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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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FRIDAY,

JUNE 24, 2016

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The meeting was convened via teleconference, at 3:00 p.m., Philip O. Alderson, M.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

PHILIP O. ALDERSON, M.D., Chairman

FRANCIS M. COSTELLO, Agreement State Representative

VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

RONALD D. ENNIS, M.D., Radiation Oncologist

STEVEN R. MATTMULLER, Nuclear Pharmacist

DARLENE F. METTER, M.D., Diagnostic Radiologist

MICHAEL O'HARA, Ph.D., FDA Representative

CHRISTOPHER J. PALESTRO, M.D., Nuclear Medicine Physician

LAURA M. WEIL, Patients' Rights Advocate

PAT B. ZANZONICO, Ph.D., Vice-Chairman

Non-Voting: ZOUBIR OUHIB

Non-Voting: RICHARD GREEN

NRC STAFF PRESENT:

PAM HENDERSON, Deputy Director, Division of Material Safety, State, Tribal and Rulemaking Programs

DOUGLAS BOLLOCK, ACMUI Designated Federal Officer

SOPHIE HOLIDAY, ACMUI Alternate Designated Federal Officer and ACMUI Coordinator

COLLEEN CASEY, RIII/DNMS/MLB

SAID DAIBES, Ph.D., NMSS/MSTR/MSEB

MICHAEL FULLER, NMSS/MSTR/MSEB

ROBERT GALLAGHAR, RI/DNMS/MB

LATISCHA HANSON, RIV/DNMS/NMSB-B

DONNA-BETH HOWE, Ph.D., NMSS/MSTR/MSEB

ERIN KENNEDY, RIII/DNMS/MLB

GRETCHEN RIVERA-CAPELLA, NMSS/MSTR/MSEB

JIM SHAFFNER, NMSS/DUWP/LLWB

TOYE SIMMONS, RIII/DNMS/MLB

MICHELLE SMETHERS, NMSS/MSTR/MSEB

KATIE TAPP, Ph.D., NMSS/MSTR/MSEB

RYAN WHITED, NMSS/DUWP/LLWB

JACK WHITTEN, RIV/DNMS/FCDB

MEMBERS OF THE PUBLIC PRESENT:

DAVE ADLER, American Society of Radiation Oncology (ASTRO)

JEFFREY BRUNETTE, Mayo Clinic

DAVID CLOSE, National Physics

ROBERT DANSEREAU, New York State Department of Health

SCOTT DUBE, Baycare

HUGH EVANS, Eckert & Ziegler Radiopharma, Inc.

JORDAN FAHLE, Alpine Group

SANDRA GABRIEL, International Atomic Energy Agency

PHILIP GRIFFIN, Utah Division of Radiation Control

ERIC HAVILAND, Baystate Health

STANLEY HAMPTON, Eli Lilly and Company

JIM HARVEY, NorthStar Medical Technologies, LLC

GREGORY HODGES, Overlook Medical Center

LINDA KROGER, University of California Davis Health System

KAREN LANGLEY, University of Utah

RALPH LIETO, St. Joseph Hospital

STEVE MARSH, Baystate Health

RICHARD MARTIN, American Association of Physicists in Medicine

MATTHEW MILLER, *unaffiliated*

MICHAEL OUMANO, Baystate Health

ANDREA RAVARD, Cedar Sinai Medical Center

GLORIA ROMANELLI, American College of Radiology

MICHAEL SHEETZ, University of Pittsburgh

DEBBY STEVA, University of Virginia

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Financial Assurance Requirements for Some
Radioactive Byproduct Material in Title 10
Code of Federal Regulations Section 30.35

Adjourn

P R O C E E D I N G S

3:02 p.m.

CHAIRMAN ALDERSON: Good afternoon. Welcome, everyone, to the ACMUI teleconference.

We're in this teleconference today to discuss two topics. The first topic is the comments of the ACMUI Subcommittee on the Draft Revisions to the Radioactive Seed Localization 35.1000 guidance. The second topic is a presentation from NRC staff regarding potential rulemaking to expand the financial insurance assurance requirements for certain radioactive byproduct material.

