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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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WEDNESDAY,

SEPTEMBER 9, 2026

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The meeting was convened via videoconference, at 1:00 p.m. EDT, Hossein Jadvar, ACMUI Chair, presiding.

MEMBERS PRESENT:

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

RICHARD L. GREEN, Vice Chair

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

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

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

RICHARD HARVEY, Dr.PH., Member

JOSH MAILMAN, Member

MELISSA C. MARTIN, Member

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

ZOUBIR OUHIB, Member

HARVEY B. WOLKOV, M.D., Member

NRC STAFF PRESENT:

Katherine TAPP, Ph.D.

ALLY MARRA

CHRISTIAN EINBERG

SARAH HOENIG

SOPHIE HOLIDAY

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

(1:10 p.m.)

MR. EINBERG: Good afternoon. As the designated federal officer for this meeting, I'm pleased to welcome you to the public meeting of the Advisory Committee on the Medical Uses of Isotopes.

My name is Chris Einberg. I am the Chief of the Medical Safety and Events Assessment Branch, and I have been designated as the federal officer for this advisory committee in accordance with 10 CFR Part 7.11.

This is an announced meeting of the committee and is being held in accordance with the rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission.

This meeting is being transcribed by the NRC, and it may also be transcribed or recorded by others.

The meeting was announced in the August 21st, 2026 edition of the Federal Register, Volume 91, pages 54408 through 54409.

The function of the ACMUI is to advise the staff on the issues and questions that arise on the medical use of byproduct material.

The committee provides counsel to the staff, but does not determine or direct the actual decisions of the staff or the commission. The NRC solicits the views of the committee and values their opinions.

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

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

Dr. Hossein Jadvar, Chair, Nuclear Medicine Physician.

CHAIR JADVAR: Present.

MR. EINBERG: Mr. Richard Green, Vice Chair, Nuclear Pharmacist.

VICE CHAIR GREEN: Present.

MR. EINBERG: Dr. Michael Folkert, Radiation Oncologist.

MEMBER FOLKERT: Present.

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

MEMBER MARTIN: Present.

MR. EINBERG: Mr. Zoubir Ouhib, Therapy Medical Physicist.

MEMBER OUHIB: Present.

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

MEMBER WOLKOV: Present.

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

MEMBER HARVEY: Present.

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

MEMBER EINSTEIN: Present.

MR. EINBERG: Dr. Joanna Fair, Diagnostic Radiologist.

MEMBER FAIR: Present.

MR. EINBERG: Dr. Michael O'Hara, FDA Representative.

MEMBER O'HARA: Present.

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

MEMBER MAILMAN: Present.

MR. EINBERG: Okay. I confirm that we have a quorum. Dr. John Angle, an interventional

radiologist consultant to the ACMUI, may participate in today's discussion, but does not have voting rights for any actions requiring a vote.

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

If a member believes that they may have a conflict of interest, as that term is broadly used within the 5 CFR Part 2635, with regard to an agenda item to be addressed by the ACMUI, this member should divulge it to the chair and to the DFO as soon as possible.

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

We are using Microsoft Teams so that members of the public and other individuals can watch online or join via phone.

The phone number for the meeting is 301-576-2978. The phone conference ID is 969086535, hashtag. Once again, 969086535, hashtag. The handouts and agenda for this meeting are available on

the NRC's ACMUI public website.

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

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

For the purposes of this meeting, the chat feature in Microsoft Teams has been disabled. Dr. Jadvar, at his discretion, may entertain comments or questions from members of the public who are participating today.

Individuals who would like to make a comment, when Dr. Jadvar opens it up for comments, may use the raise hand function to signal to our Microsoft Teams host, Ms. Hoenig, that you wish to speak.

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

When you begin your comment, please clearly state your first and last name for the record. Comments are typically addressed by the committee near the end of the presentation after the committee

has fully discussed the topic.

We will announce when we are ready for the public comment portion of the meeting and Ms. Hoenig will assist with facilitating public comments.

At this time, I ask that everyone who is not speaking to please mute your Teams microphones or phone, and I will now turn the meeting over to Dr. Jadvar, the ACMUI chair.

CHAIR JADVAR: Thank you very much, Mr. Einberg. At this time, I would like to welcome everyone to this public meeting of the ACMUI on September 9, 2026.

The first item on our agenda is an overview of the proposed rule that is entitled, Reducing Barriers to Medical Use Licensing, and this will be presented by Dr. Katie Tapp from the NRC.

Dr. Tapp, the floor is yours.

DR. TAPP: Thank you, Dr. Jadvar.

I am a senior health physicist with the NRC and I wanted to start us off with a quick overview of the proposed rule, which the ACMUI subcommittee reviewed to present on today, and the proposed rule is entitled, Reducing Barriers to Medical Use Licensing.

Next slide, please. First, I wanted to

ensure everyone knows that this proposed rule was published in the Federal Register on July 27th, 2026, for a 45-day public comment period, which ends tomorrow at 11:59 p.m. Eastern time.

Today's meeting is for the ACMUI to provide their comments to the NRC. If the public has comments today, they are for the ACMUI.

If the public would like to provide comments to the NRC for consideration on this rule, you should submit them to us through regulations.gov under Docket ID NRC 2025-1237. The NRC's estimated date to publish the final rule is in March of 2027.

Next slide, please. I'll start off with walking through the key components of the proposed rule.

The key areas in this rule include reducing burden to training and experience requirements for physicians seeking to become authorized users, establishing predictive full licensing pathways for medical technologies that are now well-established that were previously considered emerging, creating a pathway for use of direct infusion systems to administer radiopharmaceuticals with short half-lives, such as rubidium-82 generators,

and implementing additional administrative improvements to further reduce burden while preserving safety.

Next slide, please. I'll begin with the first key topic area, the proposed changes aimed at reducing burden in the training and experience requirements for physicians seeking authorized user status.

As you know, we have reviewed training experience for several years prior to Executive Order 14300.

This first change in the proposed rule is to take some of the stakeholder comments and ideas that we've come up with throughout those years and provide them in the proposed rule.

The first proposed change is for physicians who have successfully completed multiple-year accredited residency programs that include specific radiation safety training topics, would no longer need to provide individual training hours to be granted authorized user status.

Instead, successful completion of such a residency, along with attestation from the program director or another authorized user that the physician

has completed all the requirements included in the regulation, including training in the topic areas that are included in the regulation, will be sufficient to demonstrate competency for the authorized user status.

This change establishes an authorized pathway that both recognizes the depth and rigor in modern residency training programs and removes unnecessary administrative paperwork burden.

The next proposed rule would eliminate the requirement for physicians to submit paperwork demonstrating they meet the training experience specified in the regulations for lower-risk diagnostic use. The regulations would still remain. It would just be removed from the licensing process.

Third, the proposed rule would replace outdated prescriptive training requirements with a focus on device-specific and use-specific training to ensure physicians are trained on uses they perform.

This proposal would shift from static one-time training requirement to a model that emphasizes ongoing education and continued competency, something ACMUI has recommended in the past.

Finally, the NRC is proposing to broaden the definition of physicians to allow those who went

to medical school abroad to be able to become authorized users if they meet all other training and experience requirements and are licensed by the state to practice medicine without the need for an exemption by the NRC.

Next slide, please. The proposed rule would also improve efficiency by establishing predictable, risk-informed licensing pathways for several well-established emerging medical technologies that are currently licensed under 10 CFR 35.1000, commonly referred to as emerging medical technology pathway.

By transitioning mature technologies into traditional licensing subparts, the proposed rule creates a more stable, risk-informed, performance-based regulatory framework.

This transition would create uniform expectations, cuts unnecessary administrative steps, enhances predictability for applicants, and strengthens the agency's ability to license future innovations without relying on case-by-case guidance that we currently see in 35.1000.

For example, the proposed rule includes these pathways for generators, superficial ophthalmic

treatments, gamma stereotactic radiosurgery units, microsources, and other general modernizations to ensure our regulations are modern and risk-informed.

Next slide, please. Finally, the proposed rule includes several important updates that would improve efficiency, modernize outdated requirements, and allow both NRC and licensees to focus on what truly matters for radiation safety.

First, the -- such as rubidium-82 generators, used to administer very short half-lifed radiopharmaceuticals.

Because the half-life of rubidium-82 is only about 75 seconds, it is not practical to measure dosages prior to administration using traditional methods.

For over a decade, the NRC has been reliant on enforcement discretion to allow safe, clinical use of these generators.

The proposed rule incorporates these safety practices directly into regulation, giving licensees a predictable method to continue providing vital cardiac imaging procedures without unnecessary administrative hurdles.

Next, the proposed rule suggests proposed

changes to reduce administrative burden, such as proposing to remove requirements that diagnostic sodium iodide-131 require a written directive, expanding decay-in-storage from 120 days to 275 days to include lutetium-177m and cobalt-57 flood sources, and eliminating duplicative requirements for mobile medical services.

Finally, the proposed rule modernizes medical event reporting so providers only need to report cases that truly involve radiation safety significance.

Currently, some events must be reported even if they stem entirely from a medical complication unrelated to radiation safety.

The proposed rule is intended to fix this where providers would no longer be required to report events caused by emergent medical conditions, such as a heart attack, that interrupt a procedure but do not reflect a breakdown in radiation safety controls.

This allows licensees to focus on practicing medicine during an emergency and enabling the NRC and agreement states to concentrate on events related to radiation safety.

These updates collectively reduce

unnecessary burden and strengthen clarity and predictability of the regulation framework, improving patient access while maintaining robust radiation safety protections.

Next slide, please. At the end of the subcommittee's presentation and the ACMUI discussion, Dr. Jadvar may open up for public comment at his discretion.

While comments heard today may be considered by the NRC, the purpose of today's meeting is for the ACMUI to provide their comments and recommendations to --

(Pause.)

DR. TAPP: I apologize. We lost connection in the room for a second, but we're back.

