# Official Transcript of Proceedings

# NUCLEAR REGULATORY COMMISSION

Title: Public Meeting to Discuss Approaches for Rulemaking on Decommissioning Financial Assurance Requirements for Sealed and Unsealed Radioactive Materials

Docket Number: (n/a)

Location: teleconference

Date: Thursday, January 7, 2021

Work Order No.: NRC-1322 Pages 1-92

**NEAL R. GROSS AND CO., INC.**
**Court Reporters and Transcribers**
**1323 Rhode Island Avenue, N.W.**
**Washington, D.C. 20005**
**(202) 234-4433**

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

+ + + + +

PUBLIC MEETING TO DISCUSS APPROACHES FOR RULEMAKING ON DECOMMISSIONING FINANCIAL ASSURANCE REQUIREMENTS FOR SEALED AND UNSEALED RADIOACTIVE MATERIALS

+ + + + +

THURSDAY,

JANUARY 7, 2021

+ + + + +

TELECONFERENCE

+ + + + +

The Public Commenting Meeting was convened, via Teleconference, at 1:00 p.m. EDT, Sarah Lopas, facilitating.

NRC STAFF PRESENT:

SARAH LOPAS, NRC, State and Federal Liaison Project Manager, Office of Nuclear Material Safety and Safeguards (NMSS), Division of Materials Safety, Security, State, and Tribal Programs (MSST)

NRC STAFF PRESENT (CONTINUED):

PATRICIA HOLAHAN, Director, NRC/NMSS/Division of Decommissioning, Uranium Recovery, and Waste Programs (DUWP)

TORRE TAYLOR, Senior Project Manager, NRC/NMSS/ Division of Rulemaking, Environmental, and Financial Support (REFS)/MRPB

ROBERTO TORRES, Senior Health Physicist, NRC, R-IV/DNMS/MLDB

MICHELLE BEARDSLEY, Health Physicist, State Regulation Review Coordinator, NRC, NMSS/MSST/SLPB

SARA FORSTER, Health Physicist, R-III/DNMS/MLB

VINCE HOLAHAN, Senior Level Advisor for Health Physics, NMSS/MSST

JUNE CAI, Branch Chief, NRC/NMSS/REFS/MRPB

STEPHEN KOENICK, Branch Chief, NRC/NMSS/DUWP/LLWPB

JOHN TAPPERT, Director, NRC/NMSS/Division of Rulemaking, Environmental, and Financial Support

KEVIN COYNE, Deputy Director, NRC/NMSS/Division of Rulemaking, Environmental, and Financial Support

KEN KLINE, Financial Analyst, NMSS/REFS/FAB

STEVE McCARTHY, Financial Analyst, NMSS/REFS/FAB

BRIAN HARRIS, Deputy Assistant General Counsel, OGC/GCRPS/RMR

NRC STAFF PRESENT (CONTINUED):

ERIC STOCKING, Legal Intern, OGC

DON LOWMAN, Health Physicist, NMSS/MSST/MSTB

DAVID DRUCKER, Senior Project Manager,

NRC/NMSS/REFS/MRPB

CARDELIA MAUPIN, Senior Project Manager,

NRC/NMSS/DUWP/LLWPB

ADAM SCHWARTZMAN, Risk Analyst, NRC/NMSS/DUWP/RTAB

CONTENTS

P R O C E E D I N G S

1:08 p.m.

OPERATOR: Welcome and thank you for standing by.

For today's call, I would like to inform all parties that your lines have been placed in listen-only mode until the question-and-answer sessions of today's conference. To ask a question at that time on your phone, you will need to press *1, unmute your phone, and record your name, so your question can be introduced.

It is now my pleasure to turn the call over to Ms. Sarah Lopas. Thank you, and you may begin.

MS. LOPAS: Good afternoon, everybody, and welcome to the NRC's public meeting on decommissioning financial assurance requirements for sealed and unsealed radioactive material.

As Sandy, our operator said, my name is Sarah Lopas, and I'm a meeting facilitator here in the NRC's Office of Nuclear Material Safety and Safeguards.

And before I hand the meeting over to NRC management to officially start us off, I'm going to quickly cover the logistics for today's meeting.

So, Glenna, if we could have the next slide, please?

So, the audio for today is only through the telephone bridgeline. So, if you have any colleagues who are saying they can't hear the Webex, they don't know what's going on, please share with them our telephone bridgeline information.

And as Sandy, our operator, noted, everybody is in listen-only mode until we get to the Q&A and comment portions of today's meeting. And those are going to happen after the NRC staff finishes up with their technical discussion. So, at that point, as the operator said, you are going to press *1 on your phone and the operator will prompt you, and you will unmute your line and you'll be able to speak to us.

Today's meeting is being transcribed by a court reporter. So, we're asking that everybody, including NRC staff, always begin by introducing yourself, saying your name, so the court reporter can get that. And then, please speak clearly, so we can capture an accurate transcript of today's meeting.

The staff is going to outline in just a moment, when we go over today's agenda, but we will be taking a short break about midway through today's

meeting. So, during the break, it's best to just please stay on the bridgeline; don't hang up your phone, and don't close out your Webex presentation.

Today's slides, they are available in our NRC's Agencywide Documents Access and Management System. That simply means you can find them online. That accession number is ML21005A004. And I believe Glenna, who is our Webex host, she went ahead and sent a link to the slides that you could click on directly in the chat of the Webex. We are not using chat today at all. We're just using chat to send out that link to the slides. We're only going to be doing comments and questions over the phone line. So, please, the chat will be unmonitored today.

And then, finally, I want to note that we were all prepared; we were all looking nice and dressed well to be on video today with you on the Webex, but we did have some technical issues last minute, and now our video is not working for the Webex. So, you will not be able to see today's speakers, but we did get ready for you all.

So, with that, with the logistics out of the way, I'm now going to introduce Trish Holahan. Trish is the Director of the NRC's Division of Decommissioning, Uranium Recovery, and Waste Programs

here in NMSS, and she's going to kick us off.

Trish?

MS. HOLAHAN: Thank you, Sarah.

Good afternoon, and thank you for attending this public meeting to discuss alternatives for decommissioning financial assurance requirements for sealed and unsealed radioactive material.

This meeting will provide an opportunity for public input on alternatives for updating Appendix B to Part 30 to include radionuclides that are not currently listed in the Appendix. These will be used in developing the regulatory basis for the rulemaking. Appendix B is used in conjunction with the regulations for decommissioning funding requirements in 10 CFR Part 30 to determine if financial assurance is required.

Please note that this meeting is to obtain public views on the alternatives that will be discussed during the meeting. There will be a formal comment period on the regulatory basis in the future.

Several members from the Office of Nuclear Material Safety and Safeguards are here to support this meeting. Torre Taylor from the Division of Rulemaking, Environmental, and Financial Support will serve as the rulemaking project manager.

Cardelia Maupin of my Division, the Division of Decommissioning, Uranium Recovery, and Waste Programs, will serve as the technical lead.

Also, Working Group members from the Division of Decommissioning, Uranium Recovery, and Waste Programs; the Division of Material Safety, Security, State, and Tribal Programs, and also, the Division of Rulemaking, Environmental, and Financial Support; specifically, the Financial Analysis Branch, in addition to rulemaking support; the retail offices, and also the Organization of Agreement States. They're all here to support this rulemaking. Several of the presenters are from the various offices and divisions.

We look forward to an informative meeting with you today.

And now, I would like to turn the presentation over to Torre Taylor, who will, in turn, introduce the rest of the speakers.

Thank you.

MS. TAYLOR: Thank you, Trish.

Welcome, everybody, and good afternoon. Welcome to this public meeting. This is to discuss alternatives for decommissioning financial assurance requirements. And specifically, we're looking at

ways to update Appendix B and 10 CFR Part 30, which is titled, Quantities of Licensed Material Requiring Labeling.

The presenters today will be myself, Roberto Torres, who is the Senior Health Physicist in the Region IV Office, and Michelle Beardsley, a Health Physicist within NMSS within the Agreement State Program. Other members of the Working Group are here to support and answer questions if something comes up during the Q&A session.

Admin information. I think we've been through most of this. I'd just remind you again that we have a court reporter. We will have a transcript of the meeting. So, if you do have a comment or a question during the session, just identify yourself and organization, if applicable, for the record.

After the meeting, we'll have a public feedback forum. That will be, though, on the public meeting page for this meeting.

As we go through the presentation, presenters are going to reference documents and information. And at the end of the presentation slide, there are reference slides at the end, and I've included hyperlinks, where applicable or possible, or included an ADAMS accession number.

There are also miscellaneous background information slides that we're not going to go through today, but you might find helpful in the future.

Next slide, please, to the agenda.

So, we've already been through the opening remarks. The introduction and meeting logistics we've been through. I'm going to go through some of the petition background and history, kind of like why we're here doing this rulemaking. And we'll have a general technical discussion on decommissioning financial assurance requirements. Ms. Cai will talk about Agreement State information or how that they might be impacted by this rulemaking. And then we'll talk about options for revising Part 30, Appendix B, and have an open discussion and questions, and then we'll do a summary and next steps. And as Sarah noted, we'll have a 15-minute break in this presentation, so everyone can take a short break.

Next slide, please.

Okay. So, the purpose of this meeting, you know, the topic of the rulemaking is decommissioning financial assurance requirements for sealed and unsealed radioactive material. And specifically, we're going to be updating Appendix B,

Part 30, to include radionuclides not listed. And there are various ways to do that, and we'll be discussing that later in the meeting.

So, we are looking to discuss approaches and we want to seek public input from this meeting. We hope to get some input, so that we can start working on the regulatory basis that we'll be talking about later.

So, the status of the rulemaking now is to develop a regulatory basis, and from there, we'll be doing a proposed rule and a final rule. There will be opportunities for public comment at each stage, and I'll also get into how you can track the rulemaking, so you can participate as you want on that.

Next slide.

So, the background and the history. We got a petition from the Organization of Agreement States -- they're often referred to as OAS -- in 2017. It was docketed as PRM-30-66 and that is for public comment. I do have information in the reference slides for accessing the petition and the comments, if you're interested.

The main points of the petition are that the radionuclides and possession values not listed in

Appendix B is causing licensees to use a value for radionuclides not listed, and it's resulting in some licensees using decommissioning financial assurance funds where the risk doesn't really justify it or to request an exemption from the requirement for those funds.

