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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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VIDEOCONFERENCE

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WEDNESDAY,

JUNE 5, 2024

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The meeting was convened via Videoconference, at 1:00 p.m. EDT, Richard L. Green, ACMUI Vice Chairman, presiding.

MEMBERS PRESENT:

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

RICHARD L. GREEN, Vice Chairman

REBECCA ALLEN, Member

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

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

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

RICHARD HARVEY, Dr.PH, Member

JOSH MAILMAN, Member

MELISSA C. MARTIN, Member

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

ZOUBIR OUHIB, Member

MEGAN L. SHOBER, Member

HARVEY B. WOLKOV, M.D., Member

JOHN F. ANGLE, M.D., Member

NRC STAFF PRESENT:

BRIAN ALLEN, NRC

LILLIAN ARMSTEAD, NMSS, Designated Federal Officer

MARYANN AYOADE, NMSS

KEN BRENNEMAN, NMSS

DANIEL DIMARCO, NMSS

LISA DIMMICK, NRC

CYNTHIA M. FLANNERY, NMSS

TRAVIS JONES, NRC

DANIEL SHAW, NMSS

SARAH SPENCE, NMSS

KATHERINE TAPP, Ph.D., NMSS

CELIMAR VALENTIN-RODRIGUEZ, Ph.D., NMSS, Designated Federal Officer

KEVIN WILLIAMS, NMSS

CHRISTIAN EINBERG, NMSS, Designated Federal Officer

AGENDA

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

1:01 p.m.

DR. VALENTIN-RODRIGUEZ: So, we'll get started with today's meeting. Again, good afternoon. As the designated Federal Officer for this meeting, I am pleased to welcome you to this public meeting of the Advisory Committee on the Medical Uses of Isotopes.

I am Celimar Valentin-Rodriguez, and I am the Medical Radiation Safety Team Leader 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. It has been 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 May 7th, 2024, addition of the Federal Register, Volume 89, Page 38197. On May 21st, 2024, NRC publish a correction to the original Federal Register in Volume 89, Page 44714 to correct the Teams meeting link.

The purpose of this meeting today is to discuss the ACMUI's Subcommittee report on the NRC staff's draft interim staff guidance for the implementation of training and experience requirements in 10 CFR Part 35. The function of the ACMUI is to advise the staff on issues and questions that arise on the medical use and byproduct material.

The Committee provides counsel to the staff but does not determine or direct the actual decisions for 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 issue that we will discuss today. But I also recognize there may be 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?

DR. JADVAR: Present.

DR. VALENTIN-RODRIGUEZ: Mr. Richard Green?

VICE CHAIR GREEN: Present.

DR. VALENTIN-RODRIGUEZ: Ms. Rebecca

Allen?

MS. ALLEN: Present.

DR. VALENTIN-RODRIGUEZ: Dr. Michael Folkert?

DR. FOLKERT: Here.

DR. VALENTIN-RODRIGUEZ: Mr. Josh Mailman?

MR. MAILMAN: Here.

DR. VALENTIN-RODRIGUEZ: Ms. Melissa Martin?

MS. MARTIN: Here.

DR. VALENTIN-RODRIGUEZ: Dr. Michael O'Hara? Mr. Zoubir Ouhib?

MR. OUHIB: Present.

DR. VALENTIN-RODRIGUEZ: Ms. Megan Shober?

MS. SHOBER: Present.

DR. VALENTIN-RODRIGUEZ: Dr. Harvey Wolkov?

DR. WOLKOV: Present.

DR. VALENTIN-RODRIGUEZ: Dr. Richard Harvey?

DR. HARVEY: Present.

DR. VALENTIN-RODRIGUEZ: Dr. Andrew Einstein?

DR. EINSTEIN: Present.

DR. VALENTIN-RODRIGUEZ: Dr. Joanna Fair? I think I did see her join through Teams. Okay, so I can confirm --

DR. O'HARA: Sorry --

DR. VALENTIN-RODRIGUEZ: No, you're fine.

DR. O'HARA: This is Michael O'Hara. My mic was off so, I'm here.

DR. VALENTIN-RODRIGUEZ: No worries. Thank you, Dr. O'Hara. Okay, so with that I can confirm that we have a quorum of at least six members present.

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

ACMUI members must recuse themselves from participating in any agenda item in which they may have a conflict of interest unless they receive a

waiver or prior authorization from the appropriate NRC official.

Mr. Richard Green, ACMUI Vice Chair, will conduct today's meeting. Although I see that Dr. Jadvar, our Chair, is also present.

Dr. Joanna Fair recently selected as the diagnostic radiologist representative, who I see has joined us today, is pending her security clearance and will not have voting rights for any actions requiring a vote but may participate in the discussion during today's meeting.

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

Today's meeting is being transcribed by a court reporter. We are utilizing Microsoft Teams for the audio/video of today's meeting, and to view presentation material in real time. The meeting materials and agenda for this meeting can be accessed from the NRC's public meeting schedule. And the ACMUI's public website.

The phone number for the meeting is 301-576-2978. And is currently being shown on the screen. The phone conference ID is 652827577.

For the purposes of this meeting, the chat feature in Microsoft Teams has been disabled so that we can capture all comments as part of the official transcript. Mr. Green, at his discretion, may entertain comments or questions from the members of the public who are participating today.

Comments and questions are typically addressed by the Committee near the end of the presentation, after the Committee has fully discussed the topic. We will announce when we are ready for the public portion of the meeting. And we will assist in facilitating public comments.

Individuals who have joined us via Microsoft Teams, please use the raised hand function to signal to our Microsoft Teams host that you wish to speak.

If you have called in to the Microsoft Teams using your phone, please ensure you have unmuted your phone pressing star-6. When you begin your comment, please clearly state your first and last name for the record.

At this time, we have disabled all of the attendees' mics. We will enable them during the meeting. And at that point you can all use, press, or press star-6 to unmute your phone if you're on the

phone and want to provide a comment.

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

At this time, I ask that everyone who is not speaking please mute your Teams microphones, or your phone. And I will now turn over the meeting to Mr. Richard Green.

VICE CHAIR GREEN: Thank you, Dr. Valentin-Rodriguez. Again, we're here as the Advisory Committee on the Medical Use of Isotopes to hear the report out from this Subcommittee on the Training and Experience Requirements Draft Interim Guidance. And we'll hear from the Chair of this Subcommittee, Dr. Michael Folkert to present their report.

DR. FOLKERT: Mr. Green, I think you have to unmute.

(Pause.)

VICE CHAIR GREEN: Dr. Folkert, the

chair, the floor is now yours.

(Pause.)

DR. VALENTIN-RODRIGUEZ: Dr. Folkert, can you hear us?

DR. FOLKERT: I can hear you. I couldn't hear, yes, Richard Green as he muted the entire time.

VICE CHAIR GREEN: Dr. Folkert, I just announced you and your subcommittee. Are you able to hear me now?

DR. FOLKERT: I'm not hearing Richard Green at all.

DR. VALENTIN-RODRIGUEZ: He just jumped through the agenda, and he just passed on the meeting to you, Dr. Folkert, so you can go ahead with the meeting slides. We'll try to figure out on the back end if there is something going on with Mr. Green's presentation.

DR. FOLKERT: Yes, I hear you fine, but I don't hear -- I didn't hear anything from him.

All right. I'm sorry about the delay on that. That's probably technical issues on my side. I apologize.

So, I am Dr. Folkert. I am the subcommittee chair for the Training and Experience Subcommittee. And I am going to be presenting on the

comments from the Advisory Committee on the Medical Use of Isotopes.

I'd like to thank the other members of my subcommittee, as well as the rest of the ACMUI for their feedback, the NRC for the summary on this guidance and providing the platform for discussion. And thank the members of the public for joining today, which it looks like there is at least 60 so far. So, thank you very much.

So next slide, please. This is the membership of the subcommittee. The T&E Subcommittee, including Dr. Harvey, Dr. Jadvar, Ms. Martin, Ms. Shober. And we were advised by the NRC staff resource Cindy Flannery. Okay, thank you.

Next slide. Okay. So, on February 2nd the ACMUI Chair expanded the charge of the T&E for all modality subcommittee to include a review of the NRC's draft training and experience implementation guidance. A joint NRC and agreement state working group drafted this guidance in accordance with the Commission direction.

I want to emphasize that with this guidance the NRC is not recommending or instituting any changes in the current training and experience requirements in 10 CFR Part 35. This guidance is to

provide a roadmap and a resource for helping us, helping people meet those requirements.

So next slide, please. As background, so for the Commission direction and the staff requirements memorandum to SECY-20-0005, staff requirements. The rulemaking plan for T&E requirements for unsealed byproduct material in 10 CFR Part 35. The staff developed this guidance for implementing the T&E requirements in 10 CFR Part 35 medical use of byproduct material.

The NRC staff utilized information from a number of different resources, including the NUREG-1556 from the frequently asked questions on the NRC's medical tool kit. And from information based on questions received from stakeholders to develop the guidance.

Next slide, please. Next slide, please. Okay, I think the slides aren't advancing. The next slide, if you could show it, please? Unless it's frozen.