So, just to backtrack, today's meeting is for the ACMUI to provide their comments to the NRC. If a member of the public would like to provide comments to the NRC staff for consideration, those must be submitted in writing through methods described in the Federal Register Notice to receive formal consideration in this rulemaking.

To submit these comments, the member of the public should go to regulations.gov and search for

Docket ID NRC-2025-1237. And, again, the public comment period closes tomorrow night.

With that, next slide, please. Now, with that, I'll turn it over to Dr. Folkert and the ACMUI subcommittee. Thank you.

MEMBER FOLKERT: All right. Thank you very much, Dr. Tapp. And so, hopefully everyone's able to hear me now.

MS. HOENIG: Yes, we can hear you. Thank you.

MEMBER FOLKERT: Okay. Excellent.

Well, I'd like to thank the NRC for supporting and hosting this forum for discussion of this very extensive and detailed work.

I'll be presenting the report to the subcommittee on reducing barriers to medical use licensing.

Okay. We can go to the next slide, please. And I'd like to also thank the members of the subcommittee, including Dr. Fair, Dr. Harvey, Mr. Ouhib, Dr. Wolkov, and Dr. Angle, and of course Dr. Tapp, who assisted us as our staff resource in putting this together.

Next slide, please. So, this particular

subcommittee on reducing barriers to medical use licensing was first initiated by the NRC staff on November 21st of 2025.

At the time, the subcommittee was charged with reviewing and commenting on the proposed rule to amend 10 CFR 35 in response to Executive Order 14300.

Next slide, please. So, on July 27th, 2026, the NRC published the proposed rulemaking package entitled, Reducing Barriers to Medical Use Licensing Rulemaking for public comment.

As Dr. Tapp already presented, this proposal is meant to amend the NRC regulations that are contained in 10 CFR Part 35 to modernize and streamline rules regarding the medical use of radioactive materials to improve licensing flexibility and efficiency, including regulations that incorporate microsources, gamma stereotactic radiosurgery systems into traditional Part 35, training experience items, decay-in-storage provisions, medical event reporting, and other related items. And, as noted, this rulemaking is in response to Executive Order 14300.

So, move to the next slide, please. So, the ACMUI subcommittee first met with the NRC staff working group that developed the draft proposed rule

on January 7th, 2026, at which point it was a work in progress.

We were discussing proposed regulatory changes, the draft Federal Register Notice, and guidance to prepare for the committee review and comments.

And during this period, due to the timeline of the rule and that it wasn't finalized, the ACMUI did not provide recommendation to report to the NRC on the draft proposed rule.

Therefore today, September 9th, 2026, this meeting will be the first time that we're providing our review and comments to the proposed rule.

Next slide, please. And then these comments follow from a line-by-line review with the NRC staff of the Federal Register Notice, the FAQ, and the specific modifications to 10 CFR 35.

The members of the subcommittee, we want to note we appreciate the efforts of the NRC to perform this extensive overhaul of existing regulations and for the care and attention that they put into reviewing the many and diverse changes that are proposed, we commend the efforts of the NRC for their efforts in addressing the need to improve

efficiency and reduce barriers to medical use licensing for radioactive byproduct material, and we appreciate the incorporation of many recommendations from other subcommittee reports that are pertinent to the matters at hand.

Next slide, please. So, moving into specific comments, our first comment was on definition of physician.

The proposed rule aims to broaden the definition for physicians eligible to be authorized users by removing the requirement for a medical doctor or doctor of osteopathy, or DO, from the title.

And the understanding, or the spirit of this, is to allow foreign-trained physicians holding degrees such as MBBS and MBBCh -- these are the Bachelor of Medicine, Bachelor of Surgery, or their Latin versions, Baccalaureus Medicinae or Baccalaureus Chirurgiae -- to become authorized users so long as they're fully licensed to practice medicine independently in the United States and its defined territories.

Next slide, please. There is some concern, however, though, in this proposed rule. It defines physicians as anyone licensed to prescribe

drugs in the practice of medicine.

The subcommittee was concerned that this could be interpreted too broadly, potentially including non-physician nurse practitioners and other practitioners licensed to prescribe drugs.

The subcommittee disagrees with these changes as written, and recommends that rather than removing MD and DO, to explicitly mention MD, DO, as well as MBBS, MBBCh, or other physicians with equivalent license board certified or board eligible for practice.

Next slide, please. And the next specific area of comment is on recentness of training. In the proposed rule, recentness of training requirements specified in 35.59 is intended to be replaced with a performance-based continuing education model.

This addresses the current seven-year rule specified in 35.59, which is felt to be vague. It allows for exceptions to be made if the prospective AU has completed continuing education relevant to clinical practice with radioactive byproduct material, but doesn't provide guidance on the training content.

In addition, a change under 35.2059, records of continuing education and training,

licensees will be responsible for maintaining records of the continuing education and training.

Next slide, please. The subcommittee does agree with these changes. This is in keeping with prior recommendations by another subcommittee, the Training and Experience Subcommittee for All Modalities, and the ACMUI recommends that the NRC partner with professional societies to generate and administer this continuing education content.

It will be important for the continuing education material and content to have a mechanism for review by the NRC to establish whether it sufficiently covers required knowledge base information to meet requirements.

And this stems also and refers to the Subcommittee on the ADVANCE Act Report that was previously issued by the ACMUI.

Next slide, please. Another specific comment on generator training. So, generator training work experience were removed from the training experience requirements in 35.290.

And this is tied to other changes proposed in the proposed Rule 35.63, noting that for generation of isotopes with very short half-lives, that as long

as the equipment is calibrated and manufacturer's guidelines and procedures are followed, the need for enforcement discrimination is eliminated.

The subcommittee agrees with these changes, which were felt to be appropriate for simplification and efficiency without compromising radiation safety.

Next slide, please. Next large area of comment is on specialty board certification approval requirements.

The proposed rule centralizes specialty board certification approval requirements under Section 35.58, and notes that names of recognized board certifications will be maintained as they are currently on the NRC's Medical Uses Licensee Toolkit webpage.

So, in the proposed rule, most physician residency pathways would no longer require prescriptive training hour requirements, but instead must be accredited and include core information and knowledge topics that are required by the NRC in their training.

Next slide, please. So, this slide summarizes a number of the proposed residency training

pathways.

So, under nuclear medicine, diagnostic radiology, and radiation oncology, the 35.190 training for uptake, dilution, excretion studies, 35.290 training for imaging and localization studies, would all require a minimum of three years of training in the listed specialties with appropriate training experience topics.

Specific to the nuclear medicine and radiation oncology training pathways, these would be covered under 35.390, training for unsealed byproduct material for which a written directive is required, 35.392 and 35.394, which are training for sodium iodide-131 for quantities less than or equal to 1.22 and quantities greater than 1.22 gigabecquerels, or 33 millicuries.

These, again, would just require a minimum of three years of training in nuclear medicine and radiation oncology with appropriate training and experience topics.

And then specific to radiation oncology, 35.490, which is training for use of manual brachytherapy sources, and 35.690, training for remote afterloader units, teletherapy units, and gamma

stereotactic radiosurgery units, this would also require the three years of training in radiation oncology with appropriate training and experience topics. It would remove the prescriptive hours requirements.

Next slide, please. In this area, the subcommittee could not reach consensus or agreement on the subject of removing prescriptive training hours for physician residency pathways.

There were concerns raised that removing the minimum hour requirements completely for those who completed three years of residency in certain fields would overly reduce the training program accountability.

And it is noted that maintaining prescriptive hours specifically for classroom and laboratory training does help to ensure that trainees have protected time for education outside of the work experience on the required core knowledge topics.

So, there was consensus on maintaining classroom and laboratory training. Consensus could not be reached on the overall need for prescriptive work experience hour requirements.

Next slide, please. So, it is noted that

minimum hours do remain present in other sections, such as 24 hours for an authorized user for superficial ophthalmic use of beta emitters in 35.491 and eight hours for authorized users for use of sealed sources and medical devices for diagnosis in 35.590.

So, overall, the subcommittee does recommend retaining the prescriptive requirement for 80 hours of classroom and laboratory training in 35.290 and 200 hours of classroom and laboratory training in 35.390, 35.490, and 35.690.

Next slide, please. The area where consensus was not reached where opinions varied was whether completion of three years in an accredited program would suffice as a surrogate benchmark for sufficient work experience hours, the total of 700 hours of training that includes both the classroom laboratory training that we mentioned previously, as well as the 500 hours of relevant work experience.

Some members of the subcommittee agreed with the proposed changes and the proposed rule, while others recommended that the work experience hours requirement should be only for specific accredited programs in which the majority of the training fulfills the core knowledge base requirements. So,

i.e., the training program should exceed the existing minimum 700-hour requirement.

The specific suggestion was that the nuclear medicine residency met those requirements for 35.190, 35.290 and 35.390, while radiation oncology automatically meets those for 35.490 and 35.690.

Next slide, please. Moving on to the next area of comment, alternative and cross-qualification pathways.

The proposed rule retains alternative and cross-qualification pathways under 35.396, training for the parenteral administration of unsealed byproduct material requiring a written directive.

The proposed rule explicitly lists a minimum of three years of training in nuclear medicine or radiation oncology with appropriate training and experience topics as eligible for AU status for parenteral administration of unsealed byproduct material requiring a written directive and retains the prescriptive 80 hours of classroom and laboratory training.

The subcommittee was in agreement with the proposed rule on the structure for this. This is felt to be appropriate to maintain flexibility of training

to get people appropriately licensed for and authorized for these applications.

Next slide, please. Next area for specific comment is on training case numbers. The proposed rule removes prescriptive case numbers for oral and parenteral procedures under 35.390, 35.392, and 35.394, and 35.396, transitioning to a sufficient experience model instead.

More information on this is intended to be provided in guidance, but it does state that the responsibility for assessing this sufficient experience will be placed on the supervising authorized user or preceptor, and training and experience in specific parenteral radiopharmaceuticals, for example, should be generally transferable -- should be considered to be transferable to other parenteral radiopharmaceuticals.

