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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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MEETING

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MONDAY,

OCTOBER 23, 2023

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The meeting was convened via hybrid in-person and video-teleconference, at 10:00 a.m. EDT, Darlene F. Metter, ACMUI Chair, presiding.

MEMBERS PRESENT:

DARLENE F. METTER, M.D., Chair

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

REBECCA ALLEN, Member

JOHN F. ANGLE, M.D., ACMUI Consultant

ANDREW EINSTEIN, M.D., Member

MICHAEL R. FOLKERT, M.D., Ph.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 COMMISSIONERS PRESENT:

DAVID A. WRIGHT, Commissioner

NRC STAFF PRESENT:

CHRISTIAN EINBERG, Designated Federal Official, NMSS

KEVIN WILLIAMS, NMSS

CYNTHIA FLANNERY, NMSS

KATHERINE TAPP, NMSS

LILLIAN ARMSTEAD, NMSS

CHRISTINE PINEDA, NMSS

KEVIN WILLIAMS, NMSS

SARAH SPENCE, NMSS

DANIEL DIMARCO, NMSS

MARYANN AYOADE, NMSS

DANIEL SHAW, NMSS

KEN BRENNEMAN, NMSS

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

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

10:00 a.m.

MR. EINBERG: Good morning, everybody. It's great to see everybody here today. So I think we'll go ahead and get started.

So good morning. As the designated federal officer for this meeting I am pleased to welcome you to the public meeting of the Advisory Committee on the Medical Uses of Isotopes. My name is Chris Einberg. I am the Chief of the Medical Safety and Events Assessment Branch and I've 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 it may also be transcribed or recorded by others.

The meeting was announced in the October 17th, 2023 edition of the Federal Register, Volume 88, page 71611.

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 that there may be a minority of dissenting opinions. If you have such opinions, please allow them to be read into the record.

At this point I would like to perform a roll call of the ACMUI members participating today. Dr. Darlene Metter, Chair, diagnostic radiologist.

CHAIR METTER: Present.

MR. EINBERG: Dr. Hossein Jadvar, Vice Chair, nuclear medicine physician.

VICE CHAIR JADVAR: Present.

MR. EINBERG: Dr. Michael Folkert, radiation oncologist.

MEMBER FOLKERT: Present.

MR. EINBERG: 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, healthcare administrator.

MEMBER ALLEN: Present

Dr. Richard Harvey radiation safety officer.

MEMBER HARVEY: Present.

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

MEMBER EINSTEIN: Present.

MR. EINBERG: I confirm that we do have a quorum here of at least six members. Mr. Zoubir Ouhib is joining us via Microsoft Teams as he was unable to join us in-person.

I would like to welcome Dr. Folkert as this is his first in-person meeting as a member of the ACMUI. We presented him as the new brachytherapy radiation oncologist representative during the spring meeting.

All members of the ACMUI are subject to the federal ethics laws and regulations and receive annual training on these requirements. If a member believes that they may have a conflict of interest as the term is broadly used within 5 CFR Part 2635 with regards to the agenda to be addressed by the ACMUI, this member should divulge it to the Chair and the designated federal official as soon as possible before the ACMUI discusses it as an agenda item.

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

I would like to add that this is a hybrid

meeting of the ACMUI. We are in person, but we 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 number is 353440864#. Once again, 353440864#.

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

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 material 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 the specific topic the Committee has discussed and are in the room can come up to either the microphone set or up to the -- right left to the table. For those individuals in the Microsoft Teams, please use the raise hand

function to signal our Microsoft Teams host Lillian Armstead that you wish to speak. If you have called into the Microsoft Teams using your phone, please ensure you have un-muted 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 their presentation. After the Committee has fully discussed the topic we will announce when we are ready for the public comment portion of the meeting.

At this time I ask that everyone who's not speaking to please mute your Teams microphones or phone. And for those in the room, please mute your phones.

Dr. Kevin Williams will be joining us a little bit later and providing some opening remarks as well, but at this time I'd like to introduce the Medical Team. Many of you are new and may not know all of the Medical Team and who support this meeting and all the great work that we do as a Medical Team.

So I'm going to start with Lillian Armstead. Lillian Armstead is our new ACMUI coordinator. And so she joined us from the Department of Veteran Affairs a few months back and so now we

have a full-time person supporting the Committee. So you'll be seeing emails from Lillian. And so please welcome her.

Then we have Daniel DiMarco. Daniel's been with us for a few years now. He's a health physicist.

And then we have Dr. Katie Tapp, and Dr. Tapp is a medical physicist and she's been with us 15 years.

(Audio interference)

MR. EINBERG: Awesome.

(Laughter.)

DR. TAPP: Eight years.

MR. EINBERG: Eight years? Okay. Sorry. She has experience like she has 15 years.

Then we have Dr. Kenneth Brennerman. Dr. Brennerman joined us about a year ago, or a little over a year ago. He comes to us from the University of Maryland. He was the radiation safety officer at the University of Maryland Hospital there.

Then we have Cindy Flannery who's our senior health physicist on the Medical Team. And Cindy, many may remember her, but Cindy was the Medical Team leader many years ago and then she went and did other things within the agency. But she loved

medical so much she came back.

And we have Sarah Spence. Sarah joined us recently, a few months back from Rutgers University. She's a health physicist.

And you were the assistant RSO there, I believe?

MS. SPENCE: Health physicist.

MR. EINBERG: Health physicist? Okay.

And she just passed her CHP, certified health physicist, a few months back. And so we welcome here.

And then last we have Dan Shaw. Dan Shaw was the -- he joined us less than a year ago and Dan was the radiation safety officer at Walter Reed. And so we've -- we're grateful that we have such a strong team supporting us and that these wonderful people have agreed to join us.

And last but not least, we have Maryann Ayoade. She's also on the Medical Team. And many of you know Maryann from the subcommittee work, but Maryann works remotely. She's in Texas and she's a medical physicist. And there's Maryann. She came on the screen.

So thank you, Maryann.

So Mr. Williams has joined us.

I'm not sure if you're ready for your opening remarks or you want to do that a little bit later?

MR. WILLIAMS: How about a later?

MR. EINBERG: Okay. Very good.

MR. WILLIAMS: I will diverge and tell you that I just came in from -- oh, sorry. I will take this opportunity to tell you where I was. It was my mother's 82nd birthday. And so my whole family came down to -- she lives in Atlanta and we came down to surprise her over the weekend several times. She just thought it was going to be me and my wife. And so we videotaped it and she saw my son and my daughter and she was more excited. And then a friend of hers said hey yesterday let's have a nice -- for those who couldn't make the celebration she had on the 14th, let's do it tomorrow. And so she was surprised as well. My sister came down. So she got to -- surprised all around. So that's where I'm actually coming from. I just got off a plane and drove here, but I really did want to be at this meeting. And I will share my remarks later, but thanks, Chris.

MR. EINBERG: Okay. Thank you, Kevin.

And so at this point I'd like to turn the meeting over to Dr. Metter. Thank you.

CHAIR METTER: Well, thank you, Mr. Einberg.

And good morning. Welcome to the fall 2023 meeting of the ACMUI. I'm Darlene Metter, the ACMUI Chair and diagnostic radiologist. I'd also like to welcome our consultant Dr. John Angle for this Committee. He's greatly contributed to the meeting's agendas during these past few years.

Thank you very much.

So today the ACMUI meeting has several interesting topics to include a two-year analysis of the 2021 and 2022 medical events. A specific session on lutetium-177 medical events, a section focusing on veterinary regulatory protective practices, and a presentation on current rulemaking efforts in revising financial assurance of the disposition of Category 1 and Category 2 sealed sources.

Now if Mr. Williams is ready? You have some opening remarks?

(No audible response.)

CHAIR METTER: And by the way, happy birthday to your mother.

MR. WILLIAMS: Yes, see, she had this surprised face the entire time. We really did actually surprise her. She doesn't get to see my kids

that often, so I think it was really a good opportunity for us to come down.

Where am I, Chris? I apologize.

All right. So I'll give a status update of the NRC activities. I always -- I'm going to off script, but I'm really extremely proud of the Medical Team. And in that, I say all of Chris' brains, but this particular meeting does focus on the medical use of isotopes and there's a lot of work that we have going on and a lot of hard work that goes on by -- behind the scenes and a lot of hard work by you all that really actually puts this all together. We get a lot of inputs from a variety of people and we all come together and be able to distill it into -- take the complex things and make them relatively simple in plain language. And I think that's a testament to all involved in this activity.

So I'm very much appreciative of it because one, this is appraisal time. I get to take credit for that. But what I'm most proud of are the people, I mean the hard work, the dedication, the collaboration, coordination, communication. That's just demonstrated not only by Chris' team, but the ACMUI as a whole. So I'm extremely appreciative of that and I want to thank you. And thanks for allowing

me to go off script.

But I look at these things such as the infiltration extravasation rulemaking. Since the spring we've -- the comment period for the information we closed on September of 2023. We received over 200 comments from stakeholders on a number of issues. The staff plans to begin the concurrence of the proposed rule and associated draft implementation guidance in January of 2024. The staff expects to transmit these to the Committee for review and comment in the spring of 2024. We should have the proposed rule to the Commission by August of 2024.

We also have the emerging medical technologies rulemaking. We recently issued a regulatory basis document for this rulemaking in early July of this year. The 120-day comment period closes on October 31st of 2023.

The training and experience for unsealed byproduct material. The staff continues to develop the implementation guidance for training and experience requirements. The draft implementation guidance will be issued in August of 2024 as interim staff guidance and will address how persons seeking authorized individual status under Part 35 can fulfill those training and experience requirements as well as

clarify the roles and responsibilities of those persons involved in and subject to training and experience requirements. I know you will recall that the training and experience was a big issue for us before the Commission for a while and we continue to implement the Commission's direction.

Another one of the topical areas is Reg Guide -- Phase 2 for Reg Guide 8.39. The comment period for the proposed revision closed in August of 2023. We received over 60 comments. We will review and incorporate the comments into the draft guidance as appropriate. The ACMUI will receive the final draft review and comments prior to the final issuance of the Reg Guide 8.39.

I will tell you in between there there could be some different conversations that we have internally and if anything changes there, we will reach out and share that information as appropriate.

(Audio interference)?

MR. EINBERG: Introduce (audio interference)?

MR. WILLIAMS: Yes, so I said I get a second chance to do it. But some of the organizational changes. Ms. Lillian Armstead is the

ACMUI coordinator. I'm sure a number of you have spoken to her in some fashion.

Thank you, Lillian, and welcome to the team.

Theresa Clark, who normally is my deputy and would be attending these meetings, is in our Region IV Office on a rotation. And Ken Erwin, who comes from our Division of Rulemaking Environmental and Financial Systems. He's the acting deputy. He'll do that until Theresa comes back.

As Chris mentioned, Dr. Folkert's first meeting as ACMUI brachytherapy radiation oncologist. And since the fall meeting Dr. Ronald Ennis completed his second term in ACMUI and his departure left a vacancy for the ACMUI brachytherapy radiation oncologist. And as Chris had talked about, we are pleased to announce that Dr. Michael Folkert has been appointed to serve as the brachytherapy radiation oncologist. He is currently the Vice Chair and Chief of the Brachytherapy for Northwell Health Cancer Institute Radiation Medicine at the Center of Advanced Medicine in Lake Success, New York. I would have to get a little more information on that place. I'd like to go there maybe.

For our meetings an item of interest; and

Dr. Metter kind of mentioned this, Dr. Harvey will provide the Medical Events Subcommittee report for Medical Events for fiscal year '21 and '22. Dr. Tapp will discuss recent medical events related to the use of radiopharmaceuticals. I'm going to mess up this thing. Mr. Davila will provide an overview of our ICRP Publication 153, Radiation Protection in Veterinary Practice. That has a lot of interest around here as well. And Dr. Tapp will provide an overview of the NRC's regulatory framework for the release of animals following an administration of radioactive material. And finally we have a special presentation for Dr. Metter, as this will be Dr. Metter's last in-person meeting for ACMUI.

We definitely appreciate all your accomplishments. I know we'll get to that part of it, but I personally have appreciated your leadership and how you continue to move ACMUI forward as well as sharing information with the staff. I'm very appreciative and definitely will miss you.

CHAIR METTER: Thank you.

MR. WILLIAMS: Thanks for this opportunity for me to provide some opening remarks. I do wish you a productive session today and I will say I myself will be in and out because it is appraisal season and

I have four appraisals to give today. I know that. And that will be later this afternoon. But I really appreciate you meeting, meeting in person, taking of your time and giving of yourselves because it does make us better, makes us -- and I'll say smarter and better and focused. So thank you for all of your time and attention. And at this time I'm turn it back over to Lillian Armstead.

MS. ARMSTEAD: Good morning, ACMUI members, attendees, both virtual and in person. This morning I will be providing and old business report and giving a status update on some of the items in the ACMUI's recommendations and action items beginning with the year 2020.

Item 11, from 9/21/20. As part of the non-medical events report the ACMUI recommended to the NRC staff and/or NNP to evaluate the issue of detection of short-lived medical isotopes in municipal waste, and that is waste from nuclear medicine patients that might be triggering the landfill alarm.

CHAIR METTER: Excuse me, Lillian. Can you bring the microphone a little bit closer? (Audio interference)

MS. ARMSTEAD: Can you hear me now?

CHAIR METTER: That's better, yes.

MS. ARMSTEAD: Okay. Start over?

CHAIR METTER: You want her to start over? Yes, why don't you start over?

MS. ARMSTEAD: Okay. Good morning, ACMUI members, attendees, both virtual and in person. This morning I will be providing an old business report and giving a status update on some of the items from the ACMUI's recommendations and action items beginning with the year 2020.

Item 11 from 9/21/20. As part of the non-medical events report the ACMUI recommended to the NRC staff and/or NNP to evaluate the issue of detection of short-lived medical isotopes in municipal waste, and that is waste from nuclear medicine patients that might be triggering the landfill alarms and provide some level of guidance, best practices, or additional instructions. We recommend this remain open.

The NRC staff shared a voluntary survey with Agreement States via CRCPD letter. The staff is analyzing the responses from Agreement State respondents. The staff will also review current NRC regulations and any pertinent regulatory analysis to make a recommendation to the Committee in spring 2024.

Item No. 8 from 10/4/2021. The ACMUI formed a new subcommittee on the Liberty Vision Y-90

Manual Brachytherapy Source. The subcommittee is expected to provide a draft report and any recommendations at the spring 2022 ACMUI meeting. We recommend this remain open. The subcommittee will receive the guidance for review and comment in the fall of 2023. The NRC staff will plan for a public teleconference in the spring of 2024.

Item 11 from October 4th, 2021. The ACMUI endorsed the Radionuclide Generator Knowledge and Practice Requirements Subcommittee report and recommendations provided therein. We recommend this remain open. The NRC staff kicked off the Rulemaking Working Group on February 23rd, 2022. The NRC issued a regulatory basis for the rubidium-82 emerging technologies, other medical use of byproduct material in July 2023. The NRC is accepting comments on this document for 120 days until October 31st, 2023, but may extend the comment period if requested by interested stakeholders.

The proposed and final rule are due by August 2024 and March 2026, respectively.

Item 15 from 12/15/2021. The ACMUI endorsed the ACMUI Reg Guide 8.39 Subcommittee report on CivaDerm and the recommendations therein. We propose to close this. The NRC staff considered the

subcommittee's comments. The staff issued the CivaDerm memo on July 28th, 2023 and posted the memo to the NRC's medical tool kit.

Item No. 4 from December 5th, 2022. The ACMUI endorsed the Y-90 Microsphere ME Subcommittee report and the recommendations therein. We recommend this remain open. The staff is addressing the recommendations including outreach to the Society of Interventional Radiology to increase engagement and communications. This will include a webinar in June to discuss the current Y-90 microsphere guidance in medical events. The staff is 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 medical events.

Item No. 6, December 5th, 2022. The ACMUI established two subcommittees, one to create generic process checklists to be used during medical administrations and want to review the DFA draft proposed guide. The ACMUI also reestablished the Nursing Mothers Guidelines to update the 2019 guidelines. We recommend this remain open.

A subcommittee was established to review and comment on the proposed rule. The other two subcommittees are in the process of being established.

Item No. 1, May 15, 2023. During the ACMUI's spring 2023 meeting the ACMUI requested additional tentative dates from the staff for its fall 2023 meeting. We propose to close this action. Following the ACMUI's spring 2023 meeting the ACMUI tentatively scheduled its fall 2023 meeting for October 23rd through 24th, 2023.

And I should add; I should have mentioned this earlier, but what you're seeing in your handouts is different than what I'm reading. There were some last minute edits that I will get to you guys and girls before the session ends. I do apologize for that.

ACMUI and staff this completes the old business report and review of ACMUI recommendations and action items. I have proposed to close two items: No. 1 and 15. Is there a motion to accept the report?

PARTICIPANT: So moved.

CHAIR METTER: Do I have a second?

PARTICIPANT: Second.

CHAIR METTER: All in favor of approving the report as stated?

(Chorus of aye.)

CHAIR METTER: Any opposition or

abstention?

(No audible response.)

CHAIR METTER: Do we have any discussion?

(No audible response.)

CHAIR METTER: Seeing none, Ms. Armstead, the report has been unanimously approved by the ACMUI.

MS. ARMSTEAD: Thank you.

CHAIR METTER: Thank you very much for your complete report.

MS. ARMSTEAD: Thank you.

CHAIR METTER: So now we'll go onto the next agenda item, which is the open forum. Do I have any comments or suggestions for the open forum?

Yes, Mr. Green?

MEMBER GREEN: Thank you, Dr. Metter. I wish to -- for the benefit of the members of the ACMUI and the NRC Medical --

CHAIR METTER: Can you speak a little closer to the -- and yes, the mics -- I think if everybody speaks closer to the mic, we all can hear a little better.

MEMBER GREEN: All right.

CHAIR METTER: Okay. Thank you.

MEMBER GREEN: For the benefit of members of the ACMUI and the NRC Medical Radiation Safety Team

I wanted to give a short update on radiopharmaceuticals that have or will soon cease production and one that was just recently approved by the FDA. And these are all excerpted from public sources. There's no proprietary information here. They're all from news reports.

NorthStar Medical Radioisotopes announced October 5th that they will shut down their moly-99 production facilities in Deloitte, Wisconsin by the end of 2023 citing increasing costs and competition. This facility produced the RadioGenix System, the technetium-99 generator, for production of Sodium Pertechnetate Tc 99m US -- injection USP. This item was licensed under 10 CFR 35 Part 1000 -- for the court reporter that was a typo. That should have been 1000 -- and has a separate licensing guide and training requirements. As a authorized -- trained authorized user of the RadioGenix System I have used it and it is a very extensive training program and licensing guidance. So acknowledging the work of the Medical Team, but that product is being removed from the market.

There are currently two other FDA-approved manufacturers of moly-99 generators that utilize fission, Non-HEU derived tech moly-99 and a third

manufacturer has an NDA under review with the FDA for a generator using neutron capture-produced moly-99. ESNMI has reached out and evaluated the impact and it does not appear that there will be any shortage of material.