So, we did submit a rulemaking plan to the Commission in December 2019. There's the SECY No., SECY-19-0125. And again, I have a link in the back and you can read all the information provided to the Commission for their review.

The Commission did approve initiation of rulemaking. We got a Staff Requirements Memo in October 2020. Generally, they approved the initiation of the rulemaking to provide specific possession values to radionuclides that are not currently listed in Appendix B. And they did agree with the staff and directed us to seek this public input, and that's the purpose of this meeting as well.

And again, the Federal Register notice closing out the petition and how the rulemaking would be addressed is, again, in the reference slides, the link, if you want to read that.

Next slide, please.

I'm now going to turn the discussion over

to Roberto, where he'll talk about the technical discussion related to financial assurance and decommissioning financial assurance requirements.

MR. TORRES: Good afternoon. My name is Roberto Torres. I am a license reviewer and inspector within the Nuclear Regulatory Commission office in Arlington, Texas, Division of Nuclear Materials Safety.

Today, I will present the technical discussion portion of this public meeting. In the next few slides, we will discuss what is financial assurance and how is it determined, the NRC regulations for financial assurance, and we will provide examples of when a decommissioning financial assurance funding plan is needed.

Next slide, please.

What is financial assurance? Financial assurance means a guarantee or other financial arrangement provided by 10 CFR Parts 30, 40, and 70 licensees that ensures funds for decommissioning will be available when needed. This is in addition to the licensee's regulatory obligation to decommission its facilities. In other words, certain licensees, those that will meet certain criteria that will be listed in the next slide, will need to set aside a specific

monetary amount under the control of the regulatory agency for the purpose of paying for decommissioning activities.

Why is financial assurance so important? Because having adequate financial assurance for conducting decommissioning activities will avoid leaving a facility with used and unwanted sources or leaving contamination behind in a facility, and thus becoming a potential legacy issue; and also because having financial assurance will provide for adequate disposal of licensed material and will provide for the release of the facility for unrestricted use.

Next slide, please.

When is financial assurance required? There are two criteria that need to be met in order for a licensee to have the need to have financial assurance. The first criterion means that radioactive material must have a half-life greater than 120 days. And the second criterion is that a licensee must possess radioactive material in a quantity greater than the applicable activity threshold that is specified in Title 10 of the Code of Federal Regulations, Section 30.35(d), for material in sealed source form and unsealed form.

Sealed sources are defined in Part 30,

10 CFR Part 30, as any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material, while unsealed means any physical form other than a sealed source; for example, liquid, powder, or gas. These two definitions are important because they are taken into consideration when determining financial assurance.

Next slide, please.

How is financial assurance calculated? By using the table in 30.35(d). This table lists six monetary amounts of financial assurance based on order of magnitude multiples of the applicable radionuclide values in Appendix B of 10 CFR Part 30. The table in Appendix B of Part 30 is the subject of this petition for rulemaking 30-66.

To find if decommissioning funding is required, licensees compare possession limits for the specific nuclide to the nearest applicable order of magnitude exceeding that possession limit. In other words, the order of magnitude multiples listed in the 30.35(d) table is multiplied by the Appendix B to Part 30 values for a particular radionuclide. Then, the resulting activity value is compared to the licensee's possession limit listed in the license to determine if the licensee needs financial assurance

or not. In the next slide, we will show you the 30.35(d) table, and in subsequent slides we will demonstrate to you specific examples of how the 30.35(d) table and the Appendix B table are used.

Next slide.

In this slide, we are using color differentiation to simplify the explanation. Let's focus first on the unsealed material, which is shown in the blue color. In other words, the first two paragraphs of this slide.

If the licensee has a possession limit for a single radionuclide greater than 10 to the 4th times -- and I need to pause here; 10 to the 4th is 1 followed by four zeroes -- 10 to the 4th times, but less than or equal to 10 to the 5th times, the applicable quantities of Appendix B to Part 30 in unsealed form, this licensee will need to have financial assurance in the amount of $1,125,000.

If the licensee has a possession limit for a single radionuclide greater than 10 to the 3rd times, but less than or equal to 10 to the 4th times, the applicable quantities of Appendix B to Part 30 in unsealed form, this licensee will need to have financial assurance in the amount of $225,000.

Please note that, if the licensee has the

possession limit for a single radionuclide in unsealed form that is greater than 10 to the 5th times, which is the upper limit of the 30.35(d) table, this licensee will need to develop a site-specific decommissioning cost estimate with a site-specific decommissioning funding plan for financial assurance.

Now let's focus on sealed sources, which is shown in the green color. It's in the last paragraph of this slide.

If the licensee has a possession limit for a single radionuclide that is greater than 10 to the 10 times, but less than or equal to 10 to the 12th times, the applicable quantities of Appendix B to Part 30 in sealed sources or plated foils, this licensee will need to have financial assurance in the amount of $113,000.

For sealed sources, the upper limit, if a licensee exceeds the 10 to the 12th value, that licensee will have to have a site-specific decommissioning funding plan.

Please note that, for a combination of long-lived radionuclides, the unitary rule is used for determining financial assurance for Part 30, 40, and 70 licensees. That is, byproduct material licensees, source material licensees, and special

nuclear material licensees, respectively. The unity rule is explaining that 30.35(d) table, and for simplicity of the financial assurance discussion during this public meeting, in the next few slides we're going to focus only on single radionuclide calculations, because the petition of rulemaking focused on specific radionuclides used in medicine under emerging technologies.

Next slide, please.

This slide shows only a portion of the Appendix B to Part 30 values. This is not a complete list. The values range from .01 microcuries to 1,000 microcuries. Those radionuclides not specifically listed in Appendix B to Part 30 are, then, assigned a generic value of .01 microcuries for alpha-emitting radionuclides and .1 microcuries for other than alpha emitters; for example, beta and gamma emitters.

This is the table that the petition for rulemaking 30-66 asked the NRC to update to include additional radionuclides such as those being used in medical emerging technologies and to make the Appendix B table risk-informed.

The Appendix B values are based on 1/10th of the most restrictive annual limit of intake or derived air concentrations found in columns 1 and 2

of Appendix B to 10 CFR Part 20. Annual limit of intake and desires to derive air concentrations are defined in this regulation, 10 CFR Part 20.

Next slide, please.

In this slide, we are going to provide two examples of the amounts of financial assurance that is needed for unsealed materials and for a sealed source. Let's start with carbon-14 in unsealed form.

Carbon-14 is listed in the Appendix B to Part 30 table with a value of 100 microcuries, and it has a half-life greater than 120 days, specifically, 5,730 years. Multiplying the Appendix B value for carbon-14 of 100 microcuries by 10 to the 3rd, 10 to the 4th, and 10 to the 5th order of magnitude of multiples, you are seeing on the slide that we will obtain 100 millicuries for 10 to the 3rd value, 1 curie for 10 to the 4th value, and 10 curies for 10 to the 5th.

What does this mean? As shown in this slide, no financial assurance is needed for quantities of carbon-14 up to 100 millicuries. Amounts of carbon-14 over 100 millicuries and up to 1 curie will require $225,000 of financial assurance. Amounts of carbon-14 over 1 curie and up to 10 curies will require $1,125,000 of financial assurance. And

amounts of carbon-14 over 10 curies will require a site-specific decommissioning funding plan. And the NRC provides guidance on how to come up with a DFP, a decommissioning funding plan, in NUREG-1757, Volume 3, Revision 1.

Now let's look at the second example, which is Cobalt-60 in sealed form.

Please hit Enter. There. Thank you.

Cobalt-60, listed in the Appendix B to Part 30 table, has a value of 1 microcurie and it has a half-life greater than 120 days, specifically, 5.3 years. Multiplying the Appendix B value for cobalt-60 of 1 microcurie by, since it is a sealed source, multiplying by 10 to the 10th value and 10 to the 12th order of magnitude of multiples, you will obtain 10,000 curies for 10 to the 10th and a million curies for 10 to the 12th.

What does this mean? Again, no financial assurance is needed for quantities of cobalt-60 up to 10,000 curies. Amounts of cobalt-60 over 10,000 curies and up to 1 million curies will require $113,000 of financial assurance. And amounts of cobalt-60 over 1 million curies will require site-specific decommissioning funding plans.

Next slide, please.

In this slide, we are going to provide an example of the amount of financial assurance that is needed for a specific radionuclide that was mentioned in the petition for rulemaking. It is germanium-68. Germanium-68, which has a long half-life, is used to produce gallium-68, which has a short half-life of about 67 minutes.

MS. LOPAS: Hey, Roberto? Roberto?

MR. TORRES: Yes?

MS. LOPAS: Can we take a moment? Is that you shuffling paper? Somebody is shuffling paper and they need to mute themselves. I apologize for being the mean facilitator, but NRC Staff, please make sure you are muted unless you are Roberto.

All right. Sorry, Roberto. Go ahead. I really apologize.

MR. TORRES: Okay. I'm going to start again with slide 14.

In this slide, we are going to provide an example of the amount of financial assurance that is needed for a specific radionuclide that was mentioned in the petition for rulemaking. It is germanium-68. Germanium-68, which has a long half-life, is used to produce gallium-68. Gallium-68 has a short half-life of about 67 minutes. And all this happens inside a

generator. The gallium-68 is used in medical diagnoses.

The generator is a shielded container with a sorbent-based column containing the parent radionuclide germanium-68. The gallium-68, the short-lived material, which it generated as a result of decay of the germanium-68, is eluted from the column in liquid form.

Why am I explaining all of this? Because the generator doesn't meet the definition of a sealed source, which was discussed in a previous slide. So, we will have to treat the germanium-68 as an unsealed material for financial assurance purposes.

Germanium-68 is not listed in the Appendix B to Part 30 table and it has a half-life greater 120 days, specifically, 270.95 days, 271 days. Germanium-68 decays by electron capture. And I'm providing all this information and it will make sense in a moment. Therefore, the generic value for radionuclides that are not alpha emitters, the value of .1 microcuries from the Appendix B to Part 30 table is used. Multiplying the Appendix-B-generated value of .1 microcuries by 10 to the 3rd, 10 to the 4th, and 10 to the 5th order of magnitude multiples, we will obtain .1 millicuries for 10 to the 3rd value,

1 millicurie for 10 to the 4th, and 10 millicuries for 10 to the 5th.

