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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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TELECONFERENCE

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THURSDAY, AUGUST 29, 2024

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The meeting was convened via Teleconference, at 2:00 p.m. EDT, Hossein Jadvar, ACMUI Chairman, presiding.

MEMBERS PRESENT:

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

RICHARD L. GREEN, Vice Chairman

REBECCA ALLEN, Member

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

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

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

RICHARD HARVEY, Dr.PH., Member

JOSH MAILMAN, Member

MELISSA C. MARTIN, Member

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

MEGAN L. SHOBER, Member

HARVEY B. WOLKOV, M.D., Member

John F. Angle, M.D., Consultant to ACMUI

NRC STAFF PRESENT:

CHRIS EINBERG, NMSS/MSST/MSEB, Designated Federal Official

LILLIAN ARMSTEAD, NMSS

SARAH LOPAS, NMSS/MSST/MSEB

DANIEL SHAW, NMSS

KATHERINE TAPP, NMSS/MSST/MSEB

RYAN WHITED, NMSS

BRIAN ALLEN, NRC

MARYANN AYOADE, NMSS

DANIEL DIMARCO, NMSS

CYNTHIA M. FLANNERY, NMSS

TRAVIS JONES, NRC

DANIEL SHAW, NMSS

SARAH SPENCE, NMSS

TORI ROSZKOWSKI, NMSS

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

2:03 p.m.

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

My name is Chris Einberg. I'm the chief of the Medical Safety and Events Assessment Branch. And I've been designated as the federal officer for this Advisory Committee in accordance with 10 CFR Part 7.11.

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

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

The meeting was announced in the July 12, 2024 edition of the Federal Register, Volume 89, Page 57173.

The function of the ACMUI is to advise the staff on issues and questions that arise on the medical use of byproduct material. The Committee provides counsel to the staff but does not determine

or direct the actual decisions of the staff or the Commission.

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

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

Dr. Hossein Jadvar, Chair, nuclear medicine physician.

CHAIRMAN JADVAR: Present.

MR. EINBERG: Mr. Richard Green, Vice Chair, nuclear pharmacist.

VICE CHAIRMAN GREEN: Present.

MR. EINBERG: Michael Folkert, radiation oncologist.

DR. FOLKERT: Present.

MR. EINBERG: Mr. Josh Mailman, patients' rights advocate.

MR. MAILMAN: Present.

MR. EINBERG: Ms. Melissa Martin, nuclear medicine physicist.

MS. MARTIN: Present.

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

DR. O'HARA: Present.

MR. EINBERG: Mr. Zoubir Ouhib, radiation therapy physicist. Okay. He's not present.

Ms. Megan Shober, state government representative.

MS. SHOBER: Present.

MR. EINBERG: Dr. Richard -- excuse me. Dr. Harvey Wolkov, radiation oncologist.

DR. WOLKOV: Present.

MR. EINBERG: Dr. Richard Harvey, radiation safety officer.

DR. HARVEY: Present.

MR. EINBERG: Dr. Andrew Einstein, nuclear cardiologist.

DR. EINSTEIN: Present.

MR. EINBERG: Dr. Joanna Fair, diagnostic radiologist. It doesn't appear she's present. And then Ms. Rebecca Allen, health care administrator. Okay. She also is not present.

We do have a quorum though of at least six members. Dr. John Angle, interventional

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

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

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

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

I would like to add that we are also using Microsoft Teams so that members of the public and other individuals can watch online or join via phone. The phone number for the meeting is 301-576-2978. The phone conference ID is 901692104#.

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

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

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

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

For those individuals in or on Microsoft Teams, please use the raise hand function to signal to our Microsoft Teams host, Ms. Armstead, that you wish to speak. If you have called into the Microsoft Teams using your phone, please ensure you have unmuted your phone.

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

We will announce when we are ready for the public comment period of the meeting. And Ms.

Armstead or Ms. Lopas will assist in facilitating public comments.

At this time, I ask that everyone who is not speaking to please mute your Teams microphones or phone. At this point, I would like to turn it over to Dr. Jadvar.

CHAIRMAN JADVAR: Thank you very much, Mr. Einberg. And welcome, everybody, good morning or good afternoon as the case may be and welcome to this ACMUI meeting.

At this meeting, I want to invite Mr. Richard Green who is the nuclear pharmacist and the vice chair of ACMUI who also chaired this subcommittee to present the report of the subcommittee on financial assurance requirements for the disposition of Category 1 to 3 byproduct material radioactive sealed sources. Mr. Green?

VICE CHAIRMAN GREEN: Thank you, Dr. Jadvar. Hello. My name is Richard Green. I am the chairperson of the ACMUI Subcommittee on Financial Assurance Requirements for Disposition of Category 1 through 3 Byproduct Material Radioactive Sealed Sources.

I'm pleased to be able to present our subcommittee's final report today.