Regenics Pharmaceuticals, a subsidiary of Lantheus Holdings, announced on August 24th that they will no longer be producing AZEDRA iobenguane 1-131 injection indicated for the treatment of pheochromocytoma and paraganglioma due to the lack of commercial demand. Manufacturing of AZEDRA will continue into the first quarter of 2024 in order to provide doses to current patients. This radiopharmaceutical was licensed under 10 CFR 35 Part 300.

And then a new addition to the marketplace on September 29th, Cyclomedica received FDA approval for the imaging agent tech-99M Technegas for use in ventilation perfusion studies to diagnose pulmonary embolism and other respiratory pathologies. Technegas, for the preparation of technetium labeled carbon inhalation aerosol, is an oval-shaped graphite carbon crucible upon addition of Sodium Pertechnetate injection USP to the crucible. The Technegas system produces Technegas aerosol for oral inhalation, and

this radiopharmaceutical is licensed under 10 CFR 35 Part 200.

It's always dynamic. Some in, some out. So I want to make sure the Radiation Safety Medical Events Committees are aware of departures and additions to the marketplace. We may see them come up in events and perhaps MEs.

CHAIR METTER: Thank you very much, Mr. Green, for that very good update and pertinent to our patients and public and to this Committee.

Do I have any questions for Mr. Green regarding these new items that have come up?

Yes, Dr. Tapp?

DR. TAPP: Not a question, but just wanted to let everyone know that the Technegas that Mr. Green just mentioned -- the NRC was aware of it. We did do an evaluation of the Technegas to determine to make sure we agreed with the licensing pathway that he mentioned, the 35.200. And we did propose to the Standing Committee of Emerging Medical Technologies; it's an Agreement State Standing Committee, and the NRC Standing Committee that it should be licensed under 35.200. We are working on a licensing memo then for -- to hand out to the regions and the states to let them know that recommendation, assuming they

agree, and just following up with that process. So I want to let everyone know that we did evaluate it.

CHAIR METTER: Well, thank you very much.

Any questions for Dr. Tapp?

(No audible response.)

CHAIR METTER: Any other questions for Mr. Green's report or update?

MR. EINBERG: This is Chris Einberg. Yes, thank you, Mr. Green, for that update. And we do appreciate when the medical community does reach out to us and to let us know what's upcoming and what's planned on being discontinued. We're aware of the RadioGenix System being shut down. We're going to terminate our licensing guidance at the appropriate time.

CHAIR METTER: Yes, thank you. And it will be interesting what the nuclear medicine community will be doing regarding that and regarding interpretation for -- on their pulmonary embolism criteria. They'll probably have to make new guidance.

Okay. If there are no other questions for Mr. Green or for anything -- any other items that wish -- people wish to bring up in the open forum?

(No audible response.)

CHAIR METTER: Okay. Seeing none, it's a

pleasure for me to introduce our next topic for this meeting. It's the Medical Events Subcommittee report by Dr. Richard Harvey, who's going to be giving an analysis of the 2021 and 2022 medical events.

Dr. Harvey?

Dr. HARVEY: Thank you, Dr. Metter.

Good morning to everyone. It's a pleasure to be here.

So I am the Chair of the Medical Events Subcommittee, so we'll be talking about that. I'm the Chair. Dr. Folkert has joined us. Mr. Green is on the Committee, Dr. Metter, Mr. Ouhib, and Dr. Wolkov. And special thanks to our consultant, Dr. Angle, and our NRC staff resource Mr. DiMarco. Everyone has been wonderful to work with and have contributed greatly to this. So thank you to all of them.

So the Subcommittee's charge is to review the medical events to advise the Advisory Committee on the Medical Uses of Isotopes and the United States Nuclear Regulatory Commission about emerging trends that may need regulatory attention. So the NRC and the ACMUI are regularly reviewing these medical events and we're doing our review and bringing this report forward.

Medical events that occur when radioactive

materials used in health care result in unexpected radiation dose to patients, and certainly the regulations there are cited. The Medical Events Subcommittee of the ACMUI reviews the data to analyze the nature of the medical events, identify those emerging trends, and then provide recommendations to the Committee, the ACMUI Committee, as well as the Nuclear Regulatory Commission.

The period under review is FY '21 and FY '22, so October 1st, 2020 to September 30th, 2021 and October 1st, 2021 to September 30th, 2022. So we'll be focusing on that. We will see in the tables some of the earlier data and trends, but we haven't -- we're not including anything beyond September 30th, 2022.

We have kept with what I call the Dr. Ennis methodology. So Dr. Ennis did a wonderful job with the medical events. I have been elected to try to fill those big shoes. And we have remained consistent with his methodology going forward.

So there were two overarching themes: human error and inexperience. Human error seems to be influenced by communication and feedback between individuals and healthcare as well as the failure to work in teams.

Inexperience has occurred when new radiopharmaceuticals have come to market at a very quick pace and people haven't developed the experience with these radiopharmaceuticals.

Also, the dissemination of use of these radiopharmaceuticals to smaller institutions that perform these procedures at a lower frequency. There seems to be more of a problem with individuals or licensees that are not always, but in some cases -- where licensees are doing infrequent use and have limited experience.

Increasing medical events. So again, due to new radiopharmaceutical therapies coming to market, theranostic treatments, and increasing use of current therapeutic radiopharmaceuticals. We're seeing increase of lutetium agents, yttrium-90 microspheres. We're definitely seeing an increase in the volume of the number of procedures being done.

With regards to yttrium-90 microspheres, there are two common medical events. An ACMUI action that I wanted to mention was that we added two committee members. One is our consultant, Dr. Angle; the other is Dr. Folkert.

ACMUI recommendation is that the authorized users adhere to manufacturer

recommendations. One thing that's been identified is that there's anatomy that needs smaller catheter, smaller needle gauge sizes. Interventional radiologists have moved to using needle gauge sizes and catheter sizes that are smaller than what the manufacturer recommends. We believe this has contributed to some of the medical events with yttrium-90 microspheres.

The other issue is aggregation of the microspheres. So proper delivery, proper set up of the delivery box, and agitation of the microspheres is very important for our licensee so that they can deliver the microspheres without aggregation, clumping, and all of the radiopharmaceutical or the microspheres can get to the patient.

Looking first at 35.200, you can see some of the work done by Dr. Ennis and the Committee prior to my involvement. And then you can see added 2021 and 2022. The number of medical events in 35.200 is relatively small. And keeping with the Ennis methodology, items that could be or medical events that could be prevented by a time-out are wrong drug, wrong dosage, and wrong patients by the Ennis methodology. So the four medical events that occurred in 2021 could have been prevented -- at least the

Committee surmised that this could have been prevented by the use of a time-out.

Next moving to 35.300 where a written directive is required, we see a breakdown of the different types of medical events by year. We see that it's relatively constant, though there has been -- I would say -- I'll keep it this way. Let me say it that way. It's relatively constant. You see some areas where there may be some uptick. So from 2021 and 2022 a time-out may have been useful in 50 percent of the medical events that occurred in 2021. In 2022 about 30 percent of the medical events may have been prevented by the use of a time-out. Again, these are wrong drug, wrong dose, wrong patient.

Our next area is 10 CFR 35.400, Manual Brachytherapy. So we see a relatively low number of events in manual brachytherapy, which is great. We've seen in the past some significant with prostate doses being higher than expected, but that seems to have tailed off as you look at 2019 and beyond. So most of what happened in 2021 and 2022, the occurrences were relatively low.

Let's move to the next slide, which is a continuation of that slide. And you can see the totals. They are 7, 13, 5, 6, 4, 1. So relatively

stable, relatively low. The other issue is will a time-out have helped in these situations to prevent the medical events? And the other area that we looked at was was there a lack of experience or inattention and how did that play a role in medical events?

Let's move to the next slide. This is a note from previous work. After 2019 many of the medical events were re-categorized from dose to activity-based. So the potential medical event issues that we mentioned were lack of attention and inexperience.

Moving to the next slide. Summary. So potentially 9 out of 36, or 25 percent, of the medical events from the period of 2017 to 2022 may have been prevented by the use of a time-out, which is defined for this using the Ennis methodology as wrong site, wrong source, wrong patient. So using a time-out or a checklist in 2021 could have prevented three-quarters or 75 percent of the medical events that occurred. Three out of four.

The training of infrequently performed procedures did not seem to be a factor in the medical events that occurred in 2021 and 2022, although that was cited in previous years.

Increased attention during the procedure is not

a factor in the medical events observed in 2021 or 2022.

Next area to look at is 10 CFR 35.600. You can see that medical events have been relatively stable with a slight drop in 2021 and sort of back in that area of around 10 to 13 medical events. These events have occurred from a number of different reasons, and I think some of the ones that stick out were wrong position treated or the wrong reference length from the transfer tubes in HDR brachytherapy.

Moving to the next slide, what we see here is a breakdown by site treated. So GYN, or gynecological treatments still seem to be the most prevalent, the most -- had the largest number of medical events occurring at that treatment site. As you can see there are 38 as compared to the others, so 38 out of 57, certainly a large percentage.

Moving to the next slide, in summary, if you look at the medical events that may have been prevented by a time-out, which is defined in the Ennis methodology as wrong plan, wrong dose, in 2017, time-out, there was no benefit. In 2018, 30 percent, 3 out of 10 may have benefitted from a time-out. And from 2019 on no events were going -- would -- no events would have benefit from the use of a time-out. And so

that total -- this is three out of five and -- confused as to what that is, so I'll have to get back to you on that. So let me move forward because certainly the denominator is not five.

So I think there's a mistake there. That's on me. I apologize.

All right. The other issue is medical events caused by infrequent users or inattention while performing the procedure. Again, this is very difficult to determine based on the information in the nuclear medical events database. So what's been used in the past for this assessment is that wrong position is a surrogate for infrequent users and inattention. So the wrong position was treated. And you can see the breakdown. 2017, two out of eight; 2018, one out of ten, and so on. And that total was 25 percent, or 14 in 57, of these events were caused by or at least surmised to be caused by wrong position analogous from infrequent user or inattention and inappropriate levels of attention to detail.

The next area that we looked at as a committee was 35.1000. 35.1000, there were not -- there was only one additional event, none in 2022, for radioactive seed localizations. So radioactive seed localizations seem to be a relatively low occurrence

of medical events, and the one that did occur was due to seed migration in 2021.

Moving to the next slide is intravenous cardiac brachytherapy. There were no new events in this category in 2021 or 2022. So the summary from Dr. Ennis' work and the Committee's prior work is listed here. There's nothing new to present.

35.1000, specifically looking at Gamma Knife Perfexion, Icon, Esprit. Total medical events has been relatively stable; one or two, zero to two. And you can see the different causes here. In 2021 there were no medical events involving Gamma Knife of these three models. There was one due to wrong site, which was due to human error and shifting of co-registration images, and there was one where the patient motion management system failed. So two events in 2022.

We spoke briefly about yttrium-90 microspheres earlier. There are TheraSpheres and SIR-Spheres. So we're going to talk about TheraSpheres first. And we can see that it looks like there is an uptick in the number of medical events involving yttrium-90 TheraSpheres, up to 23 in 2021 and 2022. So this does seem to be fairly significant. In 2021 there were 10 cases where there was 20 percent

residual activity remaining in the delivery box, the delivery device due to the remaining radioactive material there or possibly due to leakage within that delivery set system.

Another area again was mentioned previously was wrong site and -- actually it wasn't mentioned earlier, excuse me, wrong site, where catheter placement -- there was -- well, the wrong placement size was mentioned, but placement location was not. So let me clarify that. So there were seven cases in 2022 where there was the wrong site either due to catheter placement error or the size of the catheter. And again size of the catheter, we should stay with manufacturer recommendations. At least that's our recommendation. And if you look down to the bottom, a time-out may have been useful in some of these situations. Time-out is those that were in the category of wrong dose. So for 2021 4 out of 23, or 17 percent of these medical events could have benefitted from a time-out. Two out of twenty-three, or nine percent could have benefitted from a time-out in 2022.

Infrequent or inattention. Ten out of twenty-three, or forty-three percent could have benefitted here. And this is for the residual doses

of 20 percent left in the delivery set box. So either improper set up, problems with pressure, problems with aggregation, problems with delivering the radioactive microspheres properly. And then there were 2 out of 23, or 9 percent that might have benefitted from a time-out in 2022.

Looking at SIR-Spheres, you can see that the number is relatively constant. There was an uptick in 2021 where there were 18 medical events. 2022 came back into the more normal realm of somewhere between 7 to 11. And again, you can see a breakdown. And it looked like the most prevalent situation in 2021 and 2022 with the SIR-Spheres was aggregation of the microspheres within the delivery set. So it's very important. And Mr. Green has pointed this out in the past how important it is to agitate the spheres to make sure that the spheres are delivered properly. If the spheres sit, they can settle, they can clump and aggregate and they don't get infused through the delivery set properly.

So you can see that there were quite a few: nine in 2021, six in 2022, due to aggregation of microspheres. So a time-out may have benefitted in one of the cases out of 18, or 6 percent in 2021. In 2022 one out of nine, or 11 percent may have

benefitted from a time-out. And this is defined as wrong site.

Infrequent, inattention. Two out of eighteen, or eleven percent for 2021. One out of nine, or eleven percent -- or twenty percent of the residual activity remaining in the delivery set and wasn't infused to the patient leading to another (audio interference).

In sort of some summary slides here, we want to make sure that we're recommending that people ensure their familiarity with the mechanics of the yttrium-90 microsphere delivery device and their set up procedures. They know their device well and they set it up properly and have good procedures hoping that medical events will be reduced.

Very important to confirm that all the data and the calculations in the treatment plan are correct. I think that goes without saying, but that has been something that has been an issue in the past.

Performing a time-out is something that may be beneficial to ensure that all elements of the treatment are in accordance with the written directive.

And possible elements of a time-out. And these are directly stolen/plagiarized from Dr. Ennis.

Again, obviously identifying the patient via two methods to make sure that you have the correct patient identified, identifying the proper procedure at the time of time-out, the radiopharmaceutical, the proper activity being administered, performing a second check of the dosage calculation, and that the written directive and the dosage are identical, because there have been cases where there have been errors in this area.

Other things that are applicable are the units of activity for low-dose rate prostate, identifying the anatomic location so the right site, the correct site is treated, making sure the patient and the treatment plan is accurate. Treatment plan independent second check has to be performed. You have to do a second check of the primary. Reference length was seen as an issue for the transfer tubes. If the reference length and the transfer tube is not the proper length, then we're not going to be treating the correct site. And the implant site location for radioactive seed localization is something that was identified in the past.

So these are the acronyms used on the next slide. All right? I think we're mostly familiar with these. And at this point that concludes the

presentation that I would like to give. Again, I appreciate the opportunity to participate on this Committee and it was very valuable and I think personally I learned quite a bit. I really commend all of the Committee members, Subcommittee members for all their effort.

There was some talk of potentially defining maybe some of the medical events in a slightly different way, but that's something that we're going to be looking at before our next review, so we kept with what I call the Ennis methodology, Dr. Ennis' methodology going forward.

So thank you very much for the opportunity to present and for all the help that everyone gave. If I went too quickly, I apologize. I know there was a lot to cover. And I'd be open to any questions that you may have.

CHAIR METTER: Thank you, Dr. Harvey, for a very comprehensive analysis of the unsealed and sealed source medical events for 2021 and 2022.

Do I have a motion first of all to approve the report by the Subcommittee?

(No audible response.)

CHAIR METTER: Okay. We can go ahead and ask questions.

VICE CHAIR JADVAR: Thank you, Richard, and I want to thank you and the Subcommittee members for that wonderful report.

Just a couple of observations and comments. On page 8 there is -- so there was only one extravasation over five years? I just want to -- because that has been an issue of interest and I just want to highlight that we are reporting that there's only one extravasation over five years. Is that correct?

DR. HARVEY: I don't have the raw data in front of me, so I hate to say I can't answer that 100 percent. I'm sure that your analysis is probably correct, but I don't have the raw data in front me to make that comment. I don't know if Mr. DiMarco could add anything just because he's done so much work as the NRC staff resource on this.

CHAIR METTER: Let me just -- before I make that, thank you very much. Yes, either Mr. DiMarco or Dr. Tapp, please make a comment. Thank you.

MR. DiMARCO: Hi, Daniel DiMarco, NRC. I would like to say that although that may have been listed as an extravasation in the NMED database, the NRC still and has not for this entire time recognized

any extravasation as a medical event as per the current medical event reporting criteria. So while that may be in NMED listed as extravasation, that is not a medical event for that.

CHAIR METTER: I do have a question for the NRC staff. As far as medical event reporting, is it primarily -- I know it's supposed to be when you have a medical event, you should report it to the NRC to look for trends, common trends that can help protect our patients if common trends occur such as a catheter issue with y-90 in the past. Are the primary -- people that's into medical events, are they primarily NRC or they're just also Agreement States? I mean, I know they should be, but I'm just asking what percent. Is it proportional to the percentage of NRC versus Agreement States? Because there's only -- there's a small percentage of NRC states. And I just want to ask that question.

DR. HARVEY: I would say that your assumption there is correct. The medical events that we get are primarily from Agreement States just because, like you said, most of our licensees are in Agreement States.

CHAIR METTER: Thank you.

Dr. Jadvar?

VICE CHAIR JADVAR: And I just want to highlight that under 35.300 on page 9 there are no extravasations. That's where Lutathera and Pluvicto goes for treatment. I just want to highlight that.

The other comment I have is on page -- regarding SIR-Spheres and TheraSpheres, on page -- well, there's no page number here, but under SIR-Spheres the total is all zeroes. Those should be changed. I count 61 total medical events for SIR-Spheres and you have 105 for TheraSpheres. So I'm just wondering if this difference between these two type of sphere is -- as far as the total medical events is it because of the -- a reflection of the type of -- or the prevalence of use of these methodology? There may be more people using TheraSpheres as opposed to SIR-Spheres? Or is it really something dependent upon the technique itself using either on one of these?

Perhaps you, Richard, or Dr. Angle can address that.

DR. HARVEY: So first of all, you kind of lost me. So which slide are you referring to first? We could go back and take a look at that.

VICE CHAIR JADVAR: Okay. There is no page number, so unfortunately I don't have it. So

it's under 35.1000.

MR. HARVEY: Yes.

VICE CHAIR JADVAR: Y-90 TheraSpheres, the total medical events were 105.

Is that correct?

DR. HARVEY: That is correct, from 2017 through 2022.

VICE CHAIR JADVAR: Exactly. And then next page, SIR-Spheres, the total medical events it says zero, but it really should be 61.

The last column is all zeros. That's incorrect. I added it myself.

DR. HARVEY: I apologize for that, and I did not catch that. I will get that corrected and get that resubmitted to the, to the NRC.

VICE CHAIR JADVAR: But what I'm saying is that if I added correctly, it's 61 versus 105.

Is that just because people use more TheraSpheres as opposed to SIR-Spheres, or is it something related that that difference in the medical events numbers?

Is that something related to the technique itself?

DR. HARVEY: So, I, Dr. Angle can speak to that, too. I don't know if there is a higher

volume of usage of TheraSpheres versus SIR-Spheres. I cannot answer that question.

Maybe Dr. Angle can, or maybe Mr. Green can maybe put some light on that. I'm not sure. I know they're both used very prevalently, but I don't know if one's used more than the other.

CHAIR METTER: Let me have Mr. Green, and then we'll have Dr. Angle speak.

Mr. GREEN: Thank you, Dr. Metter.