So at this time, I would like to turn the meeting over to Mr. Doug Bollock for some opening remarks.

MR. BOLLOCK: Thank you, Dr. Alderson. As the Designated Federal Officer for this meeting, I am pleased to welcome you to this public meeting of the Advisory Committee on the Medical Uses of Isotopes. My name is Doug Bollock. I am the Branch Chief of the Medical Safety & Events Assessment Branch, and I have been designated the Federal Officer for this advisory committee in accordance with 10 CFR Part 7.11.

Present today as the Alternate Designated Federal Officer is Sophie Holiday, our ACMUI

Coordinator. This announced meeting of the committee 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. It may also be transcribed or reported by others. The meeting was announced in the June 8th, 2016 edition of the Federal Register, Volume 81, pages 36964 through 36965.

The function of the committee is to advise the staff on issues and questions that arise in the medical use of byproduct materials. 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 issues that will be discussed 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'd like to perform a roll call of the ACMUI members participating today. Dr. Phil Alderson?

CHAIRMAN ALDERSON: Yes, here.

MR. BOLLOCK: Thank you. Dr. Pat

Zanzonico?

VICE CHAIRMAN ZANZONICO: Yes.

MR. BOLLOCK: Thank you. Mr. Frank Costello?

MEMBER COSTELLO: Here.

MR. BOLLOCK: Thank you. Dr. Vasken Dilsizian?

MEMBER DILSIZIAN: Present.

MR. BOLLOCK: Thank you. Dr. Ronald Ennis?

MEMBER ENNIS: Here.

MR. BOLLOCK: Thank you. Dr. Sue Langhorst?

MEMBER LANGHORST: Here.

MR. BOLLOCK: Thank you. Dr. Darlene Metter?

MEMBER METTER: Here.

MR. BOLLOCK: Thank you. Dr. Michael O'Hara?

MEMBER O'HARA: Here.

MR. BOLLOCK: Thank you. Dr. Christopher Palestro?

MEMBER PALESTRO: Here.

MR. BOLLOCK: Thank you. Dr. John Suh?

(No audible response.)

MR. BOLLOCK: Okay. Ms. Laura Weil?

(No audible response.)

MR. BOLLOCK: All right. I've confirmed we have at least seven members and a quorum. On the phone, do we have Mr. Zoubir Ouhib?

(No audible response.)

MR. BOLLOCK: And Mr. Richard Green?

MR. GREEN: Here.

MR. BOLLOCK: Thank you. All right. Mr. Ouhib has been selected as the ACMUI therapy medical physicist, and Mr. Green has been selected as our ACMUI nuclear pharmacist. Mr. Ouhib and Mr. Green are pending security clearance, but may participate in the meeting. However, they do not have voting rights.

I now ask for NRC members who are present to identify themselves. I will start with the individuals in the room.

DR. HOWE: Dr. Donna-Beth Howe.

MS. HOLIDAY: Sophie Holiday.

DR. TAPP: Dr. Katie Tapp.

(Off mic introduction.)

MS. HENDERSON: Pam Henderson.

MR. BOLLOCK: Thank you. Next, we'll go with NRC medical team employees on the phone.

MR. WHITEHEAD: This is Ryan Whitehead.

MR. FULLER: Mike Fuller.

MR. BOLLOCK: Okay. Thank you. Next, any of the RSL working group members who are on the phone.

MR. DANSEREAU: Bob Dansereau.

MR. GALLAGHAR: Bob Gallaghar.

MR. GRIFFIN: Phil Griffin.

MR. BOLLOCK: Okay. Thank you. Members of the public who notified Ms. Holiday that they would be participating in the teleconference will be captured in the transcript. Those of you who did not provide prior notification, please contact Ms. Holiday at sophie.holiday@nrc.gov. That is S-O-P-H-I-E dot H-O-L-I-D-A-Y at nrc.gov, or 301-415-7865.

We have a bridgeline available, and that phone number is 1-800-864-0940. The passcode to access the bridgeline is 8646644 followed by the pound sign. This meeting is also using the GoToWebinar application to view presentation handouts realtime. You can access this by going to www.gotowebinar.com, that's W-W-W dot G-O-T-O-W-E-B-I-N-A-R dot com, and searching for ID 108-592-011.

