

Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: ADVISORY COMMITTEE ON THE MEDICAL
 USES OF ISOTOPES

Docket Number: N/A

Location: teleconference

Date: 05-15-2023

Work Order No.: NRC-2379

Pages 1-206

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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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OPEN SESSION

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MONDAY,

MAY 15, 2023

+ + + + +

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

MEMBERS PRESENT:

DARLENE F. METTER, M.D., Chair

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

REBECCA ALLEN, Member

ANDREW EINSTEIN, M.D., Member

RICHARD L. GREEN, Member

RICHARD HARVEY, Ph.D., Member

JOSH MAILMAN, Member

MELISSA C. MARTIN, Member

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

ZOUBIR OUHIB, Member

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MEGAN L. SHOBER, Member

HARVEY B. WOLKOV, M.D., Member

NRC STAFF PRESENT:

CHRISTIAN EINBERG, Designated Federal

Official, NMSS

MARYANN AYOADE, NMSS

DANIEL DiMARCO, NMSS

EDWARD HARVEY, RES

VINCE HOLAHAN, NMSS

CHRISTINE PINEDA, NMSS

DANIEL SHAW, NMSS

KATHERINE TAPP, Ph.D., NMSS

CELIMAR VALENTIN-RODRIGUEZ, Ph.D., NMSS

KEVIN WILLIAMS, NMSS

IRENE WU, NMSS

ALSO PRESENT:

JOHN ANGLE, University of Virginia

ASHLEY COCKERHAM, Public Participant

RALPH LIETO, Public Participant

STEVEN MARSH, Public Participant

CINDY TOMLINSON, Public Participant

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P R O C E E D I N G S

8:30 a.m.

1
2
3 CHAIR METTER: Well, thank you very
4 much and good morning and welcome to the 2023
5 Spring Meeting of the ACMUI. I'm Darlene Metter,
6 diagnostic radiologist and ACMUI Chair. I hope you
7 all are having a safe and productive 2023.

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

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

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

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

24 MR. EINBERG: Thank you, Dr. Metter.

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1 Good morning. As the designated
2 federal officer for this meeting, I am pleased to
3 welcome you to this public meeting of the Advisory
4 Committee on the Medical Uses of Isotopes.

5 My name is Chris Einberg. I am the
6 chief of the Medical Safety and Events Assessment
7 Branch and have been designated as the federal
8 officer for this Advisory Committee, in accordance
9 with 10 CFR Part 7.11.

10 This is an announced meeting of the
11 committee. It is being held in accordance with the
12 rules and regulations of the Federal Advisory
13 Committee Act, and the Nuclear Regulatory
14 Commission.

15 This meeting is being transcribed by
16 the NRC and may also be transcribed or recorded by
17 others.

18 The meeting was announced in the May 5,
19 2023 edition of the Federal Register, volume 88,
20 page 29168.

21 The function of the ACMUI is to advise
22 the staff on issues and questions that arise on the
23 medical use of byproduct material. The committee
24 provides counsel to the staff but does not

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1 determine or direct the actual decisions of the
2 staff or the Commission.

3 The NRC solicits the views of the
4 committee and values their opinions. I request
5 that whenever possible we try to reach a consensus
6 on the various issues that we will discuss today.
7 But I also recognize there may be a minority or
8 dissenting opinions. If you have such opinions,
9 please allow them to be read into the record.

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

13 Dr. Darlene Metter, Chair, Diagnostic
14 Radiologist.

15 CHAIR METTER: Present.

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

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

23 Mr. Richard Green, Nuclear Pharmacist?

24 MEMBER GREEN: Present.

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

3 MEMBER MAILMAN: Present.

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

6 MEMBER MARTIN: Present.

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

9 MEMBER O'HARA: Present.

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

12 MEMBER OUHIB: Present.

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

15 MEMBER SHOBER: Present.

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

18 MEMBER WOLKOV: Present.

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

21 MEMBER ALLEN: Present.

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

24 MEMBER HARVEY: Present.

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

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

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

15 All members of the ACMUI are subject to
16 the federal ethics laws and regulations and receive
17 annual training on these requirements.

18 If a member believes that they may have
19 a conflict, or a conflict of interest as that term
20 is broadly used in 5 CFR Part 2635, with regard to
21 an agenda item to be addressed by the ACMUI, this
22 member should divulge it to the chair and the DFO
23 as soon as possible, before the ACMUI discusses it
24 as an agenda item.

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

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

11 The phone number for this meeting is
12 301-576-2978. The phone conference ID is 571779324
13 pound sign.

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

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

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

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

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1 and Dr. Brenneman.

2 Members of the public who notified Dr.
3 Valentin-Rodriguez that they would be participating
4 via Microsoft Teams will be captured as
5 participants in the transcript.

6 Those of you who did not provide prior
7 notification, please contact Dr. Valentin-Rodriguez
8 by email at cvr2@nrc.gov at the conclusion of the
9 meeting.

10 Today's meeting is being transcribed by
11 a court reporter. We are utilizing Microsoft Teams
12 for the audio of today's meeting, and to view
13 presentation material in real time.

14 The meeting materials and agenda for
15 this meeting can be accessed from the NRC's public
16 meeting schedule.

17 For the purpose of this meeting, the
18 chat feature in Microsoft Teams has been disabled.

19 Dr. Metter, at her discretion, may
20 entertain comments or questions from members of the
21 public who are participating today.

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

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

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

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

10 When you begin your comment, please
11 clearly state your first and last name for the
12 record. Comments and questions are typically
13 addressed by the committee near the end of a
14 presentation, after the committee has fully
15 discussed the topic.

16 We will announce when we are ready for
17 the public comment period portion of the meeting,
18 and Christine Pineda will assist in facilitating
19 public comments.

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

24 I will now turn the meeting over to Mr.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 So to provide a few inputs on NRC
2 activities, in regards to reporting extravasation
3 rulemaking, on May 9 we transmitted a package to
4 the Commission to recommend an approach to this
5 disposition. A petition for rulemaking received in
6 2020 and moved forward on extravasations.

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

13 The regulatory basis will be
14 transmitted to the Commission in March of, is it
15 2023 or 2024? So I'll correct that. But the
16 regulatory basis, where's Celimar?

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

19 MR. WILLIAMS: It was transmitted in
20 2023 and following Commission approval, will be
21 published in the Federal Register for a 90-day
22 public comment period.

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

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

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

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

16 Phase 2 for the revision of Reg Guide
17 8.39 regarding patient release. Approximately a
18 month ago we issued for public comment, a draft of
19 the Phase 2 revision to Regulatory Guide 8.39.

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

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

6 Nothing to report since our Fall of
7 2022 meeting, ACMUI meeting. Organizational
8 changes, I think Chris did talk about that for
9 ACMUI.

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

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

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

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

24 Items of interest for this meeting.

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

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

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

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

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

23 MS. VALENTIN-RODRIGUEZ: Thank you,
24 Kevin.

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1 Christine, can I get the next slide,
2 please?

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

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

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

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

24 The next recommendation comes from 2020

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

5 The next item is Item Number 11 from
6 2020. As part of the Non-Medical Events Report,
7 the ACMUI recommended to the NRC staff and to the
8 National Materials Program, to evaluate the issue
9 of detection of short-lived medical isotopes in
10 municipal waste, and provide some level of
11 guidance, best practices, or additional
12 recommendations.

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

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

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

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

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

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

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

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

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

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

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1 Commission in January of 2022.

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

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

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

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

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

24 Next slide, please. Thank you,

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1 Christine.

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

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

11 The next item is Item Number 4 from
12 2022. The ACMUI endorsed a Y-90 microsphere
13 medical events subcommittee report, and the
14 recommendations therein.

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

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

24 We are also looking more closely at Y-

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1 90 microsphere medical events for the next two
2 years, to evaluate if and how the use of vendor
3 tools play a role in these medical events.

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

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

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

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

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

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

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

16 And finally, Item Number 7 from 2022,
17 which was the scheduling of this meeting today. We
18 propose to close this item. The meeting as we're
19 here now, is being held May 15 through the 16,
20 2023.

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

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

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

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

7 MEMBER WOLKOV: Harvey Wolkov. Move
8 approval.

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

11 MEMBER MARTIN: I would second that.

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

14 All in favor?

15 (Chorus of aye.)

16 CHAIR METTER: Any abstain or opposed?

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

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

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

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

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

6 (Simultaneous speaking.)

7 MR. EINBERG: No.

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

10 Sorry, Chris.

11 CHAIR METTER: Thank you.

12 MR. EINBERG: Yes, no problem.

13 CHAIR METTER: Thank you very much.

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

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

21 (Pause.)

