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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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OPEN SESSION

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MONDAY,

MAY 15, 2023

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The meeting was convened via hybrid Video-Teleconference, at 8:30 a.m. EDT, Darlene F. Metter, ACMUI Chairman, presiding.

MEMBERS PRESENT:

DARLENE F. METTER, M.D., Chair

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

REBECCA ALLEN, Member

ANDREW EINSTEIN, M.D., Member

RICHARD L. GREEN, Member

RICHARD HARVEY, Ph.D., Member

JOSH MAILMAN, Member

MELISSA C. MARTIN, Member

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

ZOUBIR OUHIB, Member

MEGAN L. SHOBER, Member

HARVEY B. WOLKOV, M.D., Member

NRC STAFF PRESENT:

CHRISTIAN EINBERG, Designated Federal Official, NMSS

MARYANN AYOADE, NMSS

DANIEL DiMARCO, NMSS

EDWARD HARVEY, RES

VINCE HOLAHAN, NMSS

CHRISTINE PINEDA, NMSS

DANIEL SHAW, NMSS

KATHERINE TAPP, Ph.D., NMSS

CELIMAR VALENTIN-RODRIGUEZ, Ph.D., NMSS

KEVIN WILLIAMS, NMSS

IRENE WU, NMSS

ALSO PRESENT:

JOHN ANGLE, University of Virginia

ASHLEY COCKERHAM, Public Participant

RALPH LIETO, Public Participant

STEVEN MARSH, Public Participant

CINDY TOMLINSON, Public Participant

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P R O C E E D I N G S

8:30 a.m.

CHAIR METTER: Well, thank you very much and good morning and welcome to the 2023 Spring Meeting of the ACMUI. I'm Darlene Metter, diagnostic radiologist and ACMUI Chair. I hope you all are having a safe and productive 2023.

But before we begin, I would truly like to acknowledge and thank the NRC staff for their dedication and incredible work in the planning and organization of this meeting.

For it helps the ACMUI to do their work for the public, and the medical, and the safe medical use of isotopes. So from the ACMUI, I thank you for what you do.

So now turning to today's agenda, the ACMUI will address certain ongoing topics that are at the forefront of the committee's attention. And I truly look forward to these presentations and updates.

And now, I would like to turn the meeting over to Mr. Chris Einberg and Mr. Kevin Williams for opening comments.

MR. EINBERG: Thank you, Dr. Metter.

Good morning. As the designated federal officer for this meeting, I am pleased to welcome you to this 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 have been designated as the federal officer for this Advisory Committee, in accordance with 10 CFR Part 7.11.

This is an announced meeting of the committee. It 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 may also be transcribed or recorded by others.

The meeting was announced in the May 5, 2023 edition of the Federal Register, volume 88, page 29168.

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 a consensus on the various issues that we will discuss today. But I also recognize there may be a 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. Darlene Metter, Chair, Diagnostic Radiologist.

CHAIR METTER: Present.

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

The radiation oncologist position was just filled by Mr. Michael Folkert. He may be participating later today, but he is not a member just yet, a full member. But he may be calling in on Teams later this afternoon.

Mr. Richard Green, Nuclear Pharmacist?

MEMBER GREEN: Present.

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

MEMBER MAILMAN: Present.

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

MEMBER MARTIN: Present.

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

MEMBER O'HARA: Present.

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

MEMBER OUHIB: Present.

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

MEMBER SHOBER: Present.

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

MEMBER WOLKOV: Present.

MR. EINBERG: Ms. Rebecca Allen, Health Care Administrator?

MEMBER ALLEN: Present.

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

MEMBER HARVEY: Present.

MR. EINBERG: Dr. Andrew Einstein, Nuclear Cardiologist?

I confirm that we do have a quorum of at least six members present. As you heard, Ms. Megan Shober will be joining us via Microsoft Teams, as she was unable to join us in person.

And as I mentioned, participating online today we have Dr. Michael Folkert, who has been selected as the ACMUI's brachytherapy radiation oncologist. Dr. Folkert is pending his security clearance but may participate later today, and is welcome to make comments and ask questions at the appropriate time. However, he will not have voting rights for any actions requiring a vote.

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, or a conflict of interest as that term is broadly used in 5 CFR Part 2635, with regard to an agenda item to be addressed by the ACMUI, this member should divulge it to the chair and the DFO as soon as possible, before the ACMUI discusses it as an agenda item.

ACMUI members must recuse themselves from participating in any agenda item which they have a conflict of interest, unless they received a waiver or prior authorization from the appropriate NRC official.

I would like to add that this is a hybrid meeting of the ACMUI. We are in person, but we all are also using Microsoft Teams, so that members of the public and other individuals can watch online or join via phone.

The phone number for this meeting is 301-576-2978. The phone conference ID is 571779324 pound sign.

The handouts and agenda for this meeting are available on the NRC's ACMUI public website.

I'm now going to discuss some of the NRC staff members who are participating via Microsoft Teams.

And Dr. Celimar Valentin-Rodriguez is joining us online. And Mr. Daniel Shaw is joining us online.

In the room today, we have Sarah Spence, Daniel DiMarco, Cindy Flannery, Dr. Tapp,

and Dr. Brenneman.

Members of the public who notified Dr. Valentin-Rodriguez 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 Dr. Valentin-Rodriguez by email at cvr2@nrc.gov at the conclusion of the meeting.

Today's meeting is being transcribed by a court reporter. We are utilizing Microsoft Teams for 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. Metter, at her discretion, may entertain comments or questions from members of the public who are participating today.

Individuals who would like to ask a question or make a comment regarding a specific topic of the committee has discussed and are in the

room, can come up to either of the microphones set up in the room.

For those individuals on Microsoft Teams, please use the raised hand function to signal our Microsoft Teams host, Christine, that you wish to speak.

If you have called in to the Microsoft Teams using your phone, please ensure you have unmuted your phone.

When you begin your comment, please clearly state your first and last name for the record. Comments and questions are typically addressed by the committee near the end of a 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 Christine Pineda 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 Mr.

Kevin Williams, Director, Division of Material Safety and Safety Security State and Tribal Programs, for some opening remarks.

MR. WILLIAMS: All right, thank you, Chris.

Good morning, everyone, and welcome to the ACMUI 2023 Spring Meeting. It's always great to see all of you, and all of the NRC people, as well.

We haven't been, this is probably the second time we've gotten together face-to-face, and I think face-to-face is actually great communications.

We were just talking about that prior to the start of the meeting. So much you can, conversations you can have off the margins. So welcome and thank you.

So first, I'd like to begin thanking ACMUI for all your hard work and support to the NRC. We truly value your contributions and expertise, as we continue to tackle new issues related to the medical use of radioactive material.

As I previously stated, this is the second in-person meeting since the fall of 2019,

and we're definitely excited to continue our in-person interactions.

I'd like to highlight a few items that may be of interest to the ACMUI, and the meeting participants.

There are a number of Commission related activities. One is reporting nuclear medicine injections extravasations as medical events, the rulemaking itself.

As you know, there is a lot of energy surrounding this, with a lot of different inputs from a variety of stakeholders.

Following the ACMUI Fall 2022 meeting, the Commission issued its staff requirements memorandum for the staff's rulemaking package, to address the petition for rulemaking that we had received, which was PRM-35-22.

The Commission unanimously approved the staff's recommended option and SECY-22-0043, which has to do with the petition for rulemaking, and the rulemaking plan on reporting nuclear medicine injection extravasations as a medical event.

And as part of that, we will be amending 10 CFR Part 35 to require reporting of

nuclear medicine extravasations that require medical attention for suspected radiation injury.

Later today, Irene Wu, Project Manager for the extravasation rulemaking, will discuss the status of this rulemaking and ongoing NRC activities.

The next item that has the Commission interest is the proposed limited revision to the policy statement on the criteria for reporting abnormal occurrences, commonly referred to as AOs.

On March 29 of 2023, the Commission issued a staff requirements memorandum for the proposed limited revision to the policy statement on criteria for reporting abnormal occurrences. That was in SECY-22-0009.

An ACMUI subcommittee in 2021 reviewed the staff's proposed changes to the AO medical criteria in III.C, which is events involving the medical use of radioactive materials in patients as human research subjects.

Later today, Rigel Flora will discuss the Commission's decision, and will provide a status update on NRC activities related to the AO criteria.

So to provide a few inputs on NRC activities, in regards to reporting extravasation rulemaking, on May 9 we transmitted a package to the Commission to recommend an approach to this disposition. A petition for rulemaking received in 2020 and moved forward on extravasations.

The emerging medical technologies rulemaking, the staff has developed a regulatory base to this document for this rulemaking, and is addressing comments from the NRC regions and Agreement States, and will address comments from the ACMUI that will be discussed today.

The regulatory basis will be transmitted to the Commission in March of, is it 2023 or 2024? So I'll correct that. But the regulatory basis, where's Celimar?

MS. VALENTIN-RODRIGUEZ: It's 2023, Kevin.

MR. WILLIAMS: It was transmitted in 2023 and following Commission approval, will be published in the Federal Register for a 90-day public comment period.

The NRC staff will conduct stakeholder workshops during that time to gather stakeholder

feedback on the proposed changes to Part 35, including comments on the training and experience requirements for emerging medical technologies.

Training and experience for unsealed byproduct material, the staff is developing implementation guidance for training and experience requirements per direction of the Commission.

The draft implementation guidance will be issued in August of 2024 as interim staff guidance, and will address how a person seeking authorized individual status under Part 35, can fulfill training and experience requirements, as well as clarify the roles and responsibility of those persons involved in, and subject to training and experience requirements.

Phase 2 for the revision of Reg Guide 8.39 regarding patient release. Approximately a month ago we issued for public comment, a draft of the Phase 2 revision to Regulatory Guide 8.39.

In December of 2021 the ACMUI subcommittee provided comments to the staff on this draft, and then the staff considered those comments in concert with comments from the Agreement States, and our NRC regions.

Once the staff reviews any public comments received and incorporates the comments into the draft Guidance as appropriate, the ACMUI will receive the final draft for review and comment prior to final issuance.

Nothing to report since our Fall of 2022 meeting, ACMUI meeting. Organizational changes, I think Chris did talk about that for ACMUI.

But for the NRC, we welcome two new staff members into the Medical Radiation Safety Team. Mr. Daniel Shaw, and Ms. Sarah Spence.

In addition, we selected a new ACMUI coordinator, Ms. Lillian Armstead. And, she starts with the NRC later this month.

ACMUI changes since the Fall meeting. Dr. Ronald Ennis completed a second term, and his departure left a vacancy for the ACMUI brachytherapy radiation oncologist.

And, Chris talked about Dr. Michael Folkert has been appointed to serve as the brachytherapy radiation oncologist. And Chris also provided his credentials.

Items of interest for this meeting.

The following presentations will be discussed today. Mr. Daniel DiMarco will provide an overview of the recent medical events. Mr. Flora will provide an update on the NRC's limited revision of our AO criteria. Ms. Irene Wu will provide an update on the NRC extravasations. Dr. Celimar Valentin-Rodriguez will provide an update on medical team activities.

Thanks for this opportunity to open the meeting. I wish you a productive session today. And as far as my time goes, you will see me in and out of the meeting.

I will have to do a quick side note. Chris sent me a message are you coming? Yes, I am just addressing a couple issues before I get down here.

So there's never a dull moment in my day. So I will be in and out, but I look forward to hearing from you, and having conversations with you.

At this time, I will turn it over to Dr. Celimar Valentin-Rodriguez.

MS. VALENTIN-RODRIGUEZ: Thank you, Kevin.

Christine, can I get the next slide, please?

Good morning ACMUI members, and I'm saddened that I can't be there in person with you today.

This morning I'm going to go through the old business and action items from the ACMUI. First off, we have a 2019 recommendation where the ACMUI endorsed the evaluation of extravasations subcommittee report to note that under future revisions of Part 35 rulemakings, extravasations be captured as a type of patient intervention in the definition of patient intervention.

The NRC, we propose to close this item. In SRM-22-0043, the Commission directed the staff to amend Part 35 to require the reporting of extravasations that require medical attention for suspected radiation injury. The staff is currently developing a proposed rule.

There are two additional old business action items regarding extravasations, which later on I will also propose to close with the same justification.

The next recommendation comes from 2020

and it is the patient, and it is also related to patient intervention. And this will be, we propose to close this item with the same justification as the previous item.

The next item is Item Number 11 from 2020. As part of the Non-Medical Events Report, the ACMUI recommended to the NRC staff and to the National Materials Program, to evaluate the issue of detection of short-lived medical isotopes in municipal waste, and provide some level of guidance, best practices, or additional recommendations.

We propose that this action item remain open. The medical team presented to the OAS board, and we've agreed to a survey.

This survey was transmitted to the Agreement States earlier this year, and we've extended that to allow enough time for Agreement States to provide comments.

The new target for this action item will be Fall 2023.

The next action item, thank you, Christine. The next action item is the ACMUI's endorsement of the extravasation subcommittee's

report, which we also propose to close as we have a staff requirements memorandum for that SECY package, and the staff is currently working on the extravasation rulemaking.

The next item, Item Number 7, we formed a new subcommittee to evaluate the Liberty Vision Y-90 manual brachytherapy source licensing guidance, that the staff is currently developing.

We are proposing for this item to remain open as the staff has had to prioritize work in rulemakings, and others about this licensing guidance.

Currently the licensing guidance is being developed and so we hope to form, reform the subcommittee in the next few months to address the licensing guidance.

The next item, Number 10, the ACMUI endorsed the radionuclide generator knowledge and practice requirements subcommittee report, and the recommendations in this report.

We are proposing that this item remain open. We are addressing this item as part of the emerging medical technologies / rubidium-82 generator rulemaking, that was approved by the

Commission in January of 2022.

So we propose to close this item, or the target completion date will be in March 2026 when the Commission issues the final rule for this rulemaking.

The next item is Item Number 15, which is the ACMUI Reg Guide 8.39 subcommittee report. And that is for the CivaDerm licensing memo.

We are proposing that that action item remain open. We considered the subcommittee's comments in that memo, and we are currently revising and very close to issuing that CivaDerm memo concurrently with Reg Guide 8.39.

The next item which is related, is the actual report on the Reg Guide 8.39. As Kevin has mentioned, the Reg Guide 8.39 is out for public comment.

Once we receive public comments on Reg Guide 8.39 and address those, we will reform the ACMUI, or reestablish the ACMUI subcommittee for an additional review and comment of the final draft licensing guidance. Therefore, Item 16 we propose to close at this time.

Next slide, please. Thank you,

Christine.

Next item is a suggestion from the ACMUI members to review the rulemaking plan for the ongoing NRC effort, and that's to be the rulemaking or draft proposed rule, for the NRC effort to revise Appendix B to Part 30.

We propose to close this item as the ACMUI established a subcommittee to review the proposed rule, and we will be providing a report today.

The next item is Item Number 4 from 2022. The ACMUI endorsed a Y-90 microsphere medical events subcommittee report, and the recommendations therein.

We propose for this item to remain open. The staff is currently addressing the recommendations, including outreach, to the Society of Interventional Radiology, to increase engagement and communications.

Dr. Tapp of the medical team, will be providing a webinar to SIR in June, to discuss current Y-90 microsphere licensing guidance and medical events.

We are also looking more closely at Y-

90 microsphere medical events for the next two years, to evaluate if and how the use of vendor tools play a role in these medical events.

There was also a recommendation about issuing another information notice, which for the time being, we will not do as we issued an information notice with related topics in 2019.

So, we will continue to monitor Y-90 microsphere medical events and see if there is any other trends that would necessitate further generic communication with our licensees. Therefore, we propose that this item Number 4 from 2022 remain open.

Item Number 5 from 2023, the ACMUI endorsed the emerging medical technologies rubidium-82 generator rulemaking subcommittee report on the draft regulatory basis, and their recommendations therein.

We propose to close this item. The NRC staff considered the subcommittee's comments and the development of this draft regulatory basis, and the draft regulatory basis is currently in concurrence, and is close to being issued to the Commission.

So that's coming up in summer 2023, and we'll have approximately a 120-day public comment period at that time.

Item Number 6 from 2023 is that the ACMUI establish two subcommittees. One to create generic process checklists, and another to review the decommissioning financial assurance draft proposed rule, as well as reestablish the nursing mothers' guidelines to update the 2019 guidelines.

We propose too, for this item to remain open. We have established the decommissioning finance assurance draft proposed rule, and are in the process of establishing the other two subcommittees to address those two items later this year.

And finally, Item Number 7 from 2022, which was the scheduling of this meeting today. We propose to close this item. The meeting as we're here now, is being held May 15 through the 16, 2023.

And with that, Dr. Metter, if the members would like to take a vote on whether to accept the NRC staff's recommendations on these items.

CHAIR METTER: Thank you, Dr. Valentin-Rodriguez on your presentation of the old business.

And do I have any questions or comments from the ACMUI for what was just presented?

Seeing none, do I have a motion to approve the report as written?

MEMBER WOLKOV: Harvey Wolkov. Move approval.

CHAIR METTER: Thank you, do I have a second?

MEMBER MARTIN: I would second that.

CHAIR METTER: Dr. Richard Harvey second it. Any comments?

All in favor?

(Chorus of aye.)

CHAIR METTER: Any abstain or opposed?

Seeing none, thank you Dr. Valentin-Rodriguez. Your report has been unanimously approved by the ACMUI.

Our next item on the agenda is the open forum, which is to introduce new topics for discussion for future review by the ACMUI.

Are there any topics that the committee members would like to bring forward at this time?

Okay, seeing none, are there any topics that the NRC staff would like to bring forth at this time?

MS. VALENTIN-RODRIGUEZ: Good morning, Dr. Metter --

(Simultaneous speaking.)

MR. EINBERG: No.

MS. VALENTIN-RODRIGUEZ: -- this is Celimar. We don't have any items at this time.

Sorry, Chris.

CHAIR METTER: Thank you.

MR. EINBERG: Yes, no problem.

CHAIR METTER: Thank you very much.

Okay, so at this time in the open forum, if there are other comments that you would like to bring up for future topics, please let me know, or bring it up in one of our other discussions.

So, our next item on the agenda is the medical related events by NRC staff Daniel DiMarco.

(Pause.)

CHAIR METTER: Yes.

MR. DIMARCO: Yes, probably should turn the mic on. Okay, hello, everyone. My name is

Daniel DiMarco, I'm a health physicist here at the NRC with the Medical Radiation Safety team and I'm here to present on the status of a medical events from FY22.

Next slide, please. Just a quick overview. The dose threshold for diagnostic events precludes reportable events for most years. And each year there are approximately 150,000 therapeutic procedures performed utilizing radioactive materials.

Probably need to update this sometime soon. I'll get some information from you all later today.

Next slide, please. So, here's a table with the medical events from the past five, past six fiscal years, 2017 to 2022.

In the parenthesis there, you can see the total number of patients involved, if it was greater than the number of reports.

So, for this year we've got a total of 56 medical events, which is a little bit less than last year, but is about on par with what we've seen from previous years.

Next slide, please. So going into the

events themselves. This year we had no medical events from the 35.200 uses of byproduct material.

Next slide, please. We had 10 medical events from the 35.300 use of the byproduct material, four of them involving lutetium-177; three of them involving iodine-131; two from, of radium-223 Xofigo.

And this was our first year with an actinium-225 medical event.

Next slide, please. This event was a patient overdose involving iodine-131, where the patient was intended to receive a 5.5 gigabecquerel dose, which was signed into the medical record.

But unfortunately, the written directive, there was an error in the computer-generated written directive where the patient was technically prescribed .074 gigabecquerels.

For this event, no harm was seen because the patient received the intended dose. But this is a medical event because the dose that was, that was administered was different, was significantly over the dose that was on the written directive.

And so corrective actions included

changes to the computer-generated written directive, and procedure changes to the existing time out process.

Next slide, please. This next one was a patient overdose, where the patient was part of a therapeutic portion of a sponsored study protocol, using iodine-131.

They had a fixed activity to the administration that was limited by the kidney dose, and so they have no reliable dose estimates for the prostate. And so, the root cause was determined to be an inadequate training on this specific protocol, where corrective actions included additional training.

No adverse impacts were expected to the patient and follow up doses were cancelled due to the proximity to the kidney dose restraints for this protocol.

Next slide, please. This event was a patient underdose involving iodine-131. This patient had been administered an iodine-131 capsule but was unable to swallow it and the pill broke down in the patient's mouth.

After removing this capsule and taking

the patient to a safe room, they noticed that some of the removed pharmaceutical had leaked, leading to a contamination incident. And so, the next day, they re-tried administering this iodine-131, this time in liquid form. But the patient also failed to swallow this.

And so, they had to get a dose estimate from the first administration by bioassay, which led to the dose estimation there. And so corrective actions included having patients swallow a placebo pill prior to the administration, just to make sure that they were actually able to swallow.

And so, no persons were determined to be contaminated from that previous contamination incident, and the decontamination of all of the surfaces was successful.

Next slide, please. This event was a patient overdose involving Lutathera where the patient had a kidney disease, which required a smaller dose than the typical 200 millicurie dose, dosage.

The administering tech did not receive this written directive from the nuclear medicine department, and so the pharmacy tech drew the

typical 200 millicurie dose, without consulting this written directive.

And so, the root cause was determined to be a failure to follow established protocols, and lack of communication inter-departmental communication.

So, their corrective actions included a daily huddle to communicate key information about the therapy patients, and a secondary verification which required a physical signature on the written directive. And this patient will be followed to assess for kidney damage.

Next slide, please. This one was another patient overdose involving Lutathera. This was the third of the four treatments, where previous treatments also had prescribed a half dose of 100 millicuries due to reduced creatinine clearance in the patient.

There was a bit of a delay in treating this patient due to the suspension of radioisotope production of Lutathera, which resulted in inadequate creatinine level for the treatment.

And so, the doses to the non-target tissue was in line with parameters for a standard

treatment with this 200 millicurie administration. So, this final treatment was planned to be either a full or a half dose, depending on the patient tolerance. And so, the written directive was updated to improve verification process of this dose measurement.

Next slide, please. This next one was a patient underdose with Lutathera, where two minutes after the infusion was started, a leak was noticed in the line. The procedure was stopped and the vial and tubing were assayed, which showed no patient contamination.

The room was surveyed, appropriately decontaminated, and the root cause was determined to be equipment failure, where the corrective actions were implemented for that. And there were no clinical impact or risks to the patient from this event.

Next slide, please. This next event was a patent underdose also involving Lutathera where the patient received much smaller, .052 gigabecquerels of the dose, where they noticed that the vial had lost pressure during the treatment and attempted to, attempted to regain this pressure,

but all of those attempts failed. No contamination was found, and no serious adverse effects were noted.

Next slide, please. This event involved a radium-223 Xofigo patient overdose, where the patient was prescribed 2.13 megabecquerels, but received 6.84 megabecquerels. Similar to one of the previous Lutathera events, this was just a simple clerical error in the written directive, and the patient received the intended dose. The written directive had just incorrectly prescribed 2.13 megabecquerels to this patient.

Next slide, please. This event was a radium-223 Xofigo underdose, where the patient, where the physician noticed a leakage occurring in that 3-way stopcock and the administration, they estimated a dose given by measuring the leaked radio pharmaceutical.