DR. VALENTIN-RODRIGUEZ: What, Dr. Folkert, what slide do you see, because I see them advancing on my end. I can see Slide 10 right now on the screen.

DR. FOLKERT: Let me see. I am on Slide

5. And so, it's what it should be. The background where this guidance aims to clarify the roles and responsibilities of individuals subject to T&E requirements.

It seems to be, at least on mine, I apologize, it's frozen on Slide Number 4. There, now it's moved to, let's see, the one that's popped up right now is slide --

VICE CHAIR GREEN: Dr. Folkert, as a suggestion you might turn off your camera.

DR. FOLKERT: I see Slide 8 is on the screen now.

VICE CHAIR GREEN: You may have limited bandwidth.

MR. MAILMAN: Yes, we're seeing Slide 10. This is Josh. So may be on your end.

DR. FOLKERT: Okay. I'm still only seeing slide, you have both said Slide 10, so. Oh, it's Slide 10 in your dataset, but not Slide 10 presentation.

DR. VALENTIN-RODRIGUEZ: Yes.

DR. FOLKERT: If you -- I don't know if it's possible to go back and -- because it should be -- I believe it should be Slide 7 in your presentation stack.

DR. VALENTIN-RODRIGUEZ: Yes, we'll get to Slide 7.

DR. FOLKERT: Yes, because you're showing Slide 10.

DR. VALENTIN-RODRIGUEZ: Dr. Folkert, I advise maybe turning your camera off. It might be a bandwidth issue on your end.

DR. FOLKERT: Okay.

DR. VALENTIN-RODRIGUEZ: So that might help with you seeing --

DR. FOLKERT: All right. I'll do that.

DR. VALENTIN-RODRIGUEZ: -- yes, the slides that we see.

DR. FOLKERT: Can we go back to slide --

DR. VALENTIN-RODRIGUEZ: It should be on Slide 7 on our side.

DR. FOLKERT: Yes. That is the correct slide.

All right. So, this guidance aims to clarify the roles and responsibilities that individuals subject to T&E requirements outlines the information needed to demonstrate the necessary training and experience for individuals who are being listed on the license and explains expectations for how these individuals are to fulfill the T&E

requirements.

Next slide, please. It also importantly provides criteria for the NRC staff and agreement state regulators to evaluate the applications for licensees and applicants who are seeking to add individuals to their license as authorized individuals, including authorized users, radiation safety officers, associate radiation safety officers, authorized nuclear pharmacists, authorized medical physicists or ophthalmic physicists.

Next slide, please. And we have to note that due to ongoing medical rulemakings, this guidance is serving as an interim staff guidance as some, or many training experience requirements could change in the near future. So once the NRC is closer to distributing and promulgating these medical rulemakings, the NRC staff will then decide on the best way to transmit this guidance, whether it's through NUREG-1556 or through a standalone guidance document, which will also have additional review.

Next slide, please. So overall I said that members of the ACMUI Subcommittee on T&E found that the submitted document was very thorough and helpful. The general opinion of the Committee was that the guidance was well developed and did

effectively outline the process to list individuals as AUs, RSOs, ARSOs, ANPs, AMPs and OPs on an NRC license.

So next slide, please. However, to make things more approachable to simplify and to make this a more accessible resource, one recommendation was that presentation of the required hours, which are generally divided into classroom and laboratory hours, supervised work experience hours and/or the number of cases/supervised clinical casework required to meet the regulatory requirements for each T&E element should be presented clearly in a tabular format, perhaps as an appendix, to increase accessible.

Next slide, please. And also, to make it even more approachable, the recommendation was to create case scenarios to outline comment situations. Many of us learned by case descriptions, by example, and use those to inform our processes.

Some suggestions that were made by the Subcommittee were to create a case scenario, such as an interventional radiologist, who is seeking to be listed as an AU for liver microsphere applications. Or medical physicists taking on the role of a radiation safety officer at a new institution, a

radiation oncologist who is ten years out of training seeking to be listed as an authorized user for seed implant brachytherapy or radiopharmaceutical therapy.

Or a community radiologist who previously only worked in the diagnostic realm as the diagnostic nuclear medicine practitioner who now wanted to participate in theranostics, the application of a therapeutic and diagnostic applications of radiopharmaceuticals.

Next slide, please. And then also specifically, Section 4.1.2, roles of responsibilities, Page 6. Under the radiation safety committee, we requested to add a statement about how and when 35.1000 technologies, emerging technologies, are required to have radiation safety committee participation. Whether one could represent multiple technologies or if you need individual representatives, so on and so forth.

Next slide, please. And in Section 4.3.2.4, device-specific training, Page 17, we noted that guidance stated that training is not required to be specific to the model of the device. This is inconsistent with other guidance that require specific training for new devices and applications.

So even though an authorized user or an authorized medical physicist may be otherwise qualified in a device, they should have training in the use of an emergency procedures for the model of device or byproduct material for which the authorization is sought.

Next slide, please. In the same section it was noted that model specific training may be required under some cases under 10 CFR 35.610. But this only applies to sealed sources and remote afterloader units, teletherapy units or gamma stereotactic radiosurgery units. And there is many byproduct material uses/devices that are not covered under 10 CFR 35.610.

Now in Section 5.1 of the microsphere licensing guidance, for example, also requires authorized users to have training with the specific microsphere product for which the AUs is seeking authorization. So, a clarification of these training requirements is recommended.

Next slide, please. And again, the same section, the guidance also noted the device training must be completed in person with the device. We requested that the sentence be removed. This element must be completed in person with the device. And for

the NRC to provide specific guidance as to when and what devices or applications require both in-person and hands on training.

Next slide, please. So those were our specific questions and comments. The next slide has the acronyms used in our report. Abbreviations and acronyms used in the report.

All right, thank you very much.

VICE CHAIR GREEN: Thank you, Dr. Folkert, and the care and diligence exercise by the subcommittee on preparing this report.

Are there any questions from the ACMUI on this report? Go ahead and use the raise your hand feature. Mr. Ouhib?

MR. OUHIB: Yes. Thank you, Mr. Green. I actually have one, two, three, four, five questions regarding the report itself.

So, my first question is on Page 6 of the document. It says, like if, however, if the licensee has a radiation safety committee the RSO is prohibited by 10 CFR 35.24(f) from serving as the management representative on the committee.

And I was just wondering if there was any exception in the event that the management representative is not present for whatever situation

that might be. Are there any exceptions that the RSO can actually serve as the management representative?

DR. FOLKERT: I apologize, I still cannot hear any audio from anyone else other than the NRC Members. I am going to exit out and try to join back in. I apologize again.

DR. VALENTIN-RODRIGUEZ: Okay. Thank you, Dr. Folkert.

MR. OUHIB: Can you hear me now, Dr. Folkert?

DR. VALENTIN-RODRIGUEZ: Dr. Folkert is going to call in. Trying to see if his audio is fixed, Dr. Zoubir. But you can go ahead with your comments, we can hear you.

MR. OUHIB: You can hear me, okay.

DR. VALENTIN-RODRIGUEZ: Yes.

MR. OUHIB: Should I move on to the next question until he, there is an opportunity to answer those or how do you want me to proceed?

VICE CHAIR GREEN: The court reporter will be recording these. Let's move on to your question number two. The rest --

MR. OUHIB: Okay.

VICE CHAIR GREEN: -- of the Subcommittee can assist.

MR. OUHIB: Absolutely. Thank you. My next question is on Page 7 of the document. What it says, the RSO duties and responsibility include ensuring radiological safety, security and compliance with both the NRC and the U.S. Department of Transportation regulations and the conditions of the license.

I was just curious if the word conditions can be explicit? In other words, what is meant behind the conditions of a license? Okay.

And along that line, in that same section, there was no, nothing mentioned regarding pregnant staff, you know, recommendations or policies or whatever. There are several things that are being discussed there but none related to what should be done about pregnant staff.

Move on to Page 9. If I can get to it. Okay. This is regarding the RSO. The associate radiation safety officer. And it says the ARSO cannot assume any RSO responsibility unless the licensee designates, in writing, the ARSO as a temporary RSO.

And my question on that is, is that to be submitted to the regulation, to regulators, that state or NRC, whatever, or is that just a document

that's available in-house?

My, oops. My next question is on Page 10. This is regarding the atomic physicist, Item 2 there. Where it says, an OP is responsible for assisting the licensee in developing, implementing and maintaining written procedure to provide high confidence that the administration is in accordance with the written directives.

I think it would be great if the word procedures, written procedures, are defined in that paragraph. What is meant about that.

And my last question is on Page 16 of the document. And allow me to get to that section. Okay. Where it says, in order for the regulatory body to determine whether the classroom and laboratory training requirement are met, the applicant may need to provide information such as a transcript, completion certificate, course description, syllabus, outline and learning objectives. I was just curious whether there is a need of providing the instructors credentials?

My worry is that somebody who is not qualified to provide all that might be providing that. That is documented that, well yes, they had all this, but that person was not qualified to provide

that kind of training and education and so on.

And that concludes my questions. Thank you.

VICE CHAIR GREEN: Thank you, Mr. Ouhib. Has Dr. Folkert rejoined us via telephone?