So, i.e., training in lutetium-177 for the treatment of prostate cancer should also be applicable to the training in a lutetium-177 radiopharmaceutical for the treatment of a neuroendocrine tumor.

The proposed rule increases flexibility for new and emerging radiopharmaceutical applications with novel pathways or mechanisms of introduction.

And we will note, and then we'll be talking a little bit more about this new proposed training pathway for microsources, three hands-on cases will still be required. So, there's a little difference there.

So, next slide, please. This was another area where the subcommittee did not reach consensus on the removal of the specific number of cases.

So, under the existing pathway, supervising AU is required to sign off on each individual case and should only have done so if the trainee had been substantially involved in the case. The supervising AUs already have the responsibility for knowledge assessment.

Moving to a sufficient experience model could, and this is one of the reasons to support the proposed rule, could avoid fragmentation of training experience and a more global assessment of trainee understanding.

However, in contrast, some members of the subcommittee felt that retaining the current case minimums was needed to ensure proper training.

There was a concern that only doing one case would not provide that sufficient global

experience that would allow the authorized users to be able to assess whether the trainee had sufficient experience.

Next slide, please. So, recommendations for training case numbers. So, one recommendation was that further clarification of in-person and hands-on training should be provided in guidance.

So, as many administrations are performed with the authorized user supervising a trained staff member such as a certified nuclear medicine technologist, and it should be made clear that training should also not specifically require that each individual trainee personally deliver an oral dose to a patient or personally push the parenteral radiopharmaceutical via IV.

And it should be spelled out that experience with these applications should involve the trainee substantively in as much of the case as possible from acceptance of the radiopharmaceutical to calibration of the pharmaceutical, delivery of the drug, and post-treatment management, although all aspects of this may not be seen on the same patient.

Next slide, please. It is noted that the proposed rule appears to remove the distinction

between low- and high-dose sodium iodide-131 procedures for 35.390.

It was noted by members of the subcommittee that low- and high-dose procedures do have different release criteria in some clinics, different release instructions.

And it was felt that addressing these training issues with separate 35.392 and 35.394 pathways for the lower and higher activities of iodide-131 continues to be advised.

Next slide, please. Moving on to license amendments. The proposal to remove the requirement for radioactive materials license amendments to add authorized users for diagnostic uses under 35.100 and 35.200 applications was felt to be appropriate, as these are low-risk procedures that are best managed at a program level, and this is consistent with prior recommendations by ACMUI subcommittees, the subcommittee on the ADVANCE Act.

Next slide, please. Moving on to the integration of emerging medical technologies, the 35.1000 applications, into traditional regulations and refining of safety criteria.

So, as Dr. Tapp discussed, a number of

radioactive byproduct material applications have been managed for years under 35.1000 emerging medical technology guidance.

The proposed rule will formally integrate these EMTs into traditional 10 CFR Part 35 processes. These include, but are not limited to, microsources or microspheres, gamma stereotactic radiosurgery systems, generators, and newer ophthalmic devices.

35.57 will note that authorized users who are already approved for these applications currently under 35.1000 will not need to undergo additional training requirements except for new devices or applications for which they were not authorized previously.

Next slide, please. One of the major changes under the proposed rule is the creation of the 35.700 pathway.

This is a pathway that is meant to capture the utilization of microsources or microspheres. It has some similarities to the existing 35.400 pathway for manual brachytherapy.

The purpose of this is to align microsources with other forms of permanent manual brachytherapy to have consistent written directive

requirements, and it allows adaptation and changes to clinical scenarios so that the written directive can be updated after administration, but before the patient is discharged.

Microsources are defined as solid carriers of radioactive material delivered via parenteral methods to a treatment site, and this does include a potentially very wide range of technologies and delivery methods beyond the current widespread practice that uses glass or resin microspheres incorporating radioactive material commonly used for liver radioembolization.

Other applications that would fall under this pathway could include installation of microsources into the cerebrospinal fluid for treatment of leptomeningeal disease or distillations into surgical cavities to deliver peritoneal radiation for peritoneal carcinomatosis. And so, there's multiple avenues and applications that this pathway encompasses.

Next slide, please. The subcommittee noted that the core training pathway, 35.790, that provides training experience for these microsources, is focused completely on interventional radiology

despite the long history of nuclear medicine and radiation oncology involvement in these procedures.

And while nuclear medicine and radiation oncology physicians may obtain authorization for 35.700 applications via training under 35.390, 35.396, and 35.490, or equivalent agreement state requirements, the attestation would still come from an authorized user under 35.790, which would primarily be considered to be an interventional radiology authorized user.

This has the potential for reducing the already diminishing role of nuclear medicine and radiation oncology in microsource therapies by raising perceived barriers to authorization for these specialties.

The subcommittee recommended that nuclear medicine and radiation oncology should be explicitly added into the 35.790 training pathway due to their established role in existing microsphere and microsource procedures, as well as the increasing number and range of microsource applications and avenues for administration potentially emerging into the clinic.

The specific proposal to change

35.790(a)(1), the subparts to, has successfully completed a minimum of three years of residency training in diagnostic radiology and one year of interventional radiology in a residency or fellowship program(s), or a minimum of three years of credited residency training in nuclear medicine or radiology.

And so, that's the specific wording suggested to be added -- to be changed in the proposed rule.

Next slide, please. Next area for integration of EMTs is Gamma Stereotactic Radiosurgery Systems, or GSRs.

The GSRs, under the proposed rule, would have updated physical presence requirements, notably removing the requirement that the authorized users and authorized medical physicists must be physically present throughout the treatment, but now only during the initiation of treatments.

The authorized user must be immediately available in case of an emergency or treatment interruption, and available for the continuation of treatments or reinitiation after a treatment interruption.

The authorized medical physicists and

staff who are trained for emergency response specific to that GSR would be physically present at the machine.

No changes were recommended for physical presence requirements for high-dose rate brachytherapy remote afterloading brachytherapy applications, just in contrast to this particular radioactive byproduct material application.

In addition to this change in physical presence requirements, the proposed rule also recommends a number of changes to calibration and quality assurance regulations that address the many incremental improvements in medical technology used in these systems and to remove outdated requirements.

Next slide, please. Okay. And so, in terms of the GSRs, the proposed changes were overall felt to be reasonable by the subcommittee due to the significant advancements in safety features that are built into modern GSRs.

We note that the GSR treatments would still have the authorized user immediately available, although not necessarily at the console with the authorized medical physicist at the machine.

Both the AU and the AMP would be present

at the start of treatment. The AU must be available to determine whether re-initiation can be done after treatment interruptions, but doesn't have to be physically present.

And immediate availability is defined in 10 CFR 35.615 and in the FAQ that is provided as part of the proposed rule, that describes this as meaning the AU must be able to respond without delay, but does not need to respond in person.

The AU has to be able to evaluate the situation to provide supervision and support, and this is consistent with prior recommendations by ACMUI subcommittees. Next slide, please. The next area for EMTs is generators. The proposed rule provides clear information for generators with a number of changes throughout the proposed rule, including determinations of doses, permissible concentrations for generator-produced radionuclides, records of generator breakthrough testing, reporting a notification for eluates that are exceeding breakthrough limits, and removes a number of outdated regulations for various generators and radioisotopes created by those generators.

The subcommittee agreed with these

changes. They felt that they improved clarity of the regulations and will allow a greater flexibility for new generator technologies and integration into standard regulations rather than relying on time-consuming 35.1000 pathways. Next slide, please. Next area for EMTs are ophthalmic devices. The proposed rule makes changes throughout the regulations on the use of ophthalmic devices, replacing the overly specific terms in devices for strontium-90 with more generally -- with the more general term of beta-emitting resources and this is throughout the proposed rule.

It also removes the case requirements of five treatments and replaces it with similar sufficient experience supervised work requirements that are used in other areas in the proposed rule. And the subcommittee was in agreement with these changes. They felt that they make their regulations more generalizable and allow flexibility as new devices come into use. Next slide, please. Large area of comment is in written directives. The proposed rule removes the written directive requirement for diagnostic administrations of sodium iodide-131, specifying that it only applies to

therapeutic doses.

And "therapeutic doses" are loosely defined in the proposed rule as dosages of unsealed product material that are intended to deliver radiation use for palliative or curative treatments. Next slide, please. The subcommittee was in disagreement with this change. They did not feel that the removal of the written directive for sodium iodide-I-131 for diagnostic activity ranges suggested as safe is appropriate.

And the reason for this, is that in many cases a diagnostic dose of sodium iodide-I-131 could still lead to significant end-organ damage if given to the wrong patient. For example, a young patient with an intact thyroid. The dose of sodium iodide-I-131 used to survey patients with metastatic functioning thyroid cancer can be quite high ranging up to 30 millicurie, and a five millicurie total body dose intended for a patient with an absent thyroid inadvertently given to a patient with an intact thyroid would result in total ablation of the thyroid organ and end-organ failure.

So, this is not considered to be a safe -- that this is a activity level that is safe without the

use of a written directive. Elimination of a written directive in this setting would also go against prior recommendations of the ACMUI regarding inclusion not just of a written directive, but of a checklist in administrations to improve safety. So next slide, please. And in terms of the changes to the -- in terms of the changes -- in terms of the written directives for 35.400, manual brachytherapy, and the proposed 35.700 applications for microsources, the subcommittee recommends the addition that the treatment site should be specific.

So, for liver microsphere radioembolization, it should specify right lobe versus left lobe, for example. The subcommittee notes that there have been many medical events discussed in the Medical Events Subcommittee resulting from the incorrect lobe of liver that was treated, resulting in no therapeutic benefit and real or potential harm to patients.

Next slide, please. Additionally, the subcommittee recommended that the written directive for high dose rate, or HDR, remote afterloading brachytherapy, which falls under 35.600 applications, which currently includes the radioisotope, the

treatment site, the dose per fraction, number of fractions and total dose, should change "treatment site" to "specific site" with complete description and dosimetric goals.

