Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Advisory Committee on the Medical Uses of Isotopes

Location: teleconference

Date: 11-04-24

Work Order No.: NRC-0078 Pages 1-142

NEAL R. GROSS AND CO., INC.
Court Reporters and Transcribers
1716 14th Street, N.W.
Washington, D.C. 20009
(202) 234-4433

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

+ + + + +

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

+ + + + +

FALL 2024 MEETING

+ + + + +

MONDAY,

NOVEMBER 4, 2024

+ + + + +

The meeting was convened via Video Teleconference, at 10:00 a.m. EST, Hossein Jadvar, ACMUI Chairman, presiding.

MEMBERS PRESENT:

HOSSEIN JADVAR, M.D., Ph.D., Chairman

RICHARD L. GREEN, Vice Chairman

REBECCA ALLEN, Member

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

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

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

RICHARD HARVEY, Dr.PH., Member

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

JOHN F. ANGLE, M.D., Consultant

to the Committee

NRC STAFF PRESENT:

CHRIS EINBERG, NMSS/MSST/MSEB, Designated

Federal Official

LILLIAN ARMSTEAD, NMSS

MARYANN AYOADE, NMSS

CINDY FLANNERY, NMSS

DANIEL SHAW, NMSS

DANIEL DIMARCO, NMSS

MIKE KING, Special Assistant for the

ADVANCE Act, OEDO

TORI ROSZKOWSKI, NMSS

DAFNA SILBERFELD, Deputy Director, MSST

SARAH SPENCE, NMSS

KATHERINE TAPP, 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. As the designated federal officer for this meeting I am pleased to welcome you to the public meeting of the Advisory Committee on the Medical Uses of Isotopes. My name is Chris Einberg. I am the chief of the Medical Safety and Events Assessment Branch and I have been designated as the federal officer for this advisory committee in accordance with 10 C.F.R. 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 on October 8th, 2024 in the edition of the Federal Register, Volume 89, page 81579.

The function of the ACMUI is to advise the staff on issues and the 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'd request that whenever possible we try to reach a consensus on the various issues that we will discuss today, but I also recognize there may be a minority of dissenting opinions. If you have such opinions, please allow them to be read into the record.

At this point I would like to perform a roll call of the ACMUI members participating today.

Dr. Hossein Jadvar, Chair, nuclear medicine physician?

CHAIRMAN JADVAR: Present.

MR. EINBERG: Mr. Richard Green, Vice Chair, nuclear pharmacist?

VICE CHAIRMAN GREEN: Present.

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

MS. ALLEN: Present.

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

DR. EINBERG: Present.

MR. EINBERG: Dr. Joanna Fair,

diagnostic radiologist?

DR. FAIR: Present.

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

DR. FOLKERT: Present.

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

DR. HARVEY: Present.

MR. EINBERG: Mr. Josh Mailman, patients' right advocate?

MR. MAILMAN: Present.

MR. EINBERG: Ms. Melissa Martin, medical physicist?

MS. MARTIN: Present.

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

DR. O'HARA: Present.

MR. EINBERG: Mr. Zoubir Ouhib, therapy medical physicist?

MR. OUHIB: Present.

MR. EINBERG: Ms. Megan Shober, Agreement State representative?

MS. SHOBER: Present.

MR. EINBERG: Dr. Harvey Wolkov,

radiation oncologist?

DR. WOLKOV: Present.

MR. EINBERG: I confirm that we do have a quorum.

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

All members of the --

DR. ANGLE: Present.

MR. EINBERG: Yes, thank you, Dr. Angle.

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

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

NRC official.

I would like to add that we are also using Microsoft Teams so that members of the public and other individuals can watch online or join via phone. The phone number for the meeting is (301) 576-2978. Once again, (301) 576-2978. The phone conference ID is 277173020#. Once again, 277173020#. The handouts and the agenda for this meeting are available on the NRC's ACMUI public website.

Members of the public who notified Ms. Armstead that they would be participating via Microsoft Teams will be captured as participating in the transcript. Those of you who did not provide prior notification, please contact Ms. Armstead by email at lxa5@nrc.gov, lxa5@nrc.gov, at the conclusion of this meeting.

Today's meeting is being transcribed by a court reporter. We are utilizing Microsoft Teams for the audio of today's meeting and to view presentation material in real time. For the purpose of this meeting the chat feature in Microsoft Teams has been disabled. Dr. Jadvar, at his discretion, may entertain comments or questions from members of the public who are participating today.

For those individuals on Microsoft Teams, please use the raised hand function to signal our Microsoft Teams Host Ms. Armstead that you wish to speak. If you have a call 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 the presentation after the Committee has fully discussed the topic. We will announce when we are ready for the public comment period of the meeting and Ms. Armstead will assist in facilitating public comments.

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

I will now turn the meeting over Ms. Dafna Silberfeld, Deputy Director of the Division on Materials Safety, and Security, and Tribal Programs, for some opening remarks.

MS. SILBERFELD: Good morning, everyone.

MR. EINBERG: Is your mic on?

MS. SILBERFELD: -- hear me? I think

it's on now.

MR. EINBERG: Yes.

MS. SILBERFELD: Good morning, everyone. I'm delighted to welcome you all to our fall meeting. My name is Dafna Silberfeld and as Chris mentioned, I am the new Deputy Division Director for Materials Safety, Security, State, and Tribal Programs Division.

I've been with the Agency for more than 14 years working in the Office of the Chief Human Capital Officer, the Office of the Chief Information Officer, and the Office of Nuclear Material Safety and Safeguards within the Division of Rulemaking, Environmental, and Financial Support.

One of my favorite aspects of the division I represent today is the opportunity to engage with our diverse stakeholders and foster meaningful relationships. Over the past couple of months I've been getting up to speed on all of the incredible work that's been done over the last year and I'm excited about the opportunities that lie ahead.

I'd like to take a moment to thank the ACMUI for your hard work and dedication in supporting

the NRC on various issues. Your expertise and contributions are truly valued and I look forward to a great meeting ahead.

To kick us off at a high level I want to highlight a few items that we are working on. Let me start with two Commission-related rulemaking updates. First, the Reporting Nuclear Medicine Injection Extravasations as Medical Event Rulemaking, a proposed rule for reporting specific nuclear medicine injection extravasations as medical events is now under Commission review. This new rulemaking under 10 C.F.R. 35.3045 aims to ensure comprehensive tracking and transparency for medical events involving extravasations.

Along with the proposed rule the staff developed implementation guidance for the rule which includes regulatory guidance for all medical events including nuclear medicine injection extravasations and a draft model procedure for detecting and evaluating nuclear medicine injection extravasations. The draft guidance is also currently with the Commission for review.

Second, the staff continues to work on the rb-82 Generators and Emergency Medical

Technologies Rulemaking. This rulemaking began with Commission approval is January 2022 allowing for early stakeholder engagement including input from the ACMUI Agreement States and NRC regions. The staff issued the regulatory basis on July 3rd, 2023 for public comment and has reviewed approximately 400 individual public comments received in response.

The staff is currently working on development of the draft proposed rule and draft implementation guidance. We anticipate submitting the draft proposed rule to the Commission by January 2026 with a final rule and implementation guidance expected by early 2027.

Next, I would like to mention NRC staff activities. First, staff has developed interim guidance to address training and experience for unsealed byproduct material requirements in Part 35 responding to Commission direction. The guidance issued in August 2024 for public review and comment clarifies the qualifications and responsibilities of authorized individuals and aligns with recent Commission directives. The public comment period ends November 30th, 2024 and final guidance is expected to be issued by December 2024.

Second, the staff is process of responding to public comments on the proposed Phase 2 revision to Regulatory Guide 8.39, Release of Patients Administered Radioactive Material. This guide governing patient release following radioactive material administration is under revision to simplify the methodology and address cost-related concerns raised during the public comment period.

A comprehensive cost benefit analysis is underway with a focus on achieving balanced cost-effective solutions to licensees. Dr. Tapp will provide a detailed update on this work later today.

And third, as you are aware, on March 26th, 2024 the OIG released a report documenting the appearance of a conflict of interest involving members of the ACMUI. The OIG also found that the NRC lacks policies to ensure compliance with 5 C.F.R. 2636.502.

The NRC takes the integrity of its decision-making processes seriously, particularly regarding matters impacting public health and safety. The OIG investigation highlights areas where our internal processes led to questions about the integrity of decision making. Therefore, NRC staff

is undertaking several efforts to ensure we uphold the public trust. For example, the NRC completed an update of our internal procedures regarding the administration of the ACMUI. This update was issued in August and strengthened conflict of interest screenings and ensured procedures were consistent with updated Federal Advisory Committee Act requirements.

Next, the NRC is working to update the ACMUI Members' Guide to ensure it contains up-to-date information and additional details on members' responsibilities regarding potential and apparent conflicts of interest. We are also working with you to update your bylaws which Ms. Allen will discuss further today. In addition, the NRC staff will provide you with enhanced ethics training which will be provided tomorrow.

Finally, we have reviewed our hiring practices to include questions during candidate interviews related to ethics and conflict of interest responsibilities and ensure the Office of the General Counsel will be available to support candidate interviews to answers questions related to ethics and conflicts of interest.

Now, I would like to take a moment to talk about a few NRC organizational changes. Since the 2024 spring meeting there have been several important organizational changes within the NRC. Dr. Celimar Valentin-Rodriguez has left the Medical Radiation Safety Team and Dr. Katie Tapp has been appointed as the new team leader.

Rob Lewis, the former Deputy Office Director of the Nuclear Material Safety and Security Office, has been selected as the Deputy Executive Director of Operations overseeing areas such as materials, waste, research, and compliance.

Kathryn Brock will serve as the Acting Deputy Office Director for the Office of Nuclear Material Safety and Security for the next three months while we search for a permanent replacement.

Additionally, Kevin Williams is now on rotation as the Acting Deputy Office Director of the Office of Nuclear Security and Incident Response for the next three months. The NRC is actively seeking someone to fill in for him as the acting director of the Division of Material, Safety, Security, State, and Tribal Programs, known as MSST.

Lastly, Theresa Clark, the former Deputy

Division Director of MSST, has been appointed as a division director in the Office of Nuclear Reactor Regulations.

We also had an ACMUI member update. We welcome Dr. Fair who has completed the necessary clearance and now serves as a full ACMUI member. We look forward to Dr. Fair's insights and contributions to the Committee.

With these organizational changes in mind let's shift our focus to the agenda for today's meeting. We have several key presentations planned for today.

Ms. Allen will present on the ACMUI's Subcommittee recommended updates to the ACMUI bylaws.

Ms. Spence will provide an overview of the NRC's evaluation of Y-90 microsphere medical events following ACMUI's previous recommendations.

Mr. King will provide an overview of the Advance Act and actions NRC is taking in response.

Mr. DiMarco will provide an overview of current patient waste guidance and regulations.

Dr. Tapp will provide an update on the NRC's Medical Radiation Safety Team activities.

And Dr. Tapp will provide a status update on

the revisions to Regulatory Guide 8.39, guidance on releasing patients following administration of radioactive materials.

Before I turn it over to Dr. Jadvar, I want to thank everyone for their participation and contributions to today's discussions. I wish you all a productive and engaging session and will be available throughout the day and look forward to the insights shared here.

With that, I will now turn it over to Dr. Jadvar.

CHAIRMAN JADVAR: Thank you very much, Mr. Einberg, for your introduction, and also Ms. Silberfeld for your opening remarks.

Good morning, everyone and welcome to the 2024 fall meeting of the ACMUI. And with that, I'd like to get started with our agenda for today.

First we are going to hear from Ms. Armstead and Ms. Roszkowski who will review the past ACMUI recommendations and provide NRC responses.

Ms. Armstead?

MS. ARMSTEAD: Thank you, Dr. Jadvar.

Lillian Armstead, ACMUI Coordinator. I'll be providing the old business report and give a

status and update on some of the items from ACMUI's recommendations and action items.

Item No. 11, dated 9/21/2020. As part of the non-medical events report the ACMUI recommended to the NRC staff and/or NMP 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 triggered to landfill alarms, and provide some level of guidance, best practices, or additional instructions. Mr. DiMarco will be providing the NRC evaluation on this topic later today. Therefore, we propose to close this item today.

Item No. 10, dated 10/4/2021. The ACMUI endorsed the Radionuclide Generator Knowledge and Practice Requirements Subcommittee report and the recommendations provided therein. This item is currently open with a target completion date of March 2026. As the recommendations are being evaluated as part of developing the proposed rule for the rubidium 82 and emerging medical technology rulemaking effort.

Item 4, dated 12/5/2022. The ACMUI endorsed the Y-90 microsphere ME Subcommittee report and the recommendations therein. Ms. Spence will be

providing the NRC evaluation of Y-90 microsphere medical events following these recommendations today. Therefore, we also propose to close this item today.

Item 6, dated 12/5/2022. The ACMUI established two Subcommittees, one to create generic process checklists to be used during medical administrations and one to review the decommissioning financial assurance draft proposed rule. The ACMUI also reestablished the nursing mothers' guidelines to update the 2019 guidelines. While the Subcommittee, which reviewed the decommissioning financial assurance, provided its recommendations in 2023 the other two proposed Subcommittees are expected to report at the spring 2025 meeting. Therefore, this item will remain open until spring 2025

Item No. 1, dated 4/8/2024. The ACMUI tentatively scheduled the fall 2024 meeting for November 4th through 5th, 2024. Therefore, we propose to close this item today.

Item No. 2, dated 4/8/2024. The ACMUI formed a Subcommittee to reassess including an interventional radiologist in ACMUI membership. This Subcommittee is expected to provide a report at the spring 2025 meeting. Therefore, this item is

proposed to close in spring 2025.

Item 3, dated 4/8/2024. The ACMUI formed a Subcommittee to update the regulations in 10 C.F.R. 30.35 that deal with the financial assurance to Category 1 and Category 2 material. This Subcommittee provided its final report and recommendations to the NRC on September 10th, 2024. Therefore, we propose to close this item today.

Item 4, dated 4/8/2024. The ACMUI formed a Subcommittee to review the Committee's bylaws regarding disclosures related to conflicts of interest. Ms. Allen will be providing the Subcommittee's report and recommendations today. Therefore, we propose to close this item today.

Dr. Jadvar and ACMUI staff, this completes this old business report. As many of these items will be discussed later in the meeting, I propose we close them later. Dr. Jadvar?

CHAIRMAN JADVAR: Thank you very much, Ms. Armstead.

And Ms. Armstead again mentioned we will -- later on today, after Mr. DiMarco's presentation, we will vote for the suggested closure of these items, some of these items.

At this point our agenda is open forum. This is where the ACMUI members will identify any medical topics of interest that we want for further discussion. Any comments?

Okay. I hear none. But we have another open forum later on, so if something comes up to your mind, please mention it later today. We have actually a break scheduled now which goes from 10:45, Eastern Standard Time to 11:00. So I think we should keep our agenda on time. So why don't we take a break until 11:00 a.m., Eastern Standard Time? That will be 8:00 a.m., California Time, or Pacific Time. And then at that time we'll regroup. Thank you.

MR. EINBERG: Okay. Sounds good, Dr. Jadvar.

(Whereupon, the above-entitled matter went off the record at 10:22 a.m. and resumed at 11:00 a.m.)

MR. EINBERG: Dr. Jadvar, I've got 11:00 if you'd like to resume.

CHAIRMAN JADVAR: Thank you very much.

Welcome back, everybody. It's 11:00 a.m., Eastern Standard Time and we're going to go back to our agenda.

Next on the item is ACMUI Bylaws Subcommittee and Ms. Rebecca Allen, Health Care Administrator in the ACMUI Panel who chaired this Subcommittee will provide an update to the ACMUI bylaws.

Ms. Allen?

MS. ALLEN: Yes. Thank you, Dr. Jadvar.

This is the ACMUI Subcommittee Bylaws Subcommittee members: Myself, Mr. Richard Green, Dr. Michael O'Hara, Mr. Zoubir Ouhib, and Dr. Harvey Wolkov with our NRC staff resource Ms. Cindy Flannery.

Next slide, please? So our charge to the Bylaws Committee was to provide recommendations to revise the ACMUI bylaws considering the OIG's special inquiry with regards to appearance of conflict of interest of members. The Subcommittee should also ensure that any of the changes in the FACA final rule effective May 20th, 2024 are incorporated into the bylaws as appropriate and the staff recommends this as an opportunity to update the bylaws to ensure they contain sufficient information regarding conduct of meeting for the ACMUI public meetings.

Next slide, please? In regards to

regulatory concerns and the background of the report, as we discussed, the OIG Special Inquiry I2200187 concluded two ACMUI members had appearance of conflict of interest and suggested the NRC should consider strengthening the procedures and revising the ethics section of the ACMUI bylaws for all ACMUI members. Also, the ACMUI bylaws should be updated to the new FACA final rule effective May 20th, 2024. And background, the last revisions to our bylaws were in June of 2019.

Next slide, please? So with this updates for Section 1, originally it was titled Scheduling Agenda and Conduct of Meetings. We have separated this out to three different sections.

Section 1 now is Scheduling Full Committee Meetings. We clarified definition of active participation in the full committee meetings and we added the requirement of the designated federal officer must be present.

For Section 2 now of the bylaws, Full Meeting Agenda, we just added prioritization of the agenda items.

Section 3, Conduct of Meetings, we added the remote technology information. We added the

procedure for the meeting. We clarified a quorum and we added the chairperson expectations.

Next slide, please? For the updates for the section regarding transcripts we actually titled that Transcripts/Meeting Summary. We clarified expectations on timelines and certifying transcripts or meeting summary.

Next slide, please? For update section Appointment of Members and Reappointment of Members we added the new FACA language: membership to be fairly balanced to include those with relevant lived experience and persons with demonstrated professional or personal qualifications. We also added the reappointment of members language in accordance with September 26th, 1996 staff requirements memorandum COMSECY-96-042 on procedures for reappointment of advisory committee members.

Next slide, please? Updates on the conduct of the members. We actually -- on the conflict of interest we moved that to -- entirely to a separate section which we will discuss. We added the process for interacting with the director of the MSST. We added language about meetings not attempting to interpret ACMUI reports and added

language about special government employees conforming to NRC rules and regulations and expected to meet the highest professional standards.

Next slide, please? Updates to the adoption of amendments. We just clarified on how to propose an amendment and we added language on voting requirements.

Next slide, please? For our new sections that we have added now, we have added a new section on Subcommittees. We defined a quorum of a Subcommittee. We clarified Subcommittee chairperson responsibilities. We added language on Subcommittee deliverables must be voted on and approved by the full committee before sending to the NRC. And also the new FACA requirement where we added language on the designated federal officer must be present on all Subcommittee meetings as well.

Next slide, please? We added a new section, Appointment of Officers. We actually separated this out from the appointment of members to the -- in its own section and added input from the MSST director, the MSEB chief, and the ACMUI coordinator to match the ACMUI Policy and Procedure Manual, as well as added language to exclude the FDA

representative from being an officer to match the ACMUI Policy and Procedure Manual.

Next slide, please? In regards to our new section of Conflict of Interest we separated this out on its own section. We added language on expectations of ACMUI members for divulging possible conflicts of interest. We added the procedure to follow on the conflict of interest and recusal. We added the procedure to follow during presentations, added a procedure to follow for preparing ACMUI reports. We added language for a chairperson responsibility and we added language for the designated federal officer responsibility.

Next slide, please? We added a new section for consultants. It separated into a new section created and just added the service year language for consultants.

Next slide, please? A new section for ACMUI reports. We just added language on the process and the expectations for all ACMUI reports.

Next slide, please? The summary for the Subcommittee recommendations for updates to the ACMUI bylaws should suffice the overall charge of the Subcommittee. The old bylaws were about nine pages.

The new proposed bylaws are about 25 pages. We have also -- attached to the Subcommittee report is also a track changes version of the draft bylaws for the ACMUI members to review.

Next slide, please? For the Subcommittee comments the general opinion of the Subcommittee is that we recommend the full committee approve the new proposed bylaws. The Subcommittee also recommends establishing a five-year periodic review of the bylaws or when a revision of the significant items is needed due to the unexpected or updated changes to other requirements.

Next slide, please? And there's our abbreviations and acronyms.

Next slide? I think that may be the end of our slides.

