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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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SPRING 2025 MEETING

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MONDAY,

APRIL 7, 2025

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The meeting was convened via Video Teleconference, at 9:00 a.m. EDT, Hossein Jadvar, ACMUI Chair, presiding.

MEMBERS PRESENT:

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

RICHARD L. GREEN, Vice Chair

REBECCA ALLEN, Member

ANDREW EINSTEIN, M.D., Ph.D., Member

JOANNA R. FAIR, M.D., Ph.D., Member

MICHAEL R. FOLKERT, M.D., Ph.D., Member

RICHARD HARVEY, Dr.PH., Member

MELISSA C. MARTIN, Member

ZOUBIR OUHIB, Member

MEGAN L. SHOBER, Member

HARVEY B. WOLKOV, M.D., Member

NRC STAFF PRESENT:

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

TAMMY BLOOMER, NMSS/MSST

DANIEL DIMARCO, NMSS/MSST/MSEB

ALLY MARRA, NMSS/MSST/MSEB

DAFNA SILBERFELD, Deputy Director, MSST

KATHERINE TAPP, NMSS/MSST/MSEB

ALSO PRESENT:

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

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

9:00 a.m.

MR. EINBERG: Good morning. As the Designated Federal Officer for this meeting, I am pleased to welcome you to the public meeting of the Advisory Committee on the Medical Uses of Isotopes. My name is Chris Einberg. I am the chief of the Medical Safety and Events Assessment Branch, and I have been designed as the federal officer for this advisory committee in accordance with 10 CFR Part 7.11. This is an announced meeting of the Committee. This is being held in accordance with the rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission.

This meeting is being transcribed by the NRC, and it may be also transcribed or recorded by others. The meeting was announced in the March 9th, 2024 edition of the Federal Register, Volume 90, Page 12795.

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 the staff but does not determine or direct the actual decisions of the staff or the Commission. The NRC solicits the views of the

Committee and values their opinions.

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

At this point, I would like to perform a roll call of the ACMUI members participating today. Dr. Hossein Jadvar, chair, nuclear medicine physician.

CHAIRM JADVAR: Present.

MR. EINBERG: Mr. Richard Green, vice chair, nuclear pharmacist.

VICE CHAIR GREEN: Present.

MR. EINBERG: Michael Folkert, radiation oncologist.

DR. FOLKERT: Present.

MR. EINBERG: Ms. Melissa Martin, nuclear medicine physicist.

MS. MARTIN: Present.

MR. EINBERG: Mr. Zoubir Ouhib, radiation and therapy physicist.

MR. OUHIB: Present.

MR. EINBERG: Ms. Megan Shober, state

government representative.

MS. SHOBER: Present.

MR. EINBERG: Dr. Harvey Wolkov, radiation oncologist.

DR. WOLKOV: Present.

MR. EINBERG: Dr. Richard Harvey, radiation safety officer.

DR. HARVEY: Present.

MR. EINBERG: Dr. Andrew Einstein, nuclear cardiologist.

DR. EINSTEIN: Present.

MR. EINBERG: Dr. Joanna Fair, diagnostic radiologist.

DR. FAIR: Present.

MR. EINBERG: Ms. Rebecca Allen, health care administrator.

MS. ALLEN: Present.

MR. EINBERG: I would note that Mr. Josh Mailman, who is our patients rights advocate, is not in attendance today. I've confirmed that we have a quorum of at least six members present.

Dr. John Angle, interventional radiologist, consultant to the ACMUI, may participate in today's discussions but does not have voting rights for any actions requiring a vote. I would

note that Dr. Angle is here and present.

All members of the ACMUI are subject to the 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 the term is broadly used within 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 its agenda item. ACMUI members must recuse themselves from participating in any agenda item in which they have a conflict of interest unless they receive a waiver or prior authorization from the appropriate NRC official.

I would like to add that we are using Microsoft Teams, so the members of the public and other individuals can watch online or join via phone. The phone number for the meeting is 301-576-2978. Once again, 301-576-2978. The phone conference ID number is 312-941-521#. Once again, 312-941-521#. The handouts and agenda for this meeting are available at the NRC's ACMUI public website.

Members of the public who notified Ms. Ally Marra that they would be participating via Microsoft Teams will be captured as participants in

the transcript. Those of you who did not provide prior notification, please contact Ms. Ally Marra by email at alm8@nrc.gov at the conclusion of this meeting.

Today's meeting is being transcribed by a court reporter. We are utilizing Microsoft Teams as the audio of today's meeting 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 chat feature in Microsoft Teams has been disabled. Dr. Jadvar, at his discretion, may entertain comments or questions from members of the public who are participating today. Individuals who would like to ask questions or make a comment regarding the specific topics of the Committee as discussed and are in the room can come up to either of the microphones set up on the right of the table here.

For those individuals in Microsoft Teams, please use the raise hand function to signal to our Microsoft Team's host Ms. Ally Marra 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 comments, 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 period portion of the meeting, and Ms. Ally Marra will assist in facilitating 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. Dafna Silberfeld, deputy director of the Division of Materials Safety, Security, State, and Tribal Programs for some opening remarks.

MS. SILBERFELD: Thanks, Chris. Good morning, everyone. I'm delighted to welcome you all to our spring meeting. I would like to start by expressing my sincere gratitude for all your hard work and support of the NRC. Your contributions and expertise are truly valued as we continue to address new opportunities related to the medical use of radioactive material.

I would like to highlight a few items that may be of interest to the ACMUI and meeting

participants, starting with the ADVANCE Act. In July of 2024, the ADVANCE Act of 2024 was passed with bipartisan support in Congress. It requires the NRC to take a number of actions while maintaining the NRC's core safety and security mission. The act affects a wide range of NRC activities, including supporting the recruitment and retention of the NRC workforce, adding flexibility in the NRC's budgeting process, enhancing the regulatory framework for advanced reactors and fusion technology, and requiring initiatives to support the NRC's efficient, timely, and predictable reviews of license applications.

While much of the focus on the ADVANCE Act is in nuclear reactor and energy production, items such as efficient, timely, and predictable license application reviews will impact the entire agency and our stakeholders.

In addition, as required by the act, the NRC updated its mission statement. It now reads: The NRC protects public health and safety and advances the nation's common defense and security by enabling the safe and secure use and deployment of civilian nuclear energy technologies and radioactive materials through efficient and reliable licensing, oversight,

and regulation for the benefit of society and the environment. Dr. Tapp will talk more about these items in her presentation.

Next, the proposed rule package for reporting nuclear medicine injection extravasations as medical events rulemaking was provided to the Commission on August 27th, 2024. The staff developed a proposed rule package to codify the reporting of certain nuclear medicine injection extravasations as medical events in 10 CFR 35.3045. Along with the proposed rule, the staff developed implementation guidance for the rule, which includes regulatory guidance for all medical events, including nuclear medical injection extravasations and a draft model procedure for detecting and evaluating nuclear medicine injection extravasations. If approved, the NRC staff will issue the proposed rule for public comment before developing a final rulemaking package. The final rulemaking package will be provided to the Commission for their approval.

I would now like to mention two NRC staff activities. The staff is in the process of finalizing interim staff guidance for licensing authorized individuals' training and experience per direction of the Commission. The interim staff

guidance addresses how persons seeking authorized individual status under Part 35 can fulfill training and experience requirements, as well as clarify the rules and responsibilities of those persons involved in and subject to training experience requirements.

The interim staff guidance consolidates previous guidance on current licensing practices and does not include any new requirements or direction. The NRC staff will be continuing to look at training and experience licensing to identify areas where we can be more efficient as part of our ADVANCE Act activities. Dr. Tapp will provide more information on this later.

Second, my staff continues to actively monitor and assess emerging medical technologies to ensure both public health and safety while facilitating timely and efficient licensing processes. Since the last full ACMUI meeting last fall, my team has issued updated licensing guidance for the Technegas Aerosol and Technegas Plus Systems. Additionally, we revised the 10 CFR 35.1000 licensing guidance for the Alpha DaRT system based on early operational experiences.

Furthermore, we have developed draft licensing guidance for the Liberty Vision system, as

well as additional guidance for thorium generators and the RefleXion Biological Guidance Radiosurgery system. These documents are currently under concurrence and are set to be issued soon.

These updated and draft guidance documents are designed to support the efficient licensing of these new technologies while ensuring they are used safely and that public health and safety remain a top priority.

Now, I would like to take a moment to talk about a few NRC organizational changes since the 2024 fall meeting. Please give a warm welcome to Ms. Ally Marra, who is currently working on the medical team as the ACMUI coordinator. Lillian Armstead, our previous ACMUI coordinator, is currently on rotation to the Office of the Chief Information Officer as a project manager. Cindy Flannery, the medical team's senior health physicist, has recently retired from the group.

I also want to mention upcoming ACMUI updates. Since the fall meeting, we have gotten notice from Ms. Rebecca Allen that this will be her last ACMUI meeting. We are grateful for all of her hard work on this committee, and we will make a special presentation to Ms. Allen later in this

meeting.

Now, let's turn our attention to today's meeting agenda. We have a number of important presentations lined up. The following presentations will be discussed today: Mr. Dimarco will provide an overview of recent medical events. Dr. Harvey will report on Y-90 microsphere GI disposition medical events. Dr. Folkert will provide the training and experience requirements for All Modalities Subcommittee report on emerging medical technologies. Mr. Green will report on the Generic Process Checklist Subcommittee. And Dr. Tapp will provide an update on medical team activities, including ongoing activities related to the ADVANCE Act.

Thank you for the opportunity to open this meeting. I wish you a productive session today. I will be in and out myself, and I will now turn it over to Mr. Einberg.

MR. EINBERG: Thank you, Dafna. Dr. Jadvar, I'll turn it over to you now.

CHAIR JADVAR: Thank you very much, Mr. Einberg and Ms. Silberfeld. Good morning and welcome to the spring 2025 Meeting of the ACMUI. Before we start today's agenda, I first want to thank my colleagues on the ACMUI panel and the entire NRC staff

for their continued support and comradery. I also will conduct Joanna Fair from the University of New Mexico who has joined the panel as the new diagnostic radiologist member. Welcome.

With that, let's start today's agenda. So, first, we have Dr. Tapp who will review the past ACMUI recommendations and provide NRC responses. Dr. Tapp.

DR. TAPP: Okay. Thank you all for joining us today. I'll wait for the old business items to pop up, so we can go through some of the work we've gone through.

I apologize for those in the room for the smaller print. It is in the printouts.

The first open item I want to talk about is from 2021, and this is the ACMUI endorsed the Radionuclide Generator Knowledge and Practice Requirements Subcommittee Report and the recommendations provided therein. This report has been accepted and is open, as we are undergoing rulemaking for the rubidium generator and emerging medical technologies, and it's been rolled into that rulemaking effort.

Moving to 2022, there is a new subcommittee to create the generic process checklist

to be used during medical administrations was established in December of 2022. We're going to have a presentation from Mr. Green today, and we're posed to close that following that presentation.

Next, the Subcommittee for Nursing Mother Guidelines was reestablished to update guidelines that were last updated in 2019. This was accepted, and we're proposing for this to be closed in the fall of 2025. We had a lot of work ongoing, so this had moved over to the fall.

Moving to 2023, the ACMUI recommended that the NRC staff seek the number of annual Yttrium-90 microsphere administrations from the manufacturers. A And while the NRC gains vial data from the manufacturers for the amount of Yttrium-90 microsphere vials that are shipped, it is my understanding that the ACMUI Subcommittee on Yttrium-90 Medical Events and GI Deposition is going to recommend an additional recommendation similar to this, so we're going to propose combining those recommendations into one, assuming that subcommittee report is approved later today.

Moving to 2024, the ACMUI unanimously endorsed the report on the Subcommittee for the Akesis Galaxy RTi Draft Licensing Guidance, as

presented. We have since issued that guidance, so we are going to close that action item because we have taken your comments into that licensing guidance.

Next, the ACMUI unanimously endorsed the report from the Subcommittee on Yttrium-90 Microsphere Brachytherapy Sources and Devices for Eye90 Microspheres Licensing Guidance in April of 2024. We have since issued that report, so we closed that action item.

Next, the ACMUI provided a report with recommendations for the Liberty Vision Corporation Yttrium-90 Disc and Iwand Ophthalmic System Draft Licensing Guidance, so this action item will remain open. But we are expecting this licensing guidance to be issued soon, so we should be able to close this item soon.

Next, the ACMUI formed a subcommittee to reassess including an interventional radiologist into the ACMUI meeting. This is proposed to be discussed at the Fall 2025 or over the summer, so we will close that item when that is discussed further.

Next, the ACMUI recommended that staff provide more information on root causes and corrective actions during their annual review of

medical events and presentation to the Committee. Mr. Dimarco will provide a presentation here soon, and I believe that information is included in that presentation. This item has already been closed, but I like to keep it on the tracker just for a reminder when we do that presentation.

Next, the ACMUI unanimously endorsed the implementation of Part 35 Training and Experience Subcommittee report. This is the subcommittee report that provided comments on the interim staff guidance for training and experience licensing, and that action Ms. Silberfeld just presented on is undergoing concurrence. It should be actually issued here this week, so we're going to propose to close that item. Your comments were included in that interim staff guidance.

The next one is the ACMUI unanimously endorsed the report on Subcommittee on Financial Assurance Requirements for Deposition of Category I Through III Byproduct Material Radioactive Sealed Sources. This is the comments on the regulatory basis. The NRC staff is still working to public this regulatory basis, and we're expecting it to be published in the spring of 2025 and we're proposed to close it once it is published and we provide you guys

deposition of your comments.

And, finally, the ACMUI unanimously endorsed a report on the Subcommittee of ACMUI Bylaws regarding disclosures related to conflicts of interest. We are currently updating these bylaws. The bylaws are going through our concurrence process here internally, and we propose to close it once they are issued.

That's all I have for the old items. I believe, if I go back to it, we had a few that we're going to close after the subcommittees present today, so the one on the generic process checklist we're proposed to close after that presentation and then obtain number of annual Yttrium-90 microsphere administrations plan to merge that with the recommendation from the Yttrium-90 Medical Events Subcommittee.

CHAIR JADVAR: Thank you, Dr. Tapp. Any specific questions for Dr. Tapp? Thank you. So moving on, next item on the agenda is the open forum where the ACMUI members can identify medical topics of interest for further discussions. Any ideas? I have one, but I want others to jump in first. Please, Ms. Shober.

MS. SHOBER: Hi. Thank you. This is

Megan Shober. I was going to propose an idea for a potential subcommittee. Since quite a number of us will be rotating off the ACMUI next year, I was thinking it would be timely to have a subcommittee to put together some kind of best practices for how to write subcommittee reports, how to develop presentations, including Commission presentations.

CHAIR JADVAR: Great. Thank you. I support that. Any other ideas? Please, Mr. Ouhib.

MR. OUHIB: Yes. Looking at the medical events, I always sort of not question but sort of think about the proposed corrective actions that the institution would submit. How do we actually know for a fact that these are being implemented, one? Number two, they're adequate, who is actually making that judgment call? And not to sort of say that NRC staff are not qualified or NRC inspectors are not qualified, by no means. However, that might require clinical experience in that particular modality that's being performed, and that knowledge is very, very important and essential to actually come up and say, yes, that makes sense or, no, I don't agree with that.

And so the question might come up and say, well, what do you recommend for this? You know, my

first thought would be, you know, a qualified consultant, for instance, to actually review that and make a recommendation or put a stamp of approval.

CHAIR JADVAR: Thank you, Mr. Ouhib. Does anybody from NRC want to make a comment on this?

DR. TAPP: This microphone is on now. I thank you for that comment. For specific medical events and looking at the actions being taken for that specific medical event, that's done during inspection space. And the NRC, when a medical event occurs at an NRC facility, we do have the ability to have consultants. Actually, Dr. Angle is a consultant, and, Mr. Ouhib, I believe you've been a consultant on some of those events. So we do have the ability to look at those actions and use consultants to support our staff. And we actually, when I get to my presentation, we are going to talk about medical events today and our follow-up and how we're doing that and actions that we can take. So it's a very timely comment.

The comment, though, goes maybe to Ms. Shober is on the agreement states side. Is there anything there? Because we can provide our consultants to agreement states, I don't believe that has been taken up very often, so I don't know if you

have any comments.

MS. SHOBER: Yes. There was a pretty high bar for agreement states to qualify for that. It has been used in the past with some states.

CHAIR JADVAR: Okay. Thank you. Any other comments or ideas? Well, first, Ms. Shober, thank you for that suggestion. I think we'll form that subcommittee. In the next open forum that we're going to have in the afternoon, we can name some members to join that subcommittee.

Now, I have one idea, and that was regarding potential application of AI and deep learning in medical affairs of the NRC. There are many, many documents that are available historically, and they're relatively technical. Is it possible to use AI and deep learning techniques to go and mine all those documents and other things that are available for the benefit of the ACMUI work, for the benefit of the NRC work, or anything else that the panel can think about that regarding potential applications in that space. I don't think we've ever had. Everybody is looking at AI in many organizations to see how they can benefit from it, and I think it may be time to start thinking about that regarding NRC work and especially as it benefits

the ACMUI.

Any comments on this?

All right. Perhaps we think about maybe a subcommittee to come up and kind of brainstorm about this potential application of AI. Okay.

Any other ideas, comments? All right. Hearing none, thank you. We are going to move on to the next item on the agenda, medical-related events. And Mr. Dimarco will provide an update on recent medical events. Mr. Dimarco.