Okay. So, we've done all these calculations. What does this mean? It means that no financial assurance is needed for quantities of germanium-68 up to .1 millicuries. Amounts of germanium-68 over .1 millicuries and up to 1 millicurie will require $225,000 for financial assurance. Amounts of germanium-68 over 1 millicurie and up to 10 millicuries, will require $1,125,000. And amounts of germanium-68 over 10 millicuries, like those found in a germanium-68/gallium-68 generator, which typically has about 50 millicuries, will require a site-specific decommissioning funding plan.

Next slide, please.

In this last slide of this technical presentation, we're going to show another radionuclide that was mentioned in the petition for rulemaking. It is lutetium-177m, like in Mary, 177m, metastable. However, we need to first talk about lutetium-177, not the metastable form, just lutetium-177. That has a short half-life of 6.6 days and is an emerging medical technology that is used in unsealed form, specifically, in liquid form, to treat tumors in humans.

The short-lived lutetium-177 is produced via neutron activation in a nuclear reactor or a cyclotron and may contain a low percentage of the radiocontaminant lutetium-177m, metastable. The lutetium-177m, metastable, is not listed in Appendix B to Part 30 table. It has a half-life greater than 120 days, specifically, 161 days.

Lutetium-177m, metastable, decay mode is mainly beta with some gamma emitters. Therefore, it's not an alpha emitter. So, the generic value for radionuclides that are not alpha emitters of .1 microcuries that comes from the Appendix B to Part 30 table is used. Multiplying the Appendix-B-generated value of .1 microcuries by, then, 10 to the 3rd, 10 to the 4th, and 10 to the 5th order of magnitude multiples, we obtain .1 millicuries for 10 to the 3rd, 1 millicurie for 10 to the 4th, and 10 millicuries for 10 to the 5th.

So, what does it mean for a licensee? That no financial assurance is needed for quantities of lutetium-177m up to .1 millicuries. Amounts between .1 millicuries and 1 millicurie will require $225,000 of financial assurance. Amounts of lutetium-177m over 1 millicurie and up to 10 millicuries will require $1,125,000 of financial

assurance. Amounts of lutetium-177m over 10 millicuries will require a site-specific decommissioning funding plan.

The potential scenario for a medical licensee using the short-lived lutetium-177 is that, when the licensee removes their lutetium-177 radioactive waste that has been in decaying storage ready for disposal as ordinary trash, the licensee will find themselves that they can't dispose of the decayed lutetium-177, the short-lived nuclide, because they are still detecting radiation from the long-lived lutetium-177m, metastable.

Because the licensee now has long-lived material in their waste stream, they will need to calculate how much lutetium-177m they have in their waste to determine if they're triggering financial assurance requirements or not. If the licensee determines that they have more than .1 millicurie, the same as 100 microcuries, of lutetium-177m, metastable, in their waste, then they will need to have financial assurance in place, as described in this slide.

This concludes the technical portion of the presentation. I will now turn the presentation over to the next speaker, Michelle Beardsley.

And thank you for your attention.

MS. BEARDSLEY: Thank you, Roberto.

Good afternoon, everyone. My name is Michelle Beardsley, and I am the State Regulation Review Coordinator in the Agreement State Programs Branch at the NRC.

In this presentation, we use the term Agreement States, and for those who aren't familiar with that term, I'd like to briefly explain what Agreement States are and their regulatory responsibility.

As noted on this slide, Agreement States are those states where the governor has entered into an agreement with the NRC to have their own radiation control program. In that agreement, they confirm that their program will be both adequate to protect the public's health and safety and the environment, and also be compatible with the NRC's program. We currently have 39 Agreement States, and they regulate the majority, or about 87 percent, of our nation's licensees.

Regulations are just one element that the Agreement States need to have for their radiation control programs to be both adequate and compatible. And the regulations that would be included in this

rulemaking are a matter of both adequacy and compatibility.

Next slide, please.

In NRC Procedure Management Directive 5.9, the NRC defines six categories that are assigned to regulations which, depending on the designation, requires a different level of adoption by the Agreement States. The category designations are A, B, C, D, Health and Safety or H&S, and NRC. This rulemaking includes two regulations that are a matter of both adequacy and compatibility.

First, 10 CFR 30.35(d) is designated as Compatibility Category D. This means that, while the Agreement States don't have to adopt an identical regulation to be compatible with the NRC's program, they would still need to have some provisions or values for financial assurance for decommissioning in order to have an adequate program to protect the public health and safety and the environment.

For Appendix B to Part 30, the Compatibility Category designation is B, in boy, which means that the Agreement States need to adopt a requirement that is essentially identical to this Appendix.

For further information on the

definitions and descriptions of the Agreement State programs and the terms adequacy and compatibility, including the Management Directive I referenced earlier, please refer to the reference slides at the back of this presentation.

That concludes my presentation. I thank you for your attention, and I will hand it back to Torre Taylor.

MS. TAYLOR: Thank you, Michelle.

So, we've discussed the background and the need for the rulemaking, information about financial assurance, and decommissioning funding requirements and why it's important; and also, that Agreement States are going to need to meet adequacy and compatibility requirements. So now, we look at where do we go from here.

So, the next slide.

Here, I'm going to go through two potential alternatives and pros and cons that the staff have, read through them. We'll discuss pros and cons of Alternative 1 and Alternative 2. And I'll discuss a comment that we received on the petition about a new category for radiopharmaceutical generators within 30.35. And after that, I think we will transition; we'll have a short question session

for the technical discussion before we have our break.

Next slide. Oh, no, you're on the slide. Thank you. Nineteen.

So, Alternative 1 is to develop a new methodology based on risk and cost of decommissioning a facility where the subject radionuclide is used. We would apply that new risk methodology to all the radionuclides that are already listed in Appendix B as well as the new addition.

And then, Alternative 2, we could reconstitute Appendix B with values for labeling from Appendix C in 10 CFR Part 20.

Next slide.

So, we have pros and cons here for Alternative 1. And the pros and cons were pros and cons compared to Alternative 1 and Alternative 2 in part.

So, the pros would be:

It would be more risk-informed possession values if we did a new risk methodology.

And there would be greater savings on decommissioning financial assurance costs for a greater number of affected licensees.

And it would allow values to be set for

unlisted radionuclides with uses not now foreseen.

And then, the cons are:

It would likely result in Appendix B values that are less conservative than the values in Appendix C for labeling. This could be a concern for those who think decommissioning values should be more conservative and in line with Appendix C, Part 20.

It would also take longer to do this rulemaking due to the need for developing new risk methodology. We'd have to get some data and make some assumptions about criterion and we'd have to cover the range of activities using byproduct material, and then, how they could impact decommissioning. So it would take longer to do this rulemaking.

Next slide.

Therefore, Alternative 2, this is the one that updates the values from Appendix C.

It would result in more conservative Appendix B possession values as compared to Alternative 1.

There would be 67 radionuclides in Appendix B that would increase tenfold and another 11 that would increase a hundredfold. So, that would result in the need for less decommissioning funding.

So, that saves money there.

And it would take less time to do this rulemaking, is what we're estimating.

The cons for this alternative would be:

The possession values, again, would be less risk-informed.

And it would likely result in less decommissioning financial assurance cost savings compared to Alternative 1.

And it will result in smaller Appendix B values for key radionuclides, listed there on this slide. And of note, four of these radionuclides are special nuclear material, one of which only exists in trace quantities, but this is the part that would affect Part 70 licensees potentially. So, the funds needed for decommissioning would potentially increase as well for those groups of licensees.

And the next slide.

We did get a comment on the petition that we wanted to talk about. It's not a separate alternative, but it's something to evaluate within 30.35.

It's to add a new category for radiopharmaceutical generators. Generators, typically, are more engineered confinement than

unsealed material, but they are less than sealed sources and they are not a sealed source by definition.

Typically, they are returned to the manufacturer and distributor at the end of its useful life for that licensee.

And there is typically no need for extensive site decontamination or decommissioning.

So, that is the comment we got that we would like to evaluate and get your input on to see if we should have a new category there, so people don't have to have as much decommissioning as regular unsealed material per se, since there is this engineering confinement.

Next slide, please.

So now, we're going to turn it over to Sarah Lopas for questions and discussion on the technical discussion. If you would like to comment/ask a question, press *1 on your phone and wait for the operator's instructions, and then, Sarah will be facilitating through that discussion.

MS. LOPAS: All right. Thanks, Torre.

All right. So, as Torre said, just go ahead and press *1 on your phone. And as soon as we get somebody on the line to ask a question, Sandy,

our operator, will go ahead and unmute that line. And just a reminder, we are not using the chat function on the Webex. So, please do not send anything via chat. So, press *1 on your phone.

Oh, hi. Go ahead.

COURT REPORTER: Hi. This is the court reporter. If you could please just remember to spell your name before you start speaking, that would help me a lot.

MS. LOPAS: Yes. So, that's Graham. That's our court reporter.

So, please introduce yourself. If you have a tricky name, please spell your name. That would be really helpful.

And NRC Staff, when you respond to a question, please just introduce yourself quickly.

All right. Sandy, do we have anybody so far on the line to press *1?

OPERATOR: We have one that just came in. His name is Steve Mattmuller.

You may go ahead.

MR. MATTMULLER: Hi. This is --

MS. LOPAS: Is it Steve Mattmuller?

MR. MATTMULLER: Yes. Can you hear me?

MS. LOPAS: And just a reminder to

everybody, you have to unmute yourself on your own phone. So, if you're calling in on your own phone, just make sure you, yourself, are unmuted on your own cell phone or whatever phone you're using.

MR. MATTMULLER: Yes. Hi. This is Steve Mattmuller, S-T-E-V-E M-A-T-T-M-U-L-L-E-R.

Can you hear me? Hello? Oh, my, I'm unmuted. I'm trying. Hello?

OPERATOR: Sir, I can hear you. This is the operator.

MR. MATTMULLER: Okay. Okay. I wasn't getting a response back from anyone else. I'm sorry.

OPERATOR: That's fine.

MR. MATTMULLER: Yes. So, to continue --

MS. HOLAHAN: It looks like Sarah got disconnected, and I'm not sure -- okay, Steve Mattmuller I think had a comment, but I'm not hearing anything.

MR. MATTMULLER: Can you hear me now?

MS. HOLAHAN: Do we have Mr. Mattmuller on the phone?

MR. MATTMULLER: I'm trying. I'm not getting any response, except from the operator.