The purpose of this meeting is to, one, discuss the draft report of the ACMUI Radioactive Seed Localization, or RSL, Subcommittee; and two, discuss

the potential rulemaking to expand financial assurance requirements for some radioactive byproduct materials.

Individuals who would like to ask a question or make a comment regarding a specific issue the committee has discussed should request permission to be recognized by the ACMUI Chairman, Dr. Phil Alderson. Dr. Alderson, at his option, may entertain comments or questions from members of the public who are participating with us today. Comments and questions are usually addressed by the committee near the end of the meeting after the committee has fully discussed the topic.

I would like to also add that handouts and agenda for this meeting are available on the NRC's public website. At this time, I ask that everyone on the call who is not speaking place their phones on mute. If you do not have the capability to mute your phone, please press star 6 to utilize the conference line mute and unmute functions.

I would ask everyone to exercise extreme care to ensure that background noise is kept at a minimum, as any stray background sounds can be very disruptive on a conference call this large. At this point, I'd like to turn the meeting back over to Dr. Alderson.

CHAIRMAN ALDERSON: Thank you, Doug. So I would like to turn the meeting over to Dr. Ennis, who is Chair of the ACMUI Radioactive Seed Localization Subcommittee.

MEMBER ENNIS: Thank you, Dr. Alderson, and welcome, everyone.

The Radioactive Seed Localization Subcommittee was formed in 2015 in response to users of -- and the community of practitioners who were ready to see the localization request to the NRC for modification or adjustments to the current guidance. Our subcommittee presented its report in the fall, and I'll just briefly highlight some of those issues just to give context to the current conversation.

Largely, the recommendations we made were to bring the guidance aligned with the realities of the current situation, where breast is not the only site that's being used, where the type of isotope being used doesn't -- is not particularly germane to the guidance. Some more minor things about what kind of survey instrument ought to be used, and allowing sources to be returned to the vendor, being that explicit.

Some more substantive things that were covered in our part were questions about authorized users, and we had recommended a change to the existing

guidance allowing an authorized user under the 290 pathway who had been RSL-trained to become a product supervisor for future trainees. We more specifically outlined what ought to be included in a written directive specific to RSL. The prior guidance had been more general, and it was felt that it needed to be more specific and more tailored to RSL.

We went on to define a medical event, essentially working off the written directive and typical medical event definitions, and lastly added some recommendations regarding precautions for breastfeeding that we thought patients ought to be made aware of.

The NRC and Agreement States have formed a working group and have come out with their draft guidance, and they have shared that with us, and our subcommittee has met to discuss that. I should note that the subcommittee from last fall included Dr. Alderson, Mr. Costello, and Dr. Zanzonico. Dr. Alderson has become chair of ACMUI, and for purposes of neutrality, it was felt that he ought not continue to serve as a member of the subcommittee, and he has been replaced by Dr. Darlene Metter for the current report.

I want to take a moment here to thank all the subcommittee members for all their work on the

subcommittee. It has been a wonderful group to work with, and I think we have worked well together and come up with meaningful contributions to this discussion.

The working group made some changes to the guidance that differed from ours in a number of ways, most of them relatively minor, and our subcommittee was comfortable with that. I will comment on some of the more substantive ones and the ones in which we perhaps are not aligned with the current working group draft.

First would be the issue of a written directive. The working group has proposed to eliminate the written directive completely. We are comfortable with that despite our prior recommendation of a written directive, with the understanding that there will be documentation in the medical record pre-procedure and post-procedure that would allow regulators to determine whether a medical event has occurred.

That understanding would be considered standard medical practice, so we think of that as a reasonable understanding, but we do think it is important that that be noted.

The specific rationale for why a written directive is not necessary, as stated in our draft in our report, is -- I'll just read the sentence that we wrote just because that will be relevant in a moment.