MR. DIMARCO: Good morning, everyone. Just waiting on the slides really quick. I guess I'll just go into my introduction.

Hi, everyone. My name is Daniel Dimarco. I'm a health physicist here at the NRC on the medical team, and I'm here to give a presentation on the status of medical events from fiscal year 2024.

So the purpose of medical event reporting is to identify deficiencies in the safe use of radioactive material and ensure that corrective actions are taken to prevent recurrence. Medical events may indicate a potential problem but did not necessarily result in harm to the patient, and this medical reporting will ask us to determine if other licensees are experiencing same or similar challenges

and assessing trends or patterns and issues or concerns that any inadequacy or unreliability of specific equipment or procedures.

Next slide, please. So these are the immediate reporting requirements. I won't go into them specifically. If you're interested, you can look them up at 10 CFR 35.3045.

Next slide, please. I will go a little bit more into the best practices here where, I guess, the biggest thing is this presentation is only as good as the data that you give us as the licensees. The biggest one here that I want to look at is the do not assume the reader knows all associated regulations or current standard protocols and provide enough detail that an uninvolved individual would have a full understanding of the event. Me, up here at headquarters, I am essentially an uninvolved individual with these events, and so having more detail in these events makes these presentations and concurrently our Medical Event Subcommittee, as well as any associated generic process documents or information notices that come out that make those better.

So next slide, please. Going into the events themselves, here, you can see the events from

this year, FY '24, and the previous five years. Just looking at the totals here, you can see that we generally hover around the mid-50s to low 60s. This year, we have a little bit lower, just 48, which is actually equal to the amount that we had for FY '20. And for this year, we didn't have any events where the total number of patients involved were greater than the number of reports. So you can see here the events broken down by the regulation that they fall under.

Next slide, please. Going into the medical events themselves, starting with the 35.300 medical events. We had seven this year.

Next slide. Our first one was a patient underdose of Radium-223 where the patient was prescribed 3.3 megabecquerels but was administered 1.68 megabecquerels. The medical physicist in this case deviated from the written directive procedure to activity in the dose calibrator and then deliver the dose. However, they delivered the dose after adjusting this using an outdated and incorrect formula, after which the state initiated an investigation.

Next slide, please. This is related to that one. Another patient underdose with Radium-223

where the patient was prescribed 3.3 megabecquerels but administered 2.68. Similarly to the previous case, the medical physicist delivered the dose after adjusting it using an outdated and incorrect formula. This event was with the same patient as the previous event. However, these have been separated because it was two doses with two separate written directives one month apart on that.

Next slide, please. Next event is a patient overdose involving Lutetium-177 where the patient was prescribed 3.7 gigabecquerels but received 7.4 gigabecquerels. The original written directives called for 7.4 gigabecquerels, but the oncologist had signed a dose alteration plan to bring that down to 3.7. The alteration was not captured in the modification, and the full dose was mistakenly delivered.

Multiple root causes for this event were identified, including changes in dose not being seen, not all the employees having access to the patient electronic medical records, the unavailability of reduced dosage ordering in these medical records, and a lack of dual sign-off by the infusion nurse and the nuclear medicine staff. No adverse events are expected, and corrective actions included a changing

of the timing where the written directive completion was closer to the actual therapy, the creation of a new dose order in the electronic records, and inclusion of dual verifications and discussion of reduced dose directly with the AU. This was one of the events that occurred prior to the issuance of the information notice on medical events involving administration of therapeutic radiopharmaceuticals you can see there.

Next slide, please. This event was also a patient overdose involving Lutetium-177 where the patient was prescribed 5.5 gigabecquerels but instead received 7.4 gigabecquerels. Similarly to before, the patient was unintentionally administered the full dose, rather than the reduced dose, on the written directive. The root cause was determined to be lack of written directive review and a lack of timeout use before the procedure. No adverse effects are expected, and corrective action, the review of the written directive format and improvement of the two technologists pre-treatment timeout procedure. Additional actions included re-education, which stressed the importance of this pre-treatment timeout and attention to detail.

Next slide, please. This next event was

a patient underdose involving Lutetium-177 where the patient was prescribed 7.4 gigabecquerels but was administered 5.54. The treatment went as planned. However, a survey meter position to monitor the vial determined that the activity had been delivered to the patient. However, a post-treatment survey noted a residual activity of 1.62 gigabecquerels in the vial.

Investigation determined that, due to changes in the licensee's supply chain, a new IV set was being used, which did not have a clip to prevent backflow into the pump, which resulted in a visual constriction of the IV line. During the treatment, the technologist attempted to open up the tubing, which seemed successful after dose manipulation. However, the patient was indeed underdosed. The corrective actions included changing the procedure for infusion and repositioning the survey meter to more accurately measure the activity in the vial during treatment.

Next slide, please. This next event is a patient overdose involving Iodine-131. The patient was prescribed 3.7 gigabecquerels but received 5.92 gigabecquerels. The root cause for this was determined to be human error. The technologist

misinterpreted the AU handwriting on the written directive, and the AU failed to confirm the dose during the pre-treatment phase of the administration. Additionally, there were more minor discrepancies on the written directive which indicated a lack of oversight by the RSO.

The adverse effects included an increased cancer risk due to an additional whole-body dose. And the corrective actions included procedure updates for written directives, including typing of the prescribed dose and additional training for AUs on written directives and more frequent RSO audits of these written directives.

Next slide, please. This next event is a patient underdose involving Iodine-131 where the patient was prescribed 3.7 gigabecquerels but administered 0.148 gigabecquerels. When performing these routine radiation surveys at the end of the day, the licensee found the original 3.7 gigabecquerels capsule in the original packaging. It was determined that the patient had only been given the diagnostic capsule, rather than the therapeutic capsule. The root cause was determined to be a lack of dose confirmation on the written directive prior to administration, and the corrective actions

included education of technologists on proper patient and activity processing and revisions to procedures to provide clarity on technologist responsibilities.

Next slide, please. Going into the 35.400 medical events, we only had one this year -- next slide -- involving a patient underdose with GammaTile where the patient was prescribed 6,000 centigray but only received 3600 centigray. Forty seeds were successfully implanted into the brain for treatment. However, the patient had to be returned due to medical complications and had the seeds removed over two procedures. Seven seeds were lost post-explanation, and the state conducted an on-site investigation for these seven seeds.

Next slide, please. Going into the 35.600 medical events, we had six this year, all involving high-dose rate brachytherapy. Next slide. The first event involved a patient overdose with Iridium-192 HDR unit. This patient was prescribed 3400 centigray over 10 fractions but received 4,420 centigray. The dwell times were not verified between planning and delivery systems for eight of these fractions before this mistake was identified. The root cause was determined to be the delivery system being on a Windows XP-based personal computer that

was not able to be on the licensee network due to security reasons, which prevented communication between the planning and delivery systems, resulting in these incorrect dwell times. No effects were noted to the patient, and the treatment was considered completed.

Next slide, please. This next event was a patient overdose where the expected dose to the non-target organ was 200 centigray but was instead delivered to be 340 centigray. The first fraction of the treatment was delivered for the management of cervical cancer when the error occurred. Follow-up determined that the HDR channel assignments had been reassigned during setup, followed by a failure to confirm proper channel assignment during the pre-procedure timeout.

Next slide, please. The patient was able to proceed with the rest of the treatment successfully with no additional effects from the overdose, and the corrective actions included retraining of HDR staff on applicator configuration and verification of channel connection. And, additionally, the licensee consider using different lengths of transfer tubes for different channels to physically distinguish them from other channels

during length measurements.

Next slide, please. This event involved another patient overdose where the patient was prescribed 236.8 centigray but received 362. This patient was scheduled to receive the first fraction of a treatment but was mistakenly administered a previous patient's treatment. The physicist set up the new patient in the vault and confirmed that the patient was correct without closing the previous treatment plan. And then, after exiting the vault, the physicist closed the previous treatment plan, which then, after that, inadvertently reopening the previous treatment plan and delivering the first fraction to the wrong patient.

Next slide, please. This error was caught once they tried to upload the post-treatment summary and noticed that one was already completed. The dose evaluation was completed after this and the remaining nine fractions were changed to compensate for this overdose, resulting in a final dose only 2 percent below the original treatment plan.

The corrective actions included modifications to the patient check-in procedure, additional sign-offs on consult treatment plans, and additional verification to ensure that the computer

treatment plan and the prescribing computer treatment plan matched regarding the active patient.

Next slide, please. This event was a wrong site where the patient was prescribed three treatments of 550 centigray with a total of 1650 centigray to the uterus. However, during the third fraction, the treatment was interrupted due to fluid in the transfer tubing. The replacement tubing that they used was not the correct length, which resulted in the source being outside of the patient for about ten seconds. The localized skin dose was estimated to be about 300 centigray in a worst-case scenario where there was direct contact with a thigh and 50 centigray for a more realistic scenario where there was 8 millimeters of distance between the source and the patient's skin. And the physician noted that the dose was below the level likely to cause injury.

Next slide, please. The delivered dose to this fraction was within 20 percent of the expected dose to the uterus. And the corrective actions included leak testing tubing and a revision of procedures to verify tubing length before starting treatment, as well as new procedures developed for the interruption of treatment to adjust patient setup.

Next slide, please. This event was another patient underdose where the patient was prescribed 600 centigray in their fractions but received 100 centigray for their third treatment. The dwell positions with two ovoid applicators was successful but was obstructed with the tandem applicator. Repeated checks and attempts to correct this were unsuccessful, leading to the underdose.

Investigation of the applicator post-treatment found microfractures in the tandem, which the licensing noted seemed to be related to the autoclaving process for the applicators. Corrective actions included applicator replacement and development of additional precautionary safety features, and patient treatment was revised and then successfully completed.

Next slide, please. This event involved a patient underdose where the patient was prescribed 550 centigray per fraction but received 60.5 centigray for one fraction. The treatment time was determined to be 6 minutes and 15 seconds over 9 dwell positions. However, after starting the treatment, the timer froze at 6 minutes and 7 seconds. The physician stopped the treatment once they noticed the freeze, which was estimated to be around 30 to 40

seconds after the start of the treatment.

Investigation found the device was functioning normally and the timer freeze was unable to be replicated or verified, and so the licensee paused this HDR program until more troubleshooting could be performed.

Next slide, please. Going into the 35.1000 medical events, this year we had one medical event for gamma stereotactic radiosurgery unit and 33 events involving Y-90 microspheres.

Next slide, please. For the GSR treatment, this was a wrong site medical event where the patient was prescribed 80 gray to the left trigeminal nerve -- not a doctor, sorry for butchering that -- but was instead this full dose. But this was instead delivered fully to the right trigeminal nerve.

The medical physicist misidentified the nerves during the pre-treatment, and the reviewing nerve surgeon and oncologist did not notice the error during the plan review. The licensee stated that no adverse effects are expected, and corrective actions included implementation of new procedures for these GSR procedures and additional peer reviews by Gamma Knife-trained oncologists and a verbal timeout before

all cases.

Next slide, please. Going into the microspheres medical events, this one, the medical event did not know whether this was a TheraSphere or a SIR-Sphere event, but this was a patient overdose where the patient was prescribed 2.6 gigabecquerels but instead was delivered 3.13 gigabecquerels. The technologist drew up 3.17 gigabecquerels, and the treatment was delivered within 30 minutes of the dose being drawn. This incident was only discovered during a quarterly review a month later, and both the AU and the patient-referring physician were satisfied with the activity delivered.

Next slide, please. This event was a patient underdose where the patient was prescribed 14,700 centigray but received 5,880 centigray. The licensee suspected stasis, but, as you can see, this event is still ongoing, and we don't have any more updates for you.

Next slide, please. Similar to before, this was a patient underdose where the patient was estimated to receive 30 percent of a prescribed dose. The physician noted that, when inserting the catheter, the vein contusions may have caused the underdose to occur. However, the licensee noted the

incident did not cause stasis. And like before, this event is still under investigation.

Next slide, please. This event was a wrong site event where the patient was prescribed 2.18 gigabecquerels but instead received 0.970 gigabecquerels to the liver. During the administration, some of the dose was deposited in the stomach instead, resulting in a dose of 99 gray to the stomach. The root cause was determined to be a blockage and subsequent rupture of the catheter, noting that the administering physician felt resistance during this administration. The licensee did also note that they were using a manufacturer-recommended catheter and followed all administration protocols.

Next slide, please. The corrective actions included advising the IR AUs of this issue at conferences, notified the vendor of the event, and notified the licensee department of quality and safety. The treatment was paused to determine the extent of the adverse effects, and no symptoms were noted and the state confirmed that all recommended patients were followed for the event.

Next slide, please. This event was another wrong site where the patient was prescribed

1.31 gigabecquerels for a dose of 250 gray but was mistakenly delivered 97 gray to the stomach. The root cause was human error. The team had used a pre-treatment mapping study from a previous Y-90 administration. For this event, severe adverse effects are expected, and corrective actions included the education of all IRs and a new formal process for the treatment team to review correct MAA and angiography mapping techniques.

Next slide, please. This event was a TheraSphere microsphere event with a wrong site where the patient was prescribed 0.77 gigabecquerels but received zero gigabecquerels to the intended site. Instead, all dose was deposited to the stomach for a dose of 19,888 centigray. For this event, all recommended pre-treatment imaging was performed, including an angiogram the day of the treatment showing no stomach filling and post-treatment imaging revealed that the full dose had been deposited in the stomach.

Next slide, please. The root cause for this event was not able to be definitively determined, but the licensee believes that an atypical flow was misinterpreted during the pre-treatment planning. Additionally, the licensee

noted that, one month before the treatment, the patient was undergoing immunotherapy and angiogenesis treatment, which may have contributed to this event.

The patient was treated for adverse effects to the GI system and appears to be recovering, and corrective actions including guidance for mapping studies with regards to abnormal arterial structure, use of cone beam CT to augment to the pre-treatment studies, and clear instructions to staff about reporting requirements.

Next slide, please. This was another 1000 TheraSphere wrong site where the patient was prescribed 0.613 gigabecquerels but received 0.582 to the treatment site. Post-treatment analysis of this treatment revealed an uptake to the stomach of 1,400 to 2,000 centigray. Follow-up with the patient showed no complications to the GI system, and the root cause was suspected to be the complex vascularity of the tumor not identified by the two previous MAA mapping studies.

The licensee did state that, since the second mapping study was done the day of the treatment, it was possible that these particles may have altered the flow dynamics of the tumor, and no corrective actions were taken, given that the

administration be given according to manufacturer recommendations.

Next slide, please. So before going into these next few, I do want to say the previous four events, these were the GI deposition events, these will be talked about later today by the ACMUI subcommittee that we stood up after recognizing those four events.

Continuing on into the 35.1000 TheraSphere events, this event was a patient underdose where the patient was prescribed 1.79 gigabecquerels but received 0.67. The root cause was determined to be the unintentional use of a smaller catheter than recommended by the manufacturer.

No adverse effects were expected, and the dose delivered was determined to be clinically effective. The corrective actions included additional training on verification of catheter size for technologists and AUs and a revision of the standard operating procedures to include a step for catheter size verification.

Next slide, please. This event was a patient underdose where the patient was prescribed 1.2 gigabecquerels but received 0.82 gigabecquerels. The root cause was determined to be a kink in the

catheter, and corrective actions included reminders to check flow-through of the microcatheter prior to administration and to keep watch on the overflow vial during this administration.

Next slide, please. This event was another patient underdose where the patient was prescribed 2.072 gigabecquerels but received 1.369 gigabecquerels. This treatment was intended to be two doses, A and B, for separate sections of the liver. The dose for segment B was mistakenly delivered to segment A. However, this incident was discovered before delivering the remaining dose to segment B.

Next slide, please. This event was another patient underdose where the patient was prescribed 4.29 gigabecquerels but received 0.1 gigabecquerel. During treatment, a tubing failure led to the suspension of the treatment. This patient was rescheduled, and the kit was held for decay to send to the manufacturer for analysis.

Next slide, please. This was another TheraSphere underdose where the patient was prescribed 3.712 gigabecquerels but received 0.3 gigabecquerels. The attending physician noted no unusual signs during treatment. However, an

inspection found that the written procedures were not implemented to provide high confidence that the administration was performed in accordance with this written directive.

Additionally, a catheter smaller than recommended was used, and the individuals working under the supervision of the AU were not properly trained. The corrective actions included procedural changes to include catheter planning multiple times during the process.

Next slide, please. This was another TheraSphere underdose where the patient was prescribed 29,300 centigray but only received 9,500 centigray. This patient was prescribed two administrations of microspheres where the first vial was the underdose and the second vial was uneventful. This event was discovered surveying the waste post-treatment, and the root cause was determined to be a momentary stoppage of a microsphere's flow due to the actuation of the relief valve, which led to microspheres dropping out of suspension. The patient was scheduled for additional treatment, and no corrective actions were

taken.

Next slide, please. This was another

patient underdose where the patient was prescribed 1.304 gigabecquerels but received 0.931 gigabecquerels. Multiple root causes were identified, which were the clumping of microspheres in the V vial, occlusion of the needle puncturing the vial, or possibly kinking of the microcatheter. The corrective actions included updating procedures to lift the vial and shield out of the kit and striking it to loosen any microspheres, especially if the dosimeter readings are elevated. Additionally, flushing continuing until dosimeter readings are at background during the treatment.

Next slide, please. This was another TheraSphere underdose where the patient was prescribe 1.77 gigabecquerels but received 0.248. The patient was prescribed two treatments with two written directives, and this underdose occurred on the second treatment.