Unfortunately, Dr. Jadvar, we can't answer, I'm sorry. Unfortunately, we can't answer it directly what may be the proportionality concern here.

Couple things come to mind. One could be market share. Second could be the actual sphere composition. One's resin, one's glass. One's got a greater density, that could be physics.

The other could be the delivery apparatus. And the last one that comes to my mind is the container.

They go from a simple V-vial to a more complicated interconnected delivery apparatus where the incoming saline actually flushes and causes a vortex, to more adequately distribute them into suspension, or distribution, so they could actually leave and go out to the catheter and into the patient.

So, there's I'm sure Dr. Angle can think of more, but it's not as simple as to market share, or other factors.

CHAIR METTER: Dr. Angle?

Dr. Angle Yes, I just want to elaborate little bit on a comment Dr. Harvey made. Is it, the Y-90 delivery I think, is very unique among almost anything we talk about.

This is as you know, microspheres that are injected into a very small caliber catheter. And there's a bit of a rapid evolving market.

So not only do we not know the number of procedures being done, but also the way they're being administered is rapidly changing.

And what I mean by that is, is that up until maybe five years ago, most administrations would lobar And now I would say most administrations are segmental, or even less.

And so, operators are finding great results with this. The clinical outcomes are very encouraging in the literature, but it is going to change, I think, our medical event reporting.

We're going to see more occlusions of catheters, because smaller catheters being put in more peripherally.

We of course in this committee, lump all those medical events together. We've talked about this many times.

Maybe in terms of patient harm, that isn't as great as some other medical events, and may need a repeat procedure.

But my point being is that, the practice is changing rapidly. The administration is being done in a different manner, which is going to lead to more I think, medical events.

But their clinical impact needs to be looked at not only in terms of the whole number of patients being done, but the relative good to the relative adverse events.

CHAIR METTER: Thank you, Dr. Angle. We may have to just re-look at this Y-90 medical event and the current systems of going suubsegmental, I mean, you know, very, below the recommendation.

And maybe we'll, we might have to re-speak with industry again.

Yes, Dr. Einstein.

MEMBER EINSTEIN: Thanks. Two points, a comment and a question.

In the possible elements of a time out, I

certainly support identity of patient via two identifiers.

Some institutions specifically exclude date of birth, as I understand it, as an identifier. And, the Joint Commissions Accreditation Manual defines a patient identifier as information directly associated with an individual, that reliably identifies the individual as the person for whom the service or treatment is intended.

Acceptable identifiers may be the individual's name and assigned identification number, telephone number, date of birth, or other patient specific identifier.

I think my recommendation would be not to sort of single out name and date of birth as the two identifiers to be used.

It's going to depend upon institutional policies. We do say EG here, for example, but maybe it would be worthwhile to consider those other identifiers.

CHAIR METTER: Thank you, thank you for the comment.

Any other comments?

MEMBER EINSTEIN: Question. I'm curious why in the 35.600, the preponderance of medical events

occurred in gynecologic oncology patients.

And, it's sort of a similar question. Is that simply due to the volume of studies performed in that patient population, or is there something intrinsic, something else going on?

CHAIR METTER: Very interesting question, yes. Do I have one of the radiation oncologists? Yes, Dr. Wolkov.

MEMBER WOLKOV: What was the question you were specifically asking?

(No audible response.)

MEMBER WOLKOV: The number of GYN cases, correct?

MEMBER EINSTEIN: About 600 of medical event summary --

(Simultaneous speaking.)

MEMBER WOLKOV: Okay.

MEMBER EINSTEIN: -- to the table. Thirty-eight of the 57 events occurred in patients with GYN tumors.

MEMBER WOLKOV: Okay.

So, the, sorry, yes, Harvey Wolkov, radiation oncology.

The reason for that largely was location. The catheter placement. The device placement. So,

that was the majority of issues.

What we discussed as a committee, was perhaps on page 16 by the way, including one other factor, which partially addresses your concern, and that looks at location.

So, location of the radioactive sources. So if you look at the number of patients, actually it was fairly high in the setting of GYN tumors, because of that particular issue.

The other thing we discussed as a committee, was whether or not we should change the methodology specifically for 35.600, to include not only wrong plan, wrong dose, but also location, wrong location.

Because that then changes the statistics quite a bit.

MEMBER HARVEY: And, we agreed to look at that further going forward as a committee. And, we may make that change that Dr. Wolkov is talking about, going forward.

But we did remain consistent with Dr. Ennis' methodology for this meeting. And, I very, very much appreciate your support and the comment.

MEMBER OUHIB: This is the --

(Simultaneous speaking.)

CHAIR METTER: Thank you Dr. Wolkov --

MEMBER OUHIB: If I may interject here? Regarding the GYN, there are a few things that actually can happen.

And that is sometimes the, on the first application there is imaging. But then assuming that the applicator, GYN applicator, cylinder let's just say, can fit just fine but there is no repeated imaging.

And therefore, because of lack of re-imaging, that would lead to that.

The other thing it has to do with the prescription. There is a misunderstanding prescribing to the surface of the applicator, or 3 mm., or 2 mm. or what not. And that actually also lead to quite a few errors.

I just want to add one general comment. And, that is related to the time out and the checklist.

Unfortunately, we don't have access to the user's time out, what was actually used, or the checklist for that matter.

But I think the problem is even bigger. This is a paradigm shift. It is not whether the institution has a checklist or a time out, because I

can tell you the majority do have it.

Some is very detailed, others is a very quick okay, yes, this is this, this is this. Okay, let's move on.

But I think the big issue is really lack of focus every aspect of that procedure. And that is starting from patient verification, to actually end of treatment.

And there are distractions, and so on and so forth, and it's not like the people are not focusing, but they might not be focusing on the right thing.

And I think that's something that we probably should look into. And, I'll be happy to answer to any question on that item.

CHAIR METTER: Thank you, Mr. Ouhib.

But we have to remember what our, the NRC is. We are not actually in the practice of medicine, but we're on the regulatory prevention of overexposure to the public, a patient in the public in regarding the medical uses of radioisotopes.

So we have to be careful because there's a fine line between that, and the practice of medicine.

So I think you know, human error I think

as Mr. Harvey said, is actually a good term. And you know, as far as being very specific, I don't think it's in our purview to be that.

Is that correct, Mr. Einberg?

MR. EINBERG: Yes, that is correct, Dr. Metter.

We want to limit or prevent over exposures as much as possible, but we do not get into the practice of medicine.

And if I may take this opportunity also, I was just looking that we have a information notice that we published in 2019 on the methods to prevent medical events.

And I'm not sure if the committee, subcommittee had a chance to review that. But one of those aspects was to look at time outs. And, time outs are discussed in that information notice.

And if you know, from the staff perspective here, you know, if there is recommendations that we need to go out and update our guidance, our information notice, or generic communications if it's not being effective, then you know, would be interested in learning more about that.

Dr. Tapp is the author to that information notice. And so, I'll, I see she wanted to say

something as well, so I'll give her the opportunity, if that's all right.

CHAIR METTER: Yes, Dr. Tapp?

DR. TAPP: Yes. That information notice came out of an ACMUI meeting from Dr. Ennis, and his recommendations.

I do want to circle back though, on the practice of medicine. On ensuring that the treatment goes as directed by the authorized user, that is something that we do continue to look at.

And, one of the things for HDR is we do have requirements of minimum calibration, and quality assurance before the treatments, that are expected.

And, one of the places there is it is to make sure the source applicators are going to the location that they expect.

And, the calibration requirements kind of tie back into professional standards. So, we do go back to Zoubir, Mr. Ouhib is coming from with the AAPM.

So, there is kind of like a loop. We do make, in the role, we are making sure that the administration is in accordance with the direction of the authorized user.

So, there is a little bit of close call

there, but we do have a little role --

CHAIR METTER: Well, thank you, Dr. Tapp.

Yes, Dr. Harvey?

DR. HARVEY: Yes, I just want to beg the pardon of the NRC and the committee, for the mistakes on slides 22 and 16. They will be corrected, and they will be resubmitted. And so, I apologize for that.

Thank you.

MEMBER MAILMAN: No worries. I think I have three comments actually.

Following up to Dr. Jadvar's comment, not only in the spheres realm but in all realms, and I know it's hard to get this number, but it would be interesting to know as a percentage of the procedures done, rather than the absolute.

The absolute numbers are great, but you know, we're going to have an increasing number of certain therapies, and a declining of certain others.

And, it would be nice to know whether we're getting better or worse, as the percentage of procedures going, go forward.

Richard, do you want?

Dr. HARVEY: So, the problem I think there is the denominator and us now knowing the total number of procedures.

So, I don't know if we'd ever be able to answer that question for you.

MEMBER MAILMAN: So, I hope one day we figure out how to get the denominator in the future. The second thing I would say is, one of your points on where medical errors are more likely to occur, were in centers that did things infrequently.

But do we have a definition of what infrequently is for this? And, do we have specific recommendations for infrequently?

Because I see a general set of recommendations, but if this is happening more in places that infrequent, it would be nice to know what that, what that definition is.

We have our acronyms, but we don't have a definition and I don't know what infrequent is.

DR. HARVEY: I don't think that we have a specific definition of the number of procedures that would be used, that would be called frequent or infrequent.

I think we're looking at it just very qualitatively as in overarching you know, the sentiment --

MEMBER MAILMAN: We're using it to define that we have a delineation point. So, either we have

a delineation point that's infrequent or frequent, or we need to come up with it to be specific so we can make specific recommendations to that point.

DR. HARVEY: We can certainly address that going forward, or we can not speak of it that way if we can't do that.

I mean, it's very difficult for us to say that we you know, somebody that wants to do the treatment. Somebody doing a low volume, they may do it very, very well.

And so we, we're not trying to say that somebody is an infrequent user shouldn't do it, or anything of that nature.

So, I think we'll take a look at that as a committee, and try to get that better defined for you going forward, yes.

MEMBER MAILMAN: Right, because you're using it as a point. You want to add to that, or not?

CHAIR METTER: If Dr. Einstein has a comment.

MEMBER MAILMAN: The last, the last comment.

CHAIR METTER: Since it's going to be on this comment, Dr. Einstein?

MEMBER EINSTEIN: Yes.

In terms of your question about the denominator. So, such data are available. CMS has some publicly available data.

Unfortunately, CMS's publicly available data excludes studies performed by providers who perform the test less than 10 times in a year.

I think most people performing these tests do it more than 10 times per year. But even beyond that, one can purchase data from CMS for $500.00 per year, which may be doable for the NRC.

And, I don't know if CMS would charge the NRC for it. So, that covers Medicare data. I've purchased that for research studies and insofar as my research agreement with CMS, you know, allows, I'm happy to share that with, with the NRC.

But I'd have to check the verbiage of the agreement which I have.

Not every patient obviously is covered by CMS. There are private payers. It's also services which aggregate private payer data, it's more expensive than CMS data.

But the data's out there if you're willing to pay for it if you want to get that denominator to know what the, the rate of these events are.

CHAIR METTER: Thank you, Dr. Einstein.

Mr. Einberg?

MR. EINBERG: Yes, thank you Dr. Einstein, for that.

And just numerous years back, we did new work with the manufacturers of microspheres. And, we were able to get some data. Of course, that data is proprietary and we have to be very careful when we share that.

But we can take that as an action item, to try to work with the manufacturers to try to get some data. And Dr. Einstein, any pointers where we can look for that data would be appreciated, as well.

CHAIR METTER: Thank you.

MEMBER MAILMAN: My last point I said I'd have three, and I will keep it right to three.

You know, you do have a list of new or suggested items to reduce medical events, which is great.

Is there any concept or any idea of what a patient could do to, to help reduce medical events? Should they be proactive in this, or discussion of pro-activity to make sure that their provider has checked their data twice?

Or something that we can do in the patient community across the board to say, when having the

procedure, these are the following things to help prevent a medical event.

You know, they happen rarely. I want to be clear the numbers you're doing are, you look, there's millions of procedures going on, or tens of thousands depending on what the particular thing is.

So, these numbers on the absolute levels are low. But if there's anything that we as the recipients of these medical procedures can do to help reduce this number as well, I think taking that into account would be, would benefit us as well.

That was my three points.

DR. HARVEY: Richard Harvey, responding to Mr. Mailman's comments. And, I think those are, all your comments have been fantastic. I really like this one quite a bit.

I can't really, I don't want to speak for the NRC, but I don't think that we can tell the patients what to do.

But I do strongly believe that patients should be a very strong advocate in their own care. And they should be asking questions, and challenging their health care providers to make sure that they're given, you know, the proper treatments, and things are done properly.

But I think I would leave it to the NRC to comment on whether or not there could be guidance or recommendations, given to patients.

MEMBER MAILMAN: Yes, I'm not asking to put the onus on the patients to reduce medical events. I'm just trying to be saying that we can be part of the solution, and how, how we figure that out without putting the onus on the patient.

But to keep that number at this low level, or even reduce it.

MEMBER OUHIB: This is Zoubir Ouhib. If I may? There are certainly things that a patient can do to actually prevent certain medical error. And that is be an active participant.

At a working group, we are actually looking at that and say, and see what are the things that a patient can actually do. Ask, or verify, and so on and so forth.

To go back to the frequent and infrequent term per se, I'm not really sure if the ACMUI should be taking the lead on that.

I would say probably organizations such as ASTRO can probably better define what's infrequent, what's, and so on and so forth.

CHAIR METTER: Thank you, Mr. Zoubir.

Yes, Mr. Green?

MR. GREEN: We don't know the term frequent or infrequent. Can the contractor that runs NMED be asked to make modifications so if there is an event regarding microspheres, to inquire of the reporter of the number of procedures they do annually?

I mean, could we get data through NMED that might give us clarity?

MR. EINBERG: Chris Einberg. The NMED contractor would be restricting you know, reaching out to the manufacturers.

Now, they can work with the licensees to ask clarifying questions, but it has to be within the constructs of our regulations.

Now, we, for medical events, we require the certain details for that report. We can't go beyond that.

And so, again, but we've tried to put out guidance in the med annual report, what constitutes a good medical event report, and tips for reporting with provider training in that regard.

But we are limited in exactly what we can ask.

Dr. Tapp had a question, if that's all right.

CHAIR METTER: Yes, Dr. Tapp?

DR. TAPP: Yes, going back to what could we do with recommending for patients to advocate for themselves.

I do think the NRC would be limited in that role. We license the licensees, and not the patients.

So, I think like Mr. Ouhib had said, that's something that I think professional societies are usually more involved with its recommendations that way.

It would be hard for the NRC to put out anything for the patients.

CHAIR METTER: Thank you.

One thing that I was thinking of as far as regarding the question of the frequency of medical events, let's say for the Y-90 microspheres perhaps.

And it's not going to be in, I don't think it's going to be in the practice of medicine. But you could also add to your medical event data, has this been, has there been a medical event of this nature in the last month, and then you say last three months.

And you can kind of gauge. I mean, and you're looking at protecting the public. Because if it's been in the last month, you might, they might

have to explain it if it.

But if there hasn't been any in the last three, you know, that sort of thing. Just might ask for a short time frame.

Because if they're going to have more than you know, an x-number, they'll have it in the next three months, or one month, or something like that.

I don't know if that's going to be a doable thing.

MR. EINBERG: I'm not sure I completely understand what the question was, but let me kind of give a little bit of background that might help.

When a medical event is reported, it comes into our headquarters operations office. And those events actually come into my branch after, or medical events come into my branch.

And we do an evaluation, the medical team does an evaluation of those events immediately. And if there's any trending or trends that they see, then you know, we reach out for additional information.

We decide whether guidance is necessary, rulemaking is required, follow up inspections are required.

So, that's what we do on the medical side. The other events also come into the branch there, and

they're sent to analysis and trending groups.

And so, we do trending for different types of events, including medical events.

I'm not sure if that helps with where you were going with that.

CHAIR METTER: No, that does. That explains. You are tracking.

I think Dr. Angle has a question, or a comment.

DR. ANGLE: I was just going to get us grounded you know, back to the basics, which is there are some things that you just have to call absolute straight.

Even though the number of flights has gone up, our tolerance for planes falling out of the air is zero. And that applies to wrong site, and things.

And the comment I'd make is you know, the Joint Commission is very involved in patient advocacy for time out, and talking about we have an opportunity I suppose, to remind operators that time outs should be very detailed, and the patient should be involved in that time out.

CHAIR METTER: Thank you very much.

And just to remind you, the number of procedures that we do for therapy is a large amount,

compared to the number of medical events.

I think in my opinion, they're still small.

Are there any other questions or comments? Yes, Mr. Green.

MEMBER OUHIB: This is Zoubir Ouhib.

CHAIR METTER: Oh, I'm sorry.

MEMBER OUHIB: We did entertain actually, within this working group with the APM, that how can we approach the manufacturers for institution that they are not doing enough cases say, throughout the year.

And, to provide some sort of a plan where if they're not doing as many, to have some sort of a training whether it's six months or whatever that is, to sort of refresh you know, the users with how to proceed safely.

And, the manufacturers were sort of like open to that idea. But nothing has been sort of tackled yet.

CHAIR METTER: Thank you for that comment. Any comment on that, Mr. Einberg?

(No audible response.)

CHAIR METTER: Okay, Dr. Tapp?

DR. TAPP: (Audio interference) -- working

group that he's on AAPMs.

CHAIR METTER: Well, thank you.

So to keep on time, do I have any other -- yes, Mr. Williams?

MR. WILLIAMS: I have two questions. Mr. Einberg had mentioned that you know, based on the assessment and what you looked at over the events, is there a need for us to you know, re-look at our generic communications?

I don't think I heard an answer to that, that piece. But I would be interested in knowing do we think that's something we should look at.

And my second statement was, maybe you want to put a finer point on what Daniel had said is, because we have not made any determination that people need to report extravasations, I wouldn't infer anything from the report that you know, there are not extravasations happening because we've not required anyone to request, to report them.

I'm just trying to make sure that we don't infer anything from that because we, we haven't finished the rulemaking. We haven't made a determination.

So, I think it would be a little premature to make that statement.

CHAIR METTER: Thank you very much. Yes, those are very important comments to make, and I appreciate your comments on that. And Mr. Harvey will be taking those into consideration.

Any other comments or questions?

(No audible response.)

CHAIR METTER: So, we have comments and questions taken from our ACMUI subcommittee, our committee on the NRC staff.

Do I have any questions from the public?

(Pause.)

(No audible response.)

CHAIR METTER: Okay, seeing none, do I have a motion to approve the subcommittee -- yes, Dr. Wolkov?

MEMBER WOLKOV: Move approval of the committee report.

CHAIR METTER: Approval of the report with the suggestions, and addendums.

Okay, thank you. Do I have a second for that?

MEMBER MARTIN: Second.

CHAIR METTER: Thank you, Ms. Martin.

All in favor of the report and the additions, and the comments to be amended say aye.

(Chorus of aye.)

CHAIR METTER: Any opposition or abstentions?

(No audible response.)

CHAIR METTER: Well, thank you very much, Mr. Harvey for a very comprehensive, and thank you for the committee and NRC staff for a very comprehensive discussion.

So, just to be on time, we'll go ahead and go to our next topic, which is by Dr. Tapp, of the NRC.

She'll give an overview of the NRC requirements for veterinary release.

Dr. Tapp?