So, for example, with high dose rate brachytherapy treatments such as vaginal cylinders, the radiation prescription generally includes the length of treatment and depth of treatment from the applicator surface, and not matching the prescription could result in significant underdosage or overdosage to the target.

Similarly, surface and skin applicators such as the Leipzig, Valencia or Freiburg Flap, should have a stated depth of treatment as that prescription depth can have a significant impact on the dose to the surface, the dose to depth, if there is a mismatch.

Next slide, please. In terms of event reporting, the proposed changes to medical event reporting would allow physicians to respond appropriately to emergent patient conditions without the need to report it as a medical event. As discussed by Dr. Tapp, this would allow medical events reporting to focus on events that have a potential radiation safety significance, and it also harmonizes

dose and activity-related event reporting between microsource brachytherapy, that proposed 35.700 pathway, and traditional manual brachytherapy under 35.400.

Next slide, please. Additionally, the changes in dose reporting requirements for the embryo and fetus would exempt cases where pregnancy could not reasonably be excluded prior to administration as long as the institution was following their approved policy and procedures and a reasonable effort was made to determine pregnancy status or the dose to the embryo or fetus specifically approved by the authorized user.

The subcommittee is in agreement with these changes as they accommodate clinical realities and help us to reduce unnecessary reporting. The ability to adapt to unexpected developments allows for appropriate medical decision-making to be performed. Next slide, please. In terms of changes to storage, the expanding use of decay-in-storage, increasing allowable half-life from 120 days to 275 days, should allow the safe and cost-effective onsite decay and disposal of clinically relevant long-lived materials like metastable lutetium-177. The subcommittee is in agreement with these changes, which, again, are

consistent with prior ACMUI recommendations, specifically the Subcommittee on ADVANCE Act.

Next slide, please. The changes made for human subjects research. The proposed rule eliminates NRC medical use license amendment requirement for IRB-approved human subject research. Subcommittee was in agreement with these changes. The relevant human subject research would still have ethical oversight from the institutional review boards, and this would reduce administrative requirements without compromising patient safety.

Next slide, please. Changes made to radiation safety officers and associate radiation safety officers under 35.50. The proposed rule eliminates redundant language regarding specialty board requirements, relevant educational degree, work experience, and examination requirements for RSOs and those assigned duties and tasks as an Associate Radiation Safety Officers and incorporates them under the medical specialty board pathway under 35.58(k).

Notably, this is also done for the training for AMPs, authorized medical physicists, and authorized nuclear pharmacists, which are then referred to 35.58(l) and 35.58(m) respectively. And

it also changed the duration for temporary RSO status from 60 to 120 days per year. And overall, the subcommittee is in agreement with the proposed rule. It felt that expanding the duration for temporary RSO would allow for greater flexibility.

Next slide, please. And there are some changes also to the Radiation Safety Committee requirements under 35.24. The Radiation Safety Committee would only be required for programs with more complex radioactive byproduct materials programs, so usually multiple applications and applications that have a higher safety requirement such as those requiring written directives, and would no longer require representation from nursing.

The subcommittee does support the proposed rule as limiting the need for an RSC to focus on more complex programs with written directive applications would reduce the burden on smaller programs that are focused on low-risk diagnostic applications. But the subcommittee does want to express support for licensees to have representation from a wide range of the nursing and allied health-related disciplines that supports the clinical practice of radiopharmaceutical applications, including nursing, medical assistants,

medical office assistants, advanced practice providers, including nurse practitioners and physician assistants and associates that are involved with these administrations at the licensee's institution, as possible, as they have valuable contributions to add to the safety and use of these materials in their -- at their institutions.

Next slide, please. So, our overall conclusions on the report. As it stands, the subcommittee does not recommend that the proposed rule be submitted without addressing the following key reservations: One, we want to address the definition of "physician." The subcommittee would recommend that rather than removing MD and DO, explicitly mention these, as well as other relevant licensing -- as well as other relevant titles such as MBBS and MBBCh, or other physicians with equivalent license, board-certified or board-eligible for independent practice, to make sure that this is -- that the definition of "physician" is clear.

For the diagnostic and therapeutic applications of sodium iodide I-131, the subcommittee recommends that a written directive should still be required due to the potential for significant harm

with administration of even relatively low diagnostic activities to the wrong patient, as the example we've given before of a dose intended for a patient with a surgically absent thyroid being given to a patient with an intact thyroid, in keeping with prior recommendations by ACMUI subcommittees. For the proposed 35.790 training pathway for use of microsources, the subcommittee recommends that nuclear medicine and radiation oncology should be explicitly included under 35.790 subpart (a)(1), as detailed previously in this presentation.

And lastly, as the subcommittee could not reach consensus on the topics of prescriptive training hours for physician residency pathways or prescriptive case numbers for oral and parenteral procedures under 35.390, 35.392, 35.394, and 35.396, we recommend further public discussion during our meeting before a recommendation is developed. Next slide, please. And so, these are the acronyms used in the presentation and report. And then next slide after that --

MS. HOENIG: That's the end of your slides.

MEMBER FOLKERT: That's the end of this one. Okay.

MS. HOENIG: Yes.

MEMBER FOLKERT: All right. Thank you. Thank you for your time and for allowing me to present the -- our subcommittee's work.

CHAIR JADVAR: Thank you, Dr. Folkert, for your presentation. I also want to thank all the subcommittee members and Dr. Tapp, as the NRC staff resource, for your diligent work preparing this extensive and comprehensive report.

Now, before I open up the floor for comments, I would like to state, at this time, that the comments that are going to be made should be only with regard to the entire report, except for the non-consensus topics of prescriptive training hours for physician residency pathways and for prescriptive case numbers for oral and parenteral procedures under 35.390, .392, .394 and .396.

So, again, we're going to discuss the entire report and later on vote on it, except for these two topics. As Dr. Folkert mentioned, there was no consensus.

We are going to treat those two topics separately later in today's meeting with more discussion and separate votes for those items.

So, at this time, I want to open it up to the subcommittee members if they have any further comments regarding the entire report, except those two topics.

(Pause.)

CHAIR JADVAR: All right. I hear none. Let's move on to the rest of the ACMUI members.

Are there any comments? I see Dr. Einstein. Dr. Einstein, please.

MEMBER EINSTEIN: Yeah. I mean, I do have comments on the proposed residency training pathways, which I will hold for discussion later, as per your request, but I'd like to address one more technical point.

Well, firstly, thank you, Michael and the committee -- Dr. Folkert and the committee for a tremendous presentation. Clearly, a lot of work went into this and a lot of thought. So, thanks for your efforts.

In regards to degrees for physicians, I tend to agree that it's good to list additional degrees as you've suggested, MBBS and MBBCh; however, the question is how far do you go there?

Because if you look at the degrees given

to physicians across the country -- and I happen to do a lot of research with IAEA with investigators in over a hundred countries and if you look at the titles that people have, they vary very widely. So, I wonder if you're really capturing what you want to by adding MBBS or an MBBCh.

For example, if you go to medical school at Oxford University, you get a BM BCh. If you go to medical school at Cambridge University, you get an MB BChir or chiropathy or whatever that stands for. If you go to medical school in the Czech Republic, you get an MUDr degree.

So, there's a list of about -- and I've put this together. I'll email it to you offline, Dr. Folkert -- of about 30 different titles that physicians can get.

So, the question is -- I don't know if it is the NRC's, you know, business to, like, list credentials and check credentials.

So, I think you probably want a different approach to that rather than singling out those two degrees, which admittedly are quite common in the British and Commonwealth systems, but certainly don't cover the country -- don't cover the globe, I'm sorry,

and all the physicians who practice in our country.

In Ireland, they have this MB BCh BAO. They get a degree -- every physician, you know, every radiation oncologist like yourself, you know, or cardiologist like myself gets a degree in obstetrics, which is the third title at the end there.

So, it's just really complicated how physicians are entitled across the globe and, hence, when they come to this country.

CHAIR JADVAR: Dr. Fair?

MEMBER FAIR: Thank you. Just to speak to that, which Dr. Folkert can obviously speak to that as well, I think we definitely recognized in the subcommittee that there are a plethora of titles.

And so, I suspect Dr. Folkert doesn't need the list, and that's why we added a couple that are very commonly seen even in the United States and then said, explicitly, after that, any other physician, because we wanted to make sure that we weren't excluding people, that we were recognizing that there's lots of titles that physicians have, but that, importantly, that we were distinguishing between physician and nurse practitioner, you know, others who are able to prescribe medicine, which was how it was

originally written.

And so, that was an attempt to try to give a couple more titles to give a sense of the broad number of titles that physicians can have, and then follow it with, you know, the word "physician" is what truly matters.

So, I don't feel strongly about whether we include one, you know, I would certainly agree that including 30 different possibilities wasn't really the goal. It was really the goal to say, oh, look, besides MD and DO that we're all super familiar with in the US, there's a bunch of other titles. Here's a couple, but then there's lots more, but I'm sure, you know, any -- there's lots of ways that this could be phrased, but just we -- the subcommittee is very aware that there are lots and lots of titles for physicians.

And so, we were actually trying to be more inclusive by adding a few more rather than exclusive by just saying MD and DO.

CHAIR JADVAR: Dr. Folkert?

MEMBER FOLKERT: Yeah. I was hoping -- I agree completely with Dr. Einstein. I mean, I did say that, you know, the phrasing that we put is we, you know, we had the addition of MBBS and MBBCh just

because of how common they are, but also specifically stating other physicians with equivalent license board-certified or board-eligible to practice, you know.

So, that's -- I was hopefully going to capture the rest of the options that were out there, but, yeah, it's -- it is impossible, I think, to list all the potential acronyms that could be listed after. But I was hoping that by having that, that would capture the remainder.

CHAIR JADVAR: Very good. Any other comments by the ACMUI members on any of the parts of the report, except those two topics?

(Pause.)

CHAIR JADVAR: Okay. I hear none.

Any comments or questions that NRC staff has? I want to give them a chance to -- oh, Joanna again. Dr. Fair.