Next slide, please. I would like to acknowledge the outstanding efforts of the members of the subcommittee that included Ms. Rebecca Allen, Dr. Richard Harvey, Mr. Zoubir Ouhib and Dr. Harvey Wolkov. Our efforts were assisted by Daniel Shaw as the NRC staff resource.

Next slide, please.

The subcommittee's charge was to review the U.S. Nuclear Regulatory Commission's staff draft regulatory basis document on Financial Assurance Requirements for Disposition of Category 1-3 Byproduct Material Radioactive Sealed Sources and to provide feedback and recommendations.

Next slide, please. First, we'll start off by reviewing some of the regulatory concerns that brought about this request for this regulatory basis document.

Many licensees found themselves unprepared for the costs associated with the disposition of some Category 1-3 radioactive sealed sources.

Some licensees had inadequate financial assurance to support the disposition of Category 1-3 radioactive sealed sources due to bankruptcy or other unforeseen circumstances.

There currently is no regulatory incentive to provide the timely disposal of disused Category 1 through 3 radioactive sealed sources. In some cases, these sources are stockpiled and could have less than adequate security.

When a licensee is unable to through bankruptcy or because of abandonment, the disposition costs for some Category 1 through 3 radioactive sealed sources is borne by the federal government and taxpayers instead of the licensees who obtained value from the use of these sealed sources.

Next slide, please. Because of these regulatory concerns, the U.S. Nuclear Regulatory Commission is considering revising the requirements in Title 10 of the Code of Federal Regulations 30.35, Financial Assurance and Recordkeeping for Decommissioning. The rulemaking would establish new decommissioning financial assurance requirements for the disposition of Category 1 through 3 byproduct radioactive material sealed sources.

Next slide, please. When I personally first read this proposed governance document discussing Category 1, 2 and 3 radioactive sealed sources, I really didn't know what these categories were. I think it's worth pausing for a moment to

familiarize ourselves with the definition for these three classes of sealed sources.

If Category 1 sealed sources were not safely or securely managed, they are likely to cause permanent injury to a person who handles them or who otherwise was in contact with them for more than a few minutes.

It would probably be fatal to be close to this amount of unshielded material for a period of a few minutes to a few hours, and these sources are typically used in radio thermal generators, irradiators and radiation and teletherapy units.

Next slide, please. Category 2 sealed sources, if not safely or securely managed, could cause permanent injury to a person who handled them or was otherwise in contact with them for a short time of minutes to hours.

It could possibly be fatal to be close to this amount of unshielded radioactive material for a period of hours to days. These sources are typically used in industrial gamma radiography, high- and medium-dose rate brachytherapy and radiography.

Next slide, please. Category 3 sources, if not safely or securely managed, could cause permanent injury to a person who handled them or was

otherwise in contact with them for hours.

It could possibly, although it is unlikely, be fatal to be close to this amount of unshielded radioactive material for days to weeks. These sources are typically used in fixed industrial gauges such as level gauges, dredger gauges, conveyor gauges, spinning pipe gauges and well-logging gauges.

Next slide, please. The NRC's current regulations found in 10 CFR 30.35 require a fixed dollar of financial assurance or a decommissioning funding plan for licensees who possess byproduct material with a half-life greater than 120 days and at activity levels above certain thresholds.

However, these thresholds for sealed byproduct material are such that many licenses possessing Category 1 through 3 byproduct radioactive material sealed sources are not required to provide financial assurance for decommissioning.

Next slide, please. The Commission approved the initiation of this rulemaking with Staff Requirements Memorandum, or SECY-16-0115, entitled Staff Requirements Rulemaking Plan on Financial Assurance for Disposition of Category 1 and 2 Byproduct Material Radioactive Sealed Sources. And this was dated on December 8, 2021.

The next step in the NRC rulemaking process is the development of a regulatory basis document that serves as a precursor to a proposed rule, which brings us to today's document that this subcommittee has reviewed.

Next slide, please. This regulatory basis document summarizes the current regulatory framework, describes the regulatory issues and evaluates alternatives for establishing financial assurance requirements.

This regulatory basis also includes a cost benefit analysis that considers impacts to the NRC, to Agreement States, and to licensees for each alternative.

This is a very extensive document. I believe it was over 85 pages in length. Today, we will be doing a brief review. And I would encourage individuals to download and read the actual document.

Next slide, please. I would just point out that licensees that are subject to 10 CFR Parts 50, 52, 72, 76 and 10 CFR Part 70, Subpart H, would be exempt from this rulemaking for the facilities and activities covered under those licenses.

These licensees are already required to prepare a decommissioning plan and to demonstrate

sufficient financial assurance for decommissioning those facilities, including the disposition of any Category 1 through 3 byproduct radioactive material sealed sources.

Next slide, please. In evaluating the financial impact considerations, the following entities were considered in these evaluations. the cost to the NRC to implement. The cost to the NRC operations staff. Cost to Agreement States to implement proposed regulations. Cost to Agreement States to operate the program. Cost for the industry or licensees to implement the regulation. And the cost that may be borne by other government operations, such as the Department of Energy and the National Nuclear Security Administration.