The root cause was determined to be an incorrect cath used on the unused port of that soft cock. And so, the corrective actions included procedure revisions to prevent leakage, and additional training, and no harm is expected to the

patient.

Next slide, please. This event is our first actinium-225 event, a patient underdose. This was for a clinical trial for prostate cancer, where there was an accidental discharge of the radio pharmaceutical into the absorbent pad.

The root cause was determined to be the recession of a connection point into the tungsten shield surrounding the vial, which hindered the operation of a 3-way stopcock.

The AU had removed the connection without the required three saline flushes, and so the corrective actions included the retraining of all AUs, refreshing training on written directives, and then acquisition of an alpha detector to survey for contamination.

Next slide, please. Okay, so for FY22, there was only a single 35.400 medical event.

Next slide. This was a patient underdose involving an iodine-125 eye plaque. This plaque held 30 seeds, with an activity of 49.21 megabecquerels for each seed.

The plaque was dislodged while the patient rubbed the eye. However, the plaque was

able to be placed into the lead pouch and returned to the AU with no, no other events occurring. And so no corrective actions were taken for this.

Next slide, please. This here we had 11 35.600 medical events.

Next slide. The first event was a patient overdose involving an iridium-192 HDR unit. This patient was prescribed 10 HDR treatments, but following four of these treatments, they had noticed that some of the catheters had been mislabeled.

The planned skin dose was 26.5 Gray, but after adjustments, this dose to the skin ended up being 48.4 Gray. No adverse effects were expected, but patient will be following up more frequently.

The root cause was determined to be human error, and a lack of proper catheter identification. And so corrective actions included procedure updates to emphasize catheter identification, and modification of the planning process to include an additional review by a second physicist. The staff also received additional training.

Next slide, please. This next event is a patient underdose involving an iridium-192 unit, where two patients were both prescribed four fractions of 7 gray for a total of 28 gray.

The first patient had an underdose in fraction two of four, where only 79 percent of the fraction was delivered. And the second patient had an underdose in fraction four of four, where only 54.4 percent of the fraction was delivered.

Additionally, the second patient received the, a 48 percent greater dose to the rectum for the fraction, resulting in an overall 15.4 percent greater dose to the rectum for the full treatment.

Next slide, please. For this event, the radiation therapist had replaced a catheter, one that was an incorrect length at least for this medical facility.

The procedures required a blue catheter with 137 -- 1,377 millimeter length. But the new blue catheters are slightly longer than this, and had to be trimmed down to this correct length. Which the radiation therapist had not done.

And so, the corrective actions for this

included procedure modifications to ensure that the correct catheter is always of the appropriate length, and additional training.

And so patient one had modifications to the rest of the treatment to compensate for their underdose; and patient two had no adverse effects.

Next slide, please. This event with another HDR patient underdose where during the treatment the error messages 8C.2-dummy part switch or drive failure had displayed during the treatment after the first 15 channels were delivered.

The field service engineer suggested a reboot of the system, which was not successful. And so, the AU had stopped treatment to avoid leaving the patient under general anesthesia, which left the remaining four channels untreated.

Next slide, please. Another patient underdose with an iridium-192 unit, where the patient was treated without issue through the first channel but at the start of the second channel, there was an error which indicated that the source position had slipped at the zero centimeter mark.

The treatment was paused and a test wire was run, which showed no errors. A second

treatment, attempt at the treatment however, returned the same error and so the treatment had been cancelled after that.

The source was verified to be in the unit, and no additional dose was delivered to the patient or the staff.

Afterwards, the service engineer determined that there was a hardware issue with the active sourcing coder, which serves as a tech and check for the movement of the source. And so for corrective actions, this encoder was replaced and the HDR unit was determined operational.

The next event is a wrong site event involving an HDR unit. The patient had been intended to receive the 600 centigray to the lower nasal dorsum. However, it was prescribed to the right nasal sidewall.

This was, again, another written directive incorrect event where the patient received the, the dose in the treatment in the area that was intended, but the written directive had been incorrectly filled out. And so no adverse effects were expected for this.

Next slide, please. This was another

wrong site HDR medical event where the patient was prescribed 3,600 centigray to the skin of the left scalp. However, the physician had misidentified the treatment site where the photos were taken after the biopsy of the treatment area, but had healed over.

And so when trying to identify the same area prior to treatment, they had misidentified that area. And so potential consequences were determined to be a potential for developing skin cancer at the treated site in 20-30 years, and possible recurrence of the cancer at the untreated site.

Next slide, please. So the patient was offered additional treatment to the carcinoma, but chose only observation by the dermatologist going forward.

Corrective actions included a creation of a HDR planning policy for dermal brachytherapy, an updated commitment to policy to state that the HDR skin cancer sites will be reviewed at a peer review meeting before treatment, and better photographs of the treatment site taken, and ambiguous information requiring additional

verification going forward.

Next slide, please. This event was another wrong site with an HDR unit, where the patient had two lesions on the lower right leg. The first was treated using SBRT without incident. And the second had been prescribed 4,000 centigray over eight fractions.

However, the first fraction, that first 500 centigray fraction had been unintentionally delivered to the first lesion, which was discovered when the patient noticed that the planning circle had been drawn over the first lesion, instead of the second lesion for that second fraction, before it was treated. And so no adverse effects are expected.

Next slide, please. The root cause of this was determined to be human error, particularly failure to notice the change in positioning from supine to prone.

Contributing to this was that the two lesions were very close, about an inch and a half apart, and the second lesion was not present during the previous SBRT treatment.

And so corrective actions included

adding a pre-treatment step for multiple close lesions, and asking the patient to point to the treatment site, as well as using more verification images of the treatment site.

Next slide, please. This event was another wrong site involving an HDR source, where a patient was prescribed 2,100 centigray. The first fraction was delivered without incident. However, at some point after that, the patient had experienced complications from a hysterectomy, which was treated at a different hospital. And so did not return to the original hospital for their other treatments.

The oncologist at the new hospital had determined that that first treatment was off by 3 centimeter, and that the colon and bowel had received a dose of 700 centigray. And so corrective actions included procedure modification to require CT imaging review after insertion of the HDR applicators.

Next slide, please. This event was another wrong site involving an iridium-192 HDR unit, where the patient had received a single fraction to the left hand instead of the right hand

as prescribed.

The corrective actions for this included an immediate discussion with all clinical staff to verify the correct anatomical treatment site regarding all prescriptions going forward.

Next slide, please. This event was another wrong site with an HDR treatment where there was a deviation in the transfer tube by 2.9 centimeters. Unfortunately, this had affected 27 patients before this was, before this was discovered.

The dose to the unintended tissue was determined by recreating the intended plans and comparing that to a shifted plan, which resulted in 267 centigray of additional dose to unintended tissues per fraction.

The investigation for this event is still ongoing, and so I have no updates for you as of this time as to corrective actions.

For this treatment, this involved a PDR unit where there was a patient underdose. Specifically, three patients underdosed where you can see the prescribed and delivered doses there.

For this, there was a discrepancy

between the measured treatment distance and the treatment plan. And so the root cause was determined to be an erroneous manual entry in the reference tables. Specifically, they entered 1,248 millimeters versus the intended 1,448 millimeters. The corrective actions included a root cause analysis, procedure modification, and additional reference table verification.

Next slide, please. So this year we had 34 35.1000 medical events, two GSR unit medical events, and 30 Y-90 microspheres, or 32 Y-90 microspheres medical events.

Next slide, please. The first one involving a GSR unit was a wrong site where the patient was being treated for four lesions in the brain. However, post-treatment they had discovered that the targeting had been off by half a centimeter for all of these lesions. The delivered dose to the lesions were between 8 and 15 gray, and the max dose to the unintended healthy tissue was 21.82 to 27.09 gray.

Next slide, please. The root cause of this was a shifting of the co-registration of images between the intended target, and the treatment parameters. This was discovered after

the surgery. No adverse effects are expected, but the patient will be, will continue to be monitored.

And the corrective actions included an updated treatment procedure to include review and approval of treatment plan by two of the three team members, for all events that involve co-registration of CT MRI images.

Next slide, please. The next Gamma Knife event was another wrong site where the patient was treated for 10 brain lesions but had fallen asleep during the treatment of the first four. During the fifth treatment, the patient had woken up, but no sufficient movement was recorded to stop or delay the treatment.

This treatment was later paused to allow the patient to use the restroom, during which the therapist had noticed that the frame had moved from its original position. The remainder of the treatment was cancelled. They took new CT images, and a new treatment plan was developed for the remaining four lesions, which were all treated without incident.

The review of the initial treatment indicated that the four lesions were treated, that four of them were treated initially. Two following

the patient waking up, and the remaining four were treated after the re-planning.

Next slide, please. This is another event where the investigation is continuing to on go. So they've drawn up two most likely or worst case scenarios, one where only two lesions were affected by the movement, and one where all six of the initial lesions were affected by the movement.

In the most likely scenario, the two lesions received slightly more dose due to the higher volume of brain tissue, with no effect on the other lesions. However, in the worst-case scenario, the two lesions would be underdosed by over 50 percent, and would have a significantly high risk of occurrence.

This patient is continuing to be followed and currently, has shown no detrimental effects from the investigation from this event. And as I said before, it's still under investigation.

Next slide, please. So this first event, Y-90 TheraSphere overdose where administering, when administering the microspheres to the three separate liver segments, it was determined that these segments had been

misidentified, due to the varying anatomy of the patient.

Specifically, segment 7 had received more dose than expected, but all three targets had received an appropriate segmentectomy dose.

The root cause was determined to be the failure to identify the varying anatomy during treatment, where the corrective actions included a secondary review of pre-treatment mapping, and angiography of any administration where the location of the catheter is questioned. And if this is not effective, the AU will perform a 3-D cone beam CT to confirm the area to be treatment, and no adverse effects were expected.

Next slide. Another Y-90 TheraSphere overdose where the patient was prescribed two administrations to separate segments of the liver, where the doses had been ordered with an incorrect calibration date. And so, these segments had been, were administered a significantly higher dose than intended.

The root cause was determined to be a failure to confirm the calibration date, and a failure to check that the prescribed dose matched the measured dose during the pre-treatment checks.

The patient had been followed and no adverse effects were noted. And corrective actions included updating the Y-90 work sheets to add a new verification of dose in hand, rather than versus the written directive, and then updates to the dose ordering process, which required a second person to give their signature, and all of the personnel were trained on these new procedures.

Next slide, please. This event involved another Y-90 TheraSphere overdose, where the patient was intended to receive two vials of microspheres for the administered dose. However, the written directive was incorrectly filled out, and that only accounted for one vial.

And so, the administered activity was within two percent of the planned activity, however, it was a significant overdose, compared to the written directive. And so, the root cause was determined to be human error in filling out this written directive. And the corrective actions included personnel training and procedure updates.

Next slide. This event was another Y-90 TheraSphere overdose, where two patients were due to receive Y-90 treatment on the same day. Patient A with two vials, and Patient B with three

vials.

Patient A had one of their first vials inadvertently swapped with one of Patient B's vials. And so had been administered a significantly higher dose of Y-90 microspheres than intended.

And so, the segments two and three were prescribed 1,200 centigray, but had received 73,660 centigray. 12,000 centigray, excuse me, was prescribed.

And so, this dose was considered clinically acceptable, and no adverse effects were expected. However, Patient B's treatment was cancelled considering that none of, that the vial had been used in Patient A.

Next slide, please. The corrective actions included requiring a signed verification of dose activity by two techs, with a temporary requirement that one be a supervisor or manager.

Additionally, all dose vials are required to be reverified in the event of hand off between certified nuclear medicine technicians.

The Y-90 standard operating procedure was revised, and all staff and AUs were trained on the updates.

Ninety days following this event, a supervisor checked the cart, documentation, and calibration instrumentation for accuracy prior to the transport to the IR suite.

And these monthly audits occurred for 90 days to determine the effectiveness of these actions, after which quarterly audits were continued.

Next slide, please. This next event was a Y-90 TheraSphere underdose, where the vial septum failed under pressure during the administration.

No effects were expected, and the root cause was determined to be a failure to develop, implement, and maintain procedures. The corrective actions included a revision of procedures to specify the correct needle gauge, and revision of emergency procedures.

Next slide, please. This event was a Y-90 TheraSphere underdose, where the physician noted that there was a significantly greater resistance during the administration, but no stoppage had occurred due to intervention, or the patient. The tubing and connections were checked post-treatment, but there was, they had found no

cause for the resistance.

The overflow bottle did show some overflow, but no activity was measured in this bottle, and the dose rate at the vial was zero after administration with no contamination found.

Next slide, please. Post-treatment investigation found that microsphere to have built up at the distal and proximal ends of the catheter, but no reason could be found for this. And the manufacturer noted that the catheter was actually within the recommended size. And so corrective actions for this event included more flushes, adding more flushes during the treatment.

Next slide, please. This event was another Y-90 TheraSphere underdose where the treatment had proceeded without incident, but post-treatment survey of the waste revealed about .43 gigabecquerels of Y-90 remaining. And no contamination was detected anywhere around, and no adverse effects are expected.

Next slide, please. This event another Y-90 TheraSphere underdose, where the treatment had proceeded without incident. However, post-treatment surveys revealed that there was residual activity, which gave an estimate of the

administered dose.

The root cause was determined to be a flow issue in the microcatheter, which caused the microspheres to precipitate out of the solution. And no adverse effects to the patient are expected.

Next slide, please. This next event is a Y-90 TheraSphere underdose, where the AU had noticed a sluggish flow during the first saline flush, which was possibly due to kinking at the microcatheter, they determined. However, no contamination was identified and the AU was satisfied with the dose delivered.

The root cause was determined to be a small treatment volume, with a small vessel being treated. They noticed that more than 30 psi is required to push microspheres into these small vessels, but the built-in pressure valve did not apply a pressure greater than psi, than 30 psi. They were not able to get up to that pressure. And so no adverse effects were expected.

Next slide, please. This event was another Y-90 TheraSphere underdose, where the patient received only 26 percent of the prescribed dose. According to the AU, the treatment went according to plan and, but post-treatment surveys

revealed that the microspheres did not come out of the tubing as designed.

All the proper procedures were followed. No kinks in the tubing could be identified, and the AU had used actually a larger catheter than required. However, over 70 percent of the microspheres remained in the delivery device. No root cause could be identified, but my investigation has determined that the most likely cause was equipment failure, and so no corrective actions were identified for this event.

Next slide, please. This event was another Y-90 TheraSphere underdose where during the preparation, the oncology nurse had expelled some liquid onto the gauze to remove bubbles from the tube, from the treatment tubing. This loss of activity resulted in a smaller delivered activity, which resulted in this underdose.

No adverse effects were expected, and no additional dose was needed. Investigation determined that the proper procedure had been followed, and was not clear whether the event was caused by human error, or a product defect.

Next slide, please. This next event was another Y-90 TheraSphere underdose, where the

procedure was halted prematurely. And surveys of the waste in the room were taken where no contamination was found, but microspheres were observed clustered in the hub.

The correct microcatheter was used, and the waste survey was used to approximate the dose delivered. The root cause was determined after investigation, to be microsphere clumping between the line, between lines E and D in the kit.

Next slide, please. This event was another Y-90 TheraSphere underdose, where microspheres were clumped in the catheter and the AU was unable to administer the full dose. The root cause was determined to be the use of a microcatheter with a curve tip that ended up at the vessel wall, which blocked the flow of the microspheres through the catheter. The corrective actions included discontinuing the use of that type of microcatheter.

Next slide, please. This event was another Y-90 TheraSphere underdose, where surveys post-administration had noted that microspheres were held up in the catheter. The root cause was determined to be a clumping of microspheres in the catheter, due to problems in the procedure.

And so corrective actions included a copy of IN 1912 being provided to understand the issue, and to help prevent future incidents.

Next slide, please. This event was another Y-90 TheraSphere underdose, where the surveys of the container post-administration revealed a higher-than-expected dose after the administration in the kit.

This kit was shipped to the manufacturer after the decay of the radioactivity. And so the root cause was determined to be the intentional use of a smaller catheter than advertised, which resulted in microspheres being held up in the line. The physician determined that this, the dose delivered was effective and no corrective actions were taken.

Next slide, please. This event was another Y-90 TheraSphere underdose, specifically one of four treatments to different lobes of the liver. The three other treatments had no complications, however, this treatment the physician attempted to use a, this specific microcatheter, the TruSelect microcatheter, for over an hour to access the artery but was unsuccessful.

And so fell back on a smaller microcatheter, where some microspheres were held up in the smaller catheter. Other treatment options were considered, but the decision to use a smaller catheter was determined by the physician to be medically necessary. No adverse effects were expected, and no corrective actions were put in place.

Next slide, please. This event was another Y-90 TheraSphere underdose, where the treatment was prematurely terminated due to the unwinding of the male Leur lock connector. A second written directive was created to compensate for this underdose, and this following treatment was successful.

The information of this event was circulated to all of the impacted licensees, and the root cause was determined to be a defective Leur lock. This event was not reported initially due to insufficient written directive procedures, and so corrective actions also included casing the use of the infected administration set.

Next slide, please. This event was a Y-90 TheraSphere underdose, where the patient was successfully administered two doses of a

microsphere, but the third only administered about 5 percent of the dose where the microspheres were determined to be caught up in the tubing from the vial. Unfortunately, I was not able to find any more updates on this event so this is all the information I have.

Next slide, please. This event was another Y-90 TheraSphere underdose, where the AU had noticed some resistance during the administration and halted the treatment.

The microspheres were observed clumped in the first two inches of the delivery catheter. A second dose was ordered and delivered successfully. No contamination was identified in that first treatment, and the root cause was determined to be the use of a catheter smaller than the recommended catheter by the manufacturer.

Corrective actions included a discontinuation of these microcatheters, with a smaller inner diameter in accordance with the recommendations from the manufacturer. And no adverse effects to the patient were expected.

Next slide, please. This event was another Y-90 TheraSphere underdose, which was discovered during a review of microsphere

procedures.

The licensee had incorrectly assumed that this was not reportable, because they revised the treatment plan and written directive after the treatment. The root cause was determined to be a, the use of a smaller than recommended catheter. And the AU had stated that the dose was medically satisfactory, and the smaller diameter catheter was necessary to treat the patient. The corrective actions for this included providing additional training to staff.

Next slide, please. Similar to the last event, this was discovered during a review of microsphere procedures where they assumed that it was not reportable, because they revised the treatment plan and written directive.

Again, the root cause was determined to be the use of a smaller than recommended catheter. The dose was medically satisfactory, and the smaller diameter catheter was necessary to treat the patient.

And the corrective actions included providing additional training to staff.

Next slide, please. This event was another Y-90 TheraSphere underdose where -- stasis

was not reached, and no apparent cause was identified for this underdose.

The AU specifically had written that 12,000 centigray was the desired dose on the written directive, but the dose that was received from the manufacturer had a maximum expected dose of 11,000 centigray.

So if the written directive had been updated with this 11,000 centigray dose, then the administration would not have tripped the medical event criteria. And so the corrective actions included training to the written directive updates for this.

Next slide, please. For this event, this was a Y-90 TheraSphere to the wrong site, where the patient was prescribed that it was to the right lobe of the liver, but instead received the dose to the left lobe of the liver. The root cause was determined to be varying anatomy in the patient, and so they were brought back in afterwards to treat the correct lobe of the liver.

Next slide, please. Okay, and now we're into the SIR-Spheres medical events. This was as SIR-Spheres underdose medical event, where the tech had and ordered a full unit-dose and

mistakenly administered that full dose during the treatment.

The dose was not verified prior to the treatment, prior to the administration, and the written directive had been incorrectly filled out with both the received and the ordered doses. The root cause was determined to be human error, and the corrective action included an implementation of new procedures.

Next slide, please. This event was another Y-90 SIR-Spheres overdose, where there was a calculational error when converting from gigabecquerels to millicuries, which resulted in a larger dose being administered. Being ordered and administered.

The corrective actions included an updated written directive that explicitly lists the conversion factor from gigabecquerels to millicuries, and the conversion to be performed by the tech, not just the manufacturer or representative. No adverse effects were identified or expected for this administration.

Next slide, please. This event was a Y-90 SIR-Spheres underdose, where the root cause was determined to be a clogged catheter. The

corrective actions included an implementation of a new quality management plan, and no adverse effects are expected.

Next slide, please. This event was a Y-90 SIR-Spheres underdose, where there was an error discovered during post-treatment calculations. Unfortunately, no root cause could be determined, and no adverse effects were expected.

Next slide, please. This event was a Y-90 SIR-Spheres underdose where prior to treatment, no leakage was observed during a contrast injection. However, during the administration, the doctor had noted a small leak at the Leur lock connection.

The radiation safety staff was notified, and the doctor had tightened the connector and continued the procedure after changing the gloves. And so, the remainder of these microspheres were administered without incident.

The contaminated materials, which included the gloves and anything else that had been contaminated, were removed and surveyed to estimate the dose that was not delivered. And so that's how they got the underdose estimation.

Next slide, please. Post-treatment, they surveyed the room and found no contamination, and root cause was determined to be a lack of clear written instructions and procedures. The corrective actions included an update to the procedures, to include steps for checking the connections to delivery system, and no adverse effects were expected.

Next slide, please. This event was a Y-90 SIR-Spheres underdose, which had an apparent cause of complicated patient vascular, which inhibited the flow of microspheres, which resulted in an underdose. And no adverse effects were expected to the patient.

Next slide, please. This event was a Y-90 SIR-Sphere underdose, where the procedure was halted due to the occlusion of microspheres in the delivery line. Specifically for this medical procedure, this treatment had been the largest ever dose to date. And so, the vial was maximum volume, and the fluid actually appeared highly viscous in the vial.

The root cause was determined to be too many microspheres in the vial to be properly agitated, or possibly a dysfunctional stopcock.

The corrective actions included modification of procedures to split these, these large doses into two separate vials. And so, the patient was administered another dose to compensate for this underdose, and no adverse effects were expected.

Next slide, please. This event was a Y-90 SIR-Spheres underdose, where the procedure occurred without incident. No stasis or anything going on. However, investigations afterward determined that a member of the staff had noticed a blob of microspheres close to the vial, before the delivery.

And so, the manufacturer was notified, and recommended gentle shaking of the vial before delivery, a little bit of agitation. The AU determined that the dose delivered was effective, however, the corrective actions included checking the vial prior to delivery, and following manufacturer recommendations to shake the vial gently if accumulation is observed. So, no adverse effects were expected.

Next slide, please. This event was another Y-90 SIR-Spheres underdose, where the remaining microspheres during the procedure had been held up in the delivery system. The

investigation noted that this dose was unusually small compared to previous procedures, and so the amount remaining, the amount of remaining microspheres was approximately the same as in previous procedures. But because of the smaller size of the initial dose, it resulted in a reportable underdose.

The corrective actions included additional saline flushes to minimize the residual microspheres, and the addition of 20 percent or more, of 20 percent more activity for low dose prescriptions, specifically under the 10 millicuries, 370 megabecquerels, to account for the anticipation of residual microspheres remaining in the kit.