MEMBER FAIR: I am so sorry, because I had one that popped in my head and I've just realized I'm not sure whether it's part of the two parts that we are going to talk about separately or not.

So, refresh my memory of the two parts that we're going to talk about separately.

CHAIR JADVAR: Okay. The two parts we are going to do separately are the prescriptive training hours for the physician residency pathways, number one, and, number two, the prescriptive case numbers, training case numbers --

MEMBER FAIR: Okay.

CHAIR JADVAR: -- for oral and parenteral procedures.

MEMBER FAIR: That's what I --

CHAIR JADVAR: So, those are separate.

MEMBER FAIR: Okay. Thank you so much. I just want to make sure I wasn't missing it.

CHAIR JADVAR: Thank you. All right. I didn't hear anything from the NRC staff, I think.

All right. Sarah, I think -- Ms. Hoenig, if you like, we can open it up to the public and see if there's any comments out there.

Again, I want to emphasize everything that was presented by Dr. Folkert, except those two topics that I just mentioned. Those will be treated separately.

MS. HOENIG: Sure. So, before we open it up to the public for questions, I just want to go over a couple participation guidelines.

We definitely hope to hear from as many participants as possible, but we do ask -- we want to remind you that so this session runs smoothly and productively, if you would like to make a comment to the ACMUI members, please use the raise hand function in Teams and we will bring you over so you can unmute your microphone.

We'll bring you over as a participant, and please state your full name and your affiliation, if you feel comfortable, before your comment.

And to give everyone a fair chance to participate, we ask that you try to keep your comments to a maximum of two minutes.

And if you're approaching the two-minute mark, I will switch on my video just as a friendly reminder to ask you to please wrap up your comment.

Please remember that all comments should be directed to the ACMUI members. This meeting is specifically for the public to share feedback regarding the draft report and presentation today from the ACMUI Subcommittee on Reducing Barriers to Medical Use and Licensing rulemaking.

So, we appreciate everyone being respectful and professional so we can have a

productive comment session.

So, let's go ahead and see if we have -- and just to show you the way you will ask a question, is you're going to use the raise hand function and we will bring you over as a participant.

Let me see if we have anyone.

(Pause.)

MS. HOENIG: Yes. Go ahead, Tom. We're going to bring you over. Tom, you should be able to unmute your microphone.

MR. BOIKE: Yeah. Can you hear me okay?

MS. HOENIG: Yes, I can hear you great. Please identify yourself and your affiliation and let us know your comment.

MR. BOIKE: Yeah. Thank you. And thank you to ACMUI and the NRC for hosting this meeting, as well as the opportunity to speak and ask clarifying questions. Dr. Folkert, it's nice to see you again as well. So, my name is Tom Boike. I'm a radiation oncologist. I'm the clinical program lead for radioligand therapies in the US for Novartis. I have a history of being an AU, and I've cared for patients with radiopharmaceuticals, with brachytherapy, different techniques, as well as gamma radiosurgery.

So, these regulations and topics are very near and dear to my heart and my prior patient care.

Novartis is an innovative medicines company at the forefront of developing radioligand therapies, which is an emerging class of radiopharmaceuticals, representing what we believe is an evolution in cancer care. We've appreciated ACMUI's and the NRC's effort to ease the regulatory burden for sites and administering these therapies increasing patient access. We also appreciate this very collaborative approach and look forward to submitting our comments on the proposed regulations.

I do have two questions and clarifying, kind of, statements to ask. I'll start with one and then possibly others could go and you could come back to me just to make sure everyone has time, but, first, I'd like to talk about licensing. So, we appreciate the proposals to streamline some license amendments, requirements for clinical research, as well as for diagnostics. Currently, what we've noticed is that the regulations governing the process of obtaining and maintaining radioactive material licenses are detailed and frequently require amendments whenever providers may expand their services, when new isotopes or

therapies are introduced, when they want to participate in clinical trials, and I'll make it just a comment on the IRB there, and make changes to their facilities.

These current processes can be lengthy, so we certainly appreciate streamlining some of these, and delays can affect patients, as we know. Sites must navigate this from state to state, as well as these federal requirements, which can further complicate compliance and slow the pathway down. I did notice, and thank you, Dr. Folkert, for the support of the NRC Medical Use License Amendment for IRB-approved research.

I think possibly a clarification on which IRB can approve that, because what we see is a bit of a chicken or an egg where sometimes the IRBs -- local IRBs like to see that the site has a RAM license allowing for the therapy to be given prior to giving IRB approval. We just want to make sure we don't get into a chicken or egg situation on that. Also, if a protocol is approved by a central IRB, is that sufficient for sites that still require local IRB approval for research?

But given this purpose of rulemaking is to

reduce barriers to medical use licensing, I'm wondering if ACMUI would consider recommending additional ways of streamlining the licensing amendment process. As was mentioned in licensing, it may not be -- it may be adopted, or, in the rulemaking, that low-risk procedures, such as an amendment for adding AUs for diagnostic procedures, may not be required in the future.

But is there a possible recommendation for establishing distinct approval pathways beyond that for significant versus administrative amendments to licenses where some of these administrative amendments may be such as adding an authorized user for a therapeutic administration who had previously been an authorized user on another license, so just transferring them over. Whereas a significant amendment may be something like adding a different isotope that the center's never worked with before or even changing the location and building a new center.

Clarifying this and establishing significant versus administrative amendments may be very helpful if ACMUI is willing to consider a recommendation like that. We also have this idea of easing regulatory burden where you don't have to seek

exact compounds. So, for example, if a site participated in a clinical trial or research for a compound and then that compound becomes approved, would it be a low-risk amendment for the site to then transition that to clinical use as opposed to out of the research space?

So, another example of what might be a low-risk amendment, taking a compound that was already used by the site in research and transitioning that to clinical use once that compound becomes approved or available. I believe that these items may decrease administrative burden both to the sites as well as to the states and to the NRC who reviews these licenses, and I'll pause there.

CHAIR JADVAR: Thank you very much for those comments. Dr. Folkert, I think you have your hand up.

MEMBER FOLKERT: Yeah, I could take a stab at some of them. And so the -- I mean, as far as the converting a trial compound into clinical use, that would fall outside of the purview of the NRC. That would be an FDA, kind of, decision. And so, on that, that's one thing which we would have to -- that would be more of a discussion with the FDA.

I am all for further discussion of streamlining of licensure. It may be -- some of the suggestions that you had may be a little bit out of scope of the current changes, the proposed rule, but I would encourage that to be something that we evaluate further in the Training Experience Subcommittee for all modalities to look more at the details on those approval pathways for transferring of authorized users.

I do note that, you know, one of the things that we did want to clarify was that training in one application, one radiopharmaceutical application, should be broadly applicable to similar radiopharmaceutical applications. Like, I gave the example of, you know, the lutetium-177 for prostate cancer applications. If you're trained in that, you should be able to perform lutetium-177 therapy administrations for neuroendocrine tumors.

There shouldn't be an extensive, you know, credentialing or authorized user approval process for that. And so, because that's not the spirit -- not the intent of what the training pathways are supposed to provide, we have recommended, in other committees, to provide guidance to local radiation safety officers

to help to make that more clear, because it's not an issue that is happening at the level of the NRC. It is an issue that's happening more at the local level with local RSOs being uncomfortable, necessarily, with allowing cross-application of the different applications.

And with regards to the details about which IRB, I will have to refer that one to our NRC staff to see if they can provide a little bit more guidance on what the levels of oversight between local IRB versus central IRB would be -- how that would pertain to this particular area in radiopharmaceutical or unsealed byproduct material research.

MS. TAPP: Yeah. For the IRBs, you can find the requirement for that in 10 CFR 35.6, and that is to obtain review and approval of research from an "institutional review board" as defined and described in the federal policy for protection of human subjects. So, again, we're going over to the federal policy outside the NRC for the institutional review board and we are removing the requirement.

If you are authorized to use the material, you would not need another license, then, to do research. Once you're authorized to use the material,

the proposal would be then you need the IRB, and then you can use the material, but you don't have to go back then and get another license or amendment to then use the material after you have the IRB. So, we're trying to catch that chicken and the egg with that change.

CHAIR JADVAR: Thank you, Katie. Sarah, any other comments that you see?

MS. HOENIG: I'll go ahead and open it up again to anybody else that would like to make a comment. Again, if you're interested, anyone in the public, to make a comment, please raise your hand and we will bring you over as a participant so you can unmute your mic and share your comment.

(Pause.)

MS. HOENIG: It looks like Tom has another comment. Tom Boike, you should be over to share your comment. And, again, I just want to remind you, please keep your comment to two minutes so we can have time for the other portion and time for other people to provide comments, please. Thank you.

MR. BOIKE: Yes, and thank you. Again, I appreciate Dr. Folkert's and the committee's work on clarifying supervision, particularly for the gamma

radiosurgery as far as the AU being there for the initiation of treatment and then being able to be immediately available to answer questions, but not physically present.

I think this is also in the proposed regulations for radiopharmaceutical procedures. And I think this also is a good way to allow sites -- as you said, there's local sites with radiation safety procedures where those sites figure out how to do this in a safe, compliant way and we want to make sure that the regulations are not overly burdensome to them.

So, you know, making sure that there's a determination where their physical presence is needed based on their training and expertise, but allowing sites to adopt care models that reflect their communities where continuing to preserve patient access, for example, in rural areas with rigorous safety standards. So, adopting and finalizing this in the forthcoming guidance would be quite appropriate, we feel.

In addition, just a clinical example of a radiation oncologist serving as the AU may have signed a written directive, oversees the program, but they may be in the cancer center and the site may

administer in the radiology department with a nuclear medicine technologist just increasing that level of safety, but the radiation oncologist may be in that cancer center a little bit off away from the patient. So, this is needed for ways of personalizing that.

One thing that may be a little bit beyond, but I'd love to hear what ACMUI may consider as far as recommendations in this area or in the future, and we talked about this a little bit with nurses on radiation safety committees, but any clarification or recommendation that could come for who with proper training or under the direction of the AU, who can actually administer.

