 Perfexion.

13 The Perfexion and Icon are safer. There's
14 less intervention in setting up patient treatments.
15 There's no helmets. There's a lotless of micro-
16 switches and involvement for hands-on. So the Icon
17 and the Perfexion are much more automated in the
18 treatment process once the treatment plan has been
19 developed and it's imported into the treatment
20 console.

21 With respect to the Gamma Knife units that
22 are currently in 35.600, my perspective and my
23 experience with the Gamma Knife units is the proposed
24 physical presence requirements similar to the HDR
25 requirements would be adequate for those units also.

1 I've always been under the impression that the
2 physical presence requirements for the AU and AMP to
3 be physically present through the entire Gamma Knife
4 treatment was excessive, and I'm comparing that to
5 HDR. HDR is a much more complex procedure. There
6 are many more things that can go wrong with the device
7 with applicators.

8 So to allow the AU to leave and another
9 physician be present, and I'm not against that
10 physical presence, I'm just saying to be more
11 stringent on Gamma Knife. It really was not, in my
12 perspective, appropriate or risk-based. Thank you.

13 CHAIRMAN PALESTRO: Any other comments or
14 questions? Ms. Shober?

15 MEMBER SHOBER: This is Megan Shober. I
16 was just wondering how many of the older style Gamma
17 Knife units are still in the United States? Are
18 there still a lot, or are there basically no old
19 school ones left?

20 MS. LOHMAN: This is Susan Lohman from
21 Elekta. There are approximately 14 of the older
22 style Gamma Knife units still in use in the U.S.

23 MEMBER SHOBER: Okay. And can you comment
24 about, like, if you add Perfexion and Icon together,
25 how many are those?

1 MS. LOHMAN: In total, there are
2 approximately 135 --

3 MEMBER SHOBER: Okay. So we're down to
4 like --

5 MS. LOHMAN: -- United States.

6 MEMBER SHOBER: Yes, we're down to, like,
7 ten percent of the older 35.600.

8 MS. LOHMAN: Approximately, yes.

9 MEMBER SHOBER: Okay. That's helpful.
10 Thank you.

11 CHAIRMAN PALESTRO: Dr. Martin?

12 MEMBER MARTIN: There's one -- I'm
13 following up on the question before about the other
14 brands that are coming in, but maybe this is going to
15 be confusion because I have one of the other brands
16 c coming in down the street from our office and I had
17 a question of what they were going to do and how they
18 were going to apply the on-site rules because it is
19 definitely going to be operated by a very economical
20 radiation oncologist who will not be there most of
21 the time is my understanding, and that's why I was
22 like what kind of rules are we applying to these other
23 brands?

24 CHAIRMAN PALESTRO: Mr. Bollock?

25 MR. BOLLOCK: I can't speak for California.

1 We just don't know that. I don't know that answer.
2 But as far as, you know, the NRC's, we call it the
3 35.1000 licensing guidance. What it really is is we
4 are developing specific license conditions necessary
5 for the safe use of emerging medical technology that
6 doesn't fall under the other subsections of Part 35.
7 And those are specific to NRC licensees, and the
8 agreement states, for the NRC to agreement states,
9 there are certain levels of regulations that states
10 have to follow based on the compatibility and the
11 sections of the regulations. 35.1000 is a
12 compatibility D, which means that the agreement
13 states do not have to follow what we say in the
14 regulations. They can create their own licensing
15 guidance, licensing conditions, and license --

16 MEMBER MARTIN: I apologize. I forgot that
17 it wasn't yours.

18 MR. BOLLOCK: It's quite all right.

19 CHAIRMAN PALESTRO: Any other comments or
20 questions?

21 MEMBER SUH: So I just want to just
22 emphasize what Mr. Michael Sheetz said. So there are
23 a fundamental difference between the Model B, C, and
24 4C versus the Perfexion and the Icon system. I've
25 had 21 years experience with the Model B, C, 4C

1 Perfexion and Icon. I fully agree with his
2 assessment. The Icon and Perfexion is safer than the
3 Model B, C, or 4C, so I feel very comfortable in
4 lumping those two units together in terms of any
5 changes we make in terms of physical presence
6 requirements.

