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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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FALL 2022 MEETING

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MONDAY,

DECEMBER 5, 2022

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The meeting was convened in the Commissioner's Hearing Room, One White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:30 a.m., Darlene F. Metter, ACMUI Chairman, presiding.

MEMBERS PRESENT:

DARLENE F. METTER, M.D., Chair

HOSSEIN JADVAR, M.D., Ph.D., Vice Chair

REBECCA ALLEN, Member*

RONALD D. ENNIS, M.D., Member

RICHARD L. GREEN, Member

RICHARD HARVEY, Ph.D., Member

JOSH MAILMAN, Member

MELISSA C. MARTIN, Member

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

ZOUBIR OUHIB, Member

MEGAN L. SHOBER, Member

HARVEY B. WOLKOV, M.D., Member

ALSO PRESENT:

JOHN F. ANGLE, M.D., Consultant to the Committee

ANDREW EINSTEIN, M.D., Nuclear Cardiologist

NRC STAFF PRESENT:

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

MARYANN AYOADE, NMSS/MSST/MSEB/MRST

KENNETH BRENNEMAN, NMSS/MSST/MSEB/MRST

ANDREW CARRERA, NMSS/REFS/MRPB

THERESA CLARK, NMSS/MSST

ANITA GRAY, NMSS/MSST/SMPB

TRISHA GUPTA SARMA, NMSS/MSST/MSEB/MRST

SARAH LOPAS, NMSS/MSST

KATHERINE TAPP*, NMSS/MSST/MSEB/MRST

GREGORY TRUSSELL, NMSS/REFS/MRPB

CELIMAR VALENTIN-RODRIGUEZ, NMSS/MSST/MSEB/MRST

Daniel Dimarco, NMSS/MSST/MSEB/MRST

Cindy Flannery, NMSS/MSST/MSEB/MRST

Christine Pineda, NMSS/MSST/MSEB/MRST

Vincent Holahan, NMSS/MSST

Jill Shepherd, NMSS/REFS/MPRB

Kevin Williams, NMSS/MSST

Adam Schwartzman, NMSS/

*Present via teleconference

C-O-N-T-E-N-T-S

P R O C E E D I N G S

8:30 a.m.

CHAIR METTER: Good morning, and welcome to the fall 2022, first in-person ACMUI meeting since 2019. I'm Darlene Metter, the ACMUI Chair and diagnostic radiologist. I would first like to thank the NRC staff and the ACMUI members for their dedication in continuing our important work particularly during these challenging times.

At this time, I would also like to welcome our newest member to the ACMUI, Dr. Richard Harvey, a radiation safety officer who was appointed in July of 2022. Welcome, Dr. Harvey.

MEMBER HARVEY: Thank you.

CHAIR METTER: Dr. Ronald Ennis has been the brachytherapy radiation oncologist for the ACMUI since 2015. And I would like to acknowledge and thank him for his eight years of tremendous service and dedication and especially his invaluable reorganization and reporting of the ACMUI report on annual medical events. This will be Dr. Ennis' last meeting, and I thank you, Dr. Ennis, for your expertise, tireless service, and extreme commitment to the ACMUI.

MEMBER ENNIS: Thank you very much.

CHAIR METTER: And now I would like to turn the meeting over to Mr. Chris Einberg, the ACMUI's Designated Federal Officer for this meeting. Mr. Einberg?

MR. EINBERG: Thank you, Dr. Metter. Good morning. As the 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 Chris Einberg. I'm the 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.

This is an announced meeting with the Committee. It is being held in accordance with rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission. This meeting is being transcribed by the NRC and may also be transcribed or recorded by others.

The meeting was announced in the November 9th, 2022 edition of the Federal Register, Volume 87, page 67720. The function of the ACMUI is to advise the staff on issues and questions that arise on the medical use of byproduct material. The Committee

provides counsel to its staff but does not determine or direct the actual decisions of the staff or the Commission.

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 will discuss today. But I also recognize there may be a minority of dissenting opinions.

If you have such opinions, please allow them to be read into the record. At this point, I would like to perform a roll call of the ACMUI members participating today.

Dr. Darlene Metter, Chair and Diagnostic Radiologist?

CHAIR METTER: Present.

MR. EINBERG: Dr. Hossein Jadvar, Vice Chair and Nuclear Medicine Physician?

VICE CHAIR JADVAR: Present.

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

MEMBER ENNIS: Present.

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

MEMBER GREEN: Present.

MR. EINBERG: Mr. Josh Mailman, Patient's Rights Advocate?

MEMBER MAILMAN: Present.

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

MEMBER MARTIN: Present.

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

MEMBER O'HARA: Present.

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

MEMBER OUHIB: Present.

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

MEMBER SHOBER: Present.

MR. EINBERG: Dr. Harvey Wolkov, Radiation Oncologist?

MEMBER WOLKOV: Present.

MR. EINBERG: Ms. Rebecca Allen, Healthcare Administrator?

MEMBER ALLEN: Present.

MR. EINBERG: Dr. Richard Harvey, Radiation Safety Officer?

MEMBER HARVEY: Present.

MR. EINBERG: I confirm that we do have

a quorum of at least six members. As noted, Ms. Rebecca Allen is joining us via Microsoft Teams as she was unable to join us in person today. However, she is able to mute and unmute herself as necessary.

At the table, we have Dr. Richard Harvey and Dr. Andrew Einstein. Dr. Richard Harvey has been selected to serve as the ACMUI's Radiation Safety Officer Representative. And Dr. Andrew Einstein has been selected as the ACMUI's Nuclear Cardiologist.

Dr. Einstein's official start date is later this month. And he may participate in today's meeting and is welcome to comment and ask questions at the appropriate time. However, he will not have voting rights for any actions requiring a vote until his official start date.

All members of ACMUI are subject to federal ethics laws and regulations and receive annual training on these requirements. If a member believes that they may have a conflict of interest as that term is broadly used with 5 CFR Part 2635 with regard to an agenda item to be addressed by the ACMUI, this member should divulge it to the chair and the DFO as soon as possible before the ACMUI discusses it as an agenda item. ACMUI members must recuse themselves from participating in any agenda item in

which they may have a conflict of interest unless they receive a waiver of prior authorization from the appropriate NRC official.

I would like to add that this is a hybrid meeting with ACMUI. This is the first in-person meeting since the fall 2019 meeting. But we are also using Microsoft Teams so that members of the public and other individuals can watching online or via phone.

The phone number for the meeting is 301-576-2978. Once again, 301-576-2978. The phone conference ID is 767488798#. Once again, 767488798#. The handouts and agenda for this meeting are available on the NRC's ACMUI public website. I now ask that the NRC staff members who are participating via Microsoft Teams or phone to identify themselves. Do we have anybody online?

DR. TAPP: Katie Tapp is here.

MR. EINBERG: Thank you, Dr. Tapp. Okay. Members of the public who have notified Ms. Gupta Sarma that will participate via Microsoft Teams will be captured as participants in the transcript. Those of you who did not provide prior notification, please contact Ms. Gupta Sarma by email at Trisha.GuptaSarma@nrc.gov. And that's T-R-I-S-H-A,

dot, G-U-P-T-A-S-A-R-M-A, @nrc.gov at the conclusion of this meeting.

Today's meeting is being transcribed by a court reporter. We are utilizing Microsoft Teams for the audio of today's meetings and to view presentation material in real time. The meeting materials and agenda for this meeting can be accessed from the NRC's public meeting schedule.

For the purpose of this meeting, the tag feature in Microsoft Teams has been disabled. Dr. Metter at her discretion may entertain comments or questions from members of the public who are participating today. Individuals who would like to ask a question or make a comment regarding the specific topic of the committee as discussed and are in the room can come up to either microphone set up in the right or the left of the table.

For those individuals on Microsoft Teams, please use the raised hand function to signal to our Microsoft Teams host, Sarah Lopas, that you wish to speak. If you have called into the Microsoft Teams using your phone, please ensure you have unmuted your phone. When you begin your comment, please clearly state your first and last name for the record.

Comments and questions are typically

addressed by the Committee near the end of the presentation. After the committee has fully discussed the topic, we will announce when we are ready for the public comment portion of the meeting. And Sarah Lopas will assist in facilitating the public comments.

At this time, I ask that everyone who is not speaking to please mute your Teams microphones or phone. And for those in the room, please mute your phones. I will now turn the meeting over to Ms. Theresa Clark, Deputy Director of the Division of Material Safety, Security, and State and Tribal Programs for some opening remarks.

MS. CLARK: Thank you, Chris, and good morning, everyone. I'm Theresa Clark as Chris mentioned. And I want to add my thanks and compliments to everyone for joining us today mostly in person at this meeting and to all those joining us on the line.

There's a tremendous amount of preparation that goes underway for these meetings, both yourselves on the Committee and the numerous staff who support these meetings. We're flexing some muscles that we haven't flexed in a while. And it seems like things are going very smoothly as a result

of everyone's preparation. So thank you, and I'll try not to jinx that.

So first, just my thanks to the Committee for all of your hard work and support to the agency. The work that you do is tremendously important to the American public. We're in an ever-changing environment in the medical arena, and we really value your expertise as we look at new uses of radioactive material and continued uses as well.

I want to highlight just a few items that may be of interest to the Committee and to the participants in the meeting as we get ready for today. There are a couple of very interesting staff activities going on in the medical area. We recently, earlier this spring, submitted a package to the Commission with our recommendation on an approach to disposition, a petition for rulemaking on nuclear medicine extravasations which is a topic the Committee has considered in the past. So the Commission is considering that matter right now.

On emerging medical technologies, we have a rulemaking underway right now. And we have a regulatory basis document that's been drafted. It's been sent to our regional offices as well as the agreement states for review and we're considering

those comments right now.

We're expecting that document to go to the Commission in about March. And it'll go for public comment thereafter. And we'll have some workshops during that time frame to gather stakeholder feedback on these areas as well as training experience requirements for emerging medical technologies.

Speaking of training and experience, one of the ways that's considered is through the NRC's recognition of specialty boards. We did a first of a kind evaluation of these specialty boards this summer and made that document publicly available in our medical toolkit. And we found that most of the boards continue to satisfy the criteria in Part 35.

There were a couple that had gone into -- ceased their operations or otherwise stopped doing certification. And that's sort of a different process. We're also developing implementation guidance for training and experience based on Commission direction. And that'll be issued concurrently with the emerging medical technology's rulemaking as those two go hand in hand.

And finally, many of you are familiar with Regulatory Guide 8.39 on patient release after

medical procedures with radioactive material. We're working on an update to that document and we're planning to release the draft for public comment early next year. And last year, the subcommittee provided really valuable comments to us that we've been considering and updating that draft as well as comments from the agreement states and our regional offices.

A few mentions within the NRC organization. As most of you are probably aware, we have two new Commissioners who were confirmed in August. Commissioner Caputo is returning to the Commission. She previously served on the Commission. And Commissioner Crowell is coming to us from the state of Nevada where he worked in the State Department of Conservation and Natural Resources as well as the U.S. Department of Energy. And so we now have a full Commission with five members on it, and you'll see them all tomorrow.

We also have some staffing changes underway. We're doing a lot of hiring here at the NRC. And so we're in the middle of filling two positions that are health physics positions as well as the ACMUI coordinator position which Trisha is filling in for right now. So we appreciate Trisha

there. And so we'll announce those after the selection process is complete.

The changes on the Committee itself have already been mentioned by most of you. But I'd like to recognize that Dr. Dilsizian completed his second term. That left the vice chair position which I'm pleased that Dr. Jadvar is taking now.

Richard Harvey was already recognized. So he joins us from New York. He is from the Roswell Park Comprehensive Cancer Center there. And Dr. Einstein will be joining us officially on December 19th. And so he is also from New York, perhaps a little trend here, Columbia University as well as other very distinguished biography that I'm not going to read.

And then we will have a special recognition of Dr. Ennis later today. So please prepare to be embarrassed. That's always fun. And we are accepting nominations for the radiation oncologist brachytherapy representative that's been issued in the Federal Register and open through January 23rd.

So you'll hear lots of topics today including Ken Brenneman of our staff talking about lutetium-177, Andy Carrera speaking about a

radioactive source security and accountability rulemaking, primarily focused on Category 3 quantities of radioactive material, and Greg Trussell to speak about a rulemaking on decommissioning financial assurance for sealed and unsealed radioactive material. So a lot of interesting staff work behind those presentations. I appreciate all of their preparation.

So thanks for the opportunity to open this meeting. I wish you a productive session. Please don't be offended when I'm in and out a little bit. That's the breaks of the job. But I find this very interesting, and I'll turn it over to Trisha to continue the meeting.

MS. GUPTA SARMA: Okay. I think it's working. Good morning. My name is Trisha. I will be providing the old business report and giving a status update on some of the items from the ACMUI's recommendations and action items. Can everyone hear me? Yes? Can everyone hear me? Okay. I'll talk louder.

To start, Item 18 from September 10, 2019 states that the ACMUI endorsed the evaluation of the Extravasation Subcommittee reports as amended to note that under future revisions to Part 35 rulemaking

extravasations be captured as a type of patient intervention in the definition of patient intervention. The NRC proposes for this to remain open. The staff presented its evaluation of PRM-35-22 to the ACMUI, and the ACMUI unanimously approved the staff's recommendation option, Option 4.

The staff prepared a SECY package that includes a rulemaking plan for Commission consideration. The SECY packages were provided to the Commission on May 9th, 2022. The recommendation will stay open until the Commission votes on the rulemaking plan. The target completion date for this action is spring 2023.

The next item is Item 4 from March 30th, 2020 which states that the ACMUI endorsed the Patient Intervention Subcommittee report as presented and the recommendations provided therein to reinterpret current definition of patient intervention and to report medical events resulting from patient intervention which results in unintended permanent functional damage under 10 CFR 35.3045(b). This also has to do with extravasation. So the recommendation will stay open until the Commission votes on the rulemaking plan. The target completion date for this action is spring 2023.

Next is Item 11 from September 21st, 2020 which states that as a part of nonmedical events report, the ACMUI recommended to the NRC staff and the national materials program to evaluate the issue of detection of short lived medical isotopes in municipal waste and provide some level of guidance, best practices, or additional instructions. The NRC proposes for this to remain open. The medical team presented to the Organization of Agreement States Board and agreed with the survey to the agreement states.

The NRC staff has prepared a survey to share with the agreement states via RCPD letter pending any delays in the Office of Management and Budget Review and the RCPD. Their new target is spring 2023.

And next is Item 6 from September 2nd, 2021.That states that the ACMUI endorsed extravasation committee report as amended to support Option 4 of the subcommittee report. As previously stated, this has to do with extravasation. And the recommendation will stay open until the Commission votes on the rulemaking plan with the new target of spring 2023.

Next is Item 7 from October 4, 2021 which states that the ACMUI formed a new subcommittee on

the Liberty Vision Y-90 Manual Brachytherapy source. The subcommittee is expected to provide a draft report and any recommendations at the spring 2022 meeting. The NRC proposed to keep this open. The NRC staff is currently drafting the 35.1000 licensing guidance. The subcommittee will receive the guidance for review and comment in spring 2023. The NRC staff will plan for a public teleconference in summer 2023.

Item 10 from October 4, 2021 states that the ACMUI endorsed the Radionuclide Generator Knowledge and Practice Requirements Subcommittee report and recommendations provided therein. The subcommittee recommends that the rule language in 10 CFR 35.29 be revised to Part 2, participating in educational sessions to gain knowledge and provide supervision of, one, radionuclide generator systems and their operation, two, the measurement of radionuclidic impurities and acceptable limits, and three, the use of reagent kits with radionuclide eluate to prepare radioactive sets. The NRC will consider the subcommittee recommendation as part of the emerging medical technologies RB-82 generator rulemaking approved by the Commission on January 13, 2022. The target completion date is March 2026.

Item 12 from October 4th, 2021 states the

ACMUI formed a new subcommittee on Y-90 microspheres in medical events. The subcommittee is expected to provide a draft report and any recommendations at the spring 2022 ACMUI meeting. The NRC proposes to close this action. The ACMUI established the Committee, and the subcommittee is presenting its recommendations to the full committee later today.

Item 15 from December 15, 2021 states that the ACMUI endorsed the ACMUI Reg Guide 8.39, subcommittee report on CivaDerm and the recommendations therein. The NRC proposed to keep this open. The NRC staff considered the subcommittee's comments. The staff was apparently revising the CivaDerm memo and expects to issue the guidance once issues related to patient release are resolved and the proposed revision to Regulatory Guide 8.39. The target completion date for this is summer 2023.

Item 16 from December 15, 2021 states that ACMUI endorsed the ACMUI Reg Guide 8.39 Subcommittee report on the proposed revision to Reg Guide 8.39 and the recommendations therein. The NRC proposes to keep this open. The NRC staff addressed the subcommittee reports as well as the regional staff and agreement state comments.

The Reg Guide will go out for public comment in spring 2023. The NRC will provide the revised document to the ACMUI for a 60-day review once it has incorporated comments received from the public comment period. The target completion date is summer 2023.

I'm now into 2022. Item 1 from April 5th, 2022 states the NRC staff addressed subcommittee comments as well as regional (audio interference). The Reg Guide will go out for public comment in spring 2023. The NRC staff will provide the revised documents to the ACMUI for a 60-day review once its incorporated comments received during the public comment period.

The NRC proposes to keep this open. The NRC staff is currently working on a proposed rule and communicated the ACMUI's desires to review the proposed rule language to the working group. The tentative schedule will be for spring 2023.

Item 2 from April 5th, 2022 states due to the increased number of medical events in 2021, a suggestion was made for the ACMUI to develop generic process checklist for all user procedures. It was noted that it may be appropriate to have the professional licensing board take the lead on

developing, communicating, and standardizing the checklist. The NRC proposes to close this. This is not an action for the NRC staff. During open forum, the ACMUI may discuss what action they would like to take with respect to this recommendation.

And lastly, Item 3 from April 5th, 2022, the ACMUI tentatively scheduled its 2022 fall meeting for September 19 through the 20th, 2022. The alternate date is December 5th through 6th, 2022. And an in-person meeting is expected for these dates. The NRC proposes to close this as the meeting is held today on December 5th through the 6th, 2022.

And that completes the old business report, Dr. Metter, and the ACMUI meetings. I propose closure for three items. So is there a motion to accept the report?

CHAIR METTER: Thank you, Ms. Sarma. And I'm sorry. Can you repeat what you proposed?

MS. GUPTA SARMA: To close the three items I discussed.

CHAIR METTER: Yes. Do I have to vote on that? Do I have a motion to close the three items that were mentioned by Ms. Sarma?

MEMBER HARVEY: Motion.

CHAIR METTER: Do I have a second?

MEMBER WOLKOV: Second.

CHAIR METTER: All in favor of closing the suggested documents say aye.

(Chorus of ayes.)

CHAIR METTER: Any abstention or declines?

Hearing none, the ACMUI has unanimously approved your recommendation.

MS. GUPTA SARMA: Thank you.

CHAIR METTER: Thank you. Now at this time our next item on the agenda is the open forum where the ACMUI will identify medical topics for interest for the future. And I believe Ms. Sarma mentioned the medical event generic process checklist.

And I'd like to propose a new subcommittee for that since it's timely in regard to her comments. And I propose that the new chair for that committee be our nuclear pharmacist, Mr. Richard Green, and the proposed members to be Ms. Melissa Martin, Dr. Hossein Jadvar, Ms. Rebecca Allan, Dr. Richard Harvey, and Dr. Ennis until March 2023. Do I have any other suggestion for topics to come up in the future?

DR. VALENTIN-RODRIGUEZ: Dr. Metter, I

was just going to suggest a -- oh, sorry. I need to bring it closer. Just to the timing of the report for spring 2023.

CHAIR METTER: I'm sorry?

DR. VALENTIN-RODRIGUEZ: The timing of that report for spring 2023?

CHAIR METTER: I'd like to have at least a suggested checklist. And perhaps we can vote at that time.

DR. VALENTIN-RODRIGUEZ: Okay.

CHAIR METTER: Any other comments from the ACMUI NRC staff? Suggestions for other topics for the future?

(No response.)

CHAIR METTER: Okay. There'll be another suggestion for open forum this afternoon. And we can also introduce this topic again. So our next item on the agenda is the Y-90 Medical Event Subcommittee report by Dr. Michael O'Hara who will discuss the subcommittee recommendations on the evaluation of the Y-90 medical events. Dr. O'Hara?

MEMBER O'HARA: Good morning. This is the subcommittee report for Y-90 microsphere medical events. Next slide, please.

The agenda is as follows. I'll introduce

the Subcommittee members, the Subcommittee charge. We'll talk about key messages and talk -- a little bit about background. And then we'll talk about our vendor consultation process that we went through with Sirtex Medical and Boston Scientific, and further discussions with -- further discussions that may be necessary with both vendors. Next slide, please.

The Subcommittee members were John Angle, Vasken Dilsizian, Josh Mailman, Melissa Martin, myself, and Megan Shober. The staff resource was Katie Tapp. Next slide, please.