22 CHAIR METTER: Yes.

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

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

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

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

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

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

20 So, for this year we've got a total of
21 56 medical events, which is a little bit less than
22 last year, but is about on par with what we've seen
23 from previous years.

24 Next slide, please. So going into the

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

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

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

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

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

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

24 And so corrective actions included

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

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

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

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

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

24 After removing this capsule and taking

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

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

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

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

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

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1 typical 200 millicurie dose, without consulting
2 this written directive.

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 patient.

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

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

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

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

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

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

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

4 Next slide, please. This here we had
5 11 35.600 medical events.

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

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

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

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

5 The first patient had an underdose in
6 fraction two of four, where only 79 percent of the
7 fraction was delivered. And the second patient had
8 an underdose in fraction four of four, where only
9 54.4 percent of the fraction was delivered.

10 Additionally, the second patient
11 received the, a 48 percent greater dose to the
12 rectum for the fraction, resulting in an overall
13 15.4 percent greater dose to the rectum for the
14 full treatment.

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

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

24 And so, the corrective actions for this

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

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

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

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

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

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

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

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

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

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

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

24 Next slide, please. This was another

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

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

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

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

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1 verification going forward.

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

8 However, the first fraction, that first
9 500 centigray fraction had been unintentionally
10 delivered to the first lesion, which was discovered
11 when the patient noticed that the planning circle
12 had been drawn over the first lesion, instead of
13 the second lesion for that second fraction, before
14 it was treated. And so no adverse effects are
15 expected.

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

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

24 And so corrective actions included

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

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

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

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

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1 as prescribed.

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

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

12 The dose to the unintended tissue was
13 determined by recreating the intended plans and
14 comparing that to a shifted plan, which resulted in
15 267 centigray of additional dose to unintended
16 tissues per fraction.

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

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

24 For this, there was a discrepancy

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

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

13 Next slide, please. The first one
14 involving a GSR unit was a wrong site where the
15 patient was being treated for four lesions in the
16 brain. However, post-treatment they had discovered
17 that the targeting had been off by half a
18 centimeter for all of these lesions. The delivered
19 dose to the lesions were between 8 and 15 gray, and
20 the max dose to the unintended healthy tissue was
21 21.82 to 27.09 gray.

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

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

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

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

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

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

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

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

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

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

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

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1 misidentified, due to the varying anatomy of the
2 patient.

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

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

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

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

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

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

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

22 Next slide. This event was another Y-
23 90 TheraSphere overdose, where two patients were
24 due to receive Y-90 treatment on the same day.
25 Patient A with two vials, and Patient B with three

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1 vials.

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

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

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

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

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

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

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

5 And these monthly audits occurred for
6 90 days to determine the effectiveness of these
7 actions, after which quarterly audits were
8 continued.

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

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

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

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1 cause for the resistance.

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

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

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

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

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1 administered dose.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 microsphere, but the third only administered about
2 5 percent of the dose where the microspheres were
3 determined to be caught up in the tubing from the
4 vial. Unfortunately, I was not able to find any
5 more updates on this event so this is all the
6 information I have.

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

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

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

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

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1 procedures.

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

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

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

22 And the corrective actions included
23 providing additional training to staff.

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

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

3 The AU specifically had written that
4 12,000 centigray was the desired dose on the
5 written directive, but the dose that was received
6 from the manufacturer had a maximum expected dose
7 of 11,000 centigray.

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

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

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

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1 mistakenly administered that full dose during the
2 treatment.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 I'm not going to be talking about any

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7 And, again, calling back to those
8 35.300 and 35.600. Three of the six overdose
9 events were due to an incorrect written directive
10 where the intended dose was delivered, but the
11 written directive was just filled out wrong.

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

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

18 Next slide. Yes, questions?

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

25 MEMBER MARTIN: I was just wondering,

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

7 MR. DIMARCO: No, we just have the
8 medical events and what the procedures were.
9 However, if we do have any information for events
10 that involve more than one patient, like for some
11 of the 35,600 events, one of them was a single
12 medical event which had a single root cause, but
13 that affected 27 patients, and so if it's -- in my
14 table at the very beginning, if there were more
15 patients that had been affected, that was in the
16 parentheses there.

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

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

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

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

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

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

12 MR. DIMARCO: Yes.

13 MEMBER MARTIN: Okay.

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

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

21 MR. DIMARCO: Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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1 would be great to hear it.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 interventional program?

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

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

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

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

25 DR. TAPP: I was just going to respond

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

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

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

15 So, he did see a trend in that, I
16 think, two years ago, so we did put out an IN in
17 2019 that recommended if you haven't done a
18 procedure or if you haven't done a procedure a lot,
19 to do a mock procedure to make sure you're familiar
20 with it before you perform it. So that was the
21 previous recommendation from the ACMUI.

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

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

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

7 CHAIR METTER: Any other comments from
8 the ACMUI?

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

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

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

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

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

9 MR. DIMARCO: That's correct.

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

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

22 CHAIR METTER: Thank you.

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

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

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

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

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

25 We are meeting with AAPM and having a

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

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

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

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

25 CHAIR METTER: Dr. Angle, you have a

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1 comment?

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

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

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

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

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

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

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

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

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

25 MS. COCKERHAM: Sure, I'm Ashley

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 to implement it.

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

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

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

19 CHAIR METTER: Dr. Angle?

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

25 CHAIR METTER: Thank you and thank you

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

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

4 CHAIR METTER: Could you turn on your
5 microphone?

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

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

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

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

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

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

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

25 MEMBER WOLKOV: Harvey Wolkov. I do

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

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

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

19 CHAIR METTER: Yes, Mr. Ouhib?

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

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1 prevent another event.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 CHAIR METTER: Thank you very much.

23 MR. MARSH: Thank you.

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

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

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

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

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

12 CHAIR METTER: Yes.

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

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

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

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

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

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

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

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1 threshold of an AO.

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

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

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

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

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

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

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

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

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

25 So just hopping right into it, overall

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

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

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

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

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

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

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

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

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

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

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1 10 CFR 35.3045.

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

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

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

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

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

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

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

9 Further, the Commission had asked us to
10 evaluate the removal of Criterion 3.C.2 because
11 there are some redundancies in the language of the
12 AO reporting criteria and the criteria in 10 CFR
13 35.3045 for reporting medical events to the NRC.

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

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

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

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

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

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

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

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1 public has on our limited revision.

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

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

12 MR. EINBERG: No.

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

16 MS. PINEDA: Again, if you are a member
17 of the public and you joined by Teams, just use the
18 raise hand function in Teams, and if you called in
19 by phone, then press *5 to raise your hand and then
20 *6 to unmute yourself after I call your name.
21 Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9 MR. HARVEY: Sure.

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

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

25 CHAIR METTER: Yes, Dr. Katie Tapp is

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1 here to make a comment on that.

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

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

12 CHAIR METTER: Thank you.

13 MR. HARVEY: Thank you, Dr. Tapp.

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

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

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

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

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

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

16 So back in 2018 was the last time that
17 we officially amended 10 CFR Part 35 and it became
18 effective in January 2019 for NRC licensees and in
19 2022 for Agreement States and Agreement State
20 licensees.

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

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1 failed technetium and rubidium generators.

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

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

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

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

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

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

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

14 And the timeline really shows what's
15 going to be our schedule for this massive
16 rulemaking where we aim to include requirements for
17 calibration and dosage measurements for strontium-
18 82, rubidium-82 generators, and to establish risk-
19 informed, performance-based requirements to create
20 additional flexibility in Part 35 for the
21 regulation of existing and future emerging medical
22 technologies.

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

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1 we are really appreciative of those comments.

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

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

14 Another rulemaking effort that the NRC
15 medical team has undertaken has been the issue of
16 veterinary release. As you will know,
17 historically, most common veterinary uses of
18 byproduct material are sodium iodine-131 for the
19 treatment of hyperthyroidism in cats, and we have
20 limited guidance in NUREG-1556, Volume 7, Revision
21 1.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 slide, please. Thank you.

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

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

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

15 And so, we proposed to do that in two
16 phases, the first of which was published in April
17 2020 and that is the current version of Regulatory
18 Guide 8.39 that licensees could use, and in that
19 revision, we updated the patient release
20 information to provide example patient
21 instructions.

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

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

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

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

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

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

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

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

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

22 Training, for example, including
23 equivalency of hours, recentness of training under
24 35.59, vendor and device-specific training,
25 preceptors and their roles in T&E requirements,

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

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

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

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

25 As you all know, some of those medical

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

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

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

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

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

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

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

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

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

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1 details later today.

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

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

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

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

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

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1 isotopes.

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

5 MR. EINBERG: No.

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

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

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

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

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

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

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

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

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

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

19 MR. EINBERG: Nothing from the NRC
20 here.

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

25 (Whereupon, the above-entitled matter

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1 went off the record at 10:48 a.m. and resumed at
2 12:59 p.m.)