The administering physician noted resistance due to a kinked catheter during treatment, and the root cause was determined to be that kinked catheter due to tortuous anatomy. Flushing the catheter during treatment did not alleviate the resistance, but it did result in minor contamination of the IR suite and surveys and decontamination of

the room occurred without incident or overexposure.

Next slide, please. This event was another patient underdose where the patient was prescribed 1.347 gigabecquerels but received 1.029. The root cause was determined to be the use of a smaller-than-recommended catheter. The specific one you can see up there. Tenuous patient branch anatomy and not replacing this microcatheter after performing the bland embolization. No adverse effects were expected, and the re-treatment was not deemed to be necessary.

Next slide, please. This was another patient underdose where the patient was prescribed 560 megabecquerels but received 49.99. The root cause was determined to be clumping of microspheres due to over-tightening of the lower lock. The dose information was obtained from post-treatment analysis of the waste, and no health effects, no negative health effects were expected and the treatment was rescheduled.

Next slide, please. This was another TheraSphere underdose where the patient was prescribed 2.11 gigabecquerels but only received 0.477. No adverse effects are expected, and the state performed an on-site investigation which

determined the root cause to be a blockage of the administration line because of a faulty needle and the plunger of the administration kit.

Next slide, please. This next event was another TheraSphere underdose where the patient was prescribed 1.29 gigabecquerels but received 0.853. The administering physician noted significant resistance during the treatment and on all of the saline flushes. The root cause was determined to be clumping of the microspheres with no reason being clear. No adverse effects are expected, and the physician determined that the patient did not need to be re-treated.

Next slide, please. This was another patient underdose where the patient was prescribed 380 megabecquerels but only received 160. The root cause was determined to be an obstruction in the microcatheter where no adverse effects were expected and re-treatment plans are currently being evaluated. Additionally, no shunting was noted during the treatment, and the waste was delivered to the manufacturer for further investigation.

Next slide, please. This was another TheraSphere underdose where the patient was prescribed 489.6 gray but received 113.9. The root

cause was determined to be a blockage of the catheter due to unadministered microspheres. Re-treatment for this patient was planned, and corrective actions included procedure changes.

Next slide, please. This was another TheraSphere underdose where the patient was prescribed 3.5 gigabecquerels but received nearly zero. During the second of two administrations, post-treatment surveys indicated that nearly all of this dose remained in the delivery tubing. The patient was planned to be retreated in the future, and the state performed a reactive inspection due to this event, which determined the root cause to be the clumping of the microspheres where time between the dose preparation and the delivery being a possible complicating factor in that clumping.

Next slide, please. This was another TheraSphere underdose where the patient was prescribed 10,500 centigray and received 5,050. The tubing failure resulted in microspheres being contained in this tubing. No spill occurred, and the manufacturer representative observed this event. The remainder of the prescribed dose was scheduled to be delivered at a later date, and corrective actions included procedural changes for a more thorough

inspection of the tubing, as well as agitation of the vial prior to administration.

Next slide, please. This was another TheraSphere underdose where the patient was prescribed 1.86 gigabecquerels but received 1.019. All pre-treatment procedures were completed. However, the MAA mapping showed possible reflux to the valve. Due to this, the physician cautiously delivered the dose and removing the catheter. The survey equipment showed a higher-than-usual level of background radiation.

Post-treatment surveys indicated that there was activity remaining in the delivery system, and the root cause was determined to be the aforementioned reflux issues which caused activity to remain in the kit, as well as the physician not risking valve reflux with additional flushes. The corrective actions included patient monitoring for reflux and anatomical issues and ensuring that all additional flushes will be completed during future treatments.

Next slide, please. This is another TheraSphere underdose where the patient was prescribed 1.51 gigabecquerels and received 0.84. The treatment was administered with no complications,

and three saline flushes were completed. However, post-treatment surveys indicated residual activity in the waste.

Investigation showed a rupture in the microcatheter passing through the Y fitting, allowing microspheres to collect in this fitting, which determined the underdose there. No adverse effects to the patient were expected, and corrective actions included manufacturer communication with this catheter failure and refresher training to the staff on setup of the administration lines.

Next slide, please. This was another TheraSphere underdose where the patient was prescribed 976 megabecquerels but only received 96. The pre-treatment flush of the catheter with saline and contrast solution was uneventful, but the attempts to deliver the microspheres was unsuccessful.

The root cause was determined to be a kink in the catheter due to tortuous anatomy, possibly because of a difference in the pressure between the flushes and the microspheres where the flushes were at 200 psi and the microspheres were at 30. No adverse effects were expected, and corrective actions included education about this issue for other AUs.

Next slide, please. This was another TheraSphere patient underdose where the patient was prescribed 11,800 centigray but received 6,431. This treatment involved three vials, one of which incurred without incident. But the physician noted increased resistance when delivering the second and the third vial.

The root cause was determined to be user error. For this event, the mandrel was not removed before attempting to remove the microcatheter from the packaging, which caused internal damage to the microcatheter, which affected the yield in vials 1 and 3. No adverse effects were expected, but the patient was followed for possible re-treatment. And corrective actions included sharing awareness of proper unpackaging technique, additional monitoring by the AU, and generic discussion on IR tasks among the operational leadership.

Next slide, please. This event was another TheraSphere underdose where the patient was prescribed 12,000 centigray but only received 4,170. For this event, during the line check, when attempting to administer the microspheres, the physician experienced some difficulties, stopped the procedure, and noticed a higher-than-usual background

reading.

Imaging of the patient revealed that very little of the dose was delivered. No adverse effects were expected, but the patient was monitored for the next few weeks. And the licensee planned to hold the kit for decay and send it to the manufacturer for analysis post-decay. The corrective actions included revision of procedures.

Next slide, please. This event was another TheraSphere underdose where the patient was prescribed 562.4 megabecquerels but received 399.97. During the treatment, the AU noticed high back pressure, and possible root causes were stated to be issues with the administration set or coring of the septum, but not definitive cause was identified. No adverse effects were expected, and the dose was determined to be clinically effective. And no corrective actions were taken since there was no clear root cause and no violations identified during the investigation.

Next slide, please. This event was another TheraSphere underdose where the patient was prescribed 266.4 megabecquerels but received 207.72. The root cause was determined to be microspheres held up in the hub due to inadequate flush volume. No

adverse effects are expected, and no additional treatment was determined to be needed. And corrective actions included education with follow-up safety committee meetings and flushing the microspheres with 33 cc of fluid barring stasis.

Next slide, please. Getting into the SIR-Spheres events, this was a patient overdose where the patient was prescribed 199.8 megabecquerels but received 253.08 megabecquerels. This incident was discovered during a quarterly records review, and the root cause was determined to be the small activity of the dose where the personnel had difficulties drawing microspheres into the syringe without under or overdosing the vial. The licensee did note that treatments under 370 megabecquerels generally have around a 15-percent residual activity. No adverse effects to the patient were expected, and the dose delivered was considered clinically acceptable.

Next slide, please. This was a SIR-Spheres underdose where the patient was prescribed 499.5 megabecquerels but received 295.63. This treatment was suspended during the treatment due to tubing failure, and the patient was rescheduled. However, investigation could not find the cause of a clogged tubing, and both the manufacturer and

licensee noted that the tubing size was acceptable for the procedure.

Next slide, please. This was another patient underdose with SIR-Spheres where the patient was prescribed 708.18 megabecquerels but only received 285.64. During the treatment, a leak was discovered in the system, and the treatment was stopped, after which the connection was reestablished and the treatment continued where all the contamination was remediated.

The root cause was determined to be the treating physician's error to properly connect the tubing to the microcatheter. No adverse effects were expected, and the dose delivered was considered therapeutically adequate. Corrective actions included double-checks of all tubing and injecting contrast to check for leaks before administration.

Next slide, please. So that was all the events that happened in FY '24, and so I'll just go into some of my quick summary slides at the end here, just some of the things that I noticed when doing this presentation and possible trends to look out for.

So for the 35.300 events, the radium underdoses both resulted from the use of an

administration equation from an outdated manufacturing document, manufacturer document. It shows the importance of using current manufacturer recommendations and regularly updating your procedures based on these recommendations. This can happen for things that have been on the market for years now, so it's good to keep in mind.

The lutetium overdoses resulted from the administration of full doses instead of reduced doses where, typically, you have the 200 millicuries of lutetium being injected for these, but the written directives bringing them down to 100 to 150 to other different clinical things that are going on, and so making sure those written directives are correct and injecting the right amount is important there, and the Lutetium-177 underdose which resulted from supply chain issues and the loss of expected equipment.

Next slide, please. This iodine underdose also was due to human error where they did not confirm the dose delivery.

I do want to say that many of these issues were explored in the recent IN, IN-2024-04, written by Katie Tapp. Many of these issues are specifically called out in that information notice, so I highly recommend for anyone who hasn't seen or read through

that information notice to do so to help reduce the amount of these events occurring in radiopharmaceutical injections.

Next slide, please. Going on to the 35.600, I didn't notice identifiable trend or connecting thread from any of these events this year. As usual, human error dominated most of the root cause, usually improper use of equipment or use of improper equipment. A lot of lack of verification of proper equipment and verification of proper treatment parameters and patient treatment plans.

Next slide, please. Going on to the 35.1000, like I said before, we have those GI deposition events which you'll hear about later on today, so I won't go into them too much right now. But, however, there are a few other things that we've noticed, issues with corrective equipment usage, you know, using the right tubing, using the right catheters, making sure the lower lock is connected, these things we've seen before and the Y-90 subcommittee has talked about before previously. And one thing that stood out this year was a lot of clumping of microspheres for a variety of reasons: time between administration and dose preparation, low pressure during administration, as well as use of

that improper equipment where a smaller catheter or smaller tubing, trying to get away from the clumping of the microspheres as much as possible to deliver an accurate dose.

Next slide, please. I believe that's everything. These are my acronyms. Next slide, next slide. And that's it.

CHAIR JADVAR: Thank you, Mr. Dimarco. Does anybody have any questions or comments? Dr. Einstein.

DR. ANGLE: How can there be three Y-90 administrations when the agent that was to be used was not recorded? To me, the events you reported, it was not clear whether they were one of the two vendors. I'm just curious how that information is not reported to your --

MR. DIMARCO: So for those, that is when we have the information that comes in for the medical events, sometimes it's incomplete. And so, for that, I have to go to either the agreement state or the regional folks to help with that. And if I don't get that information in time for this presentation, then it doesn't get into this presentation unfortunately.

CHAIR JADVAR: I just want to mention that it was Dr. Angle who asked the question for the

record. Dr. Einstein.

DR. EINSTEIN: Thank you for your presentation. I'm hoping you can provide us with a little bit more information about the medical event 240289, the 35.300 Radium-223. Under dosing, where the state initiated an investigation and, yet, the same patient received an underdosing again a month later.

MR. DIMARCO: I believe, with that one, these events were discovered at the same time where it wasn't the event was discovered, then a month later the same event occurred. I believe both the events occurred, and this was discovered after both of them had occurred. So the state initiated this investigation after seeing both of those events.

DR. EINSTEIN: Got you.

CHAIR JADVAR: Dr. Folkert.

DR. FOLKERT: Thank you. So Michael Folkert. I think, going through these events, this definitely highlights something that's come up with Dr. Harvey's events committee before is that there really is a critical need for a timeout, especially for the 35.300 and the 35.600 and the HDR ones. I mean, many of these events would have been prevented by a proper timeout.

And I was just wondering, for these events, is there any documentation of the staff present, especially during the .300 procedures and how the supervision was managed?

MR. DIMARCO: I believe that the list of staff present is not a requirement for medical event reporting, no.

DR. FOLKERT: Is that something that could also be beneficial in terms of evaluating kind of the root causes of the issue and remediation for training.

CHAIR JADVAR: Mr. Ouhib.

MR. OUHIB: I have a few points to make. I think part of the timeout, also as a reminder, a question regarding was the dose modified or updated should be part of that checklist. For errors 35.300 and 35.400, it seems like it's coming mainly from support staff. We focus more on the AU, but I think we need to also focus on the support staff and how much adequate training is provided to those.

And let me just share with you, at meetings, I hear from manufacturers saying that, you know, such institution did a self-training, the physicist did a self-training, the dosimetrist is self-training. That shouldn't happen. That

shouldn't happen. It should be training from the manufacturer.

For case 230517, you know, talking about the correct plan but also the correct fraction number, that's important.

Who actually is changing that for case 230461? Was it the physicist, or was it the therapist? I mean, the physicist knows that the tube length if critical. The therapist may or may not unless she or he had training on that.

Case 240081, microfractures of GYN applicator. I'd be curious to know what's the age of that applicator? Some of you might, especially in radiation oncology, there's such a thing called end-of-life, and that is part of the package. When you purchase an applicator, it tells you specifically not how many times you use the applicator or how many time you send it for sterilization, but it's the number of years, period. After three years, the company will wash their hands. There's no liability whatsoever. You are responsible for that.

And just to share with you, I'll give an example. Many times, the case of if something like this were to happen, an attorney would put their hands on that end-of-life document. You can imagine what

the consequences are.

Again, people doing things that they're not qualified for. We need to make sure that, no, that's not your responsibility; so-and-so should be doing that.

Previous plan being used. We need safety from manufacturer where a previous plan cannot be treated if already delivered. We need some sort of an override by both the authorized user and the medical physicist to basically give them a green light to proceed.

Wrong length of tube for HDR procedure, I think manufacturer recommendation on who should be doing that again, that has to come from the manufacturer. In general here, I hear, like, flushing resistant tubing issues, setup issues, that, in my opinion, require additional training because we're seeing it again and again and again.

And that's all I have. Thank you.

CHAIR JADVAR: Mr. Green.

VICE CHAIR GREEN: I'd like to reaffirm Dr. Folkert's thoughts about the need for a pause, a timeout. And as an advertisement, this subcommittee report this afternoon on the generic process checklist where we'll make recommendations for

informational notice.

And I think, looking at the drug side, I think all of the lutetium overdoses could have been prevented with a barcode medication administration process check. It's not people, it's not color code, it's not dual verification. It's barcode, and that's something that's employed everywhere in the hospital but somehow doesn't make it into radiology and I think it should.

Anyway, thank you.

CHAIR JADVAR: Dr. Harvey.

DR. HARVEY: Richard Harvey. Thank you. Mr. Dimarco, I'm just going to have a couple of questions and clarifications. I'll give the citations. 35.300, Lutetium-177, case 230483, you mentioned that there was a timeout that wasn't performed. I was wondering if that timeout was required and not performed, or was that something that they're supposed to do that they failed to do?

MR. DIMARCO: That would be depending on what the licensee has in their procedures. I don't have the answers on that.

DR. HARVEY: Okay. I didn't know if you would or not. Just a lack of a timeout and I wasn't sure if they required it as part of their procedures

or not. Thank you.

The next one is 35.300, the I131, case number 240143. Do you know why there was a diagnostic and a therapeutic dose available or those capsules available on the day of the treatment?

MR. DIMARCO: I don't have that answer, no, unfortunately.

DR. HARVEY: Thank you. I know some of these were going to be maybe that lack of detail in the reports.

The next one was a 35.1000, Yttrium-90 microspheres. It's event number 240113. The technologist drew up the wrong dose. Was there any more information as to why they drew up the wrong dose?

MR. DIMARCO: I believe, with that one -- let's see. Do you know what page that's on?

DR. HARVEY: I have 28. I'm not positive.

MR. DIMARCO: Okay. That was one of the ones where the manufacturer himself was not indicated, correct? Yes, where the manufacturer was not indicated. For that one, I don't have the information on that. My best educated guess was that this was likely a SIR-Spheres event where there is a requirement there to draw up the correct amount of

microspheres before delivering that, as opposed to TheraSpheres. But I don't have the information on why the technologist drew up the wrong dose.

DR. HARVEY: I do understand that those draws can be challenging, especially with small amounts with high activities, and I just wondered why they drew the wrong amount maybe and wrong activity and used the wrong activity, if there was any more information.

The next one was 35.1000, TheraSpheres, medical event number 240114. The wrong size catheter was used, and we know that's been a recurring issue. The one used was 0.19 instead of 0.02. My question is does that really matter? It's a hundredth.

MR. DIMARCO: I'd have to go to the experts on --

DR. HARVEY: Maybe Dr. Angle can answer. Oh, Mr. Green.

VICE CHAIR GREEN: In my laboratory experiments with TheraSpheres being a solid glass particulate, I've literally had them in the vial pierced down through the septum and aspirate all the liquid, and they pack, geometrically pack. And you can't get three people through a doorway. I mean, it's going to prevent that from going through.

DR. HARVEY: Understood. In your opinion, do you think the one one-hundredth of an inch made a difference? You're saying yes.

VICE CHAIR GREEN: I think so. I'd defer to the people who actually know, but that's --

DR. ANGLE: I think it's very important to stay with the manufacturer's recommendation with what catheters are compatible.

DR. HARVEY: Absolutely agreed. I absolutely agree. We've advocated that in the past. I just wondered because it was such a small deviation.

Sorry. Some of these are clarifications and knowledge for myself, so I apologize. The next one is 35.1000, TheraSphere, medical event number 240032. Root cause -- I have 50. I'm not positive that all of them are the same. I had some trouble following through the slides. That's why I was leaving that out.

But the root cause was determined to be blockage of the catheter due to unadministered microspheres, and I was just wondering if there was any further information as to why those weren't administered. Was there aggregation clumping or just lack of more information?

MR. DIMARCO: Unfortunately, this is lack

of information.