DR. TAPP: I promise I won't take up the entire time so if you need a little break, stand up, you know.

Thank you guys, stuck -- good. Thank you guys for letting me speak. I'm going to move over here for the presentation, and not get distracted by the screen.

At this presentation, I'm going to talk about veterinary release. So, we're going to be switching it up a little bit to talk about animals, and the veterinary practice, and how do we release

the, how do licensees release animals from the veterinary clinics.

Next slide, please.

Before I do that, I'm going to talk first about reminder of how do we release patients. As we all know, 10 CFR, Part 35 is specifically for medical use of byproduct material.

10 CFR Part 35.75 allows medical licensees the ability to authorize release of patients, if the dose to another individual from the exposure to that patient, is not likely to exceed 5 millisieverts.

This is a per release limit. 10 CFR Part 35 is specifically for medical use. So, it's not for veterinary use.

Therefore, veterinarians and veterinary clinics cannot use 35.75 to release animals from their clinics.

Next slide, please.

So, the veterinary release regulations are contained in Part 20. Part 20 public dose limits then apply for the release.

Because the licensees and vets do not have the ability to use 35.75 and that regulation that allows the release, the licensees must have the release procedures approved on their license condition

prior to use.

So, there's no regulation that is stands for everyone. They have to have it approved prior to use.

The dose limits in Part 20 are 1 millisieverts per year from all licensed operations. So, no longer per release limit. This is from everything they're going to be exposed to from that licensee's operations.

In addition, it's .02 millisieverts in any one hour from external sources. So, the exposure from the animal to a human, they have to meet that requirement of 2 millirem in any one hour from the sources.

This is a little different from 2 millirem per hour. This limit is 2 millirem in any one hour. So, it can be slightly higher if it's going to be a shorter duration of dose rate.

Sorry, it can be a slightly higher dose rate if the animal is not around a person for that hour. So it's 2 millirem in any one hour.

So say if they, it's 4 millirem but they're there less than 30 minutes, that would be okay because they're getting less than 2 millirem in that one hour.

To use these dose limits for release, the licensees are required to demonstrate by measurement or calculation, that the dose to the individual who is likely to receive the highest dose, does not exceed the annual dose limits.

Or, that the individual cannot exceed the limits if they're continuously present near the source. Or the animal in this case.

Most veterinary license users are going to use that first one. They're going to show by measurement or calculation, that the dose to the individual is not likely to exceed the highest, the annual dose limit.

Next slide, please.

The veterinary release guidance is contained in Appendix D of NUREG 1556, Volume 7, which is to consolidate guidance for material licensees specific to academic, research and development, and other licenses of limited scope.

This is different than Volume 9 that's used in medical.

This guidance states that licensees should provide owners with written instructions to reduce dose to members of the public.

These instructions should be used as a

margin for dose reduction, but should not be relied upon as the primary way of keeping members of the public below the annual dose limits.

It also informs licensees and applicants, that the criteria for release must be submitted in the application for review and approval by a licensed viewer before implementation.

Next slide, please.

The current guidance that's in this NUREG is specific for cats treated with Iodine-131. This is the most common veterinary use, and it's very, provided in the guidance.

The guidance criteria that's approved in the guidance, is that cats are to be held not less than four days after administration.

The dose rate is less than .01 millisievert per hour at six inches. Written instructions are provided to owners.

And, licensees can demonstrate that members of the public would not receive a dose from the cat, to exceed that .02 millisieverts in any one hour, or 1 millisievert in any year.

This guidance is like I said, is very specific to the cats and the iodine, because this is what was used most frequently in the past, and what

was available.

But the guidance does state that other release criteria may be accepted on a case-by-case basis.

In addition, not just for other animals or other treatments, cats can also have different types of release criteria, but it has to be reviewed on a case-by-case basis. This is what's just approved in the guidance as like the starting point.

Next slide, please.

The NUREG does have recommendations for what should be included in the instructions to the owners.

These include that the regulatory limits, and the need to keep doses as low as reasonably achievable.

The potential radiation field surrounding the animal, and the potential dose rate, the potential dose with time at various distances.

Maintaining distance from people and public places, and in the home. Minimize time in public places.

Precautions to spread, to reduce the spread of radioactive contamination. The handling and storing of animal excretia, and the duration for

storage if it is going to be held in for the decay.

This is to avoid landfill picking up the excretia, the waste.

The permitted extent and duration of contact by individuals with the animals and handling. Talks about contaminated bedding or other objects which the animal may come into contact with, and give instructions on that.

And then, the length and time each of these precautions should be in effect.

Next slide, please.

So as I said, the guidance is very specific to cats with iodine. In 2019 the NRC received an application for release of dogs being treated with Synovetin OA.

Synovetin OA is a tin-117m colloid that's used to treat osteoarthritis in dogs' joints. What happened was Exubrion provided a template procedure to release these dogs so veterinarians in the future could use their, their procedure, and then use that for proposals so they could get a license to release animals after following treatment with their product.

Their specific proposal that the NRC reviewed was for treating both dog's elbows with a maximum of 111 megabecquerels per elbow, or 222

megabecquerels total.

For consistency and efficiency, the NRC evaluated this template provided by the manufacturer, for future licensees' use.

As described in the licensing guidance, licensees still have to provide this procedure as part of their applications if they wish to use it, even though the NRC conducted their review and had conducted our evaluation, and determined it was appropriate.

Next slide, please.

So, the procedure proposal was to allow release of the dogs with a measured dose rate of less than .45 mR per hour at 1 meter.

To provide competence that the dose limits would not be exceeded, the procedure included a multi-layer approach.

As I said, these, that dose rate there is much higher than you see in the guidance, so they provided a lot more assurance that the dose limits would not be exceeded.

They first did a technical assessment to evaluate common dog/human interactions that could potentially exceed the dose limits that are in Part 20.

They then created a release procedure, which included pre-screening questionnaire to determine if the dog had these type of behaviors.

And if they needed to stop or modify these behaviors, which could exceed the dose limit. Or potentially, if they could not stop or modify these excedures, exclude the release of the animal following treatment to ensure the dose limit is not exceeded.

The release procedure states the licensee would only provide the treatment if they're confident the owner understands the need to comply with these instructions, to ensure the dose limits wouldn't be exceeded.

And, they could comply with the behavior modifications as necessary. And the patient specific instructions are signed by the owner.

The NRC found Exubrion's proposed procedure provides adequate assurance that public dose limits would not be exceeded, when licensees perform adequate pre-screening and the instructions are followed.

Next slide, please.

A little bit about this pre-screening questionnaire. It is more --

(Audio interference.)

VICE CHAIR JADVAR: Hossein Jadvar. Very interesting report, thank you.

So, I-131 for cats and tin-117m colloid for dogs. I just wonder as a curiosity. What is the range of radionuclides that are used in veterinary medicine?

DR. TAPP: They are increasing. We have a report in our Office of Research, that has looked at some recent uses.

They are increasing. Most is Iodine-131 and tin to my knowledge, in clinical sense at this point.

But, do you have something to add?

MR. GREEN: You're correct, feline hyperthyroidism I think, is the leading veterinary use. I personally have never had any exposure with t-117m.

But we must not forget the equine use, the bone scan. There are certain parts of the country that is very, very large 200 millicurie bone scan for a horse.

DR. TAPP: There is a Yttrium-90 gel also being used in animals, but they are increasing.

CHAIR METTER: And, what is the Y-90 gel used for?

DR. TAPP: I believe it's sarcomas in dogs. But it's relatively new.

MEMBER OUHIB: This is Zoubir Ouhib. Are there any guidance as far as cremations for these animals, in the event of death?

DR. TAPP: Yes.

In the tin-117 proposal, it is a recommendation that you would tell the owner they have to, if something were to happen, to contact the RSO.

And then, they would be determined what could be done with the animal's body at that time. It would probably be a decay situation.

But there's no specific hard set guidance, but it is recommended that they contact the RSO if something were to happen.

CHAIR METTER: Yes, Dr. Einstein, and then Dr. Harvey.

MEMBER EINSTEIN: I assume because you didn't specify otherwise, that this, these dose limits would be the same for service animals and non-service animals.

So, that could lead to delay of the release of a service animal back to their, the individual for whom they are caring, because that individual would receive more than 1 millisievert over

the course of the year.

Is there any discussion about whether exemptions should be made for essential service animals?

DR. TAPP: That is a good question. I believe from the manufacturer for this one product, they did state that service animals likely would not have osteoarthritis, because they wouldn't be able to perform the activity.

So they didn't request that. So we have not done any type of valuation on that yet.

CHAIR METTER: Dr. Harvey?

DR. HARVEY: Hi, Richard Harvey.

Yes, I just wanted to clarify. I mean, I think the health medical physicists are so, should you know, be available in a consolatory role to help with this.

What I was kind of referring to before was where this practitioner wanted me to be their RSO, and accept all the responsibility as more of a third party, which is why I wasn't comfortable with it.

So, I just think that's something to watch out for. I'm sure you already know that, but I just wanted to clarify that comment from before.

Thank you, Dr. Tapp.

DR. TAPP: Thank you for the clarification.

CHAIR METTER: I do have a question.

What are the criteria for a veterinarian to become an authorized user? And for example, I think you said it's on a case-by-case basis, but who determines it?

Is there a veterinary state board? Is it the local licensee, or who determines who gets put on the license, or how they become an authorized user?

Because I guess there wouldn't be a license on, you know, in their own clinic.

DR. TAPP: And, I do believe this varies by state to state, but veterinary authorized users I do not believe are listed on a license.

I'm looking for a license reviewer.

MEMBER SHOBER: So, this is Megan Shober.

We would, you know, typical limited scope license that would cover veterinary uses, would have authorized users listed on it.

Those would typically be the veterinarians, but not the vet techs that would be handling, caring for the animals during the time they were boarded.

So, yes, absolutely the veterinarians would be listed on the license.

CHAIR METTER: And you mentioned as far as veterinarian training and experience, it's not standardized.

So, was I correct?

MEMBER SHOBER: The NUREG 1757 -- 1556, line 7, does include criteria for authorized users in general. And then the veterinary use is a subset of the whole, that whole document.

So, we would be looking for specific training and experience that did involve radioactive material, with the feline therapies.

The people that have come to us seeking approval, AU status for the I-131 therapies, I mean, that is around in clinics.

And so, those veterinarians come in usually with experience, because they would have gotten that somewhere else before they're setting up their own vet clinic.

But yes, we would be reviewing their hours, and their experience with radioactive material before we put them on the license.

CHAIR METTER: The other thing is that you know, as far as when they get their authorized use, it

is going, is it going to be like our 35.390, or is it going to be individual just for I-131, and then when the tin comes in and all these other ones, they need to get separate authorized users?

MEMBER SHOBER: So, to speak to that, we haven't seen clinics that have more than one use. So, it's either you have a vet clinic that is doing the I-131 therapy.

The clinic we have in Wisconsin that is licensed for the Exubrion, doesn't do I-131. So, we would, if there were a clinic that were having more than one type of use, yes, we would want to see experience with both products.

I would, personally. Not going to speak for all the states, or the NRC. But for certain, that's, I think that would be pretty common tactic.

DR. TAPP: Yes, to follow on with that, there is not regulatory training and experience requirements for veterinary use.

It's contained in the guidance, which gives it a little bit more flexibility for license reviewers.

But they are listed individually like, what they are approved for. And as I said, if they're going to use a release procedure, that has to be

reviewed and tied down in a license.

So it's going to be reviewed by a license reviewer, and they're going to ensure that the training's there, that there's an RSO capabilities.

And that's the tie ins. There's not in the regulations, but it's a license reviewer.

CHAIR METTER: And who would be the license reviewer? Is there a specific one let's say for OSA?

MEMBER SHOBER: So, each state, you know, would be doing that.

CHAIR METTER: Okay, thank you.

Do I have any other questions? It's a very, very interesting topic and I'm glad you brought it up because it's another scope that we're, I just personally, I knew about hyperthyroid catd I-131, but I didn't know about these other entities, and treatments.

Yes?

DR. TAPP: I see Maryann has her hand raised.

CHAIR METTER: Oh, I'm sorry. Yes, go ahead.

MS. AYOADE: Hi, not a question, just a comment for the record and for the court reporter because we did lose signal, Katie, for the

presentation.

I believe it was on your slide for the pre-screening questionnaire. The slides are available to the members of the public, and so they can look at those there.

But I didn't know if you all were fully aware that we missed about maybe 4-5 minutes of the last, towards the end of your presentation.

But just for the record, just so that it's on there and they can review the slides.

CHAIR METTER: Thank you very much Ms. Ayoade. I didn't realize that, but thank you for that very, that comment for our public members -- viewers.

Any other last comments or questions from the committee, or the NRC staff?

(No audible response.)

CHAIR METTER: Any public members in the room?

(No audible response.)

CHAIR METTER: Any public members on the call?

(No audible response.)

CHAIR METTER: Okay, thank you very much for a very interesting, and very comprehensive report. And appreciate your looking into that.

So at this point, that is our last presentation for the morning and we're a little bit early, so you have a little more time to, for lunch.

And, we will conclude the morning session of the ACMUI and we will re-adjourn at 1:30.

Thank you.

(Whereupon, the above-entitled matter went off the record at 11:52 a.m. and resumed at 1:31 p.m.)

CHAIR METTER: Good afternoon, and welcome back to the 2023 fall meeting of the ACMUI. I'm Darlene Metter, ACMUI chair and diagnostic radiologist.

Before we start our afternoon presentation, the committee needs to revote on the open items that Ms. Armstead had presented today. So may I have a motion regarding the open items for approval by the committee?

MEMBER EINSTEIN: So moved.

CHAIR METTER: Dr. Einstein moves to approve those open items. Do I have a second?

DR. HARVEY: I'll second.

CHAIR METTER: Dr. Harvey has seconded. Do I have any -- all in favor, say aye.

(Chorus of aye.)

CHAIR METTER: All opposed or abstain?

Ms. Armstead, we have unanimous approval of the open items.

Okay, for the first presentation for this afternoon will be Mr. Davila, NRC staff, on ICRP Publication 153.

Mr. Davila.

MR. EINBERG: He's going to be presenting remotely.

MR. DAVILA: Good afternoon. I think I need to be made a presenter so I can share my screen.

MS. ARMSTEAD: You should be able to do it now. And we can see the screen and we can see you. Thank you.

MR. DAVILA: Okay, perfect awesome.

Thank you so much for the introduction. Good afternoon, everybody, or good morning for those of you on the West Coast. As they mentioned, my name is Tony Davila. I am currently the Radiation Safety Officer for Tulane University.

However, I was fortunate enough to serve on the ICRP Task Group 110, Radiological Protection in Veterinary Practice under Dr. Nicole Martinez. And today I'll be giving an overview of the task group's publication.

I have no conflict of interest to declare.

However, I do have seven pets, so do what you will with that information.

I'd like to start by just kind of showing you task group members. I'm not going to, list everybody out by name. However, I do want to mention Debbie Gilley, who is not pictured here but made significant contributions.

Like I said, I'm not going to list everybody. But I do just want to point out the diverse background of the task group. We had health physicists, medical physicists, nuclear physicist, veterinary radiologists, veterinary radiation oncologists, regulators, researchers, radiation ecologists. So a wide range of disciplines were covered on the task group.

So here I have the contents of both the publication and of my presentation today. I'm essentially going to be giving everybody a guided tour through the document, highlighting some of the most important ideas.

So first even before the introduction, we have a section called why this publication. And essentially the purpose was to provide a summary of the motivation for the explicit considerations of radiological protection in veterinary practice.

Veterinary practice has changed considerably over the years, and along with it the types and number of applications of ionizing radiation have increased. And because of this evolution, the radiological risks have also increased as a result.

And these risks can affect both the animal being examined or treated, as well as the humans involved in the procedures, whether they're veterinary professionals, or laypersons, owners who may be helping out.

The objective of this publication is not to discourage veterinarians or animal user from using radiation. However, we just want to be sure that it's done safely.

Also, why now? Well, veterinarians were some of the first people to understand the importance of ionizing radiation. Pictured here is a dog who was being operated upon back in 1918 with the use of radiology.

And in fact, the chair of the first and second congress, a radiological congress, was a veterinarian. He was a close friend of William Roentgen, and he's actually the only veterinarian to have ever held the honor of chair.

And early on, most applications it was

pretty much strictly plain film radiography. So by just applying a few simple rules, it was easy to sufficiently limit the risk to staff, the animals, and even the owners and handlers. And so it was believed that, you know, the animal's not really any real risk from just plain film radiography.

However, over the past several years, applications and the availability of those applications has grown and diversified considerably. Factors such as digitalization, the increase in veterinary-specific equipment and also second-hand equipment, and even social factors have all played a role in this growth.

Kind of honing in on the social factor here, nowadays a lot of animals are considered part of the family. You know, we recognize the human-animal bond and the human -- the different benefits we get from the human-animal interactions. Just to name a few, things like, you know, stress relief, joy, empathy. You know, there's lots of benefits we derive from our relationship with animals.

And so we want to give them the best care possible. And if they're not necessarily a pet, you know, it could be a working animal and that would mean that they're part of a family's livelihood. Or maybe

it's an endangered animal or an exotic species, and it's important for conservation effort.

In all of these cases, the animals deserve the best care and their owners want the best care for them. And so that often entails some sort of radiological procedure.

And we can see this in the fact that, you know, a lot of states have some sort of law against, you know, animal cruelty. And we can even see this in our research ethos, right. We want to protect lab animals. In fact, any place that uses animals for research must have a institutional animal care and use committee, right.

And there's the three r's of animal research, you know, replacement, reduction, and refinement. And so, you know, it's evident throughout society that animals are important. And you know, monetary value can further stimulate this interest in an animal's welfare.

Again, you know, an animal research subject is -- can be very important. But also going back to the pet side of things or the family life, pet insurance has become more commonplace. And so these procedures are becoming increasingly affordable, and some pet insurances even require it as part of the

kind of eligibility screening process.

But going even beyond just the animals, you know, there's an increasing awareness of the interconnectedness of the health between human health, animal health, and environmental health and welfare. You may have heard of this as the CDC's One Health approach. Sometimes it also goes by the One Welfare approach.

And basically by optimizing, you know, the environment and animal health, we can also better human health as well. It's important to recognize, you know, the interrelationship between the human, animal, and environment.

So getting into the introduction, basically we provide our objective and the scope of the publication, along with elaborating on some of the historical background and modern motivation. As I mentioned with the advances in technology and the availability of said technology, there's a need to fully describe the radiological protection challenges in veterinary practice and how we can manage them by applying the ICRP's framework.

And the objective of the publication isn't to provide direct practice-oriented advice, but rather just kind of give an initial set of recommendations

and observations.

You know, the priority of radiological protection in veterinary medicine is still of the humans involved, however, the animal patient's protection is now also explicitly being considered. As well as protection of the environment from any veterinary nuclear medicine applications.

And this publication is intended for a wide-ranging audience. So radiological protection professionals, veterinary staff, students and anybody who would be providing education and training to those individuals. And as well as interested members of the public.

And you know, we aren't the only ones who have noticed this need. Several authorities have either updated or released some sort of guidance in regards to radiation safety in veterinary medicine. Probably the two most impactful to us or meaningful here in the States would be the NCRP's Report 148, Radiation Protection Veterinary Medicine.