CHAIRMAN JADVAR: Okay. Well, thank you very much, Ms. Allen, for this very comprehensive report. I also want to at this time thank the Subcommittee members: Richard Green, Dr. O'Hara, Zoubir Ouhib, and Dr. Wolkov for this work.

At this point I want to open it up to the Subcommittee members for any questions or comments that they have on this report.

VICE CHAIRMAN GREEN: Dr. Jadvar, if I may?

CHAIRMAN JADVAR: Yes, please. Yes.

VICE CHAIRMAN GREEN: This is Richard Green, a member of the Subcommittee. Ms. Allen went through very concisely what we did. As a member of the Subcommittee I was just very impressed at how in depth the entire work went. We just didn't review our bylaws; we looked at the Reactor Safeguards bylaws and said, well, what do they have? What do we have? Is that applicable to us? And I was very impressed at the depth. And I think the summary that Ms. Allen provided of the previous page volume versus the proposed volume really shows you how in depth this process was.

And the part I like the best is the fact that it's not static. We're recommending a cyclic review cycle. So this will be reviewed if need be. And if not, at least it will be reviewed on a calendar basis, on a five-year annual basis. Those are my thoughts. Appreciate the time.

CHAIRMAN JADVAR: Thank you, Mr. Green. I completely agree with you.

Any other comments by the other

Subcommittee members?

MR. OUHIB: Yes. Hi, this is Zoubir Ouhib.

CHAIRMAN JADVAR: Please.

MR. OUHIB: I'm a member of this Subcommittee and I echo what Mr. Green has just stated, but I also want to commend all my colleagues on that Subcommittee.

My final thought on this was really it is -- it was a very much needed update on this, basically related to -- because there were things that perhaps people were wondering how can we resolve this or how can we resolve that. And now having this report I think will be very helpful.

CHAIRMAN JADVAR: Thank you, Mr. Ouhib.

Any other comments from the Subcommittee members? Two more left.

All right. Moving on, any questions or comments by the entire ACMUI Panel members?

Okay. Hearing none, we move on to the NRC staff. Any questions or comments by the NRC staff?

MR. EINBERG: Yes, this is Chris Einberg. Yes, I just want to commend the Subcommittee for all

the work that was done in preparation of this Subcommittee report. It's very comprehensive. As I believe Zoubir pointed out, much needed to refresh our bylaws. And I think it's a good recommendation to revisit these bylaws on a periodic basis.

Most importantly here we initiated this to address the conflicts of interest issue. I think the Subcommittee and the new bylaws go a long way to strengthen those reviews of conflicts of interest, and so I commend the staff, or the Subcommittee for their work. And I would like to point out Cindy Flannery also provided technical assistance with this report as well.

Any comments from the NRC staff here on this?

No further comments here.

CHAIRMAN JADVAR: Thank you, Mr. Einberg.

Well, at this time I want to open it up to the members of the public. And I think Ms. Armstead is going to help us with that, if there are any comments.

DR. TAPP: Yes, if any members of the public have any comments, please use your raise hand

function.

I'm not seeing any hands raised at this time.

CHAIRMAN JADVAR: Okay. Thank you very much.

So I entertain a motion for the approval of the Subcommittee report by the ACMUI members.

DR. EINSTEIN: Hossein, can I just ask one technical question as I'm reviewing the develop?

CHAIRMAN JADVAR: Of course. Please.

DR. EINSTEIN: Have we changed your title from chair to chairperson?

CHAIRMAN JADVAR: I think there -- I saw chairperson somewhere.

DR. EINSTEIN: Yes, the word chairperson occurs --

VICE CHAIRMAN GREEN: Yes, we put in chairperson for -- in substitution for chair.

DR. EINSTEIN: So is that the preference of the Commission or --

MS. ALLEN: That's the new FACA rule that we've requested from chair to chairperson. And so once these are approved and the bylaws would be approved is when those -- we would see changed.

DR. EINSTEIN: Got you.

VICE CHAIRMAN GREEN: So we made it consistent with the FACA rules and with the Reactor Safeguards so they're all consistent?

DR. EINSTEIN: Got you.

CHAIRMAN JADVAR: Great. Okay. Thank you, Dr. Einstein.

Okay. So again, I entertain a motion for the approval of the Subcommittee report from the ACMUI Panel.

DR. WOLKOV: Harvey Wolkov. So moved.

CHAIRMAN JADVAR: Thank you. Any seconds?

Any seconds? Well, let's just go -- any opposed? It's easier that way.

Hearing none, any abstentions or recusals?

Hearing none, any deferring or dissenting of views?

Hearing none. So the motion and the Subcommittee report is approved. And thank you again to Ms. Allen and all the Subcommittee members for this great work.

And with that we move onto item No. 5 on

our agenda, which is Y-90 microspheres medical events, and Mrs. Spence will provide us with an overview of the NRC follow up to the ACMUI recommendations on medical events related to the use of Y-90 microspheres.

Ms. Spence?

MS. SPENCE: Thank you, Dr. Jadvar.

Good morning. My name is Sarah Spence. I'm a health physicist on the Medical Radiation Safety Team here at the NRC.

Next slide, please? Today I'm going to follow up on recommendations from the Y-90 Medical Event Subcommittee. First we'll discuss what recommendations the Subcommittee made, then I'll give a brief review of the Y-90 microsphere medical events from fiscal years 2023 and 2024. Following that I will discuss events involving vendor tools, then other events of note. Finally, I will open the floor to allow the ACMUI to discuss these findings.

Next slide, please? On December 19th, 2022 the ACMUI Subcommittee on Y-90 Microsphere Medical Events issued their final report in which the Subcommittee examined Y-90 microsphere medical events in more detail and proposed recommendations for

reducing the number of medical events involving Y-90 microspheres. In this report the Subcommittee made two recommendations to NRC staff.

First, the Subcommittee recommended the NRC evaluate the utility of software programs and checklists provided by the vendors. In response to this recommendation the NRC staff committed to following Y-90 microsphere medical events for two years and evaluating if and how vendor tools such as software or checklists play a role in these events.

Second, the Subcommittee recommended the NRC issue information notices to alert licensees of medical events and, where possible, make recommendations to prevent similar events in the future. In response to this recommendation NRC staff remains vigilant for new trends in medical events and will issue information notices when appropriate.

Next slide, please? This graph illustrates the number of reported medical events involving Y-90 microspheres each year since 2020. As you can see, the number of events in 2020 was lower, likely due to lower use of yttrium-90 microspheres during the COVID-19 pandemic, however the number of events has remained stable in the past several years.

Next slide, please? During review of all Y-90 microsphere events from fiscal year 2023 and fiscal year 2024 we found a total of 35 events in fiscal year 2023 and 36 events in fiscal year 2024. Zero events were found to be caused by problems with vendor tools; for example, software or spreadsheets, however a new anomaly was noted late in fiscal year 2024 involving gastrointestinal deposition of microspheres.

Next slide, please? No medical events that were reported in FY 2023 or FY 2024 indicated that vendor tools played a role in the cause of the events. Some events however did involve improper use of written directives or other administrative errors. One event was caused by a typographical error in listing the treatment site on the written directive. The patient was treated as intended, however the written directive did not indicate the correct segments of the liver to be treated.

Another event was caused by inconsistent use of units of activity and the use of a licensee-produced in-house spreadsheet. This spreadsheet being used was not provided by the vendor.

And finally, another event resulted from

administrative errors in ordering. Two vials were mistakenly ordered instead of one and the activity and projected dose was never verified before administering the treatment. Both vials were administered. Additionally, the written directive was not signed before administration. In all three cases the medical events were caused by human error.

Next slide, please? In summer of 2024 NRC staff received four notifications of medical events reporting microsphere deposition in the gastrointestinal system. These events occurred between the months of May and September of 2024. While GI shunting is a known complication of yttrium-90 microsphere therapy, it is unusual for the NRC to receive event notifications for this many cases in such a short period of time. It is also unknown at this time if all of these events can properly be classified as shunting or if they were due to incorrect microcatheter placement, a problem with delivery, or some other cause. The NRC Medical Team staff is currently investigating these events along with assistance from regional and Agreement State counterparts.

Next slide, please? As previously

mentioned, these events are still being investigated. It is possible that some or all of these reported events may not meet the criteria for medical events reportable to the NRC. If the licensee is using Revision 8 published in February of 2016 of the Y-90 Microsphere Licensing Guidance for TheraSphere and SIR-Spheres, a newer version of that same guidance, or the I-90 Microsphere Licensing Guidance, the licensee is not required to report overexposures to non-target tissues so long as pretreatment mapping and assessment of potential shunting was performed as per manufacturer's instructions.

For example, these evaluations could include pretreatment technetium-99m MAA and angiography during catheter placement. If a dose to a non-target structure due to shunting does not meet these criteria, the administration is likely a medical event. NRC staff is still assessing whether these criteria apply to the events received.

Next slide, please? In conclusion, there is no indication that vendor tools are contributing to the prevalence of Y-90 microsphere medical event. At this time the NRC did not identify a new trend to issue new generic communications,

however NRC staff is currently investigating an increase in reporting of GI shunting of Y-90 microspheres. If a generic issue is identified, the NRC staff will consider working with the ACMUI as appropriate to issue generic communication to inform the community.

Next slide? And I think I have one more, please. One more slide. Now I would like to open it up to the ACMUI for any questions or discussion. Thank you.

CHAIRMAN JADVAR: Thank you, Ms. Spence, for that report. Very interesting finding regarding this GI shunting that is happening recently and we look forward to hear the -- your further investigations of why this is happening or not caught on the pretreatment MAA scintigraphy.

At this time I want to open it up to the ACMUI members for any questions or comments.

DR. ANGLE: This is John Angle. I'd like to make a comment.

CHAIRMAN JADVAR: Please.

DR. ANGLE: I agree with all the findings of the report. I would like to make the observation that in smaller institutions that there's a strong

dependency of inexperienced small or infrequent users on the industry vendors. And although the tools that those industry vendors provide to calculate dose are accurate and have not been directly related to any of the adverse events, I think there's an opportunity to make them more reliable. Most of my observations are is that there's opportunities to prevent missing of steps, duplicate orders, et cetera, that perhaps could be addressed voluntarily by vendors.

CHAIRMAN JADVAR: Thank you, Dr. Angle.

Any other comments by the ACMUI members?

MS. SPENCE: Dr. Fair has her hand raised.

CHAIRMAN JADVAR: Yes, please, Dr. Fair.

DR. FAIR: I don't have a lot of experience. I have spent a little bit of time looking at the tool provided by the vendors, at least it was the TheraSphere vendor. And I had been concerned, although I think this has been addressed, that the spreadsheet that they provided, there was sort of a place for the authorized user to type in their name, but there wasn't a clear like signature that would be very clear that the actual authorized user -- I mean, electronic signature is fine, but not

when actually anybody could type the name into the spreadsheet. So it was a little bit loose.

I believe from what I've seen that that has been tightened up, but I think some communication and discussion about what that really needs to look like to be an actual signature of the authorized user may be important.

CHAIRMAN JADVAR: Thank you.

I see Mr. Green.

VICE CHAIRMAN GREEN: Thank you. Mr. Green here. A question for Ms. Spence. Appreciate the review of the tools provided by the manufacturers. Was there any attempt to look at the fit between the two tools? If a medical facility is using SIR-Spheres and then TheraSphere and then SIR-Spheres -- if they're alternating or changing between brands, is there opportunities for the tools provided to become confusing? Do they mesh well with each other? Were they compared with each other or just in their own world?

MS. SPENCE: Thank you, Dr. Green. In this case we were only looking at the medical events that arose from vendor tool use, so it didn't really capture I think what you're getting at.

VICE CHAIRMAN GREEN: A question for Dr. Angle. Is this something that should be looked at, whether it be by the Subcommittee or by the staff? Is there possible confusion between the formats or the content of the two vendor-supplied tools?

DR. ANGLE: It think it's a very worthy area of investigation, Dr. Green. It would I think be really useful to small operation (audio interference) use both agents to have some standard.

And I really liked the earlier comment, right? We all use -- I'm sorry to mention a proprietary thing, but -- something like DocuSign, right, all day long for -- at our institutions and making these things have a signature that cannot be sort of put in manually by someone else I think are two great suggestions.

And, but yes, to get back to your comment, I think that having some consistency in -- particularly in the millicurie versus gray question I think would be very, very smart.

CHAIRMAN JADVAR: Thank you, Mr. Green.

Dr. Angle, do you practice both of these Y-90 microspheres tools, or just one of them? Or what's your idea about them matching and the fit of

the two techniques?

DR. ANGLE: Yes, we do use both and I think a lot of large academic centers use both. I'd say most large academic centers have built an internal process for recording the written directive. But for small institutions that might happen to use both, I think these would be useful innovations.

CHAIRMAN JADVAR: Okay. Excellent. Thank you.

Any other comments or questions by the ACMUI members?

Okay. Hearing none, I want to move onto the NRC staff. Any comments or questions by the NRC staff?

DR. TAPP: No, we have no further comments here.

CHAIRMAN JADVAR: Okay. Well, then I'd like to open it up to the members of the public, if they have any comments. I see one hand. I don't know what the name is.

MR. WILLIAMSON: The name is Matthew Williamson.

CHAIRMAN JADVAR: Okay. Please go ahead. And please mention your affiliation.

MR. WILLIAMSON: My name is Matthew Williamson. I'm with Memorial Sloan Kettering Cancer Center. Thank you for the information. And, Ms. Spence, thank you for clarifying that these data are based on reported medical events, events that make it through to the NRC through the Agreement State process or by NRC licensees.

It would also be interesting to note the number of microsphere procedures that are being performed. If we had 36 reportable events in fiscal year 2023 and there were 100 microsphere procedures performed and then the following year we had 37 reportable events, but now we had 1,000 microsphere procedures performed, that would be interesting to understand the frequency or the rate of those occurrences. Thank you.

CHAIRMAN JADVAR: Thank you very much for that comment.

Any other comments by the members of the public?

I see another hand. Please introduce yourself and your affiliation.

Oh, Josh. It's Josh Mailman. Please, Josh.

MR. MAILMAN: Yes. No, this is Josh Mailman, a patient rights advocate. I just wanted to kind of second the notion of what the previous caller said. I think this is something that's been brought up before, understanding the total number of the universe of what we're looking at. We may actually be seeing a reduction in events, but we're just guessing at the number. And I know we've gone over this before as far as the challenges of finding what the denominator should really be, but it's something that even if we come up with somewhat of an estimate, we can gauge if as a percentage we're doing better as a community. So anyway, just thought I'd add that.

CHAIRMAN JADVAR: Thank you, Josh. I agree with you. This was discussed before. I think that knowing at least an estimate of that denominator would be important.

So now I have another hand up or had it. I think it's Dr. Tapp.

DR. TAPP: Yes, Dr. Jadvar. Thank you for your comments. We do have the information from the vendors. We get it periodically with the number of vials that they sell. That information is

proprietary, but during our medical event reports that we do every year we do show that there is a general stable trend, if not slightly decreasing trend if you look at the percentage of medical events per the use

-- or number of vials sold. So, we do have that denominator, but it is proprietary information. So, we do not share that during these meetings, but we do trend it. And it is staying stable, if not slightly decreasing, if that's helpful.

CHAIRMAN JADVAR: Okay. Thank you, Dr. Tapp.

And I see that Mr. Green has another comment.

VICE CHAIRMAN GREEN: Yes, thank you, Dr. Jadvar. As Dr. Tapp mentioned, this use -- patient use and numbers of vials sold is proprietary to the manufacturers and -- as it is with all the radiopharmaceuticals -- these are technically medical devices. But I know we can't get sales data, but is it possible to use a microcosm of looking at Medicare patient data? Now this would come in one or two years in arrears. It would be after the fact, but can we look at data that's publicly available through

Medicare for their reimbursements activities and use that as a surrogate to look at trending data over time? Is that reasonable?

DR. TAPP: Mr. Green, this is Dr. Tapp again. We could look into that, but with the number of vials sold I'm not sure what additional information having data from CMS would provide versus number of vials sold, just for the microspheres case.

VICE CHAIRMAN GREEN: Right. Microspheres are unique. You've only got two manufacturers. But this might be applicable to all radioactive drugs, the entire universe of radiopharmaceuticals, not just these two agents. If we were to look at CMS trending data it might be applied a year after the fact, but it's something that's public.

CHAIRMAN JADVAR: Thank you, Mr. Green. And I see Josh has another -- Josh Mailman?

Josh, you are muted.

MR. MAILMAN: You can't read lips? This is what we all should do by now.

CHAIRMAN JADVAR: I used to. I lost that ability.

MR. MAILMAN: Dr. Tapp, since you're able

to report that the trending is either stable or decreasing, even just that kind of reporting would be sufficient for this report. I don't need to actually know the physical number, but if -- just so we know the trends and we can better understand if this is something we need to really take corrective action on or make suggestions that we take corrective actions on, that's enough information. Don't need the actual number if you have what you have.

CHAIRMAN JADVAR: Thank you, Josh.

And I see Dr. Einstein has his hands up.

DR. EINSTEIN: Yes, in response to Mr. Green's comment, there are a variety of CMS data sets which are overlapping but contain different pieces of information. Most of the public data I think excludes procedures for whom the provider performed fewer than 10 of that CPT code, or that procedure in a year. So, it's incomplete. It's a little bit challenging. One can apply to CMS and PACE CMS, if approved, for the complete data which doesn't have that cut off at providers not performing less than 10.

My group has done that, and we have this data. It's submitted for publication in the realm

of nuclear cardiac imaging, but if it's of interest of the Commission we could run those sorts of analyses for other nuclear medicine procedures of interest. That kind of analysis is done at single points in time by the National Council on Radiation Protection and Measurements. NCRP has had a couple of reports, but they do it sort of just at one point in time and it doesn't trend over time. But with the CMS data -- like we have the data from 2010 through 2022 and have trended a variety of nuclear medicine cardiovascular procedures but could do that for really any CPT code if it's of use to this body.

CHAIRMAN JADVAR: Thank you, Dr. Einstein. Yes, that could be considered for sure.

Now I have a hand of Mr. or Ms. Larinde.

MR. LARINDE: Hi, this is Olusegun Akano Larinde. I'm affiliated with University of Illinois Hospital in Chicago. I'm of the opinion that we get some sales (phonetic) that we eventually did not use, so if we get those data from the vendor, from SIR-Spheres or TheraSphere, that might not be a representative of the denominator that you're considering here. So maybe just like Dr. Einstein said, having the data from CMS on the paid on the CPT

code might be a useful one. Thank you.

CHAIRMAN JADVAR: Thank you.

And I see that Mr. -- well, Mr. Ouhib, you had your hand up first.

MR. OUHIB: Yes, thank you. I think the data is valuable, however I think what we need to address is preventive measures to actually just reduce these events. And it seems like we go back to what we had discussed in the past of perhaps the manufacturer should require an annual training or educational module that will remind users about certain steps that could lead to undesirable outcome, per se.

CHAIRMAN JADVAR: Thank you, Mr. Ouhib.

Any other comments? I don't see any other hands.

Okay. Very good. Good discussion. And I want to thank Ms. Spence for that report.

Well, at this time in our agenda we -- it's in the lunch time. So, we're going to take a break for lunch, at least for the Eastern Standard Time. Here it's not lunch time yet in California. But so, we're going to pause until 1:30 p.m., Eastern Standard Time, 10:30 a.m., Pacific Standard Time.

And we'll regroup again as I said at 1:30 p.m. Okay? Thank you.

(Whereupon the above-entitled matter went off the record at 11:36 a.m. and resumed at 1:30 p.m.)

CHAIRMAN JADVAR: I think we can get started, Dr. Jadvar. I think, at least to my time, we have 1:30 p.m. East coast, and we can get started.

I want to welcome everybody back to the 2024 Fall meeting of the ACMUI. And we are going to start now the afternoon session of this meeting.

The first thing on the agenda is ADVANCE Act. And Mr. Mike King from NRC will give us an overview of this act. Mr. King.

MR. KING: Hi, and good afternoon, everybody. Welcome back from lunch.

So, I've been in this role now as a special assistant to the EDO for ADVANCE Act implementation about a month and a half, two months now. Time has flown by.

So, I look forward to this opportunity to kind of, in case you haven't gotten an opportunity to attend one of our public meetings to hear more about what we're doing in response to the ADVANCE Act and

what it is, to kind of share that a little bit with you. I know you are particularly interested in the implications for medical uses, but I'll share with you more broadly what's going on with the Agency and how we've kind of carved up our response into different teams. And I look forward to answering any questions you may have.