DR. HARVEY: All right. Thank you. I appreciate everyone bearing with me. The next one is 35.1000, TheraSphere, medical event number 240009. The tubing failure resulted in microspheres being contained in the device tubing. Was there any more information on the tubing failure? Did it leak? Was it the wrong size? It just says tubing failure, and it kind of left me wanting more information.

MR. DIMARCO: I believe this was due to a wrong size tubing on this one because the corrective actions included an inspection of the device tubing prior to administration, so they used the incorrect sizing tubing, which resulted in these microspheres clumping in the tubing.

DR. HARVEY: Thank you, Mr. Dimarco. I have one last one. 35.1000, TheraSphere, medical event number 230469, slide number 56 was what I have. And this is just really more for me for education. I'm unfamiliar with the term mandrel. Can someone explain that to me? Mandrel was not removed before attempting to remove the microcatheter from the packaging. I'm just unfamiliar with the term mandrel.

DR. ANGLE: This is John Angle. I can

maybe help. Many of these catheters are very fragile. They put a metal, a very fine metal stylet into the catheter to make sure it doesn't get kinked during shipping. But if that's not removed properly, it actually can lead to damage to the catheter.

DR. HARVEY: Thank you. That was just an ignorance on my part, and I appreciate the education. I'm done. Thank you very much.

MR. DIMARCO: I also had to do my research on that one, as well.

CHAIR JADVAR: Dr. Angle.

DR. ANGLE: One last question. Many of these underdosing with Y-90 appear to be catheter-plugging problems. I think we may have discussed this before, but refresh my memory: do we encourage these be reported to the mod database with the FDA because it seems like this is something that should be reported in the mod databases as a device inadequacy.

MR. DIMARCO: I believe we don't do any encouragements for other reportings but --

DR. TAPP: We don't encourage reporting outside of ours, but we should note that the FDA staffers who do Yttrium-90 and work on it do have access to our medical event database, and they're

fully aware of the events.

DR. ANGLE: Thank you.

CHAIR JADVAR: Mr. Ouhib.

MR. OUHIB: I think the user is obligated to report to the FDA on medical devices if something were to go wrong. So as users, you have that responsibility, and they need to be aware of that.

CHAIR JADVAR: Okay. I have one comment. This is 35.300, Lutetium-177, patient overdose, case 240075. It's on page 9 of your slides and 17 of the entire package, if you want to find it. Just out of curiosity, it says Lutetium-177. It doesn't say if it was a patient with prostate cancer or patient with neuroendocrine tumor. I assume prostate cancer.

As you know, in these patients, we use a fixed dose. There is no dosimetry done for each patient, so it's not dosimetry based. Now, you can certainly change the dose if necessary due to the patient's condition. The package insert says, you know, reduce it by 20 percent, if necessary. And then, if you go down to that level, you will stay at that level.

Now, this was decided to be 100 millicuries, half of the dose. I assume this was based on clinician judgment that there was either

some hepatologic or renal insufficiency and, therefore, they needed to use less dose. It's not mentioned in here, but that's what I'm assuming.

I think, when things like this happen, it's best if these kind of decisions are made, if you're trying to change the dose, the decisions are made in interdisciplinary reports. If it's only 200, it doesn't really matter. We can just do it, you know, as it is. But when it is 100 millicuries, if there was a tumor board, if the nuclear medicine person was there, an oncologist was there, you know, and everybody else participating with tumor boards, probably things like this would not happen because the decisions are made there and communication is quite clear for that particular patient. So that's one thing I think that can be communicated to some of these folks.

Also, it says no adverse effects are expected. Well, there was a decision to half the dose. I don't know if that's really a correct statement because you're going to see more hepatologic toxicity if that was the expectation to begin with or there may be nephrotoxicity if that was the expectation to begin with.

So I think these kind of things need to be

communicated. If there is dose modification, because it is not dosimetry based, please have it in tumor board so that communication is better.

Dr. Joanna Fair.

DR. FAIR: With the one on page 9, the 240075, my guess is that might have been and maybe you can clarify if this was lutetium dotatate because that is a standard dose modification from 200 to 100.

MR. DIMARCO: Yes, I believe it was dotatate. Yes.

DR. FAIR: Okay. And so it appears that they probably planned to do the dose modification based on patient factors like thrombocytopenia or something else but that that did not occur. Okay. I don't understand the 150 --

CHAIR JADVAR: Thank you, Joanna. Okay. Any other comments, questions? Okay. Please, Rebecca Allen.

MS. ALLEN: Yes. It's more maybe a question for myself, but, on page 68, the acronyms, the NMT, nuclear medicine technician, if we could change that from technologist, please.

MR. DIMARCO: I thought all the technologists. I'm sorry. That's my mistake, yes. That should be technologist.

CHAIR JADVAR: Thank you. Any other comments, questions? All right. Oh, one more. Dr. Fair.

DR. FAIR: Just a clarification. There was a discussion about barcoding that came from Dr. Green, and I'm trying to clarify do you mean if there's a dose that has a barcode on it that would indicate if you swiped it whether it was 100 millicuries or 200 millicuries? I mean, to understand it a little bit better because I think there may be some barriers to doing that.

VICE CHAIR GREEN: Yes. There are systems in use today that, if applied, would allow nuclear medicine radiological doses, pharmaceutical doses, whether it's 25 millicuries or 100 millicuries, to barcode that before administration to verify that against the electronic records.

DR. FAIR: So I think the challenge with the lutetium dotatate specifically, and I think also lutetium, the PSMA treatment, is that what comes from the manufacturer is 200 millicuries and then it has to be modified on site. And so there isn't, I think, a way to barcode that. I think the solution would be for the 100 millicuries to come from the manufacturer so that it could be checked in that way.

I'm just sort of thinking back to your suggestion --

VICE CHAIR GREEN: That would require, in my mind, a new drug, an FDA filing for a different package size, a different put-up, and then they've got to manage inventory and the ordering process. Now, if they had come to a radiopharmacy and it was drawn from the bulk vial of 200 and down to 150 or 100, as was appropriate, then it could have received a barcode medication administration label to barcode that amount.

CHAIR JADVAR: Okay. Now, thank you, Mr. Dimarco, for that very nice presentation. So it's 10:25, and we were supposed to have a break from 10:15 to 10:30. But why don't we get five-minute break, just a bathroom break, and then we continue on at 10:30 with the next presentation. Thank you.

(Whereupon, the above-entitled matter went off the record at 10:25 a.m. and resumed at 10:35 a.m.)

CHAIR JADVAR: Again, welcome back to the spring 2025 ACMUI Meeting. After this short break we are going to continue on with the next presentation, which will be on yttrium-90 microsphere gastrointestinal deposition medical events (audio interference).

DR. HARVEY: Thank you, Dr. Jadvar. Move to the next slide. It shows the Subcommittee members. Dr. Angle, who will be very important with regards to this, as our interventional radiologist (audio interference) public. I don't think mine is on, I think the public is not hearing what we're saying.

You can hear us now? Okay, thank you. Just quick introductions of the Subcommittee members, and Ms. Sarah Spence is our NRC staff resource, she's been immensely helpful. Moving to the next slide please. The Subcommittee charge is to evaluate the changes in yttrium-90 microsphere brachytherapy practice, and recent yttrium-90 microsphere medical events to identify potential cause or causes of sudden increase in the reported events involving unexpected GI deposition.

Next slide please. Some background, yttrium-90 microsphere brachytherapy has been performed for approximately 20 years using SIR-Spheres, which are a resin, or TheraSpheres, which is glass. The companies respectively are Sirtex and Boston Scientific. There were five events that have been reported to NRC's medical event database, NMED, since May 2024.

So, these events have been rare, but there has been an uptick, which resulted in the formation of this Subcommittee. These events indicated significant deposition of yttrium-90 microspheres to the gastrointestinal system with one of those events being retracted. And if I'm not mistaken, there was a sixth event that was also retracted.

Moving to the next slide please. GI deposition is a known undesirable outcome associated with microsphere brachytherapy, but the NRC typically receives very few reported medical events with GI deposition. The aforementioned five events involve TheraSpheres, but similar events have occurred in the past with Sir-Spheres.

Next slide please. Continuing on with background, prior to the yttrium-90 microsphere treatment, a mapping procedure with technetium-99m macro aggregated albumin, MAA, is performed to predict microsphere flow dynamics, and deposition in the liver, and hopefully lack thereof in the GI tract. Mapping may be performed the same day or ahead of time, days ahead of the treatment.

Timing and site of MAA injection are not standardized. Acceptable duration of time between mapping and treatment is variable based on the

authorized user experience and judgment. Next slide please. To discuss our findings, the incidence rate of these medical event depositions in the GI tract were less than 0.5 percent for yttrium-90 microsphere brachytherapy medical events as have been reported to the NRC in NMED.

The incident rate has remained unchanged, with a minor increase in events with GI deposition in 2024. It is unclear if this represents any trend at this time. The volume of treatments is increasing based on manufacturer data to the NRC. We don't have exact numbers because it's proprietary, it is something that our Subcommittee is working on with the NRC, and with the manufacturers.

But we do see increasing numbers or volume of these treatments, and again, we have seen a minor uptick in these events with GI deposition. If we go to the next slide please, we have a bar graph figure here provided by Ms. Sarah Spence, thank you very much, showing yttrium-90 medical events involving GI deposition.

Beginning in 2012 up through so far in 2025. In blue are the events, in orange are those that have been retracted. So, it definitely looks like an uptick in 2024. Again, the numbers here are

small, these are a rare occurrence, so there is high consequence, obviously, with these events, but the uptick is small in comparison to the number of treatments that are being performed, again, less than 0.5 percent.

Next slide please. Additional findings, improved imaging technology may have resulted in more events identified. So, the fact that imaging technology is being performed more readily may result in more of these being identified. There is increased use of SPECT, or Single Photon Emission Computed Tomography versus planar imaging, or lack of any post therapy imaging.

Treatments are challenging due to the difficulty of placing catheters in small vessels with tortuous paths. Not an excuse for having medical events, but certainly this is a very complicated, challenging procedure that we need the expertise of the interventional radiologist like Dr. Angle to perform.

It is very difficult to standardize the process because of patient specific anatomy, normal variance, and having the opportunity for clinical judgment and expertise. Some standardization may or may not benefit patients. Next slide please.

Licensee explanations for gastrointestinal deposition. The difference in microsphere treatment size versus technetium-99m MAA mapping was something that a few in these incidents was cited.

That because the size of MAA is different, the particle size for the MAA, the macro aggregated albumin is different than the yttrium-90 microsphere size has been cited. This is unlikely to be clinically relevant. MAA has a range of approximately 10 to 90 micrometers, and 20 to 30 micrometers is the particle size distribution for TheraSpheres, and I believe, I'm doing this off of memory, it's about 20 to 40 micrometers for the SIR-Spheres.

Moving to the next bullet, there is typo in there, it should be licensees, I apologize. Mapping and treatment, same day or not, was question that we wrestled with. Licensees have performed MAA treatments the same day or ahead of time with success. So, there doesn't seem to be a strong pattern as to whether the MAA has to be done ahead of time, versus the day of the yttrium-90 microsphere treatment.

Pharmaceuticals such as Avastin may affect the flow dynamics of MAA or yttrium-90 microspheres, these agents are or should not be taken for several

weeks prior to treatment, so that's generally what is performed. Moving to the next slide please. Our Subcommittee recommendations to the NRC. The NRC should determine the number of procedures being performed by leveraging relationships with manufacturers to provide a better understanding of medical events as it relates to the yttrium-90 procedure volume.

And we've had a couple of meetings with Boston Scientific where we are working on that. There is no apparent consistent cause for these events, none that has been identified, but we recommend continued monitoring. NRC should consider methods to inform licensees of these events. So, when these events occur, if we can get out informational notices, or whatever is appropriate that we can warn licensees, we believe that would be a valuable purpose, a valuable endeavor for the NRC.

Next slide please. Some recommendations for industry consideration. Licensees should perform post therapy imaging to determine the extent and impact of GI deposition. Hopefully our manufacturers can drive that with licensees, as well as the NRC, and us ourselves. Technitium99m MAA, particularly SPECT CT imaging in combination with

careful pre-procedure angiography are useful in screening for potential GI deposition.

So, those that are not performing post imaging, we recommend that they do. The next slide please. Continued recommendations. Manufacturers should provide additional education and training for authorized users. With regards to pitfalls, new recommendations that they might have to prevent GI deposition medical events, any concerns regarding using catheters other than recommended by the manufacturer.

Something we touched on earlier is using what is specified by the manufacturer is obviously very important, but I know that there is some justification, or some deviation from this due to patient situations under the scope of medical practice. But as much as possible, use the catheter sizes, and catheters recommended by the manufacturer.

Maintain documentation of additional provided education, manufacturer should make every effort to inform in writing their users about any unexpected medical events with recommendations as a preventative measure to avoid any possible trends. Next slide is just my acronyms. And so, at this point that concludes the presentation, and I will

turn it back over to Dr. Jadvar, and see if there is any questions.

CHAIR JADVAR: Thank you very much, Dr. Harvey. So, are there any questions or comments from the Subcommittee members? Dr. Angle?

DR. ANGLE: I'll make two comments. One, the operators routinely at the time of planning will use some type of cross sectional imaging within the procedure, that's generally what's called cone-beam CT, do angiography, confirm the area of treatment, so they carefully define the treatment and calculate a dose.

And that's not universally required or necessary, but I think it may be worth specifically pointing out that the SPECT imaging with MAA is useful, but so was the cone-beam CT. The second comment I'm going to make is maybe related to our earlier conversation. Some of these GI depositions occur because operators are trying to manage a plugged catheter.

And if you use a small syringe and a strong elbow, you can unplug most any catheter, but it may have very dire consequences. We saw in our earlier discussion of medical events, either back flow into multiple vessels, including GI, rupture of the

catheter with a proximal deposition of the beads into a different branch.

So, maybe this is a compliment of operators that are willing to say this is cath is plugged, we're going to stop now, and we'll come back another day, and just report despite the sort of shame that comes with that. So, this is mostly to applaud all the operators out there that just accept the cath is plugged, and we're going to come back another day.

CHAIR JADVAR: Thank you. Dr. Harvey?

DR. HARVEY: Dr. Richard Harvey, and just to address some of Dr. Angle's comments, I agree with him 100 percent. There are some continuing discussions that we're having, things that we did not have a chance to get to before this meeting occurred. So, one of the recommendations is to potentially, if it suits the NRC, to continue the Subcommittee, to continue working on some of those issues going forward. Thank you.

CHAIR JADVAR: Okay, thank you. Mr. Ouhib?

MR. OUHIB: Dr. Angle, what recommendation would you have for institutions that don't have that luxury of cone-beam CT? Either not perform the procedure, and refer the patient to

another institution that's better equipped, or what would be your choice?

DR. ANGLE: Yeah, I think just my personal observation is that I wouldn't perform it unless I had the luxury of cone-beam CT. I just think that in the planning phase it's essential to know that level of anatomic detail prior to administration. The SPECT CT we've talked about in our Subcommittee is not covered financially, so that's a challenge there from an institutional, and billing standpoint.

CHAIR JADVAR: Dr. Harvey?

DR. HARVEY: Richard Harvey, and just to play a little bit of devil's advocate there, I just want to point out there are licensees that are performing these procedures that don't have cone-beam CT, and are not having any medical events or issues. So, I just wanted to point that out, thank you.

CHAIR JADVAR: Great. Mr. Ouhib?

MR. OUHIB: I should say not yet.

DR. HARVEY: Richard Harvey, that might be the case.

CHAIR JADVAR: Any other comments from the Subcommittee? Dr. Fair?

DR. FAIR: Just a quick note on the background, there is a mention of the acceptable

duration of time between mapping and treatment is variable based on experience and judgment, I think it would be helpful to acknowledge also that there can be patient factors that contribute to that as well.

So, when you have patients in a rural state like New Mexico who may travel five hours to get a procedure, it may be more appropriate for them to have mapping the same day instead of having to return for example. So, it doesn't change it, it just kind of adds to that. And then I think on the licensee explanations for GI deposition, I think the jury is still out on whether tech MAA is truly kind of in character.

Especially to the glass microspheres, and so I think that there is still a question as to whether the difference in microspheres may make some difference when it comes to the mapping versus the actual procedure, but I'd also defer to Dr. Angle on that.

DR. ANGLE: I totally agree with your point.

CHAIR JADVAR: Dr. Harvey?

DR. HARVEY: Richard Harvey, I agree with that point, and it probably needs a further look. I've talked to a few IRs, and their opinion is that

the particle size, MAA versus the microspheres, is probably not clinically relevant. Again, I don't believe it's 100 percent certain with regards to that, but it's something that we did think about, and something that was researched a bit by myself and some of the people on the committee.

So, there are continuing issues to consider, and we have some of the same issues with people coming from a distance as well. I talked about that with my IRs, and again, we've seen success with same day mapping and treatment. What we do is generally we'll do our mapping within three months of the treatment just because of potential change in tumor burden, which would affect the dosimetry, as well as the changing dynamics, and the flow with the hemodynamics.

So, that's what we're doing at our organization, I'm not saying everybody else needs to do it. But I just wanted to point that out, that we've had some of those discussions, and again, it's a difficult treatment to standardize. So, thank you for the opportunity.

CHAIR JADVAR: But that's the only way we have to map, right? I mean, what else is there? Basically we have to use the MAA, right, Dr. Angle?

DR. ANGLE: Yeah, there are alternatives in development and investigation that may be a more comparable particle, but they also may be permanent, which may then alter the delivery of the actual y-90. So, the advantages and disadvantages of a more similar particle are yet to be determined.