DR. FOLKERT: Let's see, I was able to get back on.

VICE CHAIR GREEN: Okay.

DR. FOLKERT: Now I hear you at least.

VICE CHAIR GREEN: Dr. Folkert, I don't know how many of those questions you were able to catch, but I believe Dr. Ouhib had about five, five questions for the subcommittee.

DR. FOLKERT: See, the first one that I head mentioned had to do with clarifying the conditions of the license on Page 7.

MR. OUHIB: Page 6.

DR. FOLKERT: And so, it would have had -- oh. Radiation safety officer, okay.

MR. OUHIB: Yes.

DR. FOLKERT: Okay. Okay, it's 6, not 7. So, purpose of the authorized individual. And so. And in any events, now I think this is a very reasonable request to make, and so to clarify what conditions of the license means.

And I had assumed that condition of the license would be whether or not it was active or currently under review at the state level. And so, if the NRC can clarify what the conditions for license are I think that would be a good addition to the guidance.

The second question that I heard was about including direction about pregnant workers. I believe that was what he said.

VICE CHAIR GREEN: Ms. Shober, a member of the Subcommittee, has raised her hand.

MS. SHOBER: Hi. Yes, this is Megan Shober. I just wanted to provide a little clarification on the conditions of the license.

So that is referring to the actual license document itself and the conditions that are listed on the license document. So that's standard regulatory language that licensees need to be compliant with the regulations and the conditions of their license because those licensed conditions are also legally binding requirements.

DR. FOLKERT: So, clarify --

VICE CHAIR GREEN: Thank you, Dr. Shobert.

(Simultaneously speaking.)

DR. FOLKERT: -- within the document. Oh, thanks. Sorry about that. Just for interrupting.

Okay. So, I do think it would be helpful to include some clarification of that in the document to make it generally understandable what exactly is meant by the condition to the license.

So, and then the next question about training for workers who are pregnant or seeking to become pregnant. I do believe that's included in one of the referenced regulatory requirements of -- listed on Page 3 of the document.

My question for Mr. Ouhib would be, what aspects of that training, like the training guidance for what their dose limitations are or what they're reporting requirements are? Is that what he wanted to have expanded in the document?

MR. OUHIB: No. It is more like the RSO, basically define the role of the RSO. The duties of the RSO and all that. But there is nothing mentioned regarding, you know, pregnancy issues. What the role of the RSO is to monitor these situations.

DR. HARVEY: Dr. Folkert, if I may? It's Dr. Richard Harvey. I don't think that's something that would be included in the scope of this. I think

that that's clearly defined in regulations, NUREGs and other guidance documents so I don't think that's intended to be included here, but that's just my opinion.

DR. FOLKERT: Yes. And the radiation officer, the radiation safety officer is in charge of tracking dose limits and requirements for pregnant workers or workers seeking to be become pregnant, so perhaps adding the line in there just specifying that that is one of their charges in the section under RSO responsibilities on Pages 7 through 8 of the docs, 7 through 9 of the document. As it is one of their specific duties. I think that would be reasonable.

MR. OUHIB: Yes, I was just curious because it defines and lists all the responsibilities of the RSO in here. And then I notice that the pregnancy issue was simply omitted there, which is a very important one in my opinion.

DR. FOLKERT: Okay.

DR. HARVEY: Dr. Richard Harvey. Mr. Ouhib, I agree with you, it's a very important one. I don't think every duty is listed there. I don't think it's completely encompassing. So, I wouldn't expect every single duty responsibility to be listed within this report presentation.

DR. FOLKERT: So, I'm looking to see now, this is Mike Folkert, I'm looking to see if there is a comment that this list has not exhausted. So, okay. It just says, typically these duties and responsibilities including the following.

And so, we can say include, but are not limited to the following. That would be on Page 7 under the paragraph labeled, the RSO is responsible for the day-to-day oversight of the entire radiation safety program.

Because I completely agree, this is not meant to be an exhausted list.

MR. OUHIB: That is not.

DR. FOLKERT: Yes. It's supposed to be spelled out in other documents.

All right, the next question that I heard had to do with, let's see. It was on --

MR. OUHIB: Page 9.

DR. FOLKERT: Page 9. And sir, would you be so kind as to repeat the question?

MR. OUHIB: I'm sorry, I couldn't hear you?

DR. FOLKERT: Would you be so kind as to repeat the question?

MR. OUHIB: Yes. On Page 9 it talks

about the associate radiation safety officer. And on Bullet number, one, two, three, three it says, the ARSO cannot assume any responsibility unless the licensee designates, in writing, the ARSO as a temporary RSO. And my question was that, does that have to be submitted to the regulators or it's just a statement that is kept basically in house?

DR. FOLKERT: For that one I would defer to our NRC staff. Are you able to give feedback as to where the responsibility designation statement goes to?

VICE CHAIR GREEN: Ms. Shober has her hand raised.

MS. SHOBER: Thank you. Megan Shober. The regulations allow licensees to name temporary RSOs for up to 60 days without a licensing amendment. So, when that phrase, temporary RSO, is used, it means that up to 60-day designation that happens locally.

MR. OUHIB: Locally. Okay, thank you.

DR. FOLKERT: Like in locally, as within the institution itself?

MS. SHOBER: Correct.

DR. FOLKERT: Okay.

MR. OUHIB: Thank you, Ms. Shober.

DR. AYOADE: Hi, this is Maryann Ayoade

from the NRC. And Megan beat me to it. So, Megan is correct. The correct regulations for the temporary RSO does allow the licensee to name someone as a RSO temporarily. The designation, in writing, is for in-house for the licensee to keep. And for us to review, if necessary, if we need to or during inspection.

VICE CHAIR GREEN: To improve clarity of this guidance document should we ask the guidance document to be edited to clearly show that this is submitted to the local management chain of the institution, not the regulator?

DR. FOLKERT: It's Mike Folkert. I would agree. And also, in part to add a reference to the regulation that states this. Okay.

VICE CHAIR GREEN: Dr. Ouhib, have we answered your questions?

MR. OUHIB: Yes, thank you. Thank you.

DR. FOLKERT: All right.

MR. OUHIB: I think that that clarifies that so there would be no confusion.

DR. FOLKERT: Yes.

VICE CHAIR GREEN: Any other member of the ACMUI that has questions regarding the report or the draft interim guidance?

DR. FOLKERT: Well so this is Michael. His next question that was relevant to Page 16, about including the credentials of those providing the training.

And so, I do think it would be, I mean, for any course CME, educational program that the credentials are vetted for CME applications, continued medical education applications, all of the credentials, the conflicts of interest, the review of the presented material is all required. So, I would say for this that policing the credentials the individual educational activity would certainly be out of the scope of the NRC.

It's, but as far as looking to see if they are CME credentialed, if they're a part of a collegiate force that I think looking to see the source I think does make sense as part of the review of the training and the hours done. But going into the credentials of the presenters I think would be far beyond the scope of the NRC.

VICE CHAIR GREEN: Thank you, Dr. Folkert. Do we have any other comments, questions from Members of the ACMUI?

MR. OUHIB: Mr. Green, if I may? This is Zoubir Ouhib.

VICE CHAIR GREEN: Yes.

MR. OUHIB: Two items of the one, the first one on Page 6 and the last one on Page 16 that we did not address. And on Page 16 that's under 4.3.2.1. It's the last paragraph.

What it says, in order for the regulatory body to determine whether the classroom and laboratory training requirement are met, the applicant may need to provide information such as transcript, completion certificate, course description, et cetera, et cetera.

I guess my question in there, should there be a need of qualified instructors and credentials to avoid having training provided by a non-qualified person?

And, for that matter, who should that be? Who should what requirements be needed for that person providing the training, qualifications, et cetera?

DR. FOLKERT: All right, it's Mike Folkert. I think that was the point that I had been trying to -- I was addressing just right before you joined in there.

So, I mean, I think policing the credentials I do think would be far out of the scope

of anything the NRC can do. I hope you can hear me. For any sort of policy course, any continuing education course, CME course, all of those presenters do have to have their credentials reviewed. They have to disclose their conflict of interest, they have to present their course materials for approval in advance.

So, I think that the responsibilities on the source of the education, whether it's like an ASTRO CME course of an SNMMI CME course, so on, because of, I mean, if you go down to things like the radiation biology education, radiation biology is taught by people who have no authorized user status, or not clinicians. You know, they're often laboratory-based scientists so who are not, who don't have a credential for radiation biology, but they have a deep and fundamental knowledge of the subject and are providing educational training.

And so, I don't see how the NRC on any level could review that level of training that review their credentials. But the offering institutions that, so are supervised by the ACGME, by the graduate medical education groups, they review them. And ultimately, it's going to be their responsibility to assess the quality of core education and things like

radiation biology, core physics, so on and so forth.

MR. OUHIB: Okay. All right, thank you.

DR. FOLKERT: And if you could, your first on that I wasn't able to hear, the one on Page 6, or was --

MR. OUHIB: I think it was on Page 6 where, on the one before last bullet point. Let see what section that is. Give me a second here. Under radiation safety officer. RSO.