"The rationale for the working group's recommendation is that a working directive is required for therapeutic procedures. Since this is a diagnostic procedure, a working directive is not necessarily required. After we have submitted this report with further discussions, we have come to the conclusion that that language is imprecise and are going to recommend a modification in which we would recommend, say, that since this is a localization procedure, a working directive is not required." I think that really captures the essence of why this RSL is distinct and a written directive is not necessary.

Regarding the next substantive issue is authorized users, and the written -- the working group draft has opened up a new pathway for those who otherwise were not eligible under the 35.290 and 35.490 pathways. This pathway would be open to radiologists and surgeons and would call for 80 hours of training and experience, with a minimum of 40 hours of classroom and laboratory training.

And this is something that our subcommittee discussed at length, and regarding the radiologists part of the regulation, we are aware that there are radiologists whose training makes them eligible to be authorized users under 290, but there are some that are

not. However, even those have substantial education through the medical residency training in radiation protection, radiation biology, and other related subjects, such that we do feel for a low-risk procedure such as RSL, an 80-hour training would be reasonable to expect that they would then have requisite knowledge, understanding, capabilities to be authorized users for this procedure.

However, our subcommittee felt strongly that to make that eligible to surgeons or other medical professionals who did not have had -- who have not had significant radiation education in their background, we feel very strongly that that would not be an appropriate -- an appropriate guideline. We do not believe that there's a possibility of really understanding the issues surrounding radiation safety, protection, et cetera with such a brief course without, you know, significant prior education.

Regarding the next topic in terms of medical event reporting, so the working group has modified our definitions of medical events in two ways. It has eliminated the possibility of a medical event if the seeds were left in place for more than 20 percent longer than the intended amount of time. The rationale for this is quite reasonable in the sense that a few hour

delay, if the RSLs were put in the same day, could turn into a 20 percent error, but clearly not medically relevant.

So instead, the guidelines just state that if the seeds are not explanted, or not removed, then it is a medical event. And that is a much simpler way to define the time element of medical event. We support that with the caveat as stated in the -- in the working group draft, that seeds that are not removed because of patient intervention such as patient not coming for the procedure despite multiple attempts, that that is not considered a medical event.

They have also modified the medical event definition slightly when it comes to activity. We had stipulated a -- a greater than 20 percent difference between the intended activity implanted and the actual activity implanted, and the draft guidance makes it simpler just in terms of number of seeds, number of seeds implanted. If there's an error in the number of seeds implanted, then that would be a medical event. And we are comfortable with that.

The last issue is the one regarding advice regarding nursing, breastfeeding, for women who have the radioactive seeds in place. We had advised that patients be specifically advised not to breastfeed

while seeds are in place, and only after they've been removed, and that if a seed were to rupture, they ought to be advised not to breastfeed for ten half-lives.

The working group has not accepted that, feeling that that is an impingement into medical practice. Our subcommittee discussed that and continues to feel that giving such guidance, requiring such advice about breastfeeding, would be appropriate and would not be an impingement on medical practice. Our argument would be that there really is not an issue of medical judgment here where it would be appropriate for certain patients and not for others, and needing a medical understanding to really know for whom that would be inappropriate advice, nor is it actually, you know, mandating any type of procedure or treatment or medication for patients.

Those are the issues where it's really impinging on medical practice. This is really a radiation safety issue that ought to be told to everyone, and coupling that with the fact that we do feel that it would not be surprising for many involved to not be quite aware of the enhanced sensitivity of children, babies, to radioactivity and the possibility of very delayed effects on them, and may easily assume that if it's safe for the mother, it's safe for the baby. And

because of that possible fallacy, we think it is important that such a warning be given.

That really I think summarizes our subcommittee's findings, and I would now like to ask if any of the members of the subcommittee would like to add anything.

(No audible response.)

MEMBER ENNIS: Hearing none, would any of the ACMUI committee members like to ask or add anything?

MEMBER LANGHORST: Hi, this is Sue Langhorst. May I ask a few questions?

MEMBER ENNIS: Yes, please, Sue.

MEMBER LANGHORST: Actually, first I want to make a couple comments, and just -- I guess it is a question.