CHAIR JADVAR: Okay, any more questions by the Subcommittee members? Moving onto ACMUI members, any questions, comments by the rest of the ACMUI members? Very good, any questions from the NRC staff? None. Any questions from the other attendees in the room who are not NRC? Very good. Let's -- please, go ahead, Mr. Shober.

MS. SHOBER: Thank you. I'm wondering with the post treatment imaging, does anybody have any sense for what fraction of those microsphere treatments, what fraction of patients actually receive post treatment imaging?

CHAIR JADVAR: We do it all, but I don't know.

DR. HARVEY: Richard Harvey, Ms. Shober, unfortunately I cannot answer your question, but we also do it for every one of our patients except for maybe the rare occasion where something happens, but we do it for everyone.

MS. SHOBER: Yeah, I'm wondering if that's another large hospital versus small hospital difference.

DR. HARVEY: Richard Harvey, I believe, and you know this better, Dr. Jadvar, than I do, I think that's not reimbursed always, so I think that might affect larger hospitals do it, and some of the smaller hospitals don't because of the lack of the reimbursement issue. Again, I'm not saying that we shouldn't do it because of that. We obviously do it when we feel that it's important, thank you.

CHAIR JADVAR: Ms. Allen?

MS. ALLEN: And not just the lack of reimbursement, but also the utilization of the equipment to try to get those patients in and out, not knowing the exact time that you're going to be ready to do that post injection, if you only have one or two of those cameras, it makes it very difficult as well.

CHAIR JADVAR: Yeah. Well, we do bremsstrahlung imaging. I mean, you don't inject anything, it's already there. But camera time would be a potential problem, I don't know about reimbursement, so. All right, any -- Dr. Tapp?

DR. TAPP: This is Dr. Tapp, would you

like to open it to the electronic people as well?

CHAIR JADVAR: Yes, I would like to open it now to remote attendees.

DR. TAPP: For those on teams, if you want to raise your hand if you have a comment, we'll see you here, and be able to unmute your mic. We're not seeing any hands raised.

CHAIR JADVAR: Okay, very good. So, at this time let me ask questions on direction, should we go for approval of this Subcommittee report, or did you want to continue on? I think I heard that you want to perhaps continue on this path on some other things, or did I hear that wrong?

DR. HARVEY: Richard Harvey, I guess I would look to the NRC, how they would direct us. The presentation with the one typo, we could approve. We're recommending that we continue on with the discussion of these events, and looking into this, in case there may be some more potentially down the road. But certainly, I think that is up to the NRC. So, I will go follow their lead, thank you very much.

CHAIR JADVAR: Dr. Tapp, what do you think?

DR. TAPP: Yeah, to get the recommendations that you currently have in the

report, it would be best to go on it now to give us those, and then we can continue with the Subcommittee as well.

CHAIR JADVAR: Okay. Well on that note, do I have a motion for approval of this Subcommittee report?

DR. WOLKOV: Harvey Wolkov, so moved.

CHAIR JADVAR: Thank you, any seconds?

DR. HARVEY: Richard Harvey, second.

CHAIR JADVAR: All right, all in favor say aye.

(Chorus of aye.)

CHAIR JADVAR: Any opposed? Any abstention or recusals? Any differing opinions?

None heard, so the motion carries. And thank you very much to you, Dr. Harvey, and the entire Subcommittee members.

DR. HARVEY: I would also like to thank the Subcommittee for all their efforts, thank you very much. And Ms. Spence for her valued support throughout this. Thank you.

CHAIR JADVAR: Thank you. All right, moving on to the next item on the agenda, Training and Experience Requirements for all Modalities Subcommittee report on emerging medical technologies

by Dr. Folkert.

DR. FOLKERT: Michael Folkert, thank you, Dr. Jadvar. So, moving onto those slides, all right. So, we can move onto the next slide. This is the Subcommittee membership, myself as the chair, Dr. Harvey is the radiation safety officer, Dr. Jadvar is the nuclear medicine physician, Mr. Ouhib is our medical physicist in radiation ecology, Ms. Shober for agreement state representative, and our NRC staff resource, Ms. Maryann Ayoade.

All right, next slide. So, the current charge of the Training Experience Committee is to review and evaluate training experience requirements for all modalities in 10 CFR Part 35. On August 20th, 2024, the Subcommittee had received an expanded charge to provide recommendations to the NRC on knowledge topics encompassing the safety related characteristics of emerging medical technologies, or EMTs required for authorized users.

They use to fulfill their radiation safety related duties and supervision roles, the methods on how knowledge topics should be acquired, and consideration for continuing education, vendor training for new medical uses, and training on the NRC regulatory requirements. Next slide please.

And this comes from the continuing innovation in the uses of radioactive byproduct material has led to a vast array of new applications and indications in areas such as gamma knife technology, ophthalmic treatments, diffusing radioactive particle implants, and a very increasingly diverse array of diagnostic and therapeutic radiopharmaceuticals.

So, next slide please. So, these EMTs are generally classified under 35.1000, and so -- interesting, okay, the formatting changed between the two slides. So, the developments of new radiopharmaceuticals, brachytherapy applications, and other devices utilizing radioactive byproduct material normally regulated under 35.200, 35.300, 35.400, and 35.600 may incorporate novel like end radioisotope combinations or administration methods that may pose additional patient and radiation safety risks, and require additional training.

And this is not just limited to therapeutic applications, but also diagnostic applications as well. There is also a significant increase in the array of diagnostic radioligands that are integrated into clinic. Next slide please.

And so, for each medical use modality, 10

CFR 35 regulations prescribe the minimum number of hours of classroom and laboratory training, as well as supervised work experience for proposed authorized users. And the core knowledge areas include these classroom laboratory training points below, and the work experience below.

These are drawn straight from the current 10 CFR 35 regulations. But just to remember these as we go into the discussion further along. Next slide please. So, in addition to these core knowledge areas, those are the areas that we just looked at on the last slide, there has been increasing complexity around aspects of patient selection, patient and care giver education interactions, radioactive material applications with other therapies and interventions.

Pre-end post procedure dosimetry, patient monitoring release, and reporting of adverse reactions and medical events. And the Subcommittee also recognizes that the AU may not always be physically present for some of these applications. For example, the administration of therapeutic radiopharmaceuticals by certified nuclear medicine technologists, but may be monitoring the dose administration virtually.

And so as such, the independent educational needs for the entire team must be a consideration, and must also be met to ensure the safe utilization of EMTs using radioactive byproduct material. Next slide please. So, for each of these medical use modalities, 10 CFR 35 regulations detail the minimum hours for classroom and laboratory training as we mentioned earlier.

And T&E requirements for EMTs are generally described in 10 CFR 35.1000 licensing guidance. And the current regulatory framework for AU training experience was established in 2002 following a comprehensive overhaul of 10 CFR 35. And over the past two decades, the Subcommittee has revisited these requirements requiring board certification pathways, different applications of radiopharmaceuticals under 35.300, and emerging medical technologies in 2022.

And so, next slide please. So, with this explosion, a rapid increase and development of novel radiopharmaceuticals in the late 2010s, stakeholders expressed concerns with the perceived burden of T&E requirements for AUs. The NRC engaged stakeholders, the ACMUI, the agreement states, and explored options to reduce this regulatory burden for physicians

seeking opinion AUs while preserving training critical to radiation safety.

And this led the NRC staff to submit a rulemaking proposal in 2020 to modify the T&E requirements in 10 CFR 35 Subparts G and E for unsealed byproduct material. Next slide please. So, in this rulemaking proposal, the goals were to establish high level radiation safety training criteria in advance of these new EMTs, and novel radiopharmaceutical therapies.

And to eliminate the case by case approval of AUs on these licenses. The rulemaking would have eliminated the alternate pathway for unsealed byproduct material, and required AUs to be certified by a recognized specialty board, and medical specialty board seeking NRC recognition would have needed to demonstrate that their training programs meet NRC training requirements for T&E.

But in 2022 the Commission did not vote to move forward with this rulemaking plan, and maintained the status quo. They did recommend evaluation of current, especially board recognition to evaluate knowledge topics required for AUs to fulfill the radiation safety related duties and supervision roles.

You'll see this is very familiar with the current charge of the committee, the methods on how knowledge topics should be acquired. Consideration for continuing education, vendor training for new medical uses, and training of the NRC regulatory requirements. This really set the framework for this expanded charge as of August 20th, 2024.

So, moving onto the next slide. So, in 2022 the Commission approved initiation of EMT rulemaking, which would move many EMTs from 10 CFR 35.1000 to other sections of Part 35. This would codify the T&E requirements for AU physicians. In 2023 the NRC staff published their draft regulatory basis, and the EMT rulemaking currently is in the proposed rule phase.

So, as a result the staff are assessing ways to make the existing EMT T&E requirements more generalizable instead of having a customized set of T&E requirements for each licensing guidance document, and so the Subcommittee's current charge to review knowledge topics for EMTs is connected to the EMT rulemaking in an effort to make T&E elements more consistent for AUs.

So, next slide please. Moving onto some of the recommended areas regarding this charge,

knowledge acquisition and maintenance, kind of the first topic for the expanded charge. So, we recognize that while the final review and approval of AUs is primarily the responsibility of the NRC and agreement states, the Subcommittee strongly feels that the acquisition of the safety content, of the actual educational content and continuing education should primarily be the responsibility of medical boards.

Such as the American Board of Radiology and the American Board of Nuclear Medicine, accreditation counsels such as the ACGME, the Accreditation Counsel for Graduate Medical Education, and the Commission on Accreditation of Medical Physics Education Programs, or CAMPEP, and professional societies that are actively engaged in the training and certification of AUs, RSOs, ARSOs, ANPs, and ophthalmic physicists.

So, next slide please. And the professional societies are actively engaged in providing this educational content that is relevant to initial certification and maintenance of certification, and while this is not an exhaustive list, it is many of the active societies.

I do note that I have some errors on here,

it should be the Society of Nuclear Medicine and Molecular Imaging, and the American Association of Physicists and Medicine, and I was corrected by my dosimetrist, it's the American Association of Medical Dosimetrists, not ASMD. But this is not meant to represent all of the societies that are creating safety content.

But these are groups that are actively engaged, and have developed content for AUs. Next slide please. And so, there is a demonstrated interest in engagement in radiation safety educational development by the professional societies. The SNMMI and ACNM are circulating a joint practice guideline for the use of radiopharmaceuticals.

Since these slides were placed online, the ASTRO safety white paper has been released as of this past Friday, in addition ASTRO is actively involved in radiation safety through their Apex Accreditation Program, and through their Radiation Oncology Incident Learning System, the ROIL System. The American Brachytherapy Society is developing training objectives for radiopharmaceutical practice.

And the ACR has a long history of engaging in multiple societies to develop practice parameter

guidelines for a range of diagnostic and therapeutic applications, partnering with SNMMI, ACNM, ASTRO, ABS, and ARS, the American Radium Society, as well as other societies, so definite proof of active engagement there.

Next slide please. And so, the one important factor about this content though, is that it does need validation. And so, while the NRC cannot endorse or preferentially favor a training pathway, it is the recommendation of the Committee that the NRC evaluate whether educational materials or a program meets requirements for initial certification with a technology or application to make it clear when people are pursuing licensure or certification.

And it will be likely that the NRC is going to have to develop a range of training scenarios for initial certification that will depend upon the time that has elapsed since professional training was completed by the prospective AU, as well as which training pathway the prospective AU has initially completed.

This is in keeping with one of our prior T&E reports for requests for specific case scenarios, this was previously endorsed, and per Dr. Tapp's

update earlier, is going to be released this week, so we'll be proceeding along there. And just as another comment, I mean it would be having the NRC be able to basically -- this is an opportunity for the NRC to also clarify the scope of practice.

Like what applications, radiopharmaceuticals and such that AUs are able to use under 35.390, 35.396 training requirements. Next slide please. In terms of continuing medical education, the Subcommittee recognizes the role for ongoing CME in supporting quality of care and radiation safety.

And in terms of CME the Subcommittee recognizes that professional societies are actively developing and providing CME for practitioners on existing and emerging technologies through recorded virtual and in person offerings. The authorized user will need to maintain records of their CME, and we recommend that professional societies develop guidelines for CME minimum contact hours.

We would also recommend that the NRC explore the need to define minimum CME requirements for authorized users. Next slide please. So, one thing that does complicate this is that verification of ongoing training and experience in CME must follow

applicable state, local, and certification board requirements, as well as the authority of the hospital or practice clinical credentialing program.

Credentialing is a process that is not regulated by the NRC, it's a process where medical facilities grant healthcare professionals such as physicians or non-physician mid-level providers, medical physicists, nurse, medical dosimetrists, and medical technologists the ability to practice medicine within their scope of training, and this is not regulated by the NRC.

And then areas that the Committee recommended in terms of broadening the application specific knowledge base, so these are in addition to those core knowledge areas that we touched on earlier, the laboratory classroom, and work experience areas.

The practicable knowledge base for EMTs should include application specific content and documentation of training on patient assessment ineligibility, patient and care giver education on procedure and radiation safety verbally and in writing, to make sure that's very clear to the patients, and to their care givers.

How to develop site specific protocols for

administration and the use of medical technology, radiation safety and quality control for all aspects of the procedure including ordering, preparation, administration, and disposal of contamination or waste if present, components of the written directive for therapeutic administration, pre-procedure assay and dosimetry.

The role of post procedure dosimetry, patient monitoring discharge instructions, release, and management of procedural events such as a extravasations. Follow up protocols for therapeutic interventions, reporting of adverse reactions and medical events, and aspects of supervision of the healthcare team, including relevant NRC regulatory requirements, especially for those remote administered treatments.

And some of these aspects were already included in many of the educational materials that are being produce by the professional societies. Next slide please, supervision. So, the administration and use of EMTs may require the direct involvement of a range of other specialties including CNMTs, registered RNs, RSOs, and MPs under remote supervision.

Understanding of the regulatory

requirements for these roles must be required for the AU, and the educational needs of the entire healthcare team, including the licensee administrator, the CNMT, RN, ASO, and MP if available or applicable must be met to ensure the safe utilization of EMTs using radioactive byproduct material.

And the AU has to have clear understanding of these roles and limitations, and a documented plan for how they would interact with these members both when physically present, and when monitoring these administrations or procedures remotely. Next slide please.

For vendors for new EMTs and new radiopharmaceutical applications, the application vendor has a significant role in recommending and providing appropriate knowledge and training for the safe and effective use of their technology. The vendor training should cover all aspects of how to correctly use the new device or drug.

Training should include contraindications to use, and remind trainees not to modify or substitute aspects of the device or procedure without the approval of the manufacturer. We can see this is particularly relevant with many of the y-90

procedures, and any significant changes you would expect would have to go back to the NRC.

Next slide please. And then it is also the recommendation of the Subcommittee that hands on training should be expected for any new therapeutic device or drug, or for any therapeutic application that has a unique delivery platform. So, this means that the prospective user would have to conduct mock use, or supervised patient use of the device drug using the actual device, or drug, or a model device that incorporates all practical aspects of the new technology.

And this training must include opportunities for the prospective AU to ask questions about the training material, and process and receive answers in real time to validate that they've acquired this knowledge base. And the trainer, which could be either the vendor, and or a current AU must be able to directly assess the prospective AU's learning in the context of training prior to unsupervised clinical implementation.

Next slide please. And it is also the recommendation of the Subcommittee that the trainer, either the vendor representative, or an AU for the new technology, must be physically present. So, this

is in person for the training of the prospective user and their team, even in situations where the standard of care administration or use of the EMT may be performed with the AU supervising remotely.

Next slide please. For medical events, the NRC should encourage licensees to include information and annual refresher training for appropriate individuals, AUs, CNMTs, et cetera regarding medical events using radiopharmaceuticals or devices used by the license. And we recommend the information on known medical events should be included in the initial training for a new device or drug application.

Next slide please. And so, this is a summary of the overall recommendations of the Subcommittee. The core knowledge base topics, again, those are from the initial classroom lab, and work experience should be supplemented with application specific content for existing and future EMTs incorporating radioactive byproduct materials.

The NRC should enable the relevant professional societies to develop curriculum for initial training, and should explore how best to evaluate this curriculum may be incorporated into an efficient licensing process. The NRC should explore

the need to define minimum CME requirements for authorized users.

Training for new therapeutic devices or drugs, or any therapeutic application that has a unique delivery platform should be both hands on and in person with a vendor representative or an authorized user for the new technology prior to unsupervised clinical implementation.

And the NRC should encourage inclusion of information on known medical events in the annual refresher training for drugs and devices used by the licensing, and in initial training for a new drug or device application. Next slide please. These are the abbreviations used in the presentation.

CHAIR JADVAR: Thank you, Dr. Folkert, for that presentation. Any questions from the Subcommittee members? Dr. Einstein?

DR. EINSTEIN: I want to thank you for a great, and thorough presentation. You mentioned under knowledge acquisition and maintenance, the Subcommittee strongly feels that the acquisition of general safety content should primarily be the responsibility of medical boards, accreditation counsels, and professional societies.

And under medical boards, you list the

American Board of Radiology, and the American Board of Nuclear Medicine, I would just point out that about 40 percent of procedures, medical procedures involving the use of isotopes in the United States are cardiovascular procedures, and those procedures are performed by the over 8600 diplomats of the Certification Board of Nuclear Cardiology.

So, I would say it's important to include the nuclear cardiology community as well here.

DR. FOLKERT: Absolutely, and so I did want to try to emphasize that these were not in any way comprehensive lists.

