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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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FALL 2018 MEETING

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THURSDAY,

SEPTEMBER 20, 2018

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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.

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

AGENDA

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

(11:01 a.m.)

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

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

My name is Doug Bollock, I'm the Branch Chief of the Medical Safety and Events Assessment Branch and I have been designated as the federal officer for this Advisory Committee in accordance with 10 CFR Part 7.11.

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

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

others.

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

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

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

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

CHAIRMAN PALESTRO: Here.

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

VICE CHAIRMAN METTER: Here.

MR. BOLLOCK: Thank you. Dr. Vasken

Dilsizian?

MEMBER DILSIZIAN: Here.

MR. BOLLOCK: Thank you. Dr. Ronald Ennis?

MEMBER ENNIS: Here.

MR. BOLLOCK: Thank you. Mr. Richard Green?

MEMBER GREEN: Here.

MR. BOLLOCK: Thank you. Dr. Melissa Martin?

MEMBER MARTIN: Here.

MR. BOLLOCK: Thank you. Dr. Michael O'Hara?

MEMBER O'HARA: Here.

MR. BOLLOCK: Thank you. Mr. Zoubir Ouhib?

MEMBER OUHIB: Here.

MR. BOLLOCK: Thank you. Dr. Robert Schleipman?

MEMBER SCHLEIPMAN: Here.

MR. BOLLOCK: Thank you. Mr. Michael Sheetz?

MEMBER SHEETZ: Here.

MR. BOLLOCK: Thank you. Ms. Megan Shober?

MEMBER SHOBER: Here.

MR. BOLLOCK: Thank you. D. John Suh?

MEMBER SUH: Here.

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

MEMBER WEIL: Here.

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

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

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

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

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

meeting are available at the NRC's public website.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

frame.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MS. DIMMICK: Somebody needs to second it.

MEMBER WEIL: Second.

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

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

licensees between October and March.

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

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

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

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

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

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

MEMBER ENNIS: A Comment.

MS. DIMMICK: Sure.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MS. DIMMICK: If I could offer a little bit

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

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

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

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

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

MR. BOLLOCK: Well, the states are assessed

every three years.

MS. DIMMICK: Three years.

MR. BOLLOCK: Typically --

MS. DIMMICK: Four years.

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

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

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

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

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

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

SA-300?

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

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

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

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

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

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

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

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

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

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

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

I think we have been doing that the past

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

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

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

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

CHAIRMAN PALESTRO: Any comments on that?

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

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

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

MEMBER ENNIS: I move that we close this item.

CHAIRMAN PALESTRO: Second?

MEMBER SUH: John Suh, second.

CHAIRMAN PALESTRO: All in favor?

(Chorus of ayes)

CHAIRMAN PALESTRO: Any opposed?

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

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

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

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

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

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

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

MS. DIMMICK: Which number?

VICE CHAIRMAN METTER: Number 1.

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

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

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

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

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

CHAIRMAN PALESTRO: Question?

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

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

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

reflected. Unless, right.

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

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

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

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

(Laughter)

PARTICIPANT: Second.

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

(Chorus of ayes)

MS. DIMMICK: Okay. Just going through formalities.

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

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

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

CHAIRMAN PALESTRO: Any discussion or comments on that?

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

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

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

(Off microphone comments)

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

CHAIRMAN PALESTRO: Okay.

MS. DIMMICK: Yes.

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

MR. BOLLOCK: Yes.

CHAIRMAN PALESTRO: All right. Okay, fine.

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

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

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

And you're also going to hear about NRCs outreach plan by Maryann Ayoade later in this meeting. So I, so could there be a motion to close this

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

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

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

CHAIRMAN PALESTRO: Second?

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

CHAIRMAN PALESTRO: Any discussion? All in favor?

(Chorus of ayes)

CHAIRMAN PALESTRO: Any opposed?

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

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

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

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

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

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

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

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

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

A consistency in the quality of the data

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIRMAN PALESTRO: It is open for

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

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

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

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

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

MEMBER ENNIS: Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Because by evaluating these medical events

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

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

CHAIRMAN PALESTRO: Other opinions?

