Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Public Meeting on the Regulatory Basis for the Part 35 Rulemaking on Rubidium-82 Generators, Emerging Technologies, and Other Medical Use of Byproduct Material

Docket Number: (n/a)

Location: teleconference

Date: Tuesday, August 29, 2023

Work Order No.: NRC-2481 Pages 1-73

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

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

+ + + + +

PUBLIC MEETING ON THE REGULATORY BASIS FOR THE PART 35 RULEMAKING ON RUBIDIUM-82 GENERATORS, EMERGING TECHNOLOGIES, AND OTHER MEDICAL USE OF BYPRODUCT MATERIAL

+ + + + +

TUESDAY

AUGUST 29, 2023

+ + + + +

The meeting was convened via Videoconference, at 2:00 p.m. EDT, Sarah Lopas facilitating.

PRESENT:

Maryann Ayoade

Andrew Carrera

Laura Cender

Monica Ford

Antonio Gomez

Sarah Lopas

Francis O'Neill

Elizabeth Tindle-Englemann

ALSO PRESENT:

Max Amurao

Peter Crane

Willie Crawford

Scott Fuller

Tianliang Gu

Stanley Hampton

Roxanna Kimes

Koressa Lee

Bryan Lemieux

Ralph Lieto

Prasad Neti

Harrison Redman

Jerry Thomas

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

2:00 p.m.

MS. LOPAS: So good afternoon, everybody. Welcome to today's NRC public meeting on the regulatory basis for the Part 35 Rulemaking on Rubidium-82 Generators, Emerging Medical Technologies, and Other Medical Use of Byproduct Material. My name is Sarah Lopas. I'm going to be facilitating today's meeting.

As a facilitator, I want to welcome you all to this meeting regarding the Federal Register notice that was published on July 3rd, 2023 announcing the availability of the reg basis for this rulemaking to amend 10 CFR Part 35 to establish requirements for Rubidium-82 generators, emerging medical technologies, and also accommodate developments in the medical field related to new radiopharmaceuticals and EMTs. During this meeting today, staff intend to provide clarification to the information in the July 3rd, FRN and associated regulatory basis document and also explain the process of providing feedback to the NRC. Next slide. And I'm going to take a moment to record today's meeting.

So I'm going to start that now. Just a warning for everybody, we are recording today's meeting. We aren't going to be making the recording available to the public. It's more just a backup for our court reporter.

So I'm going to start that now. Okay. All right. And I'm going to try to stop the transcript. Maryann, I wonder if you can -- I'm going to close out the transcript. Okay.

All right. So just a couple of housekeeping items. So as I mentioned, today's meeting is being transcribed. But we are not collecting comments on the reg basis today.

The purpose of today's meeting is to encourage attendees and stakeholders to submit your comments through the formal comment submission process that Maryann and Andy will be going over later today. Those comments need to be submitted by October 31st, Halloween. So they're going to encourage you to submit comments using the means discussed in the FRN, and they're going to answer clarifying questions, basically help you inform those comments.

In just a moment, I'm going to take the links that are on this slide here and put them into

the chat. Our chat is open today for your questions and comments. You can go ahead and put questions and comments in the chat at any time, but we are going to hold off on addressing those until we get to the designated points in time during the staff's presentations where we're going to be taking questions and comments.

So that'll be three periods throughout the meeting where we'll stop, we'll all stop for questions, stop for Q&A. And I'll read what's in the chat as applicable. So we aren't going to be responding directly back to you in the chat for your questions, but we will be reading them aloud as applicable.

If you have technical issues with today's Teams, put that in the chat and I will do my best to be responding to that and trying to help you out with any technical issues in the chat once I stop talking right here. I do want to note that all of the things that we're mentioning today, the reg basis, the Federal Register notice, and the slides are -- if you're on the phone right now and you can't get to these links that I'm posting in Teams, you can just go to the NRC public meeting notice website and find the

notice for this meeting. And there's all those links are in the meeting notice, including these slides.

So the slide ML number if you're somebody that's familiar with ADAMS, the slides, you can find them in ADAMS at ML23122A356. So that's where you can pull up today's slides if you'd rather have them open. And you'd be able to click on the links directly there too.

Let's see. So you'll notice that everybody has their mics enabled. So please just keep an eye that you are muted. We'll do our best to keep you muted too.

When we get to the Q&A portion of today's meeting, we'll be using the raise hand function. So you'll go ahead and click that raised hand icon up top. And I'll call on you, and you will unmute yourself.

So you are in control of your own microphone. We aren't enabling attendee cameras. You'll notice that. If you are on the phone, you'll press *5 to raise your hand. And then I'll instruct you how to unmute yourself on your phone.

And you'll need to make sure that your phone is unmuted as well, like, your personal phone.

If you have yourself, like, double muted, I often do that on the meetings to be extra safe. So you'll need to hit unmute on your phone in addition to pressing *6 on your phone to unmute. But *5 to raise your hand if you're on your cell phone.

Let's see. So I will repeat those instructions when we get to the Q&A. And I just want to note that -- let's see. Like I mentioned, we do have the chat function open. And I think that's basically it for now.

I'll have more kind of facilitator-esque instructions when we get to the Q&A. But basically, we'll start with a couple presentations. We'll stop for a break. Do a little bit more presentation. Stop for break, a little bit more, and then we'll end up -- we'll conclude with questions.

So if we don't get to your questions during one of the first two Q&A rounds, we'll get to it at the end. So with that, I'm going to hand over the meeting to really officially kick us off to Theresa Clark who's going to give our opening remarks. Theresa is our deputy director her at the Division of Material Safety, Security, State and Tribal Program in the NRC's Office of Nuclear Material Safety and

Safeguards. Theresa?

MS. CLARK: Hi, thanks, Sarah. And so welcome, everyone. Good afternoon to you if you're on the eastern side of the U.S. Good morning if you're on the West Coast. We're pleased to have you here with us today to discuss a really important rulemaking and one that's been a lot of work for our working group. So I truly appreciate all of their support in developing this regulatory basis that we've been talking about today.

These medical technologies that are the subject of this rulemaking are very important for lifesaving and life sustaining activities nationwide. And so the information that goes into this regulatory basis really affects a lot of people. And we find it to be really important.

So appreciate everyone who's taken the time to participate in this meeting today. Like I said, I want to acknowledge all the major efforts of the working group. There's a lot of work that goes on behind the scenes to prepare a regulatory basis document, to do the cost analysis that helps inform some of the options, and then to do some of the outreach like this meeting. So thanks, everyone, for

their participation.

Like was mentioned before, this regulatory basis is out for public comment right now. It was published in July. And we've been working on this rulemaking for about a year and a half or so, developing the content that you see in the regulatory basis. So we're really looking forward to sharing it with you and getting more feedback through that formal comment process.

Today's meeting as Sarah mentioned is designed to help you shape those comments. We put a lot of questions into the regulatory basis in specific areas for comment. So that should help you give us the information that will really help us make a great product when we prepare the rulemaking on this.

So any comments that you want to submit in response to the Federal Register notice please feel free to do so. If we missed any questions that you think are important to helping us inform the proposed rule that we'll be developing, please feel free to make those comments and provide any new information we should consider as we progress in this rulemaking. So we'll consider all of that information as we develop the proposed rule which is the next step in our

rulemaking process.

Maryann Ayoade is going to take us through the background that helps set up the topic for this meeting. She and other members of our joint working group between the NRC and Agreement States are going to go over all the information provided in the regulatory basis document. They'll tell you how to submit comments specifically, and we will have some time as Sarah mentioned for questions and answers using the various features of this Teams meeting.

So I want to thank everyone for participating in this important meeting. This is a special project and a lot of work that goes into it. And we look forward to your thoughts on that work. And now I'll turn it over to Ms. Ayoade.