Additionally, the licensee implemented more frequent monitoring of hands-on personnel to identify potential contamination. No adverse effects were expected, and no additional dose was required.

Next slide, please. So that was all the medical events that occurred this year in FY22, and so I just wanted to give a little bit of a summary for this year.

I'm not going to be talking about any

trending, I'll just give a summary, a quick summary of what I've seen just for the events from this year.

So, for the 35.300, I've got a graph up there on some of the root causes of these events. Equipment error, written directive error, or human error.

I saw that there were a lot of written directive, or written directive errors this year where the intended dose was delivered, but there was an incorrect written directive, which is a medical event, even if the dose intended was delivered.

Additionally, there were a few full dose administration of lutetium-177s, where they had written a reduced dose on the written directive using those half doses.

And so, this year we had our first actinium-225 event which hopefully there will not be more, but as this gains in popularity, I'm sure we'll be seeing more of these.

Specifically, this one had difficulties with that lead shielded syringe, which resulted in leakage. And so, we'll be looking at that going forward.

Next slide, please. For the 35.600 events this year, there were a lot of misidentified sites events this year, as well as the use of incorrect tube, or catheter lengths.

And again, this year we had ones where multiple patients were affected by the single medical event. Specifically, by the catheter tube length problems.

And so, this I think, shows that there needs to be more, more attention to these pre-treatment checks, especially when you're using the same catheter for multiple different patients.

Next slide, please. For the 35.1000s, we see the same that we've been seeing so far, that these are primarily Y-90 microspheres, which are primarily TheraSpheres, and they're primarily underdoses.

Four of these specifically called out events due to use of smaller than recommended catheters.

However, at least in these, this year for these events, we've been seeing a lot more information about physicians saying that these smaller than recommended catheters are necessary for, for treatment with patients with these varying

anatomies, or very small, very small arteries and veins to get into.

Two events, again, were due -- called out specifically for malfunctioning Leur locks, and two events for unusually small doses, which I've been seeing more and more frequently.

And, again, calling back to those 35.300 and 35.600. Three of the six overdose events were due to an incorrect written directive where the intended dose was delivered, but the written directive was just filled out wrong.

And so those are medical events and we're continuing to look at those.

Next slide, please. Yes, I think that's everything, so here's some of the acronyms that I used. I think I've got a question slide at the end.

Next slide. Yes, questions?

CHAIR METTER: Well, thank you very much, Mr. DiMarco, for your excellent presentation. I really do appreciate those summary slides. That kind of helps to kind of coalesce with the information you have. Are there any questions from the ACMUI regarding this report? Yes, Ms. Martin?

MEMBER MARTIN: I was just wondering,

to help me put it into perspective at least, do you have the total number of procedures done? So, in other words, if we're looking at 30 incidents, is it 30 out of 100, 30 out of 1,000? Do you know or do you have the information that says how many procedures they actually did?

MR. DIMARCO: No, we just have the medical events and what the procedures were. However, if we do have any information for events that involve more than one patient, like for some of the 35.600 events, one of them was a single medical event which had a single root cause, but that affected 27 patients, and so if it's -- in my table at the very beginning, if there were more patients that had been affected, that was in the parentheses there.

MEMBER MARTIN: I do have a question regarding just what you just stated. On that medical event score 2017 to 2022, can you clarify what you meant that the total number of patients involved were greater than the number of reports? Because that doesn't kind of fit. It doesn't make sense to me.

MR. DIMARCO: Well, for the 600s, at least specifically this year where it says there

were 11 medical events there, one of those medical events involved 27 patients.

MEMBER MARTIN: Oh, I see, several patients. I understand.

MR. DIMARCO: A couple more of those involved more patients, and so that's where I get that greater number of patients than medical events, yes.

MEMBER MARTIN: So rather than counting them as individual each, you just counted them as one?

MR. DIMARCO: Yes.

MEMBER MARTIN: Okay.

MR. DIMARCO: When they have one root cause like that. For those, specifically for that one, there was one where the incorrect catheter length was used for multiple patients over a span of time.

CHAIR METTER: Okay, thank you very much for explaining.

MR. DIMARCO: Yes.

CHAIR METTER: Any other -- yes, Dr. Einstein?

MEMBER EINSTEIN: CMS had publicly available data on the number of procedures. That

should be relatively obtained. I think the data excludes sites or providers where there are less than ten procedures. One can purchase that data as well. So (audio interference).

CHAIR METTER: Thank you for that information. Any other questions? Yes, Dr. Jadvar?

VICE CHAIR JADVAR: Thank you for your report. I noticed that there's a lot of clumping issues with these TheraSpheres. Is this something that industry can help with? Is there something systematic going on here or is it --

Even though, you know, in some cases, the catheter length was correct or properly used, there was still the problem. Is that something that you think can be addressed with them and see if there's a systemic issue that can be resolved?

MR. DIMARCO: I hope that that's something that we can help resolve with the manufacturers going forward with the ACMUI Y-90 medical event subcommittee going forward with that, as well as just the staff going forward to help address that community.

So as for me personally, I don't know if this is something that's more systematic or

something that we can do anything about, but we're definitely looking to deal with that, and we've got Dr. Tapp here.

CHAIR METTER: I think Dr. Tapp has a comment to make. And I believe in the past, the ACMUI did have two presentations by industry regarding this issue, so we might have to have them update that, and then after Dr. Tapp's comment, I'd like to have Dr. Angle, our ACMUI interventional radiologist, make comments on that. Dr. Tapp?

DR. TAPP: Oh, Dr. Angle could probably speak to this better, but clumping issues with the Yttrium-90 microspheres has been something that's happened since the beginning, and as they become more subsegmental and they're getting more, trying to hit the target, getting very selective into the treatment site, they're using smaller microcatheters which is sometimes causing the clumping.

So, there's a balance between trying to get more into hitting that tumor versus the risk of clumping, so it is something I know we are tracking, the manufacturers are tracking, and the Society of Interventional Radiology is tracking, but Dr. Angle, if you have anything to add, it

would be great to hear it.

DR. ANGLE: I think it's a very important insight. John Angle from the University of Virginia. The field is definitely evolving. The lobar treatments are being replaced with multiple subsegmental injections in one session.

So, patients are having different treatments, multiple treatments in one session, often involving much smaller vessels, so this increases the likelihood of these types of events you refer to with plugging of microcatheters.

I think all of the operators are very well aware of the problem with smaller catheters, and as you saw, some adverse events here. Sometimes they have to make a choice whether to try and use an extra small microcatheter realizing it may not deliver the dose and this is a judgment that, you know, operators are having to make, but it has, I guess, been a trend.

I don't want to comment officially on it, but most of the events are underdosing and I would fully expect, unfortunately, this is going to continue. As a practitioner, I can tell you that as we do more and more segmental treatments, you're going to see more of this, so it is a problem.

I am curious about written directive errors and I wanted to ask you a question back. Is there any trend in what the written directive format is, how it's actually done at the institutional level that you can comment on when you see written directive errors just in regards to Y-90?

MR. DIMARCO: So, I did want to say this. I don't want to call this a trend because this is something that I've noticed. I did the previous year's presentation as well on this.

So, I haven't been able to see this all the way, but this is something that I specifically noticed this year for those written directive errors, because last year, I noticed that there were not nearly as many written directive errors in the same ways that we've been seeing for this year.

So, I don't want to say it's a trend right now. It's just something that happened this year, but it's definitely something to keep an eye on and I will be keeping an eye on, and going forward, seeing maybe if we need some clarification for written directives on what goes on there, or maybe even if we need a subcommittee IN here or something like that. So it's something that I'm

keeping an eye on, but no activity yet on it so far, so.

CHAIR METTER: Are there any other questions from the committee? Yes, Ms. Martin?

MEMBER MARTIN: Just a question. With particularly the TheraSpheres and SIR-Spheres, is there any way to identify or do you if these are repeat happenings at the same institutions, and if so, is there any follow-up with that institution to see if the suggested changes have an effect?

MR. DIMARCO: I haven't done any of that research. I would assume that that would probably fall more under the purview of the investigators going down there, the Agreement States and the regions just for medical facility specific problems on that.

But we also have the Y-90 INs that we sent out, and so that goes to all of the facilities there, and so that would have all of the information that would be useful for these, you know, commonly shown problems.

MEMBER MARTIN: Well, just a follow-up question with that. The other part of that is are we seeing a difference between institutions that are very active that have like a very active

interventional program?

Would you expect to see more happenings or more instances from that or are we seeing more procedures from the isolated, smaller, newer users? Are they the ones turning or having the events? That's what I was trying to differentiate.

MR. DIMARCO: I haven't done any specific research on that, but just from going on the events and seeing where these events are coming from, I would say that there's really no correlation between the size or the amount of procedures being done for the facility and whether or not a medical event happens.

I mean, obviously, there are differences in percentages there where one event from a smaller facility versus one event from a bigger facility, the percentages there at least are different, but just raw numbers-wise, these are coming from everywhere.

CHAIR METTER: Okay, thank you. So, I'm going to go to -- this is regarding the current topic? Okay, so let me have Mr. Josh Mailman, our patient advocate, make a comment, and then we'll -- I'm sorry, who was the individual? Oh, Dr. Tapp?

DR. TAPP: I was just going to respond

to that comment and that question from Ms. Martin. The events are kind of difficult to correlate to see if it's small institution, medium, or big just because it is up to the reporting.

Everyone is required to report, but we do know that the larger institutions, they are tracking. They have procedures, so they do report, I think, a little bit more than some of the smaller ones.

But we do see the reports from across the board, but Dr. Ennis, previously on the ACMUI, did recommend – he noticed in medical events that the more you use something, the less likely the events were occurring.

So, he did see a trend in that, I think, two years ago, so we did put out an IN in 2019 that recommended if you haven't done a procedure or if you haven't done a procedure a lot, to do a mock procedure to make sure you're familiar with it before you perform it. So that was the previous recommendation from the ACMUI.

CHAIR METTER: Thank you. And I believe Josh -- Mr. Ouhib, go ahead.

MEMBER OUHIB: I think the other factor that we don't seem to pay attention to is staff

rotation. You might very well have an institution that's doing a lot of cases, but their staff leave or are not available for whatever reason and somebody else will step in and do the procedure. The next thing you know is you have a problem and I think that needs to be looked at carefully.

CHAIR METTER: Any other comments from the ACMUI?

MEMBER MAILMAN: Sure, I think I have three. You know, first of all, thank you for this presentation. Looking through this and listening to it is always a little disheartening for a patient, listening to medical events that happen.

A few things, just in language, page eight of the actual handout which was 21-0448, trying to keep patient inclusion language. Patients never fail anything. The second time it mentioned that patients failed to swallow as opposed to he was unable to swallow, so really great to keep that language consistent. Patients never fail anything, so that's the first thing I noted.

We seem to have, whether it's a trend, but as more and more of these get done with lutetium being half-dose sometimes, is there -- and

I noticed that we have corrective actions at the institutions. Is this anything that is going, making recommendations nationwide or some other recommendations? Because we're going to see these half-doses and seeing this issue as well.

And I note that this is obviously through the end of fiscal year 2022, which I think is October. Is that correct?

MR. DIMARCO: That's correct.

MEMBER MAILMAN: Because one of the things that I think we need to discuss whether it's going forward or not, I think your next year report will have several Pluvicto, Lutathera misadministrations where one was given the wrong -- several patients have been misdosed with the wrong radiopharmaceutical.

And I don't know if you have any comments on what you're seeing with that going forward of if it's something that we should look at earlier before your next year's report. Those were my three comments.

CHAIR METTER: Thank you.

MR. DIMARCO: Thank you. First of all, thank you for your first comment on more inclusive language. That's something that I grapple with. I

come from a technical background, so I'm used to these kinds of languages, so thank you for reminding me of that.

As for the Lutathera, this is something that we're definitely keeping an eye on. I have a feeling that we will probably have to end up giving out some more information on these just because they're getting so popular, and so they're going to be having more and more misadministrations, especially with the way you talked about the Pluvicto, Lutathera mix-ups. That's all I really had to -- Katie, did you have something to say on that?

DR. TAPP: Yes, for the Lutathera and the new radiopharmaceuticals, we are seeing those, as you mentioned, in the new fiscal year, and we are planning to issue an information notice and get it out there on the events we've already seen because they are coming quickly.

And as you know, the Pluvicto did get FDA approval and we're seeing more patients, so we're going to try to get out an information notice of what we've seen already and keep an eye on it going forward.

We are meeting with AAPM and having a

summer school where we're going to discuss medical events and how to prevent them. So I'm hoping to use some of that information I gathered from lots of members there to help us, but if you guys, you know, want to take up actions and let us know, you'll see the information notice and provide us comments on that as well, I'm sure.

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

MEMBER OUHIB: Yeah, I think in addition, it would be really helpful if the manufacturers will actually have some sort of information related to medical events that have been recorded or whatnot and send it to all users. Here is what we have seen for this past three months or whatever. Warning, don't do this in the event of that. Avoid doing this, and so on and so forth.

I think that would connect directly with the users because I agree regulators can help with that, AAPM can help with that, but there's nothing like the manufacturer communicating directly with the users and provide them good information related to those cases.

CHAIR METTER: Dr. Angle, you have a

comment?

DR. ANGLE: Actually, just a question, maybe respective analysis of the plugging events of Y-90 over the last several years. When we administer the Y-90, of course, by putting a higher dose in, we introduce a mechanical problem.

We have to get more particles through the catheter and we've talked about how a smaller catheter is harder, but also just physically having to put more particles in, and is it possible to analyze your data looking at these adverse events? Is there a correlation between the dose and plugging events?

I guess without knowing the denominator, it's hard to analyze, but I guess my question is do we have any way to analyze are plugging events happening at much higher rates when we're putting a large dose in or is there really no correlation there?

And the reason is because I think there's a lot of theories about why we're having these plugging events and we really have been not making much progress it seems in answering this question, and I thought maybe this would be one way to dive into this a little deeper. So is that kind

of information available in the information that you get on these adverse events?

MR. DIMARCO: I think that that would be an interesting line of study. Just on first blush on that, I would say I don't think there's that much of a correlation. We see problems with larger than expected doses and smaller than expected doses where the smaller is usually just greater than 20 percent held up, not usually due to clumping.

But I think the clumping issue, as well as being, you know, those kind of larger doses, I think that's for all of the doses, as well as a lot of the information, it's hard to get just because sometimes they will split them into two vials and not tell us on the medical event reporting.

They'll just report the bulk whatever they administered, so I would have to go back to every single one. So I think it's interesting to think about that, but I don't know how I would be able to get that information.

CHAIR METTER: I do see Ms. Ashley Cockerham from industry here to answer some of these queries.

MS. COCKERHAM: Sure, I'm Ashley

Cockerham with Orchestra Life Sciences. I do regulatory consulting. As a little bit of context, I'm formerly an NRC staff employee, so many familiar faces. I also worked for Sirtex and I'm a current consultant for Boston Scientific. So I feel like I have a well-rounded view of these things. I'm going to try to address three things that I've heard.

One, the information is available on the number of procedures each year. That information is obtainable from both manufacturers. That's something that I was able to obtain as an NRC staff member. In industry, I've been able to provide that information to the NRC.

So the denominator is available at least for Y-90 microspheres from both manufacturers to help put this into context. I have not done the analysis for the trends on whether or not the incident percentage has changed in the last couple of years.

The second point, there was a comment about written directives. Both manufacturers do provide template written directives. Each facility is responsible for developing their own procedures and they may or may not implement the

manufacturer's template written directive, so that written directive can vary and does vary from site to site.

The third one is for why medical events are occurring and sort of how to prevent them. This is something that I've worked on with Boston Scientific over the last year.

So, for TheraSphere, the company does and has always provided an administration checklist, which is something that was talked about at previous meetings as sort of a timeout, best practices. You always have the same checklist.

Again, the manufacturer provides that. What the facility decides to implement is determined by their own internal procedures. As a supplement to that, we took that checklist and then said basically why do we do each one of these things? We check the Leur lock on this checklist because it prevents leaks. So there is a supplementary document available for TheraSpheres that's specific to how to prevent a medical event. It's called the safety procedures document that's provided to all representatives, and they're intended to train all of their treatment sites on that. Does that help?

CHAIR METTER: Thank you very much for that very concise update and answering some of our questions here. Does anybody from the ACMUI have questions for Ashley? Yes, Ms. Martin?

MEMBER MARTIN: Ashley, is that document provided to all of the users or only to your, the people providing the training? That safety document that you were referencing there, is that provided for the users?

MS. COCKERHAM: Yes, it would be for each treatment site.

MEMBER OUHIB: Okay, so this is provided to the users, but how can you guarantee that the users actually have used that, looked at it? And so, the reason I'm saying this, there were other documents that were sent out to the users.

And I'll use the example of end of life for devices, and I can guarantee you many of them never looked at that document and they felt like oh, I never received that document. I don't know what you're talking about, and so on and so forth.

So, I think as a suggestion perhaps if you're sending that, that you request that the users should actually send a signed form that they have actually used that information and they intend

to implement it.

CHAIR METTER: Thank you. And I believe you probably do present these presentations to the specialty societies like SIR and those groups?

MS. COCKERHAM: I think that's Katie. Yeah, I want to defer to Katie here.

DR. TAPP: We are establishing a working relationship with the Society of Interventional Radiology. We have not had a big presence there in the past, but I do have a webinar coming up, I think, middle of June that I plan to go over some of the events we've seen and precautions that we've recommended in the past, as well as licensing guidance, but in the past, we have not had a big presence at the Society of Interventional Radiology. It would be more SNMMI and AAPM and others, Astro.

CHAIR METTER: Dr. Angle?

DR. ANGLE: I just want to say that's such a, I think, it's a great initiative and I think we really should make that an ongoing process. I think it's wonderful to hear. Thank you.

CHAIR METTER: Thank you and thank you

for those words. Yes, Dr. O'Hara?

MEMBER O'HARA: I have a question. I may have missed it.

CHAIR METTER: Could you turn on your microphone?

MEMBER O'HARA: I think it's on. On page 75 on the table, I may have missed this, but what does variant anatomy mean?

MR. DIMARCO: So variant anatomy is something that we get from the event reporting. This is typically when someone using, whether the patient has either a vein that goes to a different segment or some sort of unexpected part of their anatomy where the medical event occurred because of either like going through a smaller than normal vein or something like that, and so we see that a lot in shunting at least where if the facility does not notice that beforehand, it can lead to a medical event.

CHAIR METTER: Yes, so they do, before the Y-90 mapping with MAA, and to look for any of this, quote, variant anatomy, which, Dr. Angle, I'm going to have him make a comment on, but sometimes what I've noticed is that when they split the dose for right lobe and left lobe, then between the

treatment, you have revascularization of other areas, and so you might have more shunting than expected, but let me have Dr. Angle, because he does the procedures and he's the expert on this.

DR. ANGLE: I don't have much to add to that, but we do a planning procedure. You catheterize the vessels that you're going to be injecting into, and then on the day of the procedure, you have to recreate that catheterization. And usually, that goes very smoothly, but there's no guarantees.

And so, to your point, some vessels that maybe were small a month earlier are larger and you have trouble getting the catheter into the exact same position that's appropriate, so different catheters and wires are sometimes necessary for that follow-up procedure which is, I think, an unavoidable change in the procedure, and sometimes this leads to just the inability to put the catheter in the exact same position for the follow-up procedure.

CHAIR METTER: Thank you for that clarification. Any other questions from the committee? Yes, Dr. Wolkov?

MEMBER WOLKOV: Harvey Wolkov. I do

have a quick question for you. It's a process issue. So on a minority of cases, in fact, very few, you indicate there's no further data, and I'm just wondering what's the typical follow-up for those patients?

MR. DIMARCO: So at least personally when I'm doing these presentations, there's only a certain amount of information that I can ask for in the regulations, and so for that, I usually go to either the regional offices if it's an NRC state or any of the Agreement States.

And so for that, if I don't have any information, that's just something that I have not been able to get an update from them. As for any of the patient follow-up, I'm not privy to any of that. I think that's just on the medical facility themselves as to what the follow-up would be for that, so that's the process that I use.

CHAIR METTER: Yes, Mr. Ouhib?

MEMBER OUHIB: Yeah, in a few cases, I noticed that there's a refresher course or training after a medical event, and I said it before and I'll say it again, I'm not sure why we're waiting for a medical event to have refresher training for all users. It doesn't hurt and it might very well

prevent another event.

CHAIR METTER: Thank you for that comment. I just wanted to say that, you know, as far as the NRC and what our work does, we're here as regulators to help protect the public against radiation safety. We're not here in the practice of medicine, which I think is sometimes a very fine line, so we kind of have to remember that. Dr. Jadvar, you have a comment?

VICE CHAIR JADVAR: A quick comment, I'm going to play, you know, as patient advocate. In these, you know, I understand the reporting, of course, for regulation and all of that, but are the patients, do you know if the patients are told what happened in many of these cases or we just don't care or we don't even follow that? We just kind of see what the physicians or the admin, the facility provides?

MR. DIMARCO: So in our regulations, for every medical event, the patient is required to be notified.

CHAIR METTER: Well, this has been a very, very good discussion. Any other final comments or questions from the ACMUI? NRC staff? May we open it up to the public? So are there any

public comments regarding the recent report by the NRC on the medical-related events?

MS. PINEDA: Testing. If you're a member of the public and you'd like to make a comment, you can, if you have joined the meeting using Teams, you can use the raise hand function on Teams. That's the little hand icon.

Just click on that once and then I will know, and I'll call your name and you can unmute yourself, and everyone has access to their microphones, but you do have to unmute yourself.

If you joined the meeting by telephone today, you can just press *5 and that will show me that your hand is raised on your phone, and then you'll press *6 to unmute yourself, and you might need to also unmute your cell phone. Thank you.

Okay, it looks like we have Steven Marsh. Your hand is raised.

MR. MARSH: Good morning. Thank you very much for this presentation and opening it to the public. I just had one question. Is there a possibility to get a copy of Mr. DiMarco's presentation? I'd love to share that with the Radiation Safety Committee, my staff, and the authorized users of the synopsis of that PowerPoint

presentation, all of the different events, and the root cause analysis and everything. I think that would be very helpful, as one of the other speakers alluded to, about having some refresher training.

CHAIR METTER: Yes, thank you for your comments, and I'm sorry, where did you say you were from?

MR. MARSH: Oh, Baystate Health, Springfield, Massachusetts.

CHAIR METTER: Okay, yes, so after this meeting, this whole meeting is transcribed by a court reporter, and in about a month, it should be available. Mr. Einberg, can you make a comment regarding that?

MR. EINBERG: Yeah, thank you, Dr. Metter. All of the slides right now are on the public website, so they can access those slides right now, and all of the medical events are on there as well. And we will have a meeting summary with the transcript about a month after this meeting.

CHAIR METTER: Thank you very much.

MR. MARSH: Thank you.

CHAIR METTER: Any other questions from the public? Okay, seeing none, let's go onto the

next item on our agenda which is presented by NRC staff, Mr. Flora, the revisions to the abnormal occurrence criteria.

MR. EINBERG: Yeah, I believe there's been a change to who is making the presentation. It's going to be Ed Harvey.

CHAIR METTER: Oh, I'm sorry. Thank you.