CHAIR JADVAR: Any other comments? Mr. Ouhib?

MR. OUHIB: Yeah, let me just add that the APM is quite involved in this, and they've recently actually were in the process of forming a radiopharmaceutical training essentials working group, and that is going to be very, very helpful. By the way, RPT, radiopharmaceutical therapy is heavily involved even with ASTRO as far as the training and all that.

CHAIR JADVAR: Any other comments? I'm sorry, Melissa Martin?

MS. MARTIN: I would like to just make

sure I'm understanding what you're recommending. If I'm reading here on the supervision, you have basically recommended that CNMTs, RNs, RSOs, and medical physicists can provide remote supervision to who? What are the training requirements that you're recommending for these people before they operate under remote supervision?

DR. FOLKERT: Mike Folkert, so, currently there are a lot of nuclear medicine procedures are administered under remote supervision by the authorized user, can actually ask Dr. Jadvar to comment more on that. But I'm not saying that the medical technologist would be remote, someone is physically there with the patient.

But the authorized user in many circumstances is not physically present for the administration of some of these therapies.

CHAIR JADVAR: Well, at our place it's in person, the AU is there physically actually during the procedure. And to my understanding of my colleagues at other major academic centers, the same situation, they are physically there, and Joanna can also mention. But we don't really do treatments after hours, those are unusual.

But yes, there probably will be -- there

are some situations when the AU is far away from where the procedure is being performed, and they can be done virtually. I haven't witnessed that myself, but maybe Joanna, because she lives in New Mexico, maybe that's a little different. Go ahead.

DR. FAIR: So, we're in person for all therapeutic procedures, there's an authorized user present. At diagnostic procedures, that's when the after-hours kind of circumstance may occur, and when you think about the relative risk of those two circumstances, there's a reason why they're different.

DR. FOLKERT: So, as a member of this committee, if you can clarify, you're the one who actually brought this up earlier during the discussion, that this was a practice of remote --

CHAIR JADVAR: Yes, there are some with that --

DR. FOLKERT: So, I included this at your recommendation.

CHAIR JADVAR: Yeah, that's fine, yeah. Okay, let's -- Ms. Shober first.

MS. SHOBER: Megan Shober. I do know from inspection experience that it is pretty common, certainly for I131 administration for there not to be

an authorized user present, it's very, very common. And even at some of our larger hospitals, they will administer radiopharmaceuticals sometimes with an authorized user by video connection.

So, they're not physically present, that's also relatively common. And I've observed a number of Pluvicto administrations that don't have a physician present either, so I again just want to highlight that for places that wouldn't have a nuclear medicine physician on staff all the time, it would be the exception, not the rule to be providing some of those therapies by another individual under an authorized user's supervision.

CHAIR JADVAR: Thank you. Melissa, did you have, Melissa Martin?

MS. MARTIN: I guess I'm just expressing my hesitancy to endorse some of this, because what I'm hearing around the table is that the idea is the least qualified and least experienced people in the most remote places are the ones you want to turn loose with the least supervision. So, when something goes wrong where is the training going to be for that person to handle a radiation safety problem?

That's what I'm uncomfortable with, is you're going to have quote hopefully a remote

supervision somewhere by a radiation trained physician, but I'm just saying what I'm hearing is that basically what we're endorsing is the least trained people in the furthest places with the least supervision are what we're saying is okay to turn loose.

So, where do you draw the line, is that okay for large places too? Why is it okay in remote places if it's not okay in the cities?

CHAIR JADVAR: Dr. Folkert?

DR. FOLKERT: So, we are in no way endorsing that, that is actually out of the scope of this statement. And I will say that, I mean in radiation oncology practice it is the standard that the AU is present for every single administration of any therapeutic drug. The only reason this was included is because we were informed by members of the Committee that there are practices that do have remote supervision.

And it is out of the scope for us to say that that is inappropriate, or that we can't do that. We're talking about the training requirements for the technology, for the new technologies coming in.

CHAIR JADVAR: I am not sure why Melissa, you say least qualified, why would the CNMT at a

remote place, or an RSO, I wouldn't characterize them as least qualified, they're supposed to be qualified to be doing that particular type of treatment, and be credentialed by their place, or the clinic that they're working.

And that AU who is maybe remotely on an iPad or some sort of video supervising, that person also should be well qualified to supervise that kind of treatment. And the RSO is there, yes, if something happens the RSO should be able to handle the situation if it happens. But I'm not sure why you are saying these are the least qualified people, I don't understand that qualification. There is not supposed to be the least qualified.

MS. MARTIN: Just my experience of I think what we're facing in today's world is a real dilemma in finding qualified RSOs. A lot of the physicians that were trained to handle this kind of radiopharmaceutical administration, they're the ones retiring. And we're facing many hospitals that are having a real hard time finding RSOs, and I'm just --that's just my experience.

CHAIR JADVAR: Then they shouldn't be doing it, if they don't have an RSO, and it's not on the staff, they should not be doing these treatments,

that's simple.

MS. MARTIN: I agree with you.

CHAIR JADVAR: Any other questions from the ACMUI members? Okay, Dr. Fair?

DR. FAIR: Joanna Fair, just a quick note about that is that some places employ remote RSOs, also there are RSOs that manage multiple sites, and so that's another challenge. So, it ultimately falls on whoever is actually doing the administration, which would typically be a CNMT, and so maybe the focus is really on the training of those individuals, and making sure that it's adequate to handle what circumstances may arise.

CHAIR JADVAR: Thank you, and Mr. Green?

VICE CHAIR GREEN: Dr. Folkert, during a physician's clinical training he or she does so many therapeutic procedures with a preceptor, and they sign off that you've done three of these therapies, and that's part of the process. You are advocating the important role that a vendor trainer plays, but you don't mention any qualifications for that vendor trainer.

Should that vendor trainer be an AU, or is it okay just to be an employee of XYZ Corporation?

DR. FOLKERT: For that, I actually think

I have to defer to the NRC, because that actually works into the EMT licensing guidance, and so what enforcement or what policy they have for that training.

DR. TAPP: Depends on the EMT, so I would actually go back to the ACMUI on recommendations. When a new EMT is reviewed, does it need to be an AU like yttrium-90, which didn't -- is now AUs are higher involvement in that training than when we first rolled out yttrium-90. So, it would be based on when a new EMT is coming out, and if we're doing a new condition to have training.

Vendor training for the radiation oncology side, it does not have to be an AU, it's just a vendor manufacturer training. So, it's not specified when you're looking at the radiation oncology vendor training. But there's just different points and different requirements, you'd have to look at each individually.

CHAIR JADVAR: Thank you. Go ahead, Mr. Green.

VICE CHAIR GREEN: Richard Green, I hate to bring this up, but I need to point it out. In your recommendations that all relevant professional societies develop curriculum for initial training,

nuclear pharmacists for the most part do not receive collegiate training in their pharmaceutical training programs on radiopharmaceuticals.

I included, I graduated as a pharmacist, I could work for Walgreens if I wanted to, but I got my training in a separate program post graduation. So, there is very few, there is 20 students per year that come out of Purdue, or Oklahoma, or University of New Mexico, very, very few. So, of the 3000 nuclear pharmacists in America today, only about 325 are board certified nuclear pharmacists.

So, it doesn't fit the model in a traditional physician sense of going through fellowship training. Just make sure you're aware of that.

CHAIR JADVAR: Okay. I'm going to go to Dr. Angle, because you had your hand up. Okay, so Dr. Fair?

DR. FAIR: Completely separate question, or comment about one of the recommendations about the minimum CME requirements. I think that's a complicated sphere. So, when you're getting training on a particular radiopharmaceutical, so when say the vendor comes to do training with how to administer Lutathera, there may not be any CME associated with

that.

But the critical importance is that everybody be present, and learning from that process. And by the same token, minimum CMEs are, I think very difficult to define what's the right number. Is it five hours, is it 25 hours? And so I would sort of caution a little bit about trying to do that, because I think it's a bit of a quagmire.

CHAIR JADVAR: That's fair. Ms. Rebecca Allen?

MS. ALLEN: Yes, if we could just update the abbreviations on the nuclear medicine technician to technologist? Thank you.

CHAIR JADVAR: All right. Any other comments or questions from the ACMUI members? Any questions from the NRC staff? Any questions from the non-NRC attendees in this room? Okay, let's open it up to the remote attendees for any questions or comments.

DR. TAPP: If anybody on Teams would like to make a comment or a question, please raise your hand. I am not seeing any hands raised at this time.

CHAIR JADVAR: Okay, thank you very much. Thank you, Dr. Folkert, and everybody on the Subcommittee who participated in this report. I

think we are ready for a motion of approval for this report.

DR. HARVEY: Richard Harvey, I'll make a motion to approve the report.

CHAIR JADVAR: Any seconds?

DR. WOLKOV: Harvey Wolkov, second.

CHAIR JADVAR: Thank you. All in favor say aye.

(Chorus of aye.)

CHAIR JADVAR: Any opposed? Any abstentions or recusals? And any differing opinions?

None, the motion carries, and the report is accepted, thank you so much. All right, with that we are on our agenda, at the lunch time. And we'll have time until 1:00 p.m. Eastern Standard Time, so we gather back at that time. Thank you so much.

(Whereupon, the above-entitled matter went off the record at 11:31 a.m. and resumed at 1:00 p.m.)

CHAIR JADVAR: All right, I think then we can get started, thank you everyone for being back on time. The next item on the agenda is Generic Process Checklist Subcommittee report by Mr. Green.

VICE CHAIR GREEN: Thank you, Dr. Jadvar. Get the slides up real quick. Perfect. The next

slide lists the members of the Subcommittee, I'd like to thank Ms. Allen, Dr. Harvey, Dr. Jadvar, Ms. Martin, and Mr. Ouhib for their participation in the Subcommittee, and the staff resource, Mr. Dimarco. Next slide please.

This charge dates back to December of 2022 when Dr. Darlene Metter, the ACMUI chair created a Subcommittee on the Development of a Generic Process Checklist to help reduce medical events. Next slide please. The reason this came around is there was an increased number of medical events in 2021, and the suggestion was made that the ACMUI should develop a generic process checklist for all user procedures.

That's where the word generic came up with. It was noted that it may be appropriate to ask and have professional licensing boards take a lead on developing, communicating, and standardizing checklists. I think they still play a role, but we're coming up with a generic checklist, and you'll see what we recommend.

Next slide please. So, in January of '25 the Subcommittee met and discussed what items should be on this generic process checklist to help avoid medical events in the clinical use of radioactive materials and radiation. In the development of this

checklist we understood that there's a huge range of things from external beam radiotherapy, to brachytherapy, to high rate -- all kinds of things, units, medical devices, as well as radiopharmaceuticals.

So, this example that we'll be showing and talking about today is focused on radiopharmaceuticals, but the concept is that each institution could develop a checklist patterned after this for their own modalities and their own technologies that they're employing, whether that be brachytherapy, or external beam radiation, or whichever units they have in place. Next slide please.

So, these are the elements that we thought would belong appropriately on this draft checklist. And again, we're using radiopharmaceuticals as the example. Establish the patient identity by utilizing two different methods, and determine pregnancy status if applicable. Verify the elements of this prescription, is it he correct radiopharmaceutical, is it the correct dosage of that radiopharmaceutical?

Do the laboratory results support this dose? We talked about over dosages on lutetium products that should have been reduced, and they were

not, and they were given the full thing, does the laboratory results support this dose? Do imaging results support therapy if being performed? If this patient is referred to for a therapeutic study, was there an appropriate diagnostic study that says yes, you've got PSMA active lesions?

Okay, are all -- is this the correct route of administration for this intervention, pharmaceutical or otherwise? Are all professionals working within their scope of practice? Next slide please. Conduct patient or family support education prior to administration, do you perform a consultation, and is this understood by the recipients?

Verify that the dose matches the written directive if applicable, if it's a written directive, does it comply with the requirements of 10 CFR 35.41? Not every administration is therapeutic, some diagnostic administrations require written directives, so if it's applicable, do these things comply with the requirements?

Is the route of administration patent, do you have the needle in the right vein, or are you going to extravasate? Have you measured or calculated the radiopharmaceutical activity? Then

you're going to administer that dose. Have you checked for possible extravasation of activity of that injection? Record keeping is conducted.

Are you measuring residual activity? It's not that you're required to, but are you if that's your policy and procedure. Patient release will become an important part, Reg Guide 8.39, verbal or with an interpreter if required in writing and documented. And then provide the patient before they leave the department contact information and phone numbers for nuclear medicine personnel should they need it for medical emergencies, questions, or perhaps concern of adverse events or extravasations.

Next slide please. So, those previous two slides described all the elements that we thought should be on a reasonable department's checklist. We advised that each licensee or department develop their own process checklist that is specific to their practice and processes, and that this development should start by reviewing their approved procedure documents, and accreditation organization requirements, and any national patient safety goals that may have been established.

All checklist processes should work together to ensure the five rights of medication

administration, is it the right patient, the right drug, the right route, the right dose at the right time? So, you see, we're working purposefully, very generically. Next slide please. Just because we use the word checklist, it does not mean this has to be a paper based system.

And I would prefer it not be paper based. Modern means, utilizing software platforms and bar codes could be extremely beneficial in preventing medication errors and medical events. Computerized prescription order entry, IV work flow management systems, product medication administration records and bar code medication administration I think all have a place in the hospital.

And they do, but they need to get into radiology, that's my two cents worth. Next slide please. So, we're advocating for a checklist, a department specific generated checklist, we're advocating that they use modern tools. It's been shown that modern e-prescribing can reduce medication errors in the ambulatory setting by as much as seven fold.

And a quote from a study highlighted here found that after implementation of BCMA non-timing errors had a relative risk reduction of 41 percent.

Wrong medication errors had a relative risk reduction of 57 percent. Wrong dose errors a 41 percent reduction. Wrong route 68 percent reduction. And documentation errors, an 80 percent reduction.

Significant, and I think those tools have a place in radiology and nuclear medicine. In summary, the Subcommittee developed a generic process checklist that could be adapted by licensees to help avoid medical events in the clinical use of radioactive materials and radiation. Each licensee or department should develop a process checklist that is specific to their practice and processes.

A checklist to help prevent medical events could be the most effective if they incorporate software platforms and bar coding. Next slide please. The recommendation from the Subcommittee is that each licensee or department should develop a process checklist that is specific to their practice and processes.

NRC staff should consider the best means to communicate this process checklist recommendation to licensees, either by information notice or a guidance document. So, we're not asking for a regulation, we're asking for communication. And last is our list of acronyms. So, it's a recommendation,

and we've talked about today time outs, and standard operating procedures.

And we're just formally saying this is a good idea, and we think it would be wise to have it recommended by the NRC, and by the medical staff to licensees.

CHAIR JADVAR: Thank you, Mr. Green, and I want to thank also all the Subcommittee members who participated in this. Now it's open for subcommittee members questions and comments. Dr. Wolkov?

DR. WOLKOV: Yes, I was wondering why did the committee decide to not include site? Which is typically on most checklists, surgical checklists, specialty procedure checklists.

VICE CHAIR GREEN: You're right, I think it's because our example that we used was focused on radiopharmaceuticals, so it was route of administration, which would be in that case, site, where to put the radiopharmaceutical. But for external beam radiation, in that modality it would be site.

So, you would in your department, work on a checklist appropriate for your institution, and there could be a checklist for nuclear medicine, there would be a different checklist for

brachytherapy, one for interventional radiology, they'd all have a difference, and for different modalities site would be appropriate.

CHAIR JADVAR: Are you suggesting we should add that?

DR. WOLKOV: I would think it's very important.

CHAIR JADVAR: Okay.

VICE CHAIR GREEN: Well, the example that we use is radiopharmaceuticals, but it does say in our recommendations that you adapt this to your modality and your institution.

DR. WOLKOV: I probably would have looked at the term route perhaps different than you, so I could see route being something that's distinct from site.

VICE CHAIR GREEN: Yeah, typically route would be intravenous, intradermal, intrathecal, oral.

CHAIR JADVAR: All right. Okay, Dr. Einstein?

DR. EINSTEIN: Thanks. I think this is a great effort, which will reduce errors, and really important for patients. I also have a question regarding route, and whether route is enough in a different context. This morning we heard about

misadministrations, for example an IV line kinking, or a 0.019 inch inner diameter rather than 0.02 inch, so it can be an intravenous route.

But if that intravenous line is not working properly, it's more than just the right route, I think it's the right route with -- I think the term route is too non-specific, if it's just intravenous for example, but we need the right -- I don't even know what the verbiage is, but the right mechanism with the right route as well.

VICE CHAIR GREEN: I think we used route because that's the traditional verbiage that goes with drug administration, oral inhalation, intradermal, intrathecal, IV. The kinking of the line, and the backup of brachytherapy yttrium-90 seeds was in catheter installation, which would not be, I don't think, considered intravenous, because it's done under catheter.

DR. EINSTEIN: We would use the term transcatheter, but transcatheter, you can be right in terms of delivering something in a transcatheter fashion, but if it's the wrong catheter, it's more than just the route, it's the specific device used to deliver the drug by means of that route.

VICE CHAIR GREEN: And I think that just

reemphasizes the need for each institution, and then practice site within an institution, brachytherapy, interventional radiology, nuclear medicine, to make their own checklist specifically for that department. I think that would be appropriate to have in interventional radiology is you using the right catheter?

DR. EINSTEIN: Thank you.

CHAIR JADVAR: Mr. Ouhib?