MS. AYOADE: Thank you, Ms. Clark. Good afternoon, everyone. My name is Maryann Ayoade, and I am a member of the medical radiation safety team at the NRC and also a member of the NRC agreement state working group for this rulemaking effort as Ms. Clark mentioned.

Before we begin, I would like to acknowledge and thank all of the working group members for your contribution in the development of the

regulatory basis as this project has been a major effort and also for your support in this meeting today. So for today's presentation -- next slide, please. For today's presentation, I will be providing some information on the background of the rulemaking that's associated with this regulatory basis and where we are in the rulemaking process, a quick overview of the regulatory basis document and what you can expect to see, and a general overview of the proposed changes with the highlight on the major proposed changes and the questions that the NRC is seeking additional comments and feedback on to better inform the next phase of the rulemaking.

I will then be turning it over to the other members of the working group to go over the proposed changes in more detail by technology, including those NRC questions for feedback. And then you will hear about the early feedback that we received from our regulatory counterparts in the Agreement States as well as our NRC advisory committee on the medical uses of isotopes as this is a part of our rulemaking process. And then finally, you will hear from our rulemaking and cost analyst experts on the preliminary cost analysis and the estimates for

NRC, the estimates for Agreement States, and also for our licensees and all that was considered for this rulemaking as well as the next steps in the rulemaking process and what you can expect as we move forward.

I do want to point out that in the presentation for today we have included some reference guide slides after each proposed section. And they're meant to help guide you to the existing sections of the regulations where we're proposing to make changes and where we have added new sections with proposed changes. We do not plan to speak to those slides in detail for the sake of time today, but I just want to note that they will be included in the presentation file that will be made publicly available. And I believe that link has been shared in the chat for today. Next slide.

Okay. So moving forward with the rulemaking background, what exactly are the issues that we're considering and hoping to address in this rulemaking? There are two primary issues under consideration. We're hoping to first address the ongoing challenges that are associated with licensing Rubidium generators under Part 35 by proposing changes to include requirements that will address the

calibration and dosage measurements for the Rubidium generators.

And then we're also hoping to address the challenges that are associated with licensing the existing and future emerging medical technologies under the current medical use regulations in Part 35 by establishing more risk informed and performance-based requirements which will also create more flexibility in the regulations for existing and future technologies. Now in addition to these two primary areas, we're also proposing to make revisions to other sections of Part 35 that are not associated with any one technology. And this is because we want to be able to accommodate the development that we continue to see in the medical field that are related to new radiopharmaceuticals and emerging technologies.

And that will also allow for added flexibility and more risk informed and performance-based requirements. So you will notice in the title of this rule, it also states and other medical use of byproduct material. And so that's what I'm referring to there. Next slide.

Okay. So this slide gives some information as far as the initial timeline for this

rulemaking up until where we are today. We will cover the next steps in the rulemaking process timeline a little later on towards the end of the presentation. And so as Ms. Clark mentioned, this rulemaking was initiated with the NRC staff recommendation for rulemaking to the Commission through a rulemaking plan.

And that was issued in February of 2021. That plan was then approved the following year in January of 2022. And our NRC agreement state working group was formed right after that in February of last year.

And so the working group was formed to develop the regulatory basis for the rule. And the regulatory basis which is what has been issued for comment is what serves as a precursor to the proposed rule which is the next phase of this rulemaking. And then late last year in the November-December time frame, as part of our rulemaking process, a draft version of the regulatory basis was reviewed by our regulatory counterparts in the Organization of Agreement States as well as the NRC's advisory committee on the medical uses of isotopes.

So I want to point out that a summary of

their comments and recommendations as well as the NRC's responses to the comments are included in the regulatory basis document. And their overall feedback has been considered as a part of this regulatory basis that you're reviewing. We have also included links to a copy of the draft regulatory basis, the ACMUI recommendations report, and the transcript of discussion during the public meeting that occurred last December.

And so all of those can be found using the links that are provided on this slide. You'll also hear from another working group member later on about the type of feedback and the comments that we received from these two groups. And so this brings us to where we are today with the issuance of the regulatory basis document for public comment that was issued in July. Next slide.

So this slide provides a quick overview of what to expect in the regulatory basis document. So when you review this document, you will find information on the background for this rulemaking and the current regulatory framework, including the policies, the regulations, and the guidance surrounding this rule. You will also see that it

covers an explanation of the regulatory issues and the proposed changes of the regulations and how those changes could resolve the issues.

And then you'll find sections on the NRC's evaluation of the type of approaches and also the alternatives that we considered in support of the regulatory basis as well as cost and benefit analysis for the rulemaking and the different alternatives. You will also see in there that we have included an explanation of some of the limitations that were considered, including any uncertainties in the data or the methods of analysis for this rule. Next slide. So this slide gives a quick overview of the proposed changes that are being considered in this rulemaking.

And you will find some more detailed descriptions of the changes that are currently under consideration in Appendix A of the document. So Appendix A is where you will find the proposed changes. And they've been organized by technology.

And we've also included a section that provides information on other Part 35 proposed changes that I mentioned earlier that are not necessarily associated with any one technology. You'll also find that we have included a series of NRC questions that

we're seeking additional feedback on as I mentioned earlier. These questions are alongside the proposed changes in Appendix A, and we've highlighted those in bold italic font in the reg basis document to draw your attention to it. But you will also find them in the Federal Register notice as well.

So what else do we need to know about the proposed changes? We want you to know that the changes are primarily based on the existing criteria in the guidance document. So that is the existing criteria in the emerging medical technologies licensing guidance documents and of course in the enforcement guidance memorandum for the use of Rubidium generators which are not characterized as emerging medical technologies.

And so as you may be aware, the NRC uses existing emerging medical technologies licensing guidance documents as a pathway under the current regulations in 35.1000. And we use this to license certain types of new medical use. And when a licensee commits to following the guidance in these documents, then they are also committing to following the conditions and the criteria that are set forth in those documents. So that was sort of our baseline for

the proposed changes for this rulemaking. Next slide.

So this slide was added to highlight some of the major changes that you will find in this rulemaking. You will see that we have proposed changes to the current requirements for use of unsealed byproduct material to account for calibration and dose measurements for Rubidium generators. You will also see that we've created a new subpart for the regulation of microspheres which would be referred to as Microsource Manual Brachytherapy.

And then you'll find that we are proposing to require the device specific training for some generators and emerging medical technologies. And then there are proposed changes that are requirements primarily for the regulations that are associated with gamma stereotactic radiosurgery. And there we're proposing criteria that will shift the focus from more specific device components to more of the functional element of the technologies.

This slide also includes a note about a couple of new emerging medical technologies that this rulemaking would not establish regulations for but were considered. And so we have the NorthStar RadioGenix Mo-99/Tc-99m Generator System and the

diffusing brachytherapy sources like the Alpha DaRT technology. And this is because these are newer technologies, and we determined that they are not as well -- or they're not well established and that additional operating experience is still needed in order for us to consider codifying or moving it into the existing licensing criteria for these technologies into Part 35.

Also for technologies like the NorthStar Generator, we determined that because they are more complex and they have a higher radiation risk as compared to the traditional Mo-99/Tc-99m generators and the other generators that we currently license in Part 35, the working group determined that maintaining licensing under 35.1000, the licensing guidance would be the most practical and cost effective regulatory approach. So you will see that noted in the regulatory basis document. Next slide. This slide provides information on the NRC questions for feedback that I mentioned are included in the regulatory basis document.

You'll find a series of questions that have been included throughout Appendix A because we're trying to get additional stakeholder input on certain

regulatory issues or proposed regulatory approaches to an issue. And NRC is particularly interested in feedback on the topics that you see on the slide. So we want to hear from you about whether there's enough operating experience to inform regulations for diffusion brachytherapy.

We want to know whether the effort to establish regulations for less widely used emerging medical technologies is warranted. We also want to get your feedback on the proposed regulatory framework for the new microsource manual brachytherapy for the new microsource brachytherapy subpart. And also we want to know whether there should be any changes to the training and experience requirements that we currently have for emerging medical technologies. So you'll see these questions for feedback in the regulatory basis document. Next slide.