The ACMUI Subcommittee charge to evaluate the issues -- the issue of Y-90 microsphere medical events in more depth and in consultation with the vendors proposed methods to decrease the number of Y-90 microsphere medical events. Next slide, please.

The key message: the reported number of medical events involving Y-90 microspheres is low compared to the number of treatments performed. However, it's important to evaluate the causes of the events to find ways to minimize the chance of similar types of events happening again. Next slide, please.

So the background. Hepatic radioembolization uses Y-90 microspheres for treatment of primary and metastatic liver

malignancies. Currently there are two vendors that are FDA approved for this purpose: Boston Scientific and Sirtex Medical.

During the past few years, both vendors have increased their hepatic radioembolization business by approximately 20%. The medical events reported during 2020 were low compared to the number of treatments performed. Next slide, please.

The medical events involving Y-90 administration continues to be the most common medical events. The types of medical events for Y-90 microspheres include greater than 20% residual activity remaining in the delivery device; delivery device setup errors; wrong doses given; treatment plan calculation errors; wrong site treatments, catheter placement errors; wrong dose vial selected and wrong site selected in the -- the written directive. Next slide, please.

A past ACMUI Medical Event Subcommittee noted that performance of a timeout and the use of a checklist immediately before administration of byproduct materials could have prevented some of these medical events. The NRC staff issued an Information Notice, 19-07, to inform licensees of past ACMUI recommendations. Next slide, please.

The vendor consultation. The ACMUI Subcommittee contacted the Y-90 microsphere vendors, Sirtex Medical and Boston Scientific, to discuss possible methods to reduce medical events. Both vendors voluntarily met and greatly supported the Subcommittee in this effort. Next slide, please.

The vendors were given the ACMUI Medical Event Subcommittee report presented on October 4, 2021. They were also given some general questions to start the conversation and the ACMUI proposed recommendations to prevent 35.1000 Y-90 microsphere medical events.

The vendors were also asked if these three actions are appropriate and if they have any further recommendations.

The Subcommittee proposed the following actions to the vendors as possible licensee actions to prevent medical events: review mechanism mechanics of the Y-90 microsphere delivery device and setup procedures, confirm all data and calculations in the treatment plan, and perform a timeout after the beginning of each procedure. And you know, being sure to cover the name, the date of birth, and the activity. Next slide, please.

The Sirtex -- the first company we talked

to was Sirtex Medical. Sirtex evaluated the medical events reported by the licensees in 2021 Medical Event Subcommittee Report.

They identified four causes: greater than 20% residual activity remaining in the delivery device not due to vascular stasis, the wrong dose given, treatment plan calculation errors, the wrong site treatment, catheter placement errors, wrong site written directive errors.

Sirtex agreed that greater use of the ACMUI recommendations by licensees would prevent medical events due to device setup and procedural errors. Next slide, please.

An additional action Sirtex has taken that may reduce medical events, they developed a microsphere activity calculator which can serve as a second check against the activity identified in the written directive. Next slide, please.

Also, Sirtex has enhanced their training and education certification program. All necessary nuclear medicine and radiation support staff are present at these trainings. It includes in-service site visits, and it also includes proctor assessments.

There's a minimum frequency of use to

continue treatments, and more vendor staff in close contact with the licensees. So the vendor has rearranged things to put more of their knowledgeable staff in close proximity to the -- to the end users. Next slide, please.

For Boston Scientific, the vendor identified issues and currently available potential solutions. Greater than 20% volume Y-90 spheres left in the delivery device may need improved understanding of the -- of the device and the procedures that go along with the device.

Events related to delivery device, again, enhancements to the written directive and/or increased familiarization with the device, wrong dose to calculation error, catheter placement errors or wrong dose vials. The Boston Scientific has developed software and spreadsheet tools to help with this -- this issue. Next slide, please.

Furthermore, Boston Scientific, as I said, has developed these software tools to assist licensees in the treatment, planning, and order of -- ordering of microspheres, Y-90 microspheres.

One tool is TheraSphere Now. It's an online ordering tool. TheraSphere Treatment Window Illustrator. It's a spreadsheet ordering tool. And

TheraSphere iDoc is an online dose ordering tool. Next slide, please.

The Boston Scientific also stated that their IFU, their indications for user support, supported by training of new site physicians, physician-authorized users, RSOs, and support staff goes a long way to help reduce medical events.

TheraSphere administration checklist instructs users to confirm patient identity, instructions for administration, set priming, dose vial preparation, administration set assembly, final assembly before administration, and disassembly and cleanup. Next slide, please.

The Committee believes that there should be further discussions with the vendors to understand fully how these programs can reduce medical events. What we heard from the vendors were pretty much a snapshot of what they're doing. I think -- we think that more questions can be asked with greater specificity to talk to these companies.

How the vendors -- we should know how the vendors judge the effectiveness of these programs, how the vendors test the accuracy of spreadsheet and software tools, what steps are being taken to minimize the chance of clogged microcatheters, which

cause residual activity to remain in the delivery device. This was brought up in one of the vendors' materials. So this is still an issue. Next slide, please.

Invest -- we should investigate the utility of software programs and checklists provided by the microsphere vendors with the licensees. And issue an information notice and speak at conferences to alert licensees of past medical events and share the ACMUI subcommittee recommendation actions to reduce Y-90 microsphere medical events. Next slide, please.

Thank you.

CHAIR METTER: Thank you, Dr. O'Hara, for your presentation on the Y-90 Medical Events Subcommittee report. Do I have any questions from the members of the Subcommittee?

MEMBER OUHIB: I do.

CHAIR METTER: Yes, Mr. Ouhib.

MEMBER OUHIB: Thank you. I actually have several questions regarding this, and I'll put them in different order. One of the things that came to mind regarding the manufacturer, is there any provision, just like any other delivery device, of having some sort of preventive maintenance option for

users to make sure that the device is still working as it was day one?

I think that we do it for linear -- we do it for the HDR device, we do it for several devices. Being a delivery device, the Y-90 one, I believe that that should require some sort of a maintenance on an annual basis, or after of course a medical event. That would be my first one.

I think you had stated it, but I think I have concerns about spreadsheet and Excel sheets. Unless you are the one who actually wrote the spreadsheet and Excel sheet, you fully understand what goes in and what comes out, and there are always chances of something going wrong with those spreadsheets. I think you addressed that that would be looked at and evaluated thoroughly before something happened.

The independent check or the second check, I think that I would probably suggest that different person from -- besides the one who actually did the ordering to actually do that second check. Because if it's the same person, the tendency is that, well, I did it, it's correct, I'm not going to worry about it.

I think you did mention about the medical

event. I would suggest the manufacturer should not wait like on an annual basis, but as soon as there's some sort of a medical event that has occurred, users should be informed immediately about that in something like an email or whatever that is and explain exactly what has occurred. And also provide solutions that were actually implemented to avoid a similar event.

There was a slide where it says evaluate -- that was at slide 19. I'd like to see what that means, how, to evaluate how. I think we need some specifics there. And going back, like you know, greater than 20% residual activity, that's, in my opinion that's high, and I think that's what I was stating early on, that a PMI should be recommended to make sure that none of that happened.

I think I will stop there and maybe there might be other questions. Thank you.

CHAIR METTER: Thank you for this very important question, Mr. Ouhib. Are there any other questions from the Subcommittee, or comments? Yes, Dr. Ennis?

MEMBER ENNIS: Well, first, thank the Committee. I'm really happy that we're kind of tackling this, and certainly agree with the main

conclusions that we need more questions and more clarifications to make sure really these changes, whatever we might be able to effect, are substantive.

I have two that are very -- completely different. So one simple one is I was curious, one of the vendors had suggested some minimum threshold of frequency use, which really strikes a chord. As you remember, we've talked about this in the Medical Event Subcommittee work, how we think some medical events are attributable to that.

So what threshold has been suggested or adopted by them?

MEMBER O'HARA: I didn't catch that number. That would be something I think I would follow up on, that we would need to see. And I would like to know if it's different from one vendor to the other.

MEMBER ENNIS: Because as a group we've talked about it as a concept, but really haven't put any numbers of what we think for different modalities what is a reasonable frequency use to avoid medical events. So it's an interesting question to me.

Okay, second question, totally different though, is did you look at it, and it sounded so clear to me, as I under the procedure as it's done,

obviously the physician putting in the catheters and all that is an interventional radiologist.

And as I understand it, sometimes interventional radiologists do it by themselves. They are also the authorized users, and sometimes they have an authorized user like I guess nuclear medicine or radiation oncologist collaborating with them.

So I didn't hear anything in your presentation, I don't know if the Committee talked about it, but it might be worth talking about like the differences when those two processes are happening and other medical event relationships depending on if it's a collaborative process versus not.

And I guess more specifically what I'm not totally clear on, embarrassed, eight years I'm still not clear, don't know this, but for if -- this is really for Dr. Angle probably -- an interventional radiologist who is herself or himself an authorized user, what is their training experience requirements to get that status?

MEMBER O'HARA: We talked -- primarily our discussion was with the vendors. So, much of what you're asking for we didn't discuss with the

vendors. And they didn't bring up -- one thing that was interesting with Boston Scientific was the fact that they mentioned that when their spreadsheet and software tools are used, those sites have fewer medical events.

I think that needs to be flushed out in greater detail so that we can see how effective these software tools and spreadsheets really are.

DR. ANGLE: I think that most of the training occurs in residency and involves the hours of exposure to nuclear medicine and includes Y-90 exposure. And then the actual becoming an authorized user and its applications occurs at the individual level at their site of operations and is determined really locally in conjunction with the vendor.

In other words, to respond to your question what is the training for this, experience is based on, in residency, on hours of service in nuclear medicine, and of course signed off by a program director, which we'll be talking about later. And then really their sort of credentialing with the local level I think is how the -- how they're determined whether they're certified to do this procedure or not.

MEMBER ENNIS: I guess I just need -- I

again don't really quite know the depth in depth like for radiologists in training.

Some are authorized users and some are not, and I don't -- it's not clear to me like what extra training is done for those who become authorized users versus not or how that happens. And if that's the same for people who get authorized user status because they're -- because they do nuclear medicine, or if it's different if they are interventional radiologists.

Yeah, it may just be facts that I don't know, or it may be there are differences that might be important. I guess that's what I'm trying to find out.

DR. TAPP: Dr. Metter, is it okay, if I speak? This is Dr. Tapp.

CHAIR METTER: Yes, Dr. Tapp, thank you very much.

DR. TAPP: Yeah, to answer Dr. Ennis's question, the guidance requirements for an interventional radiologist, remember this is in the guidance but the criteria is not in 10 CFR Part 35, but it's in guidance.

For an interventional radiologist, it's 80 hours of training in the radiation safety ~~in~~

aspects that are related to the yttrium-90 microspheres, in addition to being an interventional radiologist for so many years, as Dr. Angle talked about, as the residency.

So the authorized user requires the 80 hours of training in those specific aspects, and then the three cases using the microsphere apparatus that they want to -- that they're pursuing.

CHAIR METTER: Thank you, Dr. Tapp, for that clarification. Any other questions, Dr. Ennis?

MEMBER ENNIS: So, I mean, that's markedly different than authorized user training for every other radio -- radiation application. And these procedures are if anything more -- as complex as some of the complex brachytherapy procedures, for example. So I have a hard time understanding why there would be such a difference in such low requirements for interventional radiologists to do -- to be an authorized user.

It's totally fine as a collaboration with an authorized user, but I think the Committee needs to consider the role that that much lower level of training is allowed and to what degree that's playing a role.

To me it's pretty shocking, frankly. And

I can't believe it's only eight years into it that I realize this is what's allowed, but it seems to me to potentially be insufficient.

CHAIR METTER: Mr. Green, I believe you have a comment.

MEMBER GREEN: Yes, I want to thank Dr. O'Hara and the Subcommittee for an outstanding report.

I just want to point out that a shortcut was taken in the agenda where it refers to Y-90 medical events. In the report and the slide, it's correctly fully labeled as Y-90 microsphere medical events. There are radiopharmaceuticals that are Y-90 labeled, and we're not talking about those in this context.

Dr. -- Mr. Ouhib, the -- I'm not sure it's possible to do preventive maintenance because it is a single use sterile catheter that goes into the patient, and that's a single sterile, single use reservoir that contains the Y-90 spheres that saline or D5W is injected into to, not suspend the particles, but disperse them.

It's interesting both the SIR-Spheres product is a resin sphere. The TheraSpheres is a glass sphere. Both are labeled with Y-90. They both

have the same diameter, 25 microns, but a huge difference in density. One's roughly three times denser than the other. It's glass rather than resin. And if you look at the terminal velocity of these two agents.

So they're not like a -- they're not a pharmaceutical, they're a medical device. But everything else we use that we infuse into people, they're solutions. They're salts, they're antibodies. And you push them, and when you push half the liquid, you get half the activity.

Well, these are not liquids, they're particles, little glass beads. And I literally have in my handling of these devices inserted a needle into the vial with a syringe and aspirated the liquid and removed successfully all the liquid but no activity.

Because they, the beads were compacted by gravity into an aggregate mass. You've got to literally thump the bottle and back-push and regurgitate and get a vortex and make them move, and then infuse them into the patient. And that's why we get the stasis, and the plugging is that there needs to be a good understanding of operators that these are particulates.

I mean, in nuclear medicine, we have tech MAA, which is a suspension, and it has suspending agents to keep it afloat. These do not. And they're larger, they're not 13 micrometers like MAA, they're 25 microns -- micrometers.

And the density and the terminal velocity is just off the charts compared to MAA. So it's a better understanding of the dynamics of how these little guys have to be kicked up into the supernatant and moved. And that's why we're having problems with medical events.

CHAIR METTER: Thank you, Mr. Green, for that explanation. That does make sense. Are there any other comments, Mr. Ouhib?

MEMBER OUHIB: Yeah, I fully understand Mr. Green's comment and I -- and I accept that. However, the purpose of that serves two -- for two reasons. One, as I said, trying to evaluate the device, and that can be done with a small sample of actual activity. And it also serves as a training to go through that.

And I hope the intent would be to actually create a problem, the user would actually create the problem or several problems during the delivery and educate the users this is why this

happened, this is why this happened.

It's not just yes, this is how it works, but also go over how it might not work and identify every step. And make it happen so the users can see it with their own eyes and recognize the problem. And I think that's -- that's the biggest problem of training. We go over what worked but not what doesn't work.

Let me just add one more item regarding the checklist, and I hope that the Subcommittee will look into that, is that an item should be added to that in that is to evaluate that no medical event has occurred and that's right after the delivery.

In other words, they go back and say okay, did everything went okay? Did we treat the right target, did we do this, did we do this, and so on and so forth. And I think that should be done before the team goes in a different direction. Thank you.

CHAIR METTER: Thank you, Mr. Ouhib, for those excellent comments and observations. And for the other Committee members. Anybody else on the ACMUI with comments or questions for Dr. O'Hara's report? Yes, Dr. Jadvar?

VICE CHAIR JADVAR: One quick question,

Dr. O'Hara. First, thank you for your -- for that report and everybody who worked on the Subcommittee. You mentioned that with the soft -- when there's software, there's been fewer medical events. Did -- can you put a number on that, what percentage -- we don't know?

MEMBER O'HARA: No, we did -- it was a comment during the telephone interview that -- that we had.

VICE CHAIR JADVAR: That would be good to know.

MEMBER O'HARA: That's -- that's why we said that we think that further questions need to be discussed with the vendors. Because there's some -- the software, the software tools are a big -- and the spreadsheet tools are a big issue. Software is one of the biggest issues that FDA, my home institution, FDA, is dealing with right now.

So if in fact we have one vendor that is -- has said that there's a reduction in medical events in the -- in the -- by the licensees who use the software tools, I think that sounds pretty powerful and needs to be -- needs to be looked at further.

VICE CHAIR JADVAR: Thank you.

CHAIR METTER: Thank you, Dr. Jadvar.

And Ms. Shober has a comment or a question.

MEMBER SHOBER: Yeah, I have a comment. Back to the training that Dr. Ennis was asking about. One of the things that's unusual with the microsphere authorized users is that there's a number of hours, which Dr. Tapp shared, 80 hours.

But there's also a residency requirement so that diagnostic radiologist three-year residency and a one-year interventional radiology fellowship or just the three years for the diagnostic interventional combo board.

So in there there's those years of residency, there's sort of an implicit understanding that there's additional radiation safety experience that goes into that training. But I do think that it's really unusual they're the only modality where it's like that where it's kind of an implicit versus having just the, you know, other areas. It's like 200 hours of training and 500 hours of experience.

And for the Y-90 microsphere use that it's a -- we do rely more on that kind of implicit training that would occur during that three-year residency. So I don't know why it got set up like that in the beginning, but I think maybe that's where some of the tension is when you're saying 80 hours

just isn't enough hours.

Well, yeah, that's true, 80 hours isn't very many hours. But kind of underneath is that implicit training that would have come during the three years of the residency. And I don't know how to account for that in a more like quantitative way.

CHAIR METTER: I have a comment, and the NRC staff, please correct me if I interpret this in the wrong perspective, but my understanding, it's for different authorized user status. 35.290 -- of training and experience with 200 hours regarding the laboratory.

And that 80 hours actually goes with I-131 therapy, and that's for 10 CFR 35.392. and 35.394, I believe. And that is 80 hours specific to I-131 therapy.

And so I think the terminology of the 80 hours for the 35.1000 Y-90 is actually different. And as Dr. Tapp mentioned, the 80 hours is specific for Y-90 therapy. So it's really, it could have similar overlap and it's pertaining to the therapy of Y-90, as opposed to the others. For I-131 it's pertaining to the therapy of I-131.

And is that -- if NRC staff can make a comment on that. Is this working -- that's correct.

MS. LOPAS: Oh, Katie's on the line. Go ahead, Katie.

DR. TAPP: That's correct, the 80 hours is in addition, similar to the I-131. It's in addition, it's focusing on the yttrium-90 microsphere, the radiation safety considerations for unsealed byproduct material, which an interventional radiologist isn't getting in their residency if they're not doing, you know, yttrium-90 microspheres.

So it's an addition to focus on the aspects for the yttrium-90 microspheres, any unsealed byproduct material handling.

CHAIR METTER: Thank you. And Dr. Ennis, you have a comment?

MEMBER ENNIS: Just so but for a nuclear medicine radiologist, someone who trains in radiology, but becomes a nuclear medicine physician, what's their training experience requirements over and above?

VICE CHAIR JADVAR: So just to expand on what Ms. Shober mentioned, this is a four-year residency. So one year of internship then four years of residency or there's a new DR/IR combined residency, which is still four years.

And during that, you have your implicit

into that training is four months of training in nuclear medicine. And that four months translates to about 700 hours, according to my understanding. Plus the laboratory work that they -- that experience that they receive.

So if every diagnostic radiologist and every IR -- DR/IR combo resident will receive at least four months of training in nuclear medicine. That's -- they have to have that, otherwise they cannot graduate. That's part of the residency program, within the four years.

CHAIR METTER: Yes, thank you. And Dr. Angle, you have a comment?

DR. ANGLE: Yeah, I would just add that we have a lot of work to do in categorizing these adverse events. And many of them are dose calculation-related, which I think we've been talking a lot, wouldn't have the competency to do these dose calculations. But so much of them are very dependent on a very complex delivery system that, again, these residents spend five years learning how to do.

And many of the problems are getting the catheter in the right place, avoiding plugging of the catheter, etc., which are not, I guess, going to be easily defined or measured. And so we need to find

a way to bin these adverse events and then address them individually I think, I guess, is my comment.

CHAIR METTER: Thank you, Dr. Angle. Do I have any other comments or questions from the ACMUI Committee?

MEMBER ENNIS: Just for me to understand to close the loop. So the difference between someone who trains in radiology and gets AU status versus not is mostly whether having to do with whether they need it or want it. They're not doing anything extra.

VICE CHAIR JADVAR: That's correct, yeah.

MEMBER ENNIS: Okay.

CHAIR METTER: Dr. Jadvar said that's correct. Okay, any other final comments from the ACMUI Committee itself or questions for the Subcommittee or Dr. O'Hara? Yes, Ms. Shober.

MEMBER SHOBER: I just have one additional comment about the software. For the TheraSphere in particular I know that when we spoke with Boston Scientific they sort of gave us a tour of the different software features that they use.

And just one thing that I'll toss out there from my own inspection experience, responding, investigating a Y-90 microsphere medical event, our -- we had a licensee that was using the TheraSphere

spreadsheet.

And one of the comments that our licensee made is that the spreadsheet -- you know, you input your numbers and written directive number in the -- it spits out kind of the -- the activity at the time of administration and it tells you the percentage as, you know, the percentage of -- and all that.

But it doesn't -- it didn't at the time visually flag something that was outside the 20% window. And our licensee was really interested in wanting that spreadsheet to visually indicate when a planned treatment was going to be outside that 20% range on the written directive.