And I think it says, if the RSO is placed in the license management structure and meets the criteria of management as defined in the regulation in 10 CFR 35.2, then action of the RSO may be considered action of management. And my question is on the last sentence there.

However, if the licensee has a radiation safety committee, the RSO is prohibited by 10 CFR 35.24(f) from serving as the management representative on the committee. My question to that is, could there be any exception in the event that the management representative cannot be available and that RSO can act as the management representative?

DR. HARVEY: This is Dr. Richard Harvey. We keep those roles completely separate. I don't know how the NRC feels about it. If there could be

an exception to Mr. Ouhib's point, but we keep those roles completely separate for many reasons.

And it's nice to have the management representative there to help mediate situations between an RSO, and maybe other members of the committee. And, you know, it's just better, in my opinion, to clearly keep those roles separate. Segregated. That's just my feeling.

MR. OUHIB: I guess my question is that let's just say something prevented the management representative from attending at the very last minute. And you have a radiation safety committee meeting. Now you know that you're supposed to have that person present during radiation safety committee, but here you are, you don't have that person. Could there be an exception that somebody like the RSO can assume those functions? And that's all.

DR. HARVEY: Yes. This is Richard Harvey again. And so, I mean, our approach is we have a management alternate in case of situations like that. But again, there is nothing to say that the management representative and their alternate can't make the meeting as well.

So, your point is well taken. I think

it's the NRC's decision to say if they would allow that exception. So, I think your point is very important and well taken and would be very interested to hear an answer. Thank you.

MR. OUHIB: Thank you.

VICE CHAIR GREEN: Do any members of the NRC staff wish to address that last portion of Mr. Ouhib's question?

DR. AYOADE: Hi, Dr. Folkert, this is Maryann Ayoade from the NRC. So, as it relates to that situation, you know, 10 CFR 35 clearly has a definition for management in 35.2. And I believe that was included in the guidance. But as Dr. Harvey said, we tried to keep, the intent was to keep the roles of management and the RSO separate, except for situations where the RSO does meet the criteria of management.

And so, for the case that Dr. Ouhib has presented, it would have to be, you know, an exception, and that would have to mean, you know, or an exemption. And so, it would have to come in separately from what, to request that separate from what you currently authorize. Or allow.

DR. FOLKERT: Yes, this is Michael Folkert. That makes sense. And most of this

discussion I think actually would pertain more to that regulation rather than this guidance document.

DR. AYOADE: Agreed.

VICE CHAIR GREEN: Thank you. Are there any additional questions from Members of the ACMUI? I see no hands raised.

Let's open it up to any questions from Members of the NRC staff? Dr. Valentin-Rodriguez, I see your hand raised.

DR. VALENTIN-RODRIGUEZ: Thank you, Mr. Green. I had one question for Dr. Folkert. When you were, when you and Shober were discussing the temporary RSO, the ARSO, one of those bullets in the implementation guidance, you mentioned that it might be worthwhile for the NRC to clarify the regulation as well. Is that something that the Subcommittee is considering as a recommendation or, and do you all think that you can provide language at this time or is that something for further consideration for the Committee?

I just want to make sure that whatever action the ACMUI wants to recommend that it's captured as part of the report.

DR. FOLKERT: This is Michael Folkert. Yes, I wouldn't expect any full discussion on that

right now this just came up. I was merely pointing out that this, like the purpose for today's discussion is to go over the guidance document. If there are concerns about a separate regulation, I think that is a separate conversation and that should be taken up at a different time.

DR. VALENTIN-RODRIGUEZ: Okay. Yes, I just wanted to make sure if I understood the comment correctly. That's all.

Mr. Green, I was going to suggest, if there are any changes that the Committee, in full, wants to make to the draft report based on Mr. Ouhib's questions, now might be the time for the ACMUI to discuss those changes so we can capture them as part of the final report when we issue that. I don't know if you wanted to do that now. I think we have time.

VICE CHAIR GREEN: I agree. As I recall it was one recommendation to clarify that the internal designation of the alternate RSO is submitted to the institutional leadership, not to a regulator. Were there any other things that we thought required clarification?

DR. FOLKERT: This is Michael Folkert. On the section under the radiation safety officer, with the conditions of the license. And so, the,

right there we would look for language for clarifying what conditions of the license means. Because it has to do with --

DR. VALENTIN-RODRIGUEZ: Yes.

DR. FOLKERT: Oh, sorry.

DR. VALENTIN-RODRIGUEZ: No, I was just going to say, I capture that. And I think the plan would be to include that as a specific comment in that section of the report, and we would just add it as Number 7.

DR. FOLKERT: Okay.

DR. VALENTIN-RODRIGUEZ: Thank you.

DR. FAIR: Just to clarify, I may have misheard. I thought what I had just heard was that the alternate RSO would be designated at the institution. I think it was actually that the temporary RSO, that if the alternate RSO becomes the temporary RSO that that's internal. I don't think alternate RSO's are strictly internal.

VICE CHAIR GREEN: Thank you for catching that.

DR. HARVEY: This is Richard Harvey. I think it's for associate RSOs to be the temporary RSO, correct?

DR. FAIR: Yes.

DR. FOLKERT: Yes. ARSO to RSO. Yes. So, again, this is Michael Folkert again. So, in that same area there was just the clarification, the duties and responsibilities include the following. Just because it did not specifically state anything about the documentation or special considerations for pregnant workers, to make the last line of that paragraph that the RSO is responsible for daily oversight of the entire radiation safety program. To say typically these duties and responsibilities include, but are not limited to, the following.

Just to make it very explicit that this is not the exhausted sum of the list of all responsibilities of an RSO.

MR. OUHIB: I like that suggestion very much.

VICE CHAIR GREEN: Is there anything else we need to capture, Mr. Folkert?

DR. AYOADE: Hi, this is Maryann Ayoade from the NRC. Just wanted to, again, clarify that, a question about the ARSO being able to function as a temporary RSO. Again, as I mentioned before, that designation in writing is for, you know, within the institution or for the licensee.

But I also wanted to clarify that the NRC

does require that the licensee notify us when they made the change, or they want to appoint an individual as an RSO. And the notification is separate from a license amendment where they would have to submit something or information that we would have to actually amend the license to include that individual's name.

So as Megan said, for up to 60 days they have to notify us. That licensee designation in writing is for in-house with the licensee.

DR. FOLKERT: So, this is Michael Folkert. So that would be, so the specific line then we're looking at is on Page 9. The ARSO cannot assume any RSO responsibilities unless the licensee designates in writing the ARSO is a temporary RSO.

So, we should add, so it seems like the suggestion would be then, unless the designee, unless the licensee designates in writing the ARSO as a temporary RSO, and then comma, and notifies the NRC. And then I would recommend providing a link or a reference to the appropriate regulation that states this.

VICE CHAIR GREEN: Melissa, I see your hand raise.

MS. MARTIN: One question. Yes, this is

Melissa Martin, a member of the ACMUI Subcommittee on this project.

One question that has been raised is, in today's world with such a shortage of qualified radiation safety officers, is it permissible to do more than 60, in other words, if you designate your ARSO for 60 days, at the end of that 60 days you still do not have another person to be named RSO, can you do those multiple times?

DR. HARVEY: This is Richard Harvey. I can't speak for the NRC, but I think 60 days is a timeframe for you to, you know, try to make some arrangements other than extended that multiple times. And I could be incorrect on that, but I think there would have, I would think there would be able, the NRC and the agreement states would want somebody specifically designated after 60 days. But I cannot speak for them whether they would grant additional occurrences of that. Thank you.

MS. MARTIN: Thank you, Richard.

VICE CHAIR GREEN: Ms. Shober?

MS. SHOBER: Yes. Again, Megan Shober. I won't speak for the NRC either, but in my state, we require a license amendment if it's a temporary situation that's going to extend beyond the 60 days.

VICE CHAIR GREEN: Dr. Ayoade?

DR. AYOADE: Yes, this Maryann Ayoade from the NRC. So yes, for as far our regulations it is 60 days, and so it would require them submitting an amendment.

Now the regulations also allow for more than one ARSO, or more than one, I mean, temporary RSO. So, it could be another individual that qualifies, that meets the qualification to be a temporary RSO.

But if it's beyond the 60 days it would have to be an amendment. And so, they would have to submit information of the individuals, or the proposed individuals, training and experience to be named on the license as an RSO.

MS. MARTIN: Thank you very much.

VICE CHAIR GREEN: Have we succeeded in capturing all the thoughts and recommendations that you've come up with?

DR. VALENTIN-RODRIGUEZ: Mr. Green, I have captured I think all of them. They are also captured in the transcript. So, what we'll do is we'll go back to the draft report, incorporate the comments from the transcript, and we'll send the ACMUI a copy of the final draft report before we issue

it as final to ensure that we captured the appropriate changes based on the transcript.

VICE CHAIR GREEN: So, for today's purposes we still want to entertain a motion to accept this report, as amended.

DR. WOLKOV: Move we accept the report as amendment. This is Harvey Wolkov.

VICE CHAIR GREEN: Thank you, Dr. Wolkov.

DR. HARVEY: This is Richard Harvey; I'd be happy to second that.