MR. HARVEY: All right, good morning, everyone. I'll do a quick sound check. Can everyone hear me in the room?

CHAIR METTER: Yes.

MR. HARVEY: All right, excellent. So my name is Ed Harvey. I'm an abnormal occurrence coordinator in the NRC Office of Nuclear Regulatory Research. I do work closely alongside the stellar staff and the NRC's medical radiation safety team to evaluate medical events that are reported to the NRC for abnormal occurrence considerations.

But today, I'm going to go over some of the efforts that the NRC has been taking to revise the abnormal occurrence reporting criteria, but first, I'd also like to express my apologies for the last-minute change to the speaker on the agenda, so, but next slide, please.

Okay, so here is the agenda for my discussion. As you can see, I'm going to start with a little bit of background, go into some of the proposed changes that the staff made to the abnormal occurrence criteria, talk a little bit about the Commission's direction through a staff requirements memorandum or SRM, and then go over the path forward for our next steps.

I only have about ten slides to present, and then after that, I'll do my best to answer any questions that you might have.

Okay, so I'm going to start off by going a little bit back to basics to give a little background, so I do apologize if this is too fundamental.

First off, just asking the general question of what is an abnormal occurrence or AO as the NRC abbreviates? Section 208 of the Energy Reorganization Act of 1974 defines an abnormal occurrence as an unscheduled incident or event that the NRC determines to be significant from the standpoint of public health and safety.

This sounds incredibly subjective in nature. The NRC does have strict and objective criteria to determine if an event meets the

threshold of an AO.

The current AO criteria, and I apologize for not putting it here on the slide, but the current criteria are outlined in the Federal Register and this was published, last published on October 2, 2017.

So every year the NRC evaluates reported events, including several of those events that my colleague, Daniel DiMarco, just went over, and we evaluate these events against these criteria, and those that meet the threshold, we then publish them into the annual report to Congress on, I'm sorry, on abnormal occurrences.

This is actually consolidated into a NUREG publication, and as you can see on the slide here, this is just kind of a screenshot of the cover of the NUREG, but it is NUREG-0090, and then every subsequent year, the volume number kind of just goes up on them. So next slide, please.

So how did we get here today to talk about proposed changes to the AO criteria? So on the slide, you'll see a few documents that I'm going to briefly talk about here.

The story kind of starts back in 2019 when the staff issued SECY-19-0088, which is a

paper to the Commission, and we recommended that the NRC evaluate a potential revision to the current AO reporting criteria. And when I say current, I mean the criteria that are currently in place published in 2017 that I went over on the previous slide.

This recommendation came out of an initial review that the staff undertook to determine if the current criteria provided an accurate threshold for determining if an event is significant from the standpoint of public health or safety.

The Commission then responded to this SECY via an SRM, which is there in the middle there, around SECY-19-0088, that directed the staff to pursue a limited revision to the AO reporting criteria within only, it was limited to the medical event and source security areas of the current criteria.

So, in response to that SRM, the staff then issued another SECY paper back in 2022 which contained our proposed limited revision to the NRC's policy statement on reporting criteria for abnormal occurrences. Next slide, please.

So just hopping right into it, overall

there were three, what I consider three substantive changes that we recommended to the Commission back in 2022, so I'll just go over the three of those. The first one here was Criterion I.C.1 and this was a proposed, we proposed to add an exception to stolen, diverted, or abandoned sources.

So currently, any Category 1 or 2 material, excuse me, Category 1 or 2 quantity of material that is stolen, or diverted, or abandoned for any amount of time is considered an abnormal occurrence, even if that source is subsequently recovered.

So, the staff recommended to remove reporting of these events where it was clear that the intent wasn't to actually steal the material. We put some language in the policy to basically exclude those events involving sources that are stolen, diverted, or abandoned where it was evident that there was no intent to gain access to the radioactive material and then the sources were recovered with little or no risk to public health or safety.

So, an example is if someone steals a truck with a Category 2 quantity of material in the back because they wanted the truck, but not

necessarily the source. Unbeknownst to them, the source was on the back.

They recover the stolen truck with the source in there still or they recover the material afterward, perhaps in a short amount of time. This would then be excluded from reporting to Congress.

This change was not accepted by the Commission, and therefore, in the proposed limited revision, Criterion I.C.1 remains substantively unchanged in the current revision. And I think -- did the slide move? Next slide, please.

Okay, all right, so the next change was in Criterion 3.C.1 and this is the staff had proposed to the Commission that we remove the need for a written directive to qualify a medical event as an AO.

So, this proposal was accomplished by essentially striking out the language in Criterion, it's actually in 3.C.1, a level down, B, that references the written directive, and we just replaced it with prescribed dose or dosage.

This gives the NRC the latitude to consider significant medical events as abnormal occurrences that involved procedures that don't normally require a written directive as required by

10 CFR 35.3045.

This change was accepted by the Commission in the SRM, and in the proposed limited revision, we do include essentially that summarized change. Next slide, please.

And the final substantive proposed revision to the AO criteria is that in 3.C.2. This is where the NRC proposed to shift to more of a deterministic consequence-based reporting criteria for reporting medical events as AOs.

So, under this shift, in order for a medical event to qualify as an AO reported to Congress, the patient would need to experience some sort of radiation-induced injury causing permanent damage or require medical attention to prevent permanent damage to a radiation-based injury in summary there.

This change was not accepted by the Commission, and currently in the revised criteria, proposed revised criteria, 3.C.2 remains essentially unchanged from the current policy. And then next slide, please.

So, I kind of spoiled a little bit what's in the SRM by kind of telling you real time what changes were accepted and weren't, but this

slide here is a high-level pictograph of some of the information that is inside the staff requirements memorandum for this, for our SECY paper for our proposed changes.

This SRM was published March 29 of this year, and as you saw, they approved and disapproved some of the proposed changes that we put in front of the Commission.

Further, the Commission had asked us to evaluate the removal of Criterion 3.C.2 because there are some redundancies in the language of the AO reporting criteria and the criteria in 10 CFR 35.3045 for reporting medical events to the NRC.

So, they asked us to kind of take a look at that and let them know if we want to still keep those criteria inside of the current AO policy.

And then lastly, the Commission directed the staff to incorporate their comments on the draft policy revision and then publish it for comment, a 90-day comment period. So next slide, please.

So where are we at now? Here is our path forward. Number one here, we did respond to the Commission in saying that we are proposing to

maintain Criterion 3.C.2 as is. Some of the, I'll say, I guess, confusion or reasons for the redundancy is that we were kind of trying to shift the paradigm into a deterministic-based criteria as opposed to kind of tracing it back to the written directive. Our current policy is that you need to report as an AO any event that goes 50 percent or greater than the prescribed dosage or, you know, a smattering of other things, wrong treatment site, wrong patient, so on and so forth.

So, the way that that's structured versus the way that 35.3045 is structured, we need those criteria in there to make sure that we're capturing all of the safety significant events in our AO policy and reporting them to Congress.

Number two, we will incorporate the Commission comments and publish the proposed limited changes to the Federal Register for a 90-day public comment period, and then once that's out there, we will be consolidating, docketing, and evaluating all of the public comments that do come in, and then work towards a final publication.

I will say we are very, very close to getting number two done. So, once it's out there, we look forward to any and all comments that the

public has on our limited revision.

And then, I think, next slide, please. I think that's all I have as far as material to discuss, but I'm happy to attempt to answer any questions that you have for me.

CHAIR METTER: Well, thank you, Mr. Harvey, for that nice review on the updates regarding abnormal occurrence. Do I have any questions from the ACMUI for Mr. Harvey? Any other additional comments or questions from the NRC staff?

MR. EINBERG: No.

CHAIR METTER: Then let me just open it up to the public because this is a very interesting topic in my opinion.

MS. PINEDA: Again, if you are a member of the public and you joined by Teams, just use the raise hand function in Teams, and if you called in by phone, then press *5 to raise your hand and then *6 to unmute yourself after I call your name. Thank you.

We have Ralph, and I think the name is Lieto. Go ahead.

MR. LIETO: Yes, that's correct. Hello?

CHAIR METTER: Go ahead. Go ahead, Ralph. This is Darlene.

MR. LIETO: Thank you very much for the opportunity to comment. My name is Ralph Lieto. I'm a medical physicist from Michigan. I'm presently pretty much retired.

But I was very interested in Mr. Harvey's presentation in that this abnormal occurrence criteria has been something that's been addressed quite a bit in the past, and I'm very surprised that this criteria that you're asking for comments on, which I think needs to be commented on, is that that criteria about deterministic effects being taken out should remain.

I think this was something that the ACMUI had recommended a number of years ago, and I think it would have been helpful if you maybe in the future would comment in that almost nearly, if I'm not mistaken, for the past ten-plus years, the AO criteria has only been exceeded by medical events. There's very few commercial reactor events that have been reported in this.

And the other point is that even though almost all of these have been predominantly medical events, I am not aware of anything that has ever

occurred as a result of this reporting in an AO that's resulted in any change in either regulatory or guidance regarding patient safety or health.

So, it seems that a tremendous number of these events that meet these criteria would really only fall into the, you know, the realm of being of some significance if they produced some type of deterministic or radiation-induced injury, and even then, I'm sure that probably would only number in the very, very few.

So, I guess the issue is are you then stating that if we need to put this back in, we being the regulated community, that we need to comment and that the Commission would change their mind on pulling this out?

MR. HARVEY: So, I'll start by saying I encourage you to, once this is open for public comment, to submit your comment. I cannot guarantee or I cannot comment on whether or not the Commission will take that and change their minds on this.

I'm fairly new to this AO coordinator position, but I do think there was a comment -- I would imagine there was a public comment period when these proposed revisions went up before a

SECY, but I'm not 100 percent sure on that.

But long story short, I would encourage you to submit your public comment to get your thoughts expressed to the Commission because we will be responding to the comments that we receive if they're within scope.

MR. LIETO: A follow-up question, please?

MR. HARVEY: Sure.

MR. LIETO: Could you verify my recollection that this was a proposal from the ACMUI originally to change this abnormal occurrence or was this from NRC staff to put this proposed criterion into the AO criteria but was rejected?

MR. HARVEY: I think I'd have to defer to ACMUI on that. I will say the initial review, I think, back on the slides, the initial SECY paper where we evaluated the current AO criteria and requested to make revisions, I do think that came out of discussions with ACMUI back in 2019 I believe it was, but if there's anyone sitting in the room that might remember that or if folks from the medical team recall that as well, I would defer to them.

CHAIR METTER: Yes, Dr. Katie Tapp is

here to make a comment on that.

DR. TAPP: Yeah, Ed, it was actually farther back. The ACMUI made the recommendations to change the abnormal occurrence criteria before we sent it up in 2015, so this is going back even farther than the 2019.

The 2019 was a staff-led initiative, but was with support and agreement with the ACMUI, so they did have comments, but it was, 2015 was the initial request for this and it was based on a recommendation from ACMUI.

CHAIR METTER: Thank you.

MR. HARVEY: Thank you, Dr. Tapp.

MR. LIETO: Just a final comment then. I would encourage the ACMUI to at least make a motion to the Commission to have them reinsert this criterion into the AO, thresholds for reporting abnormal occurrence events from medical events. Thank you.

CHAIR METTER: Thank you for that comment. We'll look into that and take things into consideration. Any other comments from the public? Seeing none, we'll go to our next item on the agenda. Dr. Valentin-Rodriguez from the NRC will be giving medical team updates.

MS. VALENTN-RODRIGUEZ: Thank you, Dr. Metter, and thank you, Christine. Today, I will provide an update on medical-related rulemaking efforts, regulatory guidance development efforts, and other opportunities for engagement with the medical team. Next slide, please, Christine.

And this is just what I just covered, so, Christine, if I could get the next slide?

So, I wanted to give you just kind of an update on what 10 CFR Part 35, how we've planned to change it, the different rulemaking plans that the staff has submitted throughout the years.

And Christine, I think if you can hit the next button a few times, you'll get all of the items on the slide. Thank you.

So back in 2018 was the last time that we officially amended 10 CFR Part 35 and it became effective in January 2019 for NRC licensees and in 2022 for Agreement States and Agreement State licensees.

So back in 2018 in that rulemaking, we revised medical event reporting and notification requirements for permanent implant brachytherapy, and we also amended requirements for measuring moly-99 contamination and required reporting for

failed technetium and rubidium generators.

We also made some generic changes to our training and experience regulations. We addressed a petition for rulemaking regarding grandfathering of individuals who had been diplomats from a certified board previously or before October 2005, and we made changes to those same regulations to include associate radiation safety officers and medical licenses.

So, the last few years, as you see on this slide, we've submitted three rulemaking plans to the Commission, all of which the Commission had voted on. The staff's T&E rulemaking plan was disapproved by the Commission in January of 2022, but we pursued other Commission-directed actions, some of which have been completed and others that are in process and I will discuss later today.

Regarding the emerging medical technologies / rubidium-82 generator rulemaking, the Commission approved the staff's recommendation option and I'll be talking about that rulemaking a little bit in later slides.

And then last, but not least, in 2022, the Commission approved the NRC's path forward on petition for rulemaking PRM-35-22, which requested

that nuclear medicine injection extravasations that exceeded a localized dose equivalent of 50 rem be reported as medical events.

As previously mentioned, Irene Wu of the NRC staff will be providing a status update on that rulemaking, so I won't cover that today. So next slide, please, Christine. Yeah, there we go.

So, the ACMUI has already provided feedback on this rulemaking back -- last year, we provided the ACMUI with the regulatory basis for the emerging medical technologies / rubidium-82 generator rulemaking, which is what's grayed out sort of in this timeline here.

And the timeline really shows what's going to be our schedule for this massive rulemaking where we aim to include requirements for calibration and dosage measurements for strontium-82, rubidium-82 generators, and to establish risk-informed, performance-based requirements to create additional flexibility in Part 35 for the regulation of existing and future emerging medical technologies.

And so, as I mentioned, the ACMUI already provided comment on the draft regulatory basis, which the staff has already addressed, and

we are really appreciative of those comments.

The regulatory basis is in concurrence in the NRC and we are aiming to issue that in the next few weeks actually to the Commission, and after that, it will be published in the Federal Register for a 120-day public comment period. We hope to have public meetings during that time.

And then we've pushed out some of the schedule that's on the screen here to winter 2026 for the proposed rule and winter 2027 for the final rule, and this was a decision made by the NRC staff to prioritize the extravasation rulemaking. Next slide, please.

Another rulemaking effort that the NRC medical team has undertaken has been the issue of veterinary release. As you will know, historically, most common veterinary uses of byproduct material are sodium iodine-131 for the treatment of hyperthyroidism in cats, and we have limited guidance in NUREG-1556, Volume 7, Revision 1.

A few years ago, we issued a technical report for the evaluation of a radiopharmaceutical for the treatment of osteoarthritis in dogs using a tin-117m colloid, and in that case, the

manufacturer provided proposed release criteria for the NRC that relied on prescreening criteria and pet owners following instructions to a greater extent than previous practiced by the NRC.

And at that time, we issued that technical report, which is publicly available on our public website. Following this report, we established a joint NRC / Agreement State working group in October 2021 to develop recommendations to establish a framework to authorize veterinary licensees to release animals following veterinary procedures.

Right now, our regulatory framework relies on the public dose limits in 10 CFR Part 20 for that veterinary release. That is another rulemaking that we've kind of deferred for a little while.

After we started working on this rulemaking plan, the medical team received the staff requirements memorandum for training and experience for emerging medical technologies, as well as extravasations.

We have received resources from the Commission to develop a regulatory guidance for the release of animals, and so we will be proceeding

with that and then we'll proceed with the rulemaking plan as our resources, our staff resources allow. Next slide, please.

So, in terms of emerging medical technologies, we will continue to develop licensing guidance as, you know, 35.1000 will not go away after our rulemaking. On this slide here are three different technologies that we've reviewed in the last few years.

For example, the Elekta Esprit is an advanced gamma stereotactic radiosurgery unit from the manufacturers of the Leksell Gamma Knife Perfexion and Leksell Gamma Knife Icon. These units, as you all know, are licensed under 35.1000, that they are not able to meet some of the requirements because they have evolved in terms of technology.

And so recently we've issued a revised licensing guidance for the Perfexion, Icon, and Elekta Esprit to include this new gamma stereotactic radiosurgery unit.

The Liberty Vision Y-90 Discs brachytherapy source is a new single-use temporary eye applicator source that utilized Y-90 for the treatment of eye tumors and benign growths.

The ACMUI did establish a subcommittee to review the licensing guidance which the staff is still developing. We are very close to issuing that guidance for Agreement State and ACMUI comment, so we should be able to reestablish soon that subcommittee.

An interesting thing about this Liberty Vision brachytherapy source is that our regulations are written mostly for the use of strontium-90 sources for ophthalmic use of byproduct material, whereas Liberty Vision uses Y-90, and so that introduces some issues with regards to treating experience, authorized users.

And the last technology on this slide is the Akesis Galaxy RTi, which is another new gamma stereotactic radiosurgery unit for the treatment of head and neck conditions. It should be licensed under 10 CFR 35.1000. This particular unit has rotating sources in a collimator carrier. It also utilizes image-guided treatment, and it allows for table movement during treatment.

This guidance is also in development, and so in the next few months, we should be able to produce a draft licensing guidance for Agreement States and ACMUI comment on this technology. Next

slide, please. Thank you.

So back in 2018, we issued the results of the NRC's patient release program evaluation in SECY-18-0015 to the Commission.

In evaluating the NRC's patient release program, we considered rulemaking in four areas and performed dose modeling calculations, researched published data and peer-reviewed literature, and conducting extensive stakeholder outreach to really evaluate our patient release program.

At that time, we concluded that our current patient release regulations are protective of public health and safety, but that we should probably update Reg Guide 8.39.

And so, we proposed to do that in two phases, the first of which was published in April 2020 and that is the current version of Regulatory Guide 8.39 that licensees could use, and in that revision, we updated the patient release information to provide example patient instructions.

Revision 2, which you all saw a draft of back in late 2021, this has been published in the Federal Register as a draft proposed regulatory guide, and in this revision, we are proposing to

update the dosimetry equation, methodologies and tables used to calculate dose to members of the public.

So that is out for public comment as we speak for a 60-day comment period that closes sometime in June, and so as Kevin stated this morning, once the staff has received those public comments and addressed them, the ACMUI will have an opportunity to review that proposed final draft before it's issued as final. Next slide, please.

One of the Commission-directed actions that resulted from the training and experience rulemaking plan that was just approved by the Commission was the development of training and experience implementation guidance.

The Commission directed us to produce this guidance to clarify expectations on how individuals who are subject to training and experience requirements can fulfill those requirements, as well as what is the role or what is the role and responsibilities of those individuals who are subject to those requirements in 10 CFR Part 35.

Although we do have substantial guidance on medical T&E criteria in NUREG-1556,

Volume 9, which is currently in its third revision, given the types of questions that we and Agreement State staff receive routinely regarding T&E requirements, we determined that supplemental guidance would benefit those individuals who are trying to apply for authorized user individual status, as well as answer questions from our licensees.

We established a joint NRC and Agreement State working group to develop this guidance, and on this slide here, you'll see some of the topics that we'll aim to expand on in this guidance, which include what's the purpose of T&E requirements?

You'd be surprised that with some of the questions we get is that fundamental question of purpose. Expectations for individuals that are subject to these requirements. For example, how we do address 35.27 and the requirements for supervision? What is expected of those individuals who supervise under 35.27?

Training, for example, including equivalency of hours, recentness of training under 35.59, vendor and device-specific training, preceptors and their roles in T&E requirements,

multiple authorizations, for example, our regulations allow for AUs and authorized medical physicists to also serve as RSOs, and also documentation and provide further guidance on how to complete the 313a forms.

So, we are currently drafting that licensing guidance and we plan to provide the guidance to the ACMUI for review and comment, I believe, sometime early next year. Next slide, please.

Another regulatory guidance effort that we're currently undertaking is the reporting of medical events. The development of comprehensive reporting regulatory guidance for the reporting of all medical events was something that was included in the staff requirements' memorandum for the extravasations rulemaking that we received in December of last year.

And so we are developing this guidance concurrently with the extravasation proposed rule, and so we plan to issue this guidance as interim staff guidance because what we are planning to do is issue guidance on current regulatory requirements for medical event reporting.

As you all know, some of those medical

event reporting requirements will change as we move some of those technologies out of 35.1000 into the current Part 35, and therefore, once we promulgate the final rule for the emerging medical technologies / rubidium-82 generator rulemaking, we will issue that rulemaking, that reporting of medical events regulatory guidance as final.

But we plan to make that available to the public as soon as the proposed rule comes out for extravasations, and so the ACMUI will also have a chance to look at that review and comment. Next slide, please.

Household waste from nuclear medicine patients, this is an effort that we're undertaking in part due to a recommendation from the ACMUI. In a non-medical events presentation a few years ago, the ACMUI noted that there is a decline in the number of events where alarms at waste facilities or landfills are triggered.

And so, as a reminder, we don't have reporting requirements for those types of incidents at the NRC, but the ACMUI is concerned that due to the resurgence or the use of new radiopharmaceuticals that are short-lived but may have long-lived impurities, that we may be seeing

an uptick in the instances of household waste that end up at landfills, but they're not reported to the NRC.

And so we issued a survey this year to the Agreement States regarding how common these types of incidents are, whether states have any programs in place to handle these incidents, and whether additional guidance or best practices are needed.

We've extended the comment period on that survey, and so we hope to have a presentation for you all in the fall of this year to address those comments and a final recommendation from the NRC on this issue.

And then for my last slide, so we have opportunities for engagement coming up with the medical team as I've shown here, and you'll see from other presentations today, the medical team is very busy. We have a lot of efforts ongoing.

For example, we will have a public meeting on the extravasation rulemaking and request for information next week on May 24. The public meeting notice is in the public meeting notice schedule that's available on the NRC's public website and Irene will probably be providing more

details later today.

As I mentioned, Reg Guide 8.39 has a proposed draft revision out for comment, and I believe we're having a government-to-government meeting with Agreement States this week.

The regulatory basis for emerging medical technologies rulemaking will be out in the next few weeks hopefully, and then we'll also have public engagements on that.

And last, but not least, we will be holding a workshop/public meeting in September of this year on the American Board of Radiology's termination, as well as training and experience pathways available to individuals who are seeking authorized status with NRC and Agreement States.

So, with that, I turn it back to you, Dr. Metter, to see if the ACMUI or the public have any questions.

CHAIR METTER: Well, thank you very much, Dr. Valentin-Rodriguez, for the very complete report. And really, again, I'd like to acknowledge and thank the NRC staff for their tremendous work. As you can see, they are doing multiple hats in different areas just for our work and to protect the public safety in regards to the medical use of

isotopes.

I open it up to any questions from the ACMUI. Seeing none, do I have any other comments from the NRC staff?

MR. EINBERG: No.

CHAIR METTER: Thank you. And now I would like to open the comment period and questions to the public.

MS. PINEDA: Once again, if you have any questions and you're joined by Teams, just click the little hand icon, and if you have joined on your phone, just press *5 to raise your hand and then *6 to unmute yourself after I call your name. Thank you.