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

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

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

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

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

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

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

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

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

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

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

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

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1 So doing this basically 18 years, this eligibility
2 designation was an option for candidates and again,
3 this is going to disappear based on the decision on
4 December 31, 2023. Beyond that, starting January
5 1, 2024, none of these designations will be
6 available and candidates should provide relevant
7 T&E documentation if they want to be "AU" directly
8 through their employers to NRC so that their names
9 can be added to their employer's RAM license.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 So, this is charge number 2 that was

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

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

21 That concludes my subcommittee report.
22 Thank you.

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

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

4 MEMBER GREEN: So, this American Board
5 of Radiology is no longer going to have a process
6 to have their graduates, their fellows come out
7 with AU eligible. And it just makes me step back
8 and think how that relates to nuclear pharmacists.
9 On slide 5, there is a listing of the Board of
10 Pharmaceutical Specialties as a recognized
11 specialty board that pharmacists can avail
12 themselves. But I want to point out to you that
13 100 percent of all nuclear pharmacists in America
14 have come through the alternate pathway, because
15 you have to work for two years as a nuclear
16 pharmacist before you can sit for board
17 certification. So ABR is becoming like nuclear,
18 nuclear pharmacists. You -- if you want, you come
19 in, you knock on the door, and you present your
20 paperwork. And apparently, California and
21 Wisconsin don't see any problems with it, so even
22 though we're losing one, it's really no different
23 than what's already happening today.

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

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

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

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

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

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

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

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

23 CHAIR METTER: Yes, Dr. Harvey.

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

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

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

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

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

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

9 CHAIR METTER: Yes, we can.

10 MS. AYOADE: Okay. Great. I apologize
11 that I am not able to be there in person today, but
12 I'm still here and I'm following along with the
13 discussion. For the preceptor authorized user, or
14 the preceptor requirement is that that individual
15 has to be an authorized user that meets the
16 training and experience requirements that the
17 potential authorized user or authorizing individual
18 is requesting, so for the same types of uses. And
19 as far as -- I believe Dr. Metter mentioned this --
20 you know, if it's beyond the seven years, if it's
21 12 years, they have to show continuing education,
22 you know, as it relates to what it is that they've
23 been doing since that time. And the continuing
24 education has to be within the seven years along
25 with whatever supervised work experience that

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 the mike. Go --

2 MS. TOMLINSON: Hi. Cindy Tomlinson
3 with ASTRO. So, a couple of things I wanted to
4 mention. One is ASTRO now has a page on our
5 website that's sort of outlining its very -- very -
6 - 30,000-foot level, very broad umbrella outlining
7 what programs can do and what trainees can do to
8 make sure that they're leaving their programs with
9 everything intact, so all of their paperwork, all
10 the forms.

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

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

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

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

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

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

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

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

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

3 MS. AYOADE: Yes.

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

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

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

12 MEMBER EINSTEIN: Can you hear me now?

13 MS. AYOADE: I can hear you faintly.

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

17 MS. AYOADE: Yes, much better.

18 MEMBER EINSTEIN: Okay. In 35 CFR
19 290(b)(2), for example, I think among other places,
20 there's the verbiage the attestation must be
21 obtained from either one, a preceptor authorized
22 user who meets the requirements in 35.57, 35.290,
23 or 35.390 and 35.290(c)(1)(2)(g) or equivalent
24 Agreement State requirements, or two, a residency
25 program director who affirms in writing that the

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

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

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

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

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

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

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

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

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

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

20 MEMBER EINSTEIN: So, I would contend
21 that not all radiology residencies provide those
22 700 hours and certainly for cardiology fellowships,
23 it's -- there's different tracks which trainees can
24 take. Say someone wants to become a cardiac
25 electrophysiologist, which is an additional board

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

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

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

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

11 CHAIR METTER: Thank you so much for
12 that clarification.

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

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

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

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

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1 requirements.

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

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

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

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

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

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

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

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

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

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

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

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

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

8 CHAIR METTER: Well, thank you Ms.
9 Ayoadé. I believe Ashley Cockerham has a comment
10 regarding this issue.

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

17 CHAIR METTER: Thank you. Dr.
18 Einstein.

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

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

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

9 CHAIR METTER: Yes, Dr. Harvey.

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

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

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

7 CHAIR METTER: Thank you --

8 MEMBER WOLKOV: Dr. Wolkov, second.

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

12 Oh, yes, I'm sorry.

13 MS. AYOADE: Hi, Dr. Metter. I
14 apologize. This is Maryann Ayoade from NRC and for
15 those of us that were virtual, the screen did cut
16 out for like maybe the last 45 seconds to a minute.
17 But I did want to just make an additional comment
18 and just to clarify a couple of things. The NRC
19 313 Form is something, as Chris mentioned, we are
20 also reviewing as a part of that training and
21 experience implementation guidance recognizing
22 that, again, that is a guide or a way for our
23 licenses and even our license reviewers to help
24 them in the process as they receive information for
25 license reviews. We are also -- there is -- as

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

4 The other thing I wanted to mention is
5 all of the information that individuals will be
6 submitting on the training and experience alternate
7 pathway is not different from what is being
8 submitted to the specialty boards with the
9 exception of the preceptor attestation really. As
10 some of you have mentioned during this
11 presentation, if people are encouraging their
12 physicians, their potential authorized individuals
13 to make sure that they're keeping track of their
14 training and experience as they go along and not
15 just wait until the last day to try to figure out,
16 you know, what documentation do I need, who's
17 supposed to sign off on this part of my work
18 experience, who's supposed to sign off on the
19 preceptor attestation. And so, we're encouraging
20 people to keep track of their training and
21 experience documentation as they go along, use the
22 313 Form in addition to guidance that we have in
23 our NUREG-1556, Volume 9. But again, that's
24 something that we are currently looking at
25 wholeheartedly as part of this working group,

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

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

10 (Chorus of aye.)

11 CHAIR METTER: All opposed or
12 abstained?

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

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

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

19 CHAIR METTER: Yes, we can.

20 MS. WU: Okay, great.

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

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

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

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

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

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

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

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

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

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

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

17 So since then, I know the ACMUI has,
18 over the years, looked at whether extravasations
19 should continue to be excluded from medical event
20 reporting. I think there was some look-see at the
21 2008, 2009 timeframe and then, again, more recently
22 in 2019.

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

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

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

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

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

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

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

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

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

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

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

22 Then, in the May 2022 timeframe, staff
23 then provided a rulemaking plan, that being SECY-
24 22-0043 to the Commission that presented options
25 for amending Part 35.

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

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

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

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

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1 periods.

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

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

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

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

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

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

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

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

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

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

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

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1 been reviewed by the Commission.

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

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

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

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

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

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

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

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

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

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

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

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

25 Next slide, please? All right, so,

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1 here again, is the second grouping which is
2 procedures.

3 So, here's the preliminary proposed
4 rule language for a new section, which is Section
5 35.42, procedures for evaluating and reporting
6 extravasations. So, we used 35.41, procedures for
7 administrations requiring a written directive sort
8 of as a template for developing this preliminary
9 proposed rule language. So, you should see it
10 structured quite similarly.

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

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

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

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

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1 same here for 35.42 and 35.2042.

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

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

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

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

25 So, the next three slides, actually, go

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1 through those questions in the information request.

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

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

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

12 Next slide, please?

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

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

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

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1 Next slide, please?

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

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

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

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

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

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

24 Now, we don't have any preliminary
25 proposed rule language related to these questions,

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1 but we wanted to include them in the information
2 request because we had heard from some patient
3 safety groups with concerns about the inequities in
4 the health care community. And so, we're looking
5 for input on how this rulemaking can effectively
6 address these concerns.

7 Next slide, please? All right, so just
8 to highlight how the public is able to submit
9 comments on the Federal Register Notice for the
10 information request.

11 So, I mentioned earlier that this
12 information request Federal Register Notice was
13 published on April 19th with a 90-day comment
14 period.

15 And as outlined in the Federal Register
16 Notice, there are three methods for the public to
17 submit comments.

18 They can either go to regulations.gov
19 and go to our specific docket, Docket ID NRC-2022-
20 0218 and submit a comment that way. They can also
21 email us with their comments.

22 And they can also put their mail --
23 post mail their comments to us as well on the --
24 the email and the address are both included in the
25 FRN as well as the docket ID for the regs.gov.

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1 Next slide, please? So here are our
2 next steps. We are having a public meeting, as I
3 said earlier. We're going to have it next week on
4 May 24th to facilitate feedback and answer
5 questions on the information request.

6 We won't be actually collecting
7 comments at the public meeting as we want the
8 comments to be on the rulemaking docket. So
9 they're going to be needed to be submitted via the
10 methods I talked about on that previous slide.