Also we have included in the questions for feedback some additional stakeholder feedback questions in Appendix A. And these are Commission directed questions that are related to training and experience for the use of emerging medical technologies. So these questions came from a separate effort that was related to the training and experience

unsealed byproduct material that was issued by the Commission early last year, so January of last year.

And as part of the Commission's response to that separate effort, we were directed -- our staff was directed to reconsider the full complement of the training and experience requirements within our current regulatory framework. And we were asked to also obtain stakeholder comments in the following areas that you see listed on this slide. So the first is on the knowledge topics that surround the safety-related characteristics of emerging medical technologies that are required for authorized users to be able to fulfill their radiation safety-related duties and supervision roles.

The second is on the methods, so what methods and how should the knowledge topics be acquired. Finally, we have questions that are related to continuing education, vendor training for new medical uses, and then training on NRC's regulatory requirements in Part 35. So again, I want to point out that all of these stakeholder questions are in Appendix A of the regulatory basis and also in the Federal Register notice.

And they'll be covered during the rest of

the presentation by other members of the working group. I also want to emphasize that the stakeholder feedback that we receive on the regulatory basis is just as important as these questions. And we want to be able to use them to help to better inform as we move into the proposed rule phase where we'll move into writing and revising rule language.

And we ask that you please provide your feedback on these questions in addition to your feedback on the regulatory basis as a whole. So I will now turn over to the other members of our working group to go over the proposed changes and the questions for feedback in more detail, starting with Mr. Francis O'Neill. Thank you. Next slide, Christine. Great.

MR. O'NEILL: Thank you, Maryann. Appendix A-1 focuses on radionuclide generators, strontium-rubidium generators, is not considered -- lost my slide here -- is not considered an EMT emerging medical technology. And its use is currently licensed under Subpart D for material that does not require a written directive.

So it is licensed under Subpart D along with the enforcement guidance memorandum that has been

used since 2013 for outstanding technical issues related to the generator. These generators are different from other generator's license under subpart because of a short half-life, 76 seconds of Rubidium-82, and the generator's automated elution and patient infusion system. Because of this, licensees cannot meet the requirements of 10 CFR 35.60 of a calibration of the sites of radiation detectors and these generators that function dynamically as fluid moves past each sector in the tube as opposed to in a static well counter.

Additionally, they cannot meet the requirements of 10 CFR 35.63 to determine the activity of each dose administered prior to medical use. There's also the Germanium/Gallium Generators which is currently utilized under 10 CFR 35.1000 because of the risk of a specific specified permissible concentration limit for the parent radionuclide and the regulations and the potential for breakthrough and unnecessary high radiation exposure to patients.

The proposed changes made in this section would allow Rubidium generators to continue to be licensed under Subpart D but without the need for enforcement discretion. The changes would also allow

for Germanium/Gallium Generators to be licensed under Subpart D by including an established limit for the allowable concentration of Germanium-68 in each eluate of the generator. The first set of questions that we're looking for, feedback on are related to generator device specific training and dose measurements.

We want feedback on whether the RSOs need device-specific training for generator systems or whether the general awareness training on generators and their function of risk is enough. We are seeking feedback on whether and how the NRC should allow the completion of doses of measurements as a beginning of an increment administration for radionuclides other than Rubidium-82. Next slide, please. This slide is a reference guide that Ms. Ayoade referred to earlier.

This slide has been included to show you sections of regulations that we're proposing to make changes to that are related to the use of the generators. These are the generator changes. I will now turn it over to my other member, Monica Ford, from the NRC, to go over the next set of changes. Thank you. Next slide, please.

MS. FORD: Thank you, Francis. Next we

will discuss intravascular brachytherapy which is noted as Appendix A.2 and is currently regulated under 10 CFR 35.1000. Intravascular brachytherapy is a type of brachytherapy in which the sources are placed within blood vessels for treatment.

The current 10 CFR 35.1000 licensing guidance is for the best vascular beta-cath intravascular brachytherapy system which is manually controlled and uses a Strontium-90 source to deliver high doses of beta radiation. To incorporate intravascular brachytherapy into 10 CFR Part 35, the NRC is proposing revisions be made to 10 CFR Part 35, Subpart F, manual brachytherapy, as the current guidance for the intravascular brachytherapy uses references for several requirements of this subpart. Several regulatory changes are being proposed to Subpart F.

These include adding training and experience requirements similar to those outlined in 10 CFR 35.690 for physicians wishing to become authorized users and additionally including a requirement that all members of the care team receive device-specific training related to hands-on device operation, safety procedures, and clinical use

commensurate with the specific care team members role. Additional regulatory changes will include requirements for physical presence, operating and emergency procedures, servicing of the device by qualified individuals, surveys of patients and human research subjects before release to confirm the source has been removed, and radiation survey requirements similar to those described in 10 CFR 35.652. Lastly, the written directive requirements currently reflected in 10 CFR 35.40 would need to be updated to include criteria specific to intravascular brachytherapy.

Along with these changes, the NRC has posed one question related to intravascular brachytherapy that we are seeking feedback on. Question A.2.1 asks stakeholders to please provide comments on the sufficiency of the training and experience requirements for authorized users outlined in the current licensing guidance documents for intravascular brachytherapy, liquid brachytherapy, and eye applicators. Specifically, the NRC is seeking feedback on the knowledge topics encompassing the safety-related characteristics that are required for authorized users to fulfill their radiation safety-related duties and supervision roles, the methods for

acquiring knowledge topics in consideration for continuing education, vendor training for new medical uses, and training on NRC regulatory requirements. Next slide, please.

This slide reflects the list of regulations that the NRC is proposing to amend in order to incorporate intravascular brachytherapy into our regulatory framework. Next slide, please. This next slide is discussing Appendix A.3, which focuses on liquid brachytherapy sources and devices currently licensed under 10 CFR 35.1000. Liquid brachytherapy is a type of manual brachytherapy that treats cancer with devices that are implanted temporarily.

The current licensing guidance is for the GliaSite radiation therapy system. The system delivers intracavity radiation therapy to patients with malignant brain tumors following tumor resection surgery. Liquid brachytherapy has use characteristics similar to the existing medical uses in 10 CFR Part 35, Subpart F.

However, the current regulations in Subpart F do not cover all the safety concerns associated with use of liquid brachytherapy. These safety concerns include removal of all liquid from the

device, leak testing of the device before use, and the need for an authorized user with experience in radiopharmaceutical procedures to be on call to provide guidance in case of a leak. Regulatory changes being proposed will allow for this use to be regulated under 10 CFR Part 35, Subpart F.

These changes include revising the definition of manual brachytherapy to include liquid sources, updating the definition of prescribed dose, and adding a definition for source leakage. Additional changes include those for written directive requirements specific to liquid brachytherapy, requirements for leak testing prior to the start of the procedure, labeling requirements for vials and syringes associated with the procedure, contamination control, safety instructions for the safe handling of contaminated items, and the addition of the new section specific to training and experience requirements for authorized users of these devices. In addition to Question A.2.1 which I previously discussed which asked for comments on the sufficiency of training and experience requirements for authorized users for intravascular brachytherapy, liquid brachytherapy, and eye applicators, the NRC is seeking

feedback on three additional topics specifically focusing on liquid brachytherapy.

The first two questions are shown on this slide. Question A.3.1 requests comments on whether the current definition of manual brachytherapy as shown in 10 CFR 35.2 should be revised to include liquid brachytherapy and exclude microsources or if liquid brachytherapy should be included in the newly proposed Subpart I for microsources. Question A.3.2 is seeking input on whether a new requirement on contamination control is needed.

Specifically, we are asking for comments on this proposed requirement and your thoughts on if it should apply to all medical licensees or to a certain subset and why. Next slide, please. The third question we are seeking feedback on is shown as Question A.3.3. This question relates to the definition of source leakage as it relates to liquid brachytherapy.