Sometimes we see facilities or health institutions that participate in care in multiple states and they adopt really conservative approaches of either having the AU or a nuclear medicine technologist administer, whereas we see some others with trained individuals like radiation therapists or physicists that may be also taking some of the administrative roles. And so, if there's any clarification or whatnot around that, I'd be interested to hear your thoughts. Thank you. And thank you for entertaining all my comments.

CHAIR JADVAR: Thank you, Mr. Boike. Michael, does subcommittee have any comments on that at this time?

MEMBER FOLKERT: Well, I can't speak to the -- for the subcommittee on those particular points. I mean, in my own opinion, it would be good to have further discussion about which delegates can be able to perform administrations. I know, for example, radiation therapists, for example, on the radiation oncology side are extensively trained in the care and safety of patients.

Many of them are trained also to place IVs and to manage infiltration and delivery of contrast agents, for example, for simulations. And so, with appropriate training, I think it is very reasonable for them to be able to be one of the delegates that can assist an AU with administration of a radiopharmaceutical, but it would be good for us to spell that out.

And, again, I think that is another thing that would be very good to take up in training and experience, and as well as if there's any further guidance that the NRC staff can provide in that area. And as far as the presence of an authorized user

being, you know, not immediately present in a room, that is currently allowed right now. There are many nuclear medicine practices, for example, where the authorized user is not physically present, but any appropriately trained and certified nuclear medicine technologist is able to administer those radiopharmaceuticals.

So, that model does exist and it would be very good to make sure that there are very tight policies, rules and regulations and standard operating procedures at the institutional level to make sure that how that is supervised, how that person is trained, how that person is monitored, who's directly administering the radiopharmaceutical, how that's managed, are clearly delineated. And I think Dr. Harvey has a comment too.

CHAIR JADVAR: Dr. Harvey, please.

MEMBER HARVEY: Yeah, thank you very much. Basically, I echo that, but I believe that the authorized user or the certified and/or licensed, depending on your state, nuclear medicine technologist should be the one to administer the radiopharmaceutical. I think we need somebody there that's well-versed in radiation safety, as well as the

administration of the radiopharmaceutical. Thank you.

CHAIR JADVAR: Okay. I have Mr. Zoubir Ouhib.

MEMBER OUHIB: Yeah, I think that might be practical under a certain condition, and that is that designated person must have gone through a specific training. Even though the nuclear medicine tech is there, yeah, had done injection, had done that, no. It had to have a very specific training related to RPT, for instance, and that might be one way to go through it then.

CHAIR JADVAR: Thank you. Ms. Hoenig, do we have any other comments?

MS. HOENIG: Let me go ahead and check one more time. Just as a reminder -- yes, we have -- Carol Wen has her hand up. Carol, we're going to pull you over as a presenter. You should be able to unmute your mic. Just as a reminder, please try your best to keep your comment to two minutes. And if you start to go over, I will turn my video on and come over just to remind you. So, Carol, go ahead.

MS. WEN: Hi. My name is Carol from ChristianaCare in the state of Delaware. I have a question for Slides Number 22, specific comments

regarding license amendments 35.13, the proposal to remove the requirement for radioactive material license amendments to add a use for diagnostic uses 35.100 and 35.200.

So, if we have a nuclear diagnostic -- nuclear cardiology office and then we only have .100 and .200, currently we have to have authorized user on the license. So, does that mean we don't need a authorized user for those type of licenses? If that's the case, do we still require the dose -- I guess the dose ranges to be approved by an authorized user -- yeah, 32. Page 32 -- oh, I have -- so, I opened the handout through the website. Looks like we're having different --

MS. HOENIG: So, what slide are you looking for?

MEMBER FOLKERT: Yeah, it got merged. So, the numbers changed.

MS. WEN: Okay. Let me see if I can share my screen.

MS. HOENIG: You won't be able to.

MEMBER FOLKERT: It's nine slides later from -- so, if you B

MS. WEN: Oh, I won't be able to.

(Pause.)

MS. HOENIG: If you stop sharing, I can go back and share.

MS. WEN: I stopped.

(Pause.)

MS. WEN: Yeah, I guess the question is for nuclear cardiology or, for example, for a PET/CT facility if we remove the authorized user requirement, if they have, you know, their individual license, how do we go about dose range for specific diagnostic studies?

MS. HOENIG: Thank you, Carol, for your comment. I'm just going to get to slide 31. Dr. Jadvar, you all can discuss. There we go.

MS. WEN: Yeah.

CHAIR JADVAR: So, this is the slide that we're talking about?

MS. WEN: Yes.

MEMBER FOLKERT: Yes, that's the one.

CHAIR JADVAR: Okay. So, I guess there is no range in there, but I guess that can be discussed later or added. What do you think, Dr. Folkert?

MEMBER FOLKERT: Which one is --

CHAIR JADVAR: The range of low-risk

procedures, millicuries.

MEMBER FOLKERT: Yeah, is it possible for the NRC staff to comment on this? The authorized users still have to -- they still have the -- the people administering these still have to be authorized users. The site still has to have a radioactive materials license. This requirement just makes it so that they don't have to be submitting that list of authorized users on a regular basis to be constantly updated. Is there a -- Dr. Tapp, are you able to clarify anything about the activity levels? So, that's another area to --

MS. TAPP: You just hit it. You would still have to request a license for the authorized materials that you would like to possess and the amounts you want to use, and then you have to demonstrate that you're able to use them. So, I've heard PET. You would have to have facility design and have your approximate amount you're using for occupational safety and all that.

You just would not need to submit your authorized user training and experience for NRC review to be added on the license. That can be managed, then, by the site and there would be management

approval of those authorized users that they meet that training and experience. So, it's just the authorized users would no longer be listed on the license, but you still need a license with an activity limit.

CHAIR JADVAR: Thank you, Dr. Tapp. So, Sarah, I think I want to move on because we have two other items we need to talk about.

MS. HOENIG: Sure.

CHAIR JADVAR: So, at this time, I want to see if I can have a motion for the subcommittee's report -- for the entire report, except those two items that I already mentioned, the topics of the prescriptive training hours for physicians residency pathways and, number two, for prescriptive case numbers for oral and parenteral procedures. I think I have Dr. Wolkov, number one, his hand is up.

MEMBER WOLKOV: Yes, I'd like to move the subcommittee's recommendation be approved in areas where the subcommittee reached consensus of opinion.

CHAIR JADVAR: Thank you. Do I have a second?

MEMBER HARVEY: Yes. That's why I have my hand raised. I would like to second the motion made by Dr. Wolkov.

CHAIR JADVAR: Okay. Thank you so much. So, at this time, any further discussions?

(Pause.)

CHAIR JADVAR: Okay. I want to make it easy. Any opposed? Any abstentions? Any dissenting or deferring views? Very good, none heard. So, the motion is passed and I want to thank, again, the subcommittee for their wonderful work.

Now, at this point, we're going to move on to the other two topics one by one. So, the first one is with regard to the training -- the topic of the removal of the prescriptive training hours for residency pathways, and I want to ask the subcommittee to have comments on that particular topic. Dr. Harvey?

MEMBER HARVEY: Thank you, Dr. Jadvar. So, there was a dissenting opinion on the removal of the 700 hours because the experience in the residency program without those prescriptive 700 hours could vary significantly. We've all seen, on the committee, different ways that the residency training was conducted.

We've seen where maybe the training for a radiation oncologist wasn't adequate because the

nuclear medicine side wasn't very -- I'm not sure what the right word here is, but wasn't very great about, you know, the training. They were consumed with their work, they had to get through, they had to, you know, move through their normal workflow and they didn't provide the most adequate experience for the radiation oncologist when they came over. So, that's something we want to avoid.

Something else that we really want to avoid is the DR, diagnostic radiology, or the radiation oncology programs not committing their residents to come over and spend an adequate amount of time to learn the full scope and learn, in a global comprehensive way, nuclear medicine and what they need to do in 10 CFR .300.

So, without the prescriptive number of hours, there have been times where residency programs would have, and have had, not had diagnostic radiologists or radiation oncologists spend enough time in nuclear medicine to get comprehensive training to adequately perform those therapies and perform all of what is required in 10 CFR 35. Thank you.

CHAIR JADVAR: Thank you, Dr. Harvey. Dr. Fair?

MEMBER FAIR: Thank you. I think just to support what Dr. Harvey said and just give another sort of example that you might see, I think we discussed, as a subcommittee, there being some carve-outs for groups that clearly will get more than enough experience during their training in those particular areas.

And so, the carve-outs were, I believe, radiation oncology for 490 and 690 -- forgive me if I've got the numbers wrong, okay -- and then nuclear medicine for 190, 290, 390, but we were concerned about the sort of more blanket approach to other kinds of training that does involve radiation safety, but of a different nature. And so, the example I'll give is my own specialty, which is diagnostic radiology. Nuclear medicine and 190, 290 and 392 and 4 are part of the prescribed training; however, they're not sort of throughout the training.

Like, the whole training is 190, 290, 390, as it is, in some sense, with nuclear medicine where we would expect a nuclear medicine resident would get far more than the 700 hours. In diagnostic radiology in three years, which is kind of what the description was about, in principle, someone could actually have

zero time on a nuclear medicine service. Depending on how the residency program is structured, that time may actually be more towards the end of training.

And so, maybe they've had a month, maybe they've had zero, maybe they've had four, maybe they've had six. It could vary quite a bit. And so, I think that's why we were struggling with the idea of just saying, you know, three years in any of these specialties that have, you know, radiation as part of their training would likely be sufficient because the content is going to be different.

And so, just to circle back sort of advocating for carving out nuclear medicine for 190, 290, 390, radiation oncology for 490 and 690, and then sort of for everyone else that they would still need to document that 700 hours of work experience to ensure that it had really taken place before and they'd really had sufficient experience before they would be eligible to be an authorized user. So, that was kind of the thought process around that.

CHAIR JADVAR: Thank you, Dr. Fair, for that explanation. Dr. Folkert, please.