11 But the -- and if anybody is interested
12 in -- that's listening that wants to be --
13 participate in that public meeting, that
14 information is available on the NRC's public
15 meeting website.

16 As I've said a few times, the public
17 comment period for the information request ends on
18 July 18th.

19 And then, the proposed rule right now
20 is currently estimated to go to the Commission in
21 August of 2024.

22 So, what that means for the ACMUI is
23 we'll be planning to give the ACMUI an opportunity
24 to review the draft proposed rule before it goes to
25 the Commission. And right now, we're estimating

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1 that time frame to be in the -- sort of the March
2 to May 2024 time frame.

3 And after the proposed rule goes to the
4 Commission, the Commission still has to vote and
5 provide direction for the staff in a staff
6 requirements memorandum, or SRM, before we can
7 publish the proposed rule for the -- in the Federal
8 Register.

9 And right now, again, just an
10 estimation that that would be around the December
11 2024 time frame.

12 So next slide, please? With that, that
13 is the end of my presentation. I'd be happy to
14 take any questions that you may have.

15 CHAIR METTER: Thank you, Ms. Wu, for
16 that very thorough and very in-depth presentation
17 on extravasations. And I really appreciate the NRC
18 staff on their work on this.

19 Do I have any questions from the ACMUI
20 for Ms. Wu?

21 We have -- okay, we'll go this way.

22 Dr. Harvey?

23 MEMBER HARVEY: Thank you, Richard
24 Harvey, apologize.

25 I guess I have the dissenting

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1 viewpoint. I think extravasations are a very
2 important quality assurance issue for the hospital,
3 clinic, or licensee. But I don't feel it should be
4 an NRC medical event.

5 That's my comment.

6 CHAIR METTER: Thank you.

7 Mr. Green?

8 MEMBER GREEN: Thank you.

9 Appreciate the presentation, Ms. Wu.

10 I'm a little bit flustered by the use
11 of the term extravasation.

12 We're trying to get a drug into a
13 confined space and that space typically is in the
14 venous -- in the circulatory system. It could be
15 arterial or it could be venous.

16 And what we're looking at is stuff that
17 doesn't get in there or leaks out.

18 There are other confined spaces that
19 radiopharmaceuticals are injected into like
20 intrathecal for radionuclide cisternography with
21 indium-111 pentetate, or DTPA.

22 There are drugs that are no longer on
23 the market such as chromic phosphate P32 which was
24 instilled into cavities.

25 Are we concerned about exposures there

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1 where material is not depositing in the right
2 space?

3 So, I'm not sure that the E word,
4 extravasation is correct and maybe infiltration is
5 a better choice.

6 CHAIR METTER: Thank you, Mr. Green,
7 that's --

8 MS. WU: Yes.

9 Sorry, go ahead.

10 CHAIR METTER: No, go ahead. Go ahead,
11 Ms. Wu, go ahead and make a comment.

12 MS. WU: No, I was -- all I was going
13 to say was, you know, that is sort of the reason
14 behind that one question that we have in the
15 information request, if extravasations is the right
16 term or if infiltration or another term may be
17 better. That's all.

18 CHAIR METTER: Okay, thank you.

19 And Ms. Ouhib?

20 MEMBER OUHIB: Yes, thank you for a
21 great presentation.

22 I happen to share the opinion of the
23 two previous ACMUI members.

24 One good reason is that it's almost
25 like here we go again that, as we introduce another

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1 area of medical events, I'm wondering what's going
2 to happen to the authorized users for such
3 practice.

4 That maybe that would be sort of like
5 discouraging. And it's all -- we learned that a
6 long time ago with prostate brachytherapy as
7 medical events started to pop left and right and
8 all that.

9 And then, next thing you know, is
10 prostate brachytherapy is not as common anymore,
11 even though there was an effort to make it less
12 difficult, we don't see much of it. So, I think
13 that could be an issue.

14 The other question that I have for you,
15 are there any exclusions for such medical events,
16 per se, for this type of procedures?

17 I'll give you an example, a patient had
18 an injection, left, had a physical injury in the
19 area of where the injection was. Now, the patient
20 reports that they're having an issue in that area.

21 Now, is that going to be qualified as a
22 medical event?

23 And that's just a basic case that I
24 thought of now. But there could be others that
25 might not quite qualify for that.

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1 Thank you.

2 CHAIR METTER: Thank you for that
3 observation. Dr. Jadvar?

4 VICE CHAIR JADVAR: Thank you. So, I
5 just want to remind people, as was mentioned before
6 by Mr. Green, that, you know, you're trying to
7 puncture a vein to get in there to get some stuff
8 inside. That is -- there's going to be a hole
9 there.

10 When you pull the needle out, it's
11 going to be leaving a beading. That's normal.
12 That's the body.

13 Which, you know, eventually we close
14 off the platelets going there and then, trying to
15 close it up. But there's going to be a small
16 amount of bleeding. There's going to be a small
17 amount of radiotracer, in some cases, in many
18 cases, in fact, that can be right there and can
19 show up on the scans like a small dot, but very hot
20 sometimes.

21 Is that extravasation? It's not. It's
22 a normal thing. You made hole, there was bleeding.
23 There's going to be some concentration radio tracer
24 activity there.

25 And therefore, you know, it really

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1 depends on where it's infiltration or extravasation
2 and that activity at that moment of time may exceed
3 whatever threshold you want to use.

4 But because of the lymphatics, because
5 of the way the body clears it, it's going to have
6 no effect whatsoever, despite the fact that they're
7 going to be a little bit of higher activity at the
8 -- concentration of activity at that time.

9 But it will have no bearing on
10 diagnostic quality of their scan that you're
11 looking at.

12 I just want to also draw your attention
13 to a recent article that was just published a
14 couple of months in the journal from Washington
15 University.

16 They looked at almost 32,000 scans,
17 bone scans, which is a very common procedure, that
18 they have done over the years at Wash U.

19 And the extravasation rate that was
20 documented was 0.37 percent, very, very small
21 number of people. And none of them that they
22 looked into all their, you know, documentation that
23 was in the records, none of them had any long-term
24 local effects.

25 In fact, they -- it's interesting, if

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1 you go to the paper itself, they show one image,
2 which is Figure Number 2 which looks horrible. I
3 mean, there is this very large area of very intense
4 activity. But that patient had no long-term
5 effects at all, just some warm pad and elevation of
6 arm. And the quality of the scan was excellent.

7 You could make a decision if this
8 patient has metastatic disease or not. So, I think
9 what I'm saying is, that I agree with my three
10 other colleagues around the table that you're -- I
11 think you're making too much of this, I personally
12 think.

13 CHAIR METTER: Thank you very much, Dr.
14 Jadvar. Any other comments from the committee?

15 Yes, Mr. Green?

16 MEMBER GREEN: Just want to point out,
17 the professionals that we work with that work with
18 the nuclear medicine physician that perform the
19 patient administrations are appropriately referred
20 to as nuclear medicine technologists. In question
21 11, they're referred to as technicians, and that
22 should be corrected.

23 CHAIR METTER: Thank you for that
24 suggestion.

25 VICE CHAIR JADVAR: Well, since he

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1 mentioned technicians, there was one slide that
2 says blood vessel or artery. So, it should be the
3 vein or artery, because artery is a vessel.

4 So, you know, and we normally don't
5 really inject into artery unless it's Y-90, if
6 you're going to arterial system in the liver. But
7 normally, almost 100 percent of
8 radiopharmaceuticals are administered
9 intravenously.

10 CHAIR METTER: Yes, Mr. Green?

11 MEMBER GREEN: Because I'm a geek, I
12 have a list of the 55 FDA approved
13 radiopharmaceuticals that are currently approved.
14 Forty-five of them have indications for intravenous
15 administration, three are oral, one's inhaled,
16 one's intradermal, and one's intrathecal.

17 So, we've got to make sure that
18 whatever we're writing is not all
19 radiopharmaceuticals, but those that go into that
20 intravenous space.

21 CHAIR METTER: Thank you. Do I have
22 any other comments from the ACMUI or questions?

23 Any from the NRC staff? Mr. DiMarco?

24 MR. DIMARCO: Hi, Daniel DiMarco,
25 technical lead on the extravasation rulemaking.

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1 I just want to make a couple comments
2 for some of the comments from the ACMUI.

3 So, when we were determining what we
4 wanted the reportable for specifically an
5 extravasation -- for a medical event involving an
6 extravasation, we took all the comments because
7 we've been hearing this from the ACMUI and the
8 medical community for the entire time we've been
9 doing this, and we've been trying to take these
10 comments under consideration.