Specifically, we are asking for your comments on whether the limit being proposed is appropriate and an explanation supporting that position. We are also seeking your insights on what types of limits for liquid brachytherapy device

leakage should be considered by the NRC. Next slide, please. This slide reflects the list of regulations that the NRC is proposing to amend in order to incorporate liquid brachytherapy into our regulatory framework. Next slide, please.

Appendix A.4 focuses on radioactive seed localization which is currently regulated under 10 CFR 35.1000. Radioactive seed localization procedures involve using decayed radioactive seeds that were previously approved for use or treatment under 10 CFR Part 35, Subpart F or with low activity seeds approved specifically for radioactive seed localization use. Therefore, there are currently challenges in regulating this modality under 10 CFR Part 35, Subparts D, F, and G.

The NRC is proposing changes to the regulations that would allow for this use to be regulated under 10 CFR Part 35, Subpart G. The proposed changes would allow for use of sources specifically approved in a sealed source and device registry for this use and those sources that were previously approved for therapeutic use that have decayed to less than or equal to 300 microcuries. There would also be changes for requirements for

supervision, new training and experience requirements specific to this modality, record keeping requirements, and medical event reporting requirements.

Additionally, we're proposing changes to Subpart G that are similar to the requirements that are currently in Subparts F and H related to patient surveys, source accountability procedures, operating and emergency procedures, and emergency response equipment. Additionally, we are looking to add requirements to verify source activity before implantation. Unlike the first two sections that I presented on, the NRC does not have any specific questions for feedback related to radioactive seed localization. However, we would be very appreciative of any feedback you wish to share related to the proposed regulatory changes for this use. Next slide, please.

This slide reflects the list of regulations that the NRC is proposing to amend in order to incorporate radioactive seed localization into our regulatory framework. And at this time, I will turn the presentation back over to Sarah to open it up for questions. Thank you.

MS. LOPAS: Thank you, Monica. All right. So now we've reached the first break in the presentation for any questions. You can go ahead and click on the hand icon on the top of your Teams meeting. And that'll indicate to me that you want to ask a question.

I'll call on you. You will unmute yourself. Everybody does have their microphones enabled. But you do have to unmute them in order to be heard. But we're going to do it by raising hands.

You can also submit comments or questions in the chat. If you prefer that I read out your question, that's fine too. And if you have called in which I see there are several people who called in, just press *5 on your phone and that will raise your hand. I'll be able to see that you have your hand raised, and you can then -- I'll call on you and you'll press *6 to unmute your phone -- your Teams line on your phone.

So *5 if you're on the phone. Hit the hand icon if you're here joining us on Teams. I'll keep an eye out for that. Or go ahead and just put your question or comment in the chat if you'd prefer that. And also let me know if some of you that joined

late, I'll probably repost the links to the FRN and the reg basis and today's slide because I think when you join late, you don't see all the links -- excuse me, all the chat.

Okay. So here we are. We have a chat question from Ralph Lieto. The question is, is the GliaSite device still available? Never came off IND if I remember correctly. After more than 20 years, if not FDA approved, is there new data of increased use? A start is for NRC to establish how many licensees are using the device seems not even on the horizon for regulatory interest or need.

So that's a good comment, medical group. I remember when I was working with you all, we talked a little bit about this and whether we thought it was useful to codify regs for something like this. So I wonder if you all -- if anybody can talk to that maybe.

MS. AYOADE: Monica, I don't know if you wanted to take this. But that's correct, Ralph. We do have note in the document speaking to this, and we acknowledge that the GliaSite technology is no longer being distributed. And so we do account for that in this rulemaking, yeah.

MS. LOPAS: All right. Let's see. I don't see any hands raised. I'll give you just a couple more seconds to click on the raised hand icon or press *5 if you're on the phone. If you're calling in, you just press *5 and that shows me that your hand is raised if you're on the phone.

There's only two callers. Or pop it in the chat. We are going to have a couple more breaks for questions. So if we don't have any questions right now, I guess we'll just keep moving forward.

Maryann, I do want to encourage people. If you hear something that you have a question on as we're going through, go ahead and pop it in the chat and we'll get to it when we break. But if you don't want to forget about it.

Let's see. All right. I think we're set. Everybody is -- oh, we got one unmuted. Willie Crawford, I see you're unmuted. Did you have a question?

MR. CRAWFORD: I did not. Sorry.

MS. LOPAS: Oh, no worries. Apologize for calling you out. All right. I think we'll keep moving then Maryann. Does that work?

MR. CRAWFORD: Called you out. Attendance

verified. Got it.

MS. LOPAS: Got it.

MS. AYOADE: Yes, Sarah. That's correct. Thank you.

MS. LOPAS: Oh, and I do want to know one thing for verifying attendance. For the people that have called in if you want your name to be kind of on our attendance list, we ask that you email Maryann or Andy to note your name and that you attended because we only see your phone number. Okay. That's it.

MS. CENDER: All right. Thank you, Sarah. My name is Laura Cender, and I'm a health physicist out of NRC's Region 3 office. This next session focuses on eye applicator sources and devices.

Currently, Subpart F provides pathways for use of traditional, superficial Strontium-90 eye applicators. As the structure of Subpart F is limited to only these traditional eye applicators, licensing guidance has been increasingly relied on to accommodate next generation ophthalmic applicators and to address the unique safety considerations associated with their new designs and methods of use. Today, licensing guidance has been issued for the Neovista EPI-RAD Ophthalmic System and is in development for

the Liberty Vision Yttrium-90 Disc Source Ophthalmic System.

The proposed changes here are primarily to address training and experience requirements under Subpart F including additional pathways for physicians to become authorized users. Other proposed changes you'll see are related to written directive requirements, device-specific training, safety precautions, and changes promoting the use of Yttrium-90 for ophthalmic treatments. The question here as seen on previous slides, it's requesting comments on the training and experience requirements and our existing licensing guidance and if those requirements are sufficient for the use of these eye applicator sources and devices. Next slide, please.

And here we have the full list of references for proposed changes associated with ophthalmic applicator sources and devices. Next slide, please. Now we're moving on to the gamma stereotactic radiosurgery and photon emitting teletherapy units. The proposed changes described here in Appendix A.6 encompass one of the major items for this rulemaking, and that is due in part to the many significant technology advancements in this area

since Subpart H was last revised.

Advanced gamma stereotactic radiosurgery units or GSRs have undergone many major design and engineering changes as you see described in current licensing guidance documents for the different units such as the Elekta Leksell Gamma Knife Perfexion and Icon Units and Xcision GammaPod. So with the proposed changes, you'll see a shift in the regulations from referencing individual components to technologies and prescriptive quality assurance requirements that are now mostly updated to instead focusing on the regulations around the actual functional elements of the technologies that we're interested. So for example, outdated requirements to test help microswitches, trunnions, hydraulic backups, and other components that no longer exist in newer GSR units will no longer be included in Subpart H.

Instead, these proposed changes will see replacement of these outdated requirements with testing for the actual functional items of interest such as dose delivery accuracy and positional accuracy along with other functional aspects such as source output, columniation positioning and attenuation with the focus always on patient facility safety. The

proposed changes here would also include new and revised definitions related to GSR and teletherapy units to be better align the definitions used in the medical community. As you review the reg basis, you'll see changes to requirements for a licensee, including procedural submission requirements.

You'll also see revised requirements for written directives, training and experience, models with specific training and requirements for authorized users. You'll also see proposed changes and requirements for safety procedures and instructions and precautions. Full calibration measure, periodic spot checks, and records are also part of the changes that we are seeking.

We're looking forward to hearing your thoughts on these many proposed changes. And we also have some questions of our own seeking specific feedback. This first question here is seeking feedback relating to model-specific training on Subpart H devices for radiation safety officers and how the NRC should define the types of Subpart H devices that would require model-specific training, if any. Next slide, please.