Next slide, please. So, in response to SECY-16-0115, Rulemaking Plan on Financial Assurance for the Decommissioning of Category 1, 2 Byproduct Material Radioactive Sealed Sources, that was dated December 8, 2021, the NRC staff has identified several rulemaking alternatives.

We shall briefly discuss these alternatives today. These can be referred to as Alternatives 1, 2, 3, 4, 5, and there are three hybrid approaches known as 6a, 6b and 6c.

Next slide, please. Alternative 1 is maintaining the status quo. This considers no changes to the current process for assessing a license's decommissioning funding assurance requirements. The status quo is the baseline from which the staff evaluated the five other alternatives.

Next slide, please. Alternative 2 is financial assurance values that are based on device type and disposition pathway.

Next slide, please. Some possible advantages of this methodology include the following. It leverages extensive information collected and analyzed by the NRC staff to assign realistic decommissioning for national assurance requirements across a broad range of devices.

It links these DFA requirements to radiological risk, as represented by the 10 CFR Part 37 and the IAEA Code of Conduct risk-based categories.

It would be a simple implementation for many licensees requiring sources or devices that are assigned a fixed DFA financial amount.

It would provide a DFA estimate tailored to the final disposition scenario for some devices,

for example the disposition through the DOE or the NNSA or a commercial licensed low level disposal facility.

It would reduce the risks associated with under- or overpayment of DFA by tailoring these required DFA amounts to estimated disposition costs.

It would more aggressively estimate DFA requirements compared to Alternative 3, which assigns a fixed DFA amount based on the source category alone.

It would impose less burden on licensees and regulatory staff than Alternative 5, which requires a DFP from each licensee.

Next slide, please. And there are some potential disadvantages as well. It has greater complexity than other alternatives and would result in greater regulatory costs for the NRC, for Agreement States and licensees compared to the staff's recommended alternative, which is Alternative 6b.

It would require additional education and training efforts during the initial implementation phase.

It includes fixed amounts and equations used to calculate the DFA that would become outdated over time and would require necessary periodic updates.

It bases fixed DFA amounts on averages for groups of devices that may not accurately represent the depositioning costs for all individual cases.

Next slide, please. This brings us to Alternative 3, Fixed Financial Assurance Based on Source Category Alone.

Next slide, please. The advantages of this methodology include the following. This would tie the DFA requirements directly to the radiological risk, as represented by the 10 CFR Part 35 and IAEA Code of Conduct risk-based categories.

It would provide for simple implementation. And licensees that elect to use the fixed DFA amounts in Table 2 would result in less regulatory burden for both licensees and regulatory staff.

Next slide, please. And there are some potential disadvantages as well. This methodology does not link DFA requirements directly to the cost of source depositioning. So, the specified DFA amounts will significantly over- or underestimate actual costs for many dispositioning scenarios.

It is expected that many licensees would opt for a DFP in instances where the DFA amount is

overestimated, increasing the burden on licensees as well as regulators.

There is perhaps an increased regulatory risk that the DFA amount will be inadequate to provide for device disposition in cases where the fixed DFA value is an underestimate.

This includes fixed DFA amounts that would become outdated over time and will also require periodic updating.

Next slide, please. Now Alternative 4, Financial Assurance Determined by a Parametric Formula. In my first read of the proposed regulatory basis, I made a trip to the dictionary to look up the word parametric. It is defined as of, or relating to, a parameter, mathematical or statistical variable.

Next slide, please. Advantages of this methodology could include the following. This method would tie the DFA requirements to radiological risk, as represented by the 10 CFR Part 35 and the IAEA Code of Conduct risk-based categories. It would increase

parametric factors for sealed sources with increasing radiological risk.

It has parametric factors based on key

variables that drive disposal costs. The methodology is relatively simple to use and relies on source activity and disposal options provided by the applicant or licensee.

It has parametric factors based on recent 2023 disposal cost estimates that abet for a limited group of Category 1 through 3 radioactive sealed sources and devices.

The DFA requirements are adjustable over time by adjusting their parametric factors, such as the parameters that can be adjusted to increased disposal costs based on changes in the consumer price index or disposal rate schedules.

Next slide, please. Potential disadvantages in Alternative 4 were evaluated. These include the selection of parameter values that were based on the limited data set, and the NRC staff was unable to validate their parametric model for device types that were dissimilar from those used to develop this model. Consequently, their parametric formula could significantly over- or underestimate disposition costs for some types of devices.

It has greater complexity than other alternatives, which would result in greater regulatory costs for the NRC, for Agreement States

and licensees compared to the staff recommended alternative, which is Alternative 6b.

It would require periodic review and update of parametric factors by the regulator, such as

labor, transportation and disposal costs that may change frequently, which would result in an increased burden on the licensees and regulators, as resources would be needed to periodically review each license, update the DFA calculation, and adjust the associated DFA amounts.