OPERATOR: Hello. Can you hear me?

MR. MATTMULLER: I can hear you, yes.

OPERATOR: Okay. Just a minute.

MS. LOPAS: Sandy?

OPERATOR: Let me do something here.

(Pause.)

MS. LOPAS: I've got silence here. Sandy, do we have Steve Mattmuller on the phone or is there anyone else who has questions?

OPERATOR: Yes, we do. Yes, we do. Just one moment, please.

The next question belongs to Bryan Miller.

Can you hear me?

MR. MILLER: I can hear you and I could hear Steve, too.

OPERATOR: Can you hear us, Speakers?

MR. MILLER: Yes, I can. I don't believe the speakers can hear us.

OPERATOR: I don't, either. Just one moment. I'm going to disconnect you and have you come back in. Okay?

MR. MILLER: Hang up?

OPERATOR: No, don't hang up. Just hit *1 again.

MR. MILLER: All right. All right.

Okay.

MS. LOPAS: Yeah, I'm not hearing anybody, either.

MS. HOLAHAN: Who is this? Who just spoke?

MS. LOPAS: Apparently, all the attendees can hear Steve, but we can't. So, I'm not sure. They're using the chat to communicate that in Webex.

MR. MILLER: I can ask my question, and then, you can just pass that on.

MS. LOPAS: Apparently, they can hear us, too.

MR. MILLER: Steve, do you want to go first?

MS. HOLAHAN: So, those at the NRC cannot hear anybody else, but all the attendees can hear --

MS. LOPAS: Okay. Can you hear us now?

MS. HOLAHAN: Right, but we can't hear anyone else because they did confirm that they can hear us and everyone else, but, apparently, the operator is trying to talk to us and we can't hear the operator, either.

So, Adam Schwartzman suggests that we take our break now, and then, get this worked out, and so did Trish.

COURT REPORTER: This is the court reporter. I can hear both sides.

MS. LOPAS: That's weird.

MS. HOLAHAN: Yeah, that's weird.

MS. LOPAS: Okay. So, whoever can talk to the audience and be heard, I think we should take our break now -- it's what, 10 until 2:00? -- and then, come back.

OPERATOR: Hi. This is Sandy. Can you guys hear me? Can you hear me now?

MS. LOPAS: Yes, we can.

OPERATOR: Okay. They can hear us.

MS. LOPAS: Okay.

OPERATOR: I have one for the question. I put them back in the regular and asked them to come back up, to see if that would help.

Sarah, can you hear us now?

MS. LOPAS: I can certainly hear you, Sandy. I can hear everybody. I'm aware that the audience can hear NRC staff talking and trying to figure out what to do.

So, Sandy, if you would just try to have the next commenter go ahead and see if we can hear them?

OPERATOR: Okay. Let me try that.

Okay? Just a moment. Let me go back to that side of the house. So, one moment.

Bryan?

MR. MILLER: This is Bryan Miller from the State of Nebraska.

OPERATOR: Okay. Can the speakers hear this?

No, they can't.

MR. MILLER: Now can I just give my question like I was typing it into the comment section?

OPERATOR: They can't hear you.

MR. MILLER: Can you pass it on?

OPERATOR: No.

MR. MILLER: All right.

OPERATOR: They don't want me to pass it on.

The court reporter can hear you.

So, just a second. Let me do one other thing and let's see if that helps.

MR. MILLER: Can they see the comments in the chat?

OPERATOR: They should be able to, but I don't know if they'll answer you.

But just one moment.

Bryan, can you still hear me?

MR. MILLER: Yes, I can.

OPERATOR: Okay.

COURT REPORTER: This is the court reporter. I'm listed as an attending rather than a panelist. Maybe that's why I can hear both sides.

MS. LOPAS: No, we don't have any Webex audio. So, that should not be --

OPERATOR: Yes. Sarah, I can hear you now. Is this Sarah? I can hear the person other than the court reporter.

MS. LOPAS: Sandy, can you hear us?

OPERATOR: Yes. Now I can.

Okay. I'm not sure who's talking, but just one moment.

MS. LOPAS: Okay. All right. Everybody that's on the line right, all members of the public who are listening in right now, please stay on the line. I think the only way I can figure this out is if all the NRC staff that can't hear what's going on, including myself, I think, right, Sandy responded back to us, but we could not hear her.

I just want to confirm, can Torre and other folks hear me talking right now?

MS. TAYLOR: This is Torre. I can hear

you talking.

MS. LOPAS: Okay. So, for everybody that's having an issue, I'm going to suggest that NRC staff, we hang up and call back in.

Let's take our 15-minute break right now. So, it is 1:56. Let's just call it 1:55.

OPERATOR: Sarah?

MS. LOPAS: Hi. Yes, Sandy?

OPERATOR: I can hear you now.

MS. LOPAS: Okay. And now, I can hear you, yes.

OPERATOR: Okay. And everybody else should be able to hear us, too.

MS. LOPAS: Okay. I see Bryan Miller. Is he up? Is he right now the current caller unmuted?

OPERATOR: Yes.

MS. LOPAS: Unmuted? Okay.

OPERATOR: Bryan, do you want to see if you can speak?

MR. MILLER: Yes, I can. This is Bryan Miller, B-R-Y-A-N.

OPERATOR: Okay. I'm going to back to the participant side of the house and make sure his line is open. All right?

MS. LOPAS: Okay.

MR. MILLER: I can hear you.

MS. LOPAS: Okay. Hang tight, everybody.

MR. MILLER: Can you hear me now?

This is Bryan.

OPERATOR: Bryan?

MR. MILLER: Yes.

OPERATOR: Okay. Sarah, can you hear us?

MR. MILLER: I can still hear you.

OPERATOR: Okay. Just a second.

Sarah, can you hear us?

MR. MILLER: The audience can hear me, but not Sarah.

OPERATOR: Yes.

MS. LOPAS: Hello? Hello?

OPERATOR: Yes? Sarah, can you hear us?

MS. LAPPERT: Okay. This is Sarah, right?

MS. LOPAS: This is Sarah Lopas.

MS. LAPPERT: Yes, they're asking for you on the other line. I don't know how I'm doing this, but I'm like on two lines.

MS. LOPAS: Okay.

MS. LAPPERT: They're asking for you on

the other line, I guess, the general population or participant line.

MS. LOPAS: Yes, we're having trouble.

MS. LAPPERT: Yes.

COURT REPORTER: This is the court reporter. Do you want to go off the record?

MS. LOPAS: Yes, let's go off the record. Thank you, Graham.

(Whereupon, the above-entitled matter went off the record at 1:58 p.m. and resumed at 2:15 p.m.)

MS. LOPAS: All right, everybody, it is 2:15. I really apologize for those technical difficulties, but we are back and we can hear everybody.

We are now going to take our questions and get back on track with questions and finish out the rest of today's meeting.

So, please, again, press *1 to get in line to ask a question.

But we are going to start off with Bryan Miller.

So, Bryan, go ahead.

MR. MILLER: Bryan Miller, B-R-Y-A-N M-I-L-L-E-R, from the State of Nebraska.

And I'm sorry, Steve, for jumping in front of you. I think Steve might still have a question out there.

But I just had a quick question, and this is just basically how do you calculate the need for financial assurance for a facility that has both sealed and unsealed material? Question mark.

MS. LOPAS: Roberto, was that a question you could take?

MR. TORRES: Yes, yes. This is Roberto Torres, NRC Region IV. So financial assurance, we combine. In I believe slide No. 12, let's see -- slide No. 13, I use the example of unsealed material for carbon-14 and sealed cobalt-60. So the amounts will be added, and it requires some calculation. Here in NRC Region IV, we created, staff, we have a spreadsheet. We don't do manual calculations. We have a spreadsheet that will do the calculations in itself.

Back in 2013, Region IV provided financial assurance training to Agreement States. And it was agreed that we could share that table with the Agreement States because we are co-regulators. Did I answer your question?

MR. MILLER: So partially, yes.

MR. TORRES: Okay.

MR. MILLER: So if the facility had both unsealed C-14 and sealed cobalt-60, would it be kind of like a unity rule? And then for the amounts, does that spreadsheet have like the amounts that it would be? Because, you know, once you get over 10,000 curies of cobalt-60, so if you have like 9,000 curies of cobalt-60 and 99 millicuries of C-14, you know, that's --

MR. TORRES: The unity rule will apply. I will use it, yes.

MR. MILLER: Okay.

MR. TORRES: The answer is, yes, I will use the unity rule to determine the fractions of it. And based on the example that you are giving, since they are very close to the limit, to the 10 to the 3rd for unsealed material, and for the sealed material, it's close to the 10 to the 10th, it's possible that it will go over 1, the unity rule, and financial assurance will be needed.

MR. MILLER: Okay. And then do you use the greater of the two numbers, or would you use an additive of both the two numbers, the 225, and then the 113,000?

MR. TORRES: And the answer to the

question is that I will have to -- I haven't done manual calculations in a while, a long time.

MR. MILLER: Okay.

MR. TORRES: And I would rely on the calculator. So the calculator will tell me here is the amount, based on if it goes over the 10 to the 3rd, 10 to the 4th, 10 to the 5th, and it will combine sealed -- and I think this is your answer -- it will combine sealed and unsealed and will give me what is the amount. Or it will tell me it went over, it needs, yes, the decommissioning funding plan. I cannot make this calculation because it's going over the upper range limit.

MR. MILLER: And I would say that I am a regulator, state regulator. So I might get you offline and just maybe could send that especially to me.

MS. LOPAS: All right.

MR. TORRES: Okay, sir.

MR. MILLER: Thank you.

MS. LOPAS: All right. Thank you. Thank you, Roberto. Thank you, Bryan. All right.

MR. TORRES: Can I add something to Bryan?

MS. LOPAS: Yes please.

MR. TORRES: We have State Agreement Officers. So we conduct communication between Agreement States and the NRC through the SAOs. That would be the appropriate channel to use.

MS. LOPAS: Okay.

MR. MILLER: So it's contact the State Agreement State Officer?

MR. TORRES: Yes, sir.

MR. MILLER: All right.

MR. TORRES: And we do that all the time.

MR. MILLER: All right.

MS. LOPAS: All right. Great. Thank you, Roberto. Okay. Reminder to press *1 on your phone and unmute yourself if you are going to make a comment.

It looks like we have Larry Camper up next. So Sandy, can we hear from Larry, please?