And at the time that feature wasn't available. So I don't know, you know, when we're talking about spreadsheets, how accurate they are. I think it's also important to include in our evaluation how easy that information is to pick off the spreadsheet.

And I think that a visual indication, you know, when a treatment is being planned but it's outside the 20% range, you know, if that visually flags, I think it's a lot easier for the licensee to pick up that something that is out of spec.

So, I just toss that in there as a, you

know, something to look at when we're looking at those spreadsheets.

CHAIR METTER: Mr. Ouhib, you have a comment?

MEMBER OUHIB: Yeah, thank you, Megan, for shedding some lights on that. That's exactly my concern when I spoke about the user spreadsheet. I think that should be, and maybe they are doing that, I'm not sure, verified by the manufacturer that the user used the spreadsheet correctly.

And have a conversation, like not via email, no, live conversation that, okay, what did you do first, where did you go next, and so on. Is it a red light somewhere in there that indicate that your calculations are incorrect or whatnot.

That should be, it's almost like a really formal training on that to make sure that, again, I'll go back to creating some errors in the spreadsheet and see here, see what happened because you did this or because you did that, and so on. And so that the users understand.

But I am still nervous about the user spreadsheet, because only the person who actually created it knows everything about it.

CHAIR METTER: Thank you for your

comment, Mr. Ouhib. I remember back in Y-90 when it was first -- the microspheres were first introduced, there were a lot of medical events being reported because of the plus or minus 20%. And there was under-dosing.

And I believe it was related to vascular stasis, and I believe the NRC put out a guidance regarding that. Can the NRC staff comment on that?

MS. LOPAS: Katie, do you want to comment on that, or do you want me to step in?

DR. TAPP: Yeah, Dr. Metter, say it one more time, it cut out for a second.

CHAIR METTER: When Y-90 microspheres were first introduced, there were a lot of medical events being reported because of under-dosing. And so the NRC put out a guidance regarding that it wouldn't be a medical event related to vascular stasis.

And so that did not need to be reported. And so I'd like to maybe have you make a comment in regards to what Dr. -- what Mr. Ouhib brought up regarding the medical -- the administration of Y-90.

DR. TAPP: Thank you for clarifying, I was thinking of something different.

So in the licensing guidance in the

medical event criteria that is recommended by the NRC in an event of stasis or known stasis, it is not a medical event when the authorized user determines that stasis is occurring and to not force the material into the body. So it's not a medical event in the terms of stasis.

However, if it's not stasis and material is clogged in the apparatus, then that is a medical event. And I think most states, and Megan, Ms. Shober can correct me if I'm wrong, but I believe most states follow that criteria. So stasis is not reported if it's a known stasis event.

CHAIR METTER: Thank you, Dr. Tapp, for the clarification. Ms. Shober, you have a comment?

MEMBER SHOBER: Yeah, I -- that is how states function. We -- if it's due to stasis, that's not reportable.

CHAIR METTER: Thank you. Yes, Ms. Martin has a comment.

MEMBER MARTIN: On a slightly topic, excuse the voice, I was just wondering, for the radiation oncologist that want to perform these procedures, is this training for using the microspheres includes as part of their, or in addition to their brachytherapy training? Or when

does that happen into their rad onc training?

MEMBER ENNIS: I'm not aware of any radiation oncologists who do this by themselves.

MEMBER MARTIN: Okay.

MEMBER ENNIS: We don't -- they don't have training in the catheterization aspects of it the way interventional radiologists do. But they can be the authorized user in collaboration with the interventional radiologist.

MEMBER MARTIN: That combo is what I think I'm thinking of. Thank you.

CHAIR METTER: Thank you. Any other questions or comments from the ACMUI Committee? Well, thank you, Dr. O'Hara, for the very excellent presentation and the Committee and Subcommittee for the discussion on this topic.

Now, are there any questions from the NRC staff regarding Dr. O'Hara's presentation?

MR. EINBERG: Thank you, Dr. O'Hara, and the Subcommittee for the excellent work on this and the research. The recommendations here, if I'm interpreting these correctly, are for the Subcommittee to continue their work to further their discussions or further their investigations.

There's only one, I see, recommendation

that's actionable by the NRC staff, and that's to issue an Information Notice. Can you please, you know, is that your intent, you know, for the Subcommittee to continue their investigations?

MEMBER O'HARA: Yes, but I think it goes a little further than that. I think the Subcommittee believes that the NRC should look into these software and spreadsheet I would call them devices. But these software and spreadsheet issues as well.

Because the, you know, they are -- the firms are using them, they're developing them. And people are, on the licensees, are getting their hands on them and using them. So the accuracy and precision of these -- of these things needs to be looked at.

And also, the effectiveness of these devices that these software and spreadsheet devices, on what kind of reduction in medical events do their use actually cause. So those are things that really the report talks about.

MR. EINBERG: Thank you for that clarification. Dr. Tapp, do you have comments or questions regarding the Subcommittee report?

DR. TAPP: No, I do not.

MR. EINBERG: Thank you. Nothing else from the NRC.

CHAIR METTER: Thank you very much for those questions and comments. Now, are there any comments from the public or questions for the Subcommittee report?

DR. VALENTIN-RODRIGUEZ: So if you are a member of the public and you'd like to make a comment, just use the raise-hand function on Teams, that's the little hand icon. Just click on that once and that way I'll know. I'll call your name, you can unmute yourself. Everybody does have access to their microphones, but you do have to unmute yourself.

If you are on -- if you called in today, you can just press star-5 and that will show me that your hand is raised on your phone, so to speak. And you will press star-6 to unmute yourself. And just make sure that you've unmuted your cellphone if you have -- if you've kind of also double muted yourself.

All right, we've got one hand-raise. I see Bill Irwin. Bill, you can go ahead and unmute yourself.

DR. IRWIN: Okay, can you all hear me okay?

DR. VALENTIN-RODRIGUEZ: We can, go ahead.

DR. IRWIN: Okay, I was just going to

follow up on the spreadsheet issue. Something that also maybe should be brought up with the vendors if they're going to provide these spreadsheets, to provide more than just the planning part of it. We've had to develop our own data therapy worksheet where you try to estimate how much you actually delivered.

There used to be a template provided by Nordion for measuring the waste jar and whatnot in the vial beforehand to estimate how much you actually delivered. So regardless of what's on their -- on the TheraSphere Treatment Window Illustrator page, for instance, that's just a planning page.

Then there's the actual performance of it and calculation. Well, what did we actually deliver and how does that compare to the plan. So that might be something to bring up.

But just also to follow up on the idea of the spreadsheets and their use in validation is that this is a form of treatment planning software. And therefore just like other treatment planning software, it should go through validation. And both by the vendors, but also users ought to be, maybe they should go through a process, particularly if they're -- if they're new to this, is to internally validate it as well to make sure that they believe

what the calculations are telling them.

Plus, they also often have to add in their own calculations on the day of therapy. So just want to point that out.

CHAIR METTER: Thank you for your comment. Would you please identify yourself and who you're speaking for.

DR. IRWIN: Oh, yes, Bill Irwin, MD Anderson Cancer Center.

CHAIR METTER: Thank you.

DR. VALENTIN-RODRIGUEZ: Okay, let's do another call for comments. Please use the raise-hand function in Teams. And good reminder by Dr. Metter to please begin by introducing yourself and announcing who you represent or who you work with. And if you're on the phone, you'll just press star-5.

All right, Dr. Metter, I'm not seeing any more comments.

CHAIR METTER: Thank you very much for your help on this.

Well, looks like our morning session is at a break. And I know it's a little -- we're ahead of schedule. But because we have the published agenda online, our next session will be starting at 10:30.

So let's adjourn till that time.

(Whereupon, the above-entitled matter went off the record at 9:42 a.m. and resumed at 10:30 a.m.)

CHAIR METTER: Good morning and welcome back to the second half of the morning presentation for the 2022 ACMUI Fall Meeting.

Our first presentation for this next session will be by Dr. Hossein Jadvar, who'll be talking on training and experience for all modalities, the subcommittee report. Dr. Jadvar.

VICE CHAIR JADVAR: Thank you, Dr. Metter. Can I have first this slide? Okay, thank you.

So, the title of this presentation is Impacts of the American Board of Radiology's Request to Terminate NRC Recognition of the American Board of Radiology Board Certification Processes. May I have the second? Thank you.

These are the subcommittee members: Dr. Ron Ennis, Dr. Richard Harvey, Dr. Darlene Metter, Ms. Shober, Ms. Martin, and our NRC staff resource was Maryann Ayoade. I want to thank all of them for their contributions and thoughtful comments to prepare this presentation. Next slide.

Our subcommittee charge was to identify any potential impacts of the ABR's request to terminate NRC recognition and other inactive boards identified during the NRC's evaluation of the specialty boards and provide recommendations to mitigate any potential impacts, and also to review and evaluate the NRC's current board recognition criteria and provide any recommendations for actions. Next slide, please.

These are the NRC-recognized boards. There are eleven boards listed in here, and you see that two or three bullets are in red color. We're going to focus on American Board of Radiology in this presentation.

But I just want to mention at the end, the last two bullets, that there is a board called American Osteopathic Board of Nuclear Medicine, which is a very small board. It has been inactive for more than two-and-a-half years or three-and-a-half years, and right now that recognition is under review.

The last bullet is on Certification Board of Nuclear Endocrinology, CBNE, which is inactive, or has been inactive for a long time and is no longer recognized by the NRC. So, with that, we're going to talk about ABR. Next slide.

Some background material. ABR was founded in 1934 as a not-for-profit organization, and a member of the American Board of Medical Specialties, ABMS. ABR is one of the 24 specialty-certified boards for physicians.

ABR certifying board for diagnostic radiology, interventional radiology, medical physics, which- will be under either diagnostic, nuclear or -therapeutic as- well as radiation oncology, and sub-specialties within radiology, which are nuclear radiology, neuroradiology, and pediatric radiology.

The mission of ABR is to certify that their diplomates demonstrate their requisite knowledge, skill and understanding of their disciplines to the benefit of patients. Next slide, please.

Prior to 2005, ABR did not provide AUE designation on their board certificates. Between 2005 and 2023, the AUE AMP, which is authorized medical physicist-eligible, and RSO-eligible designations, was an option for candidates.

December 31, 2023 will be the last date for the AUE designation on certificates. And these include diagnostic radiology, the combined

interventional radiology, diagnostic radiology, radiation oncology, diagnostic medical physics, nuclear medical physics, and therapeutic medical physics.

From 2024 and beyond, there will be no AUE designation option. Candidates provide relevant T&E documentations through their employers directly to NRC, to add the employee to the employer's license.

There was a webinar that was on YouTube on March 30, 2022, where the ABR provided reasons for making this decision, and I summarized some of those reasons here.

They mentioned that it's not aligned with the core ABR mission and it diverts their limited resources. ABR has never issued AU status. Most radiologists are not and do not need to be AUs. ABR merely passed along documentation of T&E, and a direct pathway to becoming AU already exists.

AU requirement for the 700 hours of training and experience in nuclear radiology is an ACGME or residency requirement.

The IR/DR Forms A and B and radiation oncology two-page verification form will not be needed to be submitted to ABR anymore after December 31, 2023.

The RISE questions, which stands for Radio Isotopes Safety Exam, will not be scored separately, but the items and the questions will be incorporated into the rest of the certifying exams.

Trainees and residency programs should continue to keep T&E documentation, and T&E documentation is needed for the sixteen months embedded nuclear medicine diagnostic radiology pathway, and nuclear radiology fellows are still needed for them to sit for the exams.

For example, in this case, the nuclear radiology CAQ or "certificate of added qualification". Next slide, please.

These are just a couple of papers I thought would be useful to include. One of them is published in the American Journal of Roentgenology, which describes things that folks need to know about how to become an authorized user. So, it's a good resource.

There was also a recent news SNMNI, Society of Nuclear Medicine and Molecular Imaging newsline that was authored by George M. Segall; Dr. Segall, who is executive director of ABNM.

And in it, as you can see, it specifically says that if somebody's ABNM certificate

holder, their training and experience is entirely aligned with requirements of the NRC to be AU. Next slide.

Regarding the workforce and how many AUs are out there, this slide shows the ABNM - American Board of Nuclear -Medicine - certification- examination candidates and diplomates. As you can see, since mid-1970s, there was some decline in early 2000s, but it has stabilized and there are approximately 70 new diplomates that are added through ABNM. Next slide, please.

This slide I borrowed from Society of Nuclear Medicine and Molecular Imaging. This shows, again, the trainees for nuclear medicine who will be authorized users, and also folks who take the nuclear radiology pathway.

These are residents who completed four-year diagnostic radiology residency, and then go on and do one more year of nuclear radiology, and will sit for the ABR nuclear radiology CAQ - Certificate--Added Qualification. And as you can see, it's a relatively minor number of people who go that way. Next slide.

With regard to medical physics programs,

here is another slide I borrowed from the Society of Nuclear Medicine and Molecular Imaging, and you can see that it's relatively a stable, approximately a little more than a thousand people are enrolled in medical physics programs, and the graduates are approximately a third of that every year, about 300 medical physicists. Next slide, please.

So, what is the ramifications and potential issues with this decision? There may be potential confusion and challenges with burden on applicants and institutions, for securing AU, AMP, or RSO status for the new hires.

AUE board certification is rapid for proof of AU eligibility when that was on the certificates, and ABR may have underestimated the burden that are being placed on the applicants, preceptors and program directors.

The willingness of preceptors to sign off if the training and experience was more than a seven-year window, may be a problem. Or, if the preceptor may not be willing to sign off if they were not involved to begin with, with the applicants' training and experience.

There may be potential increasing time reviewing a T&E documentation at NRC and academic

states, and there may be possible delays that may impact practice of medicine. A person with an AUE could function immediately in their institutions.

To that, we were provided information on a couple of states in California. It takes approximately four hours per license amendment and 100 AUs are added per year.

It turns out that there was no time difference between ABR certification designation that they had, versus alternate pathways.

In Wisconsin, Ms. Shober told us that there's no apparent adverse impact on regulatory agencies, based on licensing databases, from 2020 and 2021. But this is obviously retrospective review and the AUE designation was still available.

Also, in the commissioner papers, it is stated that it takes about fifteen hours for NRC to review an application, eleven hours for the agreement states, and five hours for the licensees. So, these are approximate numbers of how long it will take to go through this evaluation. Okay, next slide, please.

So, 80 percent of the ABR certifications included AUE designation. It's unknown at this time what percent of these designated certificates were

actually added to any RAM licenses.

There needs to be alignment of ACGME, AAPMCAMPEP, and NRC T&E requirements, for AU and AMP designations. We found that there may be some misalignments in some areas.

No indications that other NRC-recognized entities will follow ABR decisions at this time. As I mentioned, CBNE is dissolved and a small board, AOBNM, is inactive and is under review at this time.

We thought that the Association of University Radiologists, or AUR, meetings may be an appropriate venue for discussions and potential publications of recommendations, which is the AUR flagship journal, called Academic Radiology, so that more people are aware of what may be their issues regarding this decision. Next slide.

So, we came up with some questions for ABR and I read through them. Can ABR reveal time spent and/or expense for including AUE designation, versus eliminating it, which is what they decided to do?

Number two, how do ABR members, and perhaps applicants' preceptors and program directors, feel about this extra burden that is placed on them by eliminating the AUE designation on board

certifications?

Number three, are there other options, rather than eliminating the AUE designation on the board certifications?

Number four, did the AUE to clinical AU conversion play into ABR's decision? And if so, what was this estimate and how was that estimate obtained?

Next question is, how many ABR certified physicists get the RSOE designation under certificates per year?

And finally, if there is a significant decrease in MPs approved to be RSOs, are there any plans to increase the number of radiologists who are prepared to become RSOs at their institutions? And next slide I think will be my acronyms. Thank you very much.

CHAIR METTER: Thank you, Dr. Jadvar, for that very in-depth presentation on this topic of training experience, and particularly with the ABR NRC recognition status. Do I have any comments from the ACMUI subcommittee regarding Dr. Jadvar's report? Mr. Ouhib?

MEMBER OUHIB: Excellent presentation. But I think, if I recall correctly, and I actually did see that YouTube presentation from the ACR, the

number one point, the ACR felt that's not their business. Period.

VICE CHAIR JADVAR: ABR.

MEMBER OUHIB: That's correct, the ABR, I should say. Yeah, it's not really their business to get into this and evaluate whether someone is an authorized user or not. This is the business of NRC, and so on and so forth. And I think that's all.

CHAIR METTER: Thank you for that comment. Any other comments or questions for the subcommittee? Yes, Dr. Harvey?

MEMBER HARVEY: Thank you. I agree with that, but I think that the ABR is being a little bit shortsighted here.

They're just going to be passing the buck. They're going to be passing the burden onto the sites, the licensees, the individuals who are applying for authorized user status and, as Dr. Jadvar pointed out, that there's going to be some significant effort that needs to be taken.

And it's going to be more difficult. It's more difficult to find preceptors. I've been in situations where preceptors are no longer living. I've had preceptors not want to sign off as indicated.

So, everything the ABR is indicating is

correct. There are alternate pathways, there are ways to do this. There are ways to get around it. But I think it's going to be more difficult for the individuals themselves to do it, and it's going to be more of a burden on regulatory staff, as well as the individual licensees. I just wanted to reiterate that, and thank you.

CHAIR METTER: Thank you, Dr. Harvey, from the radiation safety officer perspective. Anybody else on the subcommittee, or ACMUI committee, who has comments regarding this topic? Yes, Dr. Wolkov?

MEMBER WOLKOV: I do have a question. I'd like to request a point of clarification. Is there a difference between requirements of requiring an AU-eligible stamp from the ABR and the ABNM? Both require preceptor attestation prior to taking the exam?

VICE CHAIR JADVAR: Well, if you get to ABNM, there are two pathways to sit for that exam. One is to do a residency in nuclear medicine, which is three years, after finishing one year of internship.

And, as I showed one of the comments by Dr. Segall, who's the executive director ABNM, that

training and experience through those three years is entirely aligned with what is required by NRC for that person who passes the exam for the ABNM to be AU.

For ABR, there is four months of training in nuclear medicine, which is embedded into every diagnostic radiology or combined DRIR residency program. That is equivalent to about 700 hours.

There is also a sixteen-month pathway, which is embedded into a 48-month diagnostic radiology residency, and those folks can sit for the ABNM exam, and most of them do. So, they get AU automatically through that. Because, again, it's completely aligned with the NRC requirements if you do the ABNM exam.

If you want to take the ABNM exam and you just finished your diagnostic radiology, which included only four months of nuclear medicine, then you need to do one year of nuclear radiology, twelve months as a fellow, and then you can sit for the ABNM exam, and to become AU that way.

But diagnostic radiologists should be able to become AU just with those four months, because that is the 700 hours that is required. And it was just facilitated through ABR with these designations.

It was apparently much faster. As I said, most candidates chose that designation, eighty percent of them.

We don't know how many of that 80 percent that had designation, actually ended up becoming AU. We don't know that. Maybe that can be provided information at some other point by ABR to us.

But most actually were interested to have that AUE designation on the certificates from ABR after finishing four years of diagnostic radiology, in the anticipation that in the future they're going to be AUs at their institution, if necessary.

CHAIR METTER: Thank you, Dr. Jadvar. I'd also like to clarify that the 700 hours is for 35.290, which is imaging and localization, supervising diagnostic studies. And other than that, any other comments or questions? Yes, Dr. Ennis?

MEMBER ENNIS: Excuse me, question for NRC. If ABR or ACGME diagnostic radiology, and radiation oncology, were to review those requirements and assure that they are completely aligned with NRC requirements, would NRC then be able to say just having ABR certification alone, like for ABNM alone, is adequate without this additional stamp?

MS. AYOADE: Maryann Ayoade from NRC.

So, right now the regulations do not recognize the ACGME's curriculum. But we ask that the residency programs go through the ACGME-approved. And so, that would be different from what we require.

We would have to look at what ACGME's curriculum is, and if it matches what we require, and NRC requirements.

MEMBER ENNIS: So, I mean, is that what NRC did with ABNM?

MS. AYOADE: The specialty boards, when they submit the application to be recognized by NRC, we tell them they have to meet our training and experience requirements applicable to the different specialty areas that they're applying for. And then, we review what they have provided to us and make sure that it meets our training and experience requirements in those areas.

We haven't done that with ACGME. We have had to review the ACGME curriculum. When we get the applications from the different boards, they would submit it, and they do not always meet our requirements. But they're not required to.

MEMBER ENNIS: So, if the ABR said to just get ABR status -- forget about ABR specifically -- require the things that NRC requires,

then that would suffice and ABR wouldn't need an extra stamp? Am I correct? So, it's not an ACGME question?

MS. AYOADE: You wouldn't need an extra stamp but the residency program that the individual goes through has to be ACGME-approved.

MEMBER ENNIS: I'm sorry, but-- I'm trying to just figure out what ABNM did, so that ABR could do the same thing. So, what did ABR --

MS. AYOADE: They're meeting the same NRC requirements as us. The difference in what I'm hearing you guys are speaking to or trying to get clarification on, is the AU eligible understanding.