CHAIR METTER: I believe there are no comments from the public?

MS. PINEDA: We do have a comment from the ACMUI member Dr. Harvey.

MEMBER HARVEY: Yeah, Richard Harvey. I've spoken with a number of people that have had some confusion about 8.39 and one of the reports or documents that came out from ACMUI about the recommendation of the occupancy factor being 0.25.

My personal opinion is that the occupancy factor should be flexible and up to the

licensee to decide with justification. I've had a number of people reach out to me and say that why doesn't the ACMUI let us use occupancy factors of one?

And I've tried to explain to them that they can use an occupancy factor of one and be more conservative, but they are just recommending 0.25 because it's more realistic. So I just thought I'd make that comment at this point.

CHAIR METTER: Thank you very much. That is a very important comment and it just changes a lot of factors too. Any other comments or questions for the NRC presentation?

Okay, seeing none, I believe we're ahead of schedule. We've been very efficient. Any other final issues before we go to break and come back for our afternoon sessions? Mr. Einberg, anything from the NRC?

MR. EINBERG: Nothing from the NRC here.

CHAIR METTER: Okay, so let me go ahead and I'll adjourn the morning session and let's come back at 1:00 for our afternoon presentations. Thank you.

(Whereupon, the above-entitled matter

went off the record at 10:48 a.m. and resumed at 12:59 p.m.)

CHAIR METTER: Darlene Metter and I'd like to invite you back to the 2023 Spring ACMUI meeting. I'm Darlene Metter, Diagnostic Radiologist and ACMUI Chair.

So we have a very exciting update and presentation scheduled for the afternoon, and I'd like to bring Dr. Jadvar, ACMUI Member, to give his presentation on Training & Experience for all modalities. Dr. Jadvar?

VICE CHAIR JADVAR: Thank you, Dr. Metter. It's my pleasure to present the report for the subcommittee who worked on this topic of Training & Experience for all modalities. So first, I want to thank all the subcommittee members including Dr. Ron Ennis, who was with this subcommittee, but his term ended in March of 2023; Dr. Richard Harvey, Dr. Darlene Metter, Megan Shober, Melissa Martin and also, I want to thank Maryann Ayoade for -- NRC staff resource who helped us throughout this process. Next slide, please.

These are the subcommittee -- the expanded subcommittee charges. If you recall, I did present the results of the first charge, but I

repeat them here again. The charges are to identify any potential impacts of the ABR's, American Board of Radiology, requests to terminate NRC recognition and other recognized boards identified during the NRC's evaluation of its specialty boards and provide recommendations to mitigate any potential impacts.

Charge number 2 is -- was to review and evaluate the NRC's current board recognition criteria and provide any recommendations for action. Next slide, please.

So, let's focus on charge one which I just mentioned. Next slide. These are the list of the NRC-recognized boards, so that certificate holders of any of these boards can request NRC to -- for them to be granted AU status. I'm not going to read over the boards in here, but I want to focus on the ones that are in red font. One is the American Board of Radiology and then we talk about the American Osteopathic Board of Nuclear Medicine and also the Certification Board of Nuclear Endocrinology. Next slide.

So, a little bit of a background about ABR. ABR was founded in 1934 as a non-for-profit organization and a member of the American Board of

Medical Specialties, or ABMS. And ABR is one of the 24 specialty certifying boards in medicine. This ABR certifying board is for diagnostic radiology, interventional radiology, medical physics under diagnostic, nuclear, or therapeutic as well as radiation oncology and also some subspecialties of radiology including nuclear radiology, neuroradiology and pediatric radiology.

The mission of ABR is to certify that our diplomats demonstrate the requisite knowledge, skill, and understanding of their disciplines to the benefit of patients.

If you recall, in December of 2022, we discussed this charge and our findings of the subcommittee, and we had Dr. Brent Wagner, who is the ABR Executive Director, also online and he answered our questions. Next slide, please.

So, prior to 2005, ABR actually did not provide AU AMP or RSO eligible designation on any of these board certificates. But for some reason, in 2005, they decided to do -- start doing that but as you see here, they're discontinuing this eligibility designation under boards -- you can see an example of that on one of the diplomas on the side -- in end of this year, on December 31, 2023.

So doing this basically 18 years, this eligibility designation was an option for candidates and again, this is going to disappear based on the decision on December 31, 2023. Beyond that, starting January 1, 2024, none of these designations will be available and candidates should provide relevant T&E documentation if they want to be "AU" directly through their employers to NRC so that their names can be added to their employer's RAM license.

These are the reasons that were put forward by ABR for why they made this decision, and this was published in a YouTube video that you have the address there on March 30th of 2022. They reasoned that this activity was not aligned with the core ABR mission, and it diverted limited resources that they had.

Also, they mentioned that ABR has never issued AU status and most radiologists are not and do not need to be AUs. ABR basically passed along documentation of T&E and direct pathway to becoming AU, which is the alternate pathway, already exists. AU requirement for 700 hours of T&E nuclear radiology is also an ACGME or a residency requirement, so the candidate provides -- gets that education through their residency training.

They also mentioned that the IR/DR Forms A and B are no longer needed. The two-page verification form that they provided in the past for radiation oncology is also not needed to be submitted to ABR starting January 1, 2024.

Their RISE questions, which are the radioisotope safety examination questions, are also not – they're still presented to the candidates. They should know the material, but they're not going to be scored separately. And they advised that trainees and programs should continue to keep their T&E documentation. In the case of the 16 months embedded nuclear medicine diagnostic radiology pathway and also for those folks who finish their diagnostic radiology residency and are interested in doing one year of fellowship in neuroradiology, they do have to have – keep all this T&E documentation so that they can sit for the examination.

And finally, they mentioned that the ABR change or decision is more cosmetic than substantive. Next slide, please.

So what would be potential ramifications for this ABR's decision? It was discussed that this may cause potential confusion

and challenges with burden that is now basically transmitted to the applicants and institutions for securing AU, AMP, or RSO status for the new hires. AU eligibility board certification was a rapid proof for AU eligibility and possibly ABR may have underestimated the burden that was being placed on the applicants, preceptors, and program directors. Some of these preceptors may be deceased or they may be unwilling to sign off if there is more than greater – greater than seven years window or if the preceptor was not involved to begin with with the applicant's T&E. So they may not be willing to sign off.

Despite those potential issues, we looked at some of the data that was gathered by some of the members from what the situation is right now. In California, it turned out that it takes four hours for license amendment for examining if a person is eligible for AU, and there are about 100 AUs that are added per year. There was no time difference between those who had ABR certification with that eligibility designation or the person applied through the alternate pathway.

Megan Shober told us that in Wisconsin, there was no apparent adverse impact on regulatory

agencies based on licensing databases that she went through in 2020 and 2021.

And the SECY-20-0005 rulemaking plan for Training & Experience requirements, also for unsealed byproduct material, mentioned that it takes about 15 hours for NRC to examine these applications, 11 hours for the Agreement States to examine these applications, and 5 hours that the licensees have to spend to prepare the application. Next slide, please.

So, when talking with Dr. Wagner, it turned out that somewhere between 67% and 95% and on average, about 80 percent of the ABR certifications actually included this AU eligibility on their certificates. However, it was unclear and he did not really provide us a specific answer regarding what percentage of these folks who have AU-E on their certificates actually eventually end up on broad licenses. I think we found out from Dr. Angle that the IR is estimated to be around 50 percent.

Also, there is no indication that other NRC-recognized entities will follow these particular decisions by the ABR. The other two boards that I mentioned I'm going to talk about is

the CB&E, the Certification Board of Nuclear Endocrinology. This board actually has dissolved and is no longer recognized by NRC. The American Osteopathic Board of Nuclear Medicine has been inactive since March of 2019 and is no longer recognized, and it was even small when they were active.

Now there are a number of venues that we suggested these could be still more discussed and, in fact, followed up with what the ramification is as we go into 2024 and beyond regarding potential impact, but these are some of the societies or organizations that we suggested including Association of University Radiologists, Society of Chairs of Academic Radiology Departments, Society of Chairs of Academic Radiation Oncology programs, and Association of Program Directors in Radiology. And these meetings can be helpful for discussion -- further discussion on this topic as necessary. And also, a recommendation was made to perhaps publish our findings and any other issues regarding this in Academic Radiology, which is the flagship journal for AUR. Next slide, please.

So, this is charge number 2 that was

added: to review and evaluate the NRC's current board recognition criteria and provide any recommendations for action. So, we discussed this through additional virtual meetings, and the documentation that the subcommittee looked at are listed on this page. I'm not going to read through them, but the decision was made that the certification by a specialty board coupled with recentness of training, less than seven years, was sufficient for receiving AU status on a RAM license. And in those cases, attestation by a preceptor is unnecessary. And subcommittee unanimously agreed that these documents are sufficiently -- the documents above are sufficiently comprehensive and detailed in that regard and no changes are really necessary at this time. Next slide.

So, these are my references for this report and next slides show the acronyms I believe. Yes.

That concludes my subcommittee report. Thank you.

CHAIR METTER: Well, thank you, Dr. Jadvar, for that very nice and complete review of those two very important questions posed to the

ACMUI. Do I have any comments or additions from the ACMUI subcommittee on Training & Experience? Any comments from the ACMUI? Mr. Green.

MEMBER GREEN: So, this American Board of Radiology is no longer going to have a process to have their graduates, their fellows come out with AU eligible. And it just makes me step back and think how that relates to nuclear pharmacists. On slide 5, there is a listing of the Board of Pharmaceutical Specialties as a recognized specialty board that pharmacists can avail themselves. But I want to point out to you that 100 percent of all nuclear pharmacists in America have come through the alternate pathway, because you have to work for two years as a nuclear pharmacist before you can sit for board certification. So ABR is becoming like nuclear, nuclear pharmacists. You -- if you want, you come in, you knock on the door, and you present your paperwork. And apparently, California and Wisconsin don't see any problems with it, so even though we're losing one, it's really no different than what's already happening today.

CHAIR METTER: Thank you very much. That's very --

MEMBER GREEN: And there's only 353 board-certified nuclear pharmacists in the world, so the rest of them are all AUs, and they've all come through the alternate pathway.

CHAIR METTER: Well, thank you for that very important information. Ms. Martin?

MEMBER MARTIN: I would just like to -- I think it's really important that we recognize the ABR is not changing the training that the residents will get. What is changing is the documentation method. And I don't know how we emphasize enough to the graduates of the future or the graduate program directors how important it is that they maintain that documentation of the residents when they're getting their training. I agree it's not going to be a problem for those relatively recent graduates that have their paperwork together.

The challenge is for that person that's been out 10 to 15 years and doesn't have their paperwork together. One question I haven't -- the question is, is the preceptor going to be acceptable -- is it acceptable to have another colleague at, say I want to go to work at XYZ facility, is it acceptable that the -- that one of the interventional radiologists or the nuclear

medicine guy, can they sign off as preceptor, or does it have to be the preceptor from the training program.

CHAIR METTER: Thank you for that question. So first of all, there is that issue of recentness of training. So, the training has to be less than seven years when you apply for authorized user status. And since I've been in an academic site with training residents and fellows for over the last 20 -- more than 25 years, those individuals who want to be authorized users will go ahead and keep track of things before 2005. And then now I think the ABR did make it easier for them, but now they're reverting back to pre-2005. So, in my opinion, if you want to be an authorized user and you know you will want to do that for the future, you will keep your training and experience requirements to be sure you meet them for the future. Any other comments?

MEMBER GREEN: And submit before seven years is up; otherwise, you're behind the eight ball.

CHAIR METTER: Yes, Dr. Harvey.

MEMBER HARVEY: Richard Harvey. I would say that, you know, the burden has shifted.

The alternate pathway, as Mr. Green says, it works fine. It does work fine and we can do this, but there will just be more of an onus placed on the licensee and the individual themselves, but it works. So, I think what we're doing make sense, and I don't know -- to Melissa's comment, I don't know if you could accept in lieu of a preceptor's signature a colleague's. I wouldn't think that that would be acceptable, but I -- that's really not my decision to make, so that's the way I would see it.

CHAIR METTER: I have another comment. I know when I spoke to Dr. Wagner, they were expending all these ABR resources on this AU eligible designation, but the issue was what was the conversion factor for those individuals who actually had AU eligibility on their diplomate certificate that the ABR actually converted to on a license. And the number, at least in my institution, is very small. We have over 50 faculty and we have maybe 4 or 5 of us that are AUs.

VICE CHAIR JADVAR: So, to kind of respond to Melissa's question, I actually want to ask if somebody from NRC can tell us if -- do they

accept if the preceptor is not from the same training program if it's more than seven years, and is somebody else from some other -- you know, some program they never -- no? Are there are any ideas on that or is -- there may be a problem?

MS. AYOADE: Good afternoon. This is Maryann Ayoade from the Nuclear Regulatory Commission. Can you all hear me?

CHAIR METTER: Yes, we can.

MS. AYOADE: Okay. Great. I apologize that I am not able to be there in person today, but I'm still here and I'm following along with the discussion. For the preceptor authorized user, or the preceptor requirement is that that individual has to be an authorized user that meets the training and experience requirements that the potential authorized user or authorizing individual is requesting, so for the same types of uses. And as far as -- I believe Dr. Metter mentioned this -- you know, if it's beyond the seven years, if it's 12 years, they have to show continuing education, you know, as it relates to what it is that they've been doing since that time. And the continuing education has to be within the seven years along with whatever supervised work experience that

they're receiving from an individual that we also accept as a supervising individual, which also has to be an authorized user.

In the last rulemaking that was finalized in the 2018 -- it was issued in 2018 and was implemented since that timeframe, three years for Agreement States, it did allow residency program directors to act as preceptors as well, but there is a caveat to that requirement where the residency program director is affirming, you know, that the attestation represents the consensus of the residency program faculty, but at least one faculty member has to be an authorized user that meets the same requirements that that individual is requesting. So that was another option for a preceptor individual that was added in that last rulemaking that was issued back in 2018-2019 timeframe.

CHAIR METTER: Thank you, Ms. Ayoade for that clarification. Any other comments? Yes, Dr. Harvey.

MEMBER HARVEY: I'm still slightly confused, so I apologize. Can somebody else other than the preceptor that the physician trained under, can someone else act as their preceptor and

sign off on the NRC 313A form, "yes" or "no?"

MS. AYOADE: The only individuals right now that are able to act as a preceptor are the authorized user and the residency program director and that's it. And that's in the training and experience requirements for each type of use. So, if you go to, for example, radiopharmaceuticals, 10 CFR 35.390, 490, you'll see that there under the alternate pathway.

MEMBER HARVEY: Richard Harvey. So, if a physician comes to a new organization that, say, director of nuclear medicine wants to sign off as that person's preceptor, they can do that?

MS. AYOADE: If that individual that wants to act as a preceptor is an authorized user that meets the same requirements that that new individual is requesting for, yes. And the thing about it is, it's the – you're signing off on the work experience. You have to get supervised work experience, right, with the areas it is that they're requesting for use. And so that is what, you know, brings it into the NRC space as far as supervised work experience.

MEMBER HARVEY: Thank you, Ms. Ayoade. So, somebody that is -- was not their preceptor

during their residency or fellowship can act as a preceptor and sign off for them?

MS. AYOADE: That's correct. The regulations don't preclude or limit it to the authorized user that was at their previous, you know, training program.

MEMBER HARVEY: Richard Harvey. Thank you very much, very much appreciated that clarification because it wasn't really clear to me, and I think that we definitely need to understand that going forward. So, thank you very much, Ms. Ayoade.

MS. AYOADE: Any other questions from members of the ACMUI? Yes, Ms. Martin.

MEMBER MARTIN: Just thank you, Maryann, for that clarification, because Richard and I had the same question, and it's particularly coming in with the Y-90. You know, we've got people coming in that did not know 10 years ago they were going to want to use Y-90. They're willing to go through the training from the manufacturer. They're willing to do their three cases under supervision. They -- we just need to make sure that it was very clear that the current staff member that is at Facility A that is already

approved to do Y-90 procedures can serve as preceptor for the new applicant.

CHAIR METTER: Thank you. Yes, Dr. Einstein.

MEMBER EINSTEIN: (Off microphone) -- fellowship program directors as well, if so should probably state residency or fellowship program.

CHAIR METTER: Okay. Thank you very much for that comment. Any other suggestions or comments from the ACMUI members? NRC staff? Maybe open up to the public for comments and questions. I see Ms. Ashley Cockerham there standing at the podium, so do you have any questions or comments?

MS. COCKERHAM: Sure. Ashley Cockerham with Orchestra (phonetic) Life Sciences. And I think the key word to clarify on which AU can sign off is that it is an AU, not the AU. So, if you are an AU for that type of use, you can sign off for someone else. And for the example that Ms. Martin gave as someone who's done well over 100 of these amendments specifically for Y-90 over the last several years, it is very often that you cannot get the original AU to sign off on something. They may or may not have done those cases in that time period, and so it is "an" AU who

provides the attestation. You also have situations where the training is provided piecemeal, right, so maybe a certain number of hours is done in this time period at this facility and then another section here and typically, you're only going to have one attestation at the end of all of that for the cases, and that would be from an AU who is authorized or a residency program director, as Ms. Ayoade said, who is -- where at least one faculty member is an AU for that type.

I also wanted to make a comment on one of the slides where it said the number of authorized users that are coming through the board certification pathway specifically for interventional -- right there, yes -- for interventional radiologists where it says "estimated at 50 percent," again, I've been working in this space, I guess, since 2016 when I left the agency, and I would say in the hundreds of amendments that I have seen, there have been a handful come through the alternate pathway documenting the 80 hours. The documentation is inconsistent at best, and it is very difficult to obtain. I'm usually literally the person emailing an RSO at a facility saying "can you connect me to

the radiology department," saying, "can you connect me to the nuclear medicine department" trying to dig up these documents. It is extremely difficult to pull the documentation together. It is doable. Obviously, it's done in nuclear pharmacy. We've seen it in other types of uses, but I feel like I have a pretty good perspective on what it's like for IR, and it's not an easy task either for the RSO's who are trying to pull the documentation together just to get a simple amendment through. And then for the regulators who are receiving that documentation, it also takes significant more time to do that review from the perspective of the applicant.

CHAIR METTER: Well, thank you very much for that in real world practice challenges that we have with authorized user status. Any other comments from the public?

MS. PINEDA: Oh, okay. Looks like we do have a comment or questions from Ralph Lieto. Go ahead.

MR. LIETO: Thank you. Actually, Ashley kind of stole a little bit of my thunder, because I wanted to simply underscore her comments about the process to get an AU on a license. I

think it's kind of misleading in the time values that were given because basically, what you're asking is the keepers of the house how long it takes them to do something. You -- I think it would be more apropos to ask the licensees how long it takes from the time period that they acknowledge receipt by the regulator to the time that they get the actual amendment, because it takes much, much longer. It's measured in weeks. I experienced that for decades as an RSO in getting AUs authorized on a license simply because either due to volumes of things that the license reviewer is dealing with or whatever, that it is not a short turnaround time for getting an AU authorized by the alternate pathway. It is much longer than the time periods that were given in these slides. So I think that needs to be understood, and I think the fact that now everybody that's going to probably be submitting information for an AU is going to be doing it via an alternate pathway mechanism, I think it's important that we look at some ways of expediting both the documentation methodology and the approval process. Thank you.

CHAIR METTER: Thank you for your comment on that. I do see another individual at

the mike. Go --

MS. TOMLINSON: Hi. Cindy Tomlinson with ASTRO. So, a couple of things I wanted to mention. One is ASTRO now has a page on our website that's sort of outlining its very -- very -- 30,000-foot level, very broad umbrella outlining what programs can do and what trainees can do to make sure that they're leaving their programs with everything intact, so all of their paperwork, all the forms.

The other thing I wanted to mention was I do know that CRCPD did query the states on things -- some of the questions were, "Will you accept the NRC's 313A forms instead of your own state form" which would -- as trainees are leaving their programs, if they just have one form to fill out, right, and it's all filled out and they're ready to go, it doesn't matter if they're moving from California to Idaho, you know, whatever, or from an Agreement State to an NRC state if the current states will accept those.

But they also did ask about time -- how much time, and they asked a few other questions. I would recommend the ACMUI get in touch with CRCPD to get that data. I think -- I don't have it here

readily accessible. It wasn't a ton of states that responded to the survey, but it is useful information. And they did ask a few other questions. Off the top of my head, I don't remember what they are, but those were some of the questions that they asked.

CHAIR METTER: Thank you for that. Ashley Cockerham has another comment.

MS. COCKERHAM: Ashley Cockerham again. I wanted to add one additional piece that ties back to the AU verification. So when an AU does provide an attestation for another physician who is the applicant essentially, right, the Agreement States, we've really seen an increase in the diligence. They're following up on the AU status of the attester, and so not only do you need a copy of the license of the individual who's providing attestation, generally, that AU who's providing the attestation is on a broad scope license. The broad scope license does not name authorized users as individuals. So now you need a second piece of documentation, that is a letter from the RSO at the facility of the AU who is providing the signature. I regularly provide these and it's great due diligence on the Agreement State part. I'm not --

that's not the intent of my comment. I think I want everyone to understand the level of documentation and detail that's needed, and this would be for the RSO who is trying to submit the amendment. You're essentially going to your peers saying "can I get a copy of your license because your doctor is signing off on my doctor," and then get an individual letter as well. So that was one piece.

And then Cindy brought up a great point on the NRC 313A and while it would be wonderful to have a consistent form that worked for everyone, I can say there are many Agreement States who do not accept the NRC Form 313A and two, it is essentially useless when it comes to Y-90 amendments. Nothing on the NRC Form 313A is relevant to a Y-90 microsphere application. You need to create a from-scratch letter that is custom to that IR physician. So, a form is not always the answer, and we're not always going to get consistency at the Agreement State level.

CHAIR METTER: Well, thank you very much for that very important several pieces of information on that. Are there any other comments from the public?

MR. EINBERG: This is Chris. Maryann, do you want to clarify or answer the question --

MS. AYOADE: Yes.

MR. EINBERG: -- that Dr. Einstein had regarding the fellowship directors?

MS. AYOADE: Yes. Dr. Einstein, can you again just say your question again for clarity for everyone so that I don't -- I make sure I don't say it incorrectly? Hello?

If Dr. Einstein is speaking, I cannot hear him.

MEMBER EINSTEIN: Can you hear me now?

MS. AYOADE: I can hear you faintly.

MEMBER EINSTEIN: Test one, two, three. I'm going to change microphones. I think this is probably much better.

MS. AYOADE: Yes, much better.

MEMBER EINSTEIN: Okay. In 35 CFR 290(b)(2), for example, I think among other places, there's the verbiage the attestation must be obtained from either one, a preceptor authorized user who meets the requirements in 35.57, 35.290, or 35.390 and 35.290(c)(1)(2)(g) or equivalent Agreement State requirements, or two, a residency program director who affirms in writing that the

attestation represents the consensus of the residency program faculty, etcetera. In many cases, individuals will be training not in the context of a residency program but in the context of a fellowship program. That would be applicable for nuclear medicine fellows, you know, as distinguished from radiology or nuclear medicine residents. That would be the case for cardiology fellows or for cardiac advanced imaging fellows. And I'm sure there are other scenarios, too, but the verbiage specifically uses the term residency program director. Like a cardiology fellow who did their internal medicine residency somewhere else, the internal medicine residency director really has nothing to say in regard to use of radioisotopes; whereas the cardiology fellowship director and particularly like an advanced imaging fellowship would be a much more appropriate person to opine on an individual's qualifications. I guess that was a statement, not a question. So, the question is I mean should one interpret the term "residency" in a broad sense to incorporate fellowships, or should the term "fellowship" be added to this regulation?