As I discussed earlier, the proposed

changes to Subpart H would result in requirements focused on the functional elements and objectives of the technologies authorized under the Subpart. These three questions seek to understand if there are any additional functional elements critical to safety that should be addressed in this rulemaking. Similarly, comments were requested for considerations into the types of objective tests that the NRC should consider from calibration and spot check requirements.

Again, this is what we consider to be one of the major proposed changes in this rulemaking, and we're very interested in your feedback here. Next slide, please. This slide captures the full list of references for proposed changes associated with GSR and teletherapy units. Next slide. Just like the last section, the proposed changes here are another major item in this rulemaking.

These microspheres has increased significantly since the original licensing guidance was issued. And we're anticipating that additional new related technologies such as microparticles, new microsphere systems will need to be authorized in the years to come. The proposed changes you'll see here include the creation of a new subpart in Part 35 which

is Subpart I.

As you can see, we have introduced a new title for the type of use which is now microsource manual brachytherapy. These changes will include the creation of a new definition for these types of sources to be called microsources. Creating this new subpart means making several revisions throughout all of Part 35 to distinguish between current manual brachytherapy technologies and microsource manual brachytherapy.

The new Subpart I would mirror the structure of Subparts F and H for manual brachytherapy, HGR, GSR, and teletherapy use. Other requirements would be specific to these microsource brachytherapy. In the interest of time rather trying to touch on all the proposed changes associated with this section, I'll go over the many questions for comments and feedback that we have instead as they closely follow the most significant proposed changes.

So with this first question, we are requesting feedback and comments on the proposed definition of microsource and how that definition should be loaded by radiation and energy type and what sealed source and device registry considerations

should be in place. Additionally, this question seeks comments on any additional changes that may be required to ensure appropriate flexibility in Subpart I and Part 35 generally for future microsource manual brachytherapy uses. Next slide, please. The first question here, we are requesting comments on defining physiological equilibrium as well as inputs to other physiological stop points that should be taken into consideration.

And moving on, microsphere manual brachytherapy is usually performed by using a multi-disciplinary team approach. The second question is requesting feedback on the fundamentals of a successful team-approach program would look like as we consider changes to be made to the supervision requirements in 10 CFR 35.27. And our final two questions on the slide are requesting comments on microsource manual brachytherapy specific inputs and should be considered for pre- and post-implant directives -- excuse me, written directives. Next slide, please.

These first two questions are related to changes proposed to 10 CFR 35.41, procedures for administrations requiring a written directive.

Specifically, the NRC is requesting comments on whether the NRC should require documentation of activity administered and activity to the treatment site as well the required timeline that should be in place for making this determination. Additionally, comment is request on requirements for post-treatment imaging or alternative mechanisms for confirming the treatment was delivered in accordance with a written directive.

And for a final question on this slide, it's referencing authorized medical physicist. The current licensing guidance in place for use of microspheres does not define specific roles for AMPs. This last question is requesting comments as to whether there are any tasks for this category that would require an authorized medical physicist. And if so, what revised requirements should be considered for 10 CFR 35.51. Next slide, please.

Now we're getting into the questions directly related to the new proposed Subpart I. These first two questions request input into the basic boundaries for this new subpart, the types of uses to be permitted, whether uses under the section should be limited to permanent implant only, and requirements

should be considered for sealed source and the device registry of microsources, both with and without unique delivery systems. And the last question on the slide is relating to the proposed new section of 10 CFR 35.710.

This section is intended to be analogous in structure to the other sections in Part 35 such as 35.410 and 35.610, setting requirements for safety procedures and instructions specific to microsources. This question is seeking feedback on proposed procedural requirements and input on any additional aspects that should be considered. Next slide, please. This leads to the last question. Here we're seeking feedback on a proposed new section, 35.715, that will address safety precautions for use of microsources.

This question is seeking feedback on proposed items intended to establish the minimum requirements for safety precautions and any additional aspects that should be considered for inclusion. Next slide. This question is the first of several relating to training and experience requirements for authorized users that will be captured in the newly proposed 10 CFR 35.790. This is a long question essentially

asking for feedback on the currently permitted conditional authorization pathway for AUs in the licensing guidance that allows AUs to be named on a license and the limited capacity prior to completion of all three of their hands-on patient cases.

The context for originally allowing this conditional pathway stems from limited use and training opportunities for physicians at the time that the guidance was first issued. This question is seeking comment if these conditions still persist or if there are any other reasons why the NRC should or should not allow this pathway to continue. Next slide, please. This question is focused on training and experience requirements for interventional radiologists seeking to become authorized users.

With respect to classroom and laboratory training, this question is seeking comment on whether 80 hours is an appropriate training threshold. Additionally, this question seeks input on the types of individuals that should be permitted to supervised direct working experience. Next slide, please. The current licensing guidance also provides pathways for physicians that meet the training requirements described in 10 CFR 35.390 or 10 CFR 35.490 to become

authorized users for Yttrium-90 microsphere use by only completing the vendor training for delivery system operation, procedural training, and the clinical use portion, including their three hands-on patient cases.

This question is requesting feedback on whether additional training and work experience requirements should be considered and why. Next slide, please. This first question is asking if additional pathways to becoming a microsource manual brachytherapy authorized user should exist aside from the current pathways permitted in the licensing guidance for interventional radiologists and physicians that meet the training requirements of 10 CFR 35.390 or 35.490. And our final question for this section is asking about the circumstances of use for Yttrium-90 microspheres and whether the authorized users are primarily the individuals the administering the microspheres.

This question seeks comment on whether it is appropriate for other individuals to administer microspheres under the supervision of an authorized user. Next slide, please. This slide summarizes the many sections of Part 35 including the addition of the

new proposed Subpart I that would receive revision under these proposed changes. And at this point, I believe we're pausing for questions again.

MS. LOPAS: Well, Maryann, are we going a little bit further with Elizabeth.

MS. AYOADE: A little bit.

MS. CENDER: I'm sorry for that.

MS. LOPAS: No, no worries.

MS. TINDLE-ENGLEMANN: No worries. Thanks, Laura. And my name is Elizabeth Tindle-Engelmann. I'm a health physicist in our NRC Region III office. And I'm not going to talk about any specific technologies today, but I'm going to talk about a group of other changes to Part 35.

So if you remember, Maryann, the Commission directed us to look at ways to make Part 35 more flexible for future technologies that we don't currently have on our radar or things that we've heard about might be headed our way but we don't really know about in full detail yet. This is the group of things I'm going to talk about, so we might be a little bit all over the place. So if you have questions, feel free to pop them in the chat.

But we'll be covering a couple different

areas. Based on this directive to make Part 35 more flexible for future EMTs, we came up with a couple of different areas that we believe may allow future technologies to move into the applicable subpart of Part 35 without landing in 35.1000 and then requiring rulemaking. Obviously, rulemaking is time consuming and can be quite expensive. So if we can clear the pathway for some of those now, that's obviously advantageous.

So that's what I'm going to be talking about today and that's what you're going to see in Appendix A.8. And on this side, you can see one of our proposed changes is to create a requirement for licensees to develop a procedure for breakthrough testing and reporting of breakthrough for novel radionuclide generators. We also have a specific question on there.

And so we're proposing that licensees develop, implement, maintain a procedure for breakthrough testing and reporting of novel -- a breakthrough for novel radionuclide generators. There are generators on the horizon that are not Moly-99 or Strontium-82 based. And they may not have breakthrough limits that have been established by USP

or FDA.

So we're looking for feedback on whether this approach sounds sufficient or any perspectives you have on another participant might take in this area. Next slide, please. So another topic related to the novel radionuclides is a proposal for training and experience for authorized users and authorized nuclear pharmacists working with these novel radionuclide generators. We're interested in understanding what your thoughts are and if you have any specific ideas on the training and experience that should be required for these authorized users working with these novel radionuclide generators as well as the authorized nuclear pharmacists.