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

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

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

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

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

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

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

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

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

MEMBER ENNIS: Six.

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

(Off microphone comment)

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

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

MEMBER ENNIS: Okay.

CHAIRMAN PALESTRO: So the Committee can choose --

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

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

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

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

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

MEMBER WEIL: Yes, that's fine.

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

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

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

MEMBER OUHIB: I'd be happy to.

MEMBER ENNIS: Megan?

MEMBER SHOBER: Yes.

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

MEMBER WEIL: Only about a year though.

MEMBER ENNIS: Oh, a year is good enough. Will you be willing to serve?

(Laughter)

MEMBER WEIL: Yes.

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

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

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

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

MEMBER MARTIN: I'll volunteer.

MEMBER ENNIS: Excellent.

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

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

MEMBER DILSIZIAN: I'll volunteer.

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

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

PARTICIPANT: That would be six.

(Off microphone comment)

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

(Off microphone comment)

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

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

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

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

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

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

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

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

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

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

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

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

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

So, now going through the data for the three

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

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

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

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

prevented by a ''time out.''

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

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

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

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

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

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

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

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

Again, looking in review, ''time outs'' likely impact, could have an impact in about 15 percent. Next slide.

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

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

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

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

This is for SirSpheres, the prior slide was for Therasphere~~s~~, not demonstrably different, pretty similar patterns of what's common and what are the issues. Next slide.

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

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

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

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

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

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

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

And so again, some very specific things

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

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

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

And then when you're dealing with a

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

So what could NRC do to affect this or promulgate this? We thought that, and our subcommittee recommends, that NRC consider issuing an information notice alerting authorized users to these things and to the recommendations of the subcommittee about ways to prevent them in the future. Thank you. Committee members, anyone want to add to, if I left out any important things or just any other comments?

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

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

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

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

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

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

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

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

CHAIRMAN PALESTRO: Dr. Dilsizian?

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

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

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

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

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

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

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

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

CHAIRMAN PALESTRO: Other comments or questions?

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

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

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

CHAIRMAN PALESTRO: Mr. Sheetz?

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

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

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

reason for the medical event.

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

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

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

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

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

CHAIRMAN PALESTRO: Other comments or questions from the committee?

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

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

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

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

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

CHAIRMAN PALESTRO: Mr. Green?

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

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professional society.

CHAIRMAN PALESTRO: Mr. Ouhib?

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

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

CHAIRMAN PALESTRO: Dr. Ennis?

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

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

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

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

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

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

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

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

CHAIRMAN PALESTRO: Dr. Metter?

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

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

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

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

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

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

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

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

facility?

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

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

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

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

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

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

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

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

DR. HOWE: My perspective is that your

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

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

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

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

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

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

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

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

MR. BOLLOCK: Yes, that's correct.

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

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

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

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

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

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

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

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

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

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

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

brachytherapy seeds and so was discarded with the shipping box.

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

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

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

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

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

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

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

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

For personnel overexposures, there were two overexposures to personnel from PET isotope radiopharmaceutical production. These were in commercial radiopharmacies, one resulting in an extremity dose of 510 millisieverts and the other with a whole-body dose of 110 millisieverts.

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

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

There is no standard reporting requirement

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

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

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

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

I think Pennsylvania has a model landfill

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

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

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

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

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

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

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

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

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

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

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

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

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

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

do a whole lot.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

77 patients would have not been affected by that.

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

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

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

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

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

The summary of feedback is here for the

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

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

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

happen?

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

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

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

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

And last, when having two different sets of

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

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

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

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

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

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

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

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

very helpful. Next slide, please.

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

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

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

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

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

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

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

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

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

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

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

CHAIRMAN PALESTRO: Dr. Suh?

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

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

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

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

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

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

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

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

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

MR. BOLLOCK: No.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Next slide. The NRC staff conclusion after

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

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

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

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

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

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

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

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

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

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

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

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

And these are the acronyms we used. Thank you.