A little bit of background. Before taking this assignment, I was a Deputy Office Director in your Office of Nuclear Reactor Regulation. Was responsibility for the operating reactor oversight program and licensing program. And my background is primarily operating reactors. But I did have a little bit of time in the fuel cycle facility.

So, a little bit of context for the ADVANCE Act. You know, it was signed into the law, into law about three months ago now. And since that time, we have been very, very busy. And we're still fairly early in implementation, as you'll see later.

Some of the deliverables in accordance with the act go into, deep into 2027. But there are some near-term deliverables as soon as January of next year.

So next slide. So, I won't spend a lot of time on this slide or the next slide, but I'll just provide a little bit of context on how we're structured. When Mirela, our executive director for operations asked for me to be the special assistant leading up the effort, we put together a core team at the EDO level, which included a number of office directors and regional administrators and senior executives to kind of advice and provide direction at the Agency level.

And then if you go to the next slide, we've got a core team of support folks leading up the project management, ensuring that we're coordinated across the Agency on the different aspects, and everything is well coordinated. And we've got a communications expert, so we've got a, hopefully you've seen on social media and our press releases, we've tried to be very proactive in terms of communicating to the public and other stakeholders what's going on and how we're being responsive to the act.

If you go to the next slide. So, you know, the NRC has successfully evolved over the 50 year history in response to a number of changes in

our changing environment.

Over the years, while we've changed we have maintained our focus on safety and security. In response to experience we've gained with operating experience, and lessons we've learned along the way, and in response to notable events or new technologies, we've kind of evolved our programs in how we do business.

And a good example of that, in the late '90s, early 2000s we did a pretty fundamental shift in how we do our reactor oversight program. And it led to a number of improvements. And over the years we've evolved business in all of our different business lines, including medical.

So today's landscape, and the landscape that set us up for the ADVANCE Act to be signed up into law is quite different than what it was even as a few as five years ago. There is increased interest in pursuing decarbonization goals.

Not only domestically but internationally. The forecasted growth in energy demand, particularly with increase of AI and data demands and power demands associated with that is significant. And that has emerged since then. And

the overall public perception and willingness to accept nuclear has changed significantly.

So as part of our overall readiness for lessons learned from the past is we do what we call sign, post and markers. Where we look ahead and we say, what are the indications out there of the changing landscape that may impact how we are the need for us to do what we do as a regulator.

And so, I'll just share with you a number of things recently that are pretty clear indicators that things have changed. You know, if you saw it, but NEI recently released a Fiscal Year '24 survey they did to their membership talking about, trying to get a sense for what changes are potential new growth and nuclear may be coming. And it's significant.

Over 23 license renewals and subsequent license renewals are expected by 2030. Over 25 potential power uprates adding gen (audio interference) decade. And, you know, as recently announced with the Crane Energy Center with Microsoft we got two recently decommissioned plants that are considering being re-commissioned.

And, you know, the latest survey data includes forecasts of over 100 additional gigawatts

of nuclear by 2050. Above and beyond the 94 operating nuclear power plants we have today. So it's significant. And what's notable is all of that, in some way, shape or form requires our need to do our jobs and to do it well and efficiently.

So if you'll go to the next slide. So, you know, the ADVANCE Act has been in the works for quite a while. The Agency's been tracking the different amendments as they've went their way through. And there is a long history of it. If you wanted to learn more about how it's evolved overtime you can go to congress.gov and search for Sierra dot 870. So S.870. And you can see how it's evolved over time.

But as you can see, you know, it was a bipartisan, bicameral support. And it's very unprecedented in the level of detail with which it has in terms of direction to the Agency. And I'll talk with you a little bit about what some of those changes are to give you a little more context to it.

Next slide. So I'll hit on some of the areas, broader areas, but there is a lot more. And I'll show you how you can find out a lot more a little later.

One of the most notable changes, in particular interest of the Staff and some other stakeholders as well, is the act does have us update our mission statement. And it does not fundamentally change our overarching safety and security mission, but it does focus and have us update our mission statement to ensure that we, the way in which we achieve our safety and security mission is done efficiently and that we do not unnecessarily inhibit the benefits of the use of radioactive materials.

And of course from the medical industry this is something that you're used to. You know, weighing the benefits of the exposure to radiation. Comparing that against the benefits of the medical aspects of things.

So, and in fact, recently publicly available we have sent a paper to the Commission with a number of options for specific language and how the mission statement will be adjusted. And we'll await to see the direction we get from the Commission coming out of that. But we will have, consistent with the act guidance, our direction is we'll have implementing guidance that the Commission will give the staff on how to implement this updated mission

statement.

There is a number of initiatives focused around efficiency, as I mentioned. And this next one on the list, achieve an efficient, timely and predictable license application reviews is the focus. Establishing expedited procedures for reviewing qualifying new reactor licensed applications.

So for example, the Vogtle Units 3 and 4 AP1000 units that we recently approved, say for example there was another one to come in at that same location, that would be considered a qualifying. And so we're looking at procedures for how to, how we could be efficient at approving those types of applications where we've already approved them before.

Implementing changes to how we recover fees. And notable for advance reactor applications and preapplicants, there is direction to significantly reduce fees. And I think it's on the order of half. So from about $300 an hour to $150 an hour reduction in fees for those type applicants.

Next slide. So we're, there is direction to continue our focus in looking at how we would license fusion technology. Assessing our licensing

review process for new facilities at brownfield sites and former fossil fuel power plant sites. Strategies and guidance for microreactors. And, you know, easing some restrictions associated with foreigner ownership of certain licensed facilities.

Go to the next slide. And we have seen over the years an increased international collaboration. The act provides us some focus, guidance or direction to continue those efforts supporting our international partners and developing nations. And we do a fair bit of that already.

Obviously some good examples of that are coordination with Canada and the United Kingdom on SMRs. And our support to Poland on their AP1000 plants that they're looking at.

Implementing, it directs us to implement new requirements relating to nuclear fuel. Including establishing a memorandum agreement with Department of Energy. It gives us, you know, direction to establish a nuclear energy training subprogram under our university leadership program. And implement, and gives us some additional pay flexibilities and hiring authorities to address any hiring challenges we have.

So those are kind of high-level, the general areas. And if I go to the next slide I'll, you know, if you take the act early on, we did, and we carved it up into specific individual deliverables, there were 16 deliverables that were actual, you know, congressional reports.

And then there were additional actions that weren't necessarily congressional reports but were, you know, directly specified by the act which is a combined total of about 35 taskings. And then, you know, a number of those taskings were grouped because it logically made sense for the same team to go after them. And so we've got about 20, the latest count is 20 different project teams that are going on.

And each of those project teams early on, when they were given the taskings, we had them do what we called assignment alignment meetings where they met with the core team to kind of share their understanding of the tasking before them. Kind of what errors that were intending to go after.

And then we periodically met with them to kind of check and see how things are going. Look for areas of overlap potentially with other teams where

we can be efficient about how we're going at it.

In addition to things that are explicitly called out for in the act we're also looking for things through our public engagements. And internally, are there other areas where we think we could do things consistent with the spirit of the act. So where Congress just in general said, has directed us to be efficient in how we do business.

You know, have we got staff ideas or other ideas where we could be efficient. And where we see those we're going ahead and pursuing those ideas. And we're not necessarily waiting for congressional deliverable to take action on those things. Though it's a broad sweeping effort it's, pretty much every office in the Agency is involved either directly or in a support role as we kind of work through these efforts.

So it's a tremendous challenge. It's an exciting time to be at the Agency. I sense a lot of optimism from the staff looking forward to being able to help shape the future of the Agency given, you know, the unprecedented environment and challenge, and reality that we're currently operating under. So there is a lot going on and we're rising to the

occasion.

So the next few slides, they're on our public website but, and they're a bit of an eye chart so there is no way you're going to be able to kind of see the details, but I wanted to at least lay out the structure for you so that if you do go to the public website and you're interested in more details about a particular section of the act you'll be able to do it.

Across the top from left to right is by fiscal quarter. So we're starting in '24, we'll go all the out, as I mentioned, to late in '27.

And then by section of the act there are color bands across the page. And then each section of the act may have one or more projects with multiple individual tasks. And what you'll see there is little dots on the bars that are going from left to right. Some of them have the reports to Congress, some of them are internal deadlines only, and then some have congressional or commission reports.

And for each of these projects we have, you know, may or may not have public meetings depending on the nature of the project that's going on. So far to date I think we've had probably five

or six different public meetings with each of the different project teams. And then one kind of overarching ADVANCE Act public meeting where we kind of rolled out essentially the same presentation to members of the public and kind of solicited their feedback.

So like I said, there is a lot of details in here. I'm not going to go through them all for you, but if you advance ahead to the contact us, we do, and this information is on the public website as well. We list the contact information for each of the core team members and support team.

And then things that are of most interest for most of the public is we have contact information for, by section of the act. Who the individual staff lead is and their contact information.

And, you know, if we go to the next slide, as I mentioned before early we recognize the importance of being very transparent about what's going on, how we're responding to that both internally and externally. We've got an internal SharePoint site that we're sharing with the staff all the details, much more detailed than what you see here, on the individual projects that are going on.

But we did early on establish an external website. And the public website page was published October, or in August of this year. We also issued a federal register notice letting the public know that we are going to have a sequence of public meetings where they can engage us.

And if you'll see on this slide, where that orange arrow is pointing to the left, there is a link on there that shows upcoming public meetings and previous public meetings. So any meeting that's already happened associated with the ADVANCE Act you can go there and link to it, and get any materials that were published and the meeting summaries.

Any upcoming meetings within the notification period, you can come to this site and catch them all because every ADVANCE Act related public meeting has the hashtag ADVANCE NRC. And then you can see there is a contact us link on the right-hand side.

If you go to the next slide. And at every public meeting we're reinforcing this. In addition to the actual public meetings themselves anybody can share their thoughts directly with those points of contacts that we identified, or through

this contact us link.

And that gets monitored by members of the core team. As we get ideas in we direct them, direct those ideas to the most appropriate group that's working on them.

Now what's, things are evolving pretty quickly. And what has changed since we developed these slides is, if you go to the public website now there is more of a live dashboard. And it was recently public, in fact, by last Thursday or Friday we published it. And we'll be adding more and more features as we go along, but that's a live visual of where we stand with each of the different tasks and projects.

So, with that I'm happy to answer any questions you may have.

CHAIRMAN JADVAR: Thank you, Mr. King, for that overview of the ADVANCE Act. I gather that in the future follow-ups, as some of the milestones that you mentioned are achieved, you may give an update to this panel. And if anything directly affects the medical team or the work of this panel.

At this time I'm going to open it up to the ACMUI members. If they have any comments or

questions for Mr. King? Zoubir, please.

MR. OUHIB: Thank you for a very comprehensive presentation there. And I just have a simple question here.

Is that, what actually has prompted the implementation of the ADVANCE Act, is that a needs, is that demand or combination of both? Or maybe something else for that matter. Assuming that's something you can certainly share with us. Thank you.

MR. KING: Yes. I think Congress is best positioned to answer the, you know, what drove them to head down the path of developing. You can certainly get more perspective, as I mentioned, going to congress.gov and checking out the history of the act and what was behind it.

But as I mentioned, I think it's just reflective of the landscape has changed so much and there is a recognition of the important role that the Agency plays in ensuring that the, you know, the national needs for potential new development of nuclear power done safely and efficiently and in a secure way. And so, I think it's a reflection of the important role that we play and the desire to make

sure that we're ready.

CHAIRMAN JADVAR: Very good. I see that Dr. Michael Folkert has a question.

DR. FOLKERT: Yes, hi. Michael Folkert, I'm one of the ACMUI representatives.

So, I mean, I think the area that we're probably going to be the most concerned about will be the reactor based production of isotopes. I mean, is that going to fall under, pretty much completely under 203?

MR. KING: Well I think there are a number of elements of the act where there could be kind of broader implications overall. Like for example, Section 507 on inspection efficiencies, right? To the extent there is, you know, inspection changes to the inspection program that potentially could impact those type of facilities. And those could occur broader.

Any, there is an overall effort to look for efficiencies over on the licensing process. And so any requests that come in to, for existing plants to, you know, potentially expand to do those type of activities, if we gain efficiencies in those areas that could impact them then, you know, there could be

potential implications there but nothing beyond that directly that I'm aware of.

DR. FOLKERT: Okay. It just seems like it might be a good idea for us to have an opportunity to meet with William Reckley in that particular application at some point in the future.

MR. KING: Yes. And I'd encourage you if you got specifics feel free to reach out to the point of contacts we've got here.

DR. FOLKERT: All right, thank you.

MR. KING: Or I can help as well. Yes.

DR. FOLKERT: Okay, excellent.

MR. KING: Thank you.

DR. FOLKERT: Thank you very much.

MR. OUHIB: Thank you very much both of you. Any other comments or questions by the panel? I guess not.

Well thank you again very much, Mr. King, for that report.

MR. KING: Thank you for the opportunity.

CHAIRMAN JADVAR: Thank you. On to next item on the agenda which is the Medical Team updates by Dr. Katie Tapp on the medical radiation safety teams activities. Dr. Tapp.

DR. TAPP: Well thank you. And thank you again, Mr. King, for bringing us this presentation.

Now bringing it a little closer to our home and our normal activities, I'm going to give the medical radiation safety team's update.

Next slide please. In my presentation I'm going to focus on rulemaking, guidance and other efforts.

Next slide. First, to talk about the rulemakings.

Next slide please. As you know, we have two ongoing medical rulemakings right now on the medical team. The first one is on extravasations.

This is an ongoing rulemaking to amend our 10 CFR Part 35 regulations to require reporting of certain nuclear medicine extravasations. Our second ongoing rulemaking is involving emerging medical technologies and the rubidium-82 generators.

This rulemaking will establish regulatory parts for the emerging medical technologies currently regulated under 10 CFR Part 35.1000 and established flexibilities for future emerging medical technologies. I'm going to talk

about both of these rulemakings separately.

Next slide please. For the extravasation rulemaking, as you know the Commission directed the staff to begin rulemaking in 2022 in SMR-SECY-22-0043. In this the Commission directed the Staff to include reporting of certain nuclear medicine injection extravasations as medical events.

Following this direction the NRC Staff developed a proposed rule and provided this proposed rule to the Commission for their review and consideration in August of this year. The ACMUI reviewed this proposed rule and provided its recommendations to the Staff in June of 2024 before this was provided to the Commission.

As I mentioned, the proposed rule currently, is currently with the Commission for their consideration. This proposed rule proposes requiring reporting of administration of byproduct material that results, or has the potential to result in a radiation injury from extravasation as determined by a physician.

In addition, in this SRM the Commission directed the Staff to explore approaches, to reduce burden to the patients by reducing reliance of

patient reporting. Specifically, the Commission directed the Staff to evaluate whether the NRC should require licensees to develop, implement and maintain written procedures to provide high confidence that radiation safety significant extravasations will be detected and reported.

In this proposed rule, currently with the Commission further consideration, the NRC Staff did propose a performance based requirement for such procedures to be required to reduce the burden to patients and ensure events meeting this criteria are reported.

The NRC is continuing with the rulemaking on accelerated rulemaking schedule within the confines of the rulemaking process and without shortening time for public engagement and comments.

Next slide please. As I mentioned, the proposed rulemaking was sent to the Commission in August. If the Commission approves the proposed rule the NRC will issue the proposed rule for public comment expected to be in 2025.

Following receipt of these public comments, the NRC Staff will develop a final rulemaking package which we will submit to the

Commission. Once the Commission receives this they will have the ability to review it. And if they approve it, then the NRC Staff will issue this for implementation, which is expected to be around 2027.

Next slide please. The next rulemaking that's ongoing, as I mentioned, is the emerging medical technologies rulemaking and the rubidium-82 generator rulemaking. This rulemaking is to address challenges with the rubidium-82 generators where the rubidium-82 short half-life has made determination of dosages prior to administration as required per the regulations infeasible and lead to the use and enforcement discretion as a documented in an enforcement guidance memorandum.

One of the purposes of this rulemaking is to develop regulations to address this challenge so enforcement discretion will no longer be necessary. This rulemaking will also move well established emerging medical technologies from 35.1000 and establish requirements for their uses in other subparts within Part 35.

In addition, the regulations will be made to create flexibilities within Part 35 to make it easier to regulate future emerging medical

technologies within the traditional subparts of Part 35 without the need for issuing additional 35.1000 licensing guidance. As part of this rulemaking the Commission also directed the staff to reevaluate training and experience requirements for emerging medical technologies and proposed potential changes.

In addition to the Staff's evaluation, the ACMUI also has a subcommittee reviewing this effort being led by Dr. Folkert. Finally, this rulemaking is evaluating potential other changes to regulations based on new and emerging medical uses of byproduct material. This includes supervision regulations, the need for radiation safety committees, and patient release with new radiopharmaceutical therapies having multiple administrations in one treatment protocol.

Next slide please. As shown on this slide the NRC issued the regulatory basis for this rulemaking in July of 2023. We received a numerous number of comments on this, and we have been evaluating those comments. We plan to issue the proposed rule in winter of 2026, and draft implementation guidance to the Commission for their review and consideration.

Finally, we're planning to have the final rule and implementation guidance to the Commission in the winter of 2027.

Next slide please. On rulemaking outside the area of medicine, but still being worked on by the medical radiation safety team, is the veterinary release rulemaking.

This rulemaking will rekindle the effort to review veterinary release rulemakings to make a clear pathway, clear regulatory pathway for the release for animals who have been administered byproduct material. This effort, we're looking at enhancing existing codes to include animal phantom models to calculate exposures from common geometries to be able to review applications and provide guidance to licensees and criteria to release animals.

Finally, we're planning to develop a regulatory guide to provide criteria for common procedures and considerations that should be considered to ensure releases within regulatory requirements. Next slide please.

Now I'm going to switch gears and talk about guidance development and updates. Next slide

please.

The first area of guidance I want to talk about is emerging medical technologies. As you know there have been a lot of changes in the use of radioactive materials and medicine and emerging medical technology reviews have been keeping the medical team busy.

In the last year the NRC has issued two 10 CFR 35.1000 licensing guidance documents. These were for the 1-90 microspheres and the Akesis gamma stereotactic radiosurgery unit. We also expect to issue the Liberty Vision licensing guidance shortly.

We have also released licensing guidance for the Technegas system. While this guidance is not 10 CFR 35.1000, because we believe the Technegas can be licensed under 10 CFR 35.200 diagnostic radiopharmaceutical usages, this guidance was developed and issued based on questions received from license reviewers in the industry and how to license this system.

In addition to the guidance issued, the NRC Staff continues to review other emerging medical technologies. These include new microsphere devices, thorium generators, radiotracer guided

radiation therapy units, or biologically guided radiation therapy units, and targeted alpha radiotherapy. In addition, we continue to look for operational experience with all types of medical uses, but specifically with emerging medical technologies to determine if additional guidance is needed or if additional communications are needed to ensure the safe use of radioactive materials and medicine.

Next slide please. Another guidance that we've been working on is the training and experience guidance. The NRC published a notice in the federal register in August 30th, 2024, soliciting public comments on our draft interim staff guidance, guidance for implementation of 10 CFR Part 35 training and experience requirements.

This interim staff guidance is available for 60-day public comment period, which actually runs through today. The purpose of this interim staff guidance is to provide guidance on the implementation of the training and experience requirements in 10 CFR Part 35.

This interim staff guidance clarifies the roles and responsibilities of individuals subject to

the training and experience requirements in 10 CFR Part 35, outlines the information needed to demonstrate compliance with the NRC regulations, and provides step-by-step instructions for adding authorized individuals for medical use licenses. When finalized, this interim staff guidance will be intended for use by licensees, applicants, agreement states and NRC Staff.

Next slide please. An additional regulatory guide we've been working on is the regulatory guide for reporting and evaluating medical events.

This regulatory guide was worked on in conjunction with the extravasations rulemaking. But in addition to providing guidance for the extravasation rulemaking it encompasses regulatory guidance for all medical event reporting. It includes medical event reporting criteria, when to report, what to report, and how to report. It also includes information on when to report dose to an embryo fetus, written directives and procedures to ensure medical event reporting is made appropriately.