And they came to a similar conclusion. The reasons for using radiation in veterinary medicine are to either obtain optimum diagnostic information, or to achieve a specific therapeutic effect while maintaining the radiation dose to the radiological

personnel and the general public as low as reasonably achievable. In other words, the ALARA principle. Similarly, it is also important to avoid all unnecessary irradiation of the animal patient.

And so in the next section, kind of getting into the meat of the publication, it is basic concepts of radiological protection. As I mentioned, this is intended for a wide-ranging audience, so we do review dosimetric quantities, such as absorbed dose, equivalent dose, effective dose, activity. We discussed the deterministic and stochastic effects.

And it also covers the ICRP's framework for radiological protection, including things like the different exposure of situations and different exposure categories, along with the principles of protection.

So I want to talk a little bit about the, you know, biological basis for radiological protection in veterinary medicine. And we know it's really the same in, as in human medicine, right. The things that we expect to see are, you know, deterministic effects and stochastic effects.

In veterinary medicine, there tends to be this misconception with regards to the deterministic effects that radiation doses in veterinary medicine

are not high enough to produce deterministic effects. Now, this generally comes from people who I guess are still operating under the assumption that most -- that you know, it's mainly plain film radiography.

However, as I've mentioned, you know, things have changed. High dose radiological procedures are being increasingly adopted. Here I have pictured a dog that exhibited leukotrichia three months after receiving IMRT for a sino-nasal neoplasia.

Now you know, this is a trivial deterministic effect, the change in the fur color, you know, doesn't affect the dog's health. However, the effects aren't always so trivial, you know. They do, they can receive things like skin burns and you know, deterministic effects that you would expect in human medicine.

And then when it comes to stochastic effects, there's a wide-held misconception that animals don't live long enough to get radiation-induced cancer. However, we've known as early as the 1970s that this is not true. Cancer patterns in mammals are similar and relative to lifespan. So animals with shorter lifespans have shorter latency periods for cancer onset.

And there have been a large number of studies showing this. And in fact there has been a study that showed dogs who have osteosarcoma five years post-treatment of a mast cell tumor following radiotherapy.

And it is important to note that radiation sensitivity is known to differ among species. And of interest in veterinary practice is that dogs as a species are particularly cancer-prone. And in fact canine cancer prevention literature explicitly states that, you know, only to expose dogs to radiation when the benefits clearly outweighed the risks. And so you know, justification is important here.

The next section, Ethics and Values, reviews the ethical basis of the system of radiological protections with connections to veterinary and environmental ethics.

The system of radiological protection is rooted and informed by the three pillars, science, ethics, and experience. And you know, ethics kind of focuses on being able to distinguish right from wrong.

And so I'll discuss briefly some of the ethical theories that kind of underpin the ICRP's system of radiological protection. And those are utilitarianism, the ontology, and virtue ethics.

Basically, you know, utilitarianism seeks to maximize good for the greatest number of people. It's the furthering of the collective interest. Actions are preferable, based on, you know, their outcomes. And this falls in line with optimization.

On the ontology, generally that's a respect for individuals and their rights. There's like a set of obligations or rules that decides what moral or just. And this can kind of be seen in application of dose limits.

And then lastly we have virtue ethics, which is the promotion of integrity, discernment, and wisdom. And basically a moral or virtuous life is based upon some concept of human nature. And this can be seen in justification, right. Do good, do no harm.

This all builds off of the framework that ICRP kind of laid down in Publication 138. But from these ethical theories, the ICRP identified five core values, along with a few procedural values to kind of aid in the implementation of them. And that's beneficence, non-malfeasance, prudence, justice, and dignity, those are the core ones.

And then accountability, transparency, and inclusiveness. And these aren't the only values, but these are just some of the main ones here.

And so it's important to note that ethics not only encompasses what should be done, but also how it should be done. And so ethical risk evaluation and management, you know, goes, considers factors that go beyond just the magnitude of the radiation exposure and the cost associated with reducing that exposure.

And so one of the aims of this section was to make ethical ties between the values of radiological protection and ethical values in veterinary practice. And so here I've kind of outlined a few, such as animal welfare, solidarity, sustainable development, reverence for life, stewardship, respect for autonomy, and empathy.

And they all correlate well with one of the core or procedural values. And now this shouldn't be taken as either the only, you know, this is a single one-to-one relationship. These are all interrelated.

So the next section is unique aspects of veterinary practice where we discuss the similarities and differences between human medicine and veterinary medicine, kind of highlighting some of the unique veterinary challenges.

Veterinary applications of ionizing radiation and their protection challenges are to a

large extent similar to situations in human medicine. So we don't necessarily need to reinvent the wheel. Justification, optimization, and application of dose limits are still our friends.

However, radiological protection challenges specific to veterinary medicine typically arise from unique operational environments that are required when dealing with animals, and also a different combination of personnel and members of the public who could be involved.

And some of the issues I'm about to discuss is not meant to be seen as exhaustive, merely illustrative. Right, so as I kind of just touched upon, one of the unique aspects in veterinary medicine is the environment that they sometimes have to work in. They're not always specifically designed for a radiological procedure.

Sometimes veterinarians have to go out into the field, do a rad out on the farm. Or maybe if it's a, you know, if you're on a conservation and working with exotic animals.

The next one is equipment, right. So there's a prevalence of second-hand equipment from human medicine, and there's also dedicated veterinary equipment that typically falls under industrial

standards because it's not recognized as a human medical device.

And while you know, we welcome dedicated-for-purpose equipment, it's important that it meets the appropriate radiation standards. And if it's regulated as industrial equipment rather than medical, it may not always comply with the imaging quality or radiation protection standards.

And then what I have here is competence. Because there is a lot of difference worldwide, but even just within the country on the basics and specific education and training requirements that are needed. Right, radiological protection isn't necessarily covered in the veterinary curriculum. If they're lucky, they'll maybe get some of it in their radiology class.

A lot of times these procedures can have a lack of specialized staff involved, right. A veterinarian doesn't have to be a veterinary radiologist to perform or even interpret a radiograph.

And similarly, the people involved in the procedure may not be a veterinary x-ray tech, they may simply be a veterinary nurse. And there's not always the involvement of a medical or a health physicist as well.

And another thing is the uniqueness of the regulations and guidelines. There's lack of things like appropriateness criteria or diagnostic reference levels to aid the practitioners. Very little regulatory harmonization, not only worldwide, but I mean even just here within our states, right. You pick any two states and they could have very different ways of handling this.

In fact I -- there's only a few states off the top of my head that come to mind that have explicit veterinary regulations.

Additionally, in veterinary medicine there are no guards against self-referral or self-presentation. What I mean by self-referral is that the same veterinarian basically refers the dog for a radiograph and then he can perform that same radiograph and even interpret it himself.

Self-presentation in a veterinary medicine case would be a client, the owner coming to a vet and saying I want my dog to have a radiograph. And there's not a lot of methods or controls in place to prevent those.

And of course in veterinary medicine the patients come in all shapes and sizes. You could have a leopard gecko that needs to get a radiograph done.

Or maybe you work at a zoo and the elephant needs a rad of its tusk.

And as I've mentioned, the applications are becoming increasingly high dose. Pictured here in the center is a cat receiving strontium-90 brachytherapy. And of course we have pictures of dogs here that are receiving external beam therapy and other types of applications.

So how do we apply the system of radiological protection in veterinary practice? That's kind of the main theme behind Section 6, where we kind of discuss justification, optimization, and application of dose limits in the context of veterinary medicine.

So when it comes to justification, you know, obviously we want proper justification of radiological procedures. It's necessary in order to avoid the unnecessary exposure of people, animals, and the environment.

And like I said, we don't need to reinvent the wheel. The three levels of justification that we have for human medicine can be adopted. And so we have a recommendation for that here. So at level one, proper use of radiation in medicine is accepted. You would just have to change that to proper use of

radiation in veterinary medicine is accepted.

Now, generally for medicine, level one justification is taken as a given. Level two, you know, specific procedures achieves a specific objective. Again, just a slight change in the language from exposed individual to exposed animals.

And then level three, the justification of a particular procedure. Again, instead of --

(Off-record comments.)

MR. DAVILA: Instead of doing more good than harm to the individual patients it's to the individual animal patient.

Talking about justification a little bit more specifically, for medical procedures it is important that the veterinary practitioner has received appropriate training and education so they can make that justification.

And one thing that we think is warranted would be the development of decision support tools to help the clinicians with justifying procedures. And of course it's important that equipment is properly assessed for radiological protection.

And so when it comes to medical procedures, level three justification is really important, that that specific procedure should be

answering a specific clinical question.

But one thing that is unique in veterinary medicine is that we have non-medically indicated investigations. So they do perform imaging of asymptomatic animals in veterinary medicine, usually as part of screening programs. So hip or elbow dysplasia screening in dogs, but also radiographic exams of horses are another example.

And so for non-medically indicated investigations, it needs to be consistent with current clinical evidence. And so in this sense, level two justification is really important. There needs to be thorough clinical evidence and a demonstrable relationship between the imaging findings and this goal of -- and the goal of the screening.

So for example, talking about pre-sale radiographic exams of horses, there should be a demonstrable relationship between the findings of that imaging and their performance later on.

When it comes to optimization, optimization is always aimed at achieving the best levels of protection under the prevailing circumstances through an ongoing iterative process. And so, and this is usually done in two steps. You know, you want the appropriate design and construction

of the installation, along with the careful selection of the equipment.

But also in the day-to-day strategies. And so that includes things like adequate education and training of staff. Clarity of roles and positions, routine performance tests of equipment. And it all comes down to the safety culture at the organizational level.

As I've mentioned, the priority is always going to be the safety of the humans involved. But as human medicine, it's important to not confuse optimization with dose minimization.

If you focus too much on dose reduction, you could impede the diagnostic or therapeutic quality of the procedure. And then you, you know, you're providing suboptimal care or you may even have to repeat a procedure, which would not be ALARA.

And so factors to consider are going to be other occupational hazards. Radiation is just one hazard that veterinarians have to deal with. Right, as I'm sure you can imagine, if you need to do a radiograph of a live horse, just being around a live horse itself is an occupational hazard. They could very easily injure somebody.

And then of course the animal's clinical

condition needs to be considered. The use of sedation and anesthesia is something that's generally recommended in veterinary practice. However, depending on the condition of the animal, that may not be the best course of action.

When it comes to application of dose limits, I want to talk about a topic that's of interest to a lot of licensees. And that's this carer concept. And so in human medicine a carer is an individual who may be exposed to radiation as a volunteer helper providing support or care for a patient.

And this is, you know, this is something that's outside of their job. It's not their occupation to help this patient. So it's typically a loved one, a family member, a friend.

But as far as the law goes, veterinary medicine animal patients are not legally recognized as patients. So the carer designation is not applicable to them. In fact, as Ms. Tapp mentioned in her presentation earlier, all of 10 CFR 35 does not apply to veterinary medicine.

However, we believe that the concepts of patients and carer ideally should be tailored to be applicable within reason in the veterinary practice.

And obviously the issues it kind of most impacts would be things like hospital stays and release criteria. And we believe that further studies are warranted, looking specifically at doses to owners and handlers from veterinary nuclear medicine procedures.

And if an owner or a handler is deemed, you know, if the exposure of an owner is deemed justified based on the prevailing circumstances, then dose constraints should be used, potentially set above the public dose limit, like the -- like in the case of a carer to guide the optimization in a practical and proportionate way.

So recall that we have a few different exposure categories and exposure situations. On the exposure category side, an exposure could either be occupational, something you get in the line of your work. It could be medical. Or if it's not either of those, it could be public.

And an exposure situation could either be planned, meaning that you have the ability to prepare for the exposure. Or it can be existing, meaning it's already there and a decision needs to be made on how to control it. Or an emergency situation where it's unexpected.

But so where would animals fall into this?

Animal patients don't really fit neatly into any of these categories, because as I've already mentioned, they -- it's not considered medical exposure. But veterinary applications are to a large extent comparable to the human medical applications. The only difference is that in one the subject is a human, and the other the subject is an animal.

In both cases, you have occupational and public exposures occurring, but there's only medical exposure in one of those situations. And so this could lead to a bit of conflict because from a regulatory perspective, essentially veterinary practices can -- is considered comparable to an industrial application.

And this can lead to an approach where the animal is considered an object without consideration that it is indeed a sentient living creature. Or you know, neglecting unique, the necessary aspects, such as the safety of patients under anesthesia.

And so the Commission does now specify that the system include protection of the individual animal in special circumstances. And so animal patients undergoing a veterinary procedure is one such case. Others include things like animal research subjects and pets and domestic animals in a

radiological or nuclear emergency situation.

Then Section 7 is a summary of the recommendations and considerations. Basically we just kind of list the key takeaways. And this, as I've mentioned, you know, the objective of this publication was to provide an initial set of relevant observations, considerations, and general recommendations to a wide-ranging audience.

The radiological protection challenges specific to veterinary medicine come from a combination of different personnel involved, both professionals and members of the public. And also the different operational environments that may be necessary when dealing with animals.

And as I've mentioned, the priority is always of the people involved. However, the exposure of the animal does deserve explicit attention. And in general, you know, if you're able to reduce the exposure to the animal patient, that will in turn reduce exposure to staff as well, generally speaking.

And then veterinary practice, the core and procedural ethical values of the system of radiological protection are elaborated on. And we kind of take the values further and connect them to veterinary values.

And as I've mentioned a few times, veterinary applications are comparable to the human applications. And so it could benefit from similar approaches, right. We could still use justification, optimization, and dose limits, of course always taking into account all the different factors, such as economics, societal and environmental.

Then we did have a couple of annex sections. We have the roles and responsibilities section where we discuss the individual and organizational functions and the anticipated obligations.

As you all know, radiological protection requires commitment from all parties involved, right. It can't just be the RSO or even just the doctor. Everybody involved has to commit.

Just kind of quickly -- is kind of responsible for like evaluating and assessing the radiological and epidemiological studies. ICRP then kind of takes that scientific data, kind of applies ethics and values judgments to kind of issue initial recommendations, and then like the IAEA. We will take those recommendations to set -- to set regulations that then individual countries can adopt.

But more specifically in terms of the

veterinary practice, there are a few rules and responsibilities that we do highlight. A rule is the individual or organization's position or function and the responsibility is the anticipated obligation, duty, or commitment associated with that rule.

And so the first role is that of the hospital or practice. And so some of the things that they're responsible for is making sure that their installation is appropriate and that the location is fit, the location and all the equipment is fit for purpose. And of course they're responsible for maintaining the quality assurance program.

We have the role of radiological practitioner, who will generally be a veterinarian. They're responsible for the appropriateness of the procedure and how the procedure is performed. And so they must be responsible for informing and instructing any non-staff members who may be helping out.

And then we have training programs whose responsibility is to provide the adequate education and training. And they should be explicitly addressing radiological protection in those training programs.

And then the last section we have is ethical issues associated with the protection of

animals and the environment, where we elaborate on humanity's relationship with and responsibility to animals and the environment. Because you know, humans, we share our environment with many other life forms. We don't live in a vacuum.

And animals can serve a lot of different purposes, whether a companion, providing comfort or entertainment. They could be livestock providing labor or food, other commodities, or even workers from non-food service operations like therapy or military operations. And even research subjects.

So some of the specific ethical issues in veterinary practice are animal ethics, or what's also known as the animal problem, a discussion going back to the days of Aristotle, basically. What is the difference morally speaking between humans and animals?

I don't have the answer to that. But if there is no difference, how do we justify treating animals the way that we do? And if there is a difference, what is it about that difference that allows us to treat animals the way that we do?

And then of course animal welfare is always a big topic, how an individual animal's life could be improved or impoverished through our actions

or inactions and what does that mean for what we're responsible for.

And then lastly I want to touch on what I call the three-party problem in veterinary medicine. In human medicine you have the patient and the doctor, and generally they both agree pretty well on the best course of action for the patient. However, in veterinary medicine you have the veterinarian, the animal patient, and the animal's owner or guardian.

And so a lot of things -- or one of the main ethical dilemmas of the veterinarian is who should their primary responsibility be to? Is it to the animal patient, or is it to the animal owner?

Again, I don't have an answer for this, but it's just something to consider, right, because in many places the owner has property rights over the animals. And so the owner is free to do essentially what they want with their pet.

And, right, an ethical vet could maybe very well refuse to perform a certain procedure if they don't think it's in the animal's best interest. However, that owner and guardian could then just go to a practice that would be willing to accept their money for such a procedure.

But the bottom line is this, that the

Commission hopes that highlighting radiological protection concerns and related knowledge gaps will inspire additional research and development related to the evidence-based use of ionizing radiation in veterinary practice in support of the justification process.

Dedicated facilities and equipment, improved understanding of the radiosensitivity of different types of animals, and practice guidelines in support of exposure management and other relevant areas to promote health and safety of personnel, the general public, and the environment, while further improving the quality of care for the patients and healthy animals submitted to radiological procedures.

And I'll leave you with some future considerations. So that would be things like how to decontaminate livestock following an emergency. What if instead of the animal being radioactive after a procedure, what if the animal is an emotional support or a service animal and their owner received some sort of nuclear medicine procedure? What's the appropriate course of action then?

And of course there's a wide range of working animals, right, search and rescue or military or police. And of course research animals are another

group of animals that deserve special consideration. And of course for all of this, we need more dosimetric data in order to be able to make the best decision possible.

And so I thank all you guys for your attention. I do have a QR code here that you can scan to access Publication 153. And I also have my contact here as well if you ever want to reach out with any questions. And I believe we have some time for Q&A?

CHAIR METTER: Well, thank you, Mr. Davila, for that very interesting and complete and quite unique presentation on the aspects of radiologic protection in veterinary medicine.

I do have a question regarding human exposure. And I believe you had mentioned that the priority of radiologic protection in veterinary practice is that of the humans involved. And so I was wondering are the -- is the veterinarian and the veterinary technologist badged, and who checks their badges?

MR. DAVILA: So this will be up to each licensee. But generally you do see badging in place.

CHAIR METTER: Okay, thank you. Dr. Harvey has a question.

DR. HARVEY: Mr. Davila, I might have

missed it, but is there a recommended dose limit for carers, like 5 millisieverts, or something along that lines? Or is it just up to the licensee to determine?

MR. DAVILA: Well, so again, in veterinary medicine the concept of carer does not apply. So as Ms. Tapp mentioned earlier, they have to follow the public dose limit. However, our recommendation is that the concept of carer be tailored to veterinary medicine with a dose limit that is higher than the public dose limit.

MEMBER HARVEY: Maybe I misunderstood. I thought that the carers could have a higher dose limit than members of the public. Maybe I misunderstood.

CHAIR METTER: I think Dr. Tapp -- Oh, I'm sorry, Dr. Tapp does have something to say. I'm sorry, I keep interrupting you.

MR. DAVILA: No, that's okay. I was just going to say yeah, the concept of carer does not apply in veterinary medicine.

DR. TAPP: Does not apply right now.

CHAIR METTER: Sorry, thank you again. Are there -- yes? Mr. Green and then Ms. Martin.

MEMBER GREEN: Mr. Davila, personally I'm more familiar with human use of radiopharmaceuticals. Do you have any idea as to the number of nuclear

medicine licensed veterinary practices in the United States?