At this point in time, they're probably not going to be at all of our licensees' facilities. And so we're interested in how we should tackle that training and experience requirement for those types of generators. You'll also see that we're looking to determine if there are other changes that are needed for authorized medical physicist involvement in manual brachytherapy.

Currently, there is a requirement for authorized medical physicists to be involved in some

Subpart F manual brachytherapy procedures. We're looking for your input as to whether that's sufficient and whether these authorized medical physicists should be involved in additional tasks or skills that are part of these manual brachytherapy procedures that we currently have in Subpart F. We're looking for your feedback there as well. Next slide, please.

And then here you're going to see a bunch of different little things. And kind of like Laura mentioned, I'm not going to go through each of them here. But there are lots of details in the proposed changes that you'll find in Appendix A.8.

But I am going to talk about some of the specific questions. So in general, we're looking at some changes to the definition of physician. We're looking at defining a treatment regimen for patient release criteria.

We're looking at revising the requirements for radiation safety committees. We're looking at revising the requirements for supervision. We're looking at amending the requirements for written directives, looking at amending T&E requirements as it relates to recentness of training and continuing education.

We're looking at amending various recordkeeping requirements based on these other changes as well as medical event reporting requirements and safety procedures instructions and precautions for Subpart H devices. So I'm going to go through a couple of questions related to these. And if any of them spark your interest, definitely take a look at the full section in Appendix A.8 on the topics.

So the first question that you'll see on this slide is that we're looking for your thoughts as to whether we should require continuing education for authorized users. We're all familiar with the recentness of training criteria. But we're interested in understanding if we should have a continuing education requirement for authorized users.

And if so, what should be required? What should it entail? What frequency should it be acquired at? And what are the knowledge topics that should be encompassed in that continuing education element?

On this slide, you'll also see that we're looking to understand if all AUs for 35.200 need to have device-specific training on radionuclide

generators. Obviously, they supervise the use of these units on a regular basis. But they may not be regularly working with them.

In light of the discussion we had previously on novel radionuclide generators, we're interested in your thoughts on whether authorized users need training on general generators, specific types of generators, or how we should handle that. And so that's what this question is aiming to understand. Next slide, please. This one is looking at how we've seen a bit of a shift in 35.300 procedures.

So we've seen a large number of complex emerging therapeutic radiopharmaceuticals come out. And they've been able to safely go to 35.300. But we're interested in looking at whether the T&E requirements are sufficient.

And if additional training is needed, what should the scope be? How should that be acquired? And literally, this is with the intent of allowing things to land in 35.300 immediately rather than going to 35.1000 in the future based on the training gap. Next slide, please.

On this slide, you'll see that we're

looking for some training and experience insights for 35.500 devices. We previously talked about how we're proposing to put one of our emerging technologies into the section. And so we would like to understand if you think the eight hours of classroom and laboratory training for the 35.500 devices is sufficient, if we have other types of devices that are going to land in this section as well.

We'd like to consider how we can make this a little bit broader for future emerging technologies that we might not have on the horizon. So in light of that, if we need additional training, what types of training should be covered, frequency, such as that. Next slide, please. We're also looking for your input on specific changes that are needed to secure consoles for keys, consoles, keys, and passwords for HDRs, teletherapy units, and GSRs.

We've obviously seen a lot of changes in technology. The treatment console looks much different today than it did 5 years ago, 10 years ago, 20 years ago. So we're interested in input on some of those specific requirements that are in Subpart H as it relates to the security of the consoles, keys, and passwords for those units.

And you'll also see that we're looking for your input on the types of entry controls that are acceptable for these Subpart H devices. So we've heard about licensees that may be interested in lasers or some sort of entry control that is not a physical door. So we're interested in your perspectives on why a physical door should or shouldn't be required. And if it shouldn't be required, what other types of controls may be acceptable.

So I believe this is the last of our proposed changes in Appendix A. So you've made it through all of the different technologies as well as this group of other changes that we're proposing. Here you'll see the reference slide that you've seen for the other sections. And now before our next break, we're going to hit on some of the feedback we've gotten from other stakeholders so far. Next slide, please.

So I'm going to first talk about the Organization of Agreement States feedback to us. When we previously mentioned -- Maryann went over the schedule. So we issued a draft regulatory basis to the Organization of Agreement States.

If you're unfamiliar with them, they

actually represent all of the Agreement States in the U.S. And they provided feedback to us on the regulatory basis. And they responded to many of our questions which was really helpful.

It helped us not only make some changes to the regulatory basis but make edits to the questions to make sure we're asking the question in a way that we're getting the information we're looking for. In general, Organization of Agreement States indicated support of our training requirements which was great to hear. They also recommended that we consider scaling back some of the regulatory development for this rulemaking effort.

Based on this feedback, we actually had a section that we've reviewed since then. And that was for alpha diffusion manual brachytherapy. And I'll talk about this again because ACMUI also had a similar comment.

OAS recommended that we consider developing a training and experience pathway for individuals who administer radioactive materials. We didn't take any action on this item since the Commission previously instructed us to stick to the status quo while evaluating training and experience as

it comes to EMTs. So we tried to strike a balance there.

And so you'll see many questions on the T&E topic without creating that additional pathway. And then finally, OAS recommended that we consider developing a structured pathway to define metrics for determining when a type of medical use is no longer an emerging medical technology. I'd say everybody on the working group believes this is a good idea. But it's something that belongs in policy, not in regulation. So we can go to the next slide.

So now I'm going to talk about the feedback that we got from ACMUI. ACMUI is our Advisory Committee on the Medical Uses of Isotopes. They reviewed the same draft that OAS reviewed.

They established a subcommittee. And this subcommittee prepared a report. They provided lots of feedback on our approach. They also responded to many of the questions that we're seeking. And much like OAS, their input was extremely valuable to us and helped us shape the current basis that you're getting the opportunity to review.

In general, they communicated that our scope was very ambitious which I think everybody on

the working group, it was good to hear that they agreed because it does feel quite ambitious. But they thought it was reasonable. They said that we should limit our efforts to the projects that are in broader use, have clinical experience, and are technologies that we understand.

So based on this feedback, we took the opportunity as a working group to actually look at all of the technologies we were proposing to move from 35.1000 into Part 35. We looked at each of them in light of their operating experience that we have the breadth of use as well as the associated scope of regulatory changes that would be needed to move that into Part 35, one of the applicable subparts. They also suggested that we don't move the diffusing brachytherapy sources into Part 35.

This was the same comment that OAS provided to us. So we took that section out of the regulatory basis so that draft actually had nine sections in the appendix. Now you only see eight because we did remove this and are no longer seeking to move that into the bulk of Part 35.

Kind of along those lines is they recommended that we don't move Gammapod or ViewRay

into Subpart H, Part 35. As Laura mentioned, we're seeking to not have specific technology-based requirements. We're trying to take the approach of having a technology neutral regulatory requirement that is based on the outcome of a certain task.

And so based on this and the work that is required to make the changes for Gammaknife, we believe that the Gammapod and the ViewRay would automatically be able to be brought into Subpart H based on this new approach. They also recommended creating a contamination control requirement for IVB and diffusing sources if we maintain those in the regulatory basis. So Monica talked about earlier a requirement for contamination control and the questions there that was based on this recommendation from ACMUI.

They also recommended that we take a wholesale reevaluation for ophthalmic applicators. That is a relatively complex framework to navigate, and the proposed changes do bring in some new types of eye applicators which could make that a little bit more complex to navigate with some different criteria to consider. At this point in time, we have not taken a wholesale reevaluation.

We're still continuing with our proposal to bring in those sources while not changing the current regulatory framework for the currently authorized sources that are in Subpart F. We don't believe the burden and impact to licensees for those current applicators is really worth the justification for a wholesale reevaluation. But you will see some questions in that section that are really targeted to get information to help us make this determination.