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

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

VICE CHAIRMAN METTER: Okay. So first of

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

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

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

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

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

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

MEMBER DILSIZIAN: In general, the way we

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

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

Any other comments or questions? Mr. Green?

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

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

MEMBER GREEN: I'm licensed. I have a

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

CHAIRMAN PALESTRO: Mr. Ouhib?

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

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

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

CHAIRMAN PALESTRO: Any other comments? Dr. Ennis?

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

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

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

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

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

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

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

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

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

CHAIRMAN PALESTRO: Dr. Suh, question for

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

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

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

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

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

CHAIRMAN PALESTRO: Other comments or questions?

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

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

CHAIRMAN PALESTRO: Mr. Sheetz?

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

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

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

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

CHAIRMAN PALESTRO: Dr. Martin?

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

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

CHAIRMAN PALESTRO: Mr. Ouhib?

MEMBER OUHIB: Yes. And I think the other

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

CHAIRMAN PALESTRO: Any other comments?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIRMAN PALESTRO: Thank you. Any other

comments from attendees?

DR. GHESANI: Yes. This is Munir Ghesani? Can you hear me? Hello?

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

DR. GHESANI: Okay.

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

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

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

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

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

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

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

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

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

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

irrational.

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

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

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

patient advocates.

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

Thank you for your attention.

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

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

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

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

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

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

So I appreciate your time. Thank you.

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

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

CHAIRMAN PALESTRO: Yes, we can. Thank you.

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

Nuclear Regulatory Commission's requirements.

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

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

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

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

complications?

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

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

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

MEMBER ENNIS: I just want to thank --

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

DR. RAZMARIA: Aria.

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

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

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

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

Another thing would be let's say I learn

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

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

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

We're going to continue now with the

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

patient access.

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

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

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

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

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

forward.

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

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

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

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

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

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

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

MR. BOLLOCK: And Mr. Guastella thanked us.

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

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

CHAIRMAN PALESTRO: Dr. Martin?

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

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

CHAIRMAN PALESTRO: Any comments or questions from anyone on the telephone lines? Any other comments or questions from anyone? All right. Thank you, Ms. Ayoade.

Now we'll move on to some lighter fare.

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

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

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

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

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

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

Comments or questions from the committee? Mr. Green?

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

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

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

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

CHAIRMAN PALESTRO: Dr. Dilsizian.

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

But I think there were so many questions.

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

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

All right. Mr. Bollock?

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

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

CHAIRMAN PALESTRO: Dr. Metter?

VICE CHAIRMAN METTER: Yes, and thank you

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

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

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

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

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

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

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

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

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

cessation of nursing or breastfeeding.

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

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

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

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

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

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

So let's look at this external exposure.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

VICE CHAIRMAN METTER: I-131. That would

be for therapeutic or diagnostic, correct.

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

VICE CHAIRMAN METTER: Correct, correct.

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

VICE CHAIRMAN METTER: Okay. I'm sorry.

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

VICE CHAIRMAN METTER: Right. The breastfeeding interrupt time frame was the time that's listed, correct. Thank you for the clarification. CHAIRMAN PALESTRO: Any other questions or comments from the committee? Mr. Green?

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

CHAIRMAN PALESTRO: Mr. Bollock?

MR. BOLLOCK: So the committee can recommend to us how -- I mean, once the report is 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

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

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

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

CHAIRMAN PALESTRO: Ms. Shober?

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

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

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

MEMBER SHOBER: It will take care of that?

MR. BOLLOCK: Yes. For clarification.

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

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

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

MEMBER OUHIB: Right.

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

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

VICE CHAIRMAN METTER: Correct.

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

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

MEMBER OUHIB: Okay.

CHAIRMAN PALESTRO: Ms. Weil?

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

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

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

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

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

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

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

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

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

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

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

CHAIRMAN PALESTRO: Mr. Green?

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

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

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

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

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

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

MEMBER SHEETZ: Second.

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

MEMBER GREEN: On the spot.

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

later in a public setting.

MEMBER GREEN: Just off the top of my head?

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

MEMBER GREEN: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

from the attendees here in the room?