It would require additional education and training efforts during the initial implementation period. This uses parameter values based on commercial disposal estimates and limited actual device disposal experience.

Next slide, please. Now Alternative 5, Financial Assurance Based on a Decommissioning Funding Plan. Next slide, please. The advantages of this methodology could include the following.

This would provide an accurate assessment of the DFA requirements for source and device disposition that considers a license's unique circumstance.

It would be adaptable to the diverse

types of licensees that use for Category 1, 2 and 3 byproduct materials radioactive sealed sources. This is adjustable over time and can be updated as those licenses add or remove sources or devices from their license or to account for changing disposition costs.

It may provide a cost savings for some licensees. For example, if a fixed DFA amount is specified by the NRC, that represents an overestimate.

Next slide, please. Potential disadvantages were also evaluated. It would result in the highest implementation costs for the NRC, Agreement States and licensees compared to other alternatives due to the need for internal preparation or review and periodic updates to DFPs for all affected licenses.

It imposes an unnecessary burden on licensees and regulators if radioactive sealed sources or device disposition costs can be adequately estimated through another method, such as a fixed DFA amount.

Next slide, please. Alternative 6a, 6b and 6c are hybrid approaches that combine Alternatives 2, 3 and 5.

Next slide, please. Advantages of this methodology include the following. For all variations this would leverage extensive information collected and analyzed by the NRC staff to assign realistic fixed DFA amounts for many common radioactive sealed sources and devices.

All variations link DFA requirements to radiological risk, as represented by the 10 CFR Part 37 and IAEA Code of Conduct risk-based categories.

All variations provide a simple approach using fixed DFA amounts for most affected licensees, while requiring DFPs in more complex scenarios in which disposition costs are expected to vary significantly.

All variations result in lower costs for licensees, the NRC, the Agreement States compared to Alternatives 2 through 5.

Alternative 6c has the lowest cost followed by 6b and Alternative 6a.

Alternative 6b is informed by radiological risk by focusing on sources subject to Part 37 physical protection requirements. And all variations provide licensees that are eligible to use a fixed DFA values with the flexibility to prepare a DFP if they so choose.

Next slide, please. Potential disadvantages were also evaluated. This alternative uses fixed DFA amounts that would become outdated over time and requires periodic updates.

It does not include some features of Alternative 2, such as a DFA estimates that are tailored to the final disposition scenario for some devices, for example disposal through the DOE or NNSA or commercial low level waste disposal facilities.

There is a basis of fixed DFA amounts on averages for groups of devices that may not accurately represent the depositioning costs for all individual cases.

Next slide, please. This regulatory basis does not do the following. It does not provide background information on policies, laws and regulations that are related to the issue. It does explain how a change in the regulations could resolve the issue.

It identifies different approaches that could address the regulatory issue and evaluates the cost and benefits of the rulemaking and the alternatives.

It provides scientific, policy, legal and technical information used to support the evaluation.

It explains limitations on the scope and quality of the regulatory basis, such as known uncertainties in the data or method of analysis and discusses stakeholder interactions and views, to the extent that they are known.

Next slide, please. Circling back to something we discussed earlier, having a regulatory basis that requires financial assurance for the disposition of these Category 1-3 byproduct material radioactive sealed sources would accomplish several things.

It would help ensure that the affected licensees are prepared for disposition of radioactive sealed sources and will facilitate disposition of unused sealed sources.

It would help ensure adequate financial resources are available to support radioactive sealed source disposal in the event of unforeseen circumstances, such as licensee bankruptcy.

It would help ensure dispositioning costs for Category 1 through 3 radioactive sealed sources that are borne by those who receive the associated economic benefit of source utilization, and it would address recommendations on the issue provided by the Government Accountability Office, the Interagency

Radiation Source Protection and Security Task Force as well as other groups.

Next slide, please. In summary, the NRC staff recommends Alternative 6b because the staff determined that it provides the best balance of managing these radiological, financial and regulatory risks.

As described in Section 4.6, the staff estimates that under Alternative 6b approximately 90 percent of licensees would be able to use a table of fixed DFA amounts, which would limit the regulatory burden for both licensees and the regulatory staff.

As explained in further detail in Section 4.6, the NRC staff developed these fixed DFA amounts based on multiple sources of information to ensure adequate funding would be available to disposition sources without imposing an unnecessary burden on licensees. Because staff sought to develop the best estimates of the disposal costs, the staff expects Alternative 6b should limit financial risks for both regulators and licensees that could result from significant variation between DFA amounts and actual disposition costs.

Next slide, please. We have just conducted a very brief review of an extensive

document. A document that is 85 pages in length that is replete with financial data and other variables.

I would strongly encourage licensees and professional societies and associations to read through this document.

The subcommittee made several general comments on the proposed regulatory basis document. These include the general opinion that the regulatory basis document was well-developed and effectively outlined the regulatory alternatives.