This regulatory, the guidance outside the extravasations for all medical events was developed

using references that's already been available for licensees but consolidating it into one place. In addition, it rolled in information from policy statements and international standards from information notices and regulatory information summaries. Such as the regulatory information summary on patient release.

And it also includes, sorry, regulatory information summaries on patient intervention. It also includes examples for the most commonly reported medical events, and for commonly performed medical procedures.

Next slide please. Other efforts ongoing by the medical team.

Next slide please. In follow-up with, after the OIGs special inquiry we have been working on updating our ACMUI procedures and providing performance enhances in subtle areas to ensure we have strong policies and procedures for the ACMUI.

The first topic we completed was we enhanced the policy and procedure document that the NRC Staff uses to coordinate activities with the ACMUI. And this was issued in August of this year.

In addition, we're working on the bylaws

revision, as Ms. Allen presented earlier today. We are also updating the new member guidance and providing additional ethics training, which you will receive tomorrow. Finally, we are updating hiring practices to ensure that conflict of interest questions are being asked during the interview process, as well as ensuring that ethics account service from our office of general counsel will be available during the interview process to answer any questions on conflict of interests during that time.

Next slide please. Addition, we are working on updating medical inspection procedures. We're also working on revising the patient release guidance that I will be talking about later. We're also working to develop waste guidance as Mr. DiMarco will talk about next. And of course we continue to look at operational experience and provide communications as we notice trends or issues that we believe that sharing across the industry would help ensure safe use of nuclear materials and medicine.

Next slide please. These are the acronyms. And if you go to the next slide. Anytime anything comes up, please feel free to email me or email this question resource box here.

And we always have our medical uses toolkit that has lots of information. As I think everyone is aware it includes our medical event presentations that both the NRC Staff issues as well as the ACMUI develops every year.

And that's all I have. I'll open it up to, turn it back over to you, Dr. Jadvar.

CHAIRMAN JADVAR: Thank you very much, Dr. Tapp, for that update. As she mentioned, she will go over the patient release guidance later on today.

But obviously medical team is very busy with many important activities going on at the same time. But I want to open it up to the ACMUI panel members if they have any questions or comments regarding this update review. I see Zoubir Ouhib. Please.

MR. OUHIB: Sorry, I was muted. Dr. Tapp, thank you for the presentation. In one of your slides you had put that no new requirements needed, or something in that nature. I'm not sure I understood that not knowing that a procedure might require something specific. Maybe if we go back to that slide maybe we could see that.

CHAIRMAN JADVAR: I think it was the training and education slide. Yes. Yes, here.

MR. OUHIB: Not knowing that something, you know, might require something, whatever that is. How can we predict that?

DR. TAPP: So, what is meant by that no new requirements is that the interim staff guidance, that's available for public comments right now, has no new requirements. The update that the Staff is working on now is guidance to their current requirements and does not include any new requirements at this time.

MR. OUHIB: Okay, I got you. Now I understand it better. Thank you.

DR. TAPP: Thank you.

CHAIRMAN JADVAR: Thank you, Zoubir. Any other comments from the ACMUI members? Okay, hearing none, I'd like to move on to the next --

DR. TAPP: Dr. Jadvar, I see Megan. Or Ms. Shober has her hand up.

CHAIRMAN JADVAR: Oh, I didn't see that. I'm sorry. Go ahead please.

MS. SHOBER: Yes. This is Megan Shober. Just a quick question, Dr. Tapp, on the timeline for

the rulemaking. You had mentioned winter 2026 and winter 2027. I guess, do you have any sense yet for whether that's like January or December?

I wasn't sure whether it meant the beginning or the end of the year for those timelines. The EMT rulemaking is the one particular.

DR. TAPP: The EMT rulemaking, I do not have that information directly available at this time. We do have an estimated timeline available on our rulemaking website. I just don't want to speculate right now if I'm getting all three rulemakings confused. Maryann?

MS. AYOADE: Hi, Megan. Yes, no specific timeline or time frame at this time, so that's where we are is just the, like Katie mentioned, the winter of 2026 and 2027.

MS. SHOBER: Okay, thank you.

CHAIRMAN JADVAR: And I see a hand. Peter Crane? Is that from the public?

DR. TAPP: Mr. Crane is a member of the public.

CHAIRMAN JADVAR: That's okay, let's hear the question. Or comment.

DR. TAPP: Mr. Crane, your mic is muted

but you should be allowed to unmute.

CHAIRMAN JADVAR: No, still muted.

DR. TAPP: Unfortunately you're still muted, Mr. Crane.

CHAIRMAN JADVAR: All right, maybe we can get back to that later on. Let's move on. There may be some technical issue.

Let's move on to our next agenda item. Thank you, Dr. Tapp, again. This is from Mr. DiMarco who is going to tell us about the NRC evaluation of the current patient waste guidance and regulations. Mr. DiMarco.

MR. DIMARCO: Thank you, Dr. Jadvar. Hello everyone, my name is Daniel DiMarco, I'm a health physicist here on the medical team and I'll be talking about radioactive material and patient waste.

Next slide please. Just going over a quick outline of what we're going to talk about today. I'll go into a little bit of the background in some of the regulations. A little bit about patient release and separated license material.

What we have done as the NRC with communications with this, a few additional considerations looking forward into potential

guidance documents, and then I'll wrap it all up.

Next slide please. So just some background. In the fall of 2020 ACMUI meeting we got a presentation from Mr. Mike Sheetz on non-medical events. Such as events for coming out of waste streams, and things like that.

And the recommendation from that recommended that the national material program evaluate nuclear medicine patient waste found in municipal landfills. After that meeting we also got some additional stakeholder communication which requested consistence guidance in managing this waste following patient release.

Next slide please. So some of the regulations for this, 10 CFR. This is 20.2003. This allows for disposal of excreta containing licensed radioactive material into the sanitary sewer for patients that are undergoing treatment with radioactive materials.

And then we've got a regulation in 10 CFR 35.92 which allows for this material to be held for decay and storage if the half-life is less than 120 days. If the half-life is more than 120 days this material must be disposed of as low-level waste in

accordance with that 10 CFR 20.2000. I think that's Subpart K.

Next slide please. Going into patient release, 35.75. Release of individuals containing unsealed byproduct material of implant or implant containing byproduct material. This allows licensees to authorized release from control of any individual administrated byproduct material if the exposure to any other individual is not likely to exceed five millisieverts.

And as an additional requirement where the patient has to have instructions if the dose to other individuals is likely to exceed one millisievert. So that's just some of the regulations and some of the guidance around some of this.

Next slide please. Reg Guide 8.39. This provides the guidance for acceptable methods to release these patients. The dose calculations are based on external exposure. And these are primarily based on administration of therapeutic iodine-131s.

And there is not a lot of information included with recently approved radiopharmaceuticals which we'll get into a little bit later in the presentation.

This also provides guidance on instructions given to the patient since the patient is no longer under the licensees control once released. And this reg guide recommends that a health care provider discuss a plan for management of biologic waste, which includes discarded trash separately and holding it for decay.

Next slide please. Going into a little bit about separated license material. The exposure to the public may be through direct contact of this material or through exposure, or through direct contact of the patient or exposure to byproduct material separated from the patient. Such as these materials that are put into waste.

Past literature reviews found that the dose from this material that put into waste separated from the patient is expected to be very small compared to the external exposure from direct contact. However, detectible amounts of this byproduct material has ended up in unauthorized waste streams from release patients, as we saw in that fall 2020 ACMUI meeting presentation.

Next slide please. Just going into some of the communications that the NRC has had about this

issue. We've issued multiple information notices on managing waste, on managing patient waste. Three of those are up there. However, these are primarily focused on waste coming from the licensee facilities themselves, as well as best practices for these patient instructions.

No guidance for waste produced after the patient release has been developed yet. And all the waste from the facilities themselves, the licensees is required to be handled as regulated waste and handled appropriately.

Next slide please. And so, following the ACMUI recommendation in 2020 the Staff surveyed the agreement states to find if they had programs in place to manage this waste, and if new guidance would be beneficial.

Next slide please. This is the conclusions of that survey. We got responses from 11 states. Most responded that they had no guidance. And some had minimal guidance for iodine-131 patients with no guidance for newer radiopharmaceuticals.

Some indicated that issuing guidance would reduce risks and costs associated with these types of events, however, the states did note that

the radiological exposure and risk is fairly low compared to other risks present at a municipal landfill such as biological risks or chemical hazards.

Next slide please. Getting into some of the additional considerations. I'm sure you all have seen it. We saw it when some of us got to go to the most recent ASTRO conference here in D.C. Theranostics is an extremely quickly growing field in both size, the amount of doses that are being given, as well as complexity.

The, just wide range of radiopharmaceuticals that are being tested. New lutetium drugs specifically are being tested on bigger populations.

And recent clinical successes with these drugs have prompted R&D from many large drug companies. We're not just increasing the doses; we're increasing the patient population. And a lot of novel isotopes are being explored for medical use. Things that we haven't seen in the medical field ever.

Next slide please. Just talking about specifically two of those. Lutetium-177 and actinium-225. These both have potential impurities.

The metastable lutetium and actinium-227, both of which have half-lives of greater than a 120 days. And so, if detectable these impurities are longer than that decay and storage limit and must be disposed of as low-level waste.

Next slide please. And the number of clinical trials of these newer radiotherapeutics is rapidly increasing. Some trials are collecting patient excreta for analysis and transportation back to the clinic for that analysis. And there is not any guidance currently on how this activity can be safely performed.

Next slide please. And so, in conclusion I do want to state just up-front, I've said a lot of things but public dose limits are very well defined in regulations. However, there is currently a lack of guidance regarding waste following patient release.

And that's the increasing use of radiopharmaceuticals and these novel radiopharmaceuticals is leading to more waste, new questions and the increase in stakeholder interests all say to us that we should provide some guidance in this matter in the near future.

Next slide please. And so in the next step we propose to create a clear guidance regarding this waste, which would be sent to the ACMUI for review. And include a public comment period during the development of that guidance.

Next slide please. And so this is a rough timeline on that. This presentation is obviously where we're at now, November 4th. Developing this draft guidance sometime in early 2025 with hopefully ACMUI review at the spring meeting. And then a publishing of that draft guidance sometime later in 2025. But again, this is still a very rough, rough schedule for the next year or so.

Next slide please. I believe that's everything. Yes. My acronyms. And then, next slide. Any questions?

CHAIRMAN JADVAR: Thank you, Mr. DiMarco for that very important overview of the patient-based guidance. At this time I'm going to open it up to the ACMUI panel members for any questions, comments? I see Dr. Harvey.

DR. HARVEY: Yes, thank you, Dr. Jadvar. Thank you for the great report, Mr. DiMarco. This is Dr. Harvey, the RSO representative.

There has, there is or was an exception for the metastable state of lutetium-177 which has a, I believe 160.4 day half-life, that we were allowed to store that as interim waste. Is that no longer in effect or is it being proposed to be, that exception to being taken away?

DR. TAPP: Dr. Harvey, I believe that might be a state exemption or ability.

DR. HARVEY: I don't believe so, but I'll double check.

DR. TAPP: Yes. Lutetium-177, you're allowed to hold lutetium-177 waste, correct, that you have in your facilities and then hold it for decay. And as the lutetium-177 goes away, if you still detect lutetium-177m then you need to dispose of that appropriately.

I believe that's why you're holding it is to determine if the lutetium-177m is present. So that's why you're, you have that ability to hold it because licensees may not know which products had it, especially back when we were first experienced, gaining experience with lutetium-177.

DR. HARVEY: All right. Well, I'm going to have to dig up the memo and get back to you on

that because maybe I misunderstood it. Thanks.

DR. TAPP: Oh, no problem. Thank you.

CHAIRMAN JADVAR: Okay, thank you. I'm going to move on to Ms. Melissa Martin from ACMUI.

MS. MARTIN: Thank you. Dr. Tapp, one of the questions I would just like to reiterate is, one of the comments was that there would be consideration of the overall hazard of this basically short-lived isotopes going out to the public waste land, waste disposal, relative to the other types of hazards that are in the public waste disposals.

I'm not sure how that's going to be done. I just would really like to make sure that does happen because right now with the current situation, and particularly with all the new isotopes coming there is a lot of effort spent, and potentially a lot of time on disposing of these relative, very low-level radioactive materials relative to other biological and chemical hazards.

DR. TAPP: Yes, thank you for that, that reminder. And we're taking that into consideration as we go forward.

But as Mr. DiMarco was mentioning, the focus here was on the waste from patients being

released.

MS. MARTIN: Okay.

DR. TAPP: I think you may be talking about both aspects. But we are watching, with all the new radiopharmaceuticals coming out, there is lots of questions ongoing about patient release. And the medical team is definitely looking at guidance across the board. And your issue you're mentioning is an important one for us to consider as well.

MS. MARTIN: Thank you.

CHAIRMAN JADVAR: Any other questions or comments from the ACMUI members? Okay, hearing none --

DR. TAPP: Oh, Mr. Ouhib. Mr. Ouhib.

CHAIRMAN JADVAR: Oh, Ouhib. Okay, please.

MR. OUHIB: Yes. I think my comment is more like, whatever is being done we just have to make sure that we don't discourage the use of the technology of the isotope, et cetera, et cetera, where an institution would reveal this big of a headache, I'm not going to deal with this, I'm not going to provide it and so on and so forth.

So in a remote area, you know, an

institution cannot provide that type of care to their patients or these patients will have to be traveling somewhere else because a bigger institution is well equipped to take care of that, that issue. That's all I have.

CHAIRMAN JADVAR: Okay. Thank you, Zoubir. Any other comments from the ACMUI Members?

MS. MARTIN: You got, Megan's got her hand up.

CHAIRMAN JADVAR: Megan, I don't see her hand.

MS. MARTIN: Okay.

CHAIRMAN JADVAR: Okay. So let's move on to NRC Staff. Any questions or comments from the NRC Staff? Hearing none --

DR. TAPP: Dr. Jadvar --

CHAIRMAN JADVAR: Yes.

DR. TAPP: -- this is Dr. Tapp.

CHAIRMAN JADVAR: Sure.

DR. TAPP: I just wanted to go back to Dr. Harvey's comment.

CHAIRMAN JADVAR: Please.

DR. TAPP: One of the Staff here sent me the language from the memo. And the language from

the memo mentions the lutetium-177 can be held in decay and storage, and there may be small quantities in metastable lutetium-177 in that decay and store. However, if lutetium-177m is detected by survey methods it's at that point it must be disposed of as low-level radioactive waste in accordance with Part 20.

So I just wanted to make sure I read there that memo. Is that if it's detected it does have to be disposed of as low-level waste.

CHAIRMAN JADVAR: Okay, great. Thank you --

DR. TAPP: Thank you.

CHAIRMAN JADVAR: -- for that explanation. Okay, I didn't hear any questions or comments from NRC Staff, so we move on to the public. Members of the public? I see Mr. Crane, hopefully he can speak now.

MR. CRANE: Thank you. Am I audible?

CHAIRMAN JADVAR: Yes. Yes, you are audible. Please --

MR. CRANE: Okay.

CHAIRMAN JADVAR: -- give your affiliation also.

MR. CRANE: I am retired NRC. I joined the NRC just short of 50 years ago. Worked there for the rest of my career with a brief timeout to serve as an Administrative Judge and member of the Nuclear Claims Tribunal in the Republic of the Marshall Islands. I retired as Counsel for Special Projects.

I've taken a deep interest in the regulation of radiation medicine. And the regulation of I-131 in particular, in part because I myself am a thyroid cancer patient and was treated with large doses of I-131 in the era before the 1997 rule change.

I'd like to thank everyone who has presented here today for very informative, helpful, concise and useful presentations to a person. I'd like to refer to a few things quickly.

First, the Committee sensitivity to conflict of interest I think is very, very welcome. To be welcomed. Because it was not all that long ago that the issue of patient release was basically assigned to an ACMUI member who was also assigned by a professional society which declared this in its publication to be their point person on the issue with the NRC.

And at the time I suggested that it was

possible to wear too many hates. Nobody else seemed to think so. So I think this is all to the good.

With respect to veterinary, some years ago, as I made clear in filings, there was a company called Radiocat which was giving radioactive iodine to hyper thyroid cats in doses of three to six millicuries. And at the time they were advertising on their website that owners of cats had nothing to fear because the NRCs restrictions on the use of I-131 in cats were so much stricter than those on people.

And I'm wondering if the staff is saying that they are now wondering whether those restrictions are tight enough or did I misunderstand?

CHAIRMAN JADVAR: Okay, thank you, Mr. Crane, for your comments. I'm sure the NRC heard your comments --

MR. CRANE: Well, I had more to say though.

CHAIRMAN JADVAR: Oh, you still have more to say?

MR. CRANE: Yes please.

CHAIRMAN JADVAR: Oh, okay. Please, go ahead.

MR. CRANE: Okay, thank you. With regard to, oh, with regard to waste in sewage, I just mentioned a comment made by Dr. Carl Paperello, who some old timers here will remember, who was a senior manager, division director, something like that in NMSS. Came to the NRC from New York State government. Said, we always knew when somebody was being treated for thyroid cancer in Albany because we'd say the radiation spike in the sewage plant. So it's there.

And you may recall also that some years ago they were finding radioactive iodine in the Delaware River and people thought, oh my, it's being released from Three Mile Island. It wasn't. It was going through sewage plants after being eliminated from hospitals and it just wasn't, it was detectable in drinking water.

By the way, can I assume safely that the statement I submitted last week was received and filed and circulated to the Committee?

CHAIRMAN JADVAR: Yes.

MR. CRANE: Thank you. Okay. On the subject of patient release, I feel as though this committee has inherited a problem, much as you might

inherit a problem, you might inherit a piece of property that has been used without your knowledge as a waste dump. There is a great deal wrong with the present system. It didn't happen on your watch but you have inherited it and it has become your problem I'm afraid.

The whole, I mean, the central issue comes down to whether internal dose is an issue. The present rule of 1997 was grounded on the advice from just one person. A gentleman, he was a nice man but his views were extreme.

He thought that I-131 was not carcinogenic. He wrote in an article that if there were a major release of radiation from a nuclear bomb the health effects, if any, would be positive. This is not somebody on whom to base a rule that effects the health and safety of patients, their families and the public.

What the NRC did in 1997 was to flip-flop completely from the position that it had articulated very well and very soundly in 1986 and it never explained why. Nor has it explained why to this day.

What the NRC has tried to do, and I cannot believe that there is anyone in that room who is

prepared to stand up and say, yes, internal dose is inconsequential. Internal dose is not inconsequential. And to children it's a much greater danger than it is to, than is external radiation. That's why we have potassium iodine because of the danger from the milk pathway.

And as far as non-binding guidance, if all you are doing is non-binding guidance you can do it with all the good will in the world. It's going to be ignored if it conflicts with economic necessity. And in this case it's the insurance companies that have the whip hand because they have declared, across the country, that they will not pay for inpatient treatment.

And we also have one prominent nuclear medicine advocate from the community who has urged licensees to ignore regulatory guides saying, defy them, they're not binding. It is an exercise in irrelevancy so long as it remains non-binding. So long as a rule change is off the table. That is my view.

It was done of Beth Howell who was a fine public servant and all of you know her. Descended from the view that you could do without a rule change.

But her views have been overborne because there has been, at a high management level, a decision that internal dose doesn't count. And if internal dose doesn't count you can based release solely on proximity and guess at proximity. It doesn't work that way.

You have the studies from 2014 in which it says that a patient with a 100 millicuries of I-131 in his or her system can deliver a dose in transportation. In 42 minutes can deliver 100 millirems to another person. That's too much. And the staff said in 2014 that this was a source of concern in every respect.

Nothing has been done about it. And until something is done about it you will have a festering sore and you will have, inevitably, people being harmed. And I don't think that can be tolerated.

And I think it is up to the ACMUI and the Staff, and the Commission, to stand up and acknowledge that things went awry in 1997. They should never have been changed. We are at odds with national and international standards. We are an outlier in the world community. And sooner or later

it will all come to view.

CHAIRMAN JADVAR: Okay, thank you.

MR. CRANE: Let's get ahead of it --

CHAIRMAN JADVAR: Okay.

MR. CRANE: -- and fix things please.

CHAIRMAN JADVAR: Okay, sure. Thank you, Mr. Crane, for all your comments again. Let's move on.

I have one more hand here. Mr. Stanley Hampton. Please introduce, please give you affiliation, your question.