11 And so that's why we wanted to
12 determine this to be, one, to be a radiation
13 induced injury because we didn't want to see any of
14 these reportable events come from, say, like
15 someone using the -- an allergy to the tape being
16 used or any sort of local trauma because of -- an
17 injection is a traumatic event, at least for that
18 local area.

19 So that's why we have a couple of those
20 questions in there on specifically being a
21 radiation injury and what sort of medical
22 professionals should be able to consult to say that
23 this was a radiation injury versus any sort of
24 other local injury due to any other, you know,
25 these are sick patients, maybe there's something

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1 going on in the local area that isn't due to the
2 radiation.

3 So that's one thing. As for another,
4 at least with the diagnostics, the NRC does not
5 regulate image quality on that. So, we didn't want
6 to step into that area at all. Image quality is
7 strictly a medical community metric and the NRC
8 does not regulate that.

9 And I believe that was all I had to
10 say. If anyone has any other comments or questions
11 for me.

12 MEMBER OUHIB: It's a question, but I
13 think I'd like to hear it from the users is that,
14 you know, those type of things might very well be
15 included in the consent form, that the patient
16 ought to expect certain things.

17 They're not out of the ordinary.
18 They're totally normal things that could occur.

19 And now, we're saying that things that
20 could potentially occur are medical events. It
21 just doesn't make any sense to me.

22 MEMBER HARVEY: I think the distinction
23 that we have to take into account is that we get to
24 a tissue reaction level. And until we get to that
25 dose, anything below that threshold is not included

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1 as a medical event.

2 So, some of the normal routine things
3 would certainly not fall under this. And I think
4 what the NRC's done is come up with a great
5 compromise to try to make this work.

6 I still have the dissenting opinion
7 that it should not be a medical event. But I think
8 you have to meet that bar. You have to meet that
9 threshold to be included. So, I just wanted to put
10 that out there. Thank you.

11 MR. DIMARCO: Yes. And so, part of
12 that threshold, we can't set that line or we're not
13 trying to set that line for any facility with is
14 this an event something that could possibly be a
15 reportable extravasation.

16 But part of that is the dosimetry model
17 that we're formulating that will be part of the
18 guidance, an appendix in the guidance. And so that
19 will be of use to everyone.

20 And in that, we're trying to get a
21 conservative estimate of the dosimetry with the
22 addition of certain techniques like warming the
23 area or elevating the arm, and so how that changes
24 the dosimetry and how that changing dosimetry
25 changes the probability of a certain extravasation

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1 and having some sort of erythema or patient harm
2 for that.

3 CHAIR METTER: Thank you.

4 Do I have any other questions or
5 comments?

6 Yes, Mr. Ouhib?

7 MEMBER OUHIB: Yes, just a comment.
8 So, let's just take a situation where the
9 authorized user might very well predetermine or see
10 that this patient might very well have an issue.
11 I'm not sure. Okay?

12 So, choosing between reporting a
13 medical event or simply saying to the patient, I'm
14 sorry, but I might not be able to do this and
15 here's what the issue is.

16 And I'm just speculating here, this
17 might not happen, but I'd like to hear it from the
18 authorized user if that's a possibility and the
19 patient is basically sent home and not provided a,
20 you know, proper care, per se, because of that.

21 MR. DIMARCO: Thank you for that
22 comment.

23 CHAIR METTER: Okay, any other comments
24 from the ACMUI or NRC staff?

25 MS. PINEDA: Dr. Metter, I think Megan

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1 Shober may have a comment.

2 CHAIR METTER: Oh, I'm sorry.

3 Yes, Ms. Shober?

4 MEMBER SHOBER: Yes, can you hear me?

5 CHAIR METTER: Yes, we can, I'm sorry,
6 I didn't see your --

7 MEMBER SHOBER: That's all right.

8 I just wanted to point out that when we
9 had the extravasation subcommittee, a couple years
10 ago, one of the big concerns that we had was on the
11 therapeutic radiopharmaceuticals that were coming
12 on the market.

13 Our emphasis in the conclusions that we
14 -- when we got to the point of making the decision
15 about which recommendation to support for the
16 extravasation rulemaking, we were really concerned
17 about the potential for therapeutic extravasations.

18 So, I know that the study that Dr.
19 Jadvar was mentioning was about bone scans,
20 obviously, that's diagnostic.

21 But the concern was that, even if they
22 don't happen very often, that those -- if you did
23 have a therapeutic extravasation, that you could
24 have some pretty significant consequences from
25 that. Thank you.

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1 CHAIR METTER: Thank you, Ms. Shober,
2 with that very important information. Do I have
3 any other comments from the staff or the ACMUI?

4 Okay, can we open up to the public?

5 MS. PINEDA: If you're a member of the
6 public and you'd like to make a comment, again,
7 just use the little hand icon to raise your hand if
8 you're on Teams.

9 And if you've called in by phone, just
10 press star five to raise your hand and then, star
11 six to unmute yourself after I call your name.
12 Thank you.

13 MS. PINEDA: It looks like we don't
14 have anyone.

15 CHAIR METTER: Okay, it looks like
16 there are no public comments.

17 So, thank you very much for that very
18 detailed and very in-depth and thoughtful
19 presentation on extravasation. I really appreciate
20 the NRC staff and you particularly, Irene Wu,
21 regarding this presentation.

22 So, let's go to the next item on the
23 agenda. This is the ACMUI reporting structure by
24 Dr. Valentin-Rodriguez of the NRC.

25 MS. VALENTIN-RODRIGUEZ: Good

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1 afternoon, everyone. Again, as Dr. Metter
2 mentioned, I'll be providing the review of our
3 reporting structure, a discussion of our annual
4 review, and frequency of meetings, and then, I'll
5 open it up to the ACMUI for discussion.

6 Next slide, please?

7 Okay, next slide, please? So, the
8 graphic on the slide provides a graphic of the
9 current reporting structure. From the bottom up,
10 you'll see that the ACMUI reports directly to Mr.
11 Kevin Williams who you all saw this morning during
12 his opening remarks.

13 He is the Director of the Division of
14 Materials Safety, Security, State, and Tribal
15 Programs, otherwise known as MSST.

16 And reporting to Mr. Williams is Chris
17 Einberg, who's in the room today who is the Branch
18 Chief for the Medical Safety and Events Assessment
19 Branch.

20 In our division, MSST, we report to Mr.
21 John Lubinski in the Office of Nuclear Material
22 Safety and Safeguards.

23 And then, NMSS reports to the Executive
24 Director of Operations Office who is currently Mr.
25 Daniel Dorman and who reports to the Commission.

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1 So, the ACMUI does not report directly
2 to the Medical Safety and Events Assessment Branch,
3 however, within our branch resides the Medical
4 Radiation Safety Team who helps coordinate and
5 support the day to day activities of the committee.

6 During the presentation of the bylaws
7 in September 2012, the ACMUI recommended to having
8 an annual review in its reporting structure.

9 Christine, can I get the next slide,
10 please? Sorry, there we go.

11 And at that time, the ACMUI was
12 presented with an option to continue to report to
13 NMSS or to report directly to the Commission.

14 And the subcommittee report provided in
15 2012 stated that the working relationship with the
16 -- between the NRC and the ACMUI remained excellent
17 and the reporting structure through the staff
18 continued to work or function effectively.

19 And so, at that time, the subcommittee
20 and the ACMUI agreed that the associated logistics
21 with direct reporting to the Commission, such as
22 more frequent meetings, did not and does not
23 justify any change to the ACMUI's reporting
24 structure.

25 Next slide, please? So, we currently

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1 hold two meetings each year. We started to hold
2 them in person again, which are our spring and fall
3 meetings.

4 I know our May and December meetings
5 have been a little bit out of the ordinary in terms
6 of time frame. We had to do a lot of adjustments
7 post-pandemic. And so, we'll also do
8 teleconferences on an as needed basis.

9 Next slide, please? So, at this time,
10 I'll turn it over to Dr. Metter and the ACMUI for
11 discussion on whether the committee continues to be
12 satisfied with this current reporting structure,
13 what's not working about the reporting structure,
14 and any recommendations for improvement. So, thank
15 you.

16 CHAIR METTER: Thank you very much for
17 that review and reminding us how the structure
18 works for the ACMUI and with the whole NRC.

19 So do I have any questions for Dr.
20 Valentin-Rodriguez regarding the ACMUI reporting
21 structure or any comments? Any suggestions?

22 Mr. Green?

23 MEMBER GREEN: Thank you, Dr. Metter.

24 I just wanted to echo, I think comments
25 you made at least twice today, you know, there has

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1 not been a direct support person supporting the
2 ACMUI that Dr. Valentin-Rodriguez has taken that
3 upon herself personally in addition to all her
4 other activities.