And with ABR, I know the difference is in the way, when it comes to the exams the RISE exams the way that they grade the examinations to make sure that it includes the NRC requirements. But it's the same topics that are covered for ABR, where an individual can get a certificate that says ABR, and another individual could get a certificate that says ABR, AU eligible, because that individual has met all of NRC's requirements based on what ABR's examination gives, because they have a different grading system for the individuals that meet the AU eligible.

But the foundation of both boards, the

ABNM and the ABR, they've submitted their application, we've reviewed the requirements. Just like we did with reviewing this periodic review that we did. And we ensured that they meet all of the NRC's applicable requirements in 190, 290 and 390.

MEMBER ENNIS: So, I guess I'm still sorry to --

CHAIR METTER: I think I can maybe help clarify. So, the ABNM has - their- AU categories are very different. And so, the specific AU category under the ABNM has been satisfied by the ACGME-accredited nuclear medicine programs.

As far as for the ABR, it is for three other types. There are three different AU statuses, and one is for imaging and localization, which, as I mentioned before, diagnostic procedures, and the other two are for I131 therapy. And so, those are different AU statuses and they're not the same as the one that the ABNM has been recognized by the NRC.

MS. AYOADE: Yeah, and the ABR also is recognized under the radiation oncology specialty, which is what includes the 190, 290, 390. And then, there's the 490.

MEMBER ENNIS: All right, I apologize, but I'm still not really understanding what ABR could

do so that they're just being board-certified, if you had gone through an ACGME training program in nuclear medicine, diagnostic radiology, or in radiation oncology, that that would suffice the way for ABNM it suffices.

I'm not sure what's the difference conceptually between what ABR has done until now. And forget about the stamp. Like, I'm still not really understanding why the stamp is needed.

MS. AYOADE: Yeah. My understanding - because- ABR, they presented to us how they can meet NRC's requirements. And so, they want to be able to issue their ABR certificates to individuals that may not meet the additional requirements that NRC requires. So, that's where the difference is.

MEMBER ENNIS: So, do we know what those --

MS. AYOADE: So, as I said, we do sometimes get ABR certificates without the AU eligible. That was, we approved the recognition based on what they presented to us. And we're going to meet NRC's requirements, we're going to make sure that all these topic areas are covered, and the individual successfully complete the examination for

things that are applicable to whatever it is that are different sections of the regulations.

And so, that's how we recognized the ABR. And so, when we get certificates that do not include the AU-eligible seal on the certificate, then we recognize that they do not meet all of NRC's requirements.

It doesn't mean that they can't have the ABR certificate to go on to do other things, but they cannot do NRC-related activities.

MEMBER ENNIS: Mmhmm. And does anyone know what the differences are for ABR-certified positions who are and are not AU-eligible?

MS. AYOADE: It's really based on the examination. Right? Everything that they put on the examination are the same questions. But then, they rate the questions differently for the sections that are related to NRC.

And so, if an individual doesn't meet the way they grade the system for the examinations, and they don't meet the NRC's criteria based on the exams, then they do not include that AU-eligible stamp on the certificate.

CHAIR METTER: Dr. Ennis, does that help clarify?

MEMBER ENNIS: I guess so. So, it comes down to the exam. And that was the comment that part of what ABR said is they're no longer going to score RISE questions separately. So, that's the crux of the matter.

MS. AYOADE: Yes. And we did not put that as a requirement to them. Right? They presented it in their application to us for how they're going to meet NRC's requirements, because they already had a system before they came to us.

CHAIR METTER: We also have on the public, Dr. Brent Wagner, who is ABR executive director, and he will be commenting later during the public comments, on certain questions that the subcommittee has. Mr. Ouhib, you have some questions?

MEMBER OUHIB: Yeah. It's sort of a big question mark that can the ABR period - forget about the AU -ABR - and- then have some sort of an agreement that NRC would provide that information to the ABR, to include whatever the requirements are in the exam, per se? And then, there would be a continuous agreement that, yes, ABR meets NRC requirement period, when we don't need the AU anymore? Period.

MS. AYOADE: I mean, that is a

possibility. But it would have to come from the ABR to us, to show us how they're going to still meet all of the NRC's requirements in making sure that the individuals have successfully completed the examination applicable to all of our requirements. So, they would have to come back to us and present that.

CHAIR METTER: Dr. Einstein, you have a question?

DR. EINSTEIN: Yeah, two questions. One, just a clarification of verbiage. Was there a specific request of the ABR to terminate NRC recognition of this process, or did they simply say that as of the end of 2023 they're no longer going to offer this AU-E credential?

VICE CHAIR JADVAR: The second.

DR. EINSTEIN: The second. Okay. And secondly, does four months necessarily constitute 700 hours, or 620 hours? It sort of depends on how you count it. I think a lot of training programs will say that a month is four weeks.

So, 700 divided by sixteen is, like, 44 or so, and trainees often don't work 44 hours per week, especially if you count post-call days and conferences, etc.

So, it's not entirely clear to me how strictly 700 hours are interpreted.

VICE CHAIR JADVAR: You are correct. And there may be even vacation times that are taken during that time, or post-calls or pulled to other services. So, it's just in the paper, four months isn't that necessary. And that's incorporated into residency programs.

But whether that four month is completely adhered to - really four months, five days a week, let's -say - I- don't think anybody really monitors that.

DR. EINSTEIN: It could be four months but not 700 hours, in other words.

VICE CHAIR JADVAR: Right.

CHAIR METTER: In my opinion, it's going to be the preceptor who attests to the 700 hours. And in our program, we do five months of training. Ms. Martin, you had a comment?

MEMBER MARTIN: Yes, just a follow-up on the physics questions. I did discuss with the gentleman that's in charge of the residency training for medical physicists, and it was the same type of questions that's been raised for the clinicians, is to try to get the ACGME, which can't be the

accreditation of a residency, qualify the person to sit with the exam, or to be designated an AU, or an RSO, because that's the two options we have.

It is up to the program director currently, whether they sign off on an individual's training or not. He said it would take at least two years to verify that the programs do meet it.

That is going to be the goal, is to say that if you went through a CAMPEP-accredited program, that it would be recognized that you've had the adequate training to be an authorized medical physicist, but if the timing may or may not work out but looks like maybe about a year short.

CHAIR METTER: Okay, thank you for that. Any other comments or questions from the ACMUI committee? Yes, Ms. Shober?

MEMBER SHOBER: Yeah, just one impression that I have. So, I realize the ABR, you have the radiologists, and you have the radiation oncologists. From a licensing perspective, the vast majority of the radiation oncologists that we approve via licensing, come through the alternate pathway.

And they do that because they want to get approved as an authorized user before they're eligible to sit for the board. It's like, what, a

year or something?

So, we see those radiation oncologists graduate from their residency, and then almost immediately want to apply for AU status for that.

So, those positions are virtually all coming already under the alternate pathway. That's not the case for most of the diagnostic radiologists that we see. Those tend to come in later. We see a lot more of the board certificates for that.

So, I just wanted to say, I don't know how representative my experience is for licensing agencies out there, but at least for the radiation oncologists, I don't see an impact for this, because they're already circumventing the board process in order to get on the licenses sooner anyway.

But obviously, there's a lot more diagnostic radiologists that get approved on licenses, as compared to radiation oncologists.

CHAIR METTER: I believe that Dr. Wagner can clarify when he makes his comment, that for the ABR-eligible, you're not able to sit for the second part of the certification exam until thirteen months after training. Do I have any other questions or comments from the ACMUI committee?

Seeing none, any comments or questions from

the NRC staff?

MS. VALENTINRODRIGUEZ: Dr. Metter, this is Celimar Valentin with the NRC staff. So, I guess on our -end - this is for the NRC -staff - I- think the subcommittee is still in fact-finding.

And so, I believe there's no recommendations for the NRC at this time. But we will be looking at the information that you gather, to kind of go out to the public and get some public feedback after this.

So, I just wanted to make sure that at this time there's no action recommended for us.

CHAIR METTER: Thank you. And we'll open it for public comment. And after the public comments, we'll go ahead and vote on the subcommittee's report. And then, we'll also vote on the subcommittee report from this morning, on Dr. O'Hara's Y-90 medical events.

So, Ms. Lopez, do you want to go ahead and open it up and - oh-, excuse me. Ms. Shober has one other comment.

MEMBER SHOBER: Yeah, I'm sorry. I don't think there's a report for this, is there?

VICE CHAIR JADVAR: No.

CHAIR METTER: His presentation. I'm sorry, thank you. Okay. Thank you for that

clarification. Now, can we open it up to the public? And I think Dr. Wagner is on the line.

MS. LOPAS: Yes. Dr. Metter, would you like to facilitate the conversation with Dr. Wagner, or should we just open it up for Dr. Wagner to begin with the public comments then?

CHAIR METTER: Can we open it up to Dr. Wagner at this point? And I think Dr. Jadvar can ask the questions. Or, if Dr. Wagner wants to address certain specific questions at this time, or comments.

DR. WAGNER: Yeah, I can - can- you hear me okay, Dr. Metter?

CHAIR METTER: We can hear you fine, thank you.

DR. WAGNER: I can go through the questions, and I'd welcome clarification, and questions or interruptions, as we go along, this nature on addressing what the concerns are. And I'll just run down this bulleted list if you'd like.

I don't know the amount of time that was spent, or the expense, to include AU designation. I know that the staff was involved in trying to track down some missing documentation on a lot of people, because we wanted to make sure the documentation was completed correct.

And when I presented this to my board, they didn't actually didn't even ask for clarification, per se. They merely were saying - well-, my board called my boss, basically, as to how much is too much.

And already my staff has told me they're moving forward to not having to track down missing documentation for candidates with certification, because as it is, we have to check all those boxes and make sure that the documentation's been received so that it's correct and pursuant to our agreement with the NRC.

So, I don't know the answer to that. But I think my board would say it's sort of their call, as far as how much is too much. And as I said before, it does divert attention and at least some resources from that.

Just to clarify, we don't have members in the second bullet. We have stakeholders, and we certainly take the interests of those stakeholders seriously. But it really is a question for us that our stakeholders are candidates for certification, with diplomates, the program directors, the public, and, interestingly in this context, the NRC.

And we did hear some concern from program

directors earlier this year when we first made the announcement. I think partly no one likes change. We've heard much less regarding those concerns since that time; since back in March when we announced this.

And just as a reminder, we are agreeing with the NRC, so we had to give six months' notice. We gave over eighteen months' notice, to allow for the transition for all those stakeholder persons that might be impacted by this change. As I say, no one likes change, and this was such an example of that.

One of the related questions that came up it's- not directly part of these bulleted statements --that we were passing the buck. And I guess a more logical question would be, not so much why are we stopping doing this, but why did we ever start. Why did the ABR ever agree to do this? Because it's not part of our mission. It's not even close.

We're a certifying body. We're don't exist to pass through data onto the NRC, or to anyone, quite honestly. So, from the point of view, again, of my board, it was really a question of, would we ever venture into this?

And this all happened back in 2005, 2006, before my time. But that was part of the calculus

for us, was that this is probably not something that really fits. Well, clearly it does not fit within our mission.

The other options. The problem with this, and it does relate a little bit to the ACGME question, this is binary. We have to do it perfectly, or not at all.

We can't collect the data in a way that's haphazard. We can't get it right 90 percent of the time. The NRC wouldn't approve of that. We wouldn't approve of that. And that's really where the challenge is.

We can't do it halfway. We've got to do this 100 percent. We've got to make sure all the data is correct. And we do. And I think that's part of the challenge in trying to justify this from a staff and resource perspective. Because boards-are-efficient is not a requirement to be an authorized user, and as you all know.

I did want to clarify something about the seven-year, and I was just taking notes as people were talking. The seven-year limit applies to MRP eligibility status as well. So, I'm unclear as to why that duration matters from the point of training.

But we have our preceptors who even balk

at having to sign off on training that occurred outside of their window as well.

The clinical AU conversions play into our decision. I'm not sure what that means, so I'll ask that for clarification.

And then, if I can cover these last two bullets. How many physicists get the RSOE designation on the certificates? I would have to get that number for you. Dr. Metter may have provided that number to you before, I can't recall. And I don't know that off the top of my head.

I do not know - and this question came up during the -discussion - how- many diagnostic radiologists, for example, elect to be called authorized users?

I have no way to know that. I don't know if it's 50 percent, 100 percent. It's probably less than 50 percent, based on practice patterns that we see. But I don't know how many, because they don't report back to us, right? The NRC would have a better chance of knowing that than we do, and I'm not sure it's an easy ask of them either, quite honestly.

Are there any plans to increase the number of radiologists prepared to become RSOs? The ABR does not control the workforce. We have no way

to endorse that at all. So, I don't know if the market -meaning the local healthcare market --would change that, but the ABR does not control who decides to become an RSO, at the physics level, or at the diagnostic radiology level.

Also, to clarify - and, Dr. Metter, you alluded to -this - for diagnostic radiology, it is fifteen months after completion of training-. when you can sit for board certifications.

And I think with diagnostic radiologists, the urgency to become an authorized user, for those that do ultimately choose to do it as well, I think the urgency for a radiation oncologist is higher. And their first certification opportunity is in May of the calendar year following completion of training, so about nine months or ten months out from training, just to clarify that question that was asked in the discussion.

Regarding the ACGME, I'm going off-script here, only because these questions came up and I jot them down.

Maryann, you remember one of your colleagues - and this goes back to 2020 -actually - one- of your former colleagues told me, in plain language, ACGME-accredited programs are

not enough. Meaning, we couldn't use that.

I think, Maryann, you said that same thing. So, I appreciate you kind of reinforcing that. But that's not the agreement we have with the NRC. Our agreement is that we will vouch for the data and we will collect it accordingly; again, at 100 percent accuracy. We're not able to just say, oh, it's an ACGME problem because that's the training requirements in parallel. It's close, but the documentation piece we're responsible for, and that's where it falls outside of our mission.

And I just wanted to close, and I'm glad to take any further follow-on questions. The other pathway, the alternate pathway that is going directly through the NRC instead of through the ABR, and it was alluded to in the context of radiation oncology, from ABR's point of view, we're the alternate pathway. The NRC is the primary pathway.

So, if that helps kind of clarify or codify our understanding about this, is that, again, you don't need to be board-certified to be an authorized user.

And certainly, for the bulk of our diplomates, even though they are board-certified, they don't go on to become authorized users. And

that's partially anecdotal, but I think a realistic estimate that's a minority of our diplomates who wind up being authorized users.

So, with that, I'll be glad to take any clarifying questions.

CHAIR METTER: Thank you, Dr. Wagner, for taking the time to clarify some of our ACMUI questions and concerns regarding the ABR's NRC recognition. Do I have any questions from the ACMUI for Dr. Wagner? Yes, Dr. Jadvar.

VICE CHAIR JADVAR: Dr. Wagner, this is Hossein Jadvar. First of all, thank you so much for taking time to call in and answering some of our questions.

One question, has ABR already contacted the program directors and communicated what this decision is? I assume that has been done. And have they communicated that to the residents in the programs?

And have you received any feedback from residents or program directors on how they feel about this, or any comments that you heard back from them?

DR. WAGNER: Yeah, that's a great question. We actually sent our notice to the NRC in late-March in 2022. And shortly after that we

announced to the program directors via multiple channels, including the webinar that was alluded to already. That was a publicly - anyone- could attend, any questions that came up.

We've communicated directly with the program director organizations at varying meetings over the months that followed our letter notifying the NRC.

So, I don't believe there's a shortage of information out there regarding what we're planning to do. And again, the idea was to give as much notice as possible - in this case, more than eighteen months' -notice - so- that the programs, and the candidates in those programs, can make the necessary adjustments.

Initially, as I mentioned earlier, we had some, I suppose, again, this fear of change. And we were asked initially to come up with sort of a guide, if you will, or an instruction sheet, what you do next.

And we realized that essentially what we'd be doing is saying, go to the NRC's website, because it's spelled out very clearly in the application to become an authorized user, what the ultimate plan is. And I just left because I said

alternate plan.

But what the baseline plan is, to go directly to the NRC for those, based on documentation of training and experience.

And we did have, as I said earlier, some early, I think, dissatisfaction because people knew they would have to adjust. I've heard very little since that time, since about mid-summer.

If we go arguing, hey, this is a burden that the program has to pick up, and our argument is, well, again, maybe we shouldn't have been doing it to begin with. And I hope that answers your question. Incidentally, I want to thank everybody for indulging me to be here, because I'm glad to have these conversations, and I'd be glad to make my contact information available if there are follow-up questions after this session.

CHAIR METTER: Well, thank you, Dr. Wagner. Any other comments from the ACMUI? Yes, Mr. Ouhib?

MEMBER OUHIB: Dr. Wagner, first of all, thank you for being available and answering some of those questions.

And without disclosing the details, or even the items themselves, are there any discussions

going on right now between the ABR and the NRC looking to possible solutions down the road to actually help with this issue?

DR. WAGNER: I just want to make sure I understand what the issue is. So, what is the exact issue that we'd be --

MEMBER OUHIB: Well, the issue is the current item that came up regarding the ABR-AU designation no longer available, that could affect other people in being authorized users, and so and so.

In other words, they will have to go through the NRC requirement and so on, instead of having the NRC saying, like I said earlier to the NRC staff, is it possible that the NRC can, in advance, submit what the expectations are, and those items are being dealt with at the time of the exam, and so on and so forth?

DR. WAGNER: Yeah. And so, okay, I understand. I guess the amount of paperwork, the administrative burden on the programs, including the coordinators, the candidates themselves, for certification, should be about the same.

I don't know that we represent a streamlined version of that because they just have to

submit the paperwork to us, so that we can then ascertain that they are qualified to receive AU-eligibility designation on our certificate.

So, from the point of view of the programs themselves, it shouldn't matter. I can't speak to what the NRC burden, if you will, is. Because I suppose until application is made, there is no direct burden to the NRC.

I think the net-net on this is that because we're sort of overshooting the mark in that most of our diagnostic radiology certificates and that's most of the certificates we offer are receiving AU eligibility status they will never use, because their seven-year clock will expire before they ever need it, or there's never a need, of course, in their career. And again, I'm basing that on academic departments and private practice departments that just have a relatively low number of people who see or need authorized user status.

So, I can't say what the NRC burden is going to be moving forward. I'm just saying that our argument was that we represent a pass-through for a large number of people who, in fact, were never going to use this status anyway.

And as those have already alluded to, for

radiation oncologists, they don't wait for the certifications to happen. They go through the direct NRC pathway anyway because they have to, because they're already out training in practice. I hope that answers your question. But it's a little hard for me because we only sit on one corner of this. We don't control the whole process.

CHAIR METTER: Thank you for that. Ms. Shober, did you have a comment?

MEMBER SHOBER: Yeah. Just hearing this pending question about in what percentage of authorized - the- AUE candidates, how many of them, what percentage of them actually become- authorized users, I mean, I'm the back half of that.

So, if the committee is interested in that, if I can get a list, for example, of the active ABR-certified radiologists in Wisconsin, I can get that number, at least for my state. I mean, if that's still one of the big question marks here, I can at least give one data point for that.

DR. WAGNER: Yeah, I can certainly try and find that out. I don't know that --we do have state location as reported by the diplomate --

MEMBER SHOBER: Right.

DR. WAGNER: -- and if they're practicing

in more than one state, that would be a challenge. But it would be close enough. And we can certainly try to get you a list of diplomates. And it's public information, right? Anybody can log on and begin with my name into our website and find out that I'm board-certified and I'm in Tucson, Arizona.

But we can try to compile a list of diplomates across all borders, those actually who are practicing in Wisconsin, if that would give a rough estimate about what percent of diplomates ultimately turn out to be authorized users, if I understood your question correctly. But we can certainly try and compile that.

CHAIR METTER: Thank you, Dr. Wagner. Perhaps maybe, rather than going back twenty years, maybe the last five years would be more appropriate.

MEMBER SHOBER: Like, people that are currently authorized, they can see if they're currently unlicensed.

CHAIR METTER: Okay, thank you. Thank you, Dr. Wagner. Dr. Ennis has a question.

MEMBER ENNIS: Can you hear me? Yeah, so if I'm hearing you correctly, it was perceived as there's a fair amount of secretarial work to do for something that in ABR's view only a minority of their

applicants really needed, that just felt like maybe it wasn't worth the effort on the part of the ABR if a lot of diagnostic radiologists are getting the status but never really needing it.

And I'm wondering rather than - certainly, that's not the case for some of the diplomates that come from the ABR. Radiation oncologists, in particular-. Almost all of them are on AU status.

Could there be a possibility of ABR having a discussion with NRC, such that ABR certification and radiation oncology would automatically not need a stamp but automatically achieve AU status?

DR. WAGNER: Well, again, my understanding is that our agreement requires that we obtain the necessary documentation to do that. And again, we're the guarantor of the veracity of that information. And that's really where the problem is.