OPERATOR: Mr. Camper, you may go ahead.

MR. CAMPER: Thank you. Can you hear me?

MS. LOPAS: We can, yes.

MR. CAMPER: Very good. Thank you to the staff for your presentation today. It's informative, as usual. Thank you.

My question is, can you share with us the

FRN citation, discussed the petition submitted by OAS, and can you tell us a little bit more about what the OAS concerns were that led them to submit the petition?

MS. LOPAS: Okay.

MS. TAYLOR: Yes. This is Torre Taylor. Yes. What happened is, way back when, when Congress gave us additional authorities under the Energy Policy Act of 2005, there were some radionuclides that are not currently listed in Appendix B to Part 30 that had started becoming used in different medical areas. And so with that, they didn't have a value within Appendix B. So they had to use the other radionuclide calculation other than alpha emitting, because it wasn't alpha emitting, or the one for alpha, if it was.

So the bottom line is they were having to do decommissioning financial assurance funds and such just because the radionuclide wasn't listed, and that specific issue was the germanium generators because they were reaching a legal agreement to return them back to the manufacturer at some cost.

And so because the radionuclide was not listed in the Appendix, they had to get the decommissioning funding plan, which was expensive.

And so they were asking for exemption. So people have been working that way, if it was applicable, or getting the decommissioning funding.

At the very end of the slides -- let me go to the slide, reference slide on page -- if you can maneuver to those, Glenna, for me? If you go to slide 30, the petition is linked there.

MR. CAMPER: Oh, yes.

MS. TAYLOR: And the ML number is provided. The comments we received is linked there. And this, the last entry, or The Federal Register notice that closed out the petition is linked there. And it talks about how this path addressed the petition and what we're doing on that.

And then the next slide, we have the SECY paper that went to the Commission recommending rulemaking, to which the Commission agreed, the initiation of rulemaking and that SRM.

And let's see. And then on the background slide, if you could scroll to slide 34, we have a few slides on the actual background of that petition. We weren't going to speak to those in detail, since we're past that and moving forward with rulemaking. But it has some specific points that they raised about that petition that you can read

through.

And they provided some radionuclides with half-lives greater than 120 days that were proposed by commenters for listing in Appendix B. That's on the next slide, Glenna. And so that can help there to get some more specific details on the actual petition.

MR. CAMPER: Yes, that's helpful, Torre. Thank you very much.

MS. TAYLOR: You're welcome.

MS. LOPAS: Okay. Sandy, can we hear from the next caller?

OPERATOR: The next caller is Manar Sakaola. You may go ahead.

MR. SAKAOLA: Hey, how's it going? This is Manar Sakaola and Matt Williams. We're the radiation safety team at Georgetown Hospital.

We have a pretty active Lutathera program. And as you know, it has Lutathera 177m in that vial. So our question is, when it comes to financial assurance, how are we supposed to quantify the amount of 177m per vial? Because would that then affect our financial assurance, if needed?

MR. TORRES: This is Roberto Torres, NRC Region IV. That is a very good question because the

example that I used on slide -- I believe it was 15 -- that's correct, slide 15, it's a potential scenario. I don't have enough knowledge to determine how that's done. And this scenario focuses on licensees think they have short-lived material, and they find out at the very end that, okay, I'm still detecting -- after 10 half-lives or more, I'm still detecting material. Now what do I do? I need to comply with the regulations.

So that's a very good question, and I don't have an answer for it.

MR. SAKAOLA: Yes, because we have a dose calibrator. So we could identify potentially small, small amounts of that. But like you said, it would be retrospectively that we would identify. We couldn't preemptively say yes, we will have this, given "X" number of treatments per year.

So thank you for the consideration.

MR. TORRES: And thank you for your comment because your example, your comment basically shows the merit of the petition of this rulemaking. Something needs to be done, and we need to figure out what the right answer is.

MR. SAKAOLA: Thank you.

MS. LOPAS: Thank you. Okay. A

reminder to press *1 if you have a question on the technical discussion. But it sounds like now, Steve, your line is open, I think.

MR. MATTMULLER: Hi. This is Steve Mattmuller. And I'm a nuclear pharmacist at Kettering Medical Center, and I have also served on ACMUI.

And while on ACMUI, we had a subcommittee -- this is actually, I'm sorry, a bit more history that happened before the OAS petition. Our subcommittee report was on this very issue of germanium-68 and decommissioning funding plans and financial assurances. And that's on your website, and it's dated 8/12/2015. That I think would be a good background information for some of the NRC staff. And also we presented to the NRC Commissioners on March 17th, 2016.

And perhaps slide No. 3 -- I think it's 3 on that presentation -- has a picture of an iceberg, where the current use of gallium-68, we're just at the very tip of the iceberg, and below the water surface are future drugs to be used for prostate imaging for prostate cancer in men. And we just recently in our field had two new drugs approved, but they are drug manufacturing sites versus kits that

are also on the cusp of being approved quite quickly, or soon, I should say.

And so there's going to be a dramatic increase in use and demand for gallium-68 across the country once those prostate imaging kits become available. And some think it will happen within the next few months.

So this is all very important, and hopefully the group will also look at the amount of financial assurances that current generators, that sites that have a generator have to pay. Because most I think if you understand how the generators work, there is basically no risk, especially when the generator is finished. We, the sites send the generator back to the manufacturer.

So I would fully, fully support the SNM's comments that were submitted in 2017 that a third category be created for radionuclide generators. They don't fit well in either sealed or unsealed categories. And because of their unique characteristics, I think they themselves should have their own category. That would be very helpful in setting appropriate amounts of financial assurances. Because even with the exemption and even with the current levels, they're still far too much because

there just isn't a risk. Thank you.

MS. TAYLOR: This is Torre. Thank you, Steve, and thank you for those two references. Different people on the project now, and there is obviously the possibility that they did look at those reports and the information presented to the Commission. So I'll definitely pull those up and make sure the Working Group for the rulemaking has those two documents for background and other information the NRC has received.

And it's good to hear support for the separate category and the real need there, and that helps us as we determine that. Thanks.

MS. LOPAS: Okay. Sandy, can we hear from the next caller?

OPERATOR: Robert Custodio.

MS. LOPAS: Custodio?

OPERATOR: Custodio.

MS. LOPAS: Hi, Robert. Your line is open. Remember to unmute yourself.

MR. CUSTODIO: This is I guess a question or a comment. I'm not quite sure. But it was regarding the lutetium-177m. There was a question about meeting the requirement based on the activity after the fact. I guess it's a question. My

question is: wouldn't the financial assurance requirements be determined by the license possession limit, not the actual inventory on hand?

MS. LOPAS: Okay. Roberto, is that something you can address?

MR. TORRES: Yes, I can. This is Roberto Torres, NRC Region IV. And the financial assurance is calculated by what the license authorization for possession limit is. The licensee may have an inventory that's less than what it listed in the license, but we, as regulators, we don't know. So we have to go with what is authorized in the license.

MR. CUSTODIO: I don't know if that addresses the question from the two gentlemen that were inquiring about, how do we know, if we don't know the activity until after the fact?

MR. TORRES: The example that I used, it's like me being a former nuclear medicine technologist, I put myself in the shoes of a licensee. I order lutetium-177. This is short-lived material. I am not expecting to find a long-lived material. But then in the end -- and this is a potential scenario -- maybe the operational experience out there with the licensees, they're not seeing, they're not detecting the lutetium-177 because it's not being

detected, so it's being disposed of in ordinary waste.

So that's why I was very cautious of saying this is a potential scenario. And I would like to hear from the regulated community, individuals like you, what's your experience when you're at the disposal. When you need to dispose of material, decaying storage, are you detecting or not?

MR. CUSTODIO: I haven't encountered it yet, so I can't really say, no. But thank you. I think I got the clarification I needed.

MR. TORRES: Okay. Thank you.

MS. LOPAS: All right. Sandy, can we hear from Sebastiano Anzalone?

OPERATOR: You may go ahead, sir.

MR. ANZALONE: Hi. Can everybody hear me?

MS. LOPAS: We can, yes.

MR. ANZALONE: Okay. So my question, it's still kind of piggybacking on lutetium-177, the Lutathera and such. I believe it was in 2018 when the NRC released criteria in regards to differentiating lutetium-177 if it was direct radiation or manufactured, or it was decayed manufactured, which would determine if it was a

lutetium-177 metastable product. Well, most of the ones that I have encountered have the metastable present. So being it has such a long half-life, we've had to develop programs, more of a waste disposal rather than decay-in-storage programs, where we have licensed companies coming on a regular basis to dispose of that waste from the facility because of the long half-life of greater than 120 days.

So my question -- I guess part of it was answered -- is, on the license, if we're going to be going off the possession limit for parental imaging or parental therapeutics, you know, some places do multiple isotopes. So they may be doing I-131; they may be doing strontium, samarium, lutetium. You know, it's all one bulk number.

So my first question is, is that something that needs to be itemized on our licenses for those financial assurances because of the different quantities that could be possessed for those studies?

And then, No. 2, well, I guess you had answered that you'll be going off of the possession limit. So if we have a waste disposal program regularly in place, will there be some exemptions for those financial assurances to be put in place?

And then, my third question is, will the entire slide show be available for later viewing, if we need to go back and look at it?

MS. TAYLOR: This is Torre.

I can answer the slide question. They are probably available on ADAMS now, and the ML number is on the meeting logistics slide, ML21005A004. And they are linked in the meeting notice on today's schedule. So if you go to the home page and scroll to January 7th, down near the bottom, "Documents Related to Meeting," there's a link to the slides directly.

MR. ANZALONE: Great. Thank you.

MS. TAYLOR: Uh-hum.

And then, someone else has to answer one and two.

MR. TORRES: Yes. This is Roberto Torres, NRC Region IV. I am answering Question No. 1.

Again, having worked for an NRC licensed facility before, I know what you're saying. You mention iodine-131, strontium-90, samarium-153, lutetium-144. And usually, those are authorized in a license under, in your case, an Agreement State regulation. And the NRC language, lingo, will be

35.300 material.

So I understand question. You have a one-line item authorization in your license for your parenteral imaging, your liquids, for therapeutic uses.

MR. ANZALONE: Correct.