7 CHAIRMAN PALESTRO: Mr. Ouhib?

8 MEMBER OUHIB: Yes. I just have a
9 question. If you could recall the fact that you have
10 used all these basically, looking back, how often did
11 you have to actually intervene in these different
12 ones and somebody else couldn't do what needed to be
13 done?

14 MEMBER SUH: So I've had two patients seize
15 on the table at 11:00 at night. So, yes, it was
16 important that I was there. One of the changes that
17 we have made with our practice is that we put a pulse
18 oximeter on every single Gamma Knife patient because
19 when you have a long treatment you monitor them
20 through cameras, you hope the patient is doing okay.
21 The last thing I want to do is have a patient come
22 out of the machine and they were not okay.

23 So we have -- and it goes back to, I think,
24 when you talk about training and experience, the more
25 these that you do, and I've had the opportunity to do

1 thousands of these cases, you just get an inherent
2 sense of what you should and shouldn't do. So that's
3 why I'm just a big believer that when it comes to
4 training and experience -- one of the things you said,
5 to Elekta's credit, when it comes to the Gamma Knife,
6 it's very regimented in terms of the training and
7 experience that's required. So as these units, you
8 went from a Model C to a 4C to a Perfexion to an Icon,
9 you go to centers to learn how to use that device,
10 which I think is a very good model of how do you
11 understand it.

12 And, again, the machines themselves, are
13 there big differences? You could argue there's not
14 big differences, but that extra training is very
15 helpful.

16 CHAIRMAN PALESTRO: Any other questions or
17 comments? Mr. Bollock, does the committee needs to
18 approve the report, endorse the report?

19 MR. BOLLOCK: Yes.

20 MS. HOLIDAY: Dr. Palestro, this is Sophie
21 again. Before the committee makes a motion to vote
22 on the report, if I can kind of respond to what Mr.
23 Ouhib and Dr. Suh just discussed about how often he's
24 had to go back to respond for an emergency. If you'll
25 look up on the slide, number two, while it doesn't

1 say the AU necessarily, it says an AU or a physician
2 under the supervision of an AU who has been trained
3 in the operation and emergency response for the unit.
4 So this is a physician who should be able to handle
5 a medical emergency, but they have the necessary
6 training to know how to operate and perform in an
7 emergency response capacity for the unit.

8 So just to remind the committee about that.
9 Thank you.

10 CHAIRMAN PALESTRO: Mr. Ouhib?

11 MEMBER OUHIB: Yes, the only reason I asked
12 that question, I just wanted to see some of the
13 differences between these units and some might be
14 requiring more attention than others based on where
15 the technology is basically.

16 CHAIRMAN PALESTRO: Mr. Green?

17 MEMBER GREEN: Is there a way to, this is
18 trying to move, I think, from a 35.1000 into a 35.600
19 for all these devices and capture future devices.
20 Rather than calling them them out by model numbers,
21 is there a way to describe attributes of these devices
22 that would allow you to designate certain physical
23 presence requirements without naming names and model
24 numbers?

25 MR. BOLLOCK: That's exactly it. And we

1 want to be able to not have it say, if you have an
2 Icon or Perfexion you get this and if you have
3 everything else you get 600. We try to be consistent.
4 We do everything we can to be consistent in our
5 regulations and consistent with our licensing, and
6 that consistency is built on the safety of it. That's
7 why I brought up I believe this is there. I mean,
8 from early discussions with Sophie and other, you
9 know, my understanding of these devices, I think they
10 have these features that help do that. And that's,
11 you know, we want to make sure, and this will be for
12 the working group to make sure if I am comfortable
13 with incurring with it and getting it out, that that
14 is clear because that's what will make, that's what
15 will carry that consistency across for any of these
16 Gamma stereotactic radiotherapy units, right? So we
17 can be consistent, so Sophie's group is looking at it
18 the same way as Dr. Tapp's group.