You in your report say that the previous report was September 21st, 2015, and on our website, we only have an August 11, 2015, so I wasn't sure if there was a confusion of date or -- or yes --

MEMBER ENNIS: Yes, there is a confusion of date. The August 11th date is the correct date. You are right.

MEMBER LANGHORST: Okay. That shows up at the beginning and at the end --

MEMBER ENNIS: Yes.

MEMBER LANGHORST: -- of your --

MEMBER ENNIS: We will make that change, thank you.

MEMBER LANGHORST: And then the ACMUI meeting was on I think October 8th rather than 12th.

MEMBER ENNIS: Okay. Thank you.

MEMBER LANGHORST: You're welcome. And I totally agree with the conclusion of the subcommittee that written directive is not needed, but I did want to ask about authorized users, and I am looking desperately for my notes here.

First off, I see that there are four team members for this procedure. There's the authorized user, there's the radiologist who implants, there's the surgeon, and there's the pathologist. Now, the authorized user may very well be that radiologist who implants, but that authorized user could be a separate individual.

The surgeon more than likely is not a radiologist and more than likely wouldn't want to be an authorized user, and I agree with the subcommittee that a surgeon who has no radiology background should not be allowed to become an authorized user with only 40 hours of -- or, excuse me, 80 hours of total training for this procedure. I don't think that is going to limit this

procedure in any way if that change is made, as you guys have -- have recommended.

And then, quite obviously, the pathologist will be working under the authorized user too.

I wanted to clarify that the person who implants the seeds, the -- typically, that's a radiologist, they have -- they are credentialed in order to be able to perform that procedure, but the authorized user may not be credentialed to perform that procedure, and so I wanted to clarify with the subcommittee, do you agree that if the authorized user is not the person implanting the seed, would their training then be observing three implants rather than doing three implants?

So that's my question for the subcommittee.

MEMBER ENNIS: Right. So I guess nothing in either text specifically states that, but I think that would be -- that would be correct that it would be an observation as the -- as the training.

MEMBER LANGHORST: Okay. Thank you for that. I have one more question.

On the breastfeeding, if you have a ruptured seed, I would think that the precaution would be to completely eliminate breastfeeding rather than just breastfeeding in the one breast because of the

potential of the radioactive material going throughout the mother's body. So I would recommend that you not just say for that breast, but that breastfeeding be ceased totally.

That is all I had to add. Thank you.

MEMBER ENNIS: Thank you, Sue. Does anyone on the subcommittee have any comments, particularly to Sue's last point?

MEMBER COSTELLO: This is Frank, and I'll -- I think I'm in agreement with Sue.

VICE CHAIRMAN ZANZONICO: Yes, this is Pat. I agree as well. I think some of that was an oversight on my part, but exactly right, the radioiodine could get systemically distributed and -- and radioiodine is rapidly concentrating in the lactating breast, and in turn, in breast milk, and you can get significant doses to the thyroid of a nursing infant if it were in the form of iodine, so yes, I agree completely with that point.

MEMBER METTER: This is Darlene. I agree.

MEMBER ENNIS: Okay. I should make an additional comment that we -- the subcommittee actually changed its own recommendation regarding the breastfeeding issue in the following way: in the initial subcommittee report, we talked about ten half-lives of

no breastfeeding, but in the -- just for practical purposes and simplicity, we modified that in our new subcommittee report to say this -- for this child.

MEMBER ENNIS: Okay. Any other questions or comments from members of the ACMUI?

MEMBER WEIL: Yes, this is Laura Weil. I have a couple -- just two, two brief comments.

One, I would like to express support for the subcommittee's recommendation requiring the breastfeeding warning. I think it is extremely important, and I hope it will be included in the final document.

One additional concern I have regarding the explantation that is significantly delayed due to a patient's failure to present for the explantation procedure, in order for patient intervention to be a reasonable reason for not designating the delayed explantation as a medical event, I think there should be a requirement that there's documentation that all appropriate education was provided to the patient regarding the necessity of timely explantation, and that should be something that can be found and -- and documented in order for patient intervention to be used as a rationale for not designating a medical event.