MR. TORRES: And before, I said we go by the possession limits, but you can strike out iodine-131; it's short-lived. Samarium-153, I think it's short-lived. That doesn't count. So it boils down to you, under your radiation safety program, identifying, as an RSO, identifying what your long-lived material and the amounts that you have that probably are not the same on the license. The license will have a combined amount. You're only focusing on one radionuclide, and just keep track of that and calculate financial assurance only for your long-lived material, excluding all the short-lived, the iridium, I think the strontium-90, it's short-lived.

I think I answered your first question. Did I answer your --

MR. ANZALONE: As it stands right now, a Lutathera dose is standard to 200 millicuries, whether the facility uses a full 200 millicuries or

if it's based on weight, blood work. You know, there's other different components, depending on what the patient can handle at that time. So I guess, at any given time, what I'm hearing, I think, is based on maybe a monthly inventory of patients just specifically for that is kind of your best guesstimate of what a possession limit would be at a given period. Would that be correct?

MR. TORRES: Well, it depends because we don't know if that 200 millicuries of Lutathera, which is the lutetium-177, not metastable -- it's short-lived -- we don't know if the Lu-177m, metastable, is detected, which goes back to the previous question that I was asked and I didn't know an answer. So there's an uncertainty here that impedes me to answer your question clearly.

MR. ANZALONE: Well, and like I said, I'm going back off of the release that was sent out by the NRC like about two or three years ago in regards to lutetium-177 and -177 metastable, where it indicated, if it's manufactured this way, then the metastable is present if it's manufactured by decay. So then, we should probably be getting clarification from the manufacturer how it is being produced in order to determine if it's just lutetium or if

metastable is definitely present.

MR. TORRES: Me, if I'm the licensee, I will use that route. Contact your manufacturer and have them give me the tech specs and the -- I think it's a quality or purity of the material.

MR. ANZALONE: Yes, I believe it's like .02 percent or .002 percent of it is going to be, as stated, like I said, in the NRC notification of it being metastable. So there's enough there that it can be detected with that.

You know, the other concern comes in with, what happens if the waste is from like incontinence of the patient after Lutathera administration? Obviously, the urine would be contaminated. Is that going to be exempt from the financial assurance in regards to quantity or activity?

MS. TAYLOR: This is Torre Taylor.

Sara Forster put a link in our personal chat here I'm looking at now. There is a memo that was sent to the Regions regarding licensing of lutetium-177. So let me grab the hyperlink to that and put it in the chat. And I haven't read it, but it's for --

Sara, I don't know if you want to chime

in a little bit about it while I'm doing this.

MS. FORSTER: Thank you, Torre.

This is Sara Forster. I'm a Licensing Reviewer in Region III.

And this memo discussing how to handle lutetium-177 waste after using it for dosing patients is available to review. And essentially, there was an analysis done. And typically, there shouldn't be a need for financial assurance based on the fact that there just isn't that much waste that's generated. And if licensees are getting rid of their waste in a timely way, they shouldn't be accumulated so much lutetium-177m impurities in their decay-in-storage waste, so it would be triggering those limits. So that's essentially what the memo speaks to and some basic thoughts that should be in place in terms of disposal.

But, unless there's just a lot of buildup of the waste materials, where you'd have a lot of that decay in storage, you know, the decay of lutetium-177m product, that shouldn't normally -- that's the analysis that was done back in 2018.

MR. ANZALONE: Okay.

MS. FORSTER: So I don't know if that's

helpful.

MS. TAYLOR: And so I think a takeaway for the Working Group would be to look at your comment and question here, that memo, and evaluate this particular radionuclide against what you were talking about, about how it's manufactured and how much "m", metastable part, is going to be there. So I flagged that, too, so we can look for that in the transcript and talk about that in our Working Group.

MR. ANZALONE: Yes, that would be great, I mean, one. And then, two, obviously, if a facility has an established waste disposal, you know, regular waste disposal contractor coming in and removing that excess waste because of the metastable, that is kind of maybe a consideration in regards for that. And I would assume that that would fall under the disposal plan above those activities. But, like I said, a lot of this, mixing up just a regular 200-millicuries vial, so some facilities might only administer 100 millicuries to the patient, because that's what the prescribed doses called for, and the rest of it becomes waste. So that's where we have potentially seen higher readings where decay in storage is not going to be an option. So me, I think that's --

MS. TAYLOR: You had something about

exemptions, and, you know, the regulations do allow for any licensee to request an exemption from the requirements and submit their justification or basis why, and then, we review that and make a determination on that. So that would be more of a case-by-case licensee-specific and we would not generally regulate by exemption and put some carte blanche exemption in the regulations. It's more case by case, site-specific, based on that individual facility use, if you will. So the licensees always have that option.

MR. ANZALONE: Yes. And I think, also, you know, looking at the numbers that have been discussed in regards to what needs to be set aside for financial assurance, I mean, you know, just coming off of last year and going into this year, financially, a lot of these clinics, more or less, have had to stretch their dollars much thinner. So those are going to be questions that are probably going to be posed also; you know, where to locate those funds if the practices are definitely well below what previous years were because of COVID-19. Right?

MS. TAYLOR: Yes, this was a big impact year in a lot of areas.

Thank you for your comments.

MR. ANZALONE: Sure. Thank you.

MS. LOPAS: All right. In just a moment, I will share in the chat of the Webex the link to the memo that Sara Forster referenced. So just hang tight for that. I'm pulling that up as we speak.

MS. TAYLOR: I already have it in there, Sarah.

MS. LOPAS: I think you sent it to only the panelists, though, Torre.

MS. TAYLOR: Oh, I did. I did. I'm so sorry I didn't change it.

MS. LOPAS: No, no worries. No worries.

Okay. Let's go for questions. We'll keep going with questions until about three o'clock because we do have some discussion questions that I know the staff wants to go through. So we want to make sure we get to those as well.

So Sandy, can we hear from the next caller, please?

OPERATOR: Yes. Joe Power, you may go ahead.

MR. POWER: Hi. This is Joe Power. It's J-O-E P, as in Paul, O-W-E-R. I'm from the State of New Jersey and I'm a regulator in the radioactive materials program. I oversee the

financial assurance program we have.

My comment is regarding the pros and cons to the two approaches that were mentioned, specifically, the approach that aims to replace the Appendix B values in Part 30 with Appendix C, Part 20, values. From my standpoint, we have about six or seven --

MS. TAYLOR: Hang on one sec. Sorry for the interruption.

Glenna, that's slide 21. Thank you.

Go ahead. I'm sorry, Joe.

MR. POWER: No problem.

So from my standpoint as a regulator, we have about six or seven licensees that fall into this conundrum here, either with germanium/gallium generators or lutetium-177m. And just looking at their possession limits, if that particular option were put in place, I don't see that it would be of any value to them or us, because their possession limits are in the range of hundreds of millicuries.

And if this route was taken, the new values would change from the current 0.1 microcuries to 10 microcuries for both lutetium-177m and germanium-68. So at the possession limits that all of New Jersey's licensees currently have, that's

still going to put them in the range of needing a prescribed amount of financial assurance.

However, much like they've been following the guidance that's been presented by the NRC in the interim for germanium at least, the generators, all of them wind up doing a DFP anyway because the true cost to get rid of these things is much, much less than the prescribed amounts. So my comment is just that I don't see that that second option is going to be of any value to New Jersey's licensees.

And I'll also comment that, for the generators specifically, I would support a separate category because I don't think that it can be well represented at the sealed source or unsealed source.

Thank you.

MS. LOPAS: Thank you.

Okay. Yes, Sandy, can we go to the next caller, please?

OPERATOR: Yes. It is Cathy Ribaudo.

One moment, please.

Cathy, you may go ahead. Cathy?

MS. LOPAS: And, Cathy, make sure you've unmuted your own phone, Cathy.

MS. RIBAUDO: Sorry. I think I was at fault for that.

It's Cathy Ribaudo, R-I-B-A-U-D-O, and Cathy with a "C", in case that matters. I'm calling from the National Institutes of Health, a federal licensee, NIH, in Region I. And I have a similar petition on the docket.

There was a slide, and the one that we're looking at right now may be the same one I had in mind, where certain radionuclides are listed. And if you're going to revise Appendix B to add them, I wanted to just offer that there are additional radionuclides in Appendix C that are not in Appendix B and they're becoming more and more important for a medical licensee for therapeutic purposes. And these are relatively new alpha emitters to the medical arena. They're short-lived. So it probably won't make any impact for decommissioning, but there may be long half-life considerations that may come from either daughter products or contaminants.

And I just wanted to share on record that the Commission may do well to consider the addition, if you're going to amend Appendix B or Part 30, Schedule B, you may also want to consider adding radium-223, actinium-225, and thorium-227.

MS. LOPAS: All right. Thank you, Cathy.

MS. TAYLOR: Thank you. Appreciate that. I made a list.

MS. RIBAUDO: You're welcome. Thanks.

MS. LOPAS: All right. Sandy, let's go to the next caller. That's Neil Whiteside.

Neil, I think your line is open now.

MR. WHITESIDE: Yes. It's Neil Whiteside, N-E-I-L, Whiteside, from Yale New Haven Hospital.

I want to echo a lot of what was just said regarding, I think most importantly, the merging technologies. For those of us in the academic broad scope medicine categories, lutetium-177, PSMA, and gallium generators are going to be huge in the patient populations that are affected with these kind of illnesses. The volume should be very high when this becomes available.

Based on our experience with Lutathera, we had read the NRC guidance and there's published data out there on the contamination levels of the 177m. If you have a very active, large patient population, what you have left over in the vial, potentially with "m", this could become an issue.

And so I think the gentleman who talked about handling that as radioactive waste to go out

with a broker, due to its half-life, there needs to be some guidance from the NRC about when the decommissioning happens. Is it when your on-hand waste in possession exceeds that? So I think there's a lot to be worked out with the licensees.

As this is a very popular treatment arena, this is going to limit the communities and the areas outside the major medical centers in their ability to treat those patients. And so from an access-to-care standpoint, I know physicians are very excited to get these things out there and treat more people, and I would hate to see the financial implications, as the gentleman mentioned with COVID, as preventing hospitals from being able to offer these medical treatments. So I'll just leave it at that.

MS. LOPAS: Thank you, Neil.

All right. Next, we're going to do two more callers, and then, we're going to move to the discussion questions.

So next up we have Larry. And, Larry, I'm probably not going to get your name right. So if you could please spell your last name, that would be helpful. Your line is open.