MR. DAVILA: I don't have that number off the top of my head. However, I do know that there is going to be upcoming paper in the HBJ that kind of has some of that information. A colleague of mine performed a survey of several licensees, and so she is working on publishing that information.

MEMBER GREEN: Thank you.

CHAIR METTER: Ms. Martin?

MEMBER MARTIN: So I'm still confused. I heard a couple of things, that you cannot declare a workers as -- a carer as an occupational dose limit, and yet I'm hearing that you're not requiring badges to be worn by these people.

So how -- what is the recommendation as far as tracking and knowing what dose the carers are receiving? If you don't require badges on them, how do you know if they're getting more than the public limit?

MR. DAVILA: So again, right now the concept of carer doesn't apply in veterinary medicine. So there is no tracking of their doses because licensees are limiting their dose to the public dose limit.

In terms of badging staff, you know, that just follows the, you know, you're required to badge staff if they're likely to get 10% of the annual occupational limit.

MEMBER MARTIN: But do you know if you have documentation that that's being done? Do you have enough data to show that that's being done in these facilities?

MR. DAVILA: Yes, there is -- there are publications out there about the occupational doses that veterinary staff receive.

CHAIR METTER: I believe Ms. Shober has a comment as an OAS representative.

MEMBER SHOBER: So all of these sites that would be doing nuclear medicine would have a radioactive materials license. When they apply for a radioactive materials license, dosimetry is one of the items on the application form. And they -- the ones that I've seen all commit to badge their occupationally exposed workers.

So and those sites would be inspected at a regular inspection frequency. So there is regulatory oversight for the dose monitoring aspects of that work.

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

has a comment? Oh, Zoubir, sorry I didn't see you.

(Simultaneous speaking.)

CHAIR METTER: -- comment or question?

MEMBER OUHIB: Thank you. I'm just curious, how are mishaps and medical errors or medical events, whatever we want to call them, handled at the level of the veterinarian society?

MR. DAVILA: So that's actually a great question. There is actually a greater need to make veterinary licensees aware of how and where to report medical events and accidents. We do believe that those are probably -- actually not probably, those are being under-reported.

MEMBER OUHIB: Yeah, if nothing else it will be lesson learned for others.

MR. DAVILA: Correct.

MEMBER OUHIB: Thank you.

CHAIR METTER: Thank you. Are there any other questions from the committee? Any questions from the NRC staff? Any questions from the public members in the room?

MS. PICCONE: Will the slides be made available?

CHAIR METTER: Mr. Davila, did you hear that, will the slides be made available?

MR. DAVILA: Yeah, I can make them available.

CHAIR METTER: Could you put it, I guess on the ACMUI website?

MR. DAVILA: Of course.

CHAIR METTER: Okay, I'm sorry. Ms. Armstead, what did you say?

MS. ARMSTEAD: I will do that.

CHAIR METTER: Thank you. Okay, are there any -- yes, Dr. Tapp?

DR. TAPP: Just for the attendees on the line, the slides will be made available for all presentations at the end of the meeting online.

CHAIR METTER: Thank you. Are there any questions from the public? Is that a question from the public? I can't tell. Go ahead --

MR. EINBERG: If there's any questions from the public, please raise your hand. I don't see any.

CHAIR METTER: Okay, looks like there are no questions from the public.

Well, Mr. Davila, thank you for, again, for a very interesting, comprehensive, and quite unique presentation. It makes us more aware and appreciate our pets and animals. And congratulations

to -- you said you had seven pets?

MR. DAVILA: Yes, I do.

CHAIR METTER: Great, wonderful, I have four. But anyway, it's -- plus our cows. But anyway, I appreciate it.

MR. DAVILA: Yeah, thank you so much. Thank you all for having me and giving me this opportunity to speak to you guys. Greatly appreciate it.

CHAIR METTER: Thank you very much. A very unique perspective and actually an eye-opener for sure.

Okay, our next presenter is going to be Mr. Whited, who'll be NRC staff talking about the financial assurance for disposition of Category I and II byproduct material in radioactive sealed sources.

Mr. Whited.

MR. WHITED: Thank you very much, can you hear me?

CHAIR METTER: Yes, we can.

MR. WHITED: Okay. I will share my screen hopefully and pull some slides up. And can you see the slides now?

CHAIR METTER: Yes, we can.

MR. WHITED: Great.

CHAIR METTER: Yes, we can.

MR. WHITED: Okay, wonderful.

Good afternoon, everyone. My name is Ryan Whited, I am a Senior Project Manager in the Low-Level Waste and Projects Branch of the Office of Nuclear Material Safety and Safeguards.

I'm going to provide a brief presentation today on a rulemaking effort that's currently under way regarding financial assurance for the disposition of Category I, II, and III sealed radioactive sources.

A little background first. NRC's requirements for byproduct material financial assurance are contained in 10 CFR 30.35, which is entitled Financial Assurance and Recordkeeping for Decommissioning.

However, the threshold for providing financial assurance does not currently apply to a majority of radioactive sealed sources, including many Category I and II sources. And so for many licensees that had resources, there is no requirement for decommissioning or end-of-life financial planning.

However, licensees are still responsible for providing safe and secure end-of-life management for these sources. And the associated financial burden may be significant if it's not properly

considered in advance.

And this can include costs related to its kind of storage when the sources become disused, to packaging, transportation, and ultimately the selective disposition option, which could be disposal in a low-level waste site. It could be returned to a supplier for reuse or recycling.

So this effort started back in the 2015-16 timeframe. In 2016 the NRC staff conducted a scoping study to determine if additional financial assurance requirements were needed for some radioactive byproduct material, in particular sealed sources. That scoping study is documented in a SECY paper, SECY-16-0046.

And because that study led us to think about rulemaking, we then followed that with a rulemaking plan, which is SECY-16-0115, which was submitted in October of 2016. And both of those papers are publicly available on the NRC website.

And so based on the information that was collected and analyzed in these two SECY papers, the staff recommended rulemaking to expand the financial assurance requirements in 10 CFR 30.35 to include all byproduct material Category I and II sealed sources that are tracked in the national source tracking

system.

We focused on Category I and II sources because they have the highest risk significance and they're generally the most likely sealed sources to pose disposition challenges.

So in 2021, we did get Commission direction through an SRM. And in that SRM the Commission directed the staff to proceed in expanding requirements in 30.35 to require financial assurance for Category I and II byproduct material sources.

They provided some additional direction in terms of how we go about doing that and directing us to carefully explore the options to mitigate potential adverse impacts on existing and future licensees, particularly with medical users and others that benefit from the use of these radioactive materials.

They directed us to also look at Category III sources to see if financial assurance needs to be extended to those as well. And to make sure that we use a risk-informed basis for doing this that considers factors such as overall risk and the total cost of disposal.

I wanted to talk a little bit about the types of sources this rulemaking's intended to address. So the chart you see shows the distribution

of radionuclides in the National Source Tracking System. And you can see that more than 91% of the tracked Category I and II sources are cobalt-60.

And this is because cobalt-60 is used in devices that contain a lot of individual sources, such as large panoramic irradiators and Gamma Knives. About 4% of the sources are irridium-192, and another almost 4% are cesium-137.

However, NRC's financial assurance requirements don't apply to radionuclides with half-lives below 120 days. And that includes irridium-192. We don't plan to change that in this rulemaking. And so because of that our focus is really on cobalt-60, cesium-137, and americium-241.

However, it's important to understand that the NSTS tracks sources and not devices. And so if, you know, if it's -- with a panoramic irradiator with 500 sources, each one of those sources is going to be listed individually in the NSTS.

And what we found in looking at this issue is you really have to make the jump from what sources a licensees has to what devices they have. Because the kind of device is really going to drive the disposition options that are available and the associated cost.

And so where we're at right now on this effort, we're in the first stage of rulemaking, and that is the development of the regulatory basis. We established a working group that includes representatives from the NRC regions and the organization of agreement states.

That working group has been coordinating quite a bit with the Department of Energy's National Nuclear Security Administration, and also the Conference of Radiation Control Program Directors to understand costs that are associated with NNSA source recovery efforts.

NNSA operates what's called the Offsite Source Recovery Program, which deals with the higher activity, Category I and some Category II sources. And they also fund CRCPD's source collection and threat reduction program, or SCATR Program, which deals with the slightly lower activity sources that generally have a commercial disposal pathway.

We've also conducted outreach to certain stakeholders, including low-level waste disposal facilities that can accept some of these sources, low-level waste brokers, some sealed source device manufacturers and distributors. And the purpose of these meetings has been to help the working group

understand and assess various categories of devices to understand the disposition pathways and the associated costs.

The group's currently focused on identifying and analyzing potential regulatory options for the rulemaking, such as financial assurance based on what type of device that a licensee has, and possible changes to requirements for developing decommissioning funding plans.

Typically a decommissioning funding plan is a case-by-case assessment. Given the licensee and the facility they have and all of the devices they have, what is their plan when decommissioning comes around and what are they going to do with each of those sources in terms of their disposition.

And so we are looking at who's currently required to do a DFP and do we need to change some of those requirements to encompass more types of licensees.

I just want to talk a little bit about some of the issues and challenges that the working group's grappling with. This is an issue that several groups have looked at over the past 20 years, including the Interagency Radiation Source Protection and Security Task Force that NRC leads.

There was another interagency working group led by NRC that put a report out in 2010 on this issue. And those groups have generally recommended NRC do rulemaking, but the action has been deferred over the years until now. And some of the reasons for that are listed on this slide.

There's not a lot of cost data to support financial assurance requirements because in general these devices have either been picked up by NNSA and dealt with through that government-funded offsite source recovery program, or they're in storage. There have been very few disposals at commercial low-level waste facilities.

The second issue, there are many different types of devices that use these sources, Category I, II, and III sources, from small radiography devices, gauges, and calibrators, to very, very large panoramic irradiators. And so looking at the possible disposition pathways and the associated costs for all of these different kinds of devices is a complex task.

And adding to that complexity is the low-level waste disposal landscape in the United States. Disposal costs vary significantly, depending on what disposal site a licensee has access to. There typically are two places that these sources can go,

and that's the waste control specialist facility in Texas or the U.S. Ecology Facility in Washington State.

Costs can vary quite a bit between those two facilities. But only certain waste generators have access to the U.S. Ecology Facility.

And even for the Texas facility, it makes a big difference whether you're in the Texas low-level waste compact, which is the state of Texas and state of Vermont, or if you're outside of the compact. There are additional costs if you're an out-of-compact generator.

The fourth issues, and for some sources, such as those that are classified as greater than Class C low-level waste, there may be no commercial disposal pathway. For example, some of the cesium-137 blood irradiators have very high activity sources. The only place those can go right now is through NNSA. NNSA can pick them up through their offsite source recovery program.

And last thing is the range of licensees that use these sources is very broad, from very small businesses to large hospitals, universities, industrial facilities. And so looking at how this rule could impact the very diverse licensee base is a

complicated task.

And so the working group's grappling with all of these issues as we work through and develop options for this regulatory basis.

So just in summary, where we're at right now, the staff is preparing a regulatory basis to expand financial assurance requirements as we were directed to do by the Commission for Category I and II and possibly Category III byproduct material sealed sources.

We're looking at several potential regulatory options and analyzing that and doing cost-benefit analyses. And you know, we will step through those options in the regulatory basis. And we anticipate providing that draft regulatory basis for ACMUI's review next spring, in the spring of 2024.

And that is all I had for this afternoon. And I'm happy to take any questions you may have.

CHAIR METTER: Thank you, Mr. Whited, for that very interesting topic on the current status of the financial assurance disposition of Category 1 and Category 2 sealed sources. Do I have any questions or comments from the ACMUI Committee? Mr. Green?

MEMBER GREEN: Always an education. You're always going to find something you don't know

anything about. I have more experience with financial assurances for germanium generators.

And this is outside the scope of this presentation. This is Category 1, 2, and 3 sealed sources. Has the NRC teed up a review of financial assurance warranties that are currently in place and required for germanium generators?

MR. WHITED: So there's another rulemaking on that exact issue. And sometimes it is confusing to folks because there's an ongoing rulemaking on 10 CFR 30.35. And it's my -- I'm not directly involved in that rulemaking.

But it's my understanding that the germanium/gallium generator issue was one of the key things that prompted that rulemaking. And what that one is doing is it's expanding. There's a table in 30.35 of isotopes.

And depending on what kind of device you have, you go to that table and that table tells you how much financial assurance you need. Well, germanium and gallium were unlisted in that table. And so there was a petition for rulemaking to add those and other unlisted isotopes.

And that rulemaking is ahead of the one I just talked about. It's going on right now to address

some issues. And basically for those kinds of devices, licensees felt the current requirements were too burdensome, and it really was because those isotopes weren't listed in the table.

And so there's an effort ongoing to update that table and unlisted isotopes and address that issue. I'm not sure if that's exactly your question. But I just wanted to make that point that there's a separate rulemaking dealing with that issue that is believe with the Commission now for their review.

MEMBER GREEN: Thank you, Ryan. That's great. I think Mr. Einberg also has a comment.

MR. EINBERG: Actually, Cindy Flannery has some additional information on that.

MS. FLANNERY: Yeah. I mean, I guess I don't really have anything else to add to what Ryan said. He covered everything. That rulemaking, yeah, is up with the Commission, and it does address the germanium issue.

But that table that Ryan was talking about isn't going to include a lot of isotopes that aren't currently listed and updating them. It's only going to apply to -- right now, the list has many different isotopes. But it's only going to list the ones with a half-life of greater than 120 days. So several

updates to that table. And that's really the focus of that.

MEMBER GREEN: From a practical and operational standpoint, every facility, pharmacy, or medical institution that possess a germanium generator has an established contract with the germanium generator provider. But they'll accept a full return. All that is, is a less than 100-dollar FedEx fee to make it go away to an authorized place. So financial assurances warranty is an extreme.

CHAIR METTER: Thank you for that comment. Are there any comments from the public? Zoubir, I'm sorry. I can't see you. But if you'll let me know. Thank you. Go ahead, Mr. Zoubir.

MEMBER OUHIB: Okay. Thank you. I think this is a great initiative. I recall several years ago being in the state of Florida where there was a similar initiative to unload some sources. Those were cesium-137.

And you have no idea what a relief that was that we did not have to deal with anything. I mean, that was a very smooth operation unloaded. And they took on and that was fantastic because we were wondering what the heck are we going to be doing with these sources that we no longer use basically. Thank

you, Ryan, for that.

MR. WHITED: Thank you. Thank you for that comment.

CHAIR METTER: Thank you. Any other comments? Are there any comments from the public or questions?

(No audible response.)

CHAIR METTER: Okay. Seeing none, thank you again for that very updated report on this very important topic.

(Simultaneous speaking.)

MR. WHITED: We'll see you in the spring.

CHAIR METTER: Okay. Our next topic is by Dr. Katie Tapp of the NRC staff. She'll be speaking on lutetium-177, radiopharmaceutical medical events. Dr. Tapp?

DR. TAPP: Okay. Lillian is going to bring up the slides. But Ryan, you have to stop sharing your screen first. There you go.

MR. WHITED: Yes, I will do that now.

DR. TAPP: Great. I can switch. Okay. I'm going to talk about radiopharmaceutical medical events. Next slide, please. So before I talk about the events, I want to do a reminder on the written directive and then a reminder on what is a medical

event that's the rules for radiopharmaceutical therapies.

So a written directive must be dated and signed by an authorized user before the administration of iodine-131, sodium iodide greater than 1.11 megabecquarels or any therapeutic dosage of unsealed byproduct material. So basically, all therapeutic radiopharmaceuticals except for anything under 1.11 megabecquarels of iodine must include a written directive. Per administration of therapeutic dosages of unsealed byproduct material other than sodium iodide-131, the written directive must include the radioactive drug, the dosage, and the route of administration.

And then licensees must have and follow procedures to ensure high confidence that each administration is in accordance with what is in the written directive. Next slide, please. So next will be the medical event criteria that are associated with radiopharmaceutical therapies. Next slide. So the first one I like to call is deviation medical event criteria.

This has two parts to it. First, the event must meet a dose threshold. And the dose thresholds are listed on the one side which is 5 rem

effective dose equivalent, 50 rem to an organ or tissue, or 50 rem shallow dose equivalent to the skin.

In addition, there must be a deviation. So the deviations are plus or minus 20 percent the prescribed dosage or the dosage falls outside the prescribed dose range. So for radiopharmaceuticals, you're allowed to have that directive provide either a set dosage or a range of dosages.

If they use a range, if it falls outside that range, that would be a deviation. And then there's also the plus or minus 50 percent, a single fractionated dose. Historically, that wasn't used as much in radiopharmaceutical therapy. But that could become an issue going forward now that we have some fractionated therapies.

And then the corner as you see, patient intervention is excluded from this event criteria as well as all the medical event criteria. So if the event was caused by a patient intervention, it would not meet these. Can you go back one slide, Lily? I'm sorry. There you go.

The next medical event is -- I called it the error medical event criteria. And again, we still have the dose thresholds. But this one has a cause to the medical event.

So this could be, like, a wrong patient, the drug was delivered to the wrong patient, the wrong drug, the wrong route, or the wrong mode. Not as important with the radiopharmaceutical therapy for the wrong mode. But those are the cause of these type of medical events.

Again, patient intervention, it would be excluded. Next slide, please. And finally, we have the wrong site medical event criteria. Again, we have a dose threshold.

But this dose threshold is a little bit different. This one is 50 rem or more is expected to that site if the administration had been given in accordance with the written directive. So this is a medical event where the site is moved.

And you have to look at what was expected to that site. So if the site was expected to get, say, one gray but then it received two gray, that would be a medical event. But if the site was expected to get 50 rem and it only got 75 rem, it would not meet that dose threshold. I'm sorry to switch units on you there.

In addition to that dose threshold, there is the deviation. So it's, like, this medical event in addition to the dose threshold has to have a

deviation of 50 percent or more than the expected dose to that site if the administration had occurred with the way the written directive was prepared. So again, we're looking at the event and looking at what was expected to have been received on that site and then what was actually received.

I'm looking at what was the deviation. Again, this is a medical event criteria where patient intervention would not be included in reporting. So if it was involved, patient intervention that would not be reported to the NRC. Next slide, please.

For a patient intervention report, you see I cross off the dose threshold. In patient intervention reports, there is no dose threshold included. These events are reported if there's any event resulting from intervention of a patient which administration results in unintended permanent functional damage to an organ or physiological system as determined by a physician.

And patient intervention means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or permanently terminating the administration. Next slide, please. And I think we talked about this a little bit earlier about

reporting or what's required. And in the regulations, we do have the specifics of what is required for a report.

A report comes in. We are looking for what is the dose, what happened, what's the root cause, and what are the corrective actions. And the regulations are very specific about what we can ask for in these reports.

But we do have some guidance out about some best practices because we do use these medical event reports to look for trends and generic issues. And there is a bare minimum that's in the regulations that licensees can meet. But it is helpful when we get reports that have a little bit more information to help us look for trends and generic issues.

The report should allow an uninvolved individual to have full understanding of the event. As a reminder, a lot of people assume when they send in these reports that you guys are looking at it immediately or other doctors are looking at it immediately. But it's NRC staff looking at it immediately, and we are not doctors.

And there's a lot of new treatments out. We may not have been exposed to this. So we're really asking that when reports come in especially with a new

radiopharmaceutical or a device, there's a little bit more information so we can have a full understanding of the event. Takes much longer for us to go out, reach out, and play the telephone game.