MS. AYOADE: Thank you for your comment, Dr. Einstein, and I'm glad that you

restated your question with the additional information. So, that is a good comment that you brought up. Our regulations, as far as the board certification criteria, that's where you start to see the introduction of residency programs that are approved by the ACGME. That's the Accreditation Council for Graduate Medical Education. And that Accreditation Council, it's an organization that credits, as you all are maybe aware, both residency and fellowship programs. And so, we have received this question as far as the attestation requirement, and we have discussed with our legal counsel, and they have said that as long as the fellowship program meets the same requirements, so meets our same NRC regulatory requirements for a residency program, then we should be able to recognize that fellowship program. And so that's as far as that part of your comment.

MEMBER EINSTEIN: And what are those requirements? Is being ACGME-accredited sufficient for meeting NRC requirements, or there are additional requirements? I point out that all general cardiology fellowship programs -- I'd have to look into whether that's the case for osteopathic cardiology programs, I'm not sure, but

all allopathic cardiology programs are ACGME-accredited. Advanced cardiac imaging fellowships which often provide, you know, up to two years of training in use of radioisotopes are not ACGME-accredited currently.

ACGME has introduced a new category called NST, I think, Non-Standard Training program, which is used in the context -- and it's come up in the context of who's eligible to get a J1 visa to -- for non-U.S. citizens to participate in those programs. So, they call programs nonstandard programs, but they're not ACGME-accredited programs in cardiac imaging, for example.

So, it would be helpful to have clarification as to what constitutes a program meeting the standards for a residency program per the NRC.

MS. AYOADE: Thank you, Dr. Einstein. So, to respond to that, our requirements for the board certification pathway, you know, it asks or requires that all candidates that are going through that certification have to successfully complete their residency training in a related medical specialty. But in addition to that, the residency training program must meet all of our training and

experience requirement, classroom and laboratory hours and also our work experience hours. And that is in addition to the training program being approved by the ACGME.

And so, what we do when we receive an application from a specialty board saying that they want to be recognized for this specialty area, we do, you know, confirm that their training program is ACGME-approved. But we go through their criteria and we make sure that -- just as it is -- and it's written in the regulations -- just as it is in the regulations, we have to make sure that their program has at least, if it's 35.390 for radiopharmaceuticals, the 700 hours of training and experience, both in the classroom and laboratory, which requires a minimum of 200 hours of classroom and laboratory training as well as the work experience. And so just having the ACGME-approved training program doesn't just get you there.

MEMBER EINSTEIN: So, I would contend that not all radiology residencies provide those 700 hours and certainly for cardiology fellowships, it's -- there's different tracks which trainees can take. Say someone wants to become a cardiac electrophysiologist, which is an additional board

examination and ACGME-accredited specialty. In general, they're not going to complete 700 hours, they're not going to have 80 hours of coursework. However, in the same fellowship training program, you can have someone who's interested in pursuing cardiac imaging, and they will do that. So it's sort of an optional module within a training program.

CHAIR METTER: Okay. This is Darlene. Can I say a comment here as part of a residency program for radiology? It is a radiology ACGME program requirement for 35.290, which is that 700 hours and 80 --

MEMBER EINSTEIN: I stand corrected then on that point but certainly for cardiology fellowships, it's not a requirement for the program but something which a trainee who is pursuing a career in noninvasive cardiology or cardiac imaging will generally pursue. But there are colleagues who are pursuing advanced heart failure or cardio electrophysiology are not going to pursue that, so it's not a mandatory part of the program, and it would be a shame for that not to be recognized. You know, you can have one training program which fits the needs of different trainees and is

rigorous. I'm happy to share, you know, the requirements which we have in my program for trainees to get my signature so that they can take the CBNC exam, and that addresses American College of Cardiology requirements, CBNC requirements as well as NRC requirements, all of which are spelled out in what we -- in writing for what we require of our trainees who want to pursue that avenue within the training program, but it's not a mandatory part of the training program itself.

CHAIR METTER: Thank you so much for that clarification.

MS. AYOADE: This is -- okay, I have some more comments or clarification. Again, as I mentioned, our regulations don't preclude, you know, fellowship programs to be considered as a type of residency program but again, as long as that fellowship program meets our regulatory requirements for a residency program. That requirement to be an ACGME-approved residency program is -- again, it's not the only requirement but it's very important, and we've had some discussions with some members of the ACMUI including Dr. Metter about how during some of our review process with specialty boards, they have

submitted the ACGME requirements and it didn't include all of the topic areas that we require, right, and so that's an example of how yes, it has to be ACGME-approved, but the specialty board is also responsible for meeting our training and experience requirements. So they have to make sure that all of the candidates that they're approving have gone through all of the required classroom and laboratory hours, work experience hours.

MEMBER EINSTEIN: That's an important point you just raised. You said all of the candidates they're approving, not all of the candidates who -- not all of the trainees in that program so --

MS. AYOADE: All of the candidates they're approving for NRC-recognized specialty boards. And I say that because ABR gives certificates that don't include that AU-eligible designation, correct? And so as long as it has that AU-eligible designation, that lets the candidate know that, oh, I can -- I have met NRC's requirements and I can use my board certificate through the board certification pathway because this certification from ABR has guaranteed that I have met all of NRC's training and experience

requirements.

CHAIR METTER: Thank you for that clarification, Ms. Ayoade, and for your comments, Dr. Einstein. I'd like to make one comment and since I was on the Nuclear Medicine RRC for the ACGME, you know, ACGME program requirements change. And so, you know, they can change over time so then if they decrease some of their training, they may not meet the NRC recognition criteria. Just a comment. Dr. Harvey has a comment.

MEMBER HARVEY: Richard Harvey. Thank you. So, an RSO licensee, if somebody comes to me with a preceptor signature for a residency or fellowship program from Facility X, how do I know that that location is compliant and certified and they can sign off as this person's preceptor? How do I know that?

MS. AYOADE: Is that question -- this is Maryann Ayoade. Was that question for the NRC, Dr. Harvey?

MEMBER HARVEY: Anybody, I guess, that can answer it. So, you know, somebody comes from, you know, Facility X and how do I know that they meet your requirements?

MS. AYOADE: So one of the things if --

I could start on NRC's end. You know, one of the things that our license reviewers -- which is also part of the 313 Form -- is it asks for the license number where that individual is currently listed on the license or the facility where they're acting as the residency program director. You have to ask for documentation showing all of the requirements that are required.

MEMBER HARVEY: Richard Harvey. So somebody comes to me and I have to go to that residency or fellowship program and ask for that documentation to prove that they're compliant with the NRC's regulations in order to accept that preceptor certification?

MS. AYOADE: Dr. Harvey, can you just restate your last question?

MEMBER HARVEY: Yes. So, I have somebody that comes to me that did a residency or fellowship somewhere. They have a preceptor signature from that location. I do not know if that location is NRC compliant with your regulations. How would I know that and how would I know that I can accept the certification of that residency or fellowship program director because their program is compliant with the NRC's

regulations? How do I know that, or do I have to actually ask them for documentation to prove it? Thank you.

MS. AYOADE: You have -- you should be asking for documentation to prove it. As I mentioned earlier, that requirement is not just for the residency program director. He has to be, you know, part of a program or faculty where at least one other faculty members is an authorized user that is listed on a license, whether it's NRC or Agreement State, right. So, you should be able to ask for documentation of the license that lists who the authorized user is, who the residency program director is saying this person is also part of our faculty.

MEMBER HARVEY: Richard Harvey. Maryann, thank you. So, I understand the whole licensing aspect of it and the AU having to be licensed for that and getting the license, and we do that. But now I think what you're saying is that I have to get proof that the residency or fellowship program is compliant with NRC regulations in order for me to accept that preceptor certification. Do I misunderstand? Thank you.

MS. AYOADE: No. That is correct. So that is what comes with the additional option of having a preceptor other than what we used to have, which was just the authorized user, right. Now we have the option of the program -- or residency program director. And so that, you have to verify that as well.

CHAIR METTER: Well, thank you Ms. Ayoade. I believe Ashley Cockerham has a comment regarding this issue.

MS. COCKERHAM: This is Ashley Cockerham. I was just going to give you the short answer to that. Based on my experience, the answer is yes, and I spend hundreds of hours every year, me and my team of consultants, doing exactly that because that is what is required.

CHAIR METTER: Thank you. Dr. Einstein.

MEMBER EINSTEIN: What constitutes sufficient evidence that this outside facility with which you're not familiar at all meets NRC regulations? I think that's the crux of the matter, right? Like how do you prove it?

MS. COCKERHAM: Do you want the real answer? It depends on your license reviewer, and

it depends on your radiation safety committee. If it's a broad scope license, then it's an internal radiation safety committee. It's their decision so it would come to the RSO and that radiation safety committee. If it's an Agreement State, it is absolutely their decision. And if it's the NRC, it is their decision and it varies from license reviewer to license reviewer.

CHAIR METTER: Yes, Dr. Harvey.

MEMBER HARVEY: Richard Harvey. Thank you very much. So as a broad scope licensee RSO, you're saying that we make that determination. What if I make that determination and that fellowship or residency program is not compliant with the NRC? Then as an Agreement State, my Agreement State regulator is going to find fault with what I did. So I don't know if there could be a listing somewhere of all of the compliant residency-fellowship programs that would be easily accessible for people to look at or something along those lines. Thank you.

MR. EINBERG: Dr. Metter, this is Chris Einberg. You know, this is all excellent feedback and as Celimar pointed out earlier, we're developing T&E implementation guidance, and all of

this is great feedback for consideration during the development of this guidance. And, you know, the ACMUI will have an opportunity to review that, the implementation guidance. And, you know, so the target is to have interim guidance developed next August, August in 2024. So (audio interference).

CHAIR METTER: Thank you --

MEMBER WOLKOV: Dr. Wolkov, second.

CHAIR METTER: And Dr. Wolkov is a second. Any more discussion? All in favor, say aye?

Oh, yes, I'm sorry.

MS. AYOADE: Hi, Dr. Metter. I apologize. This is Maryann Ayoade from NRC and for those of us that were virtual, the screen did cut out for like maybe the last 45 seconds to a minute. But I did want to just make an additional comment and just to clarify a couple of things. The NRC 313 Form is something, as Chris mentioned, we are also reviewing as a part of that training and experience implementation guidance recognizing that, again, that is a guide or a way for our licenses and even our license reviewers to help them in the process as they receive information for license reviews. We are also -- there is -- as

Ashley mentioned, there isn't anything for the Yttrium-90 training and experience under the 313 Forms, but it can be used as a starting guide.

The other thing I wanted to mention is all of the information that individuals will be submitting on the training and experience alternate pathway is not different from what is being submitted to the specialty boards with the exception of the preceptor attestation really. As some of you have mentioned during this presentation, if people are encouraging their physicians, their potential authorized individuals to make sure that they're keeping track of their training and experience as they go along and not just wait until the last day to try to figure out, you know, what documentation do I need, who's supposed to sign off on this part of my work experience, who's supposed to sign off on the preceptor attestation. And so, we're encouraging people to keep track of their training and experience documentation as they go along, use the 313 Form in addition to guidance that we have in our NUREG-1556, Volume 9. But again, that's something that we are currently looking at wholeheartedly as part of this working group,

because we want to make sure that we're being clear in how individuals may or should be able to meet our training and experience requirements now and moving forward.

CHAIR METTER: Thank you very much for that clarification and update, Ms. Ayoade. Any other issues, any other discussion on this topic? Okay. All in favor for the report as presented, say --

(Chorus of aye.)

CHAIR METTER: All opposed or abstained?

Thank you very much. The ACMUI Committee is unanimous in approving the report of Dr. Jadvar on Training & Experience.

So, our next topic is extravasation and rulemaking by the NRC staff, Irene Wu.

MS. WU: Hi, can you all hear me okay?

CHAIR METTER: Yes, we can.

MS. WU: Okay, great.

Well, good afternoon. Thank you to the ACMUI for the opportunity to give you an update on the extravasations rulemaking.

I'm Irene Wu, the Project Manager for this rulemaking here at the NRC and, specifically,

I'm in the Materials Rulemaking and Project Management branch in the Division of Rulemaking, Environmental, and Financial Support in the Office of Nuclear Material Safety and Safeguards.

So next slide, please? So, this is the agenda for my presentation today. First, I'll give you some background on this rulemaking. And when I went back to sort like the last ACMUI meeting agendas where I saw extravasations on there, it looked like it was back in the 2021 timeframe when there was a subcommittee reviewing the NRC staff's evaluation of extravasations and medical event reporting.

So, I'll briefly cover that and then, focus more on the more recent activities including the petition, the rulemaking plan, and the latest Commission direction that we received.

And then, next on the agenda is the information request and preliminary proposed rule language which we published last month in the Federal Register.

And then, after that, I'll talk a bit about our next steps for this rulemaking.

So, we actually have a public meeting next week on the information request, so I'll talk

a little bit about that and what the schedule looks like for the proposed rule. And then lastly, I'll answer any questions you have.

So, yes, next slide, please? So back in 1980, the Commission amended Part 35 to require quarterly reporting of diagnostic misadministrations and prompt reporting of therapeutic misadministrations.

And in that 1980 final rule, the Commission had excluded radiopharmaceutical extravasations from the reporting requirements stating, in part that, extravasation frequently occurs in otherwise normal intravenous or intra-arterial injections. It's virtually impossible to avoid, and therefore, the Commission does not consider extravasation to be a misadministration.

So since then, I know the ACMUI has, over the years, looked at whether extravasations should continue to be excluded from medical event reporting. I think there was some look-see at the 2008, 2009 timeframe and then, again, more recently in 2019.

Next slide, please? So, at that brings us to the NRC staff evaluation. If you recall, that was in the January 2020 timeframe where staff

began this independent evaluation of whether extravasations should be reported as medical events.

And as part of that independent evaluation, we wanted to hear from the medical community and other stakeholders.

So, we had a public meeting in December of 2020 to provide information on the staff's evaluation and I provided on the slide the ADAMS accession number for the public meeting summary, that being ML21005A436.

And then, staff had the opportunity to provide its preliminary evaluation of reporting extravasations as medical events to the ACMUI. And at a high level, that evaluation contained, I believe it was six options with a mixture of some rulemaking options, non-rulemaking options, and then, we always include the no change option.

And the recommendation by staff was that extravasation events that require medical attention be reported as medical events.

And all of the non-rulemaking options were dismissed since staff determined that extravasations don't fit into the current medical event reporting criteria.

So, I have here on the slide that the ACMUI agreed with the staff recommendation during their September 2021 public meeting. And the ADAMS accession number for that September 2021 ACMUI meeting is on this slide.

All right, so next slide, please? So that brings us to the petition for rulemaking. So while the NRC staff evaluation was going on and progressing in 2020, we received a petition for rulemaking from Lucerno Dynamics in May of 2020 requesting that NRC revise its regulations to require medical event reporting of extravasations that result in a localized dose equivalent exceeding 50 rem.

And in the -- later that year, I think it was in September, we published a Federal Register Notice announcing the docketing of that petition.

We had a 75-day comment period. And we received close to I think 500 comment submissions during that comment period.

Then, in the May 2022 timeframe, staff then provided a rulemaking plan, that being SECY-22-0043 to the Commission that presented options for amending Part 35.

And in that rulemaking plan, staff recommended including as reportable medical events nuclear medicine injection extravasations that require medical attention versus expected radiation injury.

Staff, also in that rulemaking plan, committed to developing regulatory guidance for the reporting of extravasations, including the development of a dosimetry model that the medical community could use to help in characterizing extravasations.

And then, in December of 2022, the Commission issued its staff requirements memorandum, SRM SECY-22-0043, directing NRC staff to begin a rulemaking amending NRC's regulations to mandate medical event reporting of extravasations that require medical attention for a suspected radiation injury.

The Commission also, in that staff requirements memorandum, also directed staff to explore approaches to reduce reliance on patient reporting, develop regulatory guidance for all medical events, and to look for opportunities to accelerate the rulemaking schedule without shortening or shortchanging the public comment

periods.

Next slide, please? So, that brings us up to present day and the information request that we published in the Federal Register last month.

So, I'll step back a moment and say that, to gain efficiencies in the development of this rule, staff decided to proceed directly into the development of the proposed rule.

So, therefore, instead of developing a regulatory basis, we decided to rely on this information request to address the direction by the Commission.

And again, this is the information request that was published last month, 88 FR 24130, with a 90-day public comment period, consistent with the direction we got from the Commission to not shorten the public comment periods.

And the notice made the preliminary proposed rule language for the rulemaking available and also posed questions to obtain input from the stakeholders.

Next slide, please? All right, so the preliminary proposed rule language includes updates to two sections which I will step through in the subsequent slides, and that being 35.2, the

definition section, as well as 35.3045, which is the report and notification of a medical event.

And then, we also added to -- the preliminary proposed rule language includes the addition of two new sections, one for procedures for evaluating reporting extravasations, and then, with that, another section for the records for those procedures for evaluating and reporting extravasations, all of that being in Part 35.

And then, as I mentioned before, the information requests included not only made the preliminary proposed rule language available, but it also put forth a set of questions that we have grouped into three topics, those topics being definitions, procedures, and health care inequities.

So, for the next set of slides, I'll go through the preliminary proposed rule language for that grouping, that topic, and then, discuss the associated questions at a very high level that were in the Federal Register Notice for that topic.

And I do want to say as a disclaimer, which is on the previous slide, that the preliminary proposed rule language does not represent the final NRC staff position, nor has it

been reviewed by the Commission.

So, therefore, the preliminary proposed rule language may undergo revision during the rulemaking process.

Next slide, please? All right, so, again, we're going to start with the topic of definitions. And here is the preliminary proposed rule language for -- in Section 35.2, definitions.

The text in red on the next set of slides, including this one, show the new language being considered in the regulations.

So, we are initially putting out there three new definitions, as you see here, one for extravasation, one for medical attention, and one for suspected radiation injury.

Extravasation is sort of the word we're as opposed to infiltration. And in this case, our definition, or our proposed definition for extravasation is very specific to radiopharmaceuticals.

The medical attention definition, you know, we debated this one a lot. And we're not too sure if it's too broad or not, but that's why we're seeking public input on this preliminary proposed rule language.

And then, the suspected radiation injury definition needs to cover both notice and unnoticed injuries. And so, we're looking specifically at the lowest severity of skin deterministic effects such as erythema.

Next slide, please? So, here are the three questions that we have in the Federal Register Notice related to the new definitions that we included in the preliminary proposed rule language.

The first question is about what term is best for us to use when describing the leakage of radiopharmaceuticals from a blood vessel or artery into the surrounding issue.

Again, we -- we're using extravasation right now, but we want to hear if perhaps a different term would be better.

The second question is asking about the criteria we should use to define suspected radiation injury.

And the third question is getting at what -- to reduce the chance, severity, or symptoms should be included in the definition of medical attention.

Next slide, please? All right, so,

here again, is the second grouping which is procedures.

So, here's the preliminary proposed rule language for a new section, which is Section 35.42, procedures for evaluating and reporting extravasations. So, we used 35.41, procedures for administrations requiring a written directive sort of as a template for developing this preliminary proposed rule language. So, you should see it structured quite similarly.

The procedures here are being used to reduce the chance of an extravasation as well as the severity of the symptoms.

And with this potential regulation, licensees will need to have good techniques to be able to identify whether or not a radiation exposure will lead to an injury. So, this would most likely be through our dosimetry model, but we're leaving it up to the physicians themselves.

Next slide, please? Okay, and then, here is the preliminary proposed rule language for a new Section 35.2042 records for procedures for evaluating and reporting extravasation.

So, again, this is trying to parallel what was done in 35.41 and 35.2041, we're doing the

same here for 35.42 and 35.2042.

Mainly, it's to keep the record requirements in Subpart L of Part 35. So, we've included the preliminary proposed rule language for this new section for records for procedures for evaluating and reporting extravasations.

Next slide, please? Okay, so I think this is the last set of preliminary proposed rule language. This is for 35.3045 report and notification of a medical event.

This section currently has, you know, the instances when a licensee shall report any event as a medical events. So, we've -- we're proposing to add a third instance here for when a licensee shall report an event as a medical event, which is in the -- which is the administration of byproduct material that results in an extravasation that requires medical attention for a suspected radiation injury.

Next slide, please? Okay, so this is -- so now, for the procedures corresponding with the procedures preliminary proposed rule language, we have the most question here in the information request and related to those procedures.

So, the next three slides, actually, go

through those questions in the information request.

The first question under the procedures topic and the fourth question in the notice is about minimizing the change of the -- minimizing the chance of extravasations.

The next question, or question five in the Federal Register Notice, is about the immediate steps that should be taken after an extravasation occurs.

And question six here is about how we can determine if an extravasation occurred.

Next slide, please?

Continuing on to question seven, this is about post extravasation activities, things that a doctor can do following the event while the patient is still in the hospital for care.

Question number eight is getting at what should be included in sort of an informational sheet for patients that can be handed out to help identify possible injuries and where to go if they experience them.

Question number nine is related to the discovery of an event which then has a lot of implications for the timing of reporting. And you'll see we also have another question on timing.

Next slide, please?

All right, I think these are the last three for procedures.

So, question number ten is another question on timing, specifically when licensees should be required to provide notification of an extravasation medical event to the referring physician and individual.

Question number 11, we're trying to get at what medical professional has the skills needed to identify the severity of these extravasation.

And you see that as part of the question, we included a few examples of who that might be to help the public in answering the question.

And question number 12 is about what topics should be included in the guidance document that we're developing along with the rule package.

Next slide, please? All right, so this is the last slide on the information request questions with the last two questions related to the topic that we've labeled as health care inequities.

Now, we don't have any preliminary proposed rule language related to these questions,

but we wanted to include them in the information request because we had heard from some patient safety groups with concerns about the inequities in the health care community. And so, we're looking for input on how this rulemaking can effectively address these concerns.

Next slide, please? All right, so just to highlight how the public is able to submit comments on the Federal Register Notice for the information request.

So, I mentioned earlier that this information request Federal Register Notice was published on April 19th with a 90-day comment period.

And as outlined in the Federal Register Notice, there are three methods for the public to submit comments.

They can either go to regulations.gov and go to our specific docket, Docket ID NRC-2022-0218 and submit a comment that way. They can also email us with their comments.

And they can also put their mail -- post mail their comments to us as well on the -- the email and the address are both included in the FRN as well as the docket ID for the regs.gov.

Next slide, please? So here are our next steps. We are having a public meeting, as I said earlier. We're going to have it next week on May 24th to facilitate feedback and answer questions on the information request.

We won't be actually collecting comments at the public meeting as we want the comments to be on the rulemaking docket. So they're going to be needed to be submitted via the methods I talked about on that previous slide.