And we could before the proposed rule make a shift there. And you may see some changes based on feedback that you guys provide on the topic. And I believe that's all I wanted to talk about there. So we can go to the next slide which I think we'll be ready for a break.

MS. LOPAS: Yeah.

MS. TINDLE-ENGLEMANN: Thanks.

MS. LOPAS: All right. So before we get to the cost analysis, I'll go ahead and remind everybody just click on the raised hand icon if you want to speak your question aloud. And I'll call on you, and you can unmute yourself, *5 if you're on the phone or enter it in the chat. So we'll start with the chat questions if that's okay with the working

group.

The first question we have here is, would the current guidelines for Germanium-68, Gallium-68 breakthrough testing be maintained? Currently, breakthrough testing is performed weekly on each generator and not on every elution. Due to the energy and amount of Gallium-68 in each elution, we are not able to discern the minute amount of Germanium-68 energy until the bulk of the Gallium-68 energy has decayed down.

So the question is, would the current guidelines for Germanium-68/Gallium-68 breakthrough testing be maintained? And Fran, I don't know if you're able to answer that or any of the other working group members. And you're muted, Fran. Oh, there you go.

MR. O'NEILL: We need the guideline for the Germanium. So that’s the main issue here, because it's a long half-life and we do need that.

MS. LOPAS: So it would be maintained. Go ahead, Elizabeth. You want to --

MS. TINDLE-ENGLEMANN: Yeah, I can add to that. So the current breakthrough testing requirements are not handled through a Part 35

regulation. And so we're not proposing any changes there.

You'll see that the changes that we're calling out are very clearly highlighted as to what's applicable to the different generator systems in that Appendix A.

MS. LOPAS: Okay. All right, great. Thank you, Fran. Thank you, Elizabeth. The next question is from Judi Buckalew. What is the source of your statement that interventional radiologists only receive 80 hours of training to use microspheres? Does this track back to the June 2012 NRC guideline that set 80 hours? This was an NRC guidance document -- microsphere guidance document revised back in June 2012 staffed by former NRC staff Ashley Cockerham.

(Simultaneous speaking.)

MS. AYOADE: Okay. Go ahead.

MS. CENDER: Oh, go ahead. Oh, okay. Yes, that 80 hours is referring to the classroom and laboratory training portion of the experience in the guidance only. And yes, I went back through and it does seem that 2012 is where that first delineation for interventional radiologists came in and is formatted a little differently in the most recent

guidance. But yes, that's the source.

MS. LOPAS: Okay, great.

MS. AYOADE: And I can add to that. We have also included a question for feedback about whether the 80 hours is appropriate. And so I think it's in the A.7 section.

I couldn't pull up the number right now, but it's in there. And so we want your feedback on whether the hours is appropriate or not. And I believe Laura went over that question as well during her talk.

MS. LOPAS: Okay. All right. Let's see. I don't see any other chats. So we'll just keep moving forward. Just a reminder, keep putting your questions in the chat as you think of them. We'll stop for questions again. We're going to do one last portion of the presentation, then we'll close out with additional questions.

So raise your hand right now or just put it in the chat and we will get to it at the end. If you are on the phone, it's *5. Let me just take a quick look. I don't see any raised hands. So we'll just keep moving forward, and I think we're going to Tony, correct?

MR. GOMEZ: Thank you very much, Sarah. My name is Antonio Gomez, and I am the cost analyst on this rulemaking. I am part of the regulatory analysis and rulemaking support branch in the Division of Rulemaking, Environmental, and Financial Support.

Let's go ahead and move on to the slide, rulemaking cost analysis. The NRC staff developed a preliminary cost analysis for the rulemaking and the options. We looked at NRC rulemaking costs. We also looked at agreement state and licensee rulemaking participation costs.

And we also looked at NRC agreement state and licensee implementation of the rule. And that is developing the compatible regulations, submitting and reviewing revised procedures. And we also looked at averted costs related to the inspection of Rubidium-82 generators and emerging medical technology licensing actions.

I would like to add that after the Alternative 4 rule is effective, the Agreement States have three years to adopt compatible regulations. Agreement States will need to implement their new regulations which is assumed will be similar to the NRC implementation, that is processing licensee

amendments for affected licensees. The agreement state rulemaking cost may be lower if the Agreement States choose to incorporate the regulatory changes by reference.

Now most costs for the Alternative 4 are borne by the affected licensees for updating certain safety procedures for gamma stereotactic radiosurgery, teletherapy, or high dosage rate afterloader devices. Alternative 4 results in averted costs for the NRC, the Agreement States, and potentially also for the licensees. And that is through the increased licensing efficiency of existing and future emerging medical technologies.

The NRC would save resources by minimizing the need to develop new or update existing 10 CFR 35.1000 licensing guidance documents. Now when you review this document, you will find information on the background for this rulemaking and the current regulatory framework to include policies, regulations, and guidance. You will also see that this covers an explanation of regulatory issues and the proposed changes to the regulations and how those changes could resolve those issues.

You will find sections of the NRC's

evaluation of different approaches and alternatives that have been considered in support of the regulatory basis as well as the costs and benefits of the rulemaking and the different alternatives. And this also explains the limitations including the uncertainties and the data or methods of analysis. Next slide, please.

MS. LOPAS: Actually, Christine, can you go back one slide. I think you were one slide ahead of Tony. So yeah, go one more forward now. Yeah, just stay on that slide for now. Thank you. Are you finished up, Tony? I'm sorry if I interrupted you.

MR. GOMEZ: No, this is what I was going to cover next.

MS. LOPAS: Okay, perfect.

MR. GOMEZ: This was next slide.

MS. LOPAS: Okay. We're set. Thank you.

MR. GOMEZ: So we're where I think we need to be. Okay. Now what do I want to call out on this? There are close to 40 tables in Appendix C. And these tables show the calculations for the net cost and averted costs associated with each alternative by the stakeholders, that is the NRC, the Agreement States, and the licensees.

Now if we looked at what we have here, in Section 8, we have cost impact considerations. This contains the assumptions and descriptions of the Agreement States costs and averted costs. Table 5 includes a summary of the costs for each of the four alternatives.

Table 6 will have a breakdown of the Alternative 4 rulemaking and operating costs for the NRC, the Agreement States, and the licensees. Then we go ahead and move to Appendix B which we call the data tables. Table 7 is an emergency medical technology licensing assumptions.

And here we looked at how many emerging medical technologies the NRC has licensed to date, how many similar technologies we can expect to license in the future, and how many hours we could save on initial license and supplemental applications. And Table 8 shows data for each alternative. It is extremely important to add requirements for calibration and dosing instruments for Strontium-82, Rubidium-82 generators, and establish performance-based requirements for existing and future emerging medical technologies.

Even though Rubidium is highly toxic by

ingestion, a catastrophic generator failure could end lives and disrupt businesses and societies. So in addition, this rule would ensure that researchers to the medical field will have the required knowledge to adequately handle Rubidium when treating future medical technologies. And in contrast, it's important to understand the economic impact of this rule.

We should consider how this rule will affect already existing researchers handling Rubidium in a medical setting and the necessary cost to train this workforce. And this is one of the major reasons why we are looking for feedback. That concludes my presentation. Take it away, Andy.

MR. CARRERA: Hi, thank you, Tony. And Christine, may have the next slide, please? Thank you. And good afternoon, everyone. My name is Andy Carrera, and I'm in the Division of Rulemaking, Environmental and Financial Support in the Office of Nuclear Material Safety and Safeguards at the NRC.

So this next session is really to drive that point home about how you can prepare and submit the comments. So we've got some -- seen some good questions and have some good discussion in the meeting so far. But even though we are transcribing this

meeting for our public meeting summary, the formal way of getting those comments on the record outlined in the July 3rd Federal Register notice which I will go through that shortly.