MEMBER FOLKERT: Yeah, of course. So, now, speaking as myself, not for the committee, you

know, the reason why I leaned towards supporting the proposed rule, as written, is because the 700-hour requirement is not actually very helpful, you know.

For example, I mean, one of the things -- one of the recommendations that we've made previously in the Training Experience Subcommittee is that the focus should really be much more on knowledge topics and testing that knowledge rather than just the core hours.

A radiation oncologist, for example, will do at least 1,000 hours of work experience per year, and during the -- much of that work experience could be considered pertinent to nuclear medicine applications for both imaging and for therapeutics, prostate cancer being the most common cancer in men. Every single tumor board discussion usually incorporates review of PET imaging or the use of PSMA-based radiotherapeutics. So, amassing 700 hours of relevant clinical experience is actually a fairly trivial task.

As a former program director, I never had any problem whatsoever filling out those hours and so for -- for the residents. But, in the end, it didn't -- like, just filling out those hours, I don't

believe, was super helpful. I thought covering the knowledge topics, testing the knowledge topics, making sure that people knew and understood that, that was where I think the real work verification goes to and that's something -- that's what -- and I think that's where the focus is shifting and so with this proposed rule.

So, I was in support of removing the 700-hour requirement so that we could really focus on the knowledge topic. And to emphasize testing of those knowledge topics, I think, is really the most critical goal.

CHAIR JADVAR: Thank you, Dr. Folkert. Dr. Fair?

MEMBER FAIR: So, I absolutely agree with Dr. Folkert that it makes sense that we would focus on, you know, competence and testing and all of that rather than numbers of hours. I think the concern I have is not everybody is functioning in an ideal environment. And so, we have the ideal which Dr. Folkert is describing, which certainly, you know, I've experienced, which I've had as part of my training program as being a program director in diagnostic radiology.

So, we have the ideal, and then we have the not ideal and not every place is, you know, able to readily provide that experience. And I worry that if the hours go away, that an individual nuclear medicine physician who is part of a diagnostic residency may feel pressured to sign forms, you know, saying this is fine without really, you know, feeling super confident, but not really having a place to be able to say, well, you know, I need documentation of the 700 hours before I sign this form or whatever the case may be.

I think it's not my concern about the programs that are, you know, clearly able to provide this experience, but ones where it is really -- people are kind of hanging on by their teeth, if you will, to make sure that they achieve those minimums.

Totally agree numbers of hours do not equal, you know, competence and it's a poor surrogate. I think, unfortunately, we don't really have, you know, a great surrogate that will ensure that everyone has really achieved competence. And so, at least number of hours gives some benchmark that is more easily measured than some other things. Sorry, that was a really long-winded response.

CHAIR JADVAR: Thank you very much. Dr. Harvey, please.

MEMBER HARVEY: Yeah, thank you very much, Dr. Jadvar. I mean, I agree with Dr. Folkert. What we should be focusing on is the competence and the expertise. I agree with Dr. Fair. I've seen programs that don't provide an adequate experience and the residents are not getting the adequate training that they need, and I've seen that on both sides of the ledger.

It's very easy for nuclear medicine to not provide it, and it's also very easy for somebody else from diagnostic radiology or radiation oncology not to spend the time and the effort to go up there and get the idealized training that Dr. Folkert's talking about. So, I think keeping the 700 hours helps to ensure a better comprehensive experience. Again, the metric of the hours is limited, at best, but I hope that that forces or encourages programs to provide the proper experience for their residents. Thank you.

CHAIR JADVAR: Thank you, Dr. Harvey. Dr. Einstein, please.

(Pause.)

MS. HOENIG: You're on mute, Dr. Einstein.

Just need to unmute.

MEMBER EINSTEIN: Thanks for lots of great comments here. I fully agree with the sentiment that what we should be focusing on is competency, not just meeting number of hours. I'd like to give a couple of illustrations and I think hours is a bad metric to begin with although I recognize that it's something used in much NRC rulemaking. I took a 200-hour course myself back in the day when I was training two decades ago and it was not offered at my institution where I was training. We took an outside course.

And the guy who was running the course, which was a popular national course, he would get up and tell jokes. He was just trying to fill in 200 hours for the sake of filling in 200 hours, not for the sake of necessarily teaching us. That's not what we're looking for, for patients in this country. My own trainees, and I'm a program director, I sign letters for all of our trainees who seek to become authorized users attesting to their 700 hours or, more technically, to their 620 hours plus an 80 hour of didactics, it's hard to count hours and different programs count things differently.

Do we really know exactly how many hours

per day? We're not asking trainees to clock in and clock out. I err on the cautious side. I wonder if we'd be better off with a metric like four months of training where the primary responsibility is work with radiopharmaceuticals or something along those lines rather than counting hours, which are pretty much impossible to count, and I think four months would be an equivalent assuming a 2100-hour a year, which is an underestimate, if anything, for trainees in this country.

I also question the focus here on residency training program -- pathways as distinguished from residency or fellowship training pathways. There are many authorized users who are not trained in the context of a residency, but in the context of a fellow. That applies, of course, to cardiologists who train in nuclear cardiology. It also applies to many nuclear medicine physicians now who obtain their primary training in the context of a nuclear radiology fellowship.

I have a nuclear radiology fellow working in my lab right now and he is a radiologist in another country. He happened to go to medical school in Russia and emigrated to the United States. And as

part of the American Board of Radiology's alternate pathway, he has to do four one-year fellowship programs, the completion of which will make him be eligible to become board certified in radiology in the United States.

So, I think we want to make sure to include other people -- individuals who train not in the context of a residency program, but in a fellowship program as well. So, I would change verbiage from "residency" to "residency and/or fellowship." So, I think those are my comments.

The hours are almost unmeasurable. They're estimated. Maybe we'd be better off with months, include fellows among residents and sympathy for the sentiment expressed by Dr. Folkert and others that really what we're most concerned about is ensuring a competent workforce so that American patients derive from the best care involving medical uses of isotopes. Thank you.

CHAIR JADVAR: Thank you very much, Dr. Einstein. Very clear. Any other comments by other ACMUI members on this particular topic? I see Mr. Ouhib.

MEMBER OUHIB: Yes. I just want to

mention that I think Dr. Einstein summarized it very well and I think that the number, as far as the number of hours, I don't think that's a reliable check, per se. I think the competency has to be on the forefront if you want to ensure good quality and safe care. Thank you.

CHAIR JADVAR: Thank you very much. So, I think, in the interest of time, Sarah, can we move on to maybe one question from the public, because we still have another topic to discuss.

MS. HOENIG: Absolutely, yes. If any members of the public, just as a reminder, if you'd like to make a comment, please raise your hand and we can move you over as a presenter.

(Pause.)

MS. HOENIG: At this time, Dr. Jadvar, I don't see any hands up.

CHAIR JADVAR: Okay. Thank you. So, if you don't mind, can we move on to the motion -- that slide with the motion?

MS. HOENIG: Sure. I'm going to go ahead and share. In one minute.

CHAIR JADVAR: Yep.

MS. HOENIG: Okay.

CHAIR JADVAR: Okay. If we can make it on top of the page and a little bit bigger so people can see?

MS. HOENIG: Sure.

CHAIR JADVAR: There we go. So, just to make it easy for everyone to see, this is the first motion we're going to vote on. The motion is, if somebody makes it, but this is the text: Recommend that support of the proposed rule, as written, regarding completion of three years in accredited program would suffice as a surrogate benchmark for sufficient work experience hours, which is currently defined as total of 700 hours of training, including classroom and laboratory training, and relevant work experience.

And then I'm not going to read underneath, but those are just what is actually right now under these different rules. 35.190, which includes radiation oncology, nuclear medicine and diagnostic radiology. Under 35.290, it includes nuclear medicine, diagnostic radiology and radiation oncology. Under 35.390, it includes nuclear medicine and radiation oncology. Under 35.392 and 35.394, it includes nuclear medicine and radiation oncology.

Under 35.490, it includes only radiation oncology. And under 35.690, also radiation oncology. So, do I have a motion for -- can you bring it up again so that people can see? Yes, thank you. I see Melissa Martin.

MEMBER MARTIN: Yes. I would like to bring the motion to the committee for a vote as submitted.

CHAIR JADVAR: Okay. Do I have a second on this one?

MEMBER FOLKERT: I will second.

CHAIR JADVAR: Okay. Very good. Any further discussions on this motion? Dr. Folkert?

MEMBER FOLKERT: Oh, sorry. I was just seconding it.

CHAIR JADVAR: Oh, okay. Okay. Any further discussions?

(Pause.)

CHAIR JADVAR: All right. If not, we move on to the voting process. Any opposed?

MEMBER FAIR: Dr. Jadvar, I would request a roll call vote.

CHAIR JADVAR: Okay. Very good. Let's do it that way then. Let me see the -- make sure I do

not miss anybody. All right. Let's start with Mr. Richard Green.

VICE CHAIR GREEN: I'm in favor. Aye.

CHAIR JADVAR: Okay. Dr. Andrew Einstein?

MEMBER EINSTEIN: I respectfully vote no.

CHAIR JADVAR: Okay.

MEMBER EINSTEIN: I believe that a more comprehensive revisitation of this topic is required. For example, one year in an accredited nuclear radiology fellowship should be included if we're going to make such a change.

CHAIR JADVAR: Okay. Thank you. Dr. Folkert?

MEMBER FOLKERT: I vote in favor.

CHAIR JADVAR: Okay. Dr. Harvey Wolkov?

MEMBER WOLKOV: I vote in favor.

CHAIR JADVAR: Okay. Dr. Joanna Fair?

MEMBER FAIR: I am opposed.

CHAIR JADVAR: Okay. Thank you. Dr. Michael O'Hara?

(Pause.)

CHAIR JADVAR: Dr. O'Hara?

MS. HOENIG: He may have had to leave a little early, Dr. Jadvar.

CHAIR JADVAR: That's right.

MS. HOENIG: So, he would be abstained.

CHAIR JADVAR: Abstained, yes.