But the -- and if anybody is interested in -- that's listening that wants to be -- participate in that public meeting, that information is available on the NRC's public meeting website.

As I've said a few times, the public comment period for the information request ends on July 18th.

And then, the proposed rule right now is currently estimated to go to the Commission in August of 2024.

So, what that means for the ACMUI is we'll be planning to give the ACMUI an opportunity to review the draft proposed rule before it goes to the Commission. And right now, we're estimating

that time frame to be in the -- sort of the March to May 2024 time frame.

And after the proposed rule goes to the Commission, the Commission still has to vote and provide direction for the staff in a staff requirements memorandum, or SRM, before we can publish the proposed rule for the -- in the Federal Register.

And right now, again, just an estimation that that would be around the December 2024 time frame.

So next slide, please? With that, that is the end of my presentation. I'd be happy to take any questions that you may have.

CHAIR METTER: Thank you, Ms. Wu, for that very thorough and very in-depth presentation on extravasations. And I really appreciate the NRC staff on their work on this.

Do I have any questions from the ACMUI for Ms. Wu?

We have -- okay, we'll go this way.

Dr. Harvey?

MEMBER HARVEY: Thank you, Richard Harvey, apologize.

I guess I have the dissenting

viewpoint. I think extravasations are a very important quality assurance issue for the hospital, clinic, or licensee. But I don't feel it should be an NRC medical event.

That's my comment.

CHAIR METTER: Thank you.

Mr. Green?

MEMBER GREEN: Thank you.

Appreciate the presentation, Ms. Wu.

I'm a little bit flustered by the use of the term extravasation.

We're trying to get a drug into a confined space and that space typically is in the venous -- in the circulatory system. It could be arterial or it could be venous.

And what we're looking at is stuff that doesn't get in there or leaks out.

There are other confined spaces that radiopharmaceuticals are injected into like intrathecal for radionuclide cisternography with indium-111 pentetate, or DTPA.

There are drugs that are no longer on the market such as chromic phosphate P32 which was instilled into cavities.

Are we concerned about exposures there

where material is not depositing in the right space?

So, I'm not sure that the E word, extravasation is correct and maybe infiltration is a better choice.

CHAIR METTER: Thank you, Mr. Green, that's --

MS. WU: Yes.

Sorry, go ahead.

CHAIR METTER: No, go ahead. Go ahead, Ms. Wu, go ahead and make a comment.

MS. WU: No, I was -- all I was going to say was, you know, that is sort of the reason behind that one question that we have in the information request, if extravasations is the right term or if infiltration or another term may be better. That's all.

CHAIR METTER: Okay, thank you.

And Ms. Ouhib?

MEMBER OUHIB: Yes, thank you for a great presentation.

I happen to share the opinion of the two previous ACMUI members.

One good reason is that it's almost like here we go again that, as we introduce another

area of medical events, I'm wondering what's going to happen to the authorized users for such practice.

That maybe that would be sort of like discouraging. And it's all -- we learned that a long time ago with prostate brachytherapy as medical events started to pop left and right and all that.

And then, next thing you know, is prostate brachytherapy is not as common anymore, even though there was an effort to make it less difficult, we don't see much of it. So, I think that could be an issue.

The other question that I have for you, are there any exclusions for such medical events, per se, for this type of procedures?

I'll give you an example, a patient had an injection, left, had a physical injury in the area of where the injection was. Now, the patient reports that they're having an issue in that area.

Now, is that going to be qualified as a medical event?

And that's just a basic case that I thought of now. But there could be others that might not quite qualify for that.

Thank you.

CHAIR METTER: Thank you for that observation. Dr. Jadvar?

VICE CHAIR JADVAR: Thank you. So, I just want to remind people, as was mentioned before by Mr. Green, that, you know, you're trying to puncture a vein to get in there to get some stuff inside. That is -- there's going to be a hole there.

When you pull the needle out, it's going to be leaving a beading. That's normal. That's the body.

Which, you know, eventually we close off the platelets going there and then, trying to close it up. But there's going to be a small amount of bleeding. There's going to be a small amount of radiotracer, in some cases, in many cases, in fact, that can be right there and can show up on the scans like a small dot, but very hot sometimes.

Is that extravasation? It's not. It's a normal thing. You made hole, there was bleeding. There's going to be some concentration radio tracer activity there.

And therefore, you know, it really

depends on where it's infiltration or extravasation and that activity at that moment of time may exceed whatever threshold you want to use.

But because of the lymphatics, because of the way the body clears it, it's going to have no effect whatsoever, despite the fact that they're going to be a little bit of higher activity at the -- concentration of activity at that time.

But it will have no bearing on diagnostic quality of their scan that you're looking at.

I just want to also draw your attention to a recent article that was just published a couple of months in the journal from Washington University.

They looked at almost 32,000 scans, bone scans, which is a very common procedure, that they have done over the years at Wash U.

And the extravasation rate that was documented was 0.37 percent, very, very small number of people. And none of them that they looked into all their, you know, documentation that was in the records, none of them had any long-term local effects.

In fact, they -- it's interesting, if

you go to the paper itself, they show one image, which is Figure Number 2 which looks horrible. I mean, there is this very large area of very intense activity. But that patient had no long-term effects at all, just some warm pad and elevation of arm. And the quality of the scan was excellent.

You could make a decision if this patient has metastatic disease or not. So, I think what I'm saying is, that I agree with my three other colleagues around the table that you're -- I think you're making too much of this, I personally think.

CHAIR METTER: Thank you very much, Dr. Jadvar. Any other comments from the committee?

Yes, Mr. Green?

MEMBER GREEN: Just want to point out, the professionals that we work with that work with the nuclear medicine physician that perform the patient administrations are appropriately referred to as nuclear medicine technologists. In question 11, they're referred to as technicians, and that should be corrected.

CHAIR METTER: Thank you for that suggestion.

VICE CHAIR JADVAR: Well, since he

mentioned technicians, there was one slide that says blood vessel or artery. So, it should be the vein or artery, because artery is a vessel.

So, you know, and we normally don't really inject into artery unless it's Y-90, if you're going to arterial system in the liver. But normally, almost 100 percent of radiopharmaceuticals are administered intravenously.

CHAIR METTER: Yes, Mr. Green?

MEMBER GREEN: Because I'm a geek, I have a list of the 55 FDA approved radiopharmaceuticals that are currently approved. Forty-five of them have indications for intravenous administration, three are oral, one's inhaled, one's intradermal, and one's intrathecal.

So, we've got to make sure that whatever we're writing is not all radiopharmaceuticals, but those that go into that intravenous space.

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

Any from the NRC staff? Mr. DiMarco?

MR. DIMARCO: Hi, Daniel DiMarco, technical lead on the extravasation rulemaking.

I just want to make a couple comments for some of the comments from the ACMUI.

So, when we were determining what we wanted the reportable for specifically an extravasation -- for a medical event involving an extravasation, we took all the comments because we've been hearing this from the ACMUI and the medical community for the entire time we've been doing this, and we've been trying to take these comments under consideration.

And so that's why we wanted to determine this to be, one, to be a radiation induced injury because we didn't want to see any of these reportable events come from, say, like someone using the -- an allergy to the tape being used or any sort of local trauma because of -- an injection is a traumatic event, at least for that local area.

So that's why we have a couple of those questions in there on specifically being a radiation injury and what sort of medical professionals should be able to consult to say that this was a radiation injury versus any sort of other local injury due to any other, you know, these are sick patients, maybe there's something

going on in the local area that isn't due to the radiation.

So that's one thing. As for another, at least with the diagnostics, the NRC does not regulate image quality on that. So, we didn't want to step into that area at all. Image quality is strictly a medical community metric and the NRC does not regulate that.

And I believe that was all I had to say. If anyone has any other comments or questions for me.

MEMBER OUHIB: It's a question, but I think I'd like to hear it from the users is that, you know, those type of things might very well be included in the consent form, that the patient ought to expect certain things.

They're not out of the ordinary. They're totally normal things that could occur.

And now, we're saying that things that could potentially occur are medical events. It just doesn't make any sense to me.

MEMBER HARVEY: I think the distinction that we have to take into account is that we get to a tissue reaction level. And until we get to that dose, anything below that threshold is not included

as a medical event.

So, some of the normal routine things would certainly not fall under this. And I think what the NRC's done is come up with a great compromise to try to make this work.

I still have the dissenting opinion that it should not be a medical event. But I think you have to meet that bar. You have to meet that threshold to be included. So, I just wanted to put that out there. Thank you.

MR. DIMARCO: Yes. And so, part of that threshold, we can't set that line or we're not trying to set that line for any facility with is this an event something that could possibly be a reportable extravasation.

But part of that is the dosimetry model that we're formulating that will be part of the guidance, an appendix in the guidance. And so that will be of use to everyone.

And in that, we're trying to get a conservative estimate of the dosimetry with the addition of certain techniques like warming the area or elevating the arm, and so how that changes the dosimetry and how that changing dosimetry changes the probability of a certain extravasation

and having some sort of erythema or patient harm for that.

CHAIR METTER: Thank you.

Do I have any other questions or comments?

Yes, Mr. Ouhib?

MEMBER OUHIB: Yes, just a comment. So, let's just take a situation where the authorized user might very well predetermine or see that this patient might very well have an issue. I'm not sure. Okay?

So, choosing between reporting a medical event or simply saying to the patient, I'm sorry, but I might not be able to do this and here's what the issue is.

And I'm just speculating here, this might not happen, but I'd like to hear it from the authorized user if that's a possibility and the patient is basically sent home and not provided a, you know, proper care, per se, because of that.

MR. DIMARCO: Thank you for that comment.

CHAIR METTER: Okay, any other comments from the ACMUI or NRC staff?

MS. PINEDA: Dr. Metter, I think Megan

Shober may have a comment.

CHAIR METTER: Oh, I'm sorry.

Yes, Ms. Shober?

MEMBER SHOBER: Yes, can you hear me?

CHAIR METTER: Yes, we can, I'm sorry, I didn't see your --

MEMBER SHOBER: That's all right.

I just wanted to point out that when we had the extravasation subcommittee, a couple years ago, one of the big concerns that we had was on the therapeutic radiopharmaceuticals that were coming on the market.

Our emphasis in the conclusions that we -- when we got to the point of making the decision about which recommendation to support for the extravasation rulemaking, we were really concerned about the potential for therapeutic extravasations.

So, I know that the study that Dr. Jadvar was mentioning was bout bone scans, obviously, that's diagnostic.

But the concern was that, even if they don't happen very often, that those -- if you did have a therapeutic extravasation, that you could have some pretty significant consequences from that. Thank you.

CHAIR METTER: Thank you, Ms. Shober, with that very important information. Do I have any other comments from the staff or the ACMUI?

Okay, can we open up to the public?

MS. PINEDA: If you're a member of the public and you'd like to make a comment, again, just use the little hand icon to raise your hand if you're on Teams.

And if you've called in by phone, just press star five to raise your hand and then, star six to unmute yourself after I call your name. Thank you.

MS. PINEDA: It looks like we don't have anyone.

CHAIR METTER: Okay, it looks like there are no public comments.

So, thank you very much for that very detailed and very in-depth and thoughtful presentation on extravasation. I really appreciate the NRC staff and you particularly, Irene Wu, regarding this presentation.

So, let's go to the next item on the agenda. This is the ACMUI reporting structure by Dr. Valentin-Rodriguez of the NRC.

MS. VALENTIN-RODRIGUEZ: Good

afternoon, everyone. Again, as Dr. Metter mentioned, I'll be providing the review of our reporting structure, a discussion of our annual review, and frequency of meetings, and then, I'll open it up to the ACMUI for discussion.

Next slide, please?

Okay, next slide, please? So, the graphic on the slide provides a graphic of the current reporting structure. From the bottom up, you'll see that the ACMUI reports directly to Mr. Kevin Williams who you all saw this morning during his opening remarks.

He is the Director of the Division of Materials Safety, Security, State, and Tribal Programs, otherwise known as MSST.

And reporting to Mr. Williams is Chris Einberg, who's in the room today who is the Branch Chief for the Medical Safety and Events Assessment Branch.

In our division, MSST, we report to Mr. John Lubinski in the Office of Nuclear Material Safety and Safeguards.

And then, NMSS reports to the Executive Director of Operations Office who is currently Mr. Daniel Dorman and who reports to the Commission.

So, the ACMUI does not report directly to the Medical Safety and Events Assessment Branch, however, within our branch resides the Medical Radiation Safety Team who helps coordinate and support the day to day activities of the committee.

During the presentation of the bylaws in September 2012, the ACMUI recommended to having an annual review in its reporting structure.

Christine, can I get the next slide, please? Sorry, there we go.

And at that time, the ACMUI was presented with an option to continue to report to NMSS or to report directly to the Commission.

And the subcommittee report provided in 2012 stated that the working relationship with the -- between the NRC and the ACMUI remained excellent and the reporting structure through the staff continued to work or function effectively.

And so, at that time, the subcommittee and the ACMUI agreed that the associated logistics with direct reporting to the Commission, such as more frequent meetings, did not and does not justify any change to the ACMUI's reporting structure.

Next slide, please? So, we currently

hold two meetings each year. We started to hold them in person again, which are our spring and fall meetings.

I know our May and December meetings have been a little bit out of the ordinary in terms of time frame. We had to do a lot of adjustments post-pandemic. And so, we'll also do teleconferences on an as needed basis.

Next slide, please? So, at this time, I'll turn it over to Dr. Metter and the ACMUI for discussion on whether the committee continues to be satisfied with this current reporting structure, what's not working about the reporting structure, and any recommendations for improvement. So, thank you.

CHAIR METTER: Thank you very much for that review and reminding us how the structure works for the ACMUI and with the whole NRC.

So do I have any questions for Dr. Valentin-Rodriguez regarding the ACMUI reporting structure or any comments? Any suggestions?

Mr. Green?

MEMBER GREEN: Thank you, Dr. Metter.

I just wanted to echo, I think comments you made at least twice today, you know, there has

not been a direct support person supporting the ACMUI that Dr. Valentin-Rodriguez has taken that upon herself personally in addition to all her other activities.

And I think we've been very well supported and assisted in our activities. And I look forward to have a full-time person that can do that for us. Not that we have been famished and not supported.

But, you know, there are other things that the medical staff have to do, but I think they've done a great job in supporting us.

CHAIR METTER: Thank you.

MS. VALENTIN-RODRIGUEZ: Thank you, Mr. Green.

And as I think Chris and Kevin Williams said this morning, we have hired someone, but, you know, the bureaucracy of the federal government hiring processes can be a bit long in the tooth. So we're hoping to have her in place in the next few weeks.

And so hopefully Ms. Armstead will be here to support you in our day-to-day activities and we can resume more normal operations.

So, I appreciate your feedback.

CHAIR METTER: And Dr. Valentin-Rodriguez, I personally would like to thank you particularly for your work because I know you're doing like double duty, but also the NRC staff. They've been very -- they're very professional, very knowledgeable and really very prompt in their responses to our questions and our needs. And that only helps to make our job easier to help the public in the protection and the use and -- the medical use of isotopes.

And thank you very much.

MS. VALENTIN-RODRIGUEZ: Thank you, Dr. Metter. It's a pleasure and to be able to work alongside all these esteemed professionals.

So, I don't know, Chris, if you wanted to have some words? But we truly appreciate it from the NRC side.

MR. EINBERG: Yes, thank you, Dr. Metter.

I'm -- very kind words and, as Celimar said, you know, it's our pleasure and, again, we really do -- or, you know, from my perspective, I think we have a great team supporting the ACMUI, supporting the medical community.

And, of course, what an esteemed body

we have here. And so, I think there's very good collaboration between the NRC staff and the ACMUI members.

CHAIR METTER: So, the question still stands, do we like the current plan as far as having two meetings per year, one in the spring and one in the fall, given these general time frames?

PARTICIPANT: Yes.

CHAIR METTER: Okay, given that, I see lots of heads shaking, nodding up and down, that means yes rather than sideways. So, do I have a motion to approve?

(Off microphone comment.)

CHAIR METTER: I have a motion to approve the current schedule for meetings. Do I have a second?

MEMBER HARVEY: Richard Harvey, I will second that motion.

CHAIR METTER: Great. Any other discussion?

All in favor, say aye.

(Chorus of aye.)

CHAIR METTER: All opposed or abstain?

I hear crickets, so that means that it has unanimously been approved by the committee.

And thank you very, very much for all that you do to help us.

So, I believe we have a break right now, we're going to be a little early unless there's anything else, Mr. Einberg, do we have to cover before we go to break?

MR. EINBERG: Nothing -- sorry, nothing at all. So, yes, let's go to break then. And then we'll resume at 3:00.

CHAIR METTER: At 3:15, I believe is on my schedule.

MR. EINBERG: I'm sorry, yes, at 3:15, my apologies.

CHAIR METTER: So, we'll have a break right now, and we'll go off the air and we'll be back at 3:15.

(Whereupon, the above-entitled matter went off the record at 2:38 p.m. and resumed at 3:14 p.m.)

CHAIR METTER: Well, good afternoon, and welcome back to the 2023 Spring ACMUI Meeting. And we're just about to start our last section of today's meeting.

And I'm Darlene Metter, ACMUI Chair and Diagnostic Radiologist. And I'd like to introduce

Dr. Richard Harvey, our ACMUI (audio interference) for his presentation on the decommission financial assurance for sealed and unsealed radioactive materials.

MEMBER HARVEY: Thank you very much, Dr. Metter.

Appreciate the opportunity to submit the report and presentation today.

I guess we can go to the next slide. And can go to the next one, no financial disclosures.

Again, I just wanted to thank the entire subcommittee for all their efforts to get this done. And I very much appreciate that.

So, Ms. Allen, Dr. Jadvar, Mr. Mailman, Ms. Martin, Ms. Shober, so, thank you.

I'd also like to thank the NRC staff resource for their fantastic work. And Ms. Flannery really did all the heavy lifting on this and really made it very, very easy for us to get through this. So, thank you very much, Ms. Flannery.

And thank you to Dr. Valentin-Rodriguez for all her help in the report, ready, thank you.

So next slide, please. Our

subcommittee charge was to review and comment on the draft proposed rule for the rulemaking for decommissioning financial assurance for sealed and unsealed radioactive materials.

A quick background -- next slide, please?

Quick background is U.S. Nuclear Regulatory Commission, NRC, is proposing to amend its regulations for decommissioning financial assurance for sealed and unsealed radioactive materials.

The rulemaking would revise NRC's decommissioning funding requirements for radioactive materials based in the relative risk to the public health and safety from different radioisotopes including naturally occurring and accelerated produced radioactive material.

The potentially affected licensees are those authorized to possess radioactive materials licenses.

Next slide, please? So, the proposed rule changes, the language in 10 CFR 30.35, financial assurance and record keeping for decommissioning will remain unchanged.

The only change is the values in

Appendix B, okay, to Part 30, Appendix B to Part 30 which is entitled quantities of licensing material requiring labeling will be updated.

The values in Appendix B will be updated to those of Appendix C of 10 CFR Part 20 for radionuclides with half-lives greater than 120 days.

We don't see any significant impact to the licensees with germanium-68 or gallium-68 generators.

The benefits of this proposed rule change are to provide relief for previously unlisted radionuclides and there doesn't seem to be any expected negative impacts to the licensees.

Next slide, please? So, our recommendation -- this subcommittee -- the ACMUI subcommittee on the decommissioning of financial assurance for sealed and unsealed radioactive materials draft proposed rule recommends that the proposed rule with the changes to the table in Appendix B to Part 30 be accepted as proposed.

And then the next slide is just acronyms and I can take -- or any questions that you may have for simply changing a table.

CHAIR METTER: Thank you, Dr. Harvey,

for your committee's -- subcommittee's work on this. Do I have any other comments from Dr. Harvey's subcommittee?

Any comments or questions from the ACMUI?

Yes, Mr. Green?

MEMBER GREEN: Are we changing all the values that are in Table C to now be in Table or just those with half-lives over 120 days?

MEMBER HARVEY: Richard Harvey. We're taking everything from the one table and putting it in the other. And I don't remember off the top of my head how much overlap there might be.

So, we don't really see any impact to the group. So, I guess I don't really have a great answer to your question, unfortunately.

But the significant focus was on those greater than 120 days. Obviously, as you know, things that are less than 120 days have less stringent regulations and so most of those things can be either stored on site and managed on site and decommissioning and funding financial assurance is not necessarily required.

So, what really is impacted is those with half-lives greater than 120 days.

MEMBER GREEN: Thank you.

MEMBER HARVEY: You're welcome, Mr. Green.

CHAIR METTER: Any other questions for Dr. Harvey or any comments?

Okay, any from the NRC staff?

Any questions from the public?

Yes, sir?

MR. HOLAHAN: Yes, good afternoon, Dr. Vince Holahan. I'm Senior Level Advisor at NMSS.

To answer your question, when we started, we had 180 isotopes in Appendix B to Part 30. 130 of those isotopes were removed because their half-lives were 120 days or less.

When Appendix B to Part 20 was updated in 1991, it was increased from 260 isotopes to 757. Of those, we added back to the new Appendix B to Part 30, 105 isotopes bringing it to 154.

What we find is, for the most part, there were only changes in a couple of isotopes, cadmium-109 actually went down by a factor of 10. Most of the isotopes went up by a factor of either 10 to 100.

The only thing will be the default values of those that aren't in the table already.

Those will decrease by about a factor of 10. Thank you, ma'am.

CHAIR METTER: Thank you very much for that information. Did you have any other questions of him, Dr. Harvey?

MEMBER HARVEY: I wanted to thank him very much for his support. Thank you very much.

CHAIR METTER: Thank you. Do I have any other comments from the public?

MS. PINEDA: If you're a member of the public and you have a comment or a question, just hit the little hand icon in Teams. Or on your phone, press star five to raise your hand. Thank you.

CHAIR METTER: It looks like there's no questions from the public. Do I have a motion to approve Dr. Harvey's report to the ACMUI?

Dr. Wolkov?

MEMBER WOLKOV: Harvey Wolkov, so moved.

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

MEMBER O'HARA: Michael O'Hara, so moved.

CHAIR METTER: Thank you, Dr. O'Hara.

Any other discussion or comments?

All in favor of approving Dr. Harvey's presentation, say aye.

(Chorus of aye.)

CHAIR METTER: Any abstention or opposed?

Thank you very much, the report is approved unanimously by the ACMUI.

So, our next item on the agenda is an open forum where the ACMUI will discuss medical topics of interest for the future. Do we have any of those topics that anyone would like to bring up at this time? Ms. Martin, yes?

MEMBER MARTIN: I seem to be good at this today. I'm not sure I have all the details that I should know before I bring this up, but there was a fair amount of discussion in the physics groups that there is a proposal that will basically lower the limits requiring the increased controls for HDR units.

And I was just wondering if that has been brought to the hospitals' attention and what impact that would have on the -- because it would have a significant impact on many users that -- how that's being considered if you have to add

increased controls for all the HDR units.

MEMBER HARVEY: Dr. Martin, can you tell us what they're lowering the threshold to? Will then it include all like single irradiators?