But before we get there, I just wanted to provide some quick tips on preparing the comments. Now regulations.gov has a great document on their website that includes tips for submitting effective comments. And you should be able to click on the links provided on the slides to access the document.

You can also access the document when you are going into regulations.gov and submit your comments. Now I really urge you all to really go through the questions that we ask in the Federal Register notice and the regulatory basis document and look to answer those questions. Also, please feel free to provide comments on the preliminary cost estimate provided in the regulatory basis document which Tony just went over.

And as Theresa previously mentioned, we also welcome your thoughts and any questions that we may have missed and new information that we should be considering that wasn't part of the regulatory basis for this rulemaking. And that really helps us as we

move forward in developing the proposed rule. So may I have the next slide, please.

So all right. So I know you heard this mentioned all over already. But I'm going to repeat it anyway. So we've got three methods for submitting comments, right, the three methods for submitting comments to the NRC either through regulations.gov and go to our specific docket which is on the screen but I'll read it anyway.

It's Docket ID NRC-2018-0297. So you can submit a comment that way. And you can also email the NRC with your comments to the address rulemaking.comments@nrc.gov.

And lastly if you prefer, you can always mail your comments to the NRC at the address provided on the slide and also listed in the July 3rd Federal Register notice. And again, I'll just try to drive this home just one more time. So we really appreciate hearing all of your feedback and questions and discussion during this meeting.

But again, since this meeting isn't the venue for collecting comments to get on the official record. So please formally submit your comments using the methods that are on the slides and in the Federal

Register notice. And just a quick reminder, the comment period for the regulatory basis will end on October 31st. Next slide, please.

Okay. So far, next step, what are we going to do next? So the NRC will consider all comments assembled on the regulatory basis to inform the developer of the proposed rule. And what comes next is the staff plans to submit a draft proposed rule to the Commission for approval in late 2025 time frame.

Assuming if the Commission approves the staff's draft proposed rule, the NRC will publish the proposed rule in the Federal Register for public comment. Now the NRC, we've also published a draft regulatory analysis with cost benefit analysis and also a draft environmental analysis for public comment concurrently with the proposed rule. And we'll also be making available for comment the implementation guidance as well.

So the NRC also plans to conduct a public meeting similar to this public meeting during the comment period of the proposed rule to facilitate stakeholders' feedback, input, and comments on the proposed rule. And that will happen some time in mid-

2026. So the NRC would then consider all the comments received and the proposed rule to inform the development of the final rule which the staff plans to provide to the Commission for review and approval by mid-2027. Okay. So that's the end of my presentation.

I believe we have some time open for questions. So Sarah, I'm turning this meeting back to you. And thanks again, everyone, for your feedback and your comments on the draft regulatory basis document.

MS. LOPAS: All right, great. Thank you, Andy. Thanks for the overview of the rulemaking. So go ahead and raise your hand. Hit the raise hand icon if you want to make a -- ask a question over your microphone or make a comment.

Or if you have any questions about anything you heard today, how to submit comments, the schedule of the rulemaking, the process of the rulemaking, any kind of clarifying details that would help you submit comments on the reg basis, *5 if you're on the phone. Or just enter it in the chat. The chat has been working well today for questions, so that's great and I'll read that aloud.

I did put a bunch of links in there. Again, I reposted links so we have a link to the regs.gov website where you would go ahead and submit your comments. Again, the Federal Register notice is linked there. The actual reg basis document is linked there directly. And today's slides are linked there too.

And I will go ahead and read Ralph's question. So Ralph Lieto asks, a common issue across these proposed issues is waste disposal. I know numerous RSOs have tried to get approval to allow DIS radionuclides greater than 120 days. So that's decay-in-storage of radionuclides greater than 120 days. Is this a consideration for changes of this rulemaking? Is this being considered at all in this rulemaking? Maryann?

MS. AYOADE: Yeah. Hey, Sarah. I can take that. We are aware of this issue on the medical team. Because this rulemaking was specifically focused on new technologies and things related to new technologies, we have it included in here. But it's something that you can provide information on as part of our feedback -- I mean, as part of your feedback to us. I see Elizabeth has her hand up.

MS. TINDLE-ENGLEMANN: Yeah, I was going to add one of the things that we talked about as a working group was, do all of the emerging technologies have a disposal pathway for some of those things above 120 days? So that was one of the things that we did talk about. We weren't aware of anything that didn't have disposal pathway. So if you have other information on that, that'd be helpful to us, I think.

MS. LOPAS: Okay. Pop any other questions or clarifying questions or comments in the chat or raise your hand. Because if we don't have anything, I'll probably send it back to the working group to close us out. But let's -- I'm going to keep pushing you. Now is your chance to ask your questions, to inform your comments on the reg basis.

And just a reminder that you have until Halloween. Scary spooky, to submit your scary comments on the reg basis, Halloween is the deadline. Now you won't forget that date because you'll think about I'm going to give the NRC some scary comments on the reg basis. Halloween is the deadline to get those written comments in via regs.gov or the email or any way that Andy went over in submitting your comments on the reg basis.

And Andy, I have a clarifying question that maybe some people would be interested in, I'm interested in. What happens with comments on the reg basis? Do we republish the reg basis? Or how do folks see, like, what we did with their comments on the reg basis?

MR. CARRERA: Yeah, so after we receive a comment, we look at the comments and review the comments and kind of work out a way to work on a path forward for the reg guide for the proposed rule. But we won't be issuing a document where we are responding to each of those comments. And then these comments will be -- I mean, aggregation or bins of these comments will be summarized in the preamble of the proposed rule.

MS. LOPAS: Perfect, okay. That's where we'll kind of discuss what we heard at the reg basis space. Okay. Maryann.

MS. AYOADE: Yeah. And Andy said it correctly. I just wanted to add to that. Again, the regulatory basis gives the public an early look at our thoughts and what we're considering. This is the first time in medical rulemaking that we're issuing a regulatory basis that includes our proposed changes

and gives the members of the public a really early look, right?

Before we get into the next phase where we are actually revising rule language and connecting it to how it will be implemented later on after the rule is issued. And so as Andy mentioned, we're just going to be summarizing the comments. They are going to be part of what we consider as we move forward. And then the next phase is what people may be used to seeing where we will actually respond to -- after we issue a proposed rule and we receive those comments, we'll be responding to the comments at that phase.

MS. LOPAS: All right. Very good, Maryann. Thank you. Okay. I will -- maybe I'll just put out one last call for any comments or questions. And while we're waiting for that, I don't know, Maryann, if you had any -- or anybody in the group or Theresa have any last closing items or anything along those lines.

(Simultaneous speaking.)

MS. CLARK: Thanks everyone for their participation.

MS. LOPAS: Go ahead, Maryann.

MS. AYOADE: Yeah, no, thanks. Just again

I wanted to thank everybody for participating. We look forward to receiving feedback and comments. We want to hear from you. Like I said, this is the first time we're doing this out in the public forum in the regulatory basis phase. And we're hoping that this will help us as we move forward and give you all an early look because this is such a major rulemaking.

It touches pretty much every single section in Part 35. I know it's a lot to chew on today. But I hope that this meeting serves to help you all in, like, starting to receive information for what it is that we're looking to change and what it is that we are looking for to help better inform us as we move forward with rule language for this rulemaking. Thank you.

MS. LOPAS: Okay. And Maryann, let me just follow up with one thing. If folks have additional questions after this meeting, they hang up, they're thinking later on, can they reach out to you directly if they have questions? Or is there another point of contact that you would prefer?

MS. AYOADE: It's just myself and Andy.

MS. LOPAS: Okay. All right. I'll put those -- I'll put your emails into the chat. So

everybody has those, carrera@nrc.gov. There's Andy's email and maryann.ayoade@nrc.gov. Okay, great. I think with that, we can close out the meeting. Appreciate everybody's participation, and that concludes today's meeting. Get your comments in by October 31st. Thank you very much.

(Whereupon, the above-entitled matter went off the record at 3:32 p.m.)