MR. HAMPTON: Hi, thank you.

CHAIRMAN JADVAR: Comment.

MR. HAMPTON: Stan Hampton. I'm an RSO for Eli Lily and Company. And I want to make a comment on the slide referencing the lutetium-177 and actinium-225 contamination.

You know, technically the slide does say potential, and that's correct. But it seems like the emphasis is that all of this material is going to be contaminated. And please keep in mind that both lutetium and actinium can be produced in such a way without those containments and is typically referred to as NCA, or no carrier added.

So the slide could probably stand to be modified a little bit so that it would show that those can be produced without contamination.

CHAIRMAN JADVAR: Great. Very important. Thank you very much.

MR. HAMPTON: Thank you.

CHAIRMAN JADVAR: Thank you. Any other, we have a little more time, any more comments from the public?

Yes, there is one. Let's see, Mr. Bryan Lemieux. I hope I said that correctly. Please go ahead and give your affiliation and your comment.

MR. LEMIEUX: Brian Lemieux, University of Kentucky Health Care. I just had a quick question regarding the emerging technologies rulemaking.

At the end of that rulemaking document there was a, there's a clarification, or supposed clarification on the public dose release limit clarifying that it was going to be per course of treatment. And I was wondering if you could comment on whether that language was still there or if that was still carried through intent in that rulemaking to make that modification to the release limit?

CHAIRMAN JADVAR: Dr. Tapp, do you want

to --

DR. TAPP: Yes.

CHAIRMAN JADVAR: -- chime in?

DR. TAPP: This is Dr. Tapp with the NRC. So the document you're talking about is the regulatory basis that went out for public comment. Right now we're taking the public comments from that regulatory basis and developing a proposed rule. We have not finalized the proposed rule yet so we don't have an answer to your question yet because we haven't finished the proposed rule package yet. So the last document out was the last thing that's been published, was the regulatory basis document.

CHAIRMAN JADVAR: Okay. Thank you, Dr. Tapp. All right, so at this point I want to go back to Ms. Armstead who remember we said after DiMarco's presentation we are going to go back and, over the old business report and close some of the items that she mentioned earlier.

MS. ARMSTEAD: Yes.

CHAIRMAN JADVAR: Ms. Armstead, do you want to --

MS. ARMSTEAD: Yes, Dr. Jadvar --

CHAIRMAN JADVAR: Go ahead.

MS. ARMSTEAD: -- thank you. I have proposed closure for these items from the old business report. Item 11 dated 9/21/2022. Item Number 4 dated 12/5/2022. Item Number 1 dated 4/8/2024. Item 3 dated 4/8/2024. And Item 4 dated 4/8/2024. Is there a motion to accept the report?

MR. EINBERG: Lillian, this is Chris Einberg. Can you pull up those items so when you're going through them the ACMUI Members can see what we're discussing please?

MS. ARMSTEAD: Okay.

DR. FOLKERT: I think they were Pages 5, 6 and 7 of the packet.

MS. ARMSTEAD: Bear with me, I'm having a little difficulty with my pointer. Or my mouse.

Okay, I have proposed closure for these items from the old business report. Item 11 dated 9/21/2022. Item Number 4 dated 12/5/2022. Item Number 1 dated 4/8/2024. Item 3 dated 4/8/2024. And Item 4 dated 4/8/2024. Is there a motion to accept the report?

DR. WOLKOV: Moving acceptance. Harvey Wolkov.

MS. MARTIN: This is, second, Melissa

Martin.

CHAIRMAN JADVAR: Okay. All in favor say aye?

(Chorus of aye.)

CHAIRMAN JADVAR: Any opposed? Any abstentions? All right, thank you, the motion carries.

MS. ARMSTEAD: Thank you, Dr. Jadvar.

CHAIRMAN JADVAR: Thank you. So at this point we have a break until 3:30 p.m. Eastern standard time, at which time we regroup again for the last piece of, the part of the ACMUI meeting. So see you at 3:30 p.m. Thank you.

(Whereupon the above-entitled matter went off the record at 2:46 p.m. and resumed at 3:30 p.m.)

CHAIRMAN JADVAR: Well, it's 3:30 p.m. Eastern Standard Time and I think we should get started again. Welcome back to the 2024 Fall Meeting of the ACMUI for the last part of the meeting.

First on the agenda is a report by Dr. Katie Tapp on the status of the patient release guideline revision. Dr. Tapp.

DR. TAPP: Thank you. As I mentioned

earlier, I was going to talk about the medical staff's status on revising the patient release guidance.

Next slide, please. Thank you. During this talk I am going to talk about the regulations, then the current guidance that is currently available, the revisions, some topics on how we are addressing comments and discussion.

Next slide, please. First, I am going to go over the regulations. Next slide. So, as we all know the patient release regulations are contained in 10 CFR Part 35.75, which states "The licensee may authorize release of patients if the total radiation dose to any other individual from exposure to the release patient is not likely to exceed five millisieverts."

A licensee must provide written instructions to a patient to maintain doses ALARA or as low as reasonably achievable if the exposure to any other individual is likely to exceed one millisievert.

In addition, the regulations state a record of the basis for authorizing release is required to be kept if the exposure is calculated using retained activity, the occupancy factor of less

than 0.25 at one meter, use of biological or effective half-life, or if their calculation considers shielding.

These regulations are not changing as part of the NRC's effort to update the patient release guidance.

Next slide, please. The NRC Staff was directed by the Commission in 2011 to start evaluation of the patient release program. In 2011 specifically the NRC Staff was directed to identify gaps in patient release data.

In 2012 the Commission directed the Staff to revisit release calculations and then in 2014 the Commission directed the Staff to revise Regulatory Guide 8.39 which provides the guidance for patient release to consolidate all of the information that is contained in all guidance documents into one place. The Staff completed this evaluation in 2018.

Next slide, please. The findings of the patient release evaluation were that these regulations are adequate to protect public health and safety and rulemaking was not warranted at the time of the evaluation in 2018.

However, the evaluation identified that

an update to the guidance is warranted as the methodology provided in the guidance could underestimate exposure to members of the public in some situations such as public transportation or if a patient could not follow instructions and was closer to an individual than the assumptions used in the current guidance.

Next slide, please. What I am going to go over next is the current guidance and this is Regulatory Guide 8.39, Revision 1, that is currently available.

This not the guidance that was released for public comment but the guidance that has been finalized, or Regulatory Guide 8.39, Revision 1.

Next slide, please. This guidance workflow is provided on this slide and it starts off with a recommendation that licensees have pre-treatment discussions with patients.

This pre-treatment discussion is to cover the instructions that a patient may be given and discuss with the patient their ability to plan for following these instructions following release.

Next. The current guidance uses a baseline threshold. These are the tables that we

know. So these tables have administered activity that a patient can be released under or a measured dose rate, which if the administered activity or the measured dose rate is below the patients can be released.

The current guidance does have patient-specific calculations for administration above these thresholds that are contained in the appendix of this guidance document.

So we have done patient-specific calculations under the current guidance, but the recommendations and the guidance provided in the current patient release guidance is specific for iodine-131 for hyperthyroidism or thyroid cancer.

Following the release the recommendation is to provide instructions as necessary after the administration and then to have the patients acknowledge these instructions to acknowledge they have receipt of these instructions.

Next slide, please. The current -- The patient-specific calculation guidance is contained, like I said, in the appendix of the current guidance and there is guidance on using patient-specific occupancy factors when patients are given

instructions.

This guidance is provided specifically for iodine-131 and it also discusses using the biological half-life for iodine-131 again for hyperthyroidism or for thyroid cancer.

There is no guidance provided for patients who cannot follow instructions or exposures when the licensee knows exposures are going to occur at distances different than one meter.

So the patient-specific calculations that are provided in the current guidance are very specific to the examples and the instructions that are provided in this guidance.

Next slide, please. The current instructions recommendation in the guidance for when a licensee can use patient-specific calculation, which includes an occupancy factor of 0.25 at one meter, is that the patient will maintain distance for at least two days, sleep alone for at least one night, not to use public transportation for one day, not to have a prolonged automobile trip for at least two days, they have a sole use for a bathroom for at least two days, and drink plenty of fluids for at least two days.

The current guidance is silent on what to do when a patient informs a licensee that they cannot meet these regulations for a variety of factors.

Next slide, please. So the guidance revision. Now I am going to talk about the status of revising this guidance. Next slide, please. As you know the NRC released a draft revision to this guidance in 2023 where we requested public comments.

This draft revision increased conservatisms in the threshold assumptions to ensure that all patients released under the threshold assumptions are not likely to cause exposure over the limits.

This also provided consistent methodology to provide threshold values using patient-specific information and included beta emitters and other emerging isotopes.

Following the release of this guidance the NRC Staff received significant comment that this draft revision was too conservative and would require too much effort on the licensee's part to incorporate.

Next slide, please. The NRC has heard the comments from the public and is working with the

guidance to offer additional approaches to release these patients.

As I mentioned, the guidance revision continues to contain a baseline threshold where there is tables included so patients can be released quickly where no patient-specific information is needed.

This is in line with the current guidance and would release the majority of patients, including diagnostic patients. The NRC Staff believes that having a baseline threshold approach is necessary to release the majority of these patients.

In addition, the NRC is exploring screening criteria approach where licensees could use their instructions to develop modified values to release patients for common administered activities for currently approved administrations and then use these instructions to develop screening criteria to ask the patients can you follow these instructions and if they could then they could release the patients using these values.

The NRC is exploring multiple examples to be included in the guidance for currently approved administrations so licensees could quickly adapt the

screening criteria approach.

In addition, the NRC Staff still proposes having patient-specific calculation to be flexible for unique needs. We know that patients out there have unique needs and cannot always follow the standard instructions from licensees.

The guidance would provide patient-specific calculations for licensees to use if they desire to use it to confirm that the patient's unique needs can still allow for a release.

In addition, hold time calculations could be provided for very high activity administrations or for unique needs to allow licensees to calculate hold times based on needs and be available for planning purposes.

This could be used for treatments such as iodine-131, MIBG, where patients are currently held due to the high administered activity and licensees could then use calculations to estimate how long a patient might need to be held for radiation safety purposes.

Next slide, please. As I mentioned, the NRC Staff received numerous comments on the draft guidance for patient release that we issued in 2023.

So we are right now currently in the effort of resolving these comments and revising a proposed draft guide 8.39 to provide these guidance.

In the new proposal we are simplifying methodology to allow for simpler release pathways to allow for screening criteria to be used based on instructions and providing examples.

We are also simplifying methodology for patient-specific calculations for licensees who choose to use that. In addition, we are evaluating the cost risk benefit of the proposed draft guidance.

This evaluation is to be a full quantitative cost risk benefit analysis to ensure that the regulatory guide is beneficial if used.

Next slide, please. So what is next? We are still in this process of revising the draft guidance but once we are completed we will provide, because it is a new guidance, a new proposal, we will be providing it to the ACMUI for review and comment.

Following that and your recommendations the draft guidance will be issued for an additional round of public comments. This is because the draft guidance has significant changes from what has previously been seen.

Finally, following that round the expectation would be for final issuance of this guidance. Next slide, please. Now I am leaving it open for discussion. Thank you.

CHAIRMAN JADVAR: Thank you, Dr. Tapp, for that status report. At this time I want to open it up to the ACMUI membership if they have any questions or comments for Dr. Tapp. I see Melissa Martin. Please.

MS. MARTIN: I realized the microphone was muted. I think we've got two questions that I would have working, just being a hospital based physicist do you have an estimate of what percentage change we expect this to have for the percentage of patients you would expect to not be able to be discharged versus using the current rules?

The other question I would have is I have no idea, and maybe Mr. Harvey would, on the reaction of nursing staff, if we say we suddenly want to have these hot patients in that they have not had to take care of for several years I think it's going to be very traumatic to make this change in the care and responsibilities of our nursing staff. Thank you.

DR. TAPP: Thank you. And as the

document is not available right now for review I can't speculate too far into the future of the final document, but our current review is that we do not expect there to be any increased holding of patients.

The sole purpose of the guidance is for licensees to work with patients on the instructions and their plans after the fact to ensure that the regulations are being followed.

MS. MARTIN: Okay.

DR. TAPP: So there is no change to the regulations. So the intent is not to increase holding of patients because if a patient were to be released and they are likely to expose someone to 500 millirem they shouldn't be released with the new guidance or the old guidance.

MS. MARTIN: Okay.

DR. TAPP: So we're not expecting a change there. Thank you.

CHAIRMAN JADVAR: Dr. Harvey.

DR. HARVEY: Thank you, Dr. Jadvar. Thank you, Dr. Tapp. I agree with Dr. Tapp, I don't think this is going to increase the amount of hospital stays that we have.

With regards to Ms. Martin's comment

about, you know, nursing staff having to take care of more radioactive patients, yeah, I'm sure that there will be some anxiety and fear associated with that, but, you know, we'll have to get over that if that becomes necessary. Thank you.

CHAIRMAN JADVAR: Thank you. Any other comments by the ACMUI members? I see Mr. Ouhib, Zoubir Ouhib.

MR. OUHIB: Yes. Dr. Tapp, thank you for the presentation. Are we looking for a shift of some sort of responsibility between the providers and the patient in the new rules, or the proposed rules?

DR. TAPP: Thank you for the question. I do not think there is a shift in, as you mentioned, the regulations are still for the licensee. The licensee is ultimately responsible to ensure compliance with the regulation.

The purpose is to just confirm that the assumptions being used in the calculations are appropriate for these patients, so talking with the patients and ensuring that all patients being released are unlikely to expose other members of the public to greater than 500 millirem or 5 millisieverts.

So, no, I do not see a shift. It's still ultimately the licensee's responsibility.

MR. OUHIB: Thank you.

CHAIRMAN JADVAR: Thank you. Ms. Shober.

MS. SHOBER: Hi. Thank you. Megan Shober. I am really happy to see that the revisions will incorporate some simplified methodology for the guidance and also really encouraged to hear that the examples will include some of the more common treatments that are being performed. I think that was missing in the original drafts and I think it will be really valuable as we move forward.

I might have missed, Dr. Tapp, did you mention when that draft might be provided to ACMUI for review and comment?

DR. TAPP: I did not mention it. We are working to get it out, but as you know we have some higher priority rulemakings right now so those right now are taking precedent, but we are hoping to get it in the next few months rolled out.

Once it is out we will provide it to the ACMUI for your guys' review and we'll have a meeting to discuss it I'm sure at your discretion.

CHAIRMAN JADVAR: Thank you.

MS. SHOBER: Sure. Okay, so I guess what I am hearing is right now it's not certain whether this would be a topic for the Spring 2025 meeting or if it might be a little later than that.

DR. TAPP: Yes.

MS. SHOBER: Okay. Thank you.

CHAIRMAN JADVAR: Okay. Any other comments by the ACMUI members?

Okay. Well I am not sure if we really need to ask the NRC Staff if they have any questions but I'll ask it anyway, if there are any NRC Staff who want to comment on this topic.

DR. TAPP: Not here.

CHAIRMAN JADVAR: Okay, very good. So let's open it up to the members of the public if they have any comments. I see Mr. Crane again. Mr. Crane.

You are muted.

MR. CRANE: I wanted to -- thank you.

CHAIRMAN JADVAR: Okay, good. Go ahead.

MR. CRANE: I wanted to thank you for your patience earlier and also mention that Katie Tapp had the kindness to send me an email telling me

that she knew that I was trying to connect and that's the kind of (audio interference) I have come to expect in recent years and it's very much appreciated.

This is not just, you know, pro forma public participation, this is actual concern for (audio interference). I just --

CHAIRMAN JADVAR: You're being cut off once in a while.

MR. CRANE: -- to nurses. That's realistic. I can speak to (audio interference).

CHAIRMAN JADVAR: Mr. Crane, we can't really understand because it's getting cut off.

MR. CRANE: Oh, okay. Nothing is coming through? I got a message on my computer --

CHAIRMAN JADVAR: Right now it's okay, but it was just dropping out frequently.

MR. CRANE: Okay. To Ms. Martin's point about the reaction of nurses, I think that's realistic. I can just contribute from my own experience, oh, 30-some years ago at NIH of having a nurse come in to take blood or whatever it was and say to me I am getting out of this business, as far as I am concerned every patient is a source.

She was angry. I mean I had 150

millicuries. She didn't want to be in there with me, and I don't (audio interference).

As far as the licensee's responsibility, the licensee's responsibility ends as the patient goes out the door (audio interference) whether holding or releasing --

CHAIRMAN JADVAR: Sorry, Mr. Crane, again you dropped out.

We can't hear you at all. Okay, maybe you can reconnect later on, but let's move on with Dr. Pat Zanzonico.

DR. ZANZONICO: Yes. Hello, everyone. Thank you for the opportunity to contribute. First, I am glad that there will be no substantive revision to the optical regulations.

I think the safety and the interest of the public with the current regulations and largely with the current guidance is very well established, it's very well documented and so forth.

I am a nuclear medicine physicist here at Memorial Sloan Kettering Cancer Center and we have a very, very active radiopharmaceutical therapy program here.

We really do not encounter issues with

anxiety among nurses or other staff caring for patients who happen to remain in the hospital. It's a matter of, as you might imagine, education and orienting the staff appropriately.

We found that as long as they are fully informed of what they risks and lack of risks are there is really never any anxiety or any hesitancy in caring for these patients.

So I would just like emphasize that point, that with appropriate education orientation that has not proven to be an issue really at all.

The other point I would like to make, and this is by way of a commercial, so to speak, I am currently the chair of the MIRD Committee of the Society of Nuclear Medicine and Medical Imaging. That's the Medical Internal Radiation Dosimetry Committee.

We are in the process of preparing a downloadable piece of software based on NCRP Report Number 155, Management of Patients who Receive Therapeutic Amounts of Radioactivity.

That hopefully will provide a very intuitive and useful tool for evaluating patient release-ability compliant with the applicable

regulations as well as the during of post-release precautions. That will be freely available on our MIRDsoft website.

So I really don't have any questions, but I did want to make those comments. Thank you very much.

CHAIRMAN JADVAR: Thank you, Pat. Now let's move on to Mr. Brian Lemieux who has a question or a comment.

MR. LEMIEUX: Yes. Actually Pat beat me with his advertisement to, one of my questions was going to be specifically regarding restriction times and whether the revised guidance was --

(Simultaneous speaking.)

MR. CRANE: Beatrice, could you bring me my phone.

MR. LEMIEUX: -- whether they knew, it was whether the new guidance was going to re-address that issue in a way similar to how NCRP 155 had done it, you know.

The NRC did a great job presenting on the limitations of the old reg guide restriction time guidance with the occupancy factors and, you know, the issues around that, and so I didn't know if we

were going to get a better treatment of it in the new guidance, if that was on tap for this revision or not.

MR. CRANE: Excuse me. I got technically broken off. May I continue my comments?

CHAIRMAN JADVAR: Yes. No, just one second. Just one second, Mr. Crane.

MR. CRANE: Okay.

CHAIRMAN JADVAR: Dr. Tapp, do you want to respond back to Mr. Lemieux's comment or no?

DR. TAPP: Yes. I think one of the main, one of the purposes of the revised guidance is to help licensees be able to calculate, to explore and evaluate restriction times and their instructions to determine if they are appropriate for the regulations, but you will see that when it is given out for review for public comment. Thank you.

CHAIRMAN JADVAR: Thank you, Dr. Tapp. Okay, Mr. Crane, you are on again.

MR. CRANE: Thank you.

CHAIRMAN JADVAR: Hopefully it will work out this time.

MR. CRANE: Let's hope. So I missed the first few words that Pat Zanzonico and my greetings

to him. We know each other of old. I disagree with his analysis.

The analysis of his that I agree with was the one that he published in Thyroid Magazine in May 1997 in which he pointed out at a time when what was at issue was to preserve the 30 millicurie rule against efforts to lower it to 15 millicuries or below.

He explained why a patient released with 30 millicuries could deliver a radiation dose to another person of no more than 500 millirems. Since 500 millirems was the limit that meant 30 millicuries was fine.

I don't see, and honestly it compels me to say that it wasn't much time before the ACMUI Subcommittee headed by Dr. Zanzonico was saying that nobody knows where the 30 millicurie rule came from and said it was unnecessary and we've got people being sent out the door with 200 millicuries of I-131 from Sloan Kettering.