MEMBER ENNIS: So Laura, could you maybe

just articulate that a little more specifically, what you would like to specifically require in the medical record as a demonstration of that education?

(No audible response.)

MEMBER ENNIS: Hello?

(No audible response.)

MEMBER ENNIS: Hello?

MEMBER WEIL: Oh, I am sorry, I was muted.

MEMBER ENNIS: Oh, okay.

MEMBER WEIL: Similar to what is required for iodine-131, which is that the patient has been educated regarding the need for radiation protections for others and that there has been a process that has been followed to make sure that the patient has the information that is necessary to not be injured by the -- or injure others with -- with the radioactive seed.

There should be a check-off where, you know, information has been provided to the patient about the necessity for presenting on such-and-such a date for explantation, and the reasons for that explantation. Is that clearer?

MEMBER ENNIS: Yes. Comments from the other members of the subcommittee or members of the ACMUI on that?

VICE CHAIRMAN ZANZONICO: This is Pat. I

think that is fairly reasonable. I think the -- the patient would be given any number of instructions or follow-up instructions, as they would for any sort of procedure, and -- and including among that a statement to the effect that it's important that the patient return to have the seeds removed, for, among other reasons, avoiding a larger-than-necessary radiation dose, and I don't think that's an unreasonable point to include in -- in information given to the patient.

MEMBER ENNIS: Thank you.

MEMBER COSTELLO: And this is Frank, and I agree with Pat.

MEMBER ENNIS: Okay. Me too.

Okay. Thank you, Laura. Any other questions or comments?

MS. HOLIDAY: Hello, this is Sophie. I have a clarifying question.

MEMBER ENNIS: Go ahead, Sophie.

MS. HOLIDAY: When you guys were talking about modifying the report in terms of the safety precautions where you said that breastfeeding should be eliminated altogether, are you trying to modify the sentence that says "Patients should be advised not to breastfeed from a breast into which one or more radioactive seeds have been implanted and not yet

removed," and the other sentence, or just the one regarding the leaking seed?

MEMBER ENNIS: Just regarding the leaking seeds.

MS. HOLIDAY: Okay. Thank you.

MEMBER ENNIS: Okay. Any other comments from members of the ACMUI?

MR. GREEN: This is Richard Green. May I --

MEMBER ENNIS: Sure.

MR. GREEN: -- pose a question?

MEMBER ENNIS: Yes.

MR. GREEN: It's really on, regarding the written directive, you mentioned the intention to change the wording. Initially, it was the rationale for the working group's recommendation was that a written directive is required for therapeutic procedures, and you changed that, I believe, to state that a written directive is not required for localization procedures. Is that correct?

MEMBER ENNIS: So the way I would read it would be as follows: the prior wording was rationale for the written -- the working group's recommendation is that a written directive is required for therapeutic procedures. Since this is a diagnostic procedure,

written directive is not necessarily required.

The way I would want it to read now would be the first sentence would remain the same. The rationale for the working directive is -- well, I think it would just -- yes, I apologize. The way we would rewrite it would be "This procedure is not a diagnostic or therapeutic" -- I guess I need to work on my English here. I apologize.

MR. GREEN: My --

MEMBER ENNIS: Yes?

MR. GREEN: My concern -- my concern was --

MEMBER ENNIS: Go ahead.

MR. GREEN: -- when you change the verbiage from this is not a therapeutic procedure, this is a diagnostic procedure, and diagnostic procedures don't typically require a written directive, well, they do if it's using above 30 --

MEMBER ENNIS: Right, exactly --

MR. GREEN: -- so --

MEMBER ENNIS: -- that's exactly the issue that we kind of discussed, and that is why we really are going to -- we'll change our comment to reflect that the reason, at least in our view, that a directive is not required is because this is really neither diagnostic nor therapeutic, it is localization.

MR. GREEN: Which would fit under 35 Part 200, just imagining and localization procedures for which written directive is not required?

MS. HOLIDAY: Right, because it's not using I-131 either.

MR. GREEN: Right.

MEMBER ENNIS: Right.

MS. HOLIDAY: So it's --

MR. GREEN: It -- yes. Okay.

MEMBER ENNIS: Yes.