19 That's what, that's all we're trying to
20 get, so that's exactly the point. I think it is
21 there. It's just, you know, one of those features,
22 and I believe it's there but we just need to be
23 consistent with what those are. If you have these
24 types of, if you have this feature, this feature,
25 this feature, this feature, you can do, if we're going

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1 to have separate physical presence requirements these
2 are the things that make you do that.

3 And I understand Mr. Sheetz's point, as I
4 take it -- I don't want to put words in your mouth -
5 - is all the Gamma stereotactic units should have
6 something -- you don't agree or you think it's overly
7 burdensome with the current 600 requirements for
8 physical presence; is that correct?

9 MEMBER SHEETZ: That is correct.

10 MR. BOLLOCK: Okay. And that's a fair
11 enough point. For us, if we are going to make it
12 different, it can't, that's essentially what we've
13 been doing is changing all the rules just for these
14 two because they're new. It's not because they're
15 new, it's because they have other features or we'd
16 have to go back through a rulemaking process. We
17 have to be consistent in what we do.

18 CHAIRMAN PALESTRO: Any other comments or
19 questions? Mr. Sheetz?

20 MEMBER SHEETZ: Yes. I guess I would like
21 to make sure I understand correctly. If you're going
22 to move the Perfection and Icon back into 35.600, that
23 would require --

24 MR. BOLLOCK: It would require a
25 rulemaking, and then that would be the opportunity to

1 --

2 MEMBER SHEETZ: And so you would have to
3 eliminate a lot of the prescriptive safety procedures
4 and spot checks and so forth that are currently in
5 there.

6 MR. BOLLOCK: That's exactly what we --

7 MEMBER SHEETZ: And then you would have to
8 account for all the new types of Gamma Knives coming
9 down the line and what they will do.

10 MR. BOLLOCK: Right. We can't say --

11 MEMBER SHEETZ: I guess my recommendation
12 --

13 MR. BOLLOCK: -- and different things like
14 that and then have it cover all the units that are
15 out there.

16 MEMBER SHEETZ: I guess I'm a fan of
17 35.1000, and I think that would be very challenging
18 to come up with a useful set of regulations in 35.600
19 to cover all current and future Gamma Knife
20 stereotactic units.

21 MR. BOLLOCK: And that would be the goal.
22 That would be --

23 MEMBER SHEETZ: Please don't put me on the
24 subcommittee.

25 MR. BOLLOCK: That would be the goal of any

1 changes to 35.600 is to make it not so specific to
2 make it be able to account for all the Gamma
3 stereotactic radiotherapies, not any specifics. And
4 there are specifics. There are differences, and it's
5 clear and there's a basis for that. That is all.

6 CHAIRMAN PALESTRO: Any other comments or
7 questions? Ms. Holiday?

8 MS. HOLIDAY: So because Mr. Sheetz just
9 mentioned my favorite word, subcommittee, might it be
10 a suggestion, since this is a question that Mr.
11 Bollock has posed to the committee about what exactly
12 would it be that you believe our physical presence
13 requirements should be so that it can apply to all
14 Gamma Stereotactic radiosurgery units? Should the
15 ACMUI consider forming a subcommittee to review this
16 question? Obviously, we don't know the answer.
17 Similar to a tailored T&E approach, should there be
18 a subcommittee to look at this as well? So that when
19 staff is ready to pursue this in future rulemaking
20 that we already have the committee's position noted
21 on the record.

22 CHAIRMAN PALESTRO: Okay. Comments or
23 questions on that?

24 MR. BOLLOCK: That would be at the
25 discretion of the -- this is Doug Bollock. That

1 would be at the discretion of the committee. If you
2 feel it's important enough to review now and form a
3 subcommittee, that is well within your rights and
4 purviews.