All right. Dr. Richard Harvey?

MEMBER HARVEY: I am opposed.

CHAIR JADVAR: Okay. Thank you. Ms. Melissa Martin?

MEMBER MARTIN: I'm in favor, yes.

CHAIR JADVAR: Okay. Mr. Zoubir Ouhib?

MEMBER OUHIB: I'm in favor.

CHAIR JADVAR: Mr. Josh Mailman?

MEMBER MAILMAN: After finding the right buttons, I'll be in favor.

CHAIR JADVAR: Okay. And I think I went through everybody's name. Am I correct, Sarah?

MS. HOENIG: Yes, that is correct. Except for your thoughts on it.

CHAIR JADVAR: Okay. So, according to my count, one, two, three, four, five, six yeas. One, two, three nays. And one abstention. Am I correct?

MS. HOENIG: That's correct, besides your vote. Besides what would be your vote, Dr. Jadvar.

CHAIR JADVAR: Oh, my vote. I abstain.

MS. HOENIG: You abstain, okay.

CHAIR JADVAR: Yes. So, again, two abstains. One, two, three, four, five, six yeas. And one, two, three nays.

MS. HOENIG: Correct.

CHAIR JADVAR: Three nays, six yeas, two abstains; is that correct?

MS. HOENIG: That is correct.

CHAIR JADVAR: Okay. Very good. So, this motion actually passes. All right. With that, let's move on to the last item that we need to discuss.

MS. TAPP: Dr. Jadvar, before we move on --

CHAIR JADVAR: Yes.

MS. TAPP: -- I would like to let the members know that who had the differing opinions, they can submit differing opinions to us to add to the report and that will be submitted to the report. The complete report will have both the recommendations and the differing opinions. So, please send that to Sarah Hoenig.

CHAIR JADVAR: Yes. Thank you very much for reminding me that. Thank you. So, let's move on to the last topic that we need to also discuss, and that is the removal of the prescriptive training case

numbers under 35.390, 35.392, 35.394, and 35.396 that the subcommittee could not reach a consensus on. So, with that, I want to open it up to folks, maybe first with the subcommittee members if they want to provide any opinion, comments. Dr. Folkert?

MEMBER FOLKERT: Yeah. So, I am actually in favor of keeping the case numbers. I do think it's important to have a bare minimum for access because I do think it is far too easy for programs to completely remove it. And, you know, without having that direct hand -- without having that experience, I think it's just removing too much accountability from the programs. So, I do think it is helpful to retain a minimum case number.

CHAIR JADVAR: Okay. Thank you. Dr. Fair?

MEMBER FAIR: I feel exactly the same as Dr. Folkert on this. And it's, again, it's not the ideal circumstance where, you know, we have an enfolded nuclear radiology fellow who's getting dozens and dozens and dozens and dozens of therapies over the course of a couple of years. But if the minimum becomes one, which is what de facto it is, I think that there's the concern that the non-ideal

circumstance puts a lot of pressure on the single authorized user to approve people that have watched one therapy.

And so, I actually think three is insufficient, but it is certainly like a few scenarios where something has been given is preferable to one. So, while in some sense I would advocate for it being more, I certainly would not reduce from three the minimum required number. I think that gets us into scary and unsafe territory.

CHAIR JADVAR: Thank you, Dr. Fair. Dr. Harvey?

MEMBER HARVEY: I just want to say that I agree with Dr. Folkert and Dr. Fair. I think we need to keep the minimum number of cases. Thank you.

CHAIR JADVAR: All right. Thank you so much. Any other comments by ACMUI members?

(Pause.)

CHAIR JADVAR: All right. Any comments by the NRC staff?

(Pause.)

CHAIR JADVAR: And maybe, Sarah, maybe one question from public if there is any.

MS. HOENIG: Okay. We'll go ahead and

open it up again for public comments. Again, if you're interested in making a comment, please raise your hand.

(Pause.)

MS. HOENIG: At this time, Dr. Jadvar, I don't see any raised hands.

CHAIR JADVAR: Okay. Thank you very much. So, we can move on to a motion for this one, if somebody makes it, and I can just read it. That would be recommend support of the proposed rule, as written, regarding removal of the training case numbers under 35.390, .392, .394, and .396. Can somebody make that motion? It's Melissa Martin. Thank you.

MEMBER MARTIN: Yes, I'll make that motion.

CHAIR JADVAR: Okay. Thank you. Any seconds?

MEMBER FAIR: Can I ask a clarification?

CHAIR JADVAR: Yes, please.

MEMBER FAIR: The motion is to remove the case numbers?

CHAIR JADVAR: As written, yeah.

MEMBER FAIR: As written.

CHAIR JADVAR: Yeah.

MEMBER FAIR: So, a vote in favor --

CHAIR JADVAR: In the proposal, yes.

MEMBER FAIR: -- would be to remove the case numbers.

MEMBER MARTIN: Correct.

MEMBER FAIR: Okay. Thank you. Sorry.

CHAIR JADVAR: Okay. Let me read it again. Recommend support of the proposed rule, as written, regarding removal of the training case numbers. So, if you say yes, you are saying yes to removing it, the case numbers. If you say no, that means you don't want it removed.

MEMBER FOLKERT: Yes. Although, right now we're just motioning to vote to make that vote. Yeah.

CHAIR JADVAR: That's right. Okay, just wanted to read it, because, Dr. Fair, that's a very good question. I don't think I had a second.

MEMBER FOLKERT: I seconded to vote.

CHAIR JADVAR: Oh, you did. Okay. Thank you so much. So, any further discussions before we go to -- I think I'm going to go to roll call on this one. Okay. All right. Well, let's do this again. Mr. Richard Green?

VICE CHAIR GREEN: I oppose the motion. I would like to retain the case numbers.

CHAIR JADVAR: Okay. Thank you. Dr. Andrew Einstein?

MEMBER EINSTEIN: I oppose the motion. I'd like to retain the case numbers.

CHAIR JADVAR: Thank you. Dr. Michael Folkert?

MEMBER FOLKERT: I oppose the removal of the case numbers.

CHAIR JADVAR: Thank you. Dr. Harvey Wolkov?

MWMBER WOLKOV: I oppose the motion.

CHAIR JADVAR: Dr. Joanna Fair?

MEMBER FAIR: I oppose the motion.

CHAIR JADVAR: Dr. Michael O'Hara is not here at this time, again. So, abstain on that one. Dr. Richard Harvey?

MEMBER HARVEY: Opposed.

CHAIR JADVAR: Ms. Melissa Martin?

MEMBER MARTIN: Opposed.

CHAIR JADVAR: Mr. Zoubir Ouhib?

MEMBER OUHIB: Opposed.

CHAIR JADVAR: Mr. Josh Mailman?

MEMBER MAILMAN: Opposed.

CHAIR JADVAR: And my vote is also

opposed. So, this is unanimous opposition to this motion and there's one abstention. All right. And I don't think we had -- okay. It's very clear, actually. All right. That actually concludes this -- go ahead.

MS. TAPP: One second, Dr. Jadvar. To officially make the recommendation for us to change the rule, you should make a motion that you recommend keeping -- so, switch that motion around.

CHAIR JADVAR: Okay. So, let's -- we have another motion that we recommend keeping or retaining the training case numbers under 35.390, .392, .394, and .396 in the proposed rule. Retaining. So, that's the new motion. Can somebody make it?

MEMBER HARVEY: I can make that motion, Dr. Jadvar. I am in favor of retaining the minimum -- three minimum number of cases.

CHAIR JADVAR: Okay. And --

MEMBER MARTIN: I'll second.

CHAIR JADVAR: Okay, perfect. So, I'm going to do a roll call again on this new motion retaining the minimum -- the case numbers, training case numbers for those designations I just mentioned. So, let's roll call, again, just to make sure

everybody's voice is heard. Mr. Richard Green?

VICE CHAIR GREEN: I support retention.

CHAIR JADVAR: Okay. And Dr. Andrew Einstein?

MEMBER EINSTEIN: I vote yes, retain the case numbers.

CHAIR JADVAR: Okay, excellent. Dr. Michael Folkert?

MEMBER FOLKERT: Yes, retain the case numbers.

CHAIR JADVAR: Dr. Harvey Wolkov.

MWMBER WOLKOV: Yes, retain the case numbers.

CHAIR JADVAR: Dr. Joanna Fair?

MEMBER FAIR: Yes.

CHAIR JADVAR: And Dr. O'Hara is abstention.

Dr. Richard Harvey already said yes, but you want to say it again?

MEMBER HARVEY: I'm in favor.

CHAIR JADVAR: Ms. Melissa Martin?

MEMBER MARTIN: Yes, retain the numbers.

CHAIR JADVAR: Mr. Zoubir Ouhib?

MEMBER OUHIB: Retain the case numbers.

CHAIR JADVAR: Mr. Josh Mailman?

MEMBER MAILMAN: Retain the case numbers.

CHAIR JADVAR: And my vote is also yes. So, this is unanimous yes by the ACMUI, with one abstention, that we recommend retention of the training case numbers under 35.390, 35.392, 35.394 and 35.396 in the proposed rule. Okay. Anything else that -- I think we're done.

MS. HOENIG: I think that's it.

CHAIR JADVAR: So, I'll give it back to Mr. Einberg if there's anything else that he wants to mention before we adjourn.

MR. EINBERG: No. Good timing and great meeting, Dr. Jadvar. I just want to thank the subcommittee, the full committee, the members of the public and the NRC staff for all the hard work supporting this rulemaking. It has broad implications for all of us. And so, once again, thank you for all your hard work.

CHAIR JADVAR: Thank you, again. And I want to echo the same. I want to thank, first of all, the subcommittee. That was a lot of work. Thank you so much, all of you, and Dr. Folkert for chairing it. And then, of course, the rest of the ACMUI and all

the NRC staff. And with that, this meeting of the ACMUI on September 9th, 2026, is adjourned. Have a great day.

(Whereupon, the above-entitled matter went off the record 2:59 p.m.)