The other question was, we can't pick and choose who we apply it to. So, it has to be 100 percent of the people who might seek AU-eligibility during the course of the residency.

So, as they complete the training and we're going through the training verification

process, we collect the data on everybody but for no other choice.

Now, the only thing that would really change from our point of view is if the NRC were to accept the fact that the individual graduate in an ACGME accredited residency, and that that became then the proxy for the same thing if those measures for training and experience were in parallel.

My understanding - again, the conversation two years ago I had with the -NRC - was- that that was not so.

MEMBER ENNIS: Right. But there is --

DR. WAGNER: So, I don't know that we have the avenue that you're discussing to make that happen, unless I didn't understand the question.

CHAIR METTER: This is Darlene Metter. I have been on the ACGME, and I was a chair of the nuclear medicine RRC.

And program requirements change. And so, I think that's an issue. So, I think going perhaps the alternate pathway would be best after the NRC recognition status for the ABR ends.

Because program requirements are program requirements today, but will they be the same five, ten years from now?

MEMBER ENNIS: But just going back to my question if you don't mind, ABR certification for radiation oncology is different than ABR certification for a diagnostic radiology.

So, what I'm asking is, could ABR radiation oncology certification meet all NRC requirements, such that automatic certification would automatically lead to AU status? That's, I figure, a question both for NRC and for ABR.

DR. WAGNER: My understanding is we still have to collect that information, and that it's not as simple as merely saying that they graduated from the residency. We still have to document that they met the dosing requirements, for example, from those individuals.

In other words, we still have to verify a statement for the program that says, in addition to graduating from an ACGME-accredited program -- incidentally, it also applies to a rural college -- but in addition to that, they still have satisfied the requirements as delineated by the NRC, and we have to check that box, if you will, and make sure that 100 percent of the time we're collecting that information.

So, I don't think it helps us, because

we're still to be bound to do that. We can't create a pass-through for radiation oncology.

The other thing, incidentally, for radiation oncology it- sounds like it's a moot -point -because- they don't wait for the certification. And we're not going to award that AU eligibility until the certification exam.

MS. AYOADE: And this is Maryann Ayoade from the NRC. Dr. Wagner is right. Again, the regulations do not state that we recognize the ACGME's program requirements.

We have seen in submission of some of the ACGME's requirements, that they do not always meet the NRC's requirements. There are topic areas that are missing, they don't always specify the number of hours. So, we can't rely on that.

And if we were to do that, then that would be a whole different issue. Rulemaking, we would have to recognize the ACGME, as NRC has reviewed their program and we agree that it meets the NRC's requirements.

But that is why, like Dr. Wagner mentioned, in addition to it going through an ACGME-approved residency program, they have to make sure that the individuals are meeting the NRC's

requirements.

CHAIR METTER: Thank you for that, Maryann. I do see a question from Mr. Green.

MEMBER GREEN: So, with the American Board of Radiology opting to not expend the effort to award their diplomates, upon completion of their program, with the AU-eligible indication, it would require these individuals to achieve AU status by going through the alternate pathway.

I just want to point out - maybe pharmacists are weird, I'll admit -that - but- of the eight boards that Dr. Jadvar indicated are approved by the NRC, the Board of Pharmaceutical Specialties requires that you work for two years for 4,000 hours as a nuclear pharmacist, before you can apply to be board-certified.

So, if we say there's about 3,000 nuclear pharmacists in America, 362 are board-certified. One hundred percent of all nuclear pharmacists go to the alternate pathway. That's the way we do it.

So, here's another group of individuals will also be using the alternate pathway.

CHAIR METTER: Thank you very much for that perspective. A very interesting perspective and additional information.

And I believe Dr. Harvey, our radiation safety officer, has a comment or a question.

MEMBER HARVEY: Thank you, Dr. Wagner, for all of your input. And again, I apologize if I came off as too harsh. I didn't mean to do that, so please forgive me on that.

My concern is, I'm not afraid of change. My concern is for the candidates that want to become really board-certified.

Because really the onus really falls upon them to make sure they can get the preceptor attestations and all this information together.

Because we can't approve them to become authorized users unless they do this. So, without the board certification pathway, there is another pathway. It's just going to be more difficult for them, and I know there's a lot of burden that can be placed on many people.

So, I was just concerned really about them, not so much concerned about what we have to do as RSOs or licensees to get them approved. Thank you.

CHAIR METTER: Thank you, Dr. Harvey. Mr. Ouhib, you have a question?

MEMBER OUHIB: Yeah, I think this change

is really not a change. It's nothing new. We have done it prior to having the AU stamp on the board certification. I'm one of them that did not have the AU stamp and basically just applied nouveau. It's simple. Really, it's nothing new. It's we go back through the way we used to do it and go forward.

CHAIR METTER: Thank you. I believe other members on this committee also went prior to the AU eligible status. Any other comments from the ACMUI or questions? Dr. Angle?

DR. ANGLE: Dr. Metter, I know this is more a question for the ACGME and program directors in particular, but, you know, the real question is is this going to affect the residents' preparation to be AUs in the future?

In other words, are we going to see any diminution in their preparation as they graduate, as they prep for their boards? Are we going to take a step backwards in their preparation to be future AUs by taking this step?

DR. WAGNER: That's a great question. Certainly, my opinion is there should be no change there and the biggest reason for that is the requirements from the ACGME, from CAMPEP are not changing, so there shouldn't be a change in training

and experience and that's really what the NRC is looking at, training and experience, right?

So, I don't anticipate any change at all in the number of people who ultimately could become authorized users. That should be the same until and unless the training programs or the accreditation bodies for training programs change the requirements, because right now, it's fixed that those are required under ACGME, et cetera, so I don't think there's going to be any change at all.

The exam itself, remember in this part, but the exam in my understanding, and this is going to be for my time back in 2005, 2006, was proposed as a way to make it sort of better, meaning that there was this training experience, and the ABR path was going to be better because there were going to be a portion of the exam, dozens of items, I believe 70 items for diagnostic radiology, that would be scored separately in order to achieve this.

We're still going to include content like that in our exams but remember that you did not have that to become an authorized user. You could still go through the direct NRC pathway. So, I don't know if that answers the question. We're not expecting that there's going to be any significant changes at

the training program level.

CHAIR METTER: Thank you. Any other questions from the ACMUI? Dr. Jadvar?

VICE CHAIR JADVAR: Thank you, Dr. Wagner, again. So, the ABR decided not to give the RISE exam or score the RISE exam separately as they did before after 2024, but the content or the questions will be included among the other questions.

Why was that decision made? Can it be helpful to everyone if the RISE exam still states and, you know, you don't have to collect any paperwork, you know, but just score that separately and continue doing that?

DR. WAGNER: Well, so in the current model today through the end of next year, if you fail the RISE and have the exam, you're still board certified, I'm sorry, pass the rest of the exam. The RISE is part of the larger exam to become board certified and it's also administered as part of the core exam.

So, we're talking over 1,000 items, I think, total, 1,000 questions in two successive exams, and of that, 70 are RISE. You can pass the RISE in addition to passing the entire test to become AU eligible under the ABR definition, just diagnostic

radiology.

The reason we partitioned it out is we're basically saying, just like we don't require that you pass breast imaging, or knee MRI, or abdominal CT scanning as separate entity.

From a psychometric perspective, we're just extracting that and saying those questions will still be there, but they're part of the composite, the aggregate of about 1,000 items.

So, it's not a matter of, you know, what would we do with that information? If you didn't pass the RISE, would we do something to your certificate? And the answer is no. We are binary. You're board certified or you're not in large measure.

So, there, meaning if you were to ignore that content and not be prepared for it, you do so at your peril because your overall score would go down and potentially go down below the testing threshold, but we're not separating it out the same way we would the other 15 areas of diagnostic radiology.

And I think that's been the argument that we've used for a bunch of other things, but that will become the argument moving forward. In the past or the now, we score it separately because we need to

justify the application of the authorized user eligibility designation.

CHAIR METTER: Thank you, Dr. Wagner. Did that answer your question, Dr. Jadvar?

VICE CHAIR JADVAR: Yes.

CHAIR METTER: Thank you. I believe Dr. Ennis has a question for you, Dr. Wagner.

MEMBER ENNIS: This is actually not for you, Dr. Wagner, not yet at least, but first it's a question for Ms. Shober and for NRC. Is there, and if so, how much more time and effort for your staffs to approve someone if they come to you with an ABR stamped certificate versus they're going through the alternative pathway?

MEMBER SHOBER: So, I looked at that a couple of months ago with our data from Wisconsin. I was actually expecting it to be a bigger impact than I saw. I was, frankly, pretty surprised. So, I looked at all of the licensing actions we did in 2020, medical licensing actions to add AUs in 2020 and 2021, and there were less than five that would have taken longer if we hadn't had the ABR certificate.

So, I really was very surprised to conclude that there wouldn't be that big of an impact. So, again, I don't know how representative that is of

the whole country, but I went in expecting a particular outcome and that's not what I saw with the data.

MEMBER ENNIS: Can anyone from the NRC comment on that?

DR. VALENTIN-RODRIGUEZ: Hi, this is Celimar Valentin from the NRC. Back when we were doing our T&E evaluation for SECY20-0005, I think the staff underwent an effort to try and quantify how many hours we spent on alternate pathway and board certification amendments.

I think it was very dependent on the quality of the application. I think the estimate we gave in the paper and Dr. Jadvar had on his presentation was like 15 hours on average, but that really came from a range of ten to 100 hours.

Again, that's depending on the quality of the application, whether they submit everything or most of what we need, whether their documentation is signed by a preceptor that meets our requirements, et cetera. So, on our end, what we found is that it's very dependent on the quality of the application.

MEMBER ENNIS: So, the average was 15, and if they're coming through the ABR AU status, then how many hours is it?

DR. VALENTIN-RODRIGUEZ: Probably less than ten.

MEMBER ENNIS: Okay, so thank you.

CHAIR METTER: Thank you. Do I have any other questions for Dr. Wagner from the ACMUI? Yes, Mr. Ouhib?

MEMBER OUHIB: Yeah, I have a question for the NRC. So, do you foresee opportunities to actually improve and reduce that based on what you saw?

DR. VALENTIN-RODRIGUEZ: Yeah, so one of the things we're planning to do -- this is Celimar Valentin. Sorry, Maryann. I'll jump in and then let you go on -- is to look at our guidance and see if we can make it clarify what the expectation in terms of T&E, how to meet our requirements.

And so, if we can do that, and also make sure that all our license reviewers review the information they receive consistently and apply that information consistently, then maybe we can get to a place where we reduce the number of information requests we have to do with licensees, but again, that would be not an NRC effort, but it would be a National Materials Program effort.

MEMBER OUHIB: Right, any changes of

having some educational sessions to prepare people for that, so that way, they don't just, at the time of the application, they're like oh, I didn't know that?

DR. VALENTIN-RODRIGUEZ: Yes, so one of the things we're planning to do is to issue implementation guidance on training and experience requirements. That's going to be issued concurrent with our current schedule for our E&T rulemaking, so we foresee having something ready by mid-2024 because any changes in T&E during your E&T could affect our guidance.

And so with that, we hope to kind of clarify and provide additional information on what applicants need to meet, who needs to submit what and what is required, and maybe some additional guidance on our forms so that people can be better informed and to help meet those requirements, maybe potentially put all of the guidance that might be in different places in one spot that people can go to, and education assessments along with that, of course. Maryann?

MS. AYOADE: Yeah, I just wanted to point out before the question came in which you addressed, Celimar, Maryann Ayoade from NRC, that the

requirements for the board certification pathway really is two, one, they have to successfully complete a residency program, right, and they also have to pass the examination.

The examination has to cover topics in radiation safety, radionuclide handling, and clinical use, and the combination of those things is what was the basis for how the board certification pathway moved away from requiring the preceptor attestation which happened in the last rule.

So, I just wanted to point out the importance of the examination and why, you know, ABR has to make sure that their candidates are completing and passing an examination that is meeting all of their requirements as I mentioned.

CHAIR METTER: Thank you, Maryann, for that clarification. Any other comments or questions from the ACMUI or NRC staff? Dr. Wagner, did you have a comment?

DR. WAGNER: No. Again, thanks for giving me the opportunity to answer questions, and I think someone in your office has my contact information, my email. Reach out at any time. I'd be glad to clarify or discuss further.

CHAIR METTER: So, we can go ahead and

have that sent to the committee after this meeting, but thank you very much for your time. And I know it's an interesting topic at this time, but we appreciate your input to help us clarify and understand the actions of the ABR. Do I have any other comments from the public?

MS. LOPAS: We do have one hand raised. Jessica Clements, just you can unmute yourself and state your affiliation, please?

MS. CLEMENTS: Hi, my name is Jessica Clements. I'm a radiation safety officer and medical physicist at the University of Vermont Medical Center. I would like to share with the group that broad scope radioactive materials licenses and some specific scope radioactive materials licenses are allowed to internally improve authorized users using a process equivalent to state or NRC-approved processes.

This means that these licensees do not send AU applications to their regulators but make them available during routine inspections. I'm the former RSO for the entire southern California region of Kaiser Permanente, which maintains several hundred AUs through an internal approval process.

So, I had two comments from my experience

with license that was authorized to approve our own AUs. First, any licenses with internal approval should be considered in an analysis of the mechanisms for AU pathways. I don't believe the NRC or individual states have specifics for those that are approved, you know, with licenses with this special, you know, authorization.

And second, as the RSO that oversaw an internal process in my former role, almost all AU applicants had a certification with AU eligible on their certificate, which extremely streamlined the process.

Without it, not only would more time be required to sift through all of their records, but, you know, the quality of those submitted may not have met a minimum standard. Thank you.

MS. LOPAS: I think due to the time, we're about 15 minutes over, we're going to -- we'll have to cut off comments at this point if that's okay.

CHAIR METTER: Okay, thank you. Thank you again for that nice presentation and that excellent discussion. Thank you, Dr. Wagner, for participating and taking the time to answer our questions.

Now, to finish some work that I had not

done before the break, I'd like to have the ACMUI committee vote on Dr. Mike O'Hara's subcommittee report on Y-90 medical events. Do I have a motion to approve the subcommittee report?

MEMBER WOLKOV: Move approval of the Y-90 medical events subcommittee.

CHAIR METTER: Thank you. Do I have a second?

MEMBER HARVEY: I would second that.

CHAIR METTER: Thank you, Dr. Harvey. All in favor of approving the subcommittee report as presented, say aye?

(Chorus of ayes.)

CHAIR METTER: Any abstain or oppose? Thank you very much. Thank you, Dr. O'Hara. Your subcommittee report is unanimously approved by the ACMUI.

So, now we can go to our next agenda item is review of lutetium-177-PSMA radiopharmaceutical by Dr. Brenneman of the NRC.

DR. BRENNEMAN: Good morning. Can the committee hear me well? Great. Okay, good morning, ACMUI members and attendees. My name is Ken Brenneman and I'm with the Medical Radiation Safety Team with the Office of Nuclear Material Safety and Safeguards.

I appreciate this opportunity to present on the NRC's most recent licensing decision for the medical use of lutetium-177. Just a note, throughout this presentation, I will refer to lutetium-177 as Lu-177. Next slide, please?

Okay, to begin, in 2018, the NRC issued a licensing decision, thank you, regarding the medical use of lutetium-177 after FDA's approval of LUTATHERA, a cancer therapy agent utilizing Lu-177 to treat pancreatic cancer.

The 2018 licensing decision memo for lutetium-177's medical use is located for public view within the NRC's online Medical Toolkit at document reference number ML18136A824. Next slide, please?

NRC's 2018 licensing decision determined medical use of lutetium-177 falls under 10 CFR Part 35, Subpart E, unsealed byproduct material, written directive required.

And authorized training for the medical use of lutetium-177 should comply with 10 CFR 35.390, training for the use of unsealed byproduct material for which a written directive is required or 10 CFR 35.396, training for the parenteral administration of unsealed byproduct material requiring a written directive.

Also, waste disposal for lutetium-177 should include assessments for its long-lived metastable contaminant as the metastable form of Lu-177 may be present depending on the isotope's production method. That is whether it's produced by a direct or indirect method. Next slide, please?

So, earlier this year, the FDA approved another therapy agent utilizing lutetium-177 named PLUVICTO. This new drug aims to treat metastatic prostate cancer called PSMA-positive mCRPC.

FDA determined PLUVICTO is useful to extend life for men who have an incurable form of prostate cancer known as CRPC, castration resistant prostate cancer.

We reviewed the use of Lu-177, PLUVICTO, with respect to radionuclide safety, regulation, and its pharmacokinetic characteristics. Next slide, please?

The NRC's medical use, radiation safety, and regulatory reviews of PLUVICTO conducted assessments for Lu-177 radionuclide and progeny which assesses beta and gamma decay products, including the possibility of a 161-day half-life metastable carrier, also monitoring and measurements which

assessed post-treatment exposures and contamination detection, as well as assay criteria for Lu-177's emission energies, as well as authorized user training and experience which assessed unsealed radioactive handling and workplace exposure, as well as parental administration safety, and patient administration and release which assessed public dose, as well as licensee disposal and waste releases to sewage, also dose delivery which assessed manufacturer suggested administration methodology and worker safety, also nuclide and therapeutic agent pharmacokinetics which assessed PLUVICTO's binding efficacy, as well as free isotope carrier and non-binding agent biodistribution and excretion, as well as nuclide, progeny, and carrier biodistribution which assessed non-target uptake with respect to whole body and critical organ exposures, also was assessed was handling and storage which assessed shielding and contamination, the detection and removal, per manufacturer packaging delivery, storage, and use, as well as methods for isotope security and control, and lastly waste disposal which assessed decay in storage under Rule 10 CFR 3592 with special attention to the metastable Lu-177's long life considerations, long half-life considerations.

Next slide, please?

The NRC has revised the 2018 Lu-177 licensing memorandum to include PLUVICTO. The memo is currently in concurrence, and when accepted will be posted on the NRC's Medical Toolkit, replacing the 2018 memorandum. Next slide, please?

So, I've listed my contact information for my contact information and locations to view further PLUVICTO information, as well as the location for our new 2022 Lu-177 licensing decision memorandum.

I can be reached by email or answer questions regarding the revised Lu-177 licensing decision at the address listed above listed on the projector.

And next slide? And then I listed the acronyms used in this presentation.

CHAIR METTER: Thank you, Dr. Brenneman, for your report, and do I have any questions from the ACMUI committee? Mr. Green?

MEMBER GREEN: Thank you for that presentation. I just want to point out, in reading the FDA-approved package insert for PLUVICTO, under Section 16, the last paragraph reads lutetium-177 may be prepared using two different sources of stable

isotopes, either lutetium-176 or ytterbium-176, and it requires different waste management.

Important is the next sentence, lutetium-177 is prepared using ytterbium-176, the non-carrier added route, unless otherwise communicated on the product batch release certificate.

So, all of PLUVICTO will be clean lutetium. It's the former product, LUTATHERA, which can have the 177m contaminant in it. So, at this point, unless the batch release tells you otherwise, all PLUVICTO will be free of long-lived contaminant.

CHAIR METTER: Thank you for that clarification. That's very interesting. Any other comments or questions from the ACMUI? Ms. Shober?

MEMBER SHOBER: Yeah, I just have a quick question. I don't know if this goes into NRC review. I was really surprised on inspection a couple of months ago to find out that the LUTATHERA and PLUVICTO come in the same color lead shield, and I'm just wondering about, like, radiation safety for that.

They're both in like a mint green lead vial, like I just don't understand why a drug, two different drugs that are almost the same, but really different would look the same, you know, to casual observation. So, I don't know if that was a part of

your evaluation at all or not.

DR. BRENNEMAN: No, that was not, sorry.

CHAIR METTER: Okay.

MEMBER MAILMAN: I do think it goes farther than that. The shipping box that it's contained in is the exact same shipping box with only one label that can go over that identifies it as PLUVICTO, and I've already seen instances where that label is covered over by shipping tags, and so that what's identified in the box is not identifiable other than it's coming to you from the company.

So, I think there is some questions, both on the handling of the pig, but also how the entire thing is shipped that have been highlighted to me in several visits I've made to nuclear medicine facilities.

CHAIR METTER: Thank you for bringing that up. Perhaps the NRC can address that. Mr. Green?

MEMBER GREEN: Currently, all PLUVICTO that's being received by patients in the United States is manufactured in Italy and brought across the pond. I understand that Novartis is putting up a factory in New Jersey to manufacture PLUVICTO domestically and that may change some of the

logistics and some of the packaging.

MEMBER MAILMAN: These boxes are both coming from Millburn and Italy. They are identical. I mean, I have photos, so I'll share them later.

CHAIR METTER: Dr. Brenneman, did you want to make a comment or -- okay, we're just going to be making your comment and then we really have to move on. Go ahead.

DR. BRENNEMAN: Yeah, I don't believe that New Jersey production is happening yet? No, yeah, it's all, yeah, it's all from the same company.