MR. OUHIB: Yeah, I agree with Dr. Wolkov's recommendation as far as site, but I will go even further, and say specific site. The reason behind that is liver can be a site, but left lobe and right lobe is very specific, and therefore we must add that. The other comment that I have is regarding the electronic document per se, versus paperwork.

And I think we need to be aware of in the event of cyber security issues, or system being down, and therefore you're crippled now if you just rely on the electronic part of it. You have to have a backup as far as paper, that you can proceed with what you have to do.

CHAIR JADVAR: Any other comments? Dr. Angle?

DR. HARVEY: Wonderful initiative, and

very clear documentation. Two thoughts, one in a procedure area, the operator must be present for that time out, and I noticed we didn't make any comment about who needs to be present for this checklist, but is it in the scope of this to talk about who needs to be present for this time out?

And you could even go as far to say virtual, that's fine, but I'm just wondering if we want to do that to make this more impactful.

VICE CHAIR GREEN: The Subcommittee didn't require -- I've got to go back and look at it, I don't think we required a time out, that would be something you could put in your checklist, to have a time out, and who would be present in that time out.

CHAIR JADVAR: One more question?

MR. OUHIB: Yeah, and I think we talked about this before, is that the first question is do we have the right team? Is the rad onc present? Yes. Is the IR present? Yes. Is the medical physicist present? Yes. And if none of these key players are not present, the system is not a go, it's a halt. And I think that's important.

CHAIR JADVAR: Dr. Harvey?

DR. HARVEY: Richard Harvey, so I agree with all the points that we're making, but again, I

think Mr. Green has been pretty clear that we were just citing one example. We weren't going to make an example for every different modality, and I just -- it would be too long, too cumbersome, and you have to take this back and make it site specific.

CHAIR JADVAR: Right, I think that was called generic.

DR. HARVEY: Correct, thank you.

CHAIR JADVAR: All right, Dr. Fair?

DR. FAIR: Joanna Fair, so I agree with that. My suggestion would be that, so I like using a specific example, radiopharmaceutical administration, because you're absolutely right, it's going to be different in every different circumstance. One could potentially make another shorter list.

And say other items to be considered in different circumstances could include right personnel present, site of administration, some of the things that you're bringing up as being sort of different for the differing things, just as another this is a great example from one thing from start to finish, and then here are some other items that might be considered as part of what you might put out.

CHAIR JADVAR: Yeah, I think that's a

reasonable suggestion, we can have the right team, right site, right segment if it's a different part of the same organ. What do you think, Mr. Green?

VICE CHAIR GREEN: There are so many different medical devices, RefleXion, and gamma knife, and even SIR-Spheres is different from TheraSpheres, so I think the general concept is here. I think it would be appropriate to leave it in this state, saying it's a suggestion to do something like this, following kind of a template that's appropriate for your modality, and your device, and your procedures.

We're not prescribing that they follow this, because you may be a site that doesn't do radiopharmaceutical administration, this is just an example. And we're asking that the medical staff do information notice or a guidance document that says hey, to reduce medical events maybe each licensee should do this, it would be a good idea.

CHAIR JADVAR: Okay, any other comments? Moving onto NRC staff, any comments by the NRC staff? Mr. Einberg?

MR. EINBERG: Thank you, Mr. Green, and the rest of the Subcommittee, excellent recommendations. We're debating how we can implement

these recommendations, or have a checklist, and having an information notice, or some kind of guidance document would be great if we could do it. We're not sure that's the easiest, or whether we're able to implement through an information notice.

We're constrained by regulating by guidance, and so we have to -- if it seems like we're regulating by guidance, we can't put out an information notice. So, we're going to be debating internally how we can best get this information out to the medical community. But my question back to the Subcommittee is, is there something that the medical community can do with this information based on your recommendation to have the generic checklist?

VICE CHAIR GREEN: This is Richard Green. I think if we approve the Subcommittee report as is, we can all take the personal challenge to take it to our own professional medical societies, or those that we associate with, and see if they can, after this pattern, get their own professional group to work on it if the NRC can't do it because you can't regulate by guidance.

Then we should take this lead from the ACMUI, and see if we can't get it through the professional societies individually.

CHAIR JADVAR: Dr. Folkert?

DR. FOLKERT: Mike Folkert, I mean I think in many cases the professional societies are actually already doing this. If you look at some of the safety documentation from SNMMI, or from ASTRO, they actually do encourage this sort of checklist activity. I think one of the things that's a benefit about this is that now the NRC in some ways has a framework by which they can say yes, you have put together a checklist which we think meets the requirements.

Because this is -- I mean, almost everything in here is something that is standard of practice for radiation oncologists, except for the time outs, but now it's validated.

CHAIR JADVAR: Dr. Einstein?

DR. EINSTEIN: I'd like to follow Dr. Fair and Dr. Folkert's comments, and second Dr. Fair's comment that it would be helpful to have additional terminology here, and I think it could bring standardization, the radiation oncology community may be doing things other communities may not be. But having common verbiage I think makes it easier for other professional societies to get into this game, and to think about aspects of their particular

profession, which would be useful.

So, I think having -- it's a great example for radiopharmaceuticals here, but other common areas, I think it's -- the Subcommittee has a lot of expertise, you could come up with these other category areas in here, and make it easier for other professional societies to adopt those as they're going through their processes, like ASTRO has for example.

CHAIR JADVAR: So, what do you think, Mr. Green? I think the suggestion is to have maybe another bullet sentence as we discussed, or Dr. Fair suggested.

VICE CHAIR GREEN: I think what I'm hearing is different examples of different modality checklists. It wouldn't make sense to make a huge checklists for things on radiopharmaceuticals that are not applicable to radiopharmaceuticals. So, do we have checklist A for radiopharmaceuticals, and checklist B for brachytherapy, and checklist C for gamma knife?

Just throwing out three examples, and come up with a limited number of checklists that are kind of tweaked to those perhaps three modalities, and then say but make one that's specific for whatever

you're doing with whatever device you have, these are three examples, we gave you one so far today on radiopharmaceuticals. How many examples would you like to have, and what would those be?

CHAIR JADVAR: I think when you look at the title of this Subcommittee, it's generic process checklist to help reduce medical events. It doesn't say radiopharmaceutical medical events, so I see what you guys are saying. If it says reduce radiopharmaceutical medical events, it's very focused, it's exactly what we did.

But if you want to keep the title as reduced medical events, medical events occur in other areas, and then therefore I think it may be a reasonable suggestion to add those potential --

VICE CHAIR GREEN: Would you want checklist B and C, or do you want all the elements put into the one example that includes all modalities?

CHAIR JADVAR: Well, I'm not sure exactly what the best way, but maybe the one way would be that for example in radiation oncology clinical space, site, segment, and team would be also additional considerations. Something like that, something simple, not really complicated. Dr.

Einstein?

DR. EINSTEIN: I think you could even keep this example, because it's an excellent example, but include other data elements which might be in common between other examples. I don't think you need three examples in the report, but you've got your core example, but in addition to that list other data elements, which might be commonly used for other examples.

VICE CHAIR GREEN: So, as a possible solution, we might amend slide six, which is the first slide of the generic process elements that would go on this generic process, three additional bullets, site, segment, and team.

CHAIR JADVAR: Any other elements you can think of?

DR. FOLKERT: I think the other, and this would also be modifying in the report page two, under local customization is required, so we have those, and then the other one that would be appropriate would be applicator for brachytherapy. And I think the form of access would probably apply for most of y-90, access.

VICE CHAIR GREEN: Would catheter make more sense than form of access?

DR. FOLKERT: Catheter, yeah, access device.

CHAIR JADVAR: Access device, yeah, generic, yeah.

DR. FOLKERT: Because that would also play into some of the radiopharmaceutical approaches, because there has been increasing use, people are using ports, as well as just regular IVs, and everything in between. So, to define that.

VICE CHAIR GREEN: So, I think we could vote to adopt as amended and include on slide six site, segment, team, applicator, and access device.

CHAIR JADVAR: Dr. Einstein?

DR. EINSTEIN: I don't know if this is too technical, and how widely applicable as well, but right flush as well, or something along those lines. It's not just giving the drug through the right line, but it's making sure that that drug winds up in the patient.

CHAIR JADVAR: Okay. Dr. Fair?

DR. FAIR: I think there was some mention of patency, and that might --

CHAIR JADVAR: Yeah, there was patency.

DR. FAIR: And that might sort of generically cover that as well.

DR. FOLKERT: So, it is in your report, you do have is the route of administration patent, so it is included there, just not in the slides, but good to have it.

CHAIR JADVAR: Any other comments? So, I got to the NRC. Any questions from the attendants in the room who are not NRC? Actually let's open it up to the community, let's see if there are any questions out there, comments.

DR. TAPP: If anyone has any comments online, please raise your hand, we'll call on you.

CHAIR JADVAR: All right, with that then do I have a motion for approval of this Subcommittee report as amended with the changes we just discussed?

DR. HARVEY: Richard Harvey, motion to approve with the amendments.

DR. WOLKOV: Harvey Wolkov, second.

CHAIR JADVAR: Thank you, all in favor say aye.

(Chorus of aye.)

CHAIR JADVAR: Any opposed? Any abstentions? Any recusals? Any differing opinions?

None heard, so the motion carries. Thank you so much again to Mr. Green, and all the Subcommittee members. Okay, moving onto the next

item on the list, it's NRC medical radiation safety team updates by Dr. Tapp.

DR. TAPP: I'm going to go ahead and give a presentation on the updates ongoing here at the NRC under the medical team. Next slide please. I'm going to break this presentation up into two parts. The first part I'm going to talk about is the ADVANCE Act, and the second part is going to be on more the generic activities of the group such as rulemaking and guidance updates.

Next slide please. Starting with the ADVANCE Act, as the Committee may remember, in the spring meeting Michael King, from the NRC's office working on the ADVANCE Act came and gave a general overview of the ADVANCE Act, and today I'm going to talk more about how the ADVANCE Act now is going down into the medical team.

How is it starting to -- we're starting to look at it, and come up with ideas based on the ADVANCE Act. Next slide please. So, for background, the ADVANCE Act is actually an acronym, just like everything else in the government, it's for Accelerating Deployment of Versatile Advanced Nuclear for Clean Energy Act of 2024.

The ADVANCE Act was signed into law in

July of 2024, and it builds on prior initiatives to modernize and streamline the regulatory environment for advanced nuclear technologies including ways to facilitate American nuclear energy leadership to support development and deployment of new nuclear energy technologies, to preserve existing nuclear energy, to strengthen American's nuclear energy fuel cycle and supply chain infrastructure, and to improve the Commissions' resources and efficiency.

A main emphasis of the act is to increase the efficiency of the NRC while ensuring safety is our north star. Safety is still number one here at the NRC, but the act's focus is to increase the efficiency of our actions across the board. Next slide please. The scope of my presentation is going to focus on three parts of the ADVANCE Act.

The first part will be the mission statement, then I'll talk about the ADVANCE Act Section 507, which is on inspection and oversight, and then I'll talk about the ADVANCE Act Section 505 and materials licensing efficiencies and processes. Next slide please. As Dafna spoke earlier today, the NRC updated its mission statement following the passing of the ADVANCE Act.

Again, the updated mission statement is

the NRC protects public health and safety, and advances the nation's common defense and security by enabling the safe and secure use and deployment of civilian nuclear energy technologies and radioactive materials through efficient and reliable licensing, oversight, and regulation for the benefit of society and the environment.

As highlighted in this mission statement, safety is still our north star, it is still our priority. But we are adding enabling the safe and secure use by focusing on timeliness and goal driven results, and using risk principles. Next slide please. The ADVANCE Act Section 507 is focused on improving oversight and inspection programs.

Section 507 requires the Commission to submit a report to Congress that identifies specific improvements to nuclear reactor and materials oversight and inspection programs that the Commission may implement to maximize the efficiency through such programs where appropriate, the use of risk informed performance based procedures, expanded incorporation of information technologies, and staff training.

The NRC held a public meeting on this section December 12th, 2024, and that public meeting is available online if anybody wants to look back and

see it. Next slide please. Under this section we have a few areas we're looking at improvements and inspection planning, implementation, and technology to increase efficiency.

And there's a few areas under consideration by the medical team staff to increase these efficiencies. The first is looking at our inspection procedures. Several material inspection materials were previously revised to incorporate risk informed performance based risk modules in the last few years.

This included the nuclear radiopharmaceutical nuclear medicine inspection procedures. But additional inspection procedures are being looked at to be revised to incorporate those risk modules to ensure that riskSMART decision making tools are incorporated into these procedures. I'll talk about this further later in the presentation.

In addition, the NRC medical team is looking to assess the NRC medical event follow up process, and update this according to risk informed principles. Again, I'll talk about this further in the medical team information. And finally we're evaluating the inspection and enforcement program to identify additional efficiencies and flexibilities.

Next slide please. The ADVANCE Act Section 505 is focused on nuclear licensing efficiencies. This section is focused on reactor efficiencies, but the NRC has determined that we would like to apply this look for efficiencies across the material program as well, so we're doing this under something called Materials Licensing Efficiencies and Processes, or M-LEAP.

We're applying the same principles the NRC is directed to apply to the nuclear reactors in the materials realm. The M-LEAP empowers the licensing process to optimize and enable the efficient timeliness and predictability of regulatory decision making. The M-LEAP initiative is a core component of the NRC's strategic direction initiative to streamline licensee reviews for operating reactors, new reactors, and material licensing activities across licensing organizations and the agency consistent with the updated mission statement.

The M-LEAP is going to partner and coordinate with the reactor licensing efficiency and processes group in support of the ADVANCE Act Section 505 on nuclear licensing efficiencies. Next slide please. In this area, the ideas under consideration for medical licensing efficiency is to streamline

licensee approvals regarding training and experience for medical authorized individuals.

Again, I'll talk about this further as we get into our slides. In addition, we're looking at a landing page for emerging medical technology guidance to enhance the review process for emerging medical technologies by leveraging early stakeholder engagement to gain licensing efficiency while ensuring safety reviews are not jeopardized.

So, for this we're planning to provide information on the website for new manufacturers to come in and learn how we develop guidance, and provide more information. So, when we get to the open section, we're wondering what do you think about these ideas considered for the M-LEAP and the ADVANCE Act, and what other ideas should the NRC staff consider to increase licensing efficiency regarding the medical use of byproduct materials?

Next slide please. For those looking for more information, there is QR codes attached to these slides for how to follow our progress for the entire NRC ADVANCE Act implementation. Today we're just talking about three items that are particularly important to the medical realm, but this ADVANCE Act has a lot more items that the NRC is considering, and

if you use those QR codes, you can track the progress of all of those.

Next slide please. For more information about upcoming and past meetings, you can use this slide here. Next slide please. And if someone has an idea, especially those on the line, if you want to ask questions or submit ideas, there is a QR code for the ADVANCE Act, here it gets to the ADVANCE Act resources for the entire NRC.

Next slide please. Now I'm going to shift gears, and talk specifically about the medical rulemaking, and guidance activities ongoing in the medical team. Next slide please. Currently, the medical team is focusing on two rulemakings. The first is the extravasation rulemaking, which is in the proposed rulemaking phase.

This rulemaking would amend 10 CFR Part 35 to require reporting of certain nuclear medicine extravasations. The staff provided the proposed rule package to the Commission in August of 2024. If the Commission approves this proposed rule, the proposed rule would be published for public comments. Following the public comments, the staff would develop the final rulemaking package for the Commission consideration.

The second rulemaking is working on establishing requirements for rubidium-82 generators, as well as well-established emerging medical technologies currently regulated under 10 CFR Part 35.1000. For this rulemaking, staff is still in the development of the proposed rule language phase, and would provide this to the Commission at a later date.

Next slide please. Next, the medical team continues to work to ensure emerging medical technologies have safe and consistent licensing pathways. Since our last meeting, the medical team has updated the Alpha DaRT 10 CFR 35.1000 licensing guidance based on operational experience. This update was to alert licensees that the inner packaging that contains the applicator has the potential to become contaminated.

So, providing licensees operational experience to know to handle that packaging with care, and to conduct appropriate surveys. In addition, we're updating guidance for the RefleXion medical radiotherapy system, which is a biologically guided radiation therapy system, which uses PET to guide an onboard LINAC system.

This guidance should be posted this week.

This guidance notes that while the system is used for treatment, only the use of the PET isotope is under the NRC regulatory authority, and should be licensed under the 10 CFR 35.200. The LINAC is not regulated by the NRC because it does not contain radioactive material.

Next, there is an additional licensing guidance that we should be issuing this week, which is focusing on the research and development use of thorium generators. Thorium can be licensed as either byproduct material or source material depending on how the thorium is originally produced or generated. This guidance highlights that all currently known production processes for thorium used in these generators would allow thorium generators to be licensed as byproduct material.

The memo highlights that while generators can be used in research and development and clinical trials, the NRC continues to evaluate the need for additional conditions based on breakthrough testing and training experience for clinical use. Next, the NRC is continuing to evaluate targeted alpha radiotherapy to determine if additional guidance is necessary.

Finally, we continue to provide inspection

reports for emerging medical technologies. Next slide please. The NRC has continued to work on training and experience guidance. The interim staff guidance on training experience is in process of being finalized right now, and is expected to be released this week. The ACMUI provided comments on this guidance back in July of 2024.

As a reminder, the purpose of this interim staff guidance was to bring all the guidance documents, and document current practices in one consolidated place. The NRC provided specific guidance on the purpose of training experience, supervision, what constitutes as training and appropriate documentation, guidance on preceptors, and example form 313As.