5 CHAIRMAN PALESTRO: Ms. Holiday, let me ask
6 you, is this something that would start now or is
7 this established in a subcommittee for the future?

8 MS. HOLIDAY: As Mr. Bollock said, it's up
9 to your discretion. For the purposes of what Dr.
10 Suh's subcommittee did, that is going to affect the
11 existing 35.1000 guidance. That's staying in 35.1000
12 for now because we're very far away from rulemaking.

13 So as the chair of the committee, it's your
14 prerogative when you would like to start that
15 subcommittee, if you start it at all. I just wanted
16 to throw that out as an item for consideration.

17 CHAIRMAN PALESTRO: Okay. I think I'm
18 going to defer on that for a moment until I've had
19 time to think about it a little bit and maybe discuss
20 it more.

21 MS. HOLIDAY: Absolutely.

22 CHAIRMAN PALESTRO: Thank you.

23 MS. DIMMICK: So if I could add as you
24 think about it, the other value that it could have is
25 not just for a rulemaking but for future 35.1000

1 guidance documents for different GSR devices. The
2 current working group is actually working on two
3 different, very different GSR devices and the working
4 group is going to have to address physical presence
5 in those, and they'll need to have an idea of will
6 they need, can they apply a criteria similar to what
7 the Perfexion/Icon working group is proposing for
8 physical presence or will they need to follow the
9 rule?

10 So I guess, going forward, in terms of
11 thinking of what safety barriers do the devices
12 provide where there could be a different physical
13 presence requirement than what is in the rule. So
14 it's not just for rulemaking. It could be for future
15 guidance documents, as well, for GSR devices.

16 CHAIRMAN PALESTRO: All right. Thank you.
17 As I said, I want to think about it a little bit and
18 I want to go over the number of subcommittees that we
19 have and do my best to avoid overloading the members
20 of the committee, the ACMUI, with responsibilities on
21 multiple subcommittees. I just can't think of it off
22 the top of my head.

23 Any other comments or questions? All
24 right. there's a motion to approve Dr. Suh's report,
25 the subcommittee's report. Is there a second?

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1 MEMBER SHEETZ: Second.

2 CHAIRMAN PALESTRO: Sheetz. Any further
3 discussion? All in favor? Any opposed? Approved.

4 Mr. Bollock any other business that we need
5 to address today?

6 MR. BOLLOCK: No, that is it.

7 CHAIRMAN PALESTRO: Ms. Dimmick?

8 MS. DIMMICK: At some point, we wanted to
9 come back to the charge for the Medical Event
10 Subcommittee, so if we could try to phrase that charge
11 that would be great. Thank you.

12 CHAIRMAN PALESTRO: Dr. Ennis?

13 MEMBER ENNIS: I'll give it a try. The
14 subcommittee will review the appropriateness of the
15 required elements of medical event reporting, the
16 adherence to these requirements, and recommend
17 actions to improve reporting.

18 CHAIRMAN PALESTRO: That's certainly
19 acceptable to me, and we already have the members of
20 the subcommittee.

21 MEMBER ENNIS: We do.

22 CHAIRMAN PALESTRO: And you will chair.

23 MEMBER ENNIS: I will.

24 CHAIRMAN PALESTRO: All right. Staff
25 liaison?

1 MR. BOLLOCK: I got a volunteer. Ms.
2 Dimmick, the medical team leader, will be the staff
3 resource for that.

4 CHAIRMAN PALESTRO: Okay. Ms. Dimmick
5 will be staff resource. Thank you very much. All
6 right. Any other business? All right. Then we're
7 adjourned until 8:30 tomorrow morning. Thank you
8 all.

9 (Whereupon, the foregoing matter went off
10 the record at 4:48 p.m.)

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