5 And I think we've been very well
6 supported and assisted in our activities. And I
7 look forward to have a full-time person that can do
8 that for us. Not that we have been famished and
9 not supported.

10 But, you know, there are other things
11 that the medical staff have to do, but I think
12 they've done a great job in supporting us.

13 CHAIR METTER: Thank you.

14 MS. VALENTIN-RODRIGUEZ: Thank you, Mr.
15 Green.

16 And as I think Chris and Kevin Williams
17 said this morning, we have hired someone, but, you
18 know, the bureaucracy of the federal government
19 hiring processes can be a bit long in the tooth.
20 So we're hoping to have her in place in the next
21 few weeks.

22 And so hopefully Ms. Armstead will be
23 here to support you in our day-to-day activities
24 and we can resume more normal operations.

25 So, I appreciate your feedback.

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1 CHAIR METTER: And Dr. Valentin-
2 Rodriguez, I personally would like to thank you
3 particularly for your work because I know you're
4 doing like double duty, but also the NRC staff.
5 They've been very -- they're very professional,
6 very knowledgeable and really very prompt in their
7 responses to our questions and our needs. And that
8 only helps to make our job easier to help the
9 public in the protection and the use and -- the
10 medical use of isotopes.

11 And thank you very much.

12 MS. VALENTIN-RODRIGUEZ: Thank you, Dr.
13 Metter. It's a pleasure and to be able to work
14 alongside all these esteemed professionals.

15 So, I don't know, Chris, if you wanted
16 to have some words? But we truly appreciate it
17 from the NRC side.

18 MR. EINBERG: Yes, thank you, Dr.
19 Metter.

20 I'm -- very kind words and, as Celimar
21 said, you know, it's our pleasure and, again, we
22 really do -- or, you know, from my perspective, I
23 think we have a great team supporting the ACMUI,
24 supporting the medical community.

25 And, of course, what an esteemed body

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1 we have here. And so, I think there's very good
2 collaboration between the NRC staff and the ACMUI
3 members.

4 CHAIR METTER: So, the question still
5 stands, do we like the current plan as far as
6 having two meetings per year, one in the spring and
7 one in the fall, given these general time frames?

8 PARTICIPANT: Yes.

9 CHAIR METTER: Okay, given that, I see
10 lots of heads shaking, nodding up and down, that
11 means yes rather than sideways. So, do I have a
12 motion to approve?

13 (Off microphone comment.)

14 CHAIR METTER: I have a motion to
15 approve the current schedule for meetings. Do I
16 have a second?

17 MEMBER HARVEY: Richard Harvey, I will
18 second that motion.

19 CHAIR METTER: Great. Any other
20 discussion?

21 All in favor, say aye.

22 (Chorus of aye.)

23 CHAIR METTER: All opposed or abstain?

24 I hear crickets, so that means that it
25 has unanimously been approved by the committee.

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1 And thank you very, very much for all that you do
2 to help us.

3 So, I believe we have a break right
4 now, we're going to be a little early unless
5 there's anything else, Mr. Einberg, do we have to
6 cover before we go to break?

7 MR. EINBERG: Nothing -- sorry, nothing
8 at all. So, yes, let's go to break then. And then
9 we'll resume at 3:00.

10 CHAIR METTER: At 3:15, I believe is on
11 my schedule.

12 MR. EINBERG: I'm sorry, yes, at 3:15,
13 my apologies.

14 CHAIR METTER: So, we'll have a break
15 right now, and we'll go off the air and we'll be
16 back at 3:15.

17 (Whereupon, the above-entitled matter
18 went off the record at 2:38 p.m. and resumed at
19 3:14 p.m.)

20 CHAIR METTER: Well, good afternoon,
21 and welcome back to the 2023 Spring ACMUI Meeting.
22 And we're just about to start our last section of
23 today's meeting.

24 And I'm Darlene Metter, ACMUI Chair and
25 Diagnostic Radiologist. And I'd like to introduce

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1 Dr. Richard Harvey, our ACMUI (audio interference)
2 for his presentation on the decommission financial
3 assurance for sealed and unsealed radioactive
4 materials.

5 MEMBER HARVEY: Thank you very much,
6 Dr. Metter.

7 Appreciate the opportunity to submit
8 the report and presentation today.

9 I guess we can go to the next slide.
10 And can go to the next one, no financial
11 disclosures.

12 Again, I just wanted to thank the
13 entire subcommittee for all their efforts to get
14 this done. And I very much appreciate that.

15 So, Ms. Allen, Dr. Jadvar, Mr. Mailman,
16 Ms. Martin, Ms. Shober, so, thank you.

17 I'd also like to thank the NRC staff
18 resource for their fantastic work. And Ms.
19 Flannery really did all the heavy lifting on this
20 and really made it very, very easy for us to get
21 through this. So, thank you very much, Ms.
22 Flannery.

23 And thank you to Dr. Valentin-Rodriguez
24 for all her help in the report, ready, thank you.

25 So next slide, please. Our

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1 subcommittee charge was to review and comment on
2 the draft proposed rule for the rulemaking for
3 decommissioning financial assurance for sealed and
4 unsealed radioactive materials.

5 A quick background -- next slide,
6 please?

7 Quick background is U.S. Nuclear
8 Regulatory Commission, NRC, is proposing to amend
9 its regulations for decommissioning financial
10 assurance for sealed and unsealed radioactive
11 materials.

12 The rulemaking would revise NRC's
13 decommissioning funding requirements for
14 radioactive materials based in the relative risk to
15 the public health and safety from different
16 radioisotopes including naturally occurring and
17 accelerated produced radioactive material.

18 The potentially affected licensees are
19 those authorized to possess radioactive materials
20 licenses.

21 Next slide, please? So, the proposed
22 rule changes, the language in 10 CFR 30.35,
23 financial assurance and record keeping for
24 decommissioning will remain unchanged.

25 The only change is the values in

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1 Appendix B, okay, to Part 30, Appendix B to Part 30
2 which is entitled quantities of licensing material
3 requiring labeling will be updated.

4 The values in Appendix B will be
5 updated to those of Appendix C of 10 CFR Part 20
6 for radionuclides with half-lives greater than 120
7 days.

8 We don't see any significant impact to
9 the licensees with germanium-68 or gallium-68
10 generators.

11 The benefits of this proposed rule
12 change are to provide relief for previously
13 unlisted radionuclides and there doesn't seem to be
14 any expected negative impacts to the licensees.

15 Next slide, please? So, our
16 recommendation -- this subcommittee -- the ACMUI
17 subcommittee on the decommissioning of financial
18 assurance for sealed and unsealed radioactive
19 materials draft proposed rule recommends that the
20 proposed rule with the changes to the table in
21 Appendix B to Part 30 be accepted as proposed.

22 And then the next slide is just
23 acronyms and I can take -- or any questions that
24 you may have for simply changing a table.

25 CHAIR METTER: Thank you, Dr. Harvey,

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1 for your committee's -- subcommittee's work on
2 this. Do I have any other comments from Dr.
3 Harvey's subcommittee?

4 Any comments or questions from the
5 ACMUI?

6 Yes, Mr. Green?

7 MEMBER GREEN: Are we changing all the
8 values that are in Table C to now be in Table or
9 just those with half-lives over 120 days?

10 MEMBER HARVEY: Richard Harvey. We're
11 taking everything from the one table and putting it
12 in the other. And I don't remember off the top of
13 my head how much overlap there might be.

14 So, we don't really see any impact to
15 the group. So, I guess I don't really have a great
16 answer to your question, unfortunately.

17 But the significant focus was on those
18 greater than 120 days. Obviously, as you know,
19 things that are less than 120 days have less
20 stringent regulations and so most of those things
21 can be either stored on site and managed on site
22 and decommissioning and funding financial assurance
23 is not necessarily required.

24 So, what really is impacted is those
25 with half-lives greater than 120 days.

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1 MEMBER GREEN: Thank you.

2 MEMBER HARVEY: You're welcome, Mr.
3 Green.

4 CHAIR METTER: Any other questions for
5 Dr. Harvey or any comments?

6 Okay, any from the NRC staff?

7 Any questions from the public?

8 Yes, sir?

9 MR. HOLAHAN: Yes, good afternoon, Dr.
10 Vince Holahan. I'm Senior Level Advisor at NMSS.

11 To answer your question, when we
12 started, we had 180 isotopes in Appendix B to Part
13 30. 130 of those isotopes were removed because
14 their half-lives were 120 days or less.

15 When Appendix B to Part 20 was updated
16 in 1991, it was increased from 260 isotopes to 757.
17 Of those, we added back to the new Appendix B to
18 Part 30, 105 isotopes bringing it to 154.