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

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

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

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

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

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

CHAIRMAN PALESTRO: Thank you. Any other

comments or questions from the attendees in the room?

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

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

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

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

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

Icon and Perfexion is 35.1000 guidance.

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

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

MS. HOLIDAY: Hi, everybody. This is

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

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

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

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

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

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

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

Ms. Lohman, I just want to address that we

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

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

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

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

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

CHAIRMAN PALESTRO: Mr. Sheetz?

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

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

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

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

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

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

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

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

MEMBER SHOBER: Okay. And can you comment about, like, if you add Perfexion and Icon together, how many are those?

MS. LOHMAN: In total, there are approximately 135 --

MEMBER SHOBER: Okay. So we're down to like --

MS. LOHMAN: -- United States.

MEMBER SHOBER: Yes, we're down to, like, ten percent of the older 35.600.

MS. LOHMAN: Approximately, yes.

MEMBER SHOBER: Okay. That's helpful. Thank you.

CHAIRMAN PALESTRO: Dr. Martin?

MEMBER MARTIN: There's one -- I'm following up on the question before about the other brands that are coming in, but maybe this is going to be confusion because I have one of the other brands c coming in down the street from our office and I had a question of what they were going to do and how they were going to apply the on-site rules because it is definitely going to be operated by a very economical radiation oncologist who will not be there most of the time is my understanding, and that's why I was like what kind of rules are we applying to these other brands?

CHAIRMAN PALESTRO: Mr. Bollock?

MR. BOLLOCK: I can't speak for California.

We just don't know that. I don't know that answer. But as far as, you know, the NRC's, we call it the 35.1000 licensing guidance. What it really is is we are developing specific license conditions necessary for the safe use of emerging medical technology that doesn't fall under the other subsections of Part 35. And those are specific to NRC licensees, and the agreement states, for the NRC to agreement states, there are certain levels of regulations that states have to follow based on the compatibility and the sections of the regulations. 35.1000 is a compatibility D, which means that the agreement states do not have to follow what we say in the regulations. They can create their own licensing guidance, licensing conditions, and license --

MEMBER MARTIN: I apologize. I forgot that it wasn't yours.

MR. BOLLOCK: It's quite all right.

CHAIRMAN PALESTRO: Any other comments or questions?

MEMBER SUH: So I just want to just emphasize what Mr. Michael Sheetz said. So there are a fundamental difference between the Model B, C, and 4C versus the Perfexion and the Icon system. I've had 21 years experience with the Model B, C, 4C

Perfexion and Icon. I fully agree with his assessment. The Icon and Perfexion is safer than the Model B, C, or 4C, so I feel very comfortable in lumping those two units together in terms of any changes we make in terms of physical presence requirements.

CHAIRMAN PALESTRO: Mr. Ouhib?

MEMBER OUHIB: Yes. I just have a question. If you could recall the fact that you have used all these basically, looking back, how often did you have to actually intervene in these different ones and somebody else couldn't do what needed to be done?

MEMBER SUH: So I've had two patients seize on the table at 11:00 at night. So, yes, it was important that I was there. One of the changes that we have made with our practice is that we put a pulse oximeter on every single Gamma Knife patient because when you have a long treatment you monitor them through cameras, you hope the patient is doing okay. The last thing I want to do is have a patient come out of the machine and they were not okay.

So we have -- and it goes back to, I think, when you talk about training and experience, the more these that you do, and I've had the opportunity to do

thousands of these cases, you just get an inherent sense of what you should and shouldn't do. So that's why I'm just a big believer that when it comes to training and experience -- one of the things you said, to Elekta's credit, when it comes to the Gamma Knife, it's very regimented in terms of the training and experience that's required. So as these units, you went from a Model C to a 4C to a Perfexion to an Icon, you go to centers to learn how to use that device, which I think is a very good model of how do you understand it.

And, again, the machines themselves, are there big differences? You could argue there's not big differences, but that extra training is very helpful.

CHAIRMAN PALESTRO: Any other questions or comments? Mr. Bollock, does the committee needs to approve the report, endorse the report?

MR. BOLLOCK: Yes.