VICE CHAIR GREEN: Thank you, Dr. Harvey. Now we'll ask all members of the ACMUI if they support the report as amendment, say aye?

(Chorus of ayes.)

VICE CHAIR GREEN: There are any opposed? Any abstentions? Hearing none, it is in the affirmative.

Now we have some time to open up the phone lines to see if there are any comments from members of the public. Can we go ahead and do that now? What's the process?

DR. VALENTIN-RODRIGUEZ: Yes. Thank you, Mr. Green. So right now, I've, I'm pretty sure I've enabled everyone's mics who have joined us through the Microsoft Teams meeting. I see there is

some hands raised already. So, I will go and call on those hands raised in the order that they appear. And you should be able to enable your mics to come off mute.

So, the first person I have is Laura Evans. Laura, you can take yourself off mute if you want to comment. Okay, maybe Laura is having some issues.

The next person I see is Ralph Lieto. Ralph, can you take yourself off mute?

(Pause.)

DR. VALENTIN-RODRIGUEZ: Mr. Lieto, I see you're off mute so you can go ahead with your comment.

It might be some issues on our side with the unmute function, so let me go back and try to unmute everybody so that you all can control your own mics and come off mute. Let's try this again. Mr. Lieto, are you able to speak into your mic or are you unable to unmute yourself?

DR. FOLKERT: It's Mike Folkert. And in order for me to be able to hear anybody I had to completely close out and exit the Teams program and restart it again. I'm on a trunk line so it's not a -- and it's definitely not a bandwidth issue.

(Simultaneously speaking.)

DR. VALENTIN-RODRIGUEZ: Let's see. I've tried something else. Laura Evans, can you come off mute now? Or Ralph Lieto. I have promoted you to presenter so I think you should be able to control your mics now. Let's try that.

(Pause.)

DR. VALENTIN-RODRIGUEZ: Okay, let's try this a different way. So, please stand by while I try to figure out what's going on in the back end. Because I can hear everyone else, and I see the mics being turned on, but I can't hear if anyone is talking.

(Pause.)

DR. VALENTIN-RODRIGUEZ: Okay, let's try this again. Let's see. Laura Evans, can you unmute your mic and see if you can make a comment? You should be able to unmute your mic.

So, I'll go down the list. Ralph Lieto, can you unmute your mic?

(No response.)

MR. OUHIB: As a last resort --

DR. VALENTIN-RODRIGUEZ: Okay, let's try this again.

MR. OUHIB: -- can we use the chat box

by any chance?

DR. VALENTIN-RODRIGUEZ: Yes. So, I just enabled the chat. I am so sorry about that. I'm not sure what's happening on the back end. But I have just enabled the chat so what I'll try to do is, if you have a comment, thank you for your patience.

The chat feature should be enabled, so if you can write your comment or you're in the chat, we'll be able to read it for the transcript. The chat is turned on for the duration of the meeting. So, I really apologize. I'll keep trying on my end to see if there is anything we can do to resolve the audio issues.

In the meantime, if you can type your comments on the chat that should be enabled for everyone. And so, we'll be looking for comments there while I try to figure out if there is any other way I can fix this. So, I apologize for that.

MR. MITCHELL: Hello, this is Chris Mitchell. I was the next one on your list. I don't know if --

DR. VALENTIN-RODRIGUEZ: Okay. Yes, we can hear you, Chris. Go ahead.

MR. MITCHELL: Okay. So, if it's okay

I'll go ahead and ask my, make my comment and questions.

DR. VALENTIN-RODRIGUEZ: Yes, please. Thank you.

MR. MITCHELL: Okay. Chris Mitchell. I am the radiation safety officer at Kettering Health in Dayton, Ohio. My question and comment really are regarding the discussion that was had regarding the temporary RSO and the associate RSO.

Since the associate RSO really is, has to undergo the same training and experience requirements as the RSO, would they not be the more logical choice for, as a temporary RSO, maybe not for the 60 days, but in those situations where maybe the RSO is on leave or medical leave or whatever RSO leaves, you have an assistant RSO that's in the process. But would they not fit that bill, and would you have to submit an amendment for them to do that? Thank you.

DR. FOLKERT: This is Michael Folkert. This is definitely a question for the NRC staff to answer.

DR. AYOADE: Hi, Dr. Folkert, this is Maryann Ayoade from NRC. So, again, the regulations would only allow for an associate radiation safety officer to become a temporary RSO if that ARSO meets

the qualifications of the RSO, right?

And so, in some cases licensees are appointing multiple associate RSOs to do specific duties and tasks. So, they may not be fully qualified to do everything that that licensee is licensed for. And so again, the licensee can designate an individual, but again, the individual has to be, has to meet the qualifications of an RSO even to be listed as a temporary RSO. And I hope that clarifies the question at hand.

MR. MITCHELL: Thank you very much. That does I appreciate that.

DR. VALENTIN-RODRIGUEZ: Thanks, Maryann. Let's see. From the chat Mr. Ralph Lieto asked for the, if the document is available for public comment?

So, Mr. Lieto, the draft that the ACMUI reviewed is available on the ACMUI website. I put the link to the direct document, and to the materials for today's meeting on today's chat.

The plan is to provide this interim staff guidance for a 60-day public comment in the next few months. So, the public will have an opportunity to provide comments on this document.

And then, Ralph, I don't know if you can

come off mute now? I've tried toggling some of our audio settings, but I see your question in the chat.

Last slide of the report is confusing. What is the difference between in-person and hands on, I'm assuming training, if hands on you are in person, is this terms of different authors? His suggestion is to just use the hands-on term.

Let's see. For the folks that have their hands raised, maybe we can try for you to leave the call and then come back in. I think everyone's audio should be enabled so when you come back in you should be able to unmute yourself, and then go ahead and raise your hands and I will come on your names. I apologize for that, but hopefully that will ease that audio settings issue and we can have folks get their questions on the transcript.

Dr. Folkert, go ahead?

DR. FOLKERT: Oh yes. So, it's Michael Folkert. And so, this has to do with Ralph Lieto's comment about the in-person hands on. So, there were a couple of points within the draft guidance where they mention hands on training, in-person training. And it is a little confusing that's one of the reasons why we want to clarify.

So, hands on training you could be

practicing with a syringe for an injection, you could be practicing with a Mick applicator for LDR brachytherapy, you could be practicing with an HDR afterloader, so on and so forth. But you may or may not have a trained licensed, otherwise authorized individual like with you for the training.

And like in-person training is you've got a trained authorized user who is there with you going through the training rather than Zoom or Teams meeting, so on and so forth. So, kind of clarifying these, like when do you have to physically manipulate the device as part of the training, when do you have to have an authorized user or, you know, other specified professional trainer physically with you on site for the training? I think that was what we wanted to have clarified.

MR. OUHIB: This is Zoubir Ouhib from the ACMUI. I guess my question is, should there be, like right underneath that, a very quick short definition of the two terms basically? What is meant about in-person, what is meant about hands on.

DR. VALENTIN-RODRIGUEZ: Zoubir, I think your comment was for the Committee to make such a recommendation, correct? If I capture that correctly. To suggest to the NRC, clarify --

MR. OUHIB: That is correct. Yes.

DR. VALENTIN-RODRIGUEZ: Okay.

MR. OUHIB: Yes, that is correct. Since it was clarified, you know, it would be good to have that clarification right underneath that.

DR. FOLKERT: So, Mike Folkert. And so, part of the concern about that is that this, this is kind of mirrored in many, many, many different specific guidances for other devices. So, it's something where it actually is going to have to be addressed on other guidances. Guidances for the use of microspheres, guidance on the use for the beta-Cath device, so on and so forth.

So specifically, to this document, I mean, if we want to add something in there it would be under Section 4.3.2.4, and that's on Page 17 of the document. And let's see.

So, we had actually asked to remove the line stating, this element must be completed in person with the device. And so, because it's not really spelled out anywhere in here. It has to be in other regulations. So that's why we recommended removing the sentence from the guidance document.

So, but if we want to clarify it there, we could state something, let's see. For this, so

under scope of training, reach device we could say, so after that line that we suggest removing, this element must be completed in person with device, we could say, aspects of training could include hands on training where the perspective authorized user directly works with the device or a mock injectable.

And another possible, and another type of training is in-person training where the regulation specified authorized user or trainer who is physically present in the same room as the perspective authorized user as part of the training. That might be a bit clunky and overly worded.

VICE CHAIR GREEN: Dr. Folkert, it sounds like that suggestion would require us to go back and --

DR. FOLKERT: Wordsmith.

VICE CHAIR GREEN: -- wordsmith. And again, for a motion to approve the report as amended, including this last recommendation. A second vote.

DR. FOLKERT: Yes. So, Michael Folkert again. I mean, that was the reason why we asked for this to be removed. And so, the, you know, because we did not, because there are multiple other guidance out there that do spell out requirements. This was, this was a request for the NRC to clarify this in

their other regulations. We asked to remove this from the document.

VICE CHAIR GREEN: So that's the issue with other documents, not this document. We can let this document remain as the report recommends.

DR. FOLKERT: Yes. I mean, that was our, that's why we asked for that line to be removed.

VICE CHAIR GREEN: Okay.