19 What we find is, for the most part,
20 there were only changes in a couple of isotopes,
21 cadmium-109 actually went down by a factor of 10.
22 Most of the isotopes went up by a factor of either
23 10 to 100.

24 The only thing will be the default
25 values of those that aren't in the table already.

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1 Those will decrease by about a factor of 10. Thank
2 you, ma'am.

3 CHAIR METTER: Thank you very much for
4 that information. Did you have any other questions
5 of him, Dr. Harvey?

6 MEMBER HARVEY: I wanted to thank him
7 very much for his support. Thank you very much.

8 CHAIR METTER: Thank you. Do I have
9 any other comments from the public?

10 MS. PINEDA: If you're a member of the
11 public and you have a comment or a question, just
12 hit the little hand icon in Teams. Or on your
13 phone, press star five to raise your hand. Thank
14 you.

15 CHAIR METTER: It looks like there's no
16 questions from the public. Do I have a motion to
17 approve Dr. Harvey's report to the ACMUI?

18 Dr. Wolkov?

19 MEMBER WOLKOV: Harvey Wolkov, so
20 moved.

21 CHAIR METTER: Thank you. Do I have a
22 second for approval?

23 MEMBER O'HARA: Michael O'Hara, so
24 moved.

25 CHAIR METTER: Thank you, Dr. O'Hara.

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1 Any other discussion or comments?

2 All in favor of approving Dr. Harvey's
3 presentation, say aye.

4 (Chorus of aye.)

5 CHAIR METTER: Any abstention or
6 opposed?

7 Thank you very much, the report is
8 approved unanimously by the ACMUI.

9 So, our next item on the agenda is an
10 open forum where the ACMUI will discuss medical
11 topics of interest for the future. Do we have any
12 of those topics that anyone would like to bring up
13 at this time? Ms. Martin, yes?

14 MEMBER MARTIN: I seem to be good at
15 this today. I'm not sure I have all the details
16 that I should know before I bring this up, but
17 there was a fair amount of discussion in the
18 physics groups that there is a proposal that will
19 basically lower the limits requiring the increased
20 controls for HDR units.

21 And I was just wondering if that has
22 been brought to the hospitals' attention and what
23 impact that would have on the -- because it would
24 have a significant impact on many users that -- how
25 that's being considered if you have to add

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1 increased controls for all the HDR units.

2 MEMBER HARVEY: Dr. Martin, can you
3 tell us what they're lowering the threshold to?
4 Will then it include all like single irradiators?

5 Because, currently, it's just more than
6 one co-located together and there were regulation
7 thresholds were set so that one HDR unit had less
8 stringent regulations. Are we now talking about
9 including individual HDRs?

10 MEMBER MARTIN: That was the talk. But
11 again, this was done at a physics group discussion
12 and I don't have enough details to give you the
13 information.

14 But that was the implication that all
15 of the single units would now have to have the
16 increased controls at all times.

17 And I was -- I'm really looking for
18 information if that's really a true statement or I
19 would love for someone from the NRC or someone else
20 to disprove that.

21 MR. EINBERG: I see that Dr. Valentin
22 has her hand up and maybe she can elaborate.

23 But I haven't heard of anything.

24 MS. VALENTIN-RODRIGUEZ: Thanks, Chris.

25 Yes, so if you'll remember in the

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1 December 2022 fall meeting, we had a presentation
2 from Dr. Andy Carrera on the radioactive source
3 security and accountability rulemaking.

4 That rulemaking looks -- puts further
5 controls on Category 3 sources of material.

6 So licensees who now possess Category 3
7 sources of material, in this case, for example,
8 those who have HDR units, will have further
9 controls, including if they, for example, submit an
10 application for a license or if they want to
11 increase their amount of material to receive
12 Category 3 sources, they would have to have pre-
13 existing -- they would need to meet certain
14 conditions that would make them what we call a
15 known applicant which may subject them to, for
16 example, pre-licensing with this.

17 And there would be further requirements
18 for license verification.

19 But at this time, there would be no
20 requirement to implement what we call Part 37 or
21 what used to be called increased controls and is
22 now physical security requirements in 10 CFR Part
23 37.

24 They wouldn't be subject to those
25 specific requirements in Part 37, but there would

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1 just be a few things that they would need to meet,
2 and that would be in order to ensure security of
3 Cat 3 sources.

4 I can share that presentation from Dr.
5 Carrera from the December fall meeting to kind of
6 give you more of an update or kind of a summary of
7 what that rule -- proposed rule will entail.

8 MEMBER MARTIN: That would be much
9 appreciated because I know the AAPM group's looking
10 for that information because it impacts so many of
11 our members.

12 CHAIR METTER: Okay, thank you.

13 Any other suggestions for topics?

14 Okay, any from the NRC staff?

15 MR. EINBERG: No.

16 CHAIR METTER: So, at this time, if
17 there are any that do come up in the future, just
18 go ahead and you can email Dr. Valentin-Rodriguez
19 or myself or Mr. Chris Einberg regarding that.
20 Thank you very much.

21 So let's go on to the final item on our
22 agenda, our administrative closing by Dr. Valentin-
23 Rodriguez.

24 MS. VALENTIN-RODRIGUEZ: Thank you, Dr.
25 Metter.

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1 Today, we heard a great many topics.
2 And so, I wanted to thank the ACMUI members for
3 their thoughtful feedback as well as the presenters
4 from both NRC and the ACMUI, and also our public
5 for their input and feedback on the topics we
6 discussed today.

7 Just a brief overview of the topics
8 that were discussed, we had a very informative
9 presentation from Mr. DiMarco about our fiscal year
10 2022 medical events. We also had a presentation
11 and updates to the abnormal occurrence criteria,
12 specifically, to Medical AO criteria as well as an
13 update on ongoing medical team activities.

14 We heard from Dr. Jadvar, which turned
15 into a very lively discussion about training and
16 experience for all modalities.

17 And I wanted to assure the ACMUI
18 members as well as the public that we're working on
19 that implementation guidance that we've talked
20 about. And this is the sort of feedback that we
21 really want to hear from you all as to what are the
22 questions that you all have when implementing our
23 training experience requirements in 10 CFR Part 35.

24 We also heard the status of our
25 extravasations rulemaking, and we heard some

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1 feedback on that.

2 And I want to remind everyone there's a
3 public meeting next week, May 24th, from 1:00 to
4 4:00 p.m. Eastern Standard -- Eastern Daylight Time
5 for that.

6 And we also had a review of our ACMUI
7 reporting structure and Dr. Harvey provided a
8 report on the decommissioning financial assurance
9 proposed rule.

10 So, with that, I didn't capture any
11 action items from the NRC or ACMUI. Dr. Metter,
12 did you capture any action items at this time?

13 CHAIR METTER: No, not at this time.
14 But thank you very much for that nice, very concise
15 review.

16 MS. VALENTIN-RODRIGUEZ: So, the next
17 topic for the administrative closing will then be
18 selecting a tentative or two dates for our fall
19 meeting.

20 I've provided in advance several
21 meetings that would work in concert with a proposed
22 Commission meeting in the September and November
23 time frame.

24 Right now, on this slide, you have
25 September -- you have a few September dates --

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1 thank you.

2 The first tentative date is September
3 11 and 12 which would be Monday, Tuesday. That
4 would accommodate a full meeting on Monday and the
5 Commission meeting on Tuesday.

6 Christine, can you go back to the next
7 -- can you go to the next slide? Thank you.

8 There are no available dates right now
9 in October for a Commission meeting. So, we
10 bypassed October.

11 And then, I also offered several
12 tentative dates in September -- in November, namely
13 November 1st and 2nd, 13th and 14th, with -- and
14 those would be Commission meeting on Thursday, the
15 2nd, Tuesday, November 14th, and then, a third date
16 Wednesday, Thursday, November 15 and 16, with the
17 Commission meeting on Thursday, November 16th.

18 So, I think the November dates look to
19 be more agreeable to those who contacted me
20 beforehand with the September 11th to 12th date a
21 little bit behind in terms of votes, but not by
22 much.

23 So ,I wanted to bring it up to you all
24 for discussion so that we can pick two dates and
25 then propose that to our Office of the Secretary to

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1 get on the Commission's books for the fall.

2 CHAIR METTER: Any comments from the
3 members regarding certain dates? Yes, Dr. Jadvar?

4 VICE CHAIR JADVAR: Well,
5 unfortunately, I'm personally not available for
6 13th to 16th, I'm traveling at that time. For me,
7 my best dates are in September and then one or two
8 in November, but not during the 13th through 16th.

9 CHAIR METTER: Any other comments? I
10 think we had initially -- the majority of the
11 members kind of wanted to do -- make it abutting a
12 weekend.

13 So, any other suggestions? Yes,
14 Melissa?

15 MEMBER MARTIN: Well, just realize that
16 if you have the meeting on November 1st and 2nd,
17 that requires us to travel on Halloween.