CHAIR METTER: Okay.

MEMBER MAILMAN: That's actually -- there is for clinical trials. They're currently -- so for any of the clinical trials that are going on, there is New Jersey production. It's just not for the approved product. So, there is shipments currently going out of Millburn as well.

DR. BRENNEMAN: Okay, thank you.

CHAIR METTER: Okay, thank you. I'm going to have to cut the questions short. We are a bit behind the schedule. So, our next presenter will be Mr. Carrera from the NRC regarding radioactive source security and accountable rulemaking. Mr. Carrera?

DR. CARRERA: Good morning, ACMUI members and committee. I hope you had a wonderful weekend. So, my name is Andy Carrera and I'm one of the project leads for this radioactive source security and accountability rulemaking and I will call it the RSSA rulemaking for short. So, online with me, we have Dr. Anita Gray, who is our technical lead for this effort.

So, just by way of high-level information about this rule, so consistent with the Commission's direction -- next slide, please -- in SRM-SECY-17-0083, the NRC staff is conducting a rulemaking to revise the radioactive source security and accountability regulations.

And this rulemaking would affect applicants for a radioactive material license and licensees who transfer category 3 quantities of radioactive material. So, this rulemaking -- next slide, please?

This rulemaking would also address recommendations from several U.S. Government Accountability Office reports and would further deter someone with malicious intent from purchasing category 3 quantities of radioactive material. However, we won't be discussing those reports today.

And the NRC staff is planning to submit a draft proposed rule to the Commission for approval by December 21. Assuming approval by the Commission, the NRC plans to public the proposed rule in the Federal Register in early 2023 and then follow that up with a final rule in approximately mid-2024. May I have the next slide, please?

So, in this rulemaking, the NRC staff is proposing to amend the regulations in 10 CFR Part 30, 40, and 70 to require applicants to demonstrate that they will use the requested materials for the purposes stated on their license application.

And this regulatory change will further ensure the validity of license applicants, and that safety and security equipment are in place before the license issuance, and also would help address the concern related to a person could obtain a valid license using a fictitious company or by providing false information. May I have the next slide, please?

So, the NRC staff is also proposing that new requirements to 10 CFR Parts 30, 31, 32, 40, and 70 for a licensee transferring category 3 quantities of radioactive material to verify the recipient is authorized under its license to receive the type, form, and quantity of radioactive material to be

transferred.

Such verification would be made through the NRC's License Verification System or LVS, or by contacting the license-issuing authority for the recipient.

The proposed requirements would address a concern related to a person altering a valid license to obtain more or different quantities of radioactive material than authorized or using a counterfeit license to obtain a category 3 quantity of radioactive material. May I have the next slide, please?

So, to facilitate the implementation of the proposed regulations, the NRC staff is proposing to add a definition of category 3 quantities of radioactive materials in 10 CFR Part 30, and also add new Appendix F to the Part 30 regulations that would provide the threshold for the quantities of radioactive materials. May I have the next slide, please?

So, the NRC is also proposing to include the changes to the regulations that are administrative in nature, and these are changes that are corrective of minor non-parts in nature and do not substantially modify existing regulations in the

10 CFR Parts 30, 31, 40, and 70. Next slide, please?

So, the NRC staff expects to update NUREG 1556 series to make informing changes with this rulemaking effort.

So, that NUREG 1556 series are these guidance for implementation of the regulations, and to support and accelerate the development schedule for this proposed rule, the updates will be made in future revisions of the guidance rather than concurrently with this rulemaking.

However, an interim guidance in the form of Frequently Asked Questions (FAQs) will be added to NRC's public website and the NRC will be seeking public comment on the draft FAQs. May I have the next slide, please?

So, I mentioned before the NRC staff plans to provide the draft proposed rule to the Commission by December 21, and assuming the Commission's approval, with approval of the proposed rule, the NRC plans to publish the proposed rule in the Federal Register in early 2023, and once the proposed rule is published, the NRC plans to conduct further stakeholder engagement during the public comment period to discuss the specifics of the proposed rule and facilitate stakeholder comments on

the rule. May I have the next slide, please?

So, this comes to the end of my presentation today. If you have any questions after today, please feel free to reach out to me or Dr. Anita Gray at the information provided on this slide.

CHAIR METTER: Thank you, Mr. Carrera, for your presentation. Are there any questions from the ACMUI for Mr. Carrera on his report? Yes, Mr. Ouhib?

MEMBER OUHIB: Yeah, just a simple comment is that should this information that's going to be available to the NRC be accessible only by people who actually have sources? In other words, you don't want that information to be accessed by someone who has, you know, bad intent per se and they know the rule behind it.

DR. CARRERA: And that's why we're very careful in terms of putting in the regulatory text what are some of the criteria that would need to be in place, and those criteria will be in the pre-licensing guidance during the license application process that the staff have to go through, but those are only for your information and we wouldn't be putting it out. Thank you.

CHAIR METTER: And I believe we have a

question from Dr. Ennis.

MEMBER ENNIS: Just a clarification. So, category 3 is very high activity levels that won't affect most of the practice of medicine? Am I correct on that? I forget exactly what the definition of category 3 is.

DR. CARRERA: So, category 3, many of you know of the IAEA code of conduct, category 1 and 2 would, you know, be giving -- yeah, let me --

DR. GRAY: Yes, sorry.

DR. CARRERA: Okay.

DR. GRAY: This is Anita Gray. So, you're right, both category 1 and 2 are the most dangerous out of 1, 2, and 3, and this rule is for category 3, and for the most part, it's just your HDRs, so it will affect those sources.

So, we have thresholds of the definition of what category 3, based on the threshold of like 16 radionuclides. That's a part of this rulemaking, and so we're concerned about 16 radionuclides and we have thresholds for those nuclides.

And for this group, I think it's just iridium-192 sources, but you could look at the thresholds and determine if it affects you or not.

CHAIR METTER: Does that answer your

question, Dr. Ennis?

MEMBER ENNIS: I guess I'll have to look at it. I guess I was just getting at if this was going to affect the practice of medicine, I'm a little surprised we didn't have an opportunity to comment before it's already going to the Commission with your recommendations.

DR. CARRERA: Yes, and I do apologize for that. We are on a very tight schedule in delivering this, conducting this rulemaking in four months, and so I believe we are open to having, you know, further conversation with the committee during the proposed rule comment process.

Now, regarding, you know, the type of category 3 that would be in the medical field, I believe Anita mentioned that these are the high dose rate record therapy sources that would fall under this category.

CHAIR METTER: Okay, thank you. Any other questions? Yes, Ms. Martin?

MEMBER MARTIN: Can you give us an example of how you think these new regulations would affect the medical practice for those of us that actually are involved with HDR sources?

DR. CARRERA: So, for these sources, if

you are going to transfer it to someone, or dispose of it, or send it out to another individual, you would be going onto the License Verification System and verify that the license is current and up to date, and, you know, and they are who they say they are and they are able to accept what they wanted, you know.

CHAIR METTER: Thank you. Any other comments from the public? Just so that you know, we are a little behind schedule.

MS. LOPAS: All right, Ralph Lieto, if you'd like to unmute yourself and state your affiliation?

MR. LIETO: Yes, my name is Ralph Lieto. I'm a medical physicist. I'm not affiliated with anybody right now. I have a couple of questions.

I think one of them had been answered about what sources are affected and you did mention or indicate that these are really going to be HDR users that are going to be mostly affected in terms of the medical side, but will category 3 sources be then subject to increased controls?

DR. CARRERA: So, this rule would not subject any increased control of the category 3 quantities of radioactive material, and the Commission in SRM-SECY-17-0083 has indicated that,

you know, we will be putting license verification requirements in here, but they will not be subjected to the same type of security control as for category 1 and category 2.

MR. LIETO: The LVS, the License Verification System, is new. How does this work from the standpoint of a licensee to verify this and what their burden is? In other words, is someone going to have to submit credentials in order to be approved to access this or are they going to have to go through the NRC or the agreement state's regulatory agency to verify this?

DR. CARRERA: So, maybe I should use my lifeline, please, and call on either Adelaide Giantelli or Ernesto? If not, I can -- so, let me -- I'm not an expert on the License Verification System.

I didn't develop it, but so what happens is that if you're new coming in from the street and you want to start transferring these cat 3 sources, what you would do is you would go into the License Verification System and then you have to register yourself or get yourself registered, and then once you have that, you can go into the system and use the LVS system.

Now, if you cannot do that, if you're able to go through that route, then what you would need to do is call up your agreement state or regulatory authority and request for them to check on the license of the recipient.

MR. LIETO: Follow-up question, please?

MS. LOPAS: Quickly, Ralph, go ahead.

MR. LIETO: Does that mean that this has to be done every time they exchange a source? So, if they're doing this, say, on a quarterly basis with the same vendor over a period of years, they've got to do this every quarter?

DR. CARRERA: That's correct. Every time you would transfer, you would have to call and the license verification would have to be conducted within seven business days before the transfer.

MS. LOPAS: Thank you, Andy. All right, we have no more public comments, Dr. Metter.

CHAIR METTER: Thank you very much, Ms. Lopas. So, I'd like to go ahead and -- oh, we have one more comment?

MS. LOPAS: No, I was going to say 1:30. We're going to push lunch until 1:30.

CHAIR METTER: Okay, so we'll adjourn the meeting at this point in time, and I apologize for

the lateness, but we did have a very productive and interesting discussion this morning, and we'll rejoin at 1:30. Thank you.

(Whereupon, the above-entitled matter went off the record at 12:12 p.m. and resumed at 1:44 p.m.)

CHAIR METTER: This is Darlene Metter. I'm the ACMUI chair and a diagnostic radiologist, and welcome back to the second half of the ACMUI fall meeting.

Our first presenter is Ms. Megan Shober, our agreement state representative, who is speaking on emerging medical technologies rulemaking. Ms. Shober?

MEMBER SHOBER: Thank you. So, I'm the chairperson of our subcommittee on the emerging medical technologies rulemaking, and next slide, please?

So, the subcommittee consisted of Dr. Ennis, Mr. Green, Dr. Jadvar, Mr. Ouhib, and Dr. Wolkov, and we also had Dr. Angle as a consultant to the committee, and Maryann Ayoade was our NRC staff resource.

So, in this presentation today, I am going to talk a little bit about the background for

this rulemaking, the NRC rulemaking efforts to date, and the subcommittee recommendations that came out of it.

Our charge was to review and comment on NRC's draft regulatory basis for the emerging medical technologies and Rubidium-82 generator rulemaking. Next slide?

All right, so the last major structural revision to 10 CFR Part 35 was in 2002, so 20 years ago, and since that time, there has been a number of things that have, that just weren't around at that time.

The first major change was the Energy Policy Act. That was passed in 2005. That added accelerator produced isotopes to NRC authority. Those isotopes are used, among other things, for positron emission tomography. That includes the Rubidium-82 that's used for cardiac imaging.

And since then, we've also had several different types of stereotactic devices. They've become developed and are cropping up in different places around the country.

The microspheres, the Yttrium-90 microspheres have really taken off in the last two decades, and they're now all over the places,

hundreds of sites around the country.

We've seen a large rise in interest in alpha-emitting radioisotopes for therapy with the FDA approval almost ten years ago of the radium-223 dichloride, and now a lot of interest in actinium-225 among other isotopes.

We've also seen a huge rise in theranostics, pairing isotopes, different radioisotopes, one for diagnosis and one for therapy, and each of these technologies have different challenges, different ways that they do or don't quite fit in with the established categories in 10 CFR 35. Next slide?

So, 10 CFR 35.1000 is used when new technologies don't fit into the existing categories, and there's a lot of different reasons why the technologies maybe are outside the boundaries of what's currently in the regulations.

These are just some examples of challenges that these new technologies have provided, things that are sealed sources that behave like a liquid, things, complex devices that have components that are not covered in regulation, unsealed brachytherapy sources, authorized users that aren't coming from your traditional diagnostic radiologist

or radiation oncologist training pathway, just a lot of different things.

Anyway, these technologies have been placed in the 35.1000 and then licensing guidance has served to provide the structure for how those technologies are regulated. Next slide, please?

So, when 35.1000 was first created, it was never meant to be a permanent storage ground for these kinds of technologies, and so finally here after 20 years, we're looking at the types of technologies that are in 35.1000 and seeing what to move into the main part of the subparts in 10 CFR 35.

So, back in February of 2021, NRC staff sent a rulemaking plan up to the Commission describing several different options for how to incorporate both the Rubidium-82 generators and the emerging medical technologies into the main subparts of Part 35.

The Commission responded in January of 2022 and provided direction to staff, and then staff took that direction and developed the draft regulatory basis, which they gave to us for consideration in September of 2022. This draft regulatory basis is anticipated to come out for public comment in this spring of 2023. Next slide?

So, the three options that were in the rulemaking plan, just to briefly mention those, option one was only to focus on Rubidium generators. That is very tiny, very small-scale rulemaking. The second option was a little broader, to include the Rubidium-82 generators and then a limited incorporation of emerging medical technologies.

Option three expands on that even more, the Rubidium-82 generators, but then to broadly incorporate basically every, almost everything that is right now licensed under 35.1000, basically to put all of that into the regular subparts of Part 35. So, those were the three options and next slide?

The Commission elected for staff to pursue option three to include the Rubidium-82 generators, and then the Commission provided specific direction that all current, well-established emerging medical technologies should be incorporated into the main parts of 10 CFR Part 35, and then they also asked staff to create added flexibility to accommodate future emerging medical technologies. All right, next slide?

So, from this, the NRC staff developed the draft regulatory basis. It has basically three main sections. It goes in really deep detail about

the current policies and regulations that apply to emerging medical technologies.

Appendix A of that draft regulatory basis has detailed proposals for how to change the various sections of Part 35 to address basically the ways that the current emerging medical technologies don't quite fit in Part 35.

And then there's a section that has a large cost-benefit analysis, which we're not going to talk about any more today. So, next slide, please?

So, to review here the current policies for Rubidium-82 generators, again Rubidium-82 generators are used for cardiac imaging. The half-life of Rubidium-82 is very short. I think it's about 75 seconds.

And so, the patients -- the material comes out of the generator and it's directly infused into the patient, and so there's two challenges with that.

The first one is that the instruments, the dose calibrators that are used to measure those patient doses, they measure the activity in a dynamic mode, so it's like a millicuries per second, which is very different from normal dose calibrators, which you put your dose in, and it measures its activity,

and you take it out.

So, there aren't calibration standards for measuring dose calibrators in a dynamic mode, so Rubidium-82 generators cannot meet the requirements that are currently in 35.60.

The second challenge with Rubidium-82 generators is, again due to the short half-life, 35.63 requires patient doses that aren't unit doses to be measured in a dose calibrator prior to administration, and the Rubidium-82 generators, they basically keep a record of the dose that's been administered, but that activity value isn't available before administration. It's just recorded afterwards.

So, the NRC recognized these gaps, and way back in 2013, they published this enforcement guidance memorandum 13-003. It allowed inspectors enforcement discretion. Basically, the inspectors would not penalize the licensees for failure to meet these two regulatory requirements if they met three additional compensatory measures.

So, the licensees have to provide training to their authorized user and radiation safety officer. They have to -- the manufacturer comes in once a year and does like maintenance on the

generator system, and part of that involves verifying the dynamic measurement, that that system is functioning. And then the licensees have to keep a record of all of the doses that were administered.

So, if a licensee does those three things, inspectors come in and say okay, you know, we're not going to penalize you for not meeting these other two requirements, and that's how the enforcement discretion has worked for the last nine years.

It was meant to be temporary. It was always meant to be addressed through rulemaking eventually, and this is the rulemaking package that is going to finally allow this enforcement discretion to be retired. Next slide, please?

So, for 10 CFR 35.1000, this system is set up so that each emerging medical technology is individually evaluated to determine the radiation safety risks and any additional regulatory requirements that might be necessary, and these lead to device-specific licensing guidance.

So, some of the challenges that come out of that is that licensees, they can only commit to follow the guidance that's in use at the time that they apply for their license action, and there's a

process that they can upgrade to more recently versions of the guidance, but it's not -- like that's a choice the licensee makes.

So, different licensees out there are using different versions of the guidance at the same time. And then one of the other challenges that we're seeing is that there's no way or no official process for guidance to be retired or withdrawn, so we'll see how that plays out here in just a little bit. Next slide, please?

So, when we're looking at different ways of overseeing the use of these emerging medical technologies, there's always a balance there between what's in rulemaking and what's in guidance.

So, rulemaking is really good at consistency. It's really good at compatibility. It's really good at efficiency. We know everybody, licensees, regulators, everybody knows what the standard is.

When it comes to guidance, guidance works a little bit differently. It's very specific. You can have things that are very customized to particular technology. It's adaptable. Each technology is reviewed on its own merits. And it's flexible because it's easier to update guidance than

it is to update rules.

So, as we're moving or looking here to move things from guidance into rulemaking, we're going to be making some things more general. We lose some of the customization that's possible in the guidance, but we will gain from that consistency and efficiency.

So, it's a tradeoff. We know that going in, and that's just how this system is set up. Next slide, please?

Okay, so this is just a really snapshot look here of the proposed changes to the subparts in Part 35. In 35.200, the NRC is looking to integrate rubidium generators and germanium/gallium generators.

In the manual brachytherapy section, they're looking at adding requirements for liquid and diffusing brachytherapy, intravascular brachytherapy, and some of the ophthalmic sources.

35.500, which is sealed sources for diagnosis, we're looking to add radioactive seed localization.

In 35.600, there's pretty significant changes proposed for that area. It would really change the framework from having -- right now, 35.600

covers teletherapy, high dose-rate remote afterloaders, and the old gamma knives.

So, and those were very focused on some technology-specific components, and so 35.600 is proposed to be amended to move away from technology-specific components to more like functional radiation safety features.

So, as an example, gamma knife, the gamma knives that are currently out in use don't have helmets anymore. The rule 35.600 has quality assurance elements that are specific to helmets because helmets is what they had when they wrote the rules.

But really, from a regulatory perspective, it's not the helmet that matters. It's the function of the helmet, which was to immobilize the patient, and so by adding in 35.600, take out that specific word helmet and replace it with this idea of patient immobilization. It's more general. It can capture more technologies. You get the same goal, but you say it more broadly and it can cast a wider net.

And then the other major change would be to add a new subpart for microsources. Microsource would be a new term. It would include microspheres,

but it could potentially include other micro things, micro particles, micro who knows. It's a more general term that's not related to -- it doesn't depend on it being a sphere. All right, next slide, please?

There's also some administrative changes that have been proposed to some definitions, some different details on how radiation safety committees would be constructed. There would be some conforming changes to written directives and then that's just based on the different kind of technologies that would be added into Part 35, and then there's a more general look at adding requirements for device-specific training.

So, device-specific training is already required for HDR, both for the users, authorized users and the authorized medical physicists. Device-specific training is required for a lot of current emerging medical technologies and this would be a way to apply that concept more broadly in the regulations. So, next slide?

So, our subcommittee received this very long draft regulatory basis and one of the things that we really wanted to talk about as a subcommittee was that direction from the Commission to incorporate well-established technologies.

So, the very first question is okay, what's a well-established technology? And so, we really considered three different aspects of that. How widespread is the technology? If there's a technology that is widespread, you can have a rapid accumulation of experience and get those lessons learned quickly.

The second question is how mature is it? So, how fast is the product evolving or how stable is that product technology? And the last question is really how different is it from the things that are already included in the regulations? What's the regulatory gap?

And with the current emerging medical technologies, there's a big spectrum. There's things that are really hardly different and there's other things that are really very, very different.

So, we took a look at those and then we took a look at all of the current emerging medical technologies, and we talked about them and tried to classify them. So, the next slide, please?

So, this is what we came up with. We categorized them into these three columns, well-established, kind of limited use, and then not available. So, one of the things that we determined

when we were looking at these technologies is that three of them -- there's what, five, nine, there's 12 all together, and three of them, you can't get now. There's no one selling them and yet they still have licensing guidance on NRC's website.

So, we kind of pushed the not availables to the side and then, okay, of the nine that are left, one of them, the Liberty Vision, that guidance hasn't even come out yet. And then the rest of them, we looked at those three questions. How widespread is it? How mature is it and how different is it?

And as a subcommittee, we decided -- we came to the conclusion that five of those technologies are really pretty well-established. The germanium generators are really hardly different from the generators that are already in Part 35. IVB has been around for quite a while. Microspheres have been around for quite a while.

Radioactive seed localization came on the scene about ten years ago. And it's -- there's a lot of places that do it. And then the gamma knife, we've been working with the perfection in the Icon for quite a while now.

And those technologies are pretty mature. They're not rapidly changing. And the radiation

safety elements of that are -- there aren't a lot of question marks with this.

So as a subcommittee, we felt like these five technologies were pretty easy to consider well-established. We had a lot more conversation about the Alpha DaRT and the GammaPod. The Alpha DaRT guidance came out earlier this year.