MR. HARISIS: Sure. Larry Harisis,

H-A-R-I-S-I-S.

MS. LOPAS: Okay.

MR. HARISIS: And it's L-A-R-R-Y. I'm with the University of Nebraska at Lincoln.

So my question is, if we're going to do Alternative Method No. 2, which is combining the two Appendixes, it looks like, which is fine to an extent, because if you look at hafnium, hafnium metastable, it's either hafnium -- for example, you're looking at 178 metastable has what, two of them in there, three of them? So is there a way to differentiate that in the revised rules?

MS. LOPAS: Roberto, is that something you can address?

MR. TORRES: I need to go to Appendix C that Mr. Larry referred to. So give me a chance.

MS. LOPAS: Okay.

MS. TAYLOR: Yes, and while he's doing that -- this is Torre Taylor -- let me chime in.

You talked about merging the two. What we would do with Alternative 2 is pull in all the radionuclides that are in Appendix C and we would just populate Appendix C with those radionuclides and those numbers. So everything that's in Appendix C and those values there would also be pulled into

Appendix B.

MR. HARISIS: Right.

MS. TAYLOR: So we wouldn't be picking and choosing. We'd be just bringing them all in. And we want to make sure the list in Appendix C is comprehensive as well.

MR. HARISIS: Right. Understandable. My issue is, for research, I'm looking at hafnium. For example, hafnium-180, it has six metastables. So I mean, are we planning on including all six metastables or are we just saying metastable?

MS. TAYLOR: Oh, I see what you're saying. I'm sorry, I missed that. We'll put that down as a definite comment. We need to look at that.

MR. TORRES: This is Roberto Torres, NRC Region IV.

I am trying to follow the comment of Mr. Larry. I'm looking at Appendix C, Part 20, and I see one, two, three, four, five. Yes, there's several hafniums. There are other hafniums that are metastable. So I guess your comment is let's make sure that we get the right radionuclides in the table, if we revise the table? So can you go and, specifically, for the record, mention what those hafniums are, the ones that you're interested in,

please?

MR. HARISIS: Yes, definitely. Hafnium-178 metastable 1 has a half-life of what, 4 seconds? Whereas, the half-life of hafnium-178 metastable 2 has a half-life of 31 years. So to me, if we're adding that into the table, there's two separate ways of doing that. So I don't know which one you're planning on choosing. Or maybe we're just taking the more conservative approach? I'm not quite sure, or if you're taking any of the metastable elements of this hafnium into account.

MR. TORRES: Okay. Let me see if I can hone in on your question. The hafniums that you're referring, are they long-lived material, greater than 120 days?

MR. HARISIS: Yes.

MR. TORRES: If the answer is yes, then we need to account for those.

MR. HARISIS: Okay.

MR. TORRES: And I think I heard a yes. Okay. So on this table --

MR. HARISIS: There are also --

MR. TORRES: Go ahead.

MR. HARISIS: There's other ones that could be on that list that are less than, which is

fine, but if we're specifically saying for hafnium-178 metastable, it should be listed as hafnium-178 metastable 2.

MR. TORRES: I see what you're saying, that there subcategories of metastable that the NRC may need to consider in the list?

MR. HARISIS: Right.

MR. TORRES: Okay. Now I got it. Thank you.

MS. LOPAS: Okay. Larry, thank you for that comment. We appreciate that.

MR. HARISIS: Thank you.

MS. LOPAS: Okay. So Sandy, let's go to Steve again. And then, I know there's another person in line after Steve.

But, after Steve, Torre, we'll go ahead and go through your discussion questions, and then, we will still be open to questions and comments to everybody. So we're not shutting down questions by any means, but I do want to make sure that Torre gets to run through the discussion questions.

So Steve Mattmuller, you are open again.

MR. MATTMULLER: Okay. Great. Thank you for the additional time.

I wanted to also state in regards to

generators that we did a quick survey. There's currently about 121 sites using the gallium generator right now, and that's just for the relatively small patient population of neuroendocrine tumor patients. And to date, and not surprising at all to anyone, I don't think, there's never been an issue with these generators and there certainly hasn't been something the NRC tracks. There have been no abnormal occurrences with the use of this generator. And I wanted to put this in to help demonstrate the safety of these generators.

To change gears and to talk about lutetium-177, Lutathera that is the approved FDA radiopharmaceutical for neuroendocrine tumor patients or NET patients, N-E-T, the lutetium-177m is a contamination in this product. It's not listed on the label at all. And you typically only find it once you hold any residual waste for a long period of time after any residual lutetium-177 has decayed away, and you, then, discover you now have 177m.

So when we put the product into our recordkeeping systems, we're just putting in how much lutetium-177 we have. We don't know how much lutetium-177m we have in our product. So that complicates this whole discussion.

But also complicating that is that lutetium-177 is a very effective therapeutic radionuclide. And again, in the very near future, there will be some lutetium-177 agents for treating prostate cancer. And prostate cancer patients, as you can well imagine, is a vast, large patient population. So this is really an issue that needs to be settled sooner rather than later.

And I certainly appreciate you all looking at this issue now. Thank you.

MS. LOPAS: Okay. Thank you, Steve.

All right. And just FYI, Thomas Moore, you are next, but we are going to keep you on deck for a moment.

So Sandy, let's wait.

And we'll go back to Torre. And, Torre, if you want to move into your discussion questions, and then, we'll open up the phone lines again.

So Glenna, if you're ready to -- yes, perfect.

And, Torre, are you ready to go? And you might be muted, Torre, if you're talking.

MS. TAYLOR: I am ready. Here I am. I had to take the last of my notes there.

Okay. So we've got a few slides with

some questions that the staff have developed. Obviously, there may be other information that we need to get. So hopefully, we'll get that from you all.

So we would like your views on the different questions and any comments you have regarding the different approaches, and we have heard some of that already, and then, any other comments or suggestions that you have on updating Appendix B.

So I'm going to go through these, and Glenna is on standby to flip through the two or three slides as questions come up, so we'll have them on the screen.

So one question that we want to get views on is, is it a higher priority to update Appendix B with the Appendix C, Part 20, values versus developing a new risk methodology based on decommissioning risk? If we do develop the new risk methodology, what factors should we consider in setting values for the radionuclides? Would a tenfold reduction in Appendix B values increase any licensee's decommissioning funding requirements for those listed radionuclides there on the slide?

Next slide.

What other benefits would be gained using

one alternative over the other? Are there some things we didn't think about regarding a new risk methodology versus using the values in Appendix C, Part 20? And is one option more resource-intensive than the other for the Agreement States or for licensees in general?

And the next slide. Small print. Sorry.

If we develop a new category for Section 30.35 for these radiopharmaceutical generators, we would like to get some feedback about how we should define them and what factors should we consider in setting the requirements for the engineered confinement. And are there other regulatory requirements that we need to consider? We've got the NRC, states, and other federal agencies. State and other federal agencies were the ones that we would be less likely to know.

And then, what costs and benefits should be considered? As we go through this, we'll be looking at information about types and numbers of licensees, number of administrations per year, et cetera.

So we'd like to just kind of open it up with some inputs there for everybody, so we can take

that back with us as we start our work.

MS. LOPAS: All right. So there are our discussion questions. We will flip around and back through them, certainly, so everybody can see them. So right now, again, we just want to open up completely for all your comments, and we'll continue to take your questions because you all have been asking some great questions.

So Sandy, can we go to Thomas Moore next?

OPERATOR: Mr. Moore, your line is open.

MR. MOORE: Thank you, and thank you for the presentation.

I have a question regarding financial assurance for Part 40 licenses concerning source material. A lot of our licensees, you know, numerous licensees are purifying drinking water and doing so inadvertently concentrating uranium. And so the financial assurance section dealing with that very specifically uses the term "readily dispersible". Should we consider radionuclide material as readily dispersible or not?

MS. TAYLOR: Okay. Thank you for that. Yes, we did have that conversation in one of our Working Group meetings about the difference in how it's done in Part 40 versus Part 30. So we'll look

at that.

MS. LOPAS: Okay. So that's something we're going to take away, Torre?

MS. TAYLOR: Yes.

MS. LOPAS: Okay. Okay. And it looks like our next caller -- again, I just want to remind everybody you press *1, so press *1 on your phone to get in line to ask a question. Have your phone line unmuted by Sandy, our operator. And just a reminder to introduce yourself, to spell your name out for our court reporter, Graham. And press *1.

Let's see. Was there anything else we needed to close out with, Mr. Moore, before we move on?

MR. MOORE: No, and thank you.

MS. LOPAS: Okay. All right. So our next caller is Evan Western.

Sandy, can we hear from Evan?

OPERATOR: Evan, you may go ahead. Your line is open.

MR. WESTERN: Hi. Can you hear me? Great. Thank you. Can you hear me?

MS. LOPAS: Yes, we can.

MR. WESTERN: Okay. Great. Thanks.

I'm with Cardinal Health, and I just

wanted to touch on No. 3, the question about reducing the Appendix value, Appendix B values, for a few of those nuclides.

One of them, in particular, that stood out to me is cadmium-109, as that's an activation product in our medical production cyclotron facility. And so just as an FYI, I would imagine that getting the Appendix B updated with new values, specifically cobalt-57, would help us out in that area, but that might be offset if there were a reduction to the cadmium-109 value. So that would just be something to essentially be aware of.

The other item I would like to just mention is, again, echoing what everybody has said about the generators, particularly germanium-68. That's certainly something that we're very heavily dealing with on our side in our nuclear pharmacy. And so we would certainly be very supportive of a separate category for those types of sources.

MS. TAYLOR: All right. Thank you very much.

MS. LOPAS: Great. Yes, thank you.

MR. WESTERN: Thank you.

MS. LOPAS: Okay. So a reminder, *1 -- go ahead, Torre.

MS. TAYLOR: While we have Evan on the line still, on Question 6, do you have any thoughts right now on what factors we should consider in setting the requirements for a separate category regarding engineering confinement? Think about it. So when your opportunity for public comment comes in, be sure and comment on that.

MR. WESTERN: Definitely. Thank you.

MS. LOPAS: All right. So *1. And we don't have anybody in line right now to ask a question. So please press *1.

And I don't know if, Glenna, you wanted to move to the next slide, the next question slide, just so we can kind of refresh. Okay.