In addition, there is helpful details to include so we can catch trends quickly. And these include the manufacturer, the model, and any specifics about the supporting equipment associated with the event such as the IV pump or gauge size. A lot of times we'll hear of the incorrect gauge size was used, but we don't know what was the gauge size.

In addition, relevant information that proceeded the event. Sometimes we'll see that there wasn't enough staff. But maybe if you provide how many staff were on site would be helpful.

What staff was present, how the event was identified, including short and long-term corrective actions, and how they're actually linked to the event is helpful. And then clearly highlight if the event or corrective actions involve common industry-wide practice or procedures. This last one I think is very important.

If the event is something that's commonly used and especially, like, a software or a procedure. And it's important to let us know this is a common

practice or procedure that's done and it caused this event. So it really clearly highlights something that could impact other licensees.

So we can make immediate notification if necessary. Next slide, please. So now I'm going to cover some examples of recent radiopharmaceutical medical events. Next slide. As I think everyone here knows, there's an increasing use of radiopharmaceuticals.

In January 2018, Lutathera was approved by the FDA for treatment of some gastroenteropancreatic neuroendocrine tumors. And in March 2022, Pluvicto was approved by the FDA for treatment of some prostate cancers. In addition, there's numerous ongoing clinical trials with current and new therapeutic radiopharmaceuticals.

We have had one report of a patient receiving the wrong radiopharmaceutical. This is an event where one patient came in to receive Pluvicto and they received Lutathera. And the other patient received Lutathera when they were meant to receive Pluvicto.

That type of event we found to be a serious event. And we're hoping as there's increasingly uses and a lot more therapeutics coming

out, we really want to make sure those events are avoided. In addition, both lutetium-177 radiopharmaceuticals have a recommended standard dosage of 200 millicuries for multiple fractions unless the patient conditions warrant a reduction in dosage.

And the reduction can occur between the fractions. So they could have 200 millicuries to start and then it could be a reduction later on. In the last two years, we've had five events where an authorized user prescribed a smaller dosage based on patient lab results, but the patient still administered the full standard dose of 200 millicuries. Next slide, please.

I'll just give one example of that reduction of dose. There was a Lutathera standard dose protocol of 200 millicuries every eight weeks for a total of four doses. That's the standard protocol.

A patient was prescribed 100 millicuries by the authorized user on a later fraction due to kidney disease but received the standard dose of about 206 millicuries. The administer technologist did not review the written directive and just drew the standard dose. The root cause in this event was failure to follow established protocols and lack of

communication in the department.

This licensee had a corrective action to include a daily huddle to communication key information and secondary verification requiring physician signature on the written directive. Next slide, please. Next I want to cover types of events with the verification of activity was shown to be very important. 10 CFR 35.63 requires licensees to determine and record the activity of each dosage before medical use.

During this check, it is important that the activity be checked against the written directive immediately prior to administration because failure to do so has caused several events recently. Next slide, please. One type of event was the patient was rescheduled to receive 3.47 megabecquarels of radium-223 Xofigo. On the day of the treatment, the patient's procedure was canceled due to low blood pressure.

The licensee then kept the dosage in the hot lab for decay. One month later, the patient came back for their treatment. They received the dosage from the original vial which resulted in administration of 0.63 megabecquarels.

This demonstrates the need to verify the

dosage on a written directive immediately prior to treatment. Next slide, please. Next I'll talk about protocol and scheduling. The protocols are becoming more complex and sometimes include multiple steps and other treatments in addition to the radiopharmaceuticals.

These new products coming out have a little bit more complex protocols I think, and they're becoming more complex from one of those societies I think even than they are today. In addition, certain drugs may interfere with the distribution of the drug in the body. It is important to note that the way medical event criteria is written is not all incidents involving incorrect protocol scheduling or drug interference are reportable to the NRC per regulations.

These events can be medically important and sometimes do qualify as medical events. The NRC has been notified of several of these events. Sometimes they are medical events and sometimes we find that they aren't.

For example, if the chemo drug was given the day before versus the day after, that may not be a medical event for us because we're looking at the radiopharmaceutical and the dosing. So it doesn't

actually change the dose, but it's changing the protocol. It's medically important. Next slide, please.

The one protocol example that I wanted to highlight was during a typical -- or the standard is during a typical Lutathera treatment, an amino acid infusion begins 30 minutes prior to the radioactive drug administration to protect the kidneys by lowering the dose. In one event, a patient's Lutathera treatment began without the amino acid infusion as the amino acid line was still clamped. The technologist realized this approximately 20 minutes after the Lutathera treatment began and started an amino acid infusion.

The licensee calculated the kidneys received an estimated dose of 740 centisieverts instead of the intended 490 centisieverts and reported this event. The corrective actions include moving the amino acid solution to a separate primary IV line which would alarm if it was still clamped, training the nursing staff, and adding a pause to ensure the amino acid infusion has begun before starting the Lutathera. Next slide, please. There's also scheduling examples, and I provide this one.

It's while a patient was undergoing

lutetium-177 Lutathera infusion, they were informed by the AU that they received the chemotherapy the day before. They said the normal protocol for Lutathera treatment is for the chemotherapy to be done after the radioactive lutetium infusion. So the AU immediately stopped the infusion, and this led to an underdose and a medical event.

If they wouldn't have stopped the dosage there, it might not have been reported to the NRC because it might not have been a medical event. But I would still imagine this is medically important. You'd want the schedule correct.

So this event demonstrates that the authorized users and staff should check the status of the patient's entire protocol, especially if multiple departments are involved prior to each administration. As we're finding with these new radiopharmaceuticals, there's more staff involved, new departments that may not be used to working with nuclear medicine. And so when someone is bringing off a treatment, making sure that the entire medical departments and everyone involved is aware has been important to avoid medical events. Next slide, please.

And finally, we'll talk about set up and administration incidents. In the last two years,

we've had six events reported due to unexpected set up issues associated with the newer procedures. Everyone should be trained on a new administration and the equipment they may handle during the procedures.

With a lot of places starting up, we found that we got to make sure we're training the support staff and staff who may not have been used to handling radiopharmaceuticals. And then we can't forget about those who handle the equipment or perform set up even before the administration begins. As I mentioned, the amino acid with the clamp, that occurred before the administration even began.

That was before the nuclear medicine technologist was there and with the nursing staff. So that shows that we have to make sure the training is throughout the whole procedure. One thing we've heard from societies was cold -- administrations, including set up with the entire team, could significantly reduce the chance of an event. Next slide, please.

One of these examples was a nurse removed the clamp and opened the roller clamp on a flush bag line at the beginning of an iodine-131 IV treatment. This led to a leaking tube in an infusion system and resulted in a patient only using 53 percent of the prescribed dose. Luckily, there was no contamination.

Again, the root cause was failure to train staff on this specific procedure and the support staff. And the corrective actions in this event was to ensure nuclear medicine and radiopharmacists were trained on the infusion pump and would solely be in charge of that pump for future patients. So for this licensee, they decided to move the pump control to the nuclear medicine and radiopharmacy staff. Next slide, please.

Another one is a Xofigo administration. There's a three-way stopcock was used to allow the administration of saline in radium dichloride. An incorrect cap was used on the unused port of the three-way stopcock. The cap that was used was designed to maintain sterility of the port connection but did not prevent flow which led to a leak.

And the root cause again was failure to train staff on the equipment of this administration prior to the administration. Next slide, please. And this is the last type of events which is the leaks. In the past two years, we've had seven events associated with leaks and spills.

Some of the ones I just mentioned were included in these type of events, but I broke it down a little farther to look into what was causing these.

And four events were expected to be associated with the incorrect setup that I was just mentioning. But there are three more events associated with infusion tubing, but not setup issues were noted.

Leaks occurred with Xofigo, Lutathera, Pluvicto administrations. So they didn't seem like they were located to just one. But they occurred with different types. And one licensee reported to us that they did test the additional tubing from the same lot and identified more tubing leaked.

So they removed the entire tubing lot. So this licensee went further and testified all the tubing and found there's more leaking from their administration and IV sets. Next slide, please. So in summary, the NRC has seen an increased number of medical events associated with radiopharmaceuticals as new drugs come into the market.

I will say, I want to point out that Dr. Harvey's group, you guys might not have seen these because a lot of these events occurred in 2023. I'm reporting the events that occurred. Some of them occurred within the last month. But we're definitely seeing more events happen and different types of events happen and different types of events as these radiopharmaceuticals are coming onto the market.

Many of these events associated with the increased complexity and lack of training of staff on the new protocols before they start using them in their clinics. Many types of these events are new to the NRC such as leaks and set up issues associated with the delivery. NRC expects to see -- continue to see new types of medical events as new protocols enter the clinic. And the NRC is in the process of developing an information notice to inform licensees of these events that have been reported and then the industry recommended corrective actions. Next slide, please. I think this is the acronyms.

CHAIR METTER: Well, thank you, Dr. Tapp. That was a very, very nice and very excellent report. And it's very clear and concise. And really your examples were very helpful and help for us to understand what happened and the site's corrective actions regarding this.

And I hope that not only the people on the committee here but also the public on this call will learn from that. And I do like the idea of the information notice coming out. Do you have a time frame when that will be?

DR. TAPP: In the next couple months. We are actively working on it.

CHAIR METTER: That's very interesting because I think, like I said, the new radiopharmaceuticals and the more complexities of these therapies, I think every little step will cause -- has the potential for another issue to come up. Now are there any questions from the committee? I see a lot of questions. Okay. Let me go ahead and have Dr. Jadvar. He hasn't asked any questions recently.

VICE CHAIR JADVAR: Thank you so much for that presentation. Just one quick question. So Pluvicto package insert says that if you want to give -- if there is adverse events, you're allowed to decrease the dose by 20 percent from 200.

So let's say the patient gets 160. But then for the next fractionation -- and also it says -- the package insert says that you should not re-escalate. So it should be 160 and then 160 from then on. But suppose let's say number 3, it's 200 by mistake.

The patient is given 200. Does that constitute a medical event or not? It is not what the package insert says, but still it's 200.

DR. TAPP: If that's what the authorized user wants to give, that would not be a medical event in the written directive, right, in the written

directive.

VICE CHAIR JADVAR: Thank you.

CHAIR METTER: Dr. Harvey?

DR. HARVEY: Thank you. One comment and one question. Yeah, I did take a sneak peek just on my own to look for some of the medical events that you talked about today just for my own edification. And then the second thing was a question. And so if licensees in agreement states have stricter interpretations of the regulations, say 10 percent instead of 20 percent of prescribed activity. And if we report those because we're required to because either our license conditions or our state regulations and those come to the NRC, would they be excluded from the NMED database them?

DR. TAPP: That's a good question. The work between agreement states and the NRC, sometimes we do get events that don't meet the NRC's criteria. We do not then -- we'll work with the agreement states to see if they would like to pull it out of the NMED and see if they think it meets our criteria.

Because in NMED, we do want to keep it to NRC criteria. So we do generally probably exclude it. But there is collaboration with agreement states.

MEMBER SHOBER: Yeah, this is Megan

Shober. So once an event gets reported through the operations center, it automatically goes in NMED even if it's subsequently retracted. So once something goes in NMED, it doesn't come out.

But that being said, if we get an event report for something that's not reportable for NRC's regulations, we won't forward that report. So I think that's pretty standard practice. But of course, there's some things that's, like, you're not sure the time of the event comes in. And so those things may get reported even if they're later determined not to be reportable.

DR. HARVEY: Thank you both.

CHAIR METTER: And thank you, Megan, for that addition. Dr. Einstein?

MEMBER EINSTEIN: Andrew Einstein. Thanks for a great presentation. In the remediation plan which you cited there was a daily huddle rather than a patient-specific time out, why is that?

DR. TAPP: The corrective actions were specific to the licensees. The inspectors ensure that they believe the corrective actions are adequate. But we don't really have a say.

We just report what they report to us as what they want to do for their corrective actions.

Maybe that would be a good one for an information notice or a recommendation. But we don't know why they did what they did.

MEMBER EINSTEIN: Particularly for an institution which has already failed for one patient.

DR. TAPP: Yeah.

CHAIR METTER: I think Ms. Allen has a comment or question.

MEMBER ALLEN: Yes, first, thank you for the presentation. As an administrator looking at it, a lot of this goes back on education, training, retraining. We also know that retraining and education is a level of reliability of a one.

So it's not very reliable when you go and say part of the action plan is retraining. And so I'm looking forward to seeing the recommended corrective actions and some examples or some lead way because I think it's very important that it's easy to say we're going to retrain. And that's a part of it. But it's not going to give us the level of reliability to reduce the medical event.

CHAIR METTER: Thank you.

MEMBER ALLEN: Thank you.

CHAIR METTER: Mr. Ouhib has a question.

MEMBER OUHIB: Yeah. Thank you, Dr. Tapp.

That was a great presentation. I think in quite a few slides you talked about providing training and so on.

But I think along that line, there should be a statement that says people who have not gone through proper training or official training or manufacturer training should not be part of the procedure, period. And I think because providing training someone could still be participating until they get their training next year or in six months from now. But I think eliminating any person without any training from the procedure I think is a wise move.

DR. TAPP: I would say that one thing is for the information notice. I won't be able to add something. That would be a new regulation. I can only provide what we're seeing from the industry, corrective actions, or if you guys have recommendations into an information notice.

But I wouldn't be able to do far reaching into that. I would think if there's actions to take based on therapeutic radiopharmaceuticals that require a regulation change which I'm not sure if that would. But if something did, that would have to go into a rulemaking.

MEMBER OUHIB: When you think in the case

of our procedures or whatever, the only requirement is that someone has to be trained and know what they're doing as far as medical physicist and all of that. It's very, very clear. And if you don't have that education and that training and knowledge and all that, you can't participate in that, period.

CHAIR METTER: I do have a comment on that. Usually at sites when any new entity or any procedure, particularly therapy comes in, it's a credentialing issue. So I think it's a local issue and really like Dr. Tapp said as far as that is probably more at that level. Okay. Any other -- oh, yes, Mr. Green.

MR. GREEN: Thank you, Dr. Tapp. A great presentation. Really intrigued by the categorization of how events can occur and the error medical event where there's the wrong patient or the wrong drug or the wrong route and the importance of verification of activity, assay it.

And Ms. Allen, I appreciate your evaluation of the poor return on investment. I'll train. Doesn't last very long.

There is an industry standard throughout the hospital that is used. Needs to make its way further into radiology. That's Barcode Medication

Administration, BCMA.

And if that occurred, people are wonderful. But barcodes can do things that people should do but don't. Is it the right drug? Is it the right patient? Is it the right amount? Is it the right route?

Check the computer system. BCMA made its nuclear recommendation you might put in your advisory document. BCMA, you can impose. It should be an -- it is an industry standard in the hospital. It's not made it to nuclear yet and it should.

CHAIR METTER: Thank you, Mr. Green, for that addition, additional comment in safety issue. Mr. Mailman?

MR. MAILMAN: Thank you for an excellent presentation as well. Just for your report, though, Dr. Harvey's report later, I would assume that a patient getting Pluvicto when they should've gotten Lutathera is a medical event. I would assume when a patient getting Lutathera when they should've been getting Pluvicto is a medical event as well.

I don't consider them one medical event. I consider them two medical events because there were two patients. It was listed as a single medical event, and it may be a single screw up. But to me,

it's two patients both getting the wrong dose. And I would say for the future accounting that I would hope that it listed twice.

MR. DIMARCO: Daniel DiMarco. I remember this event specifically. This was caught when only one of the patients was given the wrong drug and the other patient had not been given the wrong drug. So they caught it at the first part of a patient. And then that second injection was canceled when they realized that they had given the wrong --

MR. MAILMAN: So this is the event from December of last year. I have to go back to it because I read it differently. But that's okay. So it was only in one patient. That's fine. And it's a single event.

MR. DIMARCO: To the best of my remembrance, that was --

MR. MAILMAN: But that's not how it was written here. So I'm just double checking.

CHAIR METTER: Okay. Thank you. Any other questions from the ACMUI? NRC staff? Any members in the public? Yes, I do have Lantheus. Do you want to come to the microphone here?

MS. THOMPSON: Hi, can you hear me? Hi, my name is Diana Thompson. I'm the director of

Radiopharmaceutical Health Physics at Lantheus. And I had two questions.

Also, first, thank you very much for your wonderful presentation, Dr. Tapp. So the first question that I wanted to ask is that because there are four doses, are the doses considered fractionated? Or is it one written directive for one administration?

DR. TAPP: That is dependent on how the authorized user writes the written directive. Across right now, I mostly see individual written directives per each treatment. And I think that's because you're drawing blood, taking labs, checking the status. So I think they're writing written directives each time right now.

MS. THOMPSON: The second question that I had was in the beginning of your presentation, you noted that you could write a dose range on a therapeutic administration. And I think I've only seen that for diagnostics. And I wanted to confirm if that is an acceptable way to document a dose on a written directive for therapeutics.

DR. TAPP: I do not have the regulations in front of me. In something that tight, I'd have to double check. I'd have to look at 35.40.

35.40 pulls up exactly what the

requirement is. And it could be different amongst agreement states. So I think everyone should double check what is required for 35.40. You're probably correct. Chris is pulling it up right now.

MS. THOMPSON: I believe 35.40 says dose. But that could be a range if that's what the clinical trial approves. And I just wanted to -- if there's examples out there that has been seen on inspection or with other products. I just wanted to clarify since it was in the slides.

DR. TAPP: Yeah, the slides could be -- because it is possible to have a medical event with a diagnostic. And diagnostics are allowed to have ranges.

MS. THOMPSON: That does clarify. Thank you very much.

MR. GREEN: I don't know the regulation. I agree you should look it up. But when you're doing a sodium iodine capsule, it all goes down the gullet. Here you have an infusion where you can have residual activity in the vial or the syringe and infusion apparatus.

So even though it measured 200, you're not getting 200 in. There's always going to be something. So I think the range makes sense. We should check the

regs.

CHAIR METTER: I do see Mr. Zoubir. Do you have a question? I do see --

(Simultaneous speaking.)

MR. OUHIB: No, I don't. My hands are down.

CHAIR METTER: Okay. I see a public member. Could you read that?

(Simultaneous speaking.)

DR. TAPP: Just one second to the virtual caller. It does say in 35.40 it's dosage. Dosage is defined in 35.2. And it is dose or dosage range.

CHAIR METTER: I have -- I can't read the -- yeah, could you pull it up? We have Nicole. Are you able to unmute, Nicole?

MS. NARDECCHIA: Hi, sure. Thank you. Thanks for the presentation. My name is Nicole Nardecchia. I work as a quality improvement and patient safety manager for radiology at Yale-New Haven Hospital.

And I just wanted to go back quick to the root cause analysis and corrective action plans that were mentioned. I don't remember who mentioned it. But I completely agree about education and retraining being a really weak form of a corrective action plan.

And I just would challenge any of the root cause analysis. I'm not sure how those are performed or how the NRC documents those. But stating that there was a failure to follow policy or protocol as a root cause, that's actually kind of -- that's the problem. That's not really the root cause. So I would just challenge maybe some of the documentation on how a root cause or corrective action plan is put into place because I think there could be more strong corrective action. Thank you.