18 VICE CHAIR JADVAR: I second Darlene's
19 mentioning because during the week, at least for
20 us, we're coming from across the country, it really
21 have to take another day off from work on Tuesday
22 to be able to be here on a Wednesday. So that's
23 why I think, you know, a coupled to a weekend would
24 be better.

25 MEMBER HARVEY: November 13th is the

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1 American Heart Association scientific sessions.

2 MEMBER MAILMAN: Of course, the
3 September date is the European Nuclear Medicine
4 meeting which is E&M is that Monday and Tuesday as
5 well as I have multiple obligations in there and
6 one of their -- there's a patient -- the
7 International Patient Meeting in Italy. So, I'm --
8 it's a hard date, but they're all hard dates. So,
9 we'll figure it out.

10 CHAIR METTER: Any other comments?

11 Because if we don't do those Monday,
12 Tuesdays, then you're confined to November 1 and 2
13 and Halloween.

14 But you know what we could do? If
15 people are not opposed to it, perhaps just send out
16 another poll for those weeks, or is that going to
17 be difficult, Dr. Valentin-Rodriguez?

18 MS. VALENTIN-RODRIGUEZ: No, I can
19 certainly send out another poll.

20 So, these dates that I proposed to you
21 all ensure that we have a date that's available to
22 the Commission for a Commission briefing. That
23 way, we can reduce travel by not having to bring
24 you all in again for a, you know, a second trip for
25 a Commission meeting.

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1 So that's why I proposed these days
2 which I consulted with our Office of the Secretary
3 on.

4 If these don't work, then we can
5 certainly go back to the drawing board. But I
6 probably -- I think we'd probably be looking at a
7 December time frame meeting, then.

8 CHAIR METTER: Yes, Mr. Green?

9 MEMBER GREEN: Before COVID, we seemed
10 to do the meeting with the Commissioners live in
11 the spring. And because of COVID, it fell on to
12 the fall.

13 Is there any thought to put that back
14 into the spring and if we did that, would we miss
15 this year's or would we do this fall and this
16 spring? Are we going to stick with spring or fall
17 or just --

18 MS. VALENTIN-RODRIGUEZ: No, we can --

19 CHAIR METTER: That was -- yes.

20 MS. VALENTIN-RODRIGUEZ: Oh, I was
21 commenting --

22 CHAIR METTER: Thank you.

23 MS. VALENTIN-RODRIGUEZ: Yes, sorry,
24 Dr. Metter, for interrupting.

25 No, I was just going to say that

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1 certainly, within the committee's purview, that is
2 an option. We could forego a Commission meeting in
3 the September -- in the fall time frame and then
4 reach out to the Commission for a spring meeting
5 date. I think that would probably be easier to
6 book at this time. We just have to ensure to get
7 on their calendar early so that we can get
8 availability of dates.

9 Their October time frame is very busy
10 this year, so their calendar is filling up.

11 So that is certainly one option to
12 forego a meeting this year and then, get back to
13 them and have the Commission meeting in the spring.

14 MEMBER GREEN: Just to be clear, the
15 ACMUI would still meet, but we would not meet with
16 the Commissioners?

17 MS. VALENTIN-RODRIGUEZ: Correct.

18 MEMBER GREEN: So, we could plan a day,
19 a Monday and Tuesday adjacent to a weekend, perhaps
20 in October, where we don't have to meet with the
21 Commissioners this fall, we could plan that face to
22 face meeting with the Commissioners in the spring?

23 MS. VALENTIN-RODRIGUEZ: Correct, I
24 could open up the week of the 16th or the 23rd.

25 CHAIR METTER: Do I -- may I ask the

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1 ACMUI, is that a reasonable proposal for y'all to
2 have the fall meeting and then we meet with the
3 Commission in the spring?

4 (Off microphone comments.)

5 CHAIR METTER: Okay, so --

6 (Off microphone comments.)

7 CHAIR METTER: Unless there's any other
8 issues that come up.

9 So, can we have a motion for that?

10 MEMBER HARVEY: Motion, Richard Harvey,
11 I'll make the motion.

12 CHAIR METTER: All right, so the motion
13 is to have a fall meeting of the ACMUI without the
14 Commission and have a Commission meeting in the
15 spring. Do I have a second for that?

16 MEMBER MARTIN: Second.

17 CHAIR METTER: Okay, I have many people
18 seconding. So, we have many seconds.

19 So any other discussion?

20 All in favor, say aye.

21 (Chorus of aye.)

22 CHAIR METTER: All opposed or abstain?

23 So, we'll go ahead and proceed with
24 that. And we'll go ahead and have the -- a poll
25 sent out regarding the appropriate dates for the

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1 fall.

2 And then also find out when the
3 Commission is meeting in the spring and put out two
4 polls for that. Maybe the first one and then, we
5 can be sure that it's already clear that it's --
6 one is just for the ACMUI, the second is for the
7 Commission meeting.

8 Yes, Mr. Green?

9 MEMBER GREEN: And part of that poll,
10 let's make sure we capture the European meetings
11 that were not on the calendar so that we can avoid
12 those.

13 CHAIR METTER: Okay.

14 Josh, is you want, go ahead and give
15 that dates to Dr. Valentin so --

16 (Off microphone comments.)

17 (Simultaneous speaking.)

18 CHAIR METTER: Okay, thank you.

19 MEMBER OUHIB: It looks like there is
20 only November -- early November that works out
21 because of the American Heart Association's then in
22 November.

23 MEMBER HARVEY: November 13th, yes.

24 Is it worth discussing the two dates
25 which Mr. Green mentioned, the 16th and 17th and

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1 the 23rd and 24th right and see if we can come to a
2 time which would work for everyone?

3 MEMBER MARTIN: I think that sounds
4 great.

5 MEMBER HARVEY: Because both of those
6 would work for me.

7 MEMBER MARTIN: What month is it?

8 MEMBER HARVEY: October 16 and 17 or
9 October 23 and 24.

10 VICE CHAIR JADVAR: There are no
11 October dates yet.

12 MS. VALENTIN-RODRIGUEZ: No, so that --
13 those would have included the Commission meeting,
14 that's why they're not -- I didn't propose them,
15 but we can certainly discuss them at this time.

16 CHAIR METTER: Why don't we go ahead
17 and have you send out a poll so people can actually
18 look at their schedule so that they're not at a
19 short notice, maybe agreeing to something that they
20 may not be able to attend.

21 So, let's go ahead and, if you don't
22 mind, DR. Valentin-Rodriguez, if you can send out a
23 poll and then we can have everybody can look at the
24 schedule and have a date that they can be sure they
25 can attend.

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1 MS. VALENTIN-RODRIGUEZ: Yes,
2 definitely. I'll add more dates to the poll and
3 resend it. Of course.

4 CHAIR METTER: And I believe we would
5 either -- would you like a Monday, Tuesday, or
6 Thursday, Friday? Or it doesn't really matter just
7 as long as it --

8 (Off microphone discussion.)

9 CHAIR METTER: I mean, there's --

10 MS. VALENTIN-RODRIGUEZ: All right, we
11 can also do Thursday, Friday if you wanted.

12 CHAIR METTER: No, we'll go ahead and
13 stick with the Monday, Tuesday.

14 MS. VALENTIN-RODRIGUEZ: Okay.

15 VICE CHAIR JADVAR: Yes, Wednesday, you
16 have to travel.

17 MS. VALENTIN-RODRIGUEZ: I know, yes,
18 okay, okay.

19 CHAIR METTER: So, we'll go ahead and
20 do Monday, Tuesday. Any other items that we need
21 to cover?

22 MS. VALENTIN-RODRIGUEZ: No, that's all
23 I had, Dr. Metter, so I turn it back to you.

24 CHAIR METTER: Well, thank you very
25 much. Do I have any final comments before we

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1 adjourn this meeting from the committee or for the
2 NRC staff?

3 MR. EINBERG: Yes, Chris Einberg,
4 again.

5 Yes, I want to echo what Dr. Valentin
6 said regarding the hard work that the committee has
7 put in, especially the two subcommittees that
8 reported out.

9 We thank the subcommittees, all the
10 members of the ACMUI, and as well as the NRC staff,
11 and the public comments that we received.

12 So, a lot to think about and we're busy
13 and we appreciate -- and you're all very busy as
14 well, and so we appreciate all the hard work and
15 the thought you put into these discussions.

16 CHAIR METTER: Thank you very much, Mr.
17 Einberg.

18 So, at this point in time, thank you
19 very much for everybody's contribution and hard
20 work and the meeting is adjourned.

21 (Whereupon, the above-entitled matter
22 went off the record at 3:39 p.m.)

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