And I do want to remind folks, while we're waiting for the next question to come in, that although we have not been using the chat for comments or questions, Glenna, our Webex host, she has put a couple of links in. I think she put one link in to the PDF to the slides for today's slides. So that's an easy way to access the slides, instead of using our wonderful ADAMS system. So if you go to the chat and you just kind of scroll all the way up, I think she's put the link in twice to the slides. It should just pop open, a PDF, for you. And then, I also

included that lutetium-177 memo that we were referencing earlier. There's a link to that as well.

Okay. So *1 for questions. We will hang out for a little while, but if there are no more questions, we will probably let Torre kind of finish up with her next steps. So *1 to ask a question or to provide some additional comments.

And, maybe, Torre -- oh, here we go. Here's Steve again, Steve and Larry again. So we'll hear from Steve and Larry.

So Steve?

MR. MATTMULLER: Hi. This is Steve Mattmuller again. Appreciate the time.

I'm curious, somewhere in the -- I haven't seen it, going quickly through the slides, but is there a list of where each individual NRC staffer, what Division he's in? And I apologize, I haven't kept up with the medical team, but is there a medical team member on this Working Group within the NRC?

MS. LOPAS: There is, yes. We don't have everyone listed there. We have someone from the Risk Assessment Performance kind of group within DUWP. We have people from the Financial Assurance Branch that supports the Regions on financial assurance

decommissioning. Said is from the Medical Group. He's on the group, and we have someone from the industrial side as well, just in case some of these radionuclides may pop up in the industrial use area.

MR. MATTMULLER: Okay. Very good. Thank you.

MS. LOPAS: Uh-hum. Oh, and I should note, as we move forward in the rulemaking, there will be presentations to our Advisory Committee for the Medical Uses of Isotopes. It's a little early now, but they're aware of the rulemaking as a general notion.

MR. MATTMULLER: Great.

MS. LOPAS: Okay. All right. Larry Camper, can we hear from Larry?

MR. CAMPER: Yes. Can you hear me?

MS. LOPAS: We can. Hi, Larry.

MR. CAMPER: Hi. How are you? Thank you.

I have a comment or observation about the discussion today. In listening to a number of the questions that were raised by folks within the medical area in terms of the amount of material to be possessed and how it can be a variable, and patient load and COVID, and what have you, it struck me that

in the course of doing the rulemaking it would be of value to the community if in the statement's consideration it was explained that financial assurance is a guarantee. It's a commitment at the time of application or award that, when that license is decommissioned, there will be adequate funds available to ensure that the material in question possessed by the license can be properly cleaned up.

So remember that it's about license termination, therefore, or in those rare instances when there's some abrupt disruption in operations that leads to a premature shut down or decommissioning, that those funds have to be available. So I think that the medical community in general would benefit from that explanation as part of the statement of consideration.

And then, the other thing is this issue of the role of patient waste, does it count against possession limits or not? I think that's something that you ought to make it a point to try to clarify for them in the statement of considerations.

So just an observation from what I heard today, and hopefully, that's helpful. Thank you.

MS. LOPAS: Thank you, Larry. Those are good points. Appreciate it.

Okay. All right. So Torre, there's nobody in the queue right now to ask a question.

But please press *1, folks, if you want to make a comment or ask a question.

I'm not saying we're going to close out, Torre, but while we're waiting for more comments and questions, then, I don't know if you wanted to cover the next couple of slides.

MS. TAYLOR: Sure. So Glenna, let's go to slide 28.

Make sure I wasn't on mute there.

So the next steps, you know, we're at the beginning stages of this rulemaking. And so we're going to be developing a regulatory basis. We'll evaluate all the comments that we've received during this public meeting. And it will be published in The Federal Register for a 60-day comment period. And that timeframe will be in December of 2021 at an early date; I'm not sure. But it will be 60 days for the public to comment on the regulatory basis.

And we'll have information in about why we're doing the rulemaking, why there weren't other alternatives, the cost-benefit assumptions, and assumptions made, and all the technical information. So that would be your first opportunity for public

comment on that.

And then, the comments on that regulatory basis will be evaluated, as the staff begins working on the proposed rule. And we'll include a summary discussion with the statements of consideration on the major comments that we receive on the basis. So that will be a high-level summary, the comments and summary of staff evaluation.

It will be in The Federal Register. You can track the rulemaking in regulations.gov under that docket ID number, which is NRC-2017-0031. And that is the hyperlink to the regulations.gov page for that docket ID, if it held the link. It didn't the first time. Hopefully, it did. But you can follow the rulemaking there, and everything will be uploaded to that docket ID, as we move through the rulemaking on that.

Next slide.

These are the two main contacts. I'm from the Division of Rulemaking, Environmental, and Financial Support. I'll be the Rulemaking Project Manager and supporting Cardelia Maupin, who will serve -- she's the Senior Project Manager as well -- and she will serve as the technical lead on this rulemaking. So the two of us together will be

working with our technical Working Group and going through this process.

I'm not sure we've mentioned -- well, I think Trish did in our opening remarks -- we do have a representative from OAS, Rajwant Bedi from California. So he's on the Working Group and will be supporting us as well and looking at the Agreement State impact issues.

Next slide.

I think I'm just going to go into closing remarks. We're at the references that I've mentioned before.

MS. LOPAS: Well, Torre, let's not close out, though, because we do have more commenters. So we're not closing out.

MS. TAYLOR: Okay.

MS. LOPAS: I just wanted to give people a chance to --

MS. TAYLOR: Okay.

MS. LOPAS: Don't worry, folks. I see a few of you on the line now.

So press *1 to ask a question, and we will keep going for as long as we need. Okay.

I'm sorry, Torre, if I wasn't clear on that.

MS. TAYLOR: Oh, no, I wasn't actually technically closing out. That was just things we know at this point.

MS. LOPAS: Okay. Okay. All right.

So let's see. Sandy, can we go to our next caller who is Larry Harisis?

And I'm sorry, Larry, if I mispronounced your name again.

MR. HARISIS: No worries.

I just want to make a quick comment for Item No. 1 for questions for discussion and for higher priority. I would definitely love to see Appendix B being updated with Appendix Charlie, Part 20, values, only because, based on our research side, cobalt-57, 2 millicuries of that in our license for a possession limit accounts for one-fifth, if we're doing a sum of fractions, of the unity rule. So if we could bring that over to make it quicker, then, yes, I could actually add more research isotopes without changing everything else.

MS. LOPAS: Okay. All right.

Torre, any follow up on that? Any additional clarification, or are we good to go with that comment?

MS. TAYLOR: No, I'm good. It's good to

get that feedback as to why that would be of value.

MS. LOPAS: Okay. All right. So Sandy, we have our next caller is Rob MacDougal, actually. So if we can hear from Rob?

MR. MacDOUGAL: Hi. Can you hear me?

MS. LOPAS: Hi. We can. Hi, Rob.

MR. MacDOUGAL: Good. Thanks.

Just listening to some of the questions and comments, it seems like there might be a priority for earlier action on certainly lutetium, metastable lutetium, applications, especially if there is a drug in the pipeline, a lutetium-based drug in the pipeline, the FDA pipeline, for prostate cancer.

And I was wondering if there might be some subset of isotopes that could be considered for earlier action in a direct final rule, like lutetium or cobalt-57 or, you know, other isotopes that commenters might want to bring to our attention, to NRC's attention. I'm sorry. I say, "our attention" because I used to be the project manager for this rulemaking when I worked for NRC just a few days ago.

But is the possibility of earlier action on a direct final rule something that the staff would be willing to consider?

MS. LOPAS: Thoughts on it, Torre?

MS. TAYLOR: Well, I don't want to comment on it because I have to think about it. But, yes, we do have a direct final rule process for actions that would be of an urgent, immediate health and safety need, based on our mission or a real -- you know, something that would be very beneficial, but would not be very controversial, and what have you. So we do have a process to evaluate that, and I can bring that back to the Working Group and we can evaluate that.

MR. MacDOUGAL: Thank you.

MS. LOPAS: All right. Thanks, Rob.

Okay. I'm not seeing anybody else in the line to ask a question or to make a comment. So let's give it one last shot.

So press *1 to make a comment or ask a question.

And I'm seeing a couple of questions coming in, again, in the chat coming in about the slides. I will ask, Glenna, if you don't mind, it seems like people probably lost the link to the slides up at the top of the chat. So if you don't mind, Glenna, sending the hyperlink to the slides again in the Webex chat, that would be helpful.

And then, the other thing that a

participant noted for me is that it seems like, Torre, that the PDF of the slides did happen to lose -- all the hyperlinks were lost when it was turned into PDF. So it's not the end of the world.

MS. TAYLOR: Yes, it just makes things a little bit tougher in that people -- I mean, everything there is referenced. The ML numbers are there. So you should still be able to go to ADAMS and look up those ML numbers. We can put a link in the chat to ADAMS, and then, you can look things up that way. And then, FRNs and things like that, you just Google the FRN number; it should pop things up for you. So we apologize for that.

MS. LOPAS: Yes. So the other thing is, if there's a document you, in particular, want that's listed and you can't find it, just let me know and I can easily get it to you. Yes.

So last chance, *1. I don't see anybody right now.

I will put the ADAMS link, the link to our ADAMS system, just so everybody has that, but I'm sure most of you are probably, unfortunately, familiar with ADAMS.

And I'm seeing another question asking, if someone wants to suggest radionuclides for

reconsideration after the seminar, who is a good person to contact? So Glenna, maybe you can share that contacts slide again, if you don't mind?

And, Torre, we don't have anybody else in the queue for a question. So I will hand it back to you and your team to close it out.

MS. TAYLOR: Okay. It was a constructive meeting. I appreciate everyone's feedback. I really didn't have anything more to say than thank you for attending and I do appreciate the participation, and do look forward to comments on the regulatory basis, when that time arrives.

And I don't know if anyone on the team would like to make any comments.

MS. HOLAHAN: This is Trish Holahan.

I would just like to say thank you for participating in this meeting and it has been extremely helpful for us. And please comment on the regulatory basis when it comes out.

And thanks to the team for the work they did on this.

MS. LOPAS: All right. So with that, I think we are going to close it out.

Sandy, thank you so much.

I guess, NRC folks, please hang on the

line because I believe Sandy will put us into post-conference.

But, otherwise, everybody else can hang up and check out the chat because there are links to our slides there and some other links.

All right. Thank you all. Have a great afternoon.

(Whereupon, at 3:24 p.m., the public commenting meeting was concluded.)