CHAIR METTER: Thank you. Dr. Tapp, can you read the next person?

DR. TAPP: Sure, Venkata Neti. I'm sorry.

MR. NETI: Yeah, can you hear me?

DR. TAPP: Yes.

MR. NETI: I'm Neti, radiation safety officer at RBHS Newark. Particularly, I do want to go into specific example, the one you mentioned as one of the examples Lutathera administered to Pluvicto patient and Pluvicto administered to Lutathera patient, these are two medical events because two patients are involved, but I have a question. In Pluvicto, we don't have any infusion. Is that correct?

Whereas for the Lutathera you have

infusion. So even the infusion is also done incorrectly thereby changing the dosimetry for Pluvicto because we are not protecting kidney by infusion for Pluvicto. But -- to the Pluvicto patient. That's the dosimetric change is the big issue from the dosimetric point of view.

DR. TAPP: The medical consequence, I would have to leave that up to the licensee and the inspectors and look it up. But wrong drug in a therapeutic would be a big concern, I think. If anybody here you guys want to add?

MR. NETI: That's true in case of Pluvicto. What about Lutathera where there was no infusion. But as for the procedure, you have the infusion. Without infusion you can't administer Lutathera. Besides the medical event, is there any consequences to the patient from the health point of view?

DR. TAPP: I do not have the -- in front of me the patient consequence in this type of view in the individual events. But when we do have a medical event, we do follow up with patient consequence. Patient consequence is a required reporting item as well as you know the states would follow up and find out the medical consequence. So an individual event,

they would follow up on that and I would be concerned in those type of events.

MR. NETI: Thank you.

CHAIR METTER: Thank you. I do not see any other questions, do you, from the public?

DR. TAPP: Mr. Neti just put his hand back up.

CHAIR METTER: Oh, but I do see one from the committee. Zoubir, go ahead.

MR. OUHIB: Yeah, I just want to comment briefly regarding the root cause that one of the attendees just brought up. We did look at this within the AAPM. And Bruce Thomadsen as probably most of you know him was the chair of this task group.

And we looked at it and just sort of thought about what would the verbiage should be. What is really required? What is needed? What could actually help understand the event itself also the remedies that would be appropriate?

And I think maybe at some point it would be worth looking into that, knowing it might not be easy. But it's almost like a mandatory form that has to be filled out by every user, per se, in the case of a medical event. And any blank is not accepted, period. Thank you.

CHAIR METTER: Thank you. I do see other individuals. I can't read their names.

DR. TAPP: Yeah, Venkata Neti.

MR. NETI: Hi, it's me again. So it's not a concern at least for Lutathera and Pluvicto, because Lutathera is for neuroendocrine and Pluvicto is for MCRP patients. Maybe written directives should include those checkmarks where it's a neuroendocrine or MCRP patient. That way we may avoid in the future some of the cases.

CHAIR METTER: I have a question for Mr. Green. Are they in different colored -- do they get distributed in different colors as far as the radiopharmaceuticals so we can identify them as different?

MR. GREEN: I don't know how many colors there are in the world. But I know there's 26 English letters in the English alphabet. And the English letters are different.

And BCMA can read letters through a barcode and tell you it's the wrong drug. I looked it up. There are 56 FDA approved drugs, 45 of which currently are intravenously administered.

There are 16 tech drugs, 9 fluorinated drugs, and 2 lutetium drugs. There's going to be a

lot more lutetium drugs coming. There's 257 lutetium clinical studies underway at clincialtrials.gov.

We will see some of them hit the marketplace. It's new, but we got to do better. And that means read the label. Sorry.

CHAIR METTER: Thank you, Mr. Green. Are there any other questions in the room here? I do not see any questions in the public. Is that correct? Oh, I'm sorry. There is. Dr. Einstein?

DR. EINSTEIN: Barcodes and labels are great. But I do think colors serve as a second check. I don't think the two of them are mutually exclusive. It would be great if drugs which can get confused are color coded appropriately as well.

CHAIR METTER: We just have to be sure not to use green and red. But anyway, okay, I do see a hand in the public. There's an individual. William?

MR. HINCHCLIFFE: Hi, yeah, William Hinchcliffe, radiation safety officer at -- Hospital. Just to sort of give a direct answer to this question, the Lutathera and the Pluvicto come in identical colored pigs, same size. They are indistinguishable at first glance.

The vials are very similar sized and the volumes are different in size but not so different to

be easily noticeable. They come from the same companies. The labels do look very similar except when you read them identically and typically do not come with patient information on the outside of the pig. So they're easy to confuse until you look at them very closely.

CHAIR METTER: Thank you very much for that confirmation of the idea of colors. Dr. Einstein?

DR. EINSTEIN: Does the NRC have regulatory capabilities of packaging materials? And could they -- could you mandate different colors?

DR. TAPP: No, it wouldn't be in the regulations today. That would fully require rulemaking. And I'd see that being a difficult one.

I know we talked about it before and I know we talked about it here. But barcoding and recommendations with different colors could come from the ACMUI. I'm just saying if there's a subcommittee that did a formal recommendation because right now I'm just taking it as a comment from Mr. Green. So I didn't know if that's something for consideration for the future.

CHAIR METTER: Since this is actually a new therapeutic that's come up with a significant

number of medical events particularly in 2023, I think we might need to form a subcommittee with maybe looking at that and suggest recommendations. But thank you. That's a very good suggestion.

DR. EINBERG: Yeah, Chris Einberg here. I was going to say as alluded, Dr. Tapp is developing the information on this right now on medical events. And this information will come to the ACMUI for review. At that time, if you want to make comments on that information notice, that's another opportunity to influence that information notice.

CHAIR METTER: Excellent. Thank you, Mr. Einberg. Okay. Any other final comments before we go to our break? Seeing none in the room or in the public chat box, let's go ahead and conclude this portion of the afternoon meeting. And we'll reconvene at 2:35. Thank you, Dr. Tapp.

MR. EINBERG: 3:35.

CHAIR METTER: I'm sorry, 3:35.

(Whereupon, the above-entitled matter went off the record at 3:22 p.m. and resumed at 3:35 p.m.)

MR. EINBERG: Yes, this is Chris Einberg. We're reconvening the meeting right now. The next agenda item is the special presentation to Dr. Metter. As you all know, this is Dr. Metter's last official

meeting of the ACMUI.

And so it's with great regret that she's going to be leaving us. She's still going to serve until the March time frame. But this is her last official meeting.

And so it's with a heavy heart that I am saying goodbye to her. But we have a special presentation from Commissioner Wright. Commissioner Wright is going to have an award for you. Commissioner Wright?

COMMISSIONER WRIGHT: Thank you so much.

MR. EINBERG: Okay. Well, are we there?

COMMISSIONER WRIGHT: All right. Well, good afternoon, everyone. And I'm pleased to be with you here today to recognize the contributions of Dr. Darlene Metter to the ACMUI and actually to the NRC as a whole. As many of you know, her term ends February 24th of next year, I believe.

So this, as you mentioned, is her last meeting as ACMUI chair and as diagnostic radiologist representative. And we want to take time, the time that we have today to recognize you for your contributions and to celebrate your service here. So first before I bring you up here, let me take a moment to recognize your expertise in the field of radiology

and to celebrate just everything that you've done, the leadership that you've provided not just to this committee but to the NRC and how we as Commissioners and the agency as a whole have benefitted from things that you have been involved in since you were appointed as a representative back in 2016.

That was seven years ago. We've had the good fortune to learn from you, from your expertise and the experience that you have and you've garnered throughout your life. You were appointed to the position of vice chair in 2018.

That was just two years after you joined the committee. And having done something like that before, that's not an easy thing to do to come in. It takes usually a couple years just to get up to speed.

And then you were appointed chair in 2019 -- in September of 2019. During your time here at the ACMUI, you had kept me and the other Commissioners well informed of this committee's views on different medical topics including presenting to the Commission and this committee's comments on things like the guidelines to nursing mothers and training and experience requirements for all modalities. And that was back just in April of 2019, pre-COVID.

You've also provide overviews of this

committee's activities in 2021 -- in 2020, 2021, and 2022 at our annual Commission briefings. And I remember these meetings, virtual and in person. And I've always appreciated your professionalism, the way you carry yourself, your clarity, and everything that you do that just enhances your presentations to the Commission.

During your tenure as well, you've actively participated in committee meetings and provided valuable advice to the NRC on very technical relevant policy issues by serving as chair and member of numerous subcommittees which by my count is almost 20 different subcommittees that you've been involved in. And again by my count, that's almost every subcommittee that you could possibly have been involved in. So you're not just good, but you're a workaholic.

I appreciate you for wanting to do that. You've been involved in everything from medical events to abnormal occurrences, from linear no-threshold petitions to Y-90 licensing guidance. And not just the committee but the NRC is better for your involvement and participation here. And I want to thank you for that.

So if you would come up here, stand by me,

I want to present you with a few tokens of our appreciation and gratitude for your eight years of dedicated service to ACMUI and to the NRC. So first is a flag of the United States that has been flown over the Capitol. It's a certificate that's been signed by Maryland U.S. Senator Chris Van Hollen which is kind of cool, I have one of these for each of my children.

A second thing is a certificate of appreciation that's signed by our chair, Chris Hanson. Okay? And then last but not least is an NRC pin, right? Now it's just like this one, and I wear it everywhere. It's very pretty. It's very nice.

And then last of the last but certainly not least is a handshake from me on behalf of the Commission thanking you for your eight years of service and everything that you've done to make this agency better and this committee better. The advice that you've given to us has been seriously taken and considered. And I just want to thank you for not just myself but the members of the commission and the NRC. Congratulations. Would you like to say something?

CHAIR METTER: Thank you, Commissioner Wright. My fellow ACMUI members and NRC staff, thank you for the privilege and honor of being a member of

the ACMUI since 2016, and as Commissioner Wright said, your vice chair in 2018 and your chair since 2019. As an ACMUI member, as you know, work can be quite intense and challenging in advising the NRC in their mission which includes protecting patients and the public health and safety in the medical uses of radioisotopes.

Despite these challenges, the ACMUI tasks have been quite rewarding. And only in large part due to the incredible expertise, support, and knowledge of the NRC staff and my fellow ACMUI members. When I attended my first meeting in 2015, Bruce Thomadsen was the ACMUI chair.

It was really a true eye opener and to be a part of this massive federal organization was totally impressive. As today, we're in a conference room with this horseshoe table. And the newest member would start at one end of the table and through their tenure rotate around the table to a final position before rotating off.

And as you remember, one member actually said, I'm falling off. But during these first meetings, my first goal was really just to observe. And I truly wanted to be a silent member.

I wanted to rotate around the room and

fall off. Unfortunately, the following year, Dr. Phil Alderson, a fellow nuclear radiologist, became the ACMUI chair. And Dr. Christopher Palestro, another nuclear medicine colleague, became the next chair. And I was soon tasked at being a chair of subcommittees regarding Y-90 microsphere, nursing guidelines, and training and experience.

And as you had heard with Commissioner Wright, I was also on several other subcommittees. The subcommittee topics and work were all really quite challenging. And especially with a highly engaged active national stakeholder audience, video recording and legal transcripts of our meetings.

However, I soon discovered that the expertise, knowledge, and support of my fellow ACMUI members and NRC staff whose teamwork contributed to the success in producing well thought out and comprehensive final subcommittee reports. During these last few years, the ACMUI experience has been very rewarding and not only in contributing to the regulatory safety of our patients and the public but in part being a part of the rich camaraderie of this organization. Thank you for this great privilege and honor to being a part of the ACMUI and NRC family.

The ACMUI experience will be a true highlight in my professional career and a very, very long lasting treasured memory. In reminiscing the final words of our recent past chair, Dr. Christopher Palestro, and I truly agree with him, the hardest thing I have had to do as an ACMUI member is leaving the ACMUI. Thank you very much.

(Pause.)

MR. EINBERG: Some members requested that the ACMUI members come up here along with the NRC staff for a group photo. And so if we can do that, it'll be a nice memory.(Pause.)

CHAIR METTER: Thank you very much, everyone.

(Pause.)

MR. EINBERG: So Dr. Metter, remember during these presentations after you give your closing remarks or your farewell, we open it up to the ACMUI staff to see if they have any thoughts that they'd like to share. And so I'll open it up to the staff right now -- to the ACMUI members. I see Dr. O'Hara has something.

MEMBER O'HARA: Yeah, I want to thank you for the example of leadership that you've shown since I've been here. I've enjoyed learning from you and

from all of my colleagues and all of our colleagues from the past. So I want to thank you and wish you the best.

CHAIR METTER: Thank you, Dr. O'Hara.

MR. EINBERG: Dr. Jadvar.

VICE CHAIR JADVAR: Darlene, we have known each other for many, many years. You have been a great colleague and friend and I always cherished it. And just want to say that I learned much from you.

Thank you for mentorship over the past few years here in the ACMUI. And I know we're going to see each other for many, many years to come. And again, I'm very privileged to have you as a friend. Thank you.

CHAIR METTER: Thank you, Dr. Jadvar. And your leadership has been very helpful to me too and your presentation as chair in all these subcommittees. And I know you'll do a great job in leadership in the ACMUI in the future. Thank you very much.

MR. EINBERG: Mr. Green?

MEMBER GREEN: How many years ago was it when we were the new fish at that corner of the table? I felt like a very small fish in a very big pond. You're very kind to be welcoming and receptive.

And your leadership has been remarkable.

I'm very impressed. I shouldn't be impressed, but you have an impressive degree of concern for the patient. And that's always forefront in your mind.

Even though we're not dealing with the patients here, we're dealing with regulations. But you always bring it back to the patient. I appreciate that.

CHAIR METTER: Thank you, Mr. Green. I do remember the time that you, myself, and Zoubir were sitting at the end of the table and just kind of being really quiet. But we weren't that quite. But it was very good.

And we are here for our patients. And I think we dedicate our lives to the safety and protection and the best of health for our patients. Thank you.

MEMBER OUHIB: And on behalf of -- sorry. Zoubir.

MEMBER OUHIB: Yes. Speaking of quiet, I just want to thank you, Dr. Metter, for all the hard work you put together. And it showed over the past years a lot of contributions to the ACMUI. Thank you so much. And it was certainly a pleasure and an honor to know and work with you. All the best.

CHAIR METTER: Thank you, Zoubir. And

I've always learned from your comments and your questions. And they're always very unique and really something that I wouldn't have thought of. But I thank you too for your contributions to the ACMUI.

MR. EINBERG: Okay. So on behalf of the NRC, I think the collaboration that we've had between the ACMUI and the NRC staff is in large part due to your leadership and your collaborative nature, your friendly nature, your welcoming. I think we've had a very good working relationship over the years. And you've really fostered that.

And so that goes without saying we're very appreciative of that, your expertise, your knowledge that you bring to the table, and your care for the patients. It's all in the interest of treating the patients and for the good for the American public. And so when Commissioner Wright went through all the subcommittees that you've been on, you've been very involved in all aspects of ACMUI.

And when you think of the reach of nuclear medicine in this country, we touch about 20 million individuals per year. You had the very influential -- you've had a very influential role in all of this. So on behalf of the NRC, I want to say thank you.

CHAIR METTER: Thank you very much. And

you've got, like I said, a great team and a great culture. And I was very honored to be -- I'm privileged to be a part of that. Thank you very much. For the open forum, any other items or comments from the ACMUI? NRC staff? Dr. Tapp?

DR. TAPP: Yes. For the open forum, I just wanted to let the ACMUI know that we have two 35.1000 documents coming to you guys for review coming up. We have the EYE90 which is a Y90 microsphere product for manual brachytherapy for HCC. And that will be coming your way.

It's similar to the TheraSphere and the SIR-Spheres and the licensing guidance document as well as we have the Akesis Galaxy which is a new gamma stereotactic radiosurgery unit used for treatment of the head and neck. And that will also be coming your way for review. We're hoping that there could be subcommittees formed to review these. And hopefully you'll have a teleconference before the next meeting in this spring so we can issue these guidance documents with your recommendations and your review for them.

CHAIR METTER: Thank you, Dr. Tapp, for that update on our upcoming subcommittees. Any other items for the open forum? Seeing none, we're on our

last portion of our meeting with our administrative closing with Ms. Armstead.

MS. ARMSTEAD: Prospective dates for the spring 2024 conference. As you can see on the calendar for the month of March, it's the 18th and the 19th of March. And for the month of May, it's the 8th and the 9th of May -- I'm sorry, April 2024. I did receive greater response from the ACMUI for the April 8th and 9th dates. Is there any further discussion for these dates?

(No audible response.)

MS. ARMSTEAD: So other than finalizing the potential spring 2024 meeting, I do not have anything else to add. Dr. Metter?

MR. EINBERG: And Dr. Metter, Chris Einberg. So can we -- assuming the tentative dates are the April 8th and 9th because that was the first priority, that's acceptable to all. Thank you.

CHAIR METTER: Do we need to vote on that? Yes, Ms. Shober.

MS. SHOBER: Yes, thanks. Are we doing a Commission briefing at the spring meeting, or are those dates -- will they take that into account?

MR. EINBERG: Dr. Tapp?

DR. TAPP: Yes, the plan at this time

would be to do a commission briefing in the spring. So the tentative dates that we would aim for is the 8th and 9th. But you're right. We have to wait for SECY to finalize dates. We're trying to get it together.

CHAIR METTER: Okay. Thank you. Do we have to vote on that?

DR. TAPP: I do believe -- I think we just hold it tentatively at this point.

MS. ARMSTEAD: Dr. Metter, there was a vote that went out last month and the team favored the 8th and the 9th.

MR. EINBERG: But what Dr. Metter was asking whether right now in the public forum do they need to vote on that. And so Dr. Tapp had something to say.

DR. TAPP: Yes, we do vote on the tentative dates to have it on those dates. So yes, there should be a vote.

CHAIR METTER: Okay. Do I have a motion to approve the tentative dates for the spring meeting as April 8th and 9th pending the Commission's scheduling and our meeting with them?

MEMBER GREEN: So moved.

MEMBER WOLKOV: Second.

CHAIR METTER: Okay. All in favor, say aye.

(Chorus of aye.)

CHAIR METTER: All opposed or abstain? Thank you. The motion is unanimously approved by the committee. Any other administrative closing items? Ms. Armstead?

MS. ARMSTEAD: That's it, Dr. Metter.

CHAIR METTER: Thank you. So Mr. Einberg, any other final comments before we close this meeting?

MR. EINBERG: I just wanted to thank the ACMUI members for all their hard work they put in throughout the year, their expertise that they bring to the NRC and to the public. I want to thank the NRC staff for putting together this meeting. And there's a lot of preparation that goes into it.

But that's all I have for right now. And I want to say goodbye to Dr. Metter. And so all the best to you.

CHAIR METTER: Thank you very much. And this concludes the 2023 fall meeting of the ACMUI. And thank you for your attention and participation and the timely updates and reports by the ACMUI members and NRC staff.

I also would like to wish you all a happy

holiday, upcoming holiday and be safe and safe travels to your home. Thank you very much. The meeting is adjourned.

(Whereupon, the above-entitled matter went off the record at 4:03 p.m.)

C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Meeting of the Advisory Committee on the Medical Uses of Isotopes

Before: US NRC

Date: 10-23-23

Place: teleconference

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate complete record of the proceedings.

Neal R Gross

Court Reporter