I don't think any of us had ever -- are at sites that would use Alpha DaRT. We don't know as much about it just a subcommittee. So we had a hard time saying that one was widespread enough to really understand the radiation safety challenges.

And Alpha DaRT is also very -- the regulatory gap is pretty different with the framework that's in Part 35 right now. And GammaPod is a different kind of stereotactic device. It targets different part of the body, has some special features.

At the end of the day, it's still a stereotactic device. So a lot of the radiation safety issues are -- there's similarities with things that are already out there. But we welcome other people's opinions about those.

And then I'll just mention the RadioGenix. The NRC staff have chosen to leave that

in 35.1000. They're not considering moving it into the other sections of the regulation. All right. Next slide, please.

So our subcommittee came up with a number of recommendations. We support the new subpart for microsources. We support incorporating the well-established emerging medical technologies into the existing subparts of Part 35.

We support a lot of the administrative changes. We're supporting device specific training. We're supporting the changes to 35.600 that would de-emphasize the pieces of technology and instead emphasize the radiation safety concerns with them. Next slide, please.

We had a long discussion about what to add to the regulation in terms of product-specific requirements. When I had that slide earlier about regulations and guidance, it's a balancing act. And when you go into regulation, you really are -- in a lot of ways, you have to make those requirements more general.

So it's a real challenge to add product-specific requirements to the regulation. And some of the product-specific requirements that were proposed in the draft regulatory basis were, in fact, for those

technologies that are not currently available. So that also was kind of a tension point.

Why are we putting product-specific requirements in the regulation if there's no product that's available to do that? And maybe there's reasons to do that, but I think it's a harder sell. We did support adding some general requirements to address simple issues with emerging medical technology.

So we say Alpha DaRT still in our opinion kind of limited. But even if it's limited, maybe that wouldn't preclude us from adding a general requirement in Part 35 to, for example, require contamination control measures for unsealed brachytherapy sources. Okay. So that's simple.

Like, generic, yeah, if you have an unsealed brachytherapy source, you got to make sure that there's not contamination. That's independent of any product-specific requirement. But Part 35 could definitely address some of those general issues.

We have some questions. Just really would like to continue -- I know this is part of the reason for public comment period that'll be coming up in a few months. But we really had some concerns

about the way the ophthalmic sources are currently regulated and proposed to be regulated. Why are they being -- like, why do they get their own focus area?

And so for ophthalmic sources in particular, they have a special section in the manual brachytherapy that's devoted to them. And so in the past, it's been kind of a situation where, okay, it doesn't meet that ophthalmic requirement. It belongs in 35.1000. And I think our subcommittee is also asking the question, well, if it doesn't belong in this specific small ophthalmic section, why isn't it just in 35.400 as a regular manual brachytherapy source?

So we feel like there may be some options besides 35.1000 for some of those ophthalmic sources. And then when it comes to the authorized medical physicists, I want to be very clear. Authorized medical physicists are necessary.

I'm not trying to say that they don't have value. They absolutely have value and they're needed. But the question is, when? When at what point is an authorized medical physicist necessary?

And I think that regulations are not clear on that about, like, what is the triggering characteristic for when an authorized medical

physicist is necessary. And so I think this will be a really good opportunity to ask some of those questions. This might be a really bad idea.

It's my idea because it really, really might be bad. But right now, we have 35.400 and we have 35.600. 35.400 is manual brachytherapy. 35.600 is the technology specific.

But I'm just asking the question. Are there technologies -- if it requires an authorized medical physicist, like, maybe it should be a 35.600. Like, I don't know. But that's part of our discussion. That's kind of one of the things that we were talking about, and that's what's going into this bullet point here, reevaluate authorized medical physicists. I think there's a broader question to ask there.

And then as a subcommittee, we also want to have -- encourage the NRC to broadly consider training for what I'm calling atypical authorized users. Again, those would be physicians that aren't diagnostic radiologists, nuclear medicine physicians, or radiation oncologists. So that would include things like the ophthalmologists.

It would include -- the question has been raised about, like, CivaDerm and dermatologists. So,

like, any other entry point for people, physicians wanting to become an authorized user. I think there's some broader questions there just in terms -- well, we talked about it this morning a little bit.

There was a number of hours and how do you actually -- what's the pathway to become an authorized user? So our subcommittee has issued a recommendation about that as well. Next slide, please. Okay. So in conclusion, our subcommittee definitely agrees many of the current emerging medical technologies are well-established and should be moved out of 35.1000.

However, at this point, the subcommittee feels that some of the emerging medical technologies should stay in 35.1000 due to limited operating experience. And then we would like to see NRC periodically assess whether the emerging medical technologies are still in use because again there's no process for that guidance to be withdrawn. And then just to know the NRC staff put a ton of effort into bringing this draft regulatory basis out.

And the rulemaking -- any kind of rulemaking is a really big effort and this one especially for some of the challenging issues that are here. So we just want to give our thanks to staff

as they have and will continue to work on this project. That's the end for me.

CHAIR METTER: Thank you, Ms. Shober, for a very challenging topic and a very excellent report. And I congratulate you and your subcommittee on a very nice presentation. Do I have any questions from the subcommittee? The ACMUI? Ms. Martin?

MEMBER MARTIN: I was just wondering with the other radiation oncologist I didn't know that ViewRay was no longer available. Is that -- yeah, that threw me.

MEMBER ENNIS: It's no longer available with cobalt sources.

MEMBER MARTIN: Thank you.

MEMBER ENNIS: They now use a 6 MV.

MEMBER MARTIN: Sure, sure. You're right. I know I'm working with a whole bunch of those.

CHAIR METTER: Any other comments from the ACMUI?

Okay. Hearing none, are there any comments from the NRC staff?

MS. LOPAS: I don't think we have any comments. I'll now open it up to the public if that's okay, Dr. Metter. Okay. So if there's any comments

from the public, you can go ahead and raise your hand using the raise hand icon. Just click on that once, and I'll instruct you to unmute yourself.

(No response.)

MS. LOPAS: All right. I'm seeing no comments, Dr. Metter.

CHAIR METTER: Well, thank you. So now that the subcommittee report has been presented, do I have a motion to approve the report?

MEMBER MARTIN: So moved.

CHAIR METTER: Ms. Martin, thank you. Do I have a second?

MEMBER HARVEY: Second.

CHAIR METTER: Dr. Harvey, thank you. All in favor of approving the subcommittee report as written, say aye.

(Chorus of ayes.)

CHAIR METTER: Any abstentions or objections?

(No response.)

CHAIR METTER: Thank you very much. The subcommittee report is unanimously approved. Thank you for your subcommittee hard work on a very challenging topic. And you did it very nicely and concisely. Appreciate it. So our next item on the

agenda is the decommissioning financial assurance for sealed and unsealed radioactive materials presented by Mr. Trussell from the NRC.

MR. TRUSSELL: Good afternoon. My name is Greg Trussell, and I am the rulemaking project manager for the decommissioning financial assurance proposed rule. And I'll be giving -- is that better? Okay. Next slide, please.

So the purpose of the meeting, our briefing today is to provide a status update to the committee on the proposed rule. I'll start off with some background, history of the rule. I'll then provide an overview of the staff's approach to the rulemaking.

And then we'll move into a discussion session and we'll answer any questions you may have. And then last, we'll go into our next steps, the time that we're currently on. Next slide, please. So background, history on this rule.

So prior to the petition, the ACMUI did issue a report and aspects that are impacted by this rulemaking. And I'll touch on that a little bit later. The rulemaking was initiated by the submittal of a petition from the Organization of Agreement States in June of 2017.

The staff reviewed the petition and we agree with this recommendation. It's been submitted rulemaking plan to the Commission. The Commission agree with the staff's recommendations to move forward with the petition's recommendations for rulemaking.

This was documented in SRM-SECY-19-0125 in October of 2020. The next step in the rulemaking process was a development in publishing the regulatory basis. The regulatory basis was published in July of this year for public comment.

The staff has reviewed those comments and consider these comments submitted on the regulatory basis and the development of proposed rule. Next slide, please. So continuing on with our background, in the ACMUI report, the ACMUI concluded that the restrictive aspects of a Decommissioning Funding Plan for a germanium and gallium generators that arise from the current Part 30 regulations were preventing or deterring the use of promising diagnostic imaging agents for patients.

Thus the ACMUI recommended that the NRC address the Decommission Funding Plan concerns relative to these generators. Next slide, please. The NRC agree with the report the Decommissioning

Funding Plan requirements could impede or limit patient access to radiopharmaceuticals developed from germanium and gallium generators that a Decommissioning Funding Plan is not necessary to ensure the safe decommissioning of facilities that use generators. By memo dated in July of 2016 and July 2017, NRC established a process for granting exemptions to the Decommissioning Funding Plan requirements.

This process will relieve the licensee from requirements for a Decommissioning Funding Plan for the possession and use of germanium/gallium generators when certain conditions are met. The process allowed exemptions from only the Decommissioning Funding Plan requirements and only for those licensees using germanium/gallium generators. Next slide, please. So the petition, the petition as I mentioned earlier was submitted by the Organization of Agreement States in April of 2017.

NRC docketed the petition on June 21st of 2017 as PRM, petition for rulemaking, 30-66. The petition requested that the NRC provides specific possession values for naturally-occurring, accelerator-produced radioactive materials,

radionuclides that are not currently listed in Appendix B to Part 30. Thus, licensees using these isotopes, especially medical licensees, would not have to apply the appendix's default values to calculate their decommissioning funding requirements. Next slide, please.

In their submittal, the petitioner made several assertions. The petitioner went on to assert that without possession values for the unlisted radionuclides, regulators are forced to evaluate new products against the default criteria and apply overly burdensome financial assurance obligations or evaluate on a case-by-case exemption process. Petitioner also asserted that rather than using exemptions on a case-by-case basis, the more appropriate way to address the inconsistencies in Part B -- Appendix B, excuse me, to Part 30 is to amend it to add appropriate nuclides and their corresponding activities. Next slide.

Additional assertions by the petitioner was that the patient health and safety are being compromised due to delays in licensing important diagnostic and therapeutic products that use radionuclides not listed in the table in Appendix B to Part 30. Also, these licensing obstacles could

discourage development of new products, diminishing the possibility of new innovative and beneficial options in both medical and industrial applications. Next slide. Let's go on to the NRC proposed approach.

As I mentioned earlier in SRM-SECY-19-0125, the Commission approved the initiation of rulemaking response to petition 30-66 to approve specific possession values for radionuclides that are not currently listed in Appendix B to Part 30. The NRC did publish a Federal Register notice in November of 2017 announcing that the agency would consider the issues raised in PRM 30-66 through the NRC's rulemaking process. Staff following the rulemaking process developed a regulatory basis that was published in the Federal Register requesting public comment.

The regulatory basis documented summarizing the current regulatory framework and describe the regulatory issues. It evaluated alternatives and presented a recommendation. NRC asked for public comment on the recommendations and the stakeholder feedback received on a regulatory basis was reviewed and did inform the development of our proposed rule and draft regulatory analysis.

So the NRC's approach will be, one, to

revise the current table in Appendix B to Part 30 using the radionuclides and quantities from Appendix C to Part 20. So thus adding radionuclides not currently listed in Appendix B to Part 30. Two, with this new table, we move all radionuclides with a half-life of 120 days or less since these radionuclides are not considered when developing the decommissioning financial assurance.

Three, default values will be set to equal the lowest values of listed radionuclides. And last, change the title to the table in Appendix B to Part 30 to reflect its proposed use for decommissioning financial assurance as opposed to labeling. By making these changes, licensees and NRC staff and agreement states would have an up-to-date table with more risk informed values for use when assessing decommissioning of financial assurance.

This proposed approach reduces or eliminates the need for exemption requests. The staff feels by providing a regulatory solution to rulemaking, the NRC would create a more stable framework for use by regulators, applicants, and licensees. So that's an overview of the proposed rule, background and history. So at this time, I'd like to open it up for any questions from the

Committee.

CHAIR METTER: Thank you for that report. Do I have any questions from the ACMUI?

Seeing none and no comments, Ms. Lopas, do we have any comments from the public?

MS. LOPAS: One second. I lost my Teams. All right. If there's any questions or comments from the public, please go ahead and click on the raise hand icon. And if you're on the phone, you can press star-5.

All right. I'm seeing no comments from the public. Oh, I believe we have a question from Ms. Shober from the ACMUI.

MEMBER SHOBER: Can you say again when you expected to have the Federal Register notice published. I missed that.

MR. TRUSSELL: For the proposed rule?

MEMBER SHOBER: Yeah.

MR. TRUSSELL: We hope to have it probably sometime next year, probably in the fall time frame.

MEMBER SHOBER: Okay. Thank you.

CHAIR METTER: Okay. Thank you. So I believe -- thank you for your presentation and on the decommission financial assurance.

MR. TRUSSELL: Yeah, one last thing. Celimar, we wanted to see if the -- this is a Federal Register notice that the Committee would like to review before we publish it.

DR. VALENTIN-RODRIGUEZ: During open forum, we can -- this is Celimar Valentin. We can propose if the ACMUI would like to review -- form a subcommittee to review the table and the values. We can do so, and we would work with Greg to make sure that's within the schedule for the proposed rule. And it would be reviewed before the proposed rule is issued to the public for comment.

CHAIR METTER: Thanks, Celimar.

MR. TRUSSELL: Sure.

CHAIR METTER: Okay. It looks like we're at a point of a break. So let's go ahead and go on to a break. And we'll resume at 3:00 o'clock with an open forum.

(Whereupon, the above-entitled matter went off the record at 2:25 p.m. and resumed at 2:59 p.m.)

CHAIR METTER: Well, good afternoon. This is Darlene Metter, ACMUI Chair and Diagnostic Radiologist. And welcome back to the afternoon session of the 2022 fall ACMUI meeting. The first

item on our agenda is an open forum where the ACMUI will identify medical topics of interest for future and further discussion. Do I have any recommendations or comments from the Committee?

(No response.)

CHAIR METTER: Okay. I would like to propose these four new subcommittees. The first will be -- I believe earlier this morning we spoke about the Medical Event Generic Checklist. And so I'd like to propose a subcommittee with a report to be made by the spring meeting.

The proposed chair is to be Mr. Richard Green, our nuclear pharmacist, with the members to be Ms. Melissa Martin, Dr. Jadvar, Ms. Rebecca Allen, Dr. Harvey. And I would like Mr. Ouhib to be the therapy medical physicist on it, and then as a consultant, Dr. Ennis, who will be sitting on the committee till March 2023. The second subcommittee -- do I have any comments or questions on that?

The second subcommittee of current medical events will update the membership. And the proposed chair will be Dr. Harvey. And the members will be the current members because -- the proposed chair because Dr. Ennis will be graduating from our subcommittee in March.

And so Dr. Harvey will be our proposed new chair with the current members still being Mr. Green, Dr. Wolkov, myself, and consultant Dr. John Angle. The third is the Nursing Mother Guidelines for the Medical Administration of Radioactive Material which presented their final report about three years ago. And there's been many new radiopharmaceuticals.

So I would like that subcommittee to be reestablished and updated for the interval radiopharmaceuticals. The chair I propose is Mr. Richard Green and the proposed members, Melissa Martin, Dr. Jadvar, Josh Mailman, and then myself since I did chair that last subcommittee. Do you have any questions or any suggestions for other members?

(No response.)

CHAIR METTER: Okay. And the fourth subcommittee that I would like to propose is what was recently discussed earlier today regarding decommissioned financial assurance plan for sealed and unsealed radioactive materials. And I'd like to have the chair for that to be Dr. Harvey. I know he's a new member, but he's a very important member. And I think his expertise would be very beneficial to

this subcommittee.

Proposed members, patient advocate, Josh Mailman, Ms. Megan Shober, and Rebecca Allen. And I would like a report since this would be a very targeted review by the spring 2023 meeting. Do I have any comments on that or any questions?

Okay. Hearing none, do I have any other suggestions for topics to be considered for future references or future discussion by the ACMUI? Yes, Dr. Ennis?

MEMBER ENNIS: I think this was covered in some discussions previously. So you may not need further conversation. But I've heard from people that with increased radiopharmaceutical use some localities are sending refuse back to patients. Like, their garbage is contaminated by urine that's radioactive or something like that.

So this seems to be a lot more of waste management issues for patients who are discharged at home, at least that's what I'm hearing. And it's all anecdotal. But some people have talked to me because they know I'm on this committee about it. So I don't know if other people are hearing about that and if that's something that we need to look into.

MEMBER MAILMAN: I mean, shouldn't that

be under the Reg 8.39 guidelines that we're discussing and editing? And I think there's already a committee that's looking at that. But I agree. It's a very large issue and challenging guidance by both industry and the individual practitioners.

CHAIR METTER: Thank you for those two comments. And I think we'll -- NRC will look at that and see the appropriate place to address that question, whether it's a new subcommittee or to have it go under Reg Guide 8.39. But thank you. Yes, Mr. Ouhib?

MEMBER OUHIB: Yes, this topic actually is being discussed everywhere, including AAPM. I know we actually discussed at Therapy Physics Committee. And the RPT which is the Radiopharmaceutical Subcommittee, we discussed this at length.

And the main issue is whose responsibility should that be for this issue. And people felt like, well, this is fine on the patient. And if that's fine on the patient, patients are going to avoid that kind of treatment because they don't want to be dealing with that kind of stuff.

And then it's, like, well, maybe we should go to the manufacturer and say, you know what?

You're sending this. Maybe you should take that responsibility and deal with it and so on. So there are a lot of sort of proposal out there. But I haven't heard a final sort of recommendation.

CHAIR METTER: Thank you for that additional information.

MEMBER MARTIN: I think there's actually an SNMMI paper on this topic. It's been recently published. It's literally hot topic.

VICE CHAIR JADVAR: I have the paper here --

MEMBER MARTIN: Yeah.

VICE CHAIR JADVAR: -- in front of me.

MEMBER MARTIN: That's why I knew it was --

VICE CHAIR JADVAR: And I second what Zoubir just mentioned that it really fell onto -- inappropriately onto the patients. And there's going to be a lot of these outpatient procedures. And they're being penalized because of this, sometimes because of the incontinence and other issues.

So it really needs to be addressed. And somebody has to take charge of this with regard to regulations that is being applied today which is not appropriate at this time. So it is a hot topic, and

there is a paper. I'm not sure if this was this month. But it is in JNM.

CHAIR METTER: Okay. Well, thank you for that. And again, I think the NRC staff will look whether it falls on the Reg Guide 8.39 or maybe another subcommittee.

DR. VALENTIN-RODRIGUEZ: This is Celimar Valentin from the medical team at the NRC. We do have an open action item to brief you all regarding best practices and whether we would take additional action on this issue. We're preparing to issue a survey to agreement states to kind of collect what other jurisdictions are doing.

We understand that there's a lot of localities, municipality kind of ordinances and jurisdictions at play here, not only NRC and agreement state overall regulations. So we're looking at that. And then what we can do is once the Reg Guide 8.39 Subcommittee ends their charge, we can take a look at whether that's the appropriate subcommittee because I do know there are some cross disciplinary boundaries here and some things that we can address. So we'll take action after that. But we plan to brief you all on that topic in the spring meeting.

CHAIR METTER: Thank you very much.

DR. VALENTIN-RODRIGUEZ: And a subcommittee can be formed after that.

CHAIR METTER: Okay. Thank you very much, Celimar. Yes, Ms. Martin?

MEMBER MARTIN: I would just encourage you to make sure you include LA County because believe or not, they've actually done a remarkably good job on this and have sort of an exemplary program on how to handle the patient waste.

CHAIR METTER: Well, thank you. Yes, Ms. Shober.

MEMBER SHOBER: I could use a refresher on what the timeline is for that Reg Guide 8.39. Forget where we are with it.

DR. VALENTIN-RODRIGUEZ: Sure. So right now, the Reg Guide 8.39 is in tech editing here at the NRC. So we've prepared a regulatory analysis, do the changes to the regulatory guide body. That should come out within the next few months or so for public comment.

That'll be -- I don't remember if it's 60 or 90 days. But two to three months public comment, and then we will address those comments from the public. And we'll get back to you with a final

proposed draft that the Reg Guide 8.39 Subcommittee can review.

MEMBER SHOBER: Okay. So for the Reg Guide 8.39 Subcommittee, there's nothing to do until after the public comment period after --

DR. VALENTIN-RODRIGUEZ: Correct.

MEMBER SHOBER: -- you've already resolved the comments and have basically, like, a draft final document?

DR. VALENTIN-RODRIGUEZ: Yes.

MEMBER SHOBER: Okay. Thank you.

CHAIR METTER: Okay. Thank you. Any other comments from the Committee or the NRC staff? Yes, Mr. Green.

MEMBER GREEN: It may just be I'm not aware of it. But I know there's a company that's submitted an application for new drug approval and the FDA sent them back to the drawing board for a few issues. But I wonder if Technegas has been evaluated by the staff and whether it'll need licensing guidance where it'd be in 35.1000. It's not approved yet. But there are a lot of physicians who sing its praises and would love to have it available in America. I'm just wondered if we're prepared for that.