Because, currently, it's just more than one co-located together and there were regulation thresholds were set so that one HDR unit had less stringent regulations. Are we now talking about including individual HDRs?

MEMBER MARTIN: That was the talk. But again, this was done at a physics group discussion and I don't have enough details to give you the information.

But that was the implication that all of the single units would now have to have the increased controls at all times.

And I was -- I'm really looking for information if that's really a true statement or I would love for someone from the NRC or someone else to disprove that.

MR. EINBERG: I see that Dr. Valentin has her hand up and maybe she can elaborate.

But I haven't heard of anything.

MS. VALENTIN-RODRIGUEZ: Thanks, Chris.

Yes, so if you'll remember in the

December 2022 fall meeting, we had a presentation from Dr. Andy Carrera on the radioactive source security and accountability rulemaking.

That rulemaking looks -- puts further controls on Category 3 sources of material.

So licensees who now possess Category 3 sources of material, in this case, for example, those who have HDR units, will have further controls, including if they, for example, submit an application for a license or if they want to increase their amount of material to receive Category 3 sources, they would have to have pre-existing -- they would need to meet certain conditions that would make them what we call a known applicant which may subject them to, for example, pre-licensing with this.

And there would be further requirements for license verification.

But at this time, there would be no requirement to implement what we call Part 37 or what used to be called increased controls and is now physical security requirements in 10 CFR Part 37.

They wouldn't be subject to those specific requirements in Part 37, but there would

just be a few things that they would need to meet, and that would be in order to ensure security of Cat 3 sources.

I can share that presentation from Dr. Carrera from the December fall meeting to kind of give you more of an update or kind of a summary of what that rule -- proposed rule will entail.

MEMBER MARTIN: That would be much appreciated because I know the AAPM group's looking for that information because it impacts so many of our members.

CHAIR METTER: Okay, thank you.

Any other suggestions for topics?

Okay, any from the NRC staff?

MR. EINBERG: No.

CHAIR METTER: So, at this time, if there are any that do come up in the future, just go ahead and you can email Dr. Valentin-Rodriguez or myself or Mr. Chris Einberg regarding that. Thank you very much.

So let's go on to the final item on our agenda, our administrative closing by Dr. Valentin-Rodriguez.

MS. VALENTIN-RODRIGUEZ: Thank you, Dr. Metter.

Today, we heard a great many topics. And so, I wanted to thank the ACMUI members for their thoughtful feedback as well as the presenters from both NRC and the ACMUI, and also our public for their input and feedback on the topics we discussed today.

Just a brief overview of the topics that were discussed, we had a very informative presentation from Mr. DiMarco about our fiscal year 2022 medical events. We also had a presentation and updates to the abnormal occurrence criteria, specifically, to Medical AO criteria as well as an update on ongoing medical team activities.

We heard from Dr. Jadvar, which turned into a very lively discussion about training and experience for all modalities.

And I wanted to assure the ACMUI members as well as the public that we're working on that implementation guidance that we've talked about. And this is the sort of feedback that we really want to hear from you all as to what are the questions that you all have when implementing our training experience requirements in 10 CFR Part 35.

We also heard the status of our extravasations rulemaking, and we heard some

feedback on that.

And I want to remind everyone there's a public meeting next week, May 24th, from 1:00 to 4:00 p.m. Eastern Standard -- Eastern Daylight Time for that.

And we also had a review of our ACMUI reporting structure and Dr. Harvey provided a report on the decommissioning financial assurance proposed rule.

So, with that, I didn't capture any action items from the NRC or ACMUI. Dr. Metter, did you capture any action items at this time?

CHAIR METTER: No, not at this time. But thank you very much for that nice, very concise review.

MS. VALENTIN-RODRIGUEZ: So, the next topic for the administrative closing will then be selecting a tentative or two dates for our fall meeting.

I've provided in advance several meetings that would work in concert with a proposed Commission meeting in the September and November time frame.

Right now, on this slide, you have September -- you have a few September dates --

thank you.

The first tentative date is September 11 and 12 which would be Monday, Tuesday. That would accommodate a full meeting on Monday and the Commission meeting on Tuesday.

Christine, can you go back to the next -- can you go to the next slide? Thank you.

There are no available dates right now in October for a Commission meeting. So, we bypassed October.

And then, I also offered several tentative dates in September -- in November, namely November 1st and 2nd, 13th and 14th, with -- and those would be Commission meeting on Thursday, the 2nd, Tuesday, November 14th, and then, a third date Wednesday, Thursday, November 15 and 16, with the Commission meeting on Thursday, November 16th.

So, I think the November dates look to be more agreeable to those who contacted me beforehand with the September 11th to 12th date a little bit behind in terms of votes, but not by much.

So ,I wanted to bring it up to you all for discussion so that we can pick two dates and then propose that to our Office of the Secretary to

get on the Commission's books for the fall.

CHAIR METTER: Any comments from the members regarding certain dates? Yes, Dr. Jadvar?

VICE CHAIR JADVAR: Well, unfortunately, I'm personally not available for 13th to 16th, I'm traveling at that time. For me, my best dates are in September and then one or two in November, but not during the 13th through 16th.

CHAIR METTER: Any other comments? I think we had initially -- the majority of the members kind of wanted to do -- make it abutting a weekend.

So, any other suggestions? Yes, Melissa?

MEMBER MARTIN: Well, just realize that if you have the meeting on November 1st and 2nd, that requires us to travel on Halloween.

VICE CHAIR JADVAR: I second Darlene's mentioning because during the week, at least for us, we're coming from across the country, it really have to take another day off from work on Tuesday to be able to be here on a Wednesday. So that's why I think, you know, a coupled to a weekend would be better.

MEMBER HARVEY: November 13th is the

American Heart Association scientific sessions.

MEMBER MAILMAN: Of course, the September date is the European Nuclear Medicine meeting which is E&M is that Monday and Tuesday as well as I have multiple obligations in there and one of their -- there's a patient -- the International Patient Meeting in Italy. So, I'm -- it's a hard date, but they're all hard dates. So, we'll figure it out.

CHAIR METTER: Any other comments?

Because if we don't do those Monday, Tuesdays, then you're confined to November 1 and 2 and Halloween.

But you know what we could do? If people are not opposed to it, perhaps just send out another poll for those weeks, or is that going to be difficult, Dr. Valentin-Rodriguez?

MS. VALENTIN-RODRIGUEZ: No, I can certainly send out another poll.

So, these dates that I proposed to you all ensure that we have a date that's available to the Commission for a Commission briefing. That way, we can reduce travel by not having to bring you all in again for a, you know, a second trip for a Commission meeting.

So that's why I proposed these days which I consulted with our Office of the Secretary on.

If these don't work, then we can certainly go back to the drawing board. But I probably -- I think we'd probably be looking at a December time frame meeting, then.

CHAIR METTER: Yes, Mr. Green?

MEMBER GREEN: Before COVID, we seemed to do the meeting with the Commissioners live in the spring. And because of COVID, it fell on to the fall.

Is there any thought to put that back into the spring and if we did that, would we miss this year's or would we do this fall and this spring? Are we going to stick with spring or fall or just --

MS. VALENTIN-RODRIGUEZ: No, we can --

CHAIR METTER: That was -- yes.

MS. VALENTIN-RODRIGUEZ: Oh, I was commenting --

CHAIR METTER: Thank you.

MS. VALENTIN-RODRIGUEZ: Yes, sorry, Dr. Metter, for interrupting.

No, I was just going to say that

certainly, within the committee's purview, that is an option. We could forego a Commission meeting in the September -- in the fall time frame and then reach out to the Commission for a spring meeting date. I think that would probably be easier to book at this time. We just have to ensure to get on their calendar early so that we can get availability of dates.

Their October time frame is very busy this year, so their calendar is filling up.

So that is certainly one option to forego a meeting this year and then, get back to them and have the Commission meeting in the spring.

MEMBER GREEN: Just to be clear, the ACMUI would still meet, but we would not meet with the Commissioners?

MS. VALENTIN-RODRIGUEZ: Correct.

MEMBER GREEN: So, we could plan a day, a Monday and Tuesday adjacent to a weekend, perhaps in October, where we don't have to meet with the Commissioners this fall, we could plan that face to face meeting with the Commissioners in the spring?

MS. VALENTIN-RODRIGUEZ: Correct, I could open up the week of the 16th or the 23rd.

CHAIR METTER: Do I -- may I ask the

ACMUI, is that a reasonable proposal for y'all to have the fall meeting and then we meet with the Commission in the spring?

(Off microphone comments.)

CHAIR METTER: Okay, so --

(Off microphone comments.)

CHAIR METTER: Unless there's any other issues that come up.

So, can we have a motion for that?

MEMBER HARVEY: Motion, Richard Harvey, I'll make the motion.

CHAIR METTER: All right, so the motion is to have a fall meeting of the ACMUI without the Commission and have a Commission meeting in the spring. Do I have a second for that?

MEMBER MARTIN: Second.

CHAIR METTER: Okay, I have many people seconding. So, we have many seconds.

So any other discussion?

All in favor, say aye.

(Chorus of aye.)

CHAIR METTER: All opposed or abstain?

So, we'll go ahead and proceed with that. And we'll go ahead and have the -- a poll sent out regarding the appropriate dates for the

fall.

And then also find out when the Commission is meeting in the spring and put out two polls for that. Maybe the first one and then, we can be sure that it's already clear that it's -- one is just for the ACMUI, the second is for the Commission meeting.

Yes, Mr. Green?

MEMBER GREEN: And part of that poll, let's make sure we capture the European meetings that were not on the calendar so that we can avoid those.

CHAIR METTER: Okay.

Josh, is you want, go ahead and give that dates to Dr. Valentin so --

(Off microphone comments.)

(Simultaneous speaking.)

CHAIR METTER: Okay, thank you.

MEMBER OUHIB: It looks like there is only November -- early November that works out because of the American Heart Association's then in November.

MEMBER HARVEY: November 13th, yes.

Is it worth discussing the two dates which Mr. Green mentioned, the 16th and 17th and

the 23rd and 24th right and see if we can come to a time which would work for everyone?

MEMBER MARTIN: I think that sounds great.

MEMBER HARVEY: Because both of those would work for me.

MEMBER MARTIN: What month is it?

MEMBER HARVEY: October 16 and 17 or October 23 and 24.

VICE CHAIR JADVAR: There are no October dates yet.

MS. VALENTIN-RODRIGUEZ: No, so that -- those would have included the Commission meeting, that's why they're not -- I didn't propose them, but we can certainly discuss them at this time.

CHAIR METTER: Why don't we go ahead and have you send out a poll so people can actually look at their schedule so that they're not at a short notice, maybe agreeing to something that they may not be able to attend.

So, let's go ahead and, if you don't mind, DR. Valentin-Rodriguez, if you can send out a poll and then we can have everybody can look at the schedule and have a date that they can be sure they can attend.

MS. VALENTIN-RODRIGUEZ: Yes, definitely. I'll add more dates to the poll and resend it. Of course.

CHAIR METTER: And I believe we would either -- would you like a Monday, Tuesday, or Thursday, Friday? Or it doesn't really matter just as long as it --

(Off microphone discussion.)

CHAIR METTER: I mean, there's --

MS. VALENTIN-RODRIGUEZ: All right, we can also do Thursday, Friday if you wanted.

CHAIR METTER: No, we'll go ahead and stick with the Monday, Tuesday.

MS. VALENTIN-RODRIGUEZ: Okay.

VICE CHAIR JADVAR: Yes, Wednesday, you have to travel.

MS. VALENTIN-RODRIGUEZ: I know, yes, okay, okay.

CHAIR METTER: So, we'll go ahead and do Monday, Tuesday. Any other items that we need to cover?

MS. VALENTIN-RODRIGUEZ: No, that's all I had, Dr. Metter, so I turn it back to you.

CHAIR METTER: Well, thank you very much. Do I have any final comments before we

adjourn this meeting from the committee or for the NRC staff?

MR. EINBERG: Yes, Chris Einberg, again.

Yes, I want to echo what Dr. Valentin said regarding the hard work that the committee has put in, especially the two subcommittees that reported out.

We thank the subcommittees, all the members of the ACMUI, and as well as the NRC staff, and the public comments that we received.

So, a lot to think about and we're busy and we appreciate -- and you're all very busy as well, and so we appreciate all the hard work and the thought you put into these discussions.

CHAIR METTER: Thank you very much, Mr. Einberg.

So, at this point in time, thank you very much for everybody's contribution and hard work and the meeting is adjourned.

(Whereupon, the above-entitled matter went off the record at 3:39 p.m.)

SOCIETY OF NUCLEAR MEDICINE & MOLECULAR IMAGING

May 9, 2023

Celimar Valentin-Rodriquez, PhD
Medical Radiation Safety Team Leader
Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852

Dear Dr. Valentin-Rodriquez,

The Society of Nuclear Medicine and Molecular Imaging (SNMMI) appreciates the Advisory Committee on the Medical Uses of Isotopes (ACMUI) including an overview of the current rulemaking regarding reporting of certain nuclear medicine injection extravasations on the May 15th meeting agenda.

We look forward to continuing to provide the medical expertise of SNMMI's 15,000 members to ensure patient access to nuclear medicine procedures providing personalized medicine optimizing patient treatment, as the rulemaking process moves forward.

This is a critical issue for the millions of patients receiving nuclear medicine procedures. We appreciate gaining additional information about the current rulemaking at the upcoming ACMUI meeting.

The safety of our patients and the highest quality of care are our top priorities. Patients must have access to valuable nuclear medicine procedures. We also must ensure that patients who would benefit from nuclear medicine procedures are not apprehensive or resistant to safe, often lifesaving procedures because of "radiation paranoia" or a "chilling effect" that can result from misinformation. We support a harm based, rather than dose-based approach, as has been recommended by the NRC.

We will be submitting comprehensive comments in response to the preliminary proposed rule, however there are two new important and relevant studies that we wanted to more immediately bring to your attention because you may not be aware of them.

These studies demonstrate both the rarity and lack of severity of extravasations in nuclear medicine. We support the NRC embarking on a thorough examination of this issue and we believe these studies provide useful new information.

1. In October 2022, the Journal of Nuclear Medicine, an independent highly regarded peer reviewed medical journal, published "Adverse clinical events at the injection site are exceedingly rare following reported radiopharmaceutical extravasation in patients undergoing 99mTc-MDP whole body bone scintigraphy: A 12-year experience | Journal of Nuclear Medicine (snmjournals.org)"

   This study looked at 31,679 patient records retrospectively from 2010 to 2022.

"Results: Retrospective review of the records of 31,679 ^{99m}Tc-MDP WBBS showed RPE documented in 118 studies (0.37%). Medical records were not retrievable for 22 patients, yielding the final cohort of 96 patients with reported RPE. The median follow-up duration was 18.9 months (IQR: 7.8-45.7 months). Short-term events were noted in four patients, of whom one was asymptomatic. Of the three symptomatic patients, two experienced mild discomfort at the injection site, and one had a tender swelling. Three of the four events had a prior intravenous contrast extravasation for a contrast-enhanced computed tomography performed earlier during the day, and a ^{99m}Tc-MDP injection later at the same site likely leading to RPE. None of the long-term local events had any plausible link with the RPE event.

Conclusion: Reported RPE were rare and short-term local symptoms were observed in three patients (0.009%), all of which were likely related to the prior higher volume intravenous contrast extravasation. The smaller volume diagnostic RP injections for WBBS are highly unlikely to cause local symptoms on their own. No patient had any long-term adverse event with a plausible link to the RPE.

2. The Journal of Nuclear Medicine (in press) "Frequency and significance of injection infiltration and associated dosimetry in clinical PET/CT: A multi-center investigation."

The primary objective of this study was to gain data on the frequency and significance of injection infiltration events in clinical PET/CT practice through quantitative analysis of 1000 subjects from 10 US imaging sites. The secondary objective was to gauge the true risk associated with dose infiltrations through detailed, anatomically specific Monte Carlo estimates of radiation dose to the highly proliferative epidermis, and the less radiation sensitive dermal and subcutaneous hypodermal tissues.

Results: In a 1000 patient multi-center investigation into frequency of infiltration events in PET, no infiltrations of >1% injected dose were found. The majority of visualized activities at injection site were external contamination, or injection apparatus.

Only 6/1000 injections had activities in excess of 6 µCi, none > 50 µCi. Frequency appears very low when cannula injections are used.

A first of its kind, skin dosimetry Monte Carlo model was developed and tested that includes the actual skin anatomy, which turned out to be critical in terms of dose distribution.

Conclusion: The risk of actual skin injury is likely significantly lower than implied in current literature due to the magnitude of beta dose absorption in the relatively radiation resistant hypodermis and dermis and sparing of the sensitive epidermis. Additional study with higher energy beta emitters, and radiopharmaceutical therapy radionuclides is warranted.

For additional background information on previously submitted comments, below are links to SNMMI's comments from November 25, 2020, and August 31, 2022, in response to NRC's request for comments on this issue.

https://s3.amazonaws.com/rdcms-snmmi/files/production/public/NRC%20Extravasation%20Public%20Comment%20final%20signed%208-31-21.pdf

https://s3.amazonaws.com/rdcms-snmmi/files/production/public/NRC%20Extravasation%20Comment%20Letter%20Final_signed%2011-25-20.pdf

One paragraph to note:

> "The question of frequency, however, is perhaps not the most relevant question for purposes of providing comment. The more relevant question is: How often are patients harmed by nuclear medicine extravasations? There are approximately 20 million doses of radiopharmaceuticals administered intravenously each year in the United States.1 In a recent meta-analysis, van der Pol, et al. summarized 37 previously published reports of the consequences of radiopharmaceutical extravasation.2 Of a total of 3016 diagnostic radiopharmaceutical extravasations, only three (< 0.1%) were associated with adverse reactions. In each case the adverse reaction was limited to the skin adjacent to the injection site and all were associated with relatively infrequently used radiopharmaceuticals. It must be emphasized that no adverse reactions were reported for the more than 3000 cases of extravasation of the commonly used 99mTc-, 123I-, 18F-, and 68Ga-labelled radiopharmaceuticals. In summary, there are no clinical data that support the Petitioner's claim that extravasation of diagnostic radiopharmaceuticals is a patient safety issue."

Thank you for your consideration. Please contact me if you have questions or I can provide additional information.

Sincerely,

Munir Ghesani, MD
President, Society of Nuclear Medicine and Molecular Imaging

PATIENTS
FOR SAFER NUCLEAR MEDICINE

May 9, 2023

To: The ACMUI Committee
Re: written statement for the May 15 ACMUI meeting for agenda item, *Rulemaking for Extravasations*

On behalf of Patients for Safer Nuclear Medicine, a national coalition advocating for transparency in the administration of radioactive materials in healthcare, we have respectfully urged the Nuclear Regulatory Commission (NRC) to seriously consider the harm caused to patients by extravasation. Unfortunately, recent instructions by the Commissioners to the NRC medical staff will only make matters worse for patients. Patients should not be required to report extravasations. Nuclear medicine providers should be responsible for reporting these misadministrations.

By the NRC's own estimation, some 28,000 major extravasations occur annually in the United States. These extravasations are large enough that they would warrant reporting to the NRC if not for an incorrect reporting exemption that has been in place for 43 years. But because of this blanket reporting exemption, no one knows for sure how many large or small extravasations occur. The Commissioners instructions to the medical staff will not improve visibility to this issue.

Extravasation has a serious economic, physical, and emotional impact on the patient and the healthcare system in general. In these 28,000 cases, no one knows the amount of radioactive material that was injected into the tissue. Consider the diagnostic flaws that result when a precisely measured amount of radioactive material is not properly administered. And what if the radiation dose to the patient's tissue is extremely high? Beyond the expense of a delayed diagnosis of tissue damage and the harm that may cause the patient, the cost of catastrophic later stage treatment can be exorbitantly high.

The Commissioners' decision places additional burdens on patients. The NRC is essentially creating rules that impose upon patients the responsibility of monitoring themselves for an indefinite period, which could range from weeks to months, or even years, to detect radiation injury, despite their inability to discern if they have been extravasated. The agency is initiating rulemaking that would place responsibility for identifying a large extravasation on the patient post-event, rather than emphasizing the need for providers to identify and mitigate extravasations when they occur.

There is another, underreported aspect to the extravasation issue: the erosion of trust in our medical professionals. How can a patient who is just starting their cancer treatment journey maintain trust in their care team when potential harm through extravasation is not disclosed immediately? By keeping critical information from a patient, medical professionals fail to act in the patient's best interest. The medical community's efforts to encourage the Commission's patient injury position actively undermines the patient/clinician relationship. With the NRC admitting that tens of thousands of patients are extravasated annually, why are the medical community and the NRC seemingly so invested in hiding extravasations from patients?

It can be inferred that medical societies endorse this course of action under the assumption that only a small fraction of patients will report, and they are banking on the patients' lack of awareness about the possible gravity of a large extravasation. A charitable reading of this position would suggest that the NRC and its nuclear medicine allies would rather protect the nuclear medicine community rather than patients.

PATIENTS
FOR SAFER NUCLEAR MEDICINE

We have expressed our concerns in letters sent to the NRC in January and March. We believe that, instead of relying on patients who are generally not medical school-trained experts to assess extravasation, the NRC should simply reaffirm that nuclear medicine providers should be responsible for reporting large extravasations.

By using the existing objective dose threshold – as is used for all other medical event reporting, including an accidental spill on a patient - licensees would be required to take immediate steps, including determining the tissue dose. We believe radiation injected under the skin should be treated with the same level of concern as radiation spilled onto the skin, which IS currently considered a reportable medical event.

With all this in mind, we recommend that the NRC rulemaking should be focused on including the word **extravasation** in the current medical event reporting section. By following our recommendation, it would be difficult for anyone to attempt to influence the adoption of a different policy in order to evade reporting. The final regulation will then ensure that large extravasations are reportable, similar to other medical events. In addition, we believe all nuclear medicine licensees should be required to do the following:

- Be certified in gaining venous access if they have responsibility for administering these radioactive drugs.
- Monitor the injection to ensure that if there is an extravasation licensees will know immediately.
- If there is an extravasation, licensees should do everything they can to reduce the radiation dose to the patient tissue.
- If there is an extravasation, licensees should assess the amount of radiation and make sure it is documented in the patient's record.
- Provide patients with information about extravasation, including symptoms to look out for.
- Inform the patient's full care team about the extravasation, to determine next steps in the best interests of the patient.

To make our position abundantly clear: we reject NRC staff's current recommendation to create a unique reporting criterion that forces the patient to 'play doctor' and detect one's own radiation injury rather than asking NRC licensees – the experts – to identify and monitor extravasations. We remain baffled that the NRC plans to make patients directly responsible for their own diagnosis and care for extravasation follow-up, rather than licensees charged with their care.

Please take the opportunity to focus on patients in your deliberations. Consider how the average patient is impacted by your decision: the potential effect to their treatment, the potential radiation damage to their tissue and skin, and the cost (both financial and emotional). Consider the wide-ranging consequence it has on the larger healthcare system: lost productivity, patient harm, higher costs, worse outcomes, and an erosion of trust. There is no better time than now to take patient-positive action.

Sincerely,

Members of the Patients for Safer Nuclear Medicine Coalition