MS. HOLIDAY: Dr. Palestro, this is Sophie again. Before the committee makes a motion to vote on the report, if I can kind of respond to what Mr. Ouhib and Dr. Suh just discussed about how often he's had to go back to respond for an emergency. If you'll look up on the slide, number two, while it doesn't

say the AU necessarily, it says an AU or a physician under the supervision of an AU who has been trained in the operation and emergency response for the unit. So this is a physician who should be able to handle a medical emergency, but they have the necessary training to know how to operate and perform in an emergency response capacity for the unit.

So just to remind the committee about that. Thank you.

CHAIRMAN PALESTRO: Mr. Ouhib?

MEMBER OUHIB: Yes, the only reason I asked that question, I just wanted to see some of the differences between these units and some might be requiring more attention than others based on where the technology is basically.

CHAIRMAN PALESTRO: Mr. Green?

MEMBER GREEN: Is there a way to, this is trying to move, I think, from a 35.1000 into a 35.600 for all these devices and capture future devices. Rather than calling them them out by model numbers, is there a way to describe attributes of these devices that would allow you to designate certain physical presence requirements without naming names and model numbers?

MR. BOLLOCK: That's exactly it. And we

want to be able to not have it say, if you have an Icon or Perfexion you get this and if you have everything else you get 600. We try to be consistent. We do everything we can to be consistent in our regulations and consistent with our licensing, and that consistency is built on the safety of it. That's why I brought up I believe this is there. I mean, from early discussions with Sophie and other, you know, my understanding of these devices, I think they have these features that help do that. And that's, you know, we want to make sure, and this will be for the working group to make sure if I am comfortable with incurring with it and getting it out, that that is clear because that's what will make, that's what will carry that consistency across for any of these Gamma stereotactic radiotherapy units, right? So we can be consistent, so Sophie's group is looking at it the same way as Dr. Tapp's group.

That's what, that's all we're trying to get, so that's exactly the point. I think it is there. It's just, you know, one of those features, and I believe it's there but we just need to be consistent with what those are. If you have these types of, if you have this feature, this feature, this feature, this feature, you can do, if we're going

to have separate physical presence requirements these are the things that make you do that.

And I understand Mr. Sheetz's point, as I take it -- I don't want to put words in your mouth -- is all the Gamma stereotactic units should have something -- you don't agree or you think it's overly burdensome with the current 600 requirements for physical presence; is that correct?

MEMBER SHEETZ: That is correct.

MR. BOLLOCK: Okay. And that's a fair enough point. For us, if we are going to make it different, it can't, that's essentially what we've been doing is changing all the rules just for these two because they're new. It's not because they're new, it's because they have other features or we'd have to go back through a rulemaking process. We have to be consistent in what we do.

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

MEMBER SHEETZ: Yes. I guess I would like to make sure I understand correctly. If you're going to move the Perfexion and Icon back into 35.600, that would require --

MR. BOLLOCK: It would require a rulemaking, and then that would be the opportunity to

--

MEMBER SHEETZ: And so you would have to eliminate a lot of the prescriptive safety procedures and spot checks and so forth that are currently in there.

MR. BOLLOCK: That's exactly what we --

MEMBER SHEETZ: And then you would have to account for all the new types of Gamma Knifes coming down the line and what they will do.

MR. BOLLOCK: Right. We can't say --

MEMBER SHEETZ: I guess my recommendation --

MR. BOLLOCK: -- and different things like that and then have it cover all the units that are out there.

MEMBER SHEETZ: I guess I'm a fan of 35.1000, and I think that would be very challenging to come up with a useful set of regulations in 35.600 to cover all current and future Gamma Knife stereotactic units.

MR. BOLLOCK: And that would be the goal. That would be --

MEMBER SHEETZ: Please don't put me on the subcommittee.

MR. BOLLOCK: That would be the goal of any

changes to 35.600 is to make it not so specific to make it be able to account for all the Gamma stereotactic radiotherapies, not any specifics. And there are specifics. There are differences, and it's clear and there's a basis for that. That is all.