The subcommittee supports the recommendation that the Agency conduct a rulemaking as described in Alternative 6b of this regulatory basis document.

The subcommittee suggests that a historical review of how financial assurance requirements have changed prior to the current regulations that are in place would be helpful.

And the subcommittee suggests that a table of examples would be helpful to licensees as well as regulators.

Specific comments include that a definition should be provided for a self-shielded irradiator.

Next slide, please. Members of the

subcommittee feel that as representatives of the medical community, we feel this regulatory basis will assist licensees to plan ahead and to make full weighted financial decisions as they contemplate acquiring new technology and sealed sources.

All of us on the subcommittee thought of our respective medical facilities where we work. We spoke with our colleagues regarding this topic. We all agree that our facilities had some initial work prepared for disposition and cessation activities, but

additional focus would be appropriate.

Next slide, please. Just a few notes on the implementation time line and process.

The estimated compliance date for the rule is 2028, by which time the NRC licensees must comply.

Agreement States will have three years to promulgate the rule. This assumes the implementation will be spread evenly over the period of 2028 through 2030. These dates will be subject to the approval of the proposed rule and final rule.

The public will have another opportunity to comment after the proposed rule is issued.

Next slide, please. The following five

slides show all of the abbreviations and acronyms used in this presentation as well as the draft regulatory guide itself. Thank you very much for the opportunity to present the subcommittee's report.

Dr. Jadvar, I will return it back to you.

CHAIRMAN JADVAR: Thank you very much, Mr. Green for that very comprehensive report. I also want to thank Ms. Allen, Mr. Ouhib and Drs. Harvey and Wolkov for their participation and help with the subcommittee and also Mr. Shaw as the NRC staff liaison to this subcommittee.

So at this time, I want to ask the subcommittee members if they have any questions or comments regarding this report.

MR. EINBERG: Dr. Jadvar, before you get into the discussion, I just wanted to note that Dr. Fair and Ms. Rebecca Allen have joined the meeting, and they are available for a conversation as well and participation. Thank you.

DR. FAIR: Yes, thank you. I'm here.

CHAIRMAN JADVAR: Thank you. Thank you. All right. So, again, any comments or questions from the subcommittee members regarding this report? Hearing None, I move to ask if there is any questions or comments by the ACMUI members. I see Ms. Shober.

MS. SHOBER: Yeah, I was wondering if, Lillian, can you go back to the slide that had the subcommittee recommendations on it?

VICE CHAIRMAN GREEN: I think that would be Slide 34. No, it would be two more slides in your deck, Lillian. Here we are.

MS. SHOBER: Thank you. My question for the subcommittee is regarding General Comment Number 4, when you say a Table of Examples would be helpful, what information were you wanting examples for -- examples of what? I guess I'm not sure what that comment is referring to.

VICE CHAIRMAN GREEN: I think if we were just to list some devices or some sealed sources, industrial density gauge or a gamma knife, a make and model, you know, just something that they can see and say, yeah, that's similar to what we have and let them easier work their way into the tables to look at the information.

MS. SHOBER: So, I thought that information was included already in Table 6. But if you're looking for something else, that's great. I just was trying to get clarity on what was missing.

VICE CHAIRMAN GREEN: Megan, I think it might be possible to do an example of city-wide

hospital that has Device A, Device B and Device C, so that this is their inventory of devices and sealed sources. So, you know, with this scenario there'd be assigned fee for A, assigned fee for B and assigned fee for C whereas another example might show that it would be more cost-effective to do a full blow decommissioning funding plan as opposed to the line-item device costs. Does that make sense?

MS. SHOBER: Okay.

CHAIRMAN JADVAR: Okay. Thank you. So, I see Dr. Einstein has his hand up.

DR. EINSTEIN: Yeah. Thank you, Mr. Green for a really comprehensive overview of the different alternatives and a pretty clear explanation of the general approaches.

My understanding is that with a 7 percent NPV the costs associated with Alternative 6b would be $44 million. I can't say that I completely understand where those costs are incurred and what they effectively gain in comparison to other approaches. Could you or someone else better or in more detail explain the economics of this and the $44 million in particular?

VICE CHAIRMAN GREEN: I would have to state that that's going beyond my depth. Do we have

any member of the NRC staff that can assist us here?

MR. SHAW: Hey, good afternoon. This is Mr. Shaw with the NRC. I also cannot speak to the total cost of 44 million. But we can speak to the cost per device as outlined through the alternative of 6b, and that would be the cost per device that they have listed in the table there.

So, the reg basis, again, to summarize for option 6b or Alternative 6b, provides a decommissioning funding assurance cost per device. And that device is theoretically per activity as well.

So, there is that associated cost. We could speak to that. But the total cap of 44 million, I'm not able to speak to that.

DR. EINSTEIN: And not to be difficult, but I think it sort of -- since we're making a judgment, that goes on the -- I don't know, the regulatory basis but also on the economics of this, I think it would be helpful to better understand the economic decision which we're voting on.