I appreciate that Mike Tuttle and others have been doing a great job of using no more I-131 than is necessary. It's a very helpful friend, but the fact is people are going into the subway all the

time, they've got to get home or they go to hotels.

Mike Tuttle told me a few years ago that it's not the same hotels in downtown Manhattan where they are going, they tend to go to places near the airport so that they can fly out because so many patients come to Sloan Kettering from abroad.

I just think you had it right in 1997. As far as the choice between hospitalizing patients and sending them, whisking them out the door, as Dr. Malmud put it so memorably in 2007, this assumes that there is a capacity to keep people. There isn't anymore.

People go in all the time. I am a co-facilitator of a thyroid cancer support group. I see the emails coming into the Thyroid Cancer Survivor Association website all the time and people will ask about in-patient treatment because they've got children at home and they are told, no, no, no, that's not the way we do it, and that's where the analysis ends.

I could tell you of another hospital in Bellevue, Washington where I asked whether they gave in-patient or out-patient and they said no more in-patient because, you see, we had a patient who took

a lot of showers as she was advised to because, you know, get the I-131 off the skin and the I-131 so permeated the grout between the tiles of the shower that they had to remove all the tiles and replace them. Never again. So it's what are you going to do if you cannot, if you do not have the capacity.

You've got lots of people with licenses out there to use I-131 who have no place to put a radioactive patient, and as far as the licensee's responsibility to ensure compliance. That ends the moment the patient is out the door.

Lastly, I will say that some years ago, many years ago, I asked in a very neutral way, I asked a professor at Penn State what do you think of the new NRC patient release rule and he reddened and said "The worst decision in that Agency's history in 35 years."

I spoke to him again more recently about the guidance given on release and he said "What gets me is when you give the patient all those instructions about what they can do to avoid contact with others and you see them nodding their heads up and down, yes, yes, yes, and you know they are going to go out the door and do exactly what they want."

In the words of Donna-Beth Howe, "We have outsourced radiation protection to the individual patient." If anybody thinks that the conscience of the individual patient is an adequate substitute for public health, look at what happened during COVID.

CHAIRMAN JADVAR: Thank you.

MR. CRANE: So that's my real world view.

CHAIRMAN JADVAR: Okay. Thank you very much, Mr. Crane.

MR. CRANE: Thank you.

CHAIRMAN JADVAR: And I see Dr. Harvey has a comment.

DR. HARVEY: Yes, just a couple. I mean there is a lot there. I think capacity, as Mr. Crane has indicated, or Dr. Crane, I'm not sure which, you know, is going to be a real problem for hospitals.

It's going to be very difficult to keep all these, you know, keep patients in for hospital stays. That's certainly a given.

I do believe it's incumbent upon the licensee to make sure that their patients are going to follow the discharge instructions that they have and, as he notes, they can nod up and down and say they are going to follow them, the directions, and

not do that.

The only thing we can do as licensees is accept their word at face value. You know, certainly if you suspect that they are not going to follow those instructions then you could consider an in-patient stay.

I would like to just say that, you know, I understand that there is a lot of animosity about the patient release and those being released and those being kept in the hospital.

I don't see a lot of negative outcomes for members of the public or members of the family based on these patients being released with 200, 300 millicuries of a radiopharmaceutical in them.

I am not saying there are no adverse effects. I am just saying -- And I'm not saying it's the best way to do it, I just don't see a lot of negative outcomes to people at this point.

CHAIRMAN JADVAR: Thank you, Dr. Harvey.

DR. HARVEY: Thank you.

CHAIRMAN JADVAR: And I see Ms. Allen, Becky Allen.

MS. ALLEN: Yes. Thank you. I just want to point out one thing as we are talking about

this between an in-patient and an out-patient stay is also the billing aspect of this, because most of the insurance companies will not approve for that in-patient stay based on those codes, so I think we just need to be careful as we are discussing it.

There is a lot more behind it and then the patients would be held liable for that as well. So just another piece of this as we go through this conversation. Thank you.

CHAIRMAN JADVAR: Okay. True. Thank you. Pat. Pat Zanzonico.

DR. ZANZONICO: Yes, thank you. As Mr. Crane said he and I have known each other for many, many years and we had a very good mutual friend, Dr. David Becker, who many of you know, late great clinical thyroidologist.

I just want to clarify one point, that a number of years ago some of these calculations were based on a much simpler physical model of a point source of I-131 which did not account for patient shielding, which is considerable, and did not account for biological clearance of I-131 iodine, which is even more considerable, so using newer models which take into account those factors patient release-

ability is consistent with the 500 millirem limit.

The other point I would like to make is here at Sloan Kettering, and I'm sure at many of the hospitals, patients are sent home to self-administer very potent, potentially very toxic, medications.

These are oral anti-cancer medications. The clinician relies on the ability and so forth of the patient to comply with the administration instructions.

There rarely, if ever, is any overdose issues. So I think that gives us some confidence that patients when given clear explicit instructions can comply with instructions not only for their own safety but for that of people around them.

So I just wanted to make those comments. Thank you.

CHAIRMAN JADVAR: Thank you, Pat. I just -- Before we go to the next comment I want to re-echo what Dr. Harvey just said a minute ago, and that was about, you know, what the evidence is, is there evidence that there is a public health adverse events from these folks or these patients who are being released on 200 or more millicurie of treatment.

I don't know other clear evidence of harm. So I just wanted to re-echo what he mentioned and I support that comment. Let's go on to Mr. Matt Barrett. Please give your affiliation.

MR. BARRETT: Hi. I don't know if you can hear me.

CHAIRMAN JADVAR: We don't hear you very well.

MR. BARRETT: Sorry. Can you hear me now?

CHAIRMAN JADVAR: Better. Much better. Please.

MR. BARRETT: Okay. Thank you. So I was more just curious if it's convenient on a licensee fact when you have the release calculations more at 33 and 392 is 33. It's convenient for some of the smaller licenses.

I didn't know if this release changes whether or not it go down to like ten or up to 50. Is there any plan on modifying the, you know, authorization side to make it match to whatever the release criteria would be or would they stay at whatever their present plan? That was it.

CHAIRMAN JADVAR: Okay. Thank you. Dr.

Tapp, do you want to take that at this time?

DR. TAPP: Sure. There is no plan to change the regulations, so no plan to change the regulations as you were mentioning there.

CHAIRMAN JADVAR: Okay, great. Thank you. I see that Mr. Ouhib has a question or comment.

MR. OUHIB: Yes. I just want to go back to what Dr. Zanzonico was talking about. I fully agree with him but I will add that as far as patient education it's not just the patient, it's family members also need to be part of that discussion, because if you have a 75-year-old or 80, whatever, or for that matter younger, but cannot, you know, keep track of what he or she is being told, I think family members can play a huge role in reminding them, explaining to them, but follow basically what needs to be done.

My other point is related to there was a discussion about the nurse being all aggravated and all that. Let's all remind the nurses, these are radiation workers, and they work on that floor.

Therefore, really, they are being monitored and there is no reason to be scared or whatever and if they then perhaps they need another

in-service to understand what needs to be done and how to proceed. Thank you.

CHAIRMAN JADVAR: Okay. I am going to give this to Josh Mailman now. Josh.

MR. MAILMAN: Hi. Josh Mailman, Patient Advocate, ACMUI. A couple things here. One, it's just not in-patients, you know, putting the patient in-patients and having that nursing staff trained, we certainly have, you know, lots of instances of patients who are then followed up in an infusion clinic for follow-on infusion in the next 24 or 48 hours where nurses and/or HCPs who have not been trained, because they are not on the same floor, are now, the word "exposed" is probably incorrect here, but who are now facing the patients who had recent radiation therapy and really haven't been trained on whether they can safely give an injection and many of them freak out or some of them, and I certainly talk to a fair amount of patients who had this happen.

So when we think about training and education, which I think is always a great idea, we need to be inclusive of all of those who may touch the patient, not just who may be in-patient.

As far as, yeah, and certainly I

understand that people may have in different areas followed the COVID restrictions, but that was different than when I believe, as my personal patients who are receiving radiotherapy are given instructions and actually are rather concerned about radiation safety because it's something that they have and that they are receiving and they want to safeguard their family as well.

So looking at the regulations where it says, you know, have a separate bathroom for at least two days, certainly, while I believe MSK has a wonderful education, I do know of an MSK patient who slept outside in their car because they only had a single bedroom and didn't have multiple bedrooms to separate themselves, or who, you know, separated themselves from their families for weeks at a time because they were over doing what the regulations, what were given to them.

So I think we need to give the patients credit that they know that this is an important thing that's going on and that we need to give them the education but not only just the regulations but the why to the regulations, what's at risk, how it works, how to talk about mitigating circumstances if you

only have one bathroom or one bedroom or you live in a studio with your, using the Manhattan example, with your family, because these are real life scenarios.

That's -- I think patients are happy to learn and especially happy to understand why you want to give them these instructions and will follow them if you give them rationale for it and will make up rationale if you don't give it to them. Thank you.

CHAIRMAN JADVAR: Thank you, Josh. I want to go to Dr. Harvey.

DR. HARVEY: Thank you, Dr. Jadvar. I guess first I agree with Mr. Ouhib and I think it's common practice to involve the spouse or family members with patients that may have some difficulty understanding instructions.

So I think what he points out is it's a great point and it is common practice to include the family members or the spouse.

I agree with Mr. Mailman and his position. I think that training and education is critical for all areas of the hospital. We have opened up radiation safety training to our entire organization so that people at least have some baseline education and awareness and then areas where

someone is going to go to get a sando injection in a clinic or something like that post-therapy we again provide training and education for those folks to make sure that they are prepared to handle those situations.

Again, it's going to be different across the board. His point is correct and well taken. I think it's just incumbent upon the licensee and the staff to anticipate those situations and prepare for those.

I think lastly was, again, going back to, you know, nurses working with patients, again it is a matter of training and education and once you get them trained and you give them the why, as Mr. Mailman indicates, it usually works out fairly well. You know, it's just when you lack the education where you might have the problem.

So it's just incumbent upon us as licensees to make sure that we are prepared for those situations. Thank you for the time.

CHAIRMAN JADVAR: Thank you, Dr. Harvey. Well we are already like 15 minutes over time for this item, but I will give Mr. Crane another chance briefly if you want to make a comment and we end it

at that point for this item. Mr. Crane.

MR. CRANE: Thank you. I will make it very quick. I certainly agree that insurance is critical. The thing of the transformed medical treatment is when insurance companies stopped paying for it and doctors and hospitals realized they might have to eat the cost, at which few hospitals are willing to do.

Washington Hospital Center will. They said anybody that gets more than 30 millicuries we hospitalize them. In the words of Ken Furman, "Then you don't have to worry about the kids."

When this issue was out for comment some years ago there were doctors saying what we need is something to strengthen our arm so that the patients who need hospitalization can get insurance coverage. We don't have any of that. That is critical.

It's something, but I don't want to hog more time than I have already.

CHAIRMAN JADVAR: Okay.

MR. CRANE: I will say that -- Let's see. Oh, as far as harm, how are you going to know. The harms we are talking about, long-term harm from radiation, it's not as though the one-year-old who is

hugged to her mother's neck because her doctor said, oh, no, no, no, no precaution is needed.

It's not as though she is going to come down with radiation-caused disease in the next six months, we're talking about long-term damage that nobody is going to know about, nobody is going to trace.

There is an old saying that no evidence of harm is not the same as evidence of no harm, and that's the crux.

CHAIRMAN JADVAR: Okay. Thank you, Mr. Crane.

MR. CRANE: Thank you very much.

CHAIRMAN JADVAR: Thank you. Dr. Fair.

DR. FAIR: I think this is a very important issue and I think keeping track of whether we are discussing the sort of external exposure from gamma radiation versus inadvertent internal consumption of the beta emitter is probably important to be thinking about.

I recognize that most of the guidance really has to do with sort of the gamma radiation that's coming off and the expected exposure to other individuals primarily.

I just want to refer everyone back specific to that to the paper by Perry Grigsby and Barry Seigel and coworkers back in 2000 where they sent everybody home with dosimeters.

Obviously they didn't -- We weren't in the era of drones so we couldn't follow people around to figure out whether or not they actually wore them, but they sent the patient's family members, pets, and rooms all had dosimeters and the maximum does to any individual pet or room was 110 millirem after sending patients home after between 50 and 150 millicuries of radioactive iodine.

I apologize, I can't think in becquerels myself. So I think thinking about it in that context those patients were sent home with two days of precautions and nothing beyond that.

I think many of us have moved to somewhat stricter precautions that we send folks home with and I think what I have observed in my practice is that many people actually are stricter than the strict precautions that we give to them.

Just as Josh was talking about, the patient who stayed in his car. Everyone I talk to about these things is very afraid of harming their

family members and so they really stay far away.

I am in a practice where we do admit patients if they have social circumstances that do not allow them to return home and follow reasonable precautions. So we take care of individuals experiencing homelessness, prisoners, and others in complex family circumstances.

I think what it ultimately requires is a very sort of targeted individualized approach and conversation with the individual to make sure that we can treat them safely and with safely to their family members.

I would couch all of this in a note that admission to the hospital is not completely benign. Not only is it costly, but not thinking so much about the cost as just some of the inherent risks of being hospitalized like, you know, hospital-acquired infections, et cetera.

So I think the overall safety of the patient and the public is sort of an overarching consideration in these cases.

CHAIRMAN JADVAR: Great points. Thank you, Dr. Fair. Well a very robust discussion on this particular item and, of course, there will be public

comments open later on and people can put their comments during that time period. Again, thank you, Dr. Tapp, for the status report and all the discussions that we had.

At this point we are going to move on to the next item, which is the open forum. Again, back to open forum. If there is anything that the ACMUI members believe or feel that it should be a medical topic of interest for further discussion now or in the future.

Okay. Hearing none we --

MR. MAILMAN: Well --

CHAIRMAN JADVAR: Yes, go ahead, Josh.

MR. MAILMAN: Early on in my tenure at the ACMUI actually with you we presented emergent isotopes and I think maybe we need to re-visit that again because looking at the number of isotopes that are now in use has radically changed from -- When we first did that presentation I am thinking that was almost 2-1/2 years ago and I think we have better data and a better understanding of what's in the clinical trials around the world.

So from that standpoint I suggest that we think about doing, adding an emerging isotope

presentation in the future.

CHAIRMAN JADVAR: Okay. Yes, that's a good point. You are right, this is a very fast moving train. There are a lot of interesting clinical trials going on and there is anticipation that in a relatively short time we are going to have additional indications for some of these tracers and maybe we should re-visit that again. Thank you, Josh. I see Mr. Green.

VICE CHAIRMAN GREEN: Yes, thank you. I just -- I like Josh's suggestion and I would recommend that we don't get into indications or this, you know, compound x is being tried for this clinical indication.

Basically, hey, what's lead-212, what's actinium-225, what's that 227 stuff that could be in there. I think if purely focused on the nuclides as was mentioned I think it would be helpful to the Staff and to other folks that are looking at what's coming down the pike so they might be able to anticipate possible radiological challenges or patient release criteria challenges.

Some of these things may not, of course, make it to market, but there are new nuclides on the

dose calibrator, new nuclides in practice.

CHAIRMAN JADVAR: Yes, very good. Well it could be a combination because, you know, as indications are being approved relatively rapidly we are going to see a lot more patients now in this radiopharmaceutical therapy domain.

So I think a combination of both that Josh and Richard mentioned would be perfect. Any other comments? Zoubir. You are muted, Zoubir.

MR. OUHIB: Sorry about that.

CHAIRMAN JADVAR: Okay. Go ahead.

MR. OUHIB: Yes. Along that line, what you just said, you know, we're seeing so many radiopharmaceutical coming through the pipeline, I think it would be good to have one session, understand the dosimetry of all of these radiopharmaceutical.

I personally know somebody who actually gave supposedly a great, great presentation at the ASTRO meeting. He happened to be a radiation oncologist.

We should really make an effort and have him come educate the group or say -- I think that will give us a better understanding, but also it might give us some tools on wait a minute, we didn't know

this or we didn't know that, and so on and so forth.

That will be applicable to the rules and so on.

CHAIRMAN JADVAR: Okay. We can discuss this with medical team and perhaps we can come up with some sort of a presentation in the future, at one of our meetings in the future. Very good suggestions. Any other comments?

Okay. So let's move on to the last item which is administrative closing. I think Ms. Armstead is going to be taking that on.

MS. ARMSTEAD: Thanks, Dr. Jadvar. Lillian Armstead, ACMUI Coordinator. At this time I have some potential dates for the Spring 2025 ACMUI meeting.

As you can see on the calendar we have April 8th, 10th, and the 29th in the month of April and in the month of May we have the 13th and the 15th as potential dates. This meeting will be the Commissioner's meeting.

The dates you select will be provided to the Staff and the Office of the Secretary and hopefully they will align with one of your proposed dates for the meeting.

CHAIRMAN JADVAR: Okay.

MS. ARMSTEAD: Dr. Jadvar?

CHAIRMAN JADVAR: Yes. Did we ever send a poll of what the preferences are or we have never done that?

MS. ARMSTEAD: You did, Dr. Jadvar, and the ACMUI selected April 8th.

CHAIRMAN JADVAR: April 8, okay.

MS. ARMSTEAD: Mm-hmm.

CHAIRMAN JADVAR: All right. Is everybody agreeable to April 8? Let's see what the panel thinks right now.

DR. EINSTEIN: Yes.

DR. FAIR: Yes.

(Chorus of yes.)

CHAIRMAN JADVAR: Okay.

MR. MAILMAN: So can I understand that April 7th and 8th would be the Commissioner's meeting or the, or is it --

MS. MARTIN: 8th and 9th.

MR. MAILMAN: 8th and 9th.

MS. MARTIN: That's what we --

CHAIRMAN JADVAR: 8th and 9th, so which is Tuesday and Wednesday.

MS. ARMSTEAD: Dr. Jadvar?

CHAIRMAN JADVAR: Yes?

MS. ARMSTEAD: It's going to be the 7th and the 8th.

MS. MARTIN: Oh, is it, okay.

CHAIRMAN JADVAR: Oh, 7th and 8th, right.

(Chorus of yes.)

(Simultaneous speaking.)

CHAIRMAN JADVAR: Monday and Tuesday.

PARTICIPANT: That's a Monday and Tuesday.

CHAIRMAN JADVAR: Okay. Is there anybody who is opposed to this Monday, 7, and Tuesday, 8, of April? Melissa, do you have a -- You had your hand up.

MS. MARTIN: No, I'm fine.

CHAIRMAN JADVAR: All right. You had your hand up.

MS. MARTIN: Oh, that was a mistake.

CHAIRMAN JADVAR: Okay, all right. All right, it looks like everybody is agreeable to April 7 and 8, just a day after my birthday, so that's good. Anything else, Ms. Armstead, as far as administrative closing?

MS. ARMSTEAD: I don't have anything else, Dr. Jadvar.

CHAIRMAN JADVAR: Oh, okay, very good. So we are really at the end of our meeting and before I adjourn the meeting I just want to make sure Mr. Einberg is good with everything. Is there anything else you want to mention, Mr. Einberg, or no?

MR. EINBERG: Yes. Thank you, Dr. Jadvar. Yes, I am good with everything as far as the conduct of the meeting, but I did want to, you know, before we adjourn just thank the ACMUI members, the NRC Staff, as well as the members of the public who have provided meaningful conversations and discussions on the various topics.

So I have nothing else further from the NRC unless Katie has anything. I'm good.

DR. TAPP: The only thing I wanted to add to Mr. Einberg was I just really appreciate everyone's time and your conversation and I really look forward -- While I think this meeting did work out virtually and I am glad to see many of your faces on the screen, I really look forward to seeing everyone in the Spring. Thank you.

CHAIRMAN JADVAR: Okay. Thank you. I

echo the same thing. I want to thank all of the ACMUI panel members, Mr. Einberg, Ms. Silberfeld, Dr. Tapp, Ms. Spence, Mr. DiMarco, Mr. King, Ms. Armstead, and the rest of the NRC Staff and the medical team, and, of course, all of the public members who spoke.

We had very good discussions today and I really appreciate it. With that I adjourn the meeting of the 2024 Fall Session and see you all in the Spring of 2025. Thank you.

(Whereupon, the above-entitled matter went off the record at 4:29 p.m.)