CHAIRMAN PALESTRO: Any other comments or questions? Ms. Holiday?

MS. HOLIDAY: So because Mr. Sheetz just mentioned my favorite word, subcommittee, might it be a suggestion, since this is a question that Mr. Bollock has posed to the committee about what exactly would it be that you believe our physical presence requirements should be so that it can apply to all Gamma Stereotactic radiosurgery units? Should the ACMUI consider forming a subcommittee to review this question? Obviously, we don't know the answer. Similar to a tailored T&E approach, should there be a subcommittee to look at this as well? So that when staff is ready to pursue this in future rulemaking that we already have the committee's position noted on the record.

CHAIRMAN PALESTRO: Okay. Comments or questions on that?

MR. BOLLOCK: That would be at the discretion of the -- this is Doug Bollock. That

would be at the discretion of the committee. If you feel it's important enough to review now and form a subcommittee, that is well within your rights and purviews.

CHAIRMAN PALESTRO: Ms. Holiday, let me ask you, is this something that would start now or is this established in a subcommittee for the future?

MS. HOLIDAY: As Mr. Bollock said, it's up to your discretion. For the purposes of what Dr. Suh's subcommittee did, that is going to affect the existing 35.1000 guidance. That's staying in 35.1000 for now because we're very far away from rulemaking.

So as the chair of the committee, it's your prerogative when you would like to start that subcommittee, if you start it at all. I just wanted to throw that out as an item for consideration.

CHAIRMAN PALESTRO: Okay. I think I'm going to defer on that for a moment until I've had time to think about it a little bit and maybe discuss it more.

MS. HOLIDAY: Absolutely.

CHAIRMAN PALESTRO: Thank you.

MS. DIMMICK: So if I could add as you think about it, the other value that it could have is not just for a rulemaking but for future 35.1000

guidance documents for different GSR devices. The current working group is actually working on two different, very different GSR devices and the working group is going to have to address physical presence in those, and they'll need to have an idea of will they need, can they apply a criteria similar to what the Perfexion/Icon working group is proposing for physical presence or will they need to follow the rule?

So I guess, going forward, in terms of thinking of what safety barriers do the devices provide where there could be a different physical presence requirement than what is in the rule. So it's not just for rulemaking. It could be for future guidance documents, as well, for GSR devices.

CHAIRMAN PALESTRO: All right. Thank you. As I said, I want to think about it a little bit and I want to go over the number of subcommittees that we have and do my best to avoid overloading the members of the committee, the ACMUI, with responsibilities on multiple subcommittees. I just can't think of it off the top of my head.

Any other comments or questions? All right. there's a motion to approve Dr. Suh's report, the subcommittee's report. Is there a second?

MEMBER SHEETZ: Second.

CHAIRMAN PALESTRO: Sheetz. Any further discussion? All in favor? Any opposed? Approved.

Mr. Bollock any other business that we need to address today?

MR. BOLLOCK: No, that is it.

CHAIRMAN PALESTRO: Ms. Dimmick?

MS. DIMMICK: At some point, we wanted to come back to the charge for the Medical Event Subcommittee, so if we could try to phrase that charge that would be great. Thank you.

CHAIRMAN PALESTRO: Dr. Ennis?

MEMBER ENNIS: I'll give it a try. The subcommittee will review the appropriateness of the required elements of medical event reporting, the adherence to these requirements, and recommend actions to improve reporting.

CHAIRMAN PALESTRO: That's certainly acceptable to me, and we already have the members of the subcommittee.

MEMBER ENNIS: We do.

CHAIRMAN PALESTRO: And you will chair.

MEMBER ENNIS: I will.

CHAIRMAN PALESTRO: All right. Staff liaison?

MR. BOLLOCK: I got a volunteer. Ms. Dimmick, the medical team leader, will be the staff resource for that.

CHAIRMAN PALESTRO: Okay. Ms. Dimmick will be staff resource. Thank you very much. All right. Any other business? All right. Then we're adjourned until 8:30 tomorrow morning. Thank you all.

(Whereupon, the foregoing matter went off the record at 4:48 p.m.)