VICE CHAIRMAN GREEN: Dr. Einstein, I think there are two things we need to clearly distinguish. There will be a regulatory burden for a licensee to fill out paperwork, for the NRC to

review the paperwork and accept the paperwork. That is a transactional cost. That's new if this regulatory basis goes forward and the rulemaking goes forward.

What is not changing is that licensees need to get rid of sources they are no longer going to use. And they are bearing those costs today. And that's part of that $44 million that you're describing is you still need to get rid of the source.

And so, this process facilitates their being cognizant of the need to decommission, cognizant of the need to dispose and plan for that disposition costing as they begin to acquire the device, not leaving it at the last-minute saying, oh, my gosh. What do we do now?

So that big value, much of that, if not most of that, is costs currently borne by licensees to get rid of sealed sources today.

DR. TAPP: And that is helpful. I pulled the regulatory analysis, and it does break it down. It is a very long document, regulatory analysis, with the total cost. You would have to go through to see each line item and have to read the whole report.

But there is a statement on Page 48 of the regulatory analysis that says that three main

cost contributors to the 6b option are the industry self-shift, which is what Mr. Green just identified. It's 52.1 million. And this is industry as a whole, not just medical, but everything the NRC regulates and Agreement States.

Industry implementation, which is about 30 million, again and then industry observation about 5.6 million.

This is offset by some gains. You really have to read the entire draft report to understand how it all rolls together in a regulatory analysis because there are gains and losses. But those are the three main drivers.

Again, this is just not medical industry. This is all industry. And I'm Dr. Tapp from the medical team. We also -- I don't know if Ryan Whited, who is the PM, I saw you come off mute for a second. But you had something to add here as well.

MR. WHITED: Yes. Thank you so much. So, my name is Ryan Whited. I am the NRC project manager. I think you captured though the summary of the components of cost really well.

I was looking at the document myself. And there is a table, it's Table 8, in the document that starts on Page 36 that breaks down the costs of

each of the alternatives that the staff evaluated.

And, again, you know, the main components of those costs really are the costs for the regulators, both NRC and the Agreement States to promulgate the rule, build up the infrastructure and then in the field, you know, as the rule's implemented, do inspections and whatever field implementation is needed for that.

So, you have those costs for the regulators, both the NRC and Agreement States. And then the industry costs. And the industry costs are things like doing the initial analysis, taking inventory of what they have and using the table or developing a DFP to come up with the financial assurance amount. Then they have to go out to a bank or other financial institution to get an instrument. And there is an initiation fee for that. And there is also an annual cost associated with that.

And then there is a periodic re-looking at the financial assurance. For example, if they have a DFP, they've got to reassess that every three years. So, there will be recurring costs associated with that across industry.

So, you know, those are the major components. That Table 8 in the document does break

them down on a pretty granular basis. And you can see, you know, for example, for 6b, that 44 million figure is the bottom line in Table 8.

DR. EINSTEIN: Yeah. That's where I got that from.

MR. WHITED: Yes. Now I believe we also have Greg Trussell on the call. And Greg is a cost analyst by trade. So, if there are more detailed questions, Greg might be able to help with that. But at a high level, I think we kind of covered the major components of that $44 million cost.

DR. EINSTEIN: So, the NRC effectively would be paying $1.8 million for the selection of Option 6b, and the Agreement States would be paying $6.7 million, and industry would bear the brunt of the costs?

MR. WHITED: I'm looking at the table. Yeah, so the reason for -

DR. EINSTEIN: And then the DOE would benefit a lot, if I'm understanding correctly.

MR. WHITED: So, a couple things. So, you know, the reason the Agreement States total is higher is because the Agreement States have a lot more of the licensees now that there are so many more Agreement States compared to the NRC licensees.

The reason DOE benefits, and that's for all the alternatives, is, you know, they have been operating a couple programs designed to recover and disposition sealed sources.

One is their offsite source recovery program, which handles the high, kind of Cat 1 and 2 high activity sources. And they also have what's called the SCATR program, which they operate through CRCPD to handle the lower activity sources.

You know, there is a discussion in the paper about if we implement these new requirements and we have licensees who are now providing financial assurance and considering the full life cycle costs of these sources, they should rely less on those DOE programs and that would give DOE the opportunity to reduce the scope of those programs. And so that's where you see that benefit to DOE from implementing this rulemaking.

DR. EINSTEIN: Okay.

CHAIRMAN JADVAR: Thank you all for this very nice discussion. I think Melissa Martin has her hand up if I'm, correct?

MS. MARTIN: Thank you, Dr. Jadvar. The question that has come forward, we have been talking about very high-level costs, and high-level

discussions. Is there a presentation or a possible breakdown as an example for -- I'll bring it down very simply, a medical facility that is looking to obtain an HDR unit. They've never had one.