RADIATION PROTECTION ISSUES ASSOCIATED WITH OUTPATIENT TREATMENT OF THYROID CANCER USING HIGH DOSES OF IODINE-131: THE U.S. EXPERIENCE

P.G. CRANE
Counsel for Special Projects
U.S. Nuclear Regulatory Commission (retired)*
Email address: kinderhook46@yahoo.com

For Session "Protecting patients, carers, comforters, and the public in nuclear medicine"

ABSTRACT

The United States Nuclear Regulatory Commission (NRC) sets no maximum activity level for the release of patients treated with radioactive iodine 131 (I-131). For decades, NRC used an activity-based standard, 1110 MBq, but since 1997, it has allowed medical licensees to use a dose-based standard by which patients can be released without regard to activity level, provided that the probable dose to any other person will not exceed 5 mSv. This limit, applicable even to infants and nursing mothers, far exceeds ICRP, IAEA, and NCRP standards. Outpatient treatment has become the norm in the U.S., even for doses of 7400 MBq and above, as insurance companies refuse to pay for inpatient care. Radioactive patients are frequently released to hotels, where they are a hazard to other guests and above all to housekeepers, who are typically women of childbearing age and may be pregnant or nursing. The dose to unsuspecting hotel workers violates a cardinal principle of radiation protection, informed consent. The NRC has also failed to ensure that practitioners and patients receive appropriate guidance about limiting exposure to others. The 15-year U.S. experience with dose-based standards for I-131 suggests that a major revision of the NRC's rules on radioactive patients is overdue.

1. INTRODUCTION

United States law gives the Nuclear Regulatory Commission (NRC), the agency which oversees nuclear power plants, the incidental duty of regulating the use of radioactive materials in medicine [1]. For decades, the NRC and its predecessor, the Atomic Energy Commission (AEC), required hospitalization for all patients administered 1110 MBq or more of iodine 131 (I-131) [2]. In 1997, however, in response to requests from medical licensees, the NRC changed its rules and began allowing doctors to administer high doses of I-131 on an outpatient basis [3]. The NRC's current rules, unchanged since 1997, present safety issues with respect to therapy doses of I-131 for thyroid cancer, therapy doses for hyperthyroidism, and diagnostic doses for thyroid cancer. This paper focuses exclusively on therapy doses for thyroid cancer.

2. DISCUSSION

2.1 The NRC rule change of 1997

Under the NRC rules in place since 1997, medical licensees treating patients with I-131 can choose between using the 1110 MBq activity standard as a default value and using a dose-based standard, under which patients can be released regardless of activity level if they are found unlikely to expose any other person to 5 mSv in a year [4]. This 5 mSv dose limit applies equally to all persons, irrespective of age, pregnancy status, and relationship to the patient. Only if the external dose to others is likely to exceed 1 mSv do the NRC's rules require licensees to provide patients with guidance on precautions for reducing radiation exposure to others.

In 1985, the NRC stated, accurately, that patients treated with I-131 are "a source of external radiation and can be a source of radioactive contamination" [5]. In 1997, however, the NRC declared that internal dose from contamination was insignificant, except for babies and nursing mothers, and stated: "[I]nternal exposures will not be considered in this analysis other than for the breast-feeding infant" [6]. The NRC conceded that exposure to patients' family members could be better controlled in a hospital setting, but pointed out that sending patients home would mean lower radiation doses to frequent hospital visitors, such as members of the clergy, and hospital orderlies [7].

* Current address: 6545 27th Avenue NW, Seattle, WA 98117, USA

The NRC's decision that its limits on I-131 should be made less stringent came just as international and national bodies were moving in the opposite direction, toward **more** stringent controls on the isotope. ICRP 60 (1991) had reduced dose limits to the public to 1 mSv per year, and the IAEA's Basic Safety Standards (1996) prescribed hospitalization for any I-131 treatment of more than 1110 MBq [8, 9]. For many nations, moreover, the 1110 MBq activity limit of the BSS was **insufficiently** strict. As of 1998, activity limits in the EU Member States ranged from 95 to 800 MBq, with most between 400 and 600 MBq [10].

2.2 Effects of the NRC rule change

Once the new rule was in place, many physicians found that insurance companies were refusing to pay for inpatient treatment with I-131 on the grounds that it was no longer necessary. For a doctor to insist on hospitalization was, therefore, to risk not being reimbursed. At a meeting of the NRC's Advisory Committee on the Medical Uses of Isotopes in 2007, two doctors (both supporters of the current rule, it should be stressed) candidly acknowledged the dominant role of insurers in the decision whether to hospitalize patients for I-131 therapy [1] [11].

A recent survey of 311 health professionals found that 15% **never** hospitalized patients for I-131 doses below 7363 MBq; 6% **never** hospitalized for doses below 11,063 MBq; and only 22% **invariably** hospitalized for doses between 7363 and 11,063 MBq [12]. In 2002, after receiving reports that released I-131 patients were exposing members of the public to radiation, the NRC Commissioners considered and rejected a proposal to require a report to the NRC if a patient caused a dose to another person of 50 mSv or more [13]. If hard data pointing to the rule's adverse effects is sparse, it is in part because the NRC has chosen not to receive it.

2.3 Radioactive patients in hotels

In changing its rules, the NRC assumed that patients would either meet the criteria for release, in which case they would go directly home, or remain hospitalized. It had not foreseen a third possibility: that some patients, either because the criteria for home release could not be met or because they lived far away, might be sent to hotels. This presents serious risks to hotel chambermaids, who in the U.S. are typically women of childbearing age. These workers do not "knowingly and willingly" accept their exposure to radiation. Unlike hospital staff and the families of patients sent home, they are unaware of the contamination and cannot take even basic precautions. A chambermaid may receive a substantial internal dose, and if she is pregnant or nursing, her baby's thyroid may also be affected. If the hotel is near a cancer center, moreover, she may clean numerous contaminated rooms in a year. Guests in adjoining rooms may also receive external radiation doses through the walls. Current estimates are that between 4 and 5 percent of patients go to hotels after receiving therapeutic doses of I-131 [14].

---

[1] Dr. Douglas Eggli: "We can't get a preceptor to admit most patients to the hospital anymore from the insurance companies since the release rule went into effect. ... If I am admitting somebody [with] less than 200 millicuries [7400 MBq], the chances that I can get an insurance authorization for a hospitalization to isolate them, **even when I have family situations that require it**, it's fighting tooth and nail with the insurance companies...."

Dr. Leon Malmud: "It is not now possible to treat a patient at our hospital and many hospitals in the Philadelphia area with I-131 in high doses for thyroid cancer because in order to do that a patient has to be isolated in a room which itself is isolated from the rooms next door. Therefore, **all patients are discharged upon treatment. We whisk them out the doors as fast as possible**. They are given outpatient doses between 100 and 200 millicuries [3700 MBq and 7400 MBq] of I-131, depending upon the extent of their thyroid cancer and occasionally, even higher doses. ... There's also an impossibility of keeping the patient in the hospital since the insurer will not cover it. The insurer will not cover it, will not cover the inpatient stay. It will cover the treatment, but not the inpatient stay. ... Being in the hospital today in most situations is an absolute impossibility. The nursing staff won't care for the patient. The other personnel in the hospital don't want to be near the patient. ... Within the hospital, this patient is an unwelcome guest currently. **Uninsured, their wonderful insurance stops because it's no longer necessary for them to be an inpatient**. The health care workers are concerned and the hospital will not allow them to stay." [Emphasis added.] [Transcript at pp. 126-130.]

In 2009, the New York City Department of Health issued a directive to medical licensees warning in forceful terms against sending radioactive patients to hotels [15]. In 2011, the NRC published a non-binding notice that "strongly discouraged" licensees from doing so [16]. The practice nevertheless continues, and even has defenders. In a March 2011 article in an online medical journal, *ASCO Post,* Dr. R. Michael Tuttle, a distinguished thyroidologist at Memorial Sloan-Kettering Cancer Center in New York, was quoted as saying that Sloan-Kettering gives outpatient doses of up to 7400 MBq of I-131 [17]. "We are absolutely comfortable that it is safe for these patients to be in a hotel," Dr. Tuttle reportedly said, adding, "Many patients don't have a choice, because they are flying in for their treatments." In context, the implication was that if they returned home to countries with stricter standards, airport radiation detectors would identify them. Currently, the chance that a radioactive patient will be identified in a hotel or motel is virtually nil, unless, as happened in Illinois in 2007, the person occupying a room just vacated by an I-131 patient happens to work in a nuclear power plant, and the contamination on his skin sets off the plant's radiation alarms [18].

2.4 The NRC reaffirms the 1997 rule

In 2005, the present writer, a retired NRC lawyer who had in the past received I-131 treatments totaling over 28,000 MBq, filed a petition asking the NRC to revisit its rules on release of radioactive patients [18]. A supplementary filing in 2006 raised the issue of radioactive patients in hotels and the resulting risk to chambermaids [19]. The NRC denied the petition in 2008, in a decision that rejected the idea of adopting a 1mSv limit for infants and children, and made no mention of hotels [20]. (In 2009, a federal court dismissed the resulting appeal on procedural grounds, accepting the NRC's argument that because the petitioner's I-131 treatments had occurred long in the past, he was insufficiently affected by the NRC's rule to be allowed to challenge it in court [21].) At the same time that it denied the petition, the NRC issued a "Regulatory Issue Summary" [22] that drew medical licensees' attention to ICRP 94 [23] and ICRP 103 [24] and their warnings about the hazard to infants and children from I-131 patients. Acknowledging that the 1997 rule had been based on the assumption that internal dose presented insignificant risks, the NRC notice asked doctors to "consider" hospitalizing patients with children at home. It made clear, however, that the request was not binding.

2.5 The current situation

Not only is U.S. practice regarding radioactive patients unconservative by comparison with world practice, it has failed to provide appropriate safety guidance to aid licensees and patients in minimizing radiation doses to others. Although NCRP 155 [25] (a report which reaffirms earlier NCRP recommendations of a 1 mSv dose limit for children, pregnant women, and the public) includes sample precautions for thyroid patients treated with I-131, the NRC has not recommended their use. Instead, current NRC guidance suggests that licensees obtain and use a pamphlet issued in **1987**, when the 1110 MBq activity standard still applied [26]. The NRC's approach to human I-131 patients contrasts with its stringent rules for cats treated with I-131 for feline hyperthyroidism Typically administered doses of 111 to 222 MBq, they must be hospitalized for a minimum of 72 hours [27].

3. CONCLUSION

The IAEA has recently revised the BSS to eliminate the 1110 MBq activity limit on I-131, and endorsed the dose-based approach to protecting the public from treated patients [28]. In its February 23, 2010 "Position statement on release of patients after radionuclide therapy" [29], the IAEA implied that "global harmonization" had been achieved among ICRP 94, SRS 63 [30], EC publication Radiation Protection 97 [10], and the NRC's 1997 guidelines. Any such apparent harmonization is purely illusory, however, so long as the IAEA adheres to the 1 mSv dose standard for exposure to the public, while the NRC's standard is 5 mSv, even for infants and pregnant women. The IAEA and ICRP have yet to address the pressing issue of highly radioactive patients sent to hotels. The exposure of unsuspecting and unprotected hotel chambermaids to I-131 contamination is medically and ethically unacceptable and deserves condemnation. A revision of the NRC's regulations to bring them into conformity with international norms is overdue.

REFERENCES

[1] UNITED STATES CONGRESS, Atomic Energy Act of 1954, 42 United States Code [U.S.C.] 2201 et seq., Energy Reorganization Act of 1974, 42 U.S.C. 5801.
[2] OFFICE OF THE FEDERAL REGISTER, 51 Federal Register [FR] 36932 (Oct. 16, 1986).
[3] U.S. NUCLEAR REGULATORY COMMISSION, Criteria for the Release of Individuals Administered Radioactive Material, 62 FR 4120 (Jan. 29, 1997).
[4] U.S. NUCLEAR REGULATORY COMMISSION, 10 Code of Federal Regulations 35.75.
[5] U.S. NUCLEAR REGULATORY COMMISSION, 50 FR 30616 (July 26, 1985).
[6] U.S. NUCLEAR REGULATORY COMMISSION, NUREG-1492, Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material (Feb. 1997) 16.
[7] U.S. NUCLEAR REGULATORY COMMISSION, 62 FR 4123 (Jan. 29, 1997).
[8] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, ICRP Publication 60: 1990 Recommendations of the ICRP, Annals of the ICRP Volume 21/1-3, Pergamon Press, Oxford (1991).
[9] FOOD AND AGRICULTURAL ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OGANISATION, NUCLEAR ENERGY AGENCY OF THE ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, IAEA, Vienna (1996).
[10] EUROPEAN COMMISSION, Radiation Protection 97, Radiation Protection Following Iodine-131 Therapy (exposures due to out-patients or discharged in-patients), Office for Official Publications of the European Communities, Luxembourg (1998).
[11] U.S. NUCLEAR REGULATORY COMMISSION, Advisory Committee on the Medical Uses of Isotopes, Meeting Transcript (Oct. 27, 2007) 177, 187-191.
[12] GREENLEE, C. et al., current safety practices relating to I-131 administration for diseases of the thyroid: a survey of physicians and allied practitioners, Thyroid **21** (2011) 151.
[13] U.S. NUCLEAR REGULATORY COMMISSION, Commission Voting Record, SECY-02-0111, Proposed rule to amend 10 CFR Part 35 to require licensees to notify of an individual receiving a dose exceeding 50 millisieverts (5 rem) from a patient released under 10 CFR 35.75 (Aug. 27, 2002).
[14] STERNBERG, S., It kills thyroid cancer, but is radiation safe?, USATODAY (Nov. 19, 2007).
[15] NEW YORK CITY DEPT. OF HEALTH AND MENTAL HYGIENE, Information Notice ORH 2009-01 (June 29, 2009).
[16] U.S. NUCLEAR REGULATORY COMMISSION, Regulatory Issue Summary 2011-01, NRC Policy on Release of Iodine-131 Therapy Patients Under 10 CFR 35.75 to Locations Other Than Private Residences (Jan. 25, 2011).
[17] BATH, C., How can patients who receive radioactive iodine treatment for thyroid cancer reduce the chance of radiation risks to others, ASCO POST 2:4 (March 2011).
[18] ALONSO-ZALDIVAR, R., Alarm over radiation from thyroid cancer patients, Associated Press (Oct. 20, 2010).
[19] CRANE, P.G., Petition for Partial Revocation of the Patient Release Criteria Rule (Sep. 2, 2005); see 70 FR 75752 (Dec. 2, 2005); Comment #11 on Petition, NRC Docket No. PRM-35-18 (Jan. 30, 2006).
[20] U.S. NUCLEAR REGULATORY COMMISSION, Peter G. Crane, Denial of Petition for Rulemaking, 73 FR 29445 (May 21, 2008).
[21] U.S. COURT OF APPEALS FOR THE NINTH CIRCUIT, *Peter G. Crane v. U.S. Nuclear Regulatory Commission et al.*, No. 08-72973 (unpublished memorandum, Aug. 19, 2009).
[22] U.S. NUCLEAR REGULATORY COMMISSION, Regulatory Issue Summary 2008-11, Precautions to Protect Children Who May Come in Contact with Patients Released After Therapeutic Administration of Iodine-131 (May 12, 2008).
[23] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Release of Patients after Therapy with Unsealed Radionuclides, ICRP Publication 94, Annals of the ICRP 34(2), Pergamon Press, Oxford (2004).
[24] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, The 2007 Recommendations of the International Commission on Radiological Protection, ICRP Publication No. 103, Ann. ICRP 37 I, Elsevier, Amsterdam and New York (2007).

[25] NATIONAL COUNCIL ON RADIATION PROTECTION & MEASUREMENTS, Management of Radionuclide Therapy Patients, NCRP Report No. 155, NCRP, Bethesda (2006).
[26] U.S. NUCLEAR REGULATORY COMMISSION, Consolidated Guidance About Materials Licenses (NUREG-1556), Vol. 9, Rev. 2, App. U, U-11.
[27] UNITED STATES NUCLEAR REGULATORY COMMISSION, Memorandum to Thomas Essig re Summary of July 9, 2002, Public Meeting with Radiocat, LLC, re Release of Cats Treated with I-131.
[28] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection and Safety of Radiation Sources, International Basic Safety Standards, Interim Edition, IAEA Safety Standards Series No. GSR Part 3 (Interim), IAEA, Vienna (2011).
[29] INTERNATIONAL ATOMIC ENERGY AGENCY, Position statement on release of patients after radionuclide therapy, IAEA, Vienna (2010-02-23).
[30] INTERNATIONAL ATOMIC ENERGY AGENCY, Release of Patients after Radionuclide Therapy, Safety Reports Series No. 63, IAEA, Vienna (2009).

BIBLIOGRAPHY

AMERICAN THYROID ASSOCIATION et al., Joint Statement on Radioactive Precautions Following Radioactive Iodine Therapy (Oct. 20, 2010)

BARRINGTON, S.F.., et al., Measurement of the internal dose to families of outpatients treated with I-131 for hyperthyroidism, Eur. J. Nucl. Med. Mol. Imaging **35** (2008) 2097-2104.

BARRINGTON, S.F., et al., Radiation exposure of the families of outpatients treated with radioiodine (iodine-131) for hyperthyroidism, Eur. J. Nuc. Med. **26** (1999) 686-692.

BEASLEY, C.W., et al., Release instructions for hyperthyroid patients treated with I-131, Thyroid **21** (2911) 1163-1165.

BRITISH INSTITUTE OF RADIOLOGY, Working Party of the Radiation Protection Committee, Patients leaving hospital after administration of radioactive substances, Br. J. Radiol. **72** (1999) 121-125.

DE KLERK, J.M.H., I-131 Therapy: Inpatient or outpatient? J. Nucl. Med. **41** (2000) 1876-1878.

EUROPEAN COMMISSION, Radiation Protection 100, Guidance for protection of unborn children and infants irradiated due to parental medical exposures, Office for Official Publications of the European Communities, Luxembourg (1998).

GRIGSBY, P.W., et al., Radiation exposure from outpatient radioactive iodine (I-131) therapy for thyroid carcinoma, J. Am. Med. Assn. **283** 17 (2000) 2272-4.

HENNESSEY, J.V., et al., comments regarding practice recommendations of the American Thyroid Association for radiation safety in the treatment of thyroid disease with radioiodine, Thyroid **11** (2912) 336-338.

JACOBSON, A.P., et al., Contamination of the home environment by patients treated with iodine-131: initial results, Am. J. Public Health, **68** 3 (March 1978) 225-230.

KLOOS, R., Survey of radioiodine therapy safety practices highlights the need for user-friendly recommendations, Thyroid **21** (2011) 97-99.

LANGHORST, S., et al., Advisory Committee on the Medical Use of Isotopes (ACMUI), Patient Release Report (2010)

MARKEY, E.J., "Radioactive Roulette: How the Nuclear Regulatory Commission's Cancer Patient Radiation Rules Gamble with Public Health and Safety," report by staff of Rep. Markey, U.S. House of Representatives (2010)

MONSIEURS, M., Real-life radiation to relatives of patients treated with iodine-131: a study in eight centres in Flanders (Belgium), Eur. J. Nucl. Med. Mol. Imaging **25** (1998) 1368-1376.

PANZEGRAU, B., et al., Outpatient therapeutic I-131 for thyroid cancer, J. Nucl. Med. Technol. **33** (2005) 28-30.

REINERS, C., LAßMANN, M., Radioiodine (I-131) treatment of hyperthyroidism: radiation protection and quality assurance, Eur. J. Nuc. Med. **26** (1999) 683-685.

RÉMY, H., et al., Thyroid cancer patients treated with I-131: radiation dose to relatives after discharge from the hospital, Thyroid **22** (2012) 59-63.

SHAPIRO, D., MOELLER, D., population exposures from radionuclides in medicine – as low as reasonably achievable? Am. J. Public Health **68** (1978) 219.

SIEGEL, J.A., et al., licensee over-reliance on conservatisms in NRC guidance regarding the release of patients treated with I-131, Health Phys. **93** 6 (2007) 667-677.

SISSON, J.C., et al., Radiation safety in the treatment of patients with thyroid diseases by radioiodine I-131: practice recommendations of the American Thyroid Association, Thyroid **21** (2011) 335-346; *see also* Correction, Thyroid **21** (2011) 689.