DR. VALENTIN-RODRIGUEZ: So, Dr. Folkert, I think based on your discussion with Mr. Green there is no need to amend the report further because I think you've captured that already in your report, correct?

VICE CHAIR GREEN: I agree.

DR. VALENTIN-RODRIGUEZ: Okay.

DR. FOLKERT: Yes.

DR. VALENTIN-RODRIGUEZ: Okay. Let's see. Are there any folks with their hands raised who can unmute themselves and let, and try and speak? Otherwise, I'll go to the chat that I see a question or two.

DR. RAZMARIA: Hi there. Can you hear me?

DR. VALENTIN-RODRIGUEZ: Yes, we can hear you.

DR. RAZMARIA: Hi, how are you? This is Ali Aria Razmaria. I'm calling in from, I'm a nuclear medicine physician from Memorial Sloan Kettering Cancer Center.

Yes, again, thank you for the ACMUI Members on the Subcommittee for the report. And I just want to kind of bring up a topic here that, kind of reading through the regulations that has caught my eyes, and also pertains the training and experience requirements. And I wanted to share that at this opportunity with my comment and the ACMUI in general.

So, again, that goes along the lines of what Mr. Ouhib, he has mentioned regarding insuring quality. How that can be maintained in terms of what training and experience requirements.

And again, it's clear that obviously NRC cannot police the requirements and have the standards of training that has been provided, but thinking there are measures in place in terms of, you know, the medical field we rely on which pertains to like residency trainings that are created by bodies that basically have accreditation and instruments in place that we rely in the medical field on.

So again, in that regard I just want to kind of point out that we have a discrepancy that is

kind of apparent in the regulations. And again, I wish I could, because I have the regulations, NRC regulations, up here. I wish we could have shared that. Is it possible to share those? I know I will try --

DR. VALENTIN-RODRIGUEZ: We can try to pull up the regulations --

DR. RAZMARIA: Okay.

DR. VALENTIN-RODRIGUEZ: -- if you let us know what the --

DR. RAZMARIA: Yes. So, I think --

DR. VALENTIN-RODRIGUEZ: -- number --

DR. RAZMARIA: Because if I could try if that's possible. Can you see those? I mean, this is not pulled up as NRC website, this is kind of --

DR. VALENTIN-RODRIGUEZ: Okay.

DR. RAZMARIA: -- foreign material. Kind of we see here, obviously this is about Part 35, medical use of byproduct materials. Particularly we're interested in training and experience requirements.

And I just want to kind of point out, in terms of the Subpart E, which kind of pertains to unsealed byproduct material and the corresponding training and experience requirements. And I just

wanted to kind of point that out. And kind of different tabs here.

So, if you read here, we see, in terms of what is needed in order to be able to basically confidently administer or use those products is successfully complete residency training in radiation therapy and nuclear medicine training program and other related specialties.

But I just want to put that in contrast, what we have in place in subpart for, if we go back, it's Subpart, basically in 35.494, brachytherapies. You kind of see there really explicitly mentioned in the regulations, successfully complete minimum three years of residency training in a radiation oncology program approved by the residency review committee of accreditation counsel for graduate medical education.

So, your kind of relying here, the NRC is relying here on a third-party established accreditation body, so, which kind of oversees all the practice of medical field. It gets started from family medicine, surgery, radiology, et cetera.

So, we are relying on an external body to basically, to keep that accreditation. So, we need to police the educators, but these are kind of the standard, standards that we go in the medical field

by.

So, the same thing applies to like training for user remote after loading units, teletherapy units, and gamma stereotactic radiosurgery. Again, we see the same thing for radiation oncology has been kind of very proactive in kind of having those requirements explicitly mentioned in the regulation.

So here again, successfully complete a minimum of three years of residency training. And this is kind of the first point. So, there are subsequent points that point out like alternative pathways. But again, you're relying here heavily on kind of medical bodies, accreditation bodies that are kind of giving us their assurance, this is quality training that has been pursued by people who are kind of using these devices.

So, three years of residency training in a radiation therapy program approved by the residency review committee, accreditation costs for grad medical education.

So, again, going back to the training for use of on unsealed byproduct material, again, by no means less dangerous or less prone to side effects, if you will, but we have the kind of rudimentary

mention of what training is, so basically successfully complete residency training in radiation therapy or nuclear medicine.

Again, we know that unsealed byproduct materials have been kind of traditionally used by nuclear medicine as a field and a program-related medical specialty, again, not really kind of going into the details as we have it in the other two training and experience requirements.

So, again, a very clear disparity in terms of how to maintain or assure quality in terms of training for people who pursue this or people who are providing the training for people that are interested in becoming authorized users.

Again, you see here that, again, this goes hand-in-hand with having an examination, again, in Part 4 the brachytherapy, examinations have to be passed by the candidates.

That kind of provides the board certification, specialty board, and this applies for like, you know, teletherapy units as well. Again, not as clearly stated for unsealed byproduct materials.

So, yes, again, since we are at the point where we are discussing what are, you know, what is

the quality of training, you know, what it should look like going into future, again, very well worded out or kind of spelled out for radiation oncology applications, brachytherapy, teletherapy, but not so much for nuclear medicine application, which kind of this area has been traditionally within the nuclear medicine field, again not that specific language.

Again, I think that's kind of, you know, at this point, I just want to kind of bring up this disparity in regulation, the wording of the regulation, and kind of towards the point of how we can in the future improve or maintain, establish the quality that we want to see these products being used by -- for the people who are candidates where people providing the training.

So, I just wanted to kind of bring that up at this point and, you know, have kind of, you know, a response or comments from the ACMUI or NRC staff.

DR. VALENTIN-RODRIGUEZ: Thank you for your comment, Dr. Razmaria. Let's see. I think there was some back and forth in the chat. Let's see, looking at the next comment.

Mr. Bryant, if you want to come off mute, otherwise I will share your question and read through

it. I think Dr. Folkert responded to it, but your question was "Can a proposed authorized physician user be added without considering recentness of training to an NRC RAM license if the proposed individual was previously but not currently listed on an NRC RAM license for all uses applied for?"

Dr. Folkert responding, "Yes, they would use NRC Form 313A, Authorized User Requesting Authorization for Use of Seal Sources Defined Under 10 CFR 35.400 or 35.600. Instructions are in Section 4.6 of the proposed guidance."

Mr. Bryant, I don't know if you wanted to come off mute to add anything.

(Simultaneous speaking.)

DR. FOLKERT: This is Michael Folkert. Just to -- Oh, sorry. Yes, okay.

MR. BRYANT: Yes, so perfect. It sounds like my microphone is working now.

DR. FOLKERT: Yes.

MR. BRYANT: So that was the question. I just wanted to make sure there wasn't like a time bar that existed as far as on the time that would have elapsed from the time that the proposed authorized user would apply to be added to a RAM license and the time that they were last listed on an

active radioactive materials license.

So, let's say that it was ten years ago when the individual was last employed and working in the field and was on a byproduct license as an authorized user?

DR. VALENTIN-RODRIGUEZ: Dr. Folkert, I think that's something that the NRC could consider as a potential scenario --

MR. BRYANT: Yes.

DR. VALENTIN-RODRIGUEZ: -- to add to the guidance if I think I understood Mr. Bryant's question correctly.

DR. FOLKERT: Yes, this is Michael Folkert again. Yes, that's -- I mean he captured -- That's exactly one of the ones that we specifically requested.

And so, as a case example, a 10-year out radiation oncologist who wanted to, you know, get set up, because you could do one of the standard pathways or you could do the preceptor attestation. That is the one that is listed under Section 4.7, and it explains the preceptor attestation method of getting on the license.

So, but, yes, we should -- I mean providing an explicit case example for some of these

very common scenarios I think is absolutely a need and clearly wanted by the public.

DR. VALENTIN-RODRIGUEZ: Thank you, Dr. Folkert. Ralph Lieto, I think you can unmute yourself now. Let's see if this works.

MR. LIETO: Can you hear me?

DR. VALENTIN-RODRIGUEZ: Yes. I apologize for all the issues, but we can hear you now.

MR. LIETO: It's probably not on your end. I ended up changing computers.

DR. VALENTIN-RODRIGUEZ: Okay.

MR. LIETO: My name is Ralph Lieto. I am a retired RSO, and medical physicist and I am asking this on behalf of myself.

I had a couple of questions. My main one has to do with the last slide where it talks about "in person" versus "hands on." I am trying to understand what that difference is.

Was that just maybe different authors of the document using their respective terms or is there some difference between "in person" and "hands on" that I just don't fathom? So, it's directed not only to the Committee, the subcommittee, but also NRC.

DR. FOLKERT: Hi. It's Mike Folkert.

So, I think maybe while you were switching computers, we had a discussion about that as well. I apologize if it was confusing in the presentation.

We actually did not want that to be discussed at all in the guidance. We actually asked for it to be removed from the guidance, because there are elements of -- there is definitions of these aspects of training in specific guidance that are more in line with specific applications, radiopharmaceutical applications, device applications, so on and so forth, and so it was a request to the NRC to address when devices and applications require both in person and hands on training.