Is there a proposal somewhere that says what it would actually cost them in these new fees compared to what it would cost them what would they be paying currently under the current set up, what it would cost under the new fees because this will all factor in to medical facilities that are making decisions as to whether to add these brachytherapy sources to their facilities or not.

And I realize this is a granular question, but I think somewhere we need that actual breakdown to real life examples because this is what the hospitals need to know.

VICE CHAIRMAN GREEN: Melissa, I think that's why we, as a subcommittee, suggested that there be some examples, such as you are describing, provided.

It would be hard to say what the costs are going to be currently borne by the licensee. They are going to acquire that device and may not be looking forward to 15 years from now when it needs to get retired.

And this whole process will require them to focus, not just on the new thing under the Christmas tree, but 15 years from now when it's lived its life, how to get rid of it and what the cost to be borne.

So, I think most of the costs are going to be borne already, but this just focuses their attention on the end-of-life cycle and not the new sparkly thing.

MS. MARTIN: Thank you.

CHAIRMAN JADVAR: Thank you. And I think Ms. Shober has another question.

MS. SHOBER: Yes. Thank you. Megan Shober. I have just a comment on Melissa's question. To speak to the HDR situation specifically, they would not be subject to this regulatory change because iridium-192, the half-life is less than 120 days. And that's outside the scope of financial assurance the way the regulations are currently and with the proposed changes. So, it would not impact HDR facilities.

MS. MARTIN: You just made my day. Thank you very much.

CHAIRMAN JADVAR: Okay. Thank you, Megan. Okay. Any other comments or questions by

the ACMUI members? Okay. Moving on to any additional comments or questions by the NRC staff? Hearing None, so I guess at this time I'm going to ask the help of Ms. Sarah Lopas to navigate us through the potential questions from the remote attendees.

MS. LOPAS: Sure. So, at this point in time, I would ask people that are joining us via Teams to use the raise hand function. So, you just need to click once on the little raise hand function and that will bring you to the top of the list so I can see that, you know, you will be able to unmute your microphone.

And if you have joined us on a cell phone, all you need to do is press star 5 on your cell phone and that will raise your hand, that will show me. I see Dr. Wallner has his hand raised. Go ahead, Dr. Wallner, you can unmute yourself and start by introducing yourself, please.

And you will have to unmute yourself. So, click on the microphone, Dr. Wallner. And I hope that will work for you. All right. Dr. Wallner, I see you that you should have access to your microphone. So, try it one more time. I am assuming there is some sort of issue going on here. But you do have to click once on the microphone icon to unmute

yourself. I cannot unmute you.

Let me try one more thing for you, Dr. Wallner. I am going to try to switch your status. I am going to send you back as an attendee and then re-promote you, and we'll see if that works. Okay. Now I'm going to scroll down and find you. Hopefully, I can find you.

Hang on a second. Okay. Now try to go ahead and enable your microphone or unmute yourself. See if that works. Dr. Wallner? Because I am seeing you there, and I am seeing that your mic is enabled. Let me try this one more time.

All right. I just disabled and then enabled your microphone again. So, see if you're able to unmute yourself Dr. Wallner.

Okay. I apologize that this is not working. Dr. Wallner, the last thing I will ask you to do is to maybe exit out of the Teams meeting and then rejoin if you want to give that a try and then we'll try you again if that's okay. But we have time to wait for you.

All right. For other folks, anybody else want to give it a whirl and see if their microphones work? Just use the raise hand. Press once on the raise hand button. If you're on the phone, you press

star 5.

And I'm not seeing any other raised hands, but we will wait for Dr. Wallner to rejoin us. Okay. Josh, go ahead, please.

MR. MAILMAN: Yeah, it's less of a comment, but more of a fill time while we're waiting. So, first of all, thank you for this presentation, Richard. It's a pretty complex topic, and I really enjoyed the overview.

I am especially thinking forward to not just find the bright shiny equipment now but also figuring out how we properly dispose of them or safely dispose of them 15, 16 years from now because it's just too easy to buy things now and not think of what we're going to do with it later.

So, I really appreciate -- I know this was a really complex topic. And thank you for the overview that you provided.

MS. LOPAS: All right. And I am not seeing that Dr. Wallner has rejoined us yet so. Let's see.

CHAIRMAN JADVAR: Maybe another time filler while we wait for Dr. Wallner.

MS. LOPAS: Yeah.

CHAIRMAN JADVAR: Richard, can you just

very briefly mention the major differences between 6a, 6b and 6c. Because in the presentation, 6b was presented very nicely with advantages and disadvantages, but 6a and 6c were not -- I don't think they had any slides.

VICE CHAIRMAN GREEN: Let me see if I can get to that.

CHAIRMAN JADVAR: By the way, this was Hossein Jadvar asking.

VICE CHAIRMAN GREEN: Let's see if I can find that first. Okay. That's going to be on Page 20 of the document. Let's slide down to 20 really quick.

DR. FOLKERT: And this is Mike Folkert. It looks like in the meantime, Dr. Wallner is on the list now. I see him -- Paul Wallner under five further down.