RADIATION PROTECTION ISSUES ASSOCIATED WITH OUTPATIENT TREATMENT OF THYROID CANCER USING HIGH DOSES OF IODINE-131: THE U.S. EXPERIENCE

P.G. CRANE
Counsel for Special Projects
U.S. Nuclear Regulatory Commission (retired)*
Email address: kinderhook46@yahoo.com

For Session "Protecting patients, carers, comforters, and the public in nuclear medicine"

ABSTRACT

The United States Nuclear Regulatory Commission (NRC) sets no maximum activity level for the release of patients treated with radioactive iodine 131 (I-131). For decades, NRC used an activity-based standard, 1110 MBq, but since 1997, it has allowed medical licensees to use a dose-based standard by which patients can be released without regard to activity level, provided that the probable dose to any other person will not exceed 5 mSv. This limit, applicable even to infants and nursing mothers, far exceeds ICRP, IAEA, and NCRP standards. Outpatient treatment has become the norm in the U.S., even for doses of 7400 MBq and above, as insurance companies refuse to pay for inpatient care. Radioactive patients are frequently released to hotels, where they are a hazard to other guests and above all to housekeepers, who are typically women of childbearing age and may be pregnant or nursing. The dose to unsuspecting hotel workers violates a cardinal principle of radiation protection, informed consent. The NRC has also failed to ensure that practitioners and patients receive appropriate guidance about limiting exposure to others. The 15-year U.S. experience with dose-based standards for I-131 suggests that a major revision of the NRC's rules on radioactive patients is overdue.

1. INTRODUCTION

United States law gives the Nuclear Regulatory Commission (NRC), the agency which oversees nuclear power plants, the incidental duty of regulating the use of radioactive materials in medicine [1]. For decades, the NRC and its predecessor, the Atomic Energy Commission (AEC), required hospitalization for all patients administered 1110 MBq or more of iodine 131 (I-131) [2]. In 1997, however, in response to requests from medical licensees, the NRC changed its rules and began allowing doctors to administer high doses of I-131 on an outpatient basis [3]. The NRC's current rules, unchanged since 1997, present safety issues with respect to therapy doses of I-131 for thyroid cancer, therapy doses for hyperthyroidism, and diagnostic doses for thyroid cancer. This paper focuses exclusively on therapy doses for thyroid cancer.

2. DISCUSSION

2.1 The NRC rule change of 1997

Under the NRC rules in place since 1997, medical licensees treating patients with I-131 can choose between using the 1110 MBq activity standard as a default value and using a dose-based standard, under which patients can be released regardless of activity level if they are found unlikely to expose any other person to 5 mSv in a year [4]. This 5 mSv dose limit applies equally to all persons, irrespective of age, pregnancy status, and relationship to the patient. Only if the external dose to others is likely to exceed 1 mSv do the NRC's rules require licensees to provide patients with guidance on precautions for reducing radiation exposure to others.

In 1985, the NRC stated, accurately, that patients treated with I-131 are "a source of external radiation and can be a source of radioactive contamination" [5]. In 1997, however, the NRC declared that internal dose from contamination was insignificant, except for babies and nursing mothers, and stated: "[I]nternal exposures will not be considered in this analysis other than for the breast-feeding infant" [6]. The NRC conceded that exposure to patients' family members could be better controlled in a hospital setting, but pointed out that sending patients home would mean lower radiation doses to frequent hospital visitors, such as members of the clergy, and hospital orderlies [7].

* Current address: 6545 27th Avenue NW, Seattle, WA 98117, USA

The NRC's decision that its limits on I-131 should be made less stringent came just as international and national bodies were moving in the opposite direction, toward **more** stringent controls on the isotope. ICRP 60 (1991) had reduced dose limits to the public to 1 mSv per year, and the IAEA's Basic Safety Standards (1996) prescribed hospitalization for any I-131 treatment of more than 1110 MBq [8, 9]. For many nations, moreover, the 1110 MBq activity limit of the BSS was **insufficiently** strict. As of 1998, activity limits in the EU Member States ranged from 95 to 800 MBq, with most between 400 and 600 MBq [10].

2.2 Effects of the NRC rule change

Once the new rule was in place, many physicians found that insurance companies were refusing to pay for inpatient treatment with I-131 on the grounds that it was no longer necessary. For a doctor to insist on hospitalization was, therefore, to risk not being reimbursed. At a meeting of the NRC's Advisory Committee on the Medical Uses of Isotopes in 2007, two doctors (both supporters of the current rule, it should be stressed) candidly acknowledged the dominant role of insurers in the decision whether to hospitalize patients for I-131 therapy [1] [11].

A recent survey of 311 health professionals found that 15% **never** hospitalized patients for I-131 doses below 7363 MBq; 6% **never** hospitalized for doses below 11,063 MBq; and only 22% **invariably** hospitalized for doses between 7363 and 11,063 MBq [12]. In 2002, after receiving reports that released I-131 patients were exposing members of the public to radiation, the NRC Commissioners considered and rejected a proposal to require a report to the NRC if a patient caused a dose to another person of 50 mSv or more [13]. If hard data pointing to the rule's adverse effects is sparse, it is in part because the NRC has chosen not to receive it.

2.3 Radioactive patients in hotels

In changing its rules, the NRC assumed that patients would either meet the criteria for release, in which case they would go directly home, or remain hospitalized. It had not foreseen a third possibility: that some patients, either because the criteria for home release could not be met or because they lived far away, might be sent to hotels. This presents serious risks to hotel chambermaids, who in the U.S. are typically women of childbearing age. These workers do not "knowingly and willingly" accept their exposure to radiation. Unlike hospital staff and the families of patients sent home, they are unaware of the contamination and cannot take even basic precautions. A chambermaid may receive a substantial internal dose, and if she is pregnant or nursing, her baby's thyroid may also be affected. If the hotel is near a cancer center, moreover, she may clean numerous contaminated rooms in a year. Guests in adjoining rooms may also receive external radiation doses through the walls. Current estimates are that between 4 and 5 percent of patients go to hotels after receiving therapeutic doses of I-131 [14].

---

[1] Dr. Douglas Eggli: "We can't get a preceptor to admit most patients to the hospital anymore from the insurance companies since the release rule went into effect. ... If I am admitting somebody [with] less than 200 millicuries [7400 MBq], the chances that I can get an insurance authorization for a hospitalization to isolate them, **even when I have family situations that require it**, it's fighting tooth and nail with the insurance companies...."

Dr. Leon Malmud: "It is not now possible to treat a patient at our hospital and many hospitals in the Philadelphia area with I-131 in high doses for thyroid cancer because in order to do that a patient has to be isolated in a room which itself is isolated from the rooms next door. Therefore, **all patients are discharged upon treatment. We whisk them out the doors as fast as possible**. They are given outpatient doses between 100 and 200 millicuries [3700 MBq and 7400 MBq] of I-131, depending upon the extent of their thyroid cancer and occasionally, even higher doses. ... There's also an impossibility of keeping the patient in the hospital since the insurer will not cover it. The insurer will not cover it, will not cover the inpatient stay. It will cover the treatment, but not the inpatient stay. ... Being in the hospital today in most situations is an absolute impossibility. The nursing staff won't care for the patient. The other personnel in the hospital don't want to be near the patient. ... Within the hospital, this patient is an unwelcome guest currently. **Uninsured, their wonderful insurance stops because it's no longer necessary for them to be an inpatient**. The health care workers are concerned and the hospital will not allow them to stay." [Emphasis added.] [Transcript at pp. 126-130.]

In 2009, the New York City Department of Health issued a directive to medical licensees warning in forceful terms against sending radioactive patients to hotels [15]. In 2011, the NRC published a non-binding notice that "strongly discouraged" licensees from doing so [16]. The practice nevertheless continues, and even has defenders. In a March 2011 article in an online medical journal, *ASCO Post,* Dr. R. Michael Tuttle, a distinguished thyroidologist at Memorial Sloan-Kettering Cancer Center in New York, was quoted as saying that Sloan-Kettering gives outpatient doses of up to 7400 MBq of I-131 [17]. "We are absolutely comfortable that it is safe for these patients to be in a hotel," Dr. Tuttle reportedly said, adding, "Many patients don't have a choice, because they are flying in for their treatments." In context, the implication was that if they returned home to countries with stricter standards, airport radiation detectors would identify them. Currently, the chance that a radioactive patient will be identified in a hotel or motel is virtually nil, unless, as happened in Illinois in 2007, the person occupying a room just vacated by an I-131 patient happens to work in a nuclear power plant, and the contamination on his skin sets off the plant's radiation alarms [18].

2.4 The NRC reaffirms the 1997 rule

In 2005, the present writer, a retired NRC lawyer who had in the past received I-131 treatments totaling over 28,000 MBq, filed a petition asking the NRC to revisit its rules on release of radioactive patients [18]. A supplementary filing in 2006 raised the issue of radioactive patients in hotels and the resulting risk to chambermaids [19]. The NRC denied the petition in 2008, in a decision that rejected the idea of adopting a 1mSv limit for infants and children, and made no mention of hotels [20]. (In 2009, a federal court dismissed the resulting appeal on procedural grounds, accepting the NRC's argument that because the petitioner's I-131 treatments had occurred long in the past, he was insufficiently affected by the NRC's rule to be allowed to challenge it in court [21].) At the same time that it denied the petition, the NRC issued a "Regulatory Issue Summary" [22] that drew medical licensees' attention to ICRP 94 [23] and ICRP 103 [24] and their warnings about the hazard to infants and children from I-131 patients. Acknowledging that the 1997 rule had been based on the assumption that internal dose presented insignificant risks, the NRC notice asked doctors to "consider" hospitalizing patients with children at home. It made clear, however, that the request was not binding.

2.5 The current situation

Not only is U.S. practice regarding radioactive patients unconservative by comparison with world practice, it has failed to provide appropriate safety guidance to aid licensees and patients in minimizing radiation doses to others. Although NCRP 155 [25] (a report which reaffirms earlier NCRP recommendations of a 1 mSv dose limit for children, pregnant women, and the public) includes sample precautions for thyroid patients treated with I-131, the NRC has not recommended their use. Instead, current NRC guidance suggests that licensees obtain and use a pamphlet issued in **1987**, when the 1110 MBq activity standard still applied [26]. The NRC's approach to human I-131 patients contrasts with its stringent rules for cats treated with I-131 for feline hyperthyroidism Typically administered doses of 111 to 222 MBq, they must be hospitalized for a minimum of 72 hours [27].

3. CONCLUSION

The IAEA has recently revised the BSS to eliminate the 1110 MBq activity limit on I-131, and endorsed the dose-based approach to protecting the public from treated patients [28]. In its February 23, 2010 "Position statement on release of patients after radionuclide therapy" [29], the IAEA implied that "global harmonization" had been achieved among ICRP 94, SRS 63 [30], EC publication Radiation Protection 97 [10], and the NRC's 1997 guidelines. Any such apparent harmonization is purely illusory, however, so long as the IAEA adheres to the 1 mSv dose standard for exposure to the public, while the NRC's standard is 5 mSv, even for infants and pregnant women. The IAEA and ICRP have yet to address the pressing issue of highly radioactive patients sent to hotels. The exposure of unsuspecting and unprotected hotel chambermaids to I-131 contamination is medically and ethically unacceptable and deserves condemnation. A revision of the NRC's regulations to bring them into conformity with international norms is overdue.

REFERENCES

[1] UNITED STATES CONGRESS, Atomic Energy Act of 1954, 42 United States Code [U.S.C.] 2201 et seq., Energy Reorganization Act of 1974, 42 U.S.C. 5801.
[2] OFFICE OF THE FEDERAL REGISTER, 51 Federal Register [FR] 36932 (Oct. 16, 1986).
[3] U.S. NUCLEAR REGULATORY COMMISSION, Criteria for the Release of Individuals Administered Radioactive Material, 62 FR 4120 (Jan. 29, 1997).
[4] U.S. NUCLEAR REGULATORY COMMISSION, 10 Code of Federal Regulations 35.75.
[5] U.S. NUCLEAR REGULATORY COMMISSION, 50 FR 30616 (July 26, 1985).
[6] U.S. NUCLEAR REGULATORY COMMISSION, NUREG-1492, Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material (Feb. 1997) 16.
[7] U.S. NUCLEAR REGULATORY COMMISSION, 62 FR 4123 (Jan. 29, 1997).
[8] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, ICRP Publication 60: 1990 Recommendations of the ICRP, Annals of the ICRP Volume 21/1-3, Pergamon Press, Oxford (1991).
[9] FOOD AND AGRICULTURAL ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OGANISATION, NUCLEAR ENERGY AGENCY OF THE ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, IAEA, Vienna (1996).
[10] EUROPEAN COMMISSION, Radiation Protection 97, Radiation Protection Following Iodine-131 Therapy (exposures due to out-patients or discharged in-patients), Office for Official Publications of the European Communities, Luxembourg (1998).
[11] U.S. NUCLEAR REGULATORY COMMISSION, Advisory Committee on the Medical Uses of Isotopes, Meeting Transcript (Oct. 27, 2007) 177, 187-191.
[12] GREENLEE, C. et al., current safety practices relating to I-131 administration for diseases of the thyroid: a survey of physicians and allied practitioners, Thyroid **21** (2011) 151.
[13] U.S. NUCLEAR REGULATORY COMMISSION, Commission Voting Record, SECY-02-0111, Proposed rule to amend 10 CFR Part 35 to require licensees to notify of an individual receiving a dose exceeding 50 millisieverts (5 rem) from a patient released under 10 CFR 35.75 (Aug. 27, 2002).
[14] STERNBERG, S., It kills thyroid cancer, but is radiation safe?, USATODAY (Nov. 19, 2007).
[15] NEW YORK CITY DEPT. OF HEALTH AND MENTAL HYGIENE, Information Notice ORH 2009-01 (June 29, 2009).
[16] U.S. NUCLEAR REGULATORY COMMISSION, Regulatory Issue Summary 2011-01, NRC Policy on Release of Iodine-131 Therapy Patients Under 10 CFR 35.75 to Locations Other Than Private Residences (Jan. 25, 2011).
[17] BATH, C., How can patients who receive radioactive iodine treatment for thyroid cancer reduce the chance of radiation risks to others, ASCO POST 2:4 (March 2011).
[18] ALONSO-ZALDIVAR, R., Alarm over radiation from thyroid cancer patients, Associated Press (Oct. 20, 2010).
[19] CRANE, P.G., Petition for Partial Revocation of the Patient Release Criteria Rule (Sep. 2, 2005); see 70 FR 75752 (Dec. 2, 2005); Comment #11 on Petition, NRC Docket No. PRM-35-18 (Jan. 30, 2006).
[20] U.S. NUCLEAR REGULATORY COMMISSION, Peter G. Crane, Denial of Petition for Rulemaking, 73 FR 29445 (May 21, 2008).
[21] U.S. COURT OF APPEALS FOR THE NINTH CIRCUIT, *Peter G. Crane v. U.S. Nuclear Regulatory Commission et al.*, No. 08-72973 (unpublished memorandum, Aug. 19, 2009).
[22] U.S. NUCLEAR REGULATORY COMMISSION, Regulatory Issue Summary 2008-11, Precautions to Protect Children Who May Come in Contact with Patients Released After Therapeutic Administration of Iodine-131 (May 12, 2008).
[23] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Release of Patients after Therapy with Unsealed Radionuclides, ICRP Publication 94, Annals of the ICRP 34(2), Pergamon Press, Oxford (2004).
[24] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, The 2007 Recommendations of the International Commission on Radiological Protection, ICRP Publication No. 103, Ann. ICRP 37 I, Elsevier, Amsterdam and New York (2007).

[25] NATIONAL COUNCIL ON RADIATION PROTECTION & MEASUREMENTS, Management of Radionuclide Therapy Patients, NCRP Report No. 155, NCRP, Bethesda (2006).
[26] U.S. NUCLEAR REGULATORY COMMISSION, Consolidated Guidance About Materials Licenses (NUREG-1556), Vol. 9, Rev. 2, App. U, U-11.
[27] UNITED STATES NUCLEAR REGULATORY COMMISSION, Memorandum to Thomas Essig re Summary of July 9, 2002, Public Meeting with Radiocat, LLC, re Release of Cats Treated with I-131.
[28] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection and Safety of Radiation Sources, International Basic Safety Standards, Interim Edition, IAEA Safety Standards Series No. GSR Part 3 (Interim), IAEA, Vienna (2011).
[29] INTERNATIONAL ATOMIC ENERGY AGENCY, Position statement on release of patients after radionuclide therapy, IAEA, Vienna (2010-02-23).
[30] INTERNATIONAL ATOMIC ENERGY AGENCY, Release of Patients after Radionuclide Therapy, Safety Reports Series No. 63, IAEA, Vienna (2009).

BIBLIOGRAPHY

AMERICAN THYROID ASSOCIATION et al., Joint Statement on Radioactive Precautions Following Radioactive Iodine Therapy (Oct. 20, 2010)

BARRINGTON, S.F.., et al., Measurement of the internal dose to families of outpatients treated with I-131 for hyperthyroidism, Eur. J. Nucl. Med. Mol. Imaging **35** (2008) 2097-2104.

BARRINGTON, S.F., et al., Radiation exposure of the families of outpatients treated with radioiodine (iodine-131) for hyperthyroidism, Eur. J. Nuc. Med. **26** (1999) 686-692.

BEASLEY, C.W., et al., Release instructions for hyperthyroid patients treated with I-131, Thyroid **21** (2911) 1163-1165.

BRITISH INSTITUTE OF RADIOLOGY, Working Party of the Radiation Protection Committee, Patients leaving hospital after administration of radioactive substances, Br. J. Radiol. **72** (1999) 121-125.

DE KLERK, J.M.H., I-131 Therapy: Inpatient or outpatient? J. Nucl. Med. **41** (2000) 1876-1878.

EUROPEAN COMMISSION, Radiation Protection 100, Guidance for protection of unborn children and infants irradiated due to parental medical exposures, Office for Official Publications of the European Communities, Luxembourg (1998).

GRIGSBY, P.W., et al., Radiation exposure from outpatient radioactive iodine (I-131) therapy for thyroid carcinoma, J. Am. Med. Assn. **283** 17 (2000) 2272-4.

HENNESSEY, J.V., et al., comments regarding practice recommendations of the American Thyroid Association for radiation safety in the treatment of thyroid disease with radioiodine, Thyroid **11** (2912) 336-338.

JACOBSON, A.P., et al., Contamination of the home environment by patients treated with iodine-131: initial results, Am. J. Public Health, **68** 3 (March 1978) 225-230.

KLOOS, R., Survey of radioiodine therapy safety practices highlights the need for user-friendly recommendations, Thyroid **21** (2011) 97-99.

LANGHORST, S., et al., Advisory Committee on the Medical Use of Isotopes (ACMUI), Patient Release Report (2010)

MARKEY, E.J., "Radioactive Roulette: How the Nuclear Regulatory Commission's Cancer Patient Radiation Rules Gamble with Public Health and Safety," report by staff of Rep. Markey, U.S. House of Representatives (2010)

MONSIEURS, M., Real-life radiation to relatives of patients treated with iodine-131: a study in eight centres in Flanders (Belgium), Eur. J. Nucl. Med. Mol. Imaging **25** (1998) 1368-1376.

PANZEGRAU, B., et al., Outpatient therapeutic I-131 for thyroid cancer, J. Nucl. Med. Technol. **33** (2005) 28-30.

REINERS, C., LAßMANN, M., Radioiodine (I-131) treatment of hyperthyroidism: radiation protection and quality assurance, Eur. J. Nuc. Med. **26** (1999) 683-685.

RÉMY, H., et al., Thyroid cancer patients treated with I-131: radiation dose to relatives after discharge from the hospital, Thyroid **22** (2012) 59-63.

SHAPIRO, D., MOELLER, D., population exposures from radionuclides in medicine – as low as reasonably achievable? Am. J. Public Health **68** (1978) 219.

SIEGEL, J.A., et al., licensee over-reliance on conservatisms in NRC guidance regarding the release of patients treated with I-131, Health Phys. **93** 6 (2007) 667-677.

SISSON, J.C., et al., Radiation safety in the treatment of patients with thyroid diseases by radioiodine I-131: practice recommendations of the American Thyroid Association, Thyroid **21** (2011) 335-346; *see also* Correction, Thyroid **21** (2011) 689.