The general thinking that hands on training means that you train with the device or a mock version of the device yourself, whereas in person is you have a qualified person with you, physically with you in a room, not on a Teams chat or a Zoom chat or anything like that, going over the use of the device or the application.

But as far as the guidance was concerned, we had actually asked for it to be removed from the guidance so it would not be part of this draft.

MR. LIETO: But -- Okay. But then you

are asking that just from that respective section but wherever it's used in the document, is that correct, because the terms are used about four or five times throughout the document?

So, some cases there is "hands on," the term is used, and in other places, in a couple other instances the term "in person" is used. So, I am still not clear in terms of the way you described "in person," how that does not mean that the person is actually hands on with the device or some mock of it. So --

(Simultaneous speaking.)

MR. LIETO: I think this is something that needs to be fixed in the document and also in terms of with NRC, but I think the term, it should be just one term and not two terms.

I think "hands on" is used in other NRC documents if my memory serves me right.

DR. FOLKERT: Yeah, I think it is.

MR. LIETO: Like in the regulatory guidance documents.

DR. FOLKERT: Yeah.

MR. LIETO: So that was my one point. The other is I think Maryann mentioned a comment about that you could have more than one temporary RSO

designated during some type of transition, especially in larger programs.

I don't -- I'm pretty sure that's not common knowledge and I would recommend to the writing committee that they clarify and maybe even specify that point in a discussion about temporary RSOs, or excuse me, the associate RSOs becoming temporary, because I think that's a very important point and could aid licensees very much. Thank you.

DR. VALENTIN-RODRIGUEZ: Thank you, Ralph. Again, thanks for putting up with our audio issues. Let's see. I am looking for more hands raised. Any other attendees who would like to comment.

I think the audio now is working so you can go ahead and unmute yourself or raise your hand and I'll call on you.

(Pause.)

DR. VALENTIN-RODRIGUEZ: Okay. William Hinchcliffe, go ahead.

MR. HINCHCLIFFE: Hi. William Hinchcliffe. I am the radiation safety officer for Yale New Haven Hospital. Actually, on this point for the temporary radiation safety officer I just wanted to clarify Ms. Ayoade's comments for 35.24(c), that

the 60 days a licensee makes for an individual qualified radiation safety officer, the 60 days is specific to the individual and not the licensee.

I was looking and there is a little bit between 35.24(c) and 35.24(d) and whether it can be multiple individuals longer than 60 days or is the 60 days tied to the licensee in an annual year, in a year?

DR. AYOADE: This is Maryann Ayoade from the NRC. I can clarify that some more because I believe that's what you are asking for, some more clarification.

So, as you mentioned the regulations in 35.24 does allow for the temporary RSO to serve in that role for up to 60 days each year, right, and then it is in I believe 10 CRF 35.14 the notification where the licensee has to notify NRC within 30 days of any changes, including that of the temporary RSO. I hope that clarifies your question.

MR. HINCHCLIFFE: I think the actual clarification was whether the 60 days is for the individual or the 60 days is the maximum for a licensee to have any temporary RSO. So --

(Simultaneous speaking.)

DR. AYOADE: The 60 days is for the

individual to function as a temporary RSO on the license, or for the licensee.

MR. HINCHCLIFFE: Okay. So --

DR. AYOADE: So, to function as a temporary RSO.

MR. HINCHCLIFFE: For that individual. So, if you had two individuals you could have a temporary RSO for 60 days and then you could in writing have a new individual be a temporary RSO for 60 additional days as long as you notified the NRC per 35.14?

DR. AYOADE: Yes. I believe from what you said, yes, that's correct.

MR. HINCHCLIFFE: Okay. Thank you.

DR. VALENTIN-RODRIGUEZ: Thanks, William. Matt Barrett, I think you can come off mute. I see your question in the chat. If you can't unmute yourself then I can go ahead and read it, but I figured I'd give you the chance to come off mute.

MR. BARRETT: Yes. Let me try to clarify (audio interference) --

DR. VALENTIN-RODRIGUEZ: See, I think your connection is coming in and out, Matt, so maybe I can read the question and if that's fixed on your end you can come off mute.

Your question is "Would this be acceptable, 10 CFR 35.24(d), a licensee may simultaneously or sequentially appoint more than one temporary radiation safety officer in accordance with Paragraph C of this section if needed to ensure that the licensee has a temporary radiation safety officer that satisfied the requirements to be a radiation safety officer for each of the different types of uses of byproduct material permitted by the license?"

So, I don't know, maybe you can come off mute now. Is that what the NRC is allowing? I think based on your quoting of regulations I think, yes, it would be allowed, but I don't know.

Maryann, maybe you can -- I think that's what you were speaking to earlier.

DR. AYOADE: Yes. Hi, Celimar, this is Maryann Ayoade. So, it looks like in is quote of 35.24(d) he included the language "or sequentially," right.

DR. VALENTIN-RODRIGUEZ: Yes.

DR. AYOADE: And currently the regulation says "simultaneously."

DR. VALENTIN-RODRIGUEZ: Right.

DR. AYOADE: And so currently the regulation's intention is not for that to be the case.

But, again, on the case-by-case basis, you know, as you notify us and you present the information to the NRC or the agreement states, you know, we would have to evaluate it on a case-by-case basis.

DR. VALENTIN-RODRIGUEZ: Let's see. I think he added something. The chat says "I am just" -- Okay. "I am just trying to clarify is that what we are verbally saying?" And I think Maryann clarified that. Okay.

I don't see any other hands raised. Anyone else from the public who would like to make a comment feel free to come off mute or raise your hand and I'll call on you.

It looks like the enabling mic feature for all of you should be active so you can come off mute. Dr. Carol Marcus, I see your hand raised. Go ahead.

(Pause.)

DR. MARCUS: Can you hear me now?

DR. VALENTIN-RODRIGUEZ: Yes, we can hear you.

DR. MARCUS: Oh, okay. You'll have to forgive me, but the first hour and a quarter of this meeting I couldn't hear because there was some speaker issue, but it's resolved now, so I don't know

if this was discussed at all.

I was concerned that preceptor attestation in nuclear medicine now does not include assurance of clinical competence but only radiation safety competence.

The NRC has a statement that it's the job of the Board of Medicine to regulate clinical competence. Number one, it's not the job of the Board of Medicine, they don't do that.

Once you pass Part 1, 2, and 3 of the National Board Exams as long as you pay your fee you get a license. In the very, very unlikely event that somebody makes a complaint to the Board of Medicine about your performance they will appoint a board-certified person in nuclear medicine to look at what went on and to decide if you are competent, if that's the question, but that hardly ever happens.

I think it would really be important that the preceptor attest to the clinical competence of the physician because the physician is not board certified in a field, you know, that is recognized by the NRC.

If you just -- You know, radiation safety is pretty simple and almost anybody can learn it pretty fast, but clinical competence is something

else.

When I was teaching radiation oncology residents to do radiopharmaceutical therapy, they, you know, satisfied the case numbers and things like that, but that wasn't enough.

I had, you know, extensive discussions of all the cases from a medical point of view and I had a comprehensive written examination for each resident and a passing grade was a 100. If you didn't get something right, you had to do it over till you got it right.

So that my criteria for clinical competence was more than what was set out in the regulations because I simply wouldn't attest to that unless I thought these residents could actually do the job.

So, I basically am asking the ACMUI how you are going to assure that the people you license to do radiopharmaceutical therapy, for example, are clinically competent, you know.

If, you know, the Board of Radiology says that the requirements of their residency program no longer meet the NRC requirements -- Actually, it hasn't met the NRC requirements in 20 years, but they finally realized that they were lying so they stopped

this nonsense.

But what are we going to do about this preceptor thing? Somebody has to decide that the person is competent and usually it's the boards, the specialty boards, but now you're talking about licensing people who don't have specialty boards and, you know, you better make sure they are competent.

I mean if the NRC has any job at all, you know, you certainly don't want to license people who aren't competent to do radiopharmaceutical therapy and then shrug your shoulders when they screw up and say, oh, well, it was the Board of Medicine's fault, not ours.

That just does not fly at least in my thinking. Well, I'm done. Anyone like to talk about this?

DR. FOLKERT: It's Mike Folkert from the ACMUI. I mean my personal opinion on this is that it should be the responsibility of the specialty board and the professional groups.

I know, for example, for radiation oncology they are taking a very active role in this through ASTRO. They are developing training curriculum that is specific to radiopharmaceuticals.

The ACGME requirements have been expanded

to require increased numbers of cases for performance of radiopharmaceuticals even in order to just to graduate regardless of the NRC requirements.

It's actually currently above the old NRC requirements, the number of cases that radiation oncology residents are required to finish in order to graduate now.

So, you know, my opinion is that it is the responsibility of the specialty board and of the professional societies that oversee the education of radiation oncologists, in all areas, but I am most aware of the radiation oncology residents, and so to make sure that they are up to speed and clinically competent for these.

I know they have also included radiopharmaceutical questions into our oral boards, which is a direct one-on-one, you know, testing of knowledge.

So that's where I think the clinical competency should be for the, at least for the board areas. From the clarification that we had seen back in 2018, they do still require attestation for folks who are not trained by a specialty board, and so preceptor attestation.