Going forward, the NRC plans to evaluate training experience processes for efficiency, as I had mentioned before. This includes a look at modernizing forms, enabling training curriculums from professional societies, and using those for the training and experience as you guys mentioned before, looking at your recommendation, and exploring the feasibility of authorized user database.

Next slide please. As I mentioned before, the NRC is evaluating our follow up to medical events.

I provided this photo here of an older teletherapy unit to give you an idea of when the NRC last updated its medical event follow up procedure. The reason we're evaluating this process is we'll be using the risk triplet to determine what can go wrong, how likely is it, and what are the consequences if we make changes.

Our focus of this evaluation is going to be looking at the scope of the follow-up inspection, and on the timing. We will greatly appreciate all the recommendations the Committee has here as we make this update. Next slide please. I also mentioned before we're looking at inspection procedures updates using the risk modules.

The inspection procedures that we're planning to update are the brachytherapy, the Gamma Stereotactic Radiosurgery Units, Medical Broadscopes, and radiopharmacies. Next slide please. We continue to work on patient release guidance. As stated at the last meeting, the current patient release guidance is focused on releasing only iodine-131 patients, and does not provide guidance as to what a licensee is to do when a patient has plans, or needs that differ from the generic patients used in the guidance.

The NRC staff continues to review the draft guidance to ensure licensees will have consistent methodology to release all patients, and have a method to evaluate post release instructions to ensure that patients who can follow those instructions are safe when they return home. Next, we continue to develop the waste guidance as Mr. Dimarco discussed at the last meeting.

The waste guidance will be used to support decision making on what to do with patient waste after patients have been released from hospitals. We believe there is an increasing need for this waste guidance due to the changing patient population with newly approved radiopharmaceuticals. In addition, we continue to share operational experience through generic communications, and at presentations at professional society meetings.

Next slide please. Finally, we continue to work on updating the ACMUI procedures. We updated our internal policy and procedures, hiring procedures, and provided additional ethics training last fall. We are in the process of updating the bylaws and new member guidance now, and the bylaws are in concurrence right now, being finalized. Next slide please. And that's my acronyms, and I'll turn

it over to you.

CHAIR JADVAR: Thank you, Dr. Tapp. First I want to see if there is any questions or comments from the ACMUI members. No? Then let's -- okay, Mr. Ouhib?

MR. OUHIB: Yeah, just curious on the time line regarding this plan of action.

DR. TAPP: So, for the ADVANCE Act items, those items are moving relatively fast. We do plan to make sure we have efficiencies in reviewing those, and taking actions when we can, as quick as we possibly can. The inspection procedures, those will take longer, we do plan to take time, and really review those inspection procedures, make sure that we're making the updates as appropriate through the risk modules.

So, that one would be a little bit longer, but for the ADVANCE Act licensing efficiencies, those we're going to try to make as quick as we possibly can while ensuring safety, and not jeopardizing that.

CHAIR JADVAR: Okay, any other comments by the panel? Let's see if there is any also questions from the community.

DR. TAPP: If you have any questions online, please raise your hand.

CHAIR JADVAR: Okay, I guess not. Thank you very much.

DR. TAPP: Thank you.

CHAIR JADVAR: And we are going to move onto our next item, which I think is a special recognition of Ms. Allen.

MS. BLOOMER: Good afternoon, my name is Tammy Bloomer, I'm the acting division director for the Division of Materials Safety Safeguards State and Tribal. Normally I'm the division director in Region IV, and so I'm back and forth, and back and forth. We're here today really, and I'm here to acknowledge all of the contributions of Ms. Allen to the Committee over the last several years.

Many of you know that her term ends this September, and we really wanted to celebrate the service that you've provided. Ms. Allen was appointed as the healthcare administrator representative in May 2021. During that time the NRC has been grateful for all that we've learned from you, the insights have been extraordinarily valuable.

She has led or contributed to several high priority ACMUI initiatives, including chairing both ACMUI bylaws subcommittees, engaging in multiple subcommittees, the Generic Process Checklist

Subcommittee, Membership of an Interventional Radiologist Subcommittee, Financial Assurance Requirements for Disposition of Categories One through Three Byproduct Material, Radioactive Sealed Source Subcommittee, there's one of those words.

Akesis Galaxy RTi Subcommittee, Subcommittee on Decommissioning, Financial Assurance for Sealed and Unsealed Radioactive Material Draft Proposed Rule, Subcommittee on Yttrium-90 Microsphere Brachytherapy Y-90 Microsphere Devices, Liberty Vision Subcommittee, and Alpha DaRT Subcommittee. I want to thank you for your hard work and dedication.

If you would come up here we have some things for you. We did have a flag flown over the Capitol for you, but it has not arrived yet, so we will be sending that to you. And then we also have our certificate, it's not here. Is it here? I was looking for the blue envelope, I'm sorry. Certificate of appreciation signed by Chairman Wright.

And a 50 year -- it's the blue envelope. This is a 50 year, and here is the coin that we have celebrating the 50 year anniversary of the NRC.

MS. ALLEN: Thank you, Ms. Bloomer. As I step away from my role as the healthcare

administrator on the ACMUI, I want to express my deepest gratitude for the privilege of serving alongside such dedicated professionals. The collaboration, expertise, and commitment within this Committee has truly been inspiring.

It has been an honor to contribute to the important work of ensuring the safe and effective use of radioactive materials and patient care. I want to thank Mr. Einberg and the NRC for giving me this opportunity. I also want to extend my sincere appreciation to the NRC staff for their unwavering professionalism, expertise, and commitment to patient safety and regulatory excellence.

I am truly grateful for your dedication to upholding the highest standards, while adhering to the organization mission and values. While my tenure may be ending, my support for the mission and vision of the ACMUI, and the NRC remains steadfast. The work this Committee does is vital, and I have no doubt it will continue to uphold its mission with excellence.

I look forward to seeing the continued advancements and impact of this remarkable team. Thank you for the opportunity to be a part of it over the last four years.

CHAIR JADVAR: Ms. Allen, we're going to miss you, and I want to thank you personally, and I think I can speak on behalf of the entire panel, that we really enjoyed having you on the panel, we benefitted from your expertise, and good luck with everything else.

MS. ALLEN: Thank you very much.

CHAIR JADVAR: Any other comments anybody wants to make, please. All right, thank you so much. Okay, I think this is now the time for break, and we are going to be breaking until 3:00 p.m. Eastern Standard Time. Do we want to -- it depends on the Committee, I don't know what they have planned there. Depends on the NRC, what they want to do.

Yeah, you want to keep on the schedule, that's what I figured. Okay, so we have almost an hour, a little bit more than an hour of break. Enjoy your lunch again, thank you.

(Whereupon, the above-entitled matter went off the record at 1:51 p.m. and resumed at 3:02 p.m.)

CHAIR JADVAR: Thank you very much. Welcome back to the spring 2025 ACMUI Meeting. This is the last portion of our meeting today, and the first item is ACMUI reporting structure, given by Ms.

Marra.

MS. MARRA: Hello, thank you. So, let me just share this. Okay, so for the outline we're going to go through the current reporting structure, our annual review, meetings, and discussion. Our current structure is starting with the Commission down to the EDO, then to our director, then below that is Tammy, our director of MSST.

And then ACMUI is below that, and then MSEB. In September 2012, the ACMUI recommended to have an annual review of this reporting structure. For meetings we have two meetings each year, one in the spring, April, May, and then one in the fall, October or November. There is approximately two to three teleconferences as needed. And I open it up to the ACMUI to discuss. Any changes?

CHAIR JADVAR: Any changes? Nope.

MS. MARRA: Perfect.

VICE CHAIR GREEN: I think this might be a time, I don't recommend any changes, but I do think there is great value in coming face to face for these two meetings, and being cost conscious, I think we accomplish a lot remotely in subcommittees via teleconferences, but I think there's great value in coming together.

CHAIR JADVAR: It's a balance, and I think that balance is there.

MS. MARRA: Our current points of contact are Tammy Bloomer, who is our MSST director, Dafna, who is our deputy MSST director, Chris, who is our DFO and chief of MSEB, and then me as the ACMUI coordinator. And these are our acronyms, and that's it.

CHAIR JADVAR: Thank you very much. So, I guess we can move on to the open forum. I have three subcommittees that I wanted to talk about. One subcommittee, if you recall, maybe you don't recall, but it was formed during the break before, and this is Subcommittee on Giving Advice on ADVANCE Act of July 2024 Mission Statement.

So, I think this is something helpful, and it goes along with probably what the commissioners want us to think about, and debate on, and see how we can be more efficient in many ways, and how ACMUI can contribute to that mission statement. The proposed subcommittee members are Dr. Harvey as chair, Dr. Folkert as subcommittee member, Ms. Shober, Josh Mailman as patient advocate, and myself in that subcommittee.

Any comment, questions, it's okay?

Everybody accepts? Okay, great. The next subcommittee that was proposed this morning actually by Ms. Shober, is Subcommittee for ACMUI Generic Reporting Process. And Megan Shober is proposed as the chair, Dr. Harvey Wolkov as one of the subcommittee members, Zoubir as another subcommittee member, Mr. Green, and Josh Mailman again as our patient advocate.

Any comments, questions? Great. And then the other subcommittee that I suggested was tentatively entitled Potential AI Deep Learning Applications for NRC Medical Enterprise. I am proposing Dr. Andrew Einstein as the chair, who is not here now. Dr. Joanna Fair, Josh Mailman again as our patient advocate, Dr. Folkert, and myself. Any questions or comments? Dr. Joanna Fair?

DR. FAIR: Do you need to be an AI expert to be on this subcommittee?

CHAIR JADVAR: No, no.

VICE CHAIR GREEN: Is this the right time to express when you want these reports back from these subcommittees?

CHAIR JADVAR: I think we can at least have something by fall 2025, which is September, October time frame. That gives us what? Is that

good enough?

DR. TAPP: I think for the last two that would be fine. For the mission statement and the ADVANCE Act, that is moving relatively quickly, so we may want to start here relatively soon, and have maybe a summer teleconference if the Subcommittee is ready to report.

CHAIR JADVAR: Yeah, so a little quicker for the ADVANCE Act than the work with the other two. Any comments on any of these three subcommittees, please.

MR. EINBERG: Yeah, on the AI Subcommittee, can you clarify what the charge is, what you're going to be looking at? Are you looking at the AI applications for the medical industry, or are you going to be making recommendations for the NRC staff's use of AI?

CHAIR JADVAR: Staff use of AI, and NRC medical, as I said, enterprise. Basically how all these reporting that we have, all the things that your guys are dealing with, the reports, can AI help in that, to mine the data better, to provide help in coming up with potential gaps in knowledge or information that maybe human observer doesn't see clearly, or easily.

So, that that can be brought up and discussed. And I think it in some sense is also aligned with the idea of efficiency. Because if you have that kind of tool, somehow available, then you can be more efficient in finding again, those gap areas, and work on them, and access the data, or information much, much faster, and easier.

MR. EINBERG: Yeah, I think that's a worthy effort, and just we do have the NMED database, that's -- I'm not sure where we are just yet as an agency allowing AI tools, but recommendations are certainly welcome. I just reached out to somebody at the agency to inform me where we are with they're looking at the use of AI at the agency, and if it's appropriate, we may consider having that person do a briefing at the next meeting as well.

CHAIR JADVAR: Thank you. And Katie, we look forward to reports assigned for each of these subcommittees when you have the chance.

DR. TAPP: I think we'll take it back, and consider it, and get you guys the support members as soon as we can.

CHAIR JADVAR: Thank you, very good. Dr. Folkert?

DR. FOLKERT: I was going to say there has

been some AI analysis of events in the MAUDE database, for example. So, there is even potentially some models we could follow, because that would be a great way to examine all the medical events, and so to generate a report on that.

CHAIR JADVAR: Exactly, yeah, perfect. Any other comments or questions? Please, Dr. Tapp.

DR. TAPP: One thing I'm thinking is for the ADVANCE Act Subcommittee, there may be some potential there that there is some spin off, because as I mentioned, there is a lot undergoing. I know that the initial focus is going to be on the mission, and the guidance there, but if there is a spin off, can we go back to you, Dr. Jadvar, and recommend opening maybe another subcommittee?

CHAIR JADVAR: Sure, yeah, let's see how it goes.

DR. TAPP: Thank you.

CHAIR JADVAR: Okay, we still have open forum, anything else that anybody wants to bring up at this time? Hearing none, we can go to the last item of the day, administrative closing. Ms. Marra?

MS. MARRA: Thank you. So, for potential dates for the Fall 2025 ACMUI Meeting we have September 15th and 16th, and October 27th and 28th if

you would like to discuss which dates you were thinking of having.

CHAIR JADVAR: So, Ms. Marra, did you get kind of the list of who prefers what?

MS. MARRA: Yes, I did.

CHAIR JADVAR: So, how many preferred which one, the September dates, how many the other dates?

MS. MARRA: Not everyone has responded to the poll, but so far we have six for September, and seven for October.

CHAIR JADVAR: Any comments on the preference here? Let me just look at my schedule, sorry.

MR. OUHIB: Likewise I'd prefer October, September is hurricane season, at least in Florida.

CHAIR JADVAR: September is what you're saying?

MR. OUHIB: No, no --

CHAIR JADVAR: Oh, okay. All right, so October 27th and 28th, right?

MS. MARRA: Correct.

CHAIR JADVAR: Those are Monday, Tuesday, and then what was the other date?

MS. MARRA: September 15th and 16th.

CHAIR JADVAR: Both are fine with me. I'm good with October, I think it's probably better.

MS. MARRA: Okay, perfect, so I'm hearing October 27th and 28th as the preferred dates. The dates you select will be provided to the staff in the Office of the Secretary, and hopefully they will align with one of your proposed dates for the meeting.

CHAIR JADVAR: Okay, thank you.

MS. MARRA: Thank you.

CHAIR JADVAR: Everybody agrees, October? Okay.

DR. FAIR: Joanna Fair, just to clarify, so when will we have the final dates if they're being provided to a different office to pick?

MS. MARRA: The final dates will be probably given closer to the meeting, generally about two to three months out. I will note that this will be into a new fiscal year, so it will be pending a budget there, but we should have a set date relatively -- knowing that this will be a date that works for everybody here, relatively soon.

And then release that date two to three months out, if that makes sense. Where we initiate travel, and yeah.

DR. FAIR: So, the budget year starts

October 1st?

MS. MARRA: October 1st.

DR. FAIR: So currently you would know, one would know whether or not there were a budget for the meeting in the fall if it were in September, but we don't know about the budget for October, is that correct?

MS. MARRA: I think we will have a general idea here relatively soon. We'll put it onto the schedule, and let you know, but with everything about travel, we probably will make the final call on travel as we get a little bit closer to the ACMUI meeting, either September or October, we still need to be a little closer.

DR. FAIR: Okay, thank you.

MS. MARRA: Dr. Harvey?

DR. HARVEY: Richard Harvey, could we pivot to September if we needed to?

MS. MARRA: Yeah, if we needed to pivot to September, and if that worked for the group, but I am hearing some people may not be able to make September, so I would lean towards the October date, and October works for the NRC as well.

MR. EINBERG: And I'll add as well that currently it's not budgeted for September, we've got

to then put money in the budget for an ACMUI meeting, another ACMUI meeting this fiscal year. So, next fiscal year would work better. It doesn't mean that we couldn't do it, and find some money, but right now it's looking better to have it next fiscal year.

CHAIR JADVAR: Okay, anything else?

MR. EINBERG: If we want to revisit the open forum, I don't think you gave the public an opportunity to see if they had any comments.

CHAIR JADVAR: Sure, okay. So, let's open up the channels and see if there is any questions, or comments from the community at this time. Hearing none, okay, thank you. Thank you, Chris. Anything else before we adjourn? Please.

MS. SHOBER: Were there leftover things from the old business that we needed to close after the reports were given?

CHAIR JADVAR: Katie did the old business. Dr. Tapp?

DR. TAPP: Thank you, Ms. Shober. So, for the old business, we do have going back to those reports today that were approved, with the Yttrium-90 Medical Event GI Deposition Subcommittee, you had a recommendation similar to item number six in 2023, which was the NRC staff will seek to obtain the number

of annual yttrium-90 microsphere administrations from the manufacturers.

Is the Committee -- would the Committee find it appropriate to roll that recommendation together, so we track it together as one with the one in the Subcommittee report today?

CHAIR JADVAR: Yeah.

DR. TAPP: Do you guys want to vote on that?

CHAIR JADVAR: Richard?

DR. HARVEY: Make a motion to approve the melding of those two recommendations into one.

CHAIR JADVAR: Any seconds? All in favor say aye.

(Chorus of aye.)

CHAIR JADVAR: Any opposed? Any abstentions?

Motion passes.

DR. TAPP: And the other is item six from 2022, and that item was the creation of the generic process checklist to be used during the medical administrations. Based on the Subcommittee report today being approved, would there be a proposal to close that item?

CHAIR JADVAR: Do I have a motion?

DR. HARVEY: Second.

CHAIR JADVAR: Okay, all in favor say aye.

(Chorus of aye.)

CHAIR JADVAR: Any opposed? Any abstentions?

Motion passes.

DR. TAPP: And those were the two I had on my list.

CHAIR JADVAR: Okay, thank you so much. Thank you, Ms. Shober, for reminding us. Any other item that is left? All right, with that we come to the conclusion of the spring 2025 ACMUI meeting, and the meeting is adjourned. Thank you everyone.

(Whereupon, the above-entitled matter went off the record at 3:18 p.m.)