DR. VALENTIN-RODRIGUEZ: Could you repeat that?

MEMBER GREEN: Technegas.

DR. VALENTIN-RODRIGUEZ: Technegas? I'll look into that. I don't think it's -- we keep kind of a spreadsheet of everything that we're aware of. I don't know that that's one of the technologies that we're aware of at this time. But we can also engage with FDA on that.

MEMBER GREEN: Real briefly, it's sodium pertechnetate. But you put it in a carbon graphite crucible under argon gas with high voltage and you zap it. And you evaporate it into radioactive technetium dust and the patient inhales it. So it's a little bit than normal.

DR. VALENTIN-RODRIGUEZ: Well, thank you for bringing it up. I think this is one of those venues. We'll look it into it. Thank you, Mr. Green.

DR. TAPP: So if I may, this is Dr. Tapp. We did hear about this. I believe we heard about it right before in 2019 during the pandemic. But we did pause on it because I think they slowed it down. But it's good to hear about it again. We did start an evaluation, and we have some notes. So thank you.

CHAIR METTER: Thank you, Dr. Tapp. Any

other comments from the Committee? Yes, Dr. Jadvar.

VICE CHAIR JADVAR: We have an FDA representative here. Is it going to get approved? It's been many years now. Have you -- no comment.

CHAIR METTER: Okay. Thank you. So it looks like if there's no other suggestions at this point in time, if there are any others after this meeting, you can address it to myself and Celimar and we'll go ahead and look into it and look at it appropriately. So now comes the next item on our agenda which is very sad but actually very nice because I really appreciate his expertise and his contribution and dedication to the ACMUI, a special recognition for Dr. Ennis. And I have Ms. Theresa Clark from NRC.

MS. CLARK: So I promised an embarrassment face. I have things to hand you, but first the embarrassment. You have to earn them. So is the is on? Okay.

I'm Theresa Clark again. Hi. So Dr. Ronald Ennis, we're recognizing you for eight years of service to the Committee. You were appointed as the radiation oncologist brachytherapy representative in March 2015. So not quite eight years, but we'll keep you for the last few months.

You've contributed to several high priority initiatives, including chairing several subcommittees, a lot of which we've heard about today. So Alpha DaRT medical events which already came up in various discussions today, medical event reporting, radioactive seed localization as the chair, and then an extremely long list of subcommittees which I'm not going to read. But really appreciate that.

Some of the ones that caught my eye were the emerging medical technologies which Megan was talking about earlier, ACMUI institutional memory, that sounds really good, and various other reporting and training experience committees. So thank you for lending your expertise to that. We truly appreciate it. You brought a lot to us.

You have just served the NRC during your career, of course. You've been a leader in several professional organizations including ASTRO for radiation oncology where you've been involved in government relations for over a decade, Lincoln Society and ABR which was discussed as well. Over 40 peer review publications, over 80 abstracts, proceedings, letters, invited chapters, and publications, I'm exhausted just reading this.

And so I'm going to present you with a few tokens of our deep appreciation. I can't hold all this stuff, so I'm going to let some of it down as I present it to you. So let's see.

We have NRC lapel pin which is very shiny. Please enjoy. I have a certificate of appreciation from Chair Hansen recognizing your eight years of service and leadership, almost eight years. And then on the back of that and associated, there's a flag that was flown over the Capitol compliments of Chris Van Hollen.

And there's a certificate on the back that says we flew it over the Capitol in your honor. That's one of the cooler gifts that we get to give out. So thank you very much and congratulations for all of your contributions.

(Applause.)

CHAIR METTER: Thank you very much, Ms. Clark, for that excellent presentation and Dr. Ennis for your service. Do I have any comments from the ACMUI, some memories, or other things?

MEMBER GREEN: Dr. Ennis is a very gentle man because I'm a drug guy. I do drugs for a living. I'm a drug dealer, and he doesn't use drugs. He uses a whole lot of devices and other things that apply

radiation in aspects I have no knowledge of. He's been very gentle in the education process that I've been able to absorb. Thank you.

VICE CHAIR JADVAR: Well, I worked with Dr. Ennis for only about three years, most of it during pandemic. But anyway, I want to thank you for contributing intelligently. And I really value your comments in the subcommittees that I worked with you.

Thank you so much. I'm sorry that you're leaving us. I wish you were here more. But again, I really enjoyed the brief time we had together.

MEMBER OUHIB: Dr. Ennis, it has been a pleasure and an honor working with you for these last six, seven years probably. We miss that soft voice with powerful content. That is for sure. You always have the right thing at the right time. So we'll miss you. Thank you for all your service.

MEMBER WOLKOV: Ron, you are an inspiration to so many of us in our field. So we thank you for that. You are the argument against term limits.

Certainly wish I could work with you a lot longer on this Committee. I value every contribution you've made. Every comment you have made has been right on the mark. And easy to see why

so many people are so fond of you personally. So I will greatly miss you on this Committee.

CHAIR METTER: Ron, you have been an incredible member of this Committee. And for the eight years you've been serving, when you presented the medical events summary and you organized it and made it so that I could understand it too, it was amazing. And I think the way you handled it and the way you evaluated it to look at common threads within it to help our stakeholders to prevent these medical events, I think that was an incredible value to the public and our licensees. And I really appreciate that, and thank you very much. I always look forward to your reports.

MEMBER O'HARA: Dr. Ennis, I have really enjoyed sitting at this table with you. I have watched your critical thinking and have been amazed. It's been very helpful for me both here and at the FDA. So have a good time and enjoy all the free time that you're getting back from not being here and thank you.

MR. EINBERG: Yeah, Dr. Ennis, it's been a pleasure working with you on behalf of the NRC and NRC staff. We understand how much time and commitment you've put into the subcommittee. As people have

mentioned, you've done the medical event evaluations.

We know how much work goes into evaluating those medical events and looking for commonalities. And your advice and guidance has been very appreciated by the NRC staff. And we've taken your advice and we'll miss you very much. So good luck to you.

CHAIR METTER: And I believe, Dr. Ennis, it's your turn where you'll be making some thoughts about leaving the ACMUI.

MEMBER ENNIS: Do I get to embarrass all of you in return? So anyway, thank you very much for those kind words. And eight years went really fast. I'm really grateful. That's really the main thing.

I'm really grateful to have had this opportunity. Really grateful to ASTRO who had nominated me and for the NRC people who chose me. it really brought together for me a lot of interest and has been really a pleasure.

I think the work that we do is important and has a major -- potential major impact. And to be able to be part of that and help shape that for a few years was very meaningful to me. This will be a very important part of my career.

This gift is really for me very touching.

As it was alluded to, I have worked a lot on ASTRO's behalf in government relations and care a lot about this country. And it's just very powerful, meaningful.

I must say to have been able to serve the country in this way. Not to be too morbid, but my grandmother's nine siblings and parents did not have the fortune of my grandmother to leave Eastern Europe in the 1920s and they were all murdered in 1942. And this country embraced her and many people like her in a way that has made our lives much, much better.

And so I'm eternally grateful to this country for that. Hope it continues to be that kind of a country. So that's why that's so special to me. Not to be downer.

But on a brighter note, I really enjoyed working with everyone who's been on the Committee, all the former members of the subcommittee. We have a great camaraderie and really I've enjoyed very much, especially when we have in-person meetings and get to spend some time together and with NRC staff. So it's really been wonderful.

I'll use this opportunity as a complete friend of NRC to just put out there, like, maybe two thoughts to think about. If feels a little bit like

the medical part of NRC doesn't get enough resources that it should get. And it feels like that may slow things down in a way that doesn't have to be that slow.

Linked to -- I do think also -- and again, this is as a friend and not, like, as a harsh criticism by any means because I think overall things are great. But things do move very slowly compared to what's going on in the rest of my life -- professional life. And some of it is the nature of the structure of the regulations that create the NRC and how it has to function because that's what Congress has required.

But I do wonder whether there's some opportunity for not being -- being a little more responsive a little quicker. Not the responses, NRC is responsive to everything. But the pace, it seems a little bit out of line with what's going on in the rest of the country.

And again, just among friends, if there's a way to kind of move that, I think that would be healthy. But again, this is minor compared. In the big picture, everyone here has been always committed to doing the right thing and figuring out the right regulation.

And it doesn't necessarily happen in all situations -- in all regulatory situations. So the level function is extremely high. The integrity is extremely high. And those are the most important things.

So those comments are really minor. But since I had the microphone, I figured I would share those thoughts. But I will very much miss working here.

I don't know I will fill with the time, probably just more Netflix or something. I wish there wasn't a term limit. I think I would be up for a third term. But it's time to let someone younger step forward. So that's cool too.

CHAIR METTER: Thank you very much, Dr. Ennis. And we will miss you. We definitely will miss you. So our next item on the agenda is the administrative closing by NRC staff. Ms. Gupta Sarma?

MS. GUPTA SARMA: Good afternoon. This is Trisha Gupta Sarma again. So I recently provided a set of dates to the ACMUI to propose a time for our spring meeting.

So on the screen, you can see the March calendar. There are a lot of conferences during March

and a lot of holidays. And it's also very close to December as this meeting was much later.

So our proposed dates and the ones that

I got the most responses for were on May 15th and May 1st. There were some April dates as well, April 24th and May 22nd. But the most responses were May 15th and May 1st.

So is there any discussion as far as these recommended dates? May 15th had the most responses. It can be two -- yeah, it'll be two days. It'll be two days. Sorry, go ahead.

MS. GUPTA SARMA: The first being May 15th. Oh, May 1st. Oh, okay.

CHAIR METTER: I just wanted to remind you that May 14th is Mothers' Day.

MS. GUPTA SARMA: I can make note of that.

VICE CHAIR JADVAR: Is it Monday, Tuesday or just --

MS. GUPTA SARMA: Monday, Tuesday.

VICE CHAIR JADVAR: Monday, Tuesday.

CHAIR METTER: I personally like May 1st.

VICE CHAIR JADVAR: I vote for May 1st also. I have to be home for Mothers' Day.

CHAIR METTER: Okay. So let's do this. How many would be able to make the May 1st one?

MS. GUPTA SARMA: Like, everyone. I'm not sure about online.

MEMBER ALLEN: This is Rebecca Allen.

Yes, May the 1st would work.

CHAIR METTER: Just out of curiosity, how many would make the May 15th?

MS. GUPTA SARMA: So make it, but not happy about it..

MEMBER SHOBER: Okay. You know what? Would you mind? Since it's a very close and I can't count everybody, maybe send out a Doodle Poll and see what that comes out to be.

MS. GUPTA SARMA: Yeah, definitely.

CHAIR METTER: Okay. Thank you. So it will either be May 1st or May 15th for two days.

MEMBER MAILMAN: And just to -- there will be a hybrid option as well. May 1st, I'm in Ghana for a nuclear medicine conference in Ghana. So I won't -- I may be able to remote in. But physically I can't be in two places.

CHAIR METTER: Okay. Thank you for that. We'll go ahead and make the -- do the poll and with that comment regarding Mr. Mailman.

MS. GUPTA SARMA: Other than that, -- any other comments on the spring meeting? Okay. I'll send out another Doodle Poll then. Other than finalizing the spring 2023 meetings, things that happened in today's meeting, just wanted to summarize

a little bit.

The full committee unanimously accepted the Y-90 Subcommittee report which included issuing an information notice to licensee and potentially reviewing vendor, the spreadsheets, and other tools. There was a subcommittee form for generic process checklists. The full committee unanimously approved the Emerging Medical Technologies Rb-82 Subcommittee report.

And another subcommittee was formed for decommissioning financial assurance for sealed and unsealed radioactive materials. The subcommittee for nursing mothers' guidelines was reestablished. And another subcommittee was formed on updating membership.

And I think that was it. So thank you to all the speakers and thank you again to Dr. Ennis for all of your service. That's all I have.

CHAIR METTER: Thank you for this administrative closing. So this ends our first in-person meeting since 2019. And really it was really wonderful seeing you all. Are there any final comments that anybody from the ACMUI would like to say or the NRC staff? Yes, Melissa.

MEMBER MARTIN: Are we starting tomorrow

at 8:00? Are we starting at 10:00? Because the agenda is at 10:00.

DR. VALENTIN-RODRIGUEZ: This is Celimar. There's a few members that need to complete their security clearance process. So that has been scheduled by our NSIR office at 8:00 a.m.

That's not the full subcommittee. We have the Commission meeting at 10:00 a.m. We'll be meeting earlier. We have a room reserved upstairs so we can meet here before the meeting.

But yes, I will let you know if you are one of the ones that needs to be here earlier to complete that security clearance process. But we wanted to take advantage that everyone is in person to complete that. So that's why some members might need to be in earlier tomorrow.

CHAIR METTER: Celimar, should we meet you down in the lobby maybe at 9:30?

DR. VALENTIN-RODRIGUEZ: At 9:00, yeah.

CHAIR METTER: Nine o'clock?

DR. VALENTIN-RODRIGUEZ: Yes.

CHAIR METTER: Okay. Thank you.

MR. EINBERG: Yeah. So yeah, thank you on behalf of the NRC for meeting in person. This was great seeing everybody for the first time. We had

very engaging discussions on numerous topics.

And thank you to all the subcommittees, the Y-90 Subcommittee. The ABR discussions were very useful, and I think we learned a lot from that. And even though it went over a little bit, but there's a lot we can take back next week.

Internally, the staff is going to regroup and start strategizing about developing T&E guidance. And so those discussions were very useful in that regard. Very good topic discussions on the EMT rulemaking reg basis. So thank you, Megan, for your presentation.

And we established several new subcommittees. So you have the -- ACMUI is going to be busy in the next few months. Thank you, Dr. Harvey, for joining us and Dr. Einstein. It's great to have such august members and joined the other august members of the Committee here.

So Dr. Ennis, thank you for your comments. Again, those are pointed comments. We value your input. And so we're always seeking to improve as well. As you know, resources are limited and we're all competing for the same resources.

And hopefully we'll try to get new additional staff on our team. So we're looking

forward to getting several new members on our team. So hopefully, things will improve.

We're going to get a new ACMUI coordinator who's accepted the position. So we've been kind of pinch-hitting for a while. So we're hoping things are going to kind of speed up a little bit. But thank you. So I have no further remarks other than to say thank you, everybody.

CHAIR METTER: Well, thank you. Well, I have a comment. I would like to thank the NRC staff, the ACMUI, and our meeting presenters and the public for their participation and particularly Dr. Brent Wagner from the ABR to help answer and inform us of our questions that we had for the ABR.

And lastly, my sincere appreciation for the contributions and service of Dr. Ronald Ennis. And you will not be clearly, you will be dearly missed. And other than that, I'd like to get a round of applause for Dr. Ennis.

(Applause.)

CHAIR METTER: So we see that he's a little red right now. But that's okay.

(Laughter.)

CHAIR METTER: So if there are no comments, this concludes the fall 2022 ACMUI meeting.

And happy holidays to you all, and see you next year.

(Whereupon, the above-entitled matter went off the record at 3:33 p.m.)

Meeting of the Advisory Committee on the Medical Uses of Isotopes
U.S. Nuclear Regulatory Commission
December 5, 2022
Statement of Mary Ajango, Patients for Safer Nuclear Medicine Coalition.

As a representative of the **Patients for Safer Nuclear Medicine Coalition**, I speak on behalf of countless thousands of patients who are now or have been nuclear medicine patients. Virtually every one of us has been directly and personally affected by cancer. On behalf of these patients, I am writing to ask ACMUI for additional information regarding:

- New evidence relevant to the Committee's recommendations on medical event reporting and extravasations
- Your patient injury recommendation
- The agenda item on Lutetium-177 therapies

As the ACMUI knows, extravasations – even those that result in a high dose to skin or tissue or cause patient injury – are treated differently than other unintentional irradiation medical events and are exempted from reporting requirements. This is due to an NRC policy dating back to 1980.

For years, the ACMUI and its allied industry groups have variously claimed to the NRC that extravasations are inconsequential, unavoidable, or infrequent; and that establishing consistent regulatory requirements with a goal of protecting patients would be overly burdensome. This position stands in stark contrast to reality. In addition to the mounting evidence already provided to the ACMUI and the NRC, a recent Italian study submitted for publication in the *European Journal of Nuclear Medicine & Molecular Imaging (EJNMMI)* also directly contradicts the ACMUI positions. The study demonstrates that:

- Extravasations are a regular, common occurrence
- Extravasations can and should be avoided to protect against tissue damage, prevent misdiagnosis and wrong course of treatment
- Monitoring injection quality is key, and it is not difficult to conduct dosimetry if extravasations occur

What is the ACMUI response to the study? If the ACMUI position is unchanged in the face of this new information, can the ACMUI attempt to explain to the NRC how its position is still tenable? This study runs counter to the ACMUI claims and advice to the NRC, and we hope you will recognize that this new study is yet another compelling reason to support extravasation reporting.

Yet, unfortunately, ACMUI has doubled down on its anti-patient position. After consulting with leaders of the SNMMI and ACR, the ACMUI patient industry recommendation puts the onus on patients to:

- Determine that an extravasation has occurred
- Return to the center that caused the extravasation
- Have a doctor responsible for the safe administration of radioactive drugs examine this injury

- Report the extravasation based on this evaluation report

Our coalition rejects this approach, which places an excessive undue burden on patients who already have to cope with a devastating, life-changing diagnosis. As the EJNMMI article demonstrates, hospitals have the ability to monitor for extravasations during the administration of these drugs. If patients are extravasated, they should be notified immediately. Providers must do what they can to minimize accidental exposure **before it causes injury**. Providers should also measure the amount of radiation so patients and their physicians can fully understand the implications of the nuclear medicine procedures.
The ACMUI's suggested solution - asking patients to self-report and allowing nuclear medicine centers to determine on their own whether to report or not - also compounds systemic health inequities, particularly for the Black community. Current and historic mistrust of the medical community is well-documented. Patients of color are far less likely to report to their physicians when they have been injured, compared other patient demographic groups. And from our conversations with vascular access experts, patients of color are far more likely to be extravasated because nuclear medicine technologists continue to gain IV access through one of two methods - either through blind sticks or by using infrared vein finding equipment. We believe this standard of care is outdated and does not take physiological differences such as skin color into account.

It is abundantly clear that asking patients to self-report is not the answer. Ensuring that large extravasations are treated like any other medical event will provide hospitals with the necessary incentive to monitor for extravasations and update best practices, such as using ultrasound, to guide vascular access.

In addition, PSNM is especially interested in the ACMUI agenda item regarding Lutetium-177 therapies. Extravasations during radiotherapies is of great concern. From our members and from discussion with nuclear medicine physicians, we are aware of several centers in the United States that have extravasated doses of Lutetium-177. With that in mind, how would you answer the following:

- How many patients have been extravasated during administration of Lutetium-177 based radiopharmaceuticals?
- Without widespread injection quality monitoring, how could you possibly know the number of extravasations that have occurred?
- In 2008 and 2009 transcripts, the ACMUI claimed that extravasation reporting would cause administrative burdens. Other than that, why does ACMUI continue to believe that therapy extravasations and any large diagnostic extravasations that exceed reporting thresholds should not be reported like other medical events?

The coalition recently welcomed our 30th advocacy group member, Veterans Prostate Cancer Awareness. Their decision to join us indicates just how important this issue and extravasation of Lutetium-177 therapies is to patients. They recognize that now is the time to require extravasation reporting. We trust that, after considering our stance on this crucial matter, you will also reconsider your position. Thank you for your attention and we look forward to your response.

Statement of Mary Ajango, Patients for Safer Nuclear Medicine Coalition.

Dear Sarah, I am Kari Lato and I represent the Patients for Safer Nuclear Medicine coalition. The chat feature is currently off for the ACMUI meeting and I cannot attend the open forum. The coalition has submitted a written comment already regarding extravasations and the Lutetium presentation but we want to share our thoughts on the Y-90 sphere discussion earlier today.

Dr. O'Hara's Key Message slide is interesting. He mentioned that the reported number of medical events is low, but it is important to evaluate the cause of events to minimize the chance of similar types of events from happening again. Patients are curious. Why does the ACMUI takes this approach with Y-90 spheres but not with extravasations? The ACMUI has also stated extravasations are very rare, but does not recommend evaluating the causes of extravasations that can irradiate patients healthy arm tissue with high doses of radiation.

During the presentation and discussion, there was also talk about the importance of ensuring the spheres were delivered as intended, so one would know if there is a medical event at the conclusion of the case. From a patient experience, we endorse this approach. Just like we want to know if we have been extravasated with a high dose of radiation.

Our coalition is aware from an article submitted for publication in the European Journal of Nuclear Medicine. The article discusses that there are many different technologies that exist that can monitor radiopharmaceutical administrations; can't the NRC require that existing monitoring technology be used to ensure that these spheres are not in the delivery catheter? Patients would want to know if there therapy has been delivered completely.

Thank you for delivering our comment to the ACMUI committee members.