So that is still requiring the

attestation, but I know that the professional societies are taking an active role in making sure that clinical competency is met.

DR. MARCUS: Well, if that's the case then I would expect the American Board of Radiology to say that the requirements for radiopharmaceutical therapy are now met by accepted radiation oncology residency programs, but they haven't said that yet, have they?

The last thing I heard was that neither diagnostic radiology residency programs nor radiation oncology residency programs, neither of them meet the requirements for radiopharmaceutical therapy.

I mean I like the idea of the residency programs being altered to really establish competence, but then it's up to the Board to ask the NRC to then recognize their Board as competent, like we have for the American Board of Nuclear Medicine, but that hasn't happened yet as far as I know.

DR. VALENTIN-RODRIGUEZ: Thank you, Dr. Marcus. Dr. Einstein, did you want to make a comment?

DR. EINSTEIN: Yes. I would second Dr. Folkert's thoughts about this as well. I appreciate Dr. Marcus' concerns in ensuring quality of care, but

it doesn't seem to me to be the bailiwick of the Nuclear Regulatory Commission to ensure clinical competence, which is really more the bailiwick of organizations which are approved by the American Board of Medical Specialties and smaller organizations which are affiliated with organizations that are affiliated with the American Board of Medical Specialties.

You know, fundamentally the NRC is not a clinical competency accrediting or a credentialing organization. So, while, you know, your comments are very valid, I think to a certain degree you may be barking up the wrong tree, as the expression goes.

Like I think you'll have ACMUI members who are sympathetic to your concern, but NRC is probably not the mechanism through which to ensure such clinical competency.

DR. MARCUS: I agree with you completely. The NRC is completely non-competent in clinical anything.

What I am just pointing out is that the only group that was providing assurance of clinical competence was these preceptors and now the preceptor only attests to radiation safety competence, which is pretty simple and pretty basic, but not the clinical

competence.

So, if the person is not board certified, you know, board recognized by the NRC for its competence in this area and the preceptor is not attesting to clinical competence nobody is attesting to clinical competence, and I think that's a problem.

I think that until the American Board of Radiology says, okay, now our boards in radiation oncology are consistent with clinical competency in radiopharmaceutical therapy and they get the NRC to recognize them, fine, we let the American Board of Radiology determine clinical competence, but we don't have that. We don't have anything.

DR. EINSTEIN: It's a problem as you point out and it's a problem with the system, but it's not a problem, you know, for the NRC. That's not NRC's part of the system as I understand it.

So, I encourage you to move forward with these concerns, but I don't know that moving forward through ACMUI is the right way to do that.

DR. MARCUS: Well unless you have a situation where the person can be called clinically competent by the board that he has taken, if you would say that the -- I mean your last chance of establishing clinical competence is the preceptor

and, you know, it's been a joke for many years because most nuclear medicine people are in a radiology department and if they don't declare the residents clinically competent they're not going to have a job.

So, for years and years and years the preceptors declared clinical competence when they were really were very uncomfortable with that. When the NRC said we no longer need these preceptor statements in diagnostic and therapeutic radiology they were very happy because then they didn't have to be responsible for determining clinical competence, but that -- And now that you've put the preceptors back in here, and I think maybe we shouldn't have it.

Unless you are Board certified in nuclear medicine or nuclear radiology, which I assume now includes therapy, it originally just included diagnostic nuclear medicine, why do you need an alternate pathway?

I mean the radiation oncologists to practice radiation oncology you have to be board certified in radiation oncology period. There isn't any alternative thing.

It would seem to me if the radiopharmaceutical therapy should require that you be boarded in a Board that is recognized by the NRC

as establishing clinical competence.

DR. EINSTEIN: Again, I agree that you should be boarded by such a board, but I don't know that it's the NRC's role to establish that, which fundamentally is a check of clinical competency. This is not a clinical organization.

DR. FOLKERT: So, Michael Folkert, if it's okay to join in again on that one.

DR. VALENTIN-RODRIGUEZ: Yes.

DR. FOLKERT: I mean we are very sympathetic to the needs of ascertaining and confirming clinical competency and this is an entire area of focus for me as a former residency program director and constantly involved in education and safety training, and so for radiation therapy, brachytherapy, and radiopharmaceuticals.

I mean this is actively being worked on by the professional societies. One of the big programs that is being developed, SNMMI has it, ASTRO has it, the accreditation programs that look at centers of excellence for radiopharmaceutical administration.

They are taking a deep dive into competency, into safety, into how well these patients are being taken care of, and people are going to be

applying for these accreditations and in the end, you know, patients will have the choice to go to places that are accredited that have that stamp of approval for high quality care in terms of radiopharmaceuticals.

So, this is, you know, so this venue for looking at safety is very critical for the Nuclear Regulatory Commission, but in the areas that are looking at clinical competency and for high quality deliver of care with radiopharmaceuticals, these are established and growing right now.

There are multiple accreditation programs through ACR, ASTRO, and SNMMI, that are looking specifically at this area and, you know, it's going to be very obvious to patients which places have satisfied this, which places have received these marks of approval, and which have not.

DR. VALENTIN-RODRIGUEZ: Thank you, Dr. Folkert. This is Celimar. I just wanted to step in for the interest of time. It is 2:52 and our meeting is scheduled to end at 3:00.

I just wanted to give Mr. Green and Dr. Jadvar enough time to summarize the meeting as well as put in a vote for the amendments to the report.

So, I appreciate everyone's interest in

this topic. I know that we'll have more public meetings once we issue this document for public comment, and so the public will have an opportunity to weigh in with their own comments.

So, Mr. Green, if I can go ahead and summarize the discussions for the meeting so you can call for a vote on the amended report.

VICE CHAIR GREEN: Yes, please do.

DR. VALENTIN-RODRIGUEZ: Thank you, Mr. Green. So, for today besides the report that was included as a handout I have the following amendments that will be done to the draft report before it is issued as final.

One is to clarify what the NRC means by "conditions of a license." The next is to clarify and add more detail to the section on assistant and temporary RSOs, associate RSOs, and how that can be and the difference between notification and especially to clarify the 60-day requirement in 35.24.

The next issue that will be amended in the report is to clarify that RSO responsibilities are inclusive but not limited to the list that is already included in the draft implementation staff guidance.

So those are the changes that I noted. Was there anything I missed before Mr. Green you can call on the vote?

DR. JADVAR: Wasn't there a definition of "hands on" and "in person" clarification?

VICE CHAIR GREEN: There was no definition. There was an ask to remove that language.

DR. JADVAR: Remove, yes.

PARTICIPANT: Okay.

VICE CHAIR GREEN: And that's in the report.

DR. VALENTIN-RODRIGUEZ: Do you want to -- Is the ACMUI asking to amend that comment in the report, or should we keep it as is?

DR. FOLKERT: Let's see. So, this is Michael Folkert. Looking at the report and as was mentioned that there were a couple points where "in person" or "hands on" was mentioned besides that one spot, so there are two mentions of "in person" and let's see, and then "hands on" I believe there were two other mentions of it.

DR. VALENTIN-RODRIGUEZ: Okay. I'm good with that.

DR. FOLKERT: And so, we just have to be

thorough for getting those. So, yes, so it has training and -- So, for example, on Page 26 where it says, "hands on device operation" we could remove "hands on" and have "training in device operation."

And then overall the NRC though does have to be, has to have a definition of "in person" versus "hands on" and where the crossover is because it's critical for the training and certification for different devices and applications throughout all the different applications that we have.

DR. VALENTIN-RODRIGUEZ: So, from your comment what I understand is you want to keep the current recommendation but maybe propose a second one to clarify "hands on" versus "in person?"

DR. FOLKERT: No. Yes, so this is not for the report.

DR. VALENTIN-RODRIGUEZ: Okay.

DR. FOLKERT: Specifically for the report to remove these comments of "hands on" versus "in person."

DR. VALENTIN-RODRIGUEZ: Okay.

DR. FOLKERT: But outside of the report I mean the NRC needs to have a policy for what is hands on and what is in person.

DR. VALENTIN-RODRIGUEZ: Okay. So, I'll

take that back as an action for the NRC staff then. I just wanted to clarify that. Thank you, Dr. Folkert.

If there is nothing else, I think Mr. Green I can turn the meeting back to you so you can call on the vote.

VICE CHAIR GREEN: Okay. I believe we do need to have a second vote. We have amended the report from our previous vote. So, are there any votes to accept the report as amended?

DR. HARVEY: I can make a motion. This is Richard Harvey. I will make the motion to accept the report with the revisions and clarifications.

VICE CHAIR GREEN: Thank you, Doctor. Any seconds?

DR. EINSTEIN: Second.

PARTICIPANT: Second.

VICE CHAIR GREEN: Thank you, Andrew Einstein. Okay, all in favor say aye.

(Chorus of ayes.)

VICE CHAIR GREEN: Any opposed?

And any abstentions?

Hearing none, the vote is unanimous.

Well, that concludes our time this afternoon and I would like to thank you for

participating and for the Subcommittee for their excellent work and report. We will now stand adjourned.

(Whereupon the above-entitled matter went off the record at 2:57 p.m.)