MS. MARTIN: That's not Dr. Wolkov.

VICE CHAIRMAN GREEN: So, Dr. Jadvar, the alternatives 6a and 6b and 6c are hybrid approaches that combines 2, 3 and 5. So there's a fixed DFA amount that are provided for many common sources while other instances that will force the licensee to prepare a DFP. So 6a applies to all licenses possessing Category 1-3 byproduct material

radioactive sealed sources.

6b applies to only Category 1-3 licenses that are subject to physical protection requirements of 10 CFR Part 35. And 6c applies to licenses possessing only Category 1 or 2 byproduct material radioactive sealed sources that are subject to the physical protection requirements. So, there are the nuances between the a, b and c.

CHAIRMAN JADVAR: Perfect. Thank you so much.

MS. LOPAS: Okay. Dr. Wallner, let's try your microphone again. My fingers are crossed. All right. Let's see. Let me try one more time. Let me try that trick of switching your status. And Dr. Wallner, if you don't mind raising your hand for me again so that I can easily identify you. There you go. Great. I like that you can at least hear me.

All right. So, I do see that your microphone is enabled, but I'm just not sure why you are unable to unmute yourself.

So let me pull up the meeting information quickly. Dr. Wallner worst case scenario, would you be amenable to calling in on the cell phone if you're -- if you'd like to do that. If you have a pen

available, I can give you the phone number right now. It's also available on the meeting notice. But the phone number is 1-301-576-2978. That's 301-576-2978 and then you'll have to enter a conference ID, which is 901692104#, 901692104#.

And so, I suggest maybe trying to call in on your cell phone potentially. And we will see if that works. Lillian, maybe it would be helpful just to flash to the very first slide, the beginning slide, where it does list the phone number just in case anybody else is having any issues with microphones.

And in the meantime, if anybody else would like to make a comment, just try to raise your hand, hand raise icon, hit that once.

All right. I think I may -- Dr. Wallner did you just pop on? Are you 23 -

DR. WALLNER: I did. Thank you all for your patience.

MS. LOPAS: Finally. Yeah.

DR. WALLNER: I must apologize. There is something wrong at one of our ends, either mine or yours.

MS. LOPAS: Yeah.

DR. WALLNER: I just have a very brief comment. It's Paul Wallner, W-A-L-L-N-E-R,

representing the American College of Radiology. I want to commend the staff and the subcommittee for the work. I think it's a Herculean effort.

If there is final rulemaking that does relate to Alternative 6b, which I think is okay, I think there should be built into the rulemaking though a fixed interval for review of the tables, the financial data on the tables. And I commend the fact that perhaps 90 percent of licensees could use those tables.

But there should be a fixed period for review. And there should be some method by which an interim analysis or interim appeal could be initiated if there is some significant change in cost of disposal.

VICE CHAIRMAN GREEN: I think those were all very good points. Thank you for bringing them forward. I think those are things that I think the public should formally comment on.

I don't think we'll revise the ACMUI subcommittee report, but I think those are very valid points and should be brought out and clarified. Thank you.

DR. WALLNER: Thank you.

MS. LOPAS: Okay. I'm going to do a last

call for any public comments with the hand raise icon or if you're on the phone, you press star 5 to raise your hand.

And I'm not seeing any, so ACMUI, I will hand it back to you all.

CHAIRMAN JADVAR: Thank you, Sarah, very much. So, I think at this time, the last piece is to finalize the subcommittee's report. And I want to ask for a motion for acceptance of the subcommittee's report.

DR. HARVEY: This is Dr. Richard Harvey. I would be happy to make that motion.

CHAIRMAN JADVAR: Thank you, Richard. Go ahead.

MS. MARTIN: This is Melissa Martin. I second that motion.

CHAIRMAN JADVAR: Okay. Wonderful. All in favor say aye.

(Chorus of ayes.)

CHAIRMAN JADVAR: Thank you. Is there any opposed?

(No audible response.)

CHAIRMAN JADVAR: Any abstention or recusals?

And finally, is there any dissenting or

deferring views or comments? Hearing None, the subcommittee report is finalized and approved by the ACMUI.

I want to again thank Richard Green and all the other subcommittee members and the NRC staff and finally also Mr. Einberg for today's meeting.

And unless there is anything that Mr. Einberg or anybody else wants to say, we can go ahead and adjourn the meeting.

MR. EINBERG: Yeah, you know, thank you, Dr. Jadvar. Yeah, no, I would also like to echo your sentiments and thank the subcommittee, the ACMUI staff members, the NRC staff and then also Sarah Lopas for facilitating this and so excellent discussion, and the members of the public and Dr. Wallner for your comments.

So, thank you so much. And I think we can go ahead and adjourn the meeting.

CHAIRMAN JADVAR: Thank you so much. Meeting is adjourned. Bye-bye.

(Whereupon the above-entitled matter went off the record at 3:10 p.m.)