MR. GREEN: Thank you.

MEMBER COSTELLO: This is Frank. Strictly speaking, it's not 35 200 because there are other things that you put in that category. This is 35 1000. But it has similarity to 35 200.

MEMBER ENNIS: That -- that is accurate, Richard?

(No audible response.)

MEMBER ENNIS: Okay. And other questions or comments from members of the ACMUI?

MEMBER METTER: This is Darlene.

MEMBER ENNIS: Yes, Darlene?

MEMBER METTER: You know on the part when -- about consent before the medical event and the patient didn't return? Perhaps Rich we could add it in

that last sentence, where it says the subcommittee report supports a position that a medical event has not occurred in the event patient fails to return for the surgical removal procedure despite informed consent and risk -- I mean, and with procedure risk, considering this to be an instance of patient intervention, we should actually kind of add that to the part there because I think that is, like it was said, it is important to --

MEMBER ENNIS: Right.

MEMBER METTER: -- have, you know, when a patient was informed of the, you know, the risk of the procedure.

MEMBER ENNIS: Yes, that would be a good place to -- to put in some wording. Yes.

Thank you. Any other questions or comments?

(No audible response.)

MEMBER ENNIS: Okay. Hearing none, are there any questions or comments from members of the public?

THE OPERATOR: If you would like to ask any questions over the phone lines, please press star 1, make sure your phone is unmuted, and record your name at the prompt.

(No audible response.)

THE OPERATOR: Okay, sir. And at this time, we have no questions.

MEMBER ENNIS: Okay. All right, then. So just to review then before we vote, the modifications to our -- our report, our subcommittee report that is in response to the working group draft, the modifications that we are making include the dates referenced by Sue, clarification of the reasons for Dr. Metter and Dr. Alderson changing places on the committee, the language for our rationale for why we are accepting of not needing a written directive because of it being a localization procedure, our -- the recommendation that additional verbiage be put in that the -- there should be evidence that the patient was advised of the importance of returning for the explantation, as Laura had suggested.

So with those modifications to the report, I believe Dr. Alderson we can --

CHAIRMAN ALDERSON: Yes.

MEMBER ENNIS: -- have a vote on --

CHAIRMAN ALDERSON: Yes --

MEMBER ENNIS: -- on the report?

CHAIRMAN ALDERSON: -- so would the subcommittee like to make a motion for a vote on this

report? And I'd remind everyone that no second is needed because this is coming from a subcommittee.

MEMBER ENNIS: We would.

VICE CHAIRMAN ZANZONICO: This is Pat. I'll make a motion to accept the subcommittee report contingent on the changes specified.

CHAIRMAN ALDERSON: Good. Thank you, Pat. So how many are in favor of that? Say aye.

(Chorus of ayes.)

CHAIRMAN ALDERSON: Are any opposed? State aye.

(No audible response.)

CHAIRMAN ALDERSON: Are there any abstentions?

(No audible response.)

CHAIRMAN ALDERSON: Hearing none, is there any -- there obviously is no discussion on this vote. It's unanimous in favor of the motion. Thank you, Dr. Ennis.

MEMBER ENNIS: Thank you very much, Dr. Alderson.

CHAIRMAN ALDERSON: So this concludes the first topic on the agenda, and I want to thank all the subcommittee members for their work on this report.

We are moving on now to the second subject.

Is Ryan Whitehead or Jim Schaffner on the call, the NRC people?

MR. WHITEHEAD: Yes, Ryan Whitehead is here.

CHAIRMAN ALDERSON: Good. I will turn the meeting over to Mr. Whitehead to provide the committee with an overview of the potential rulemaking to the expanded financial assurance requirements in 10 CFR 30.35 for certain radioactive byproduct materials.

MR. WHITEHEAD: Thank you, Dr. Alderson, and thank you to the committee for agreeing to have us present this afternoon.

I am Ryan Whitehead. I am a project manager in the Low-Level Waste Branch at the NRC, and my co-project manager for this effort is Mr. Jim Schaffner.

We are going to take probably ten minutes to just kind of walk you through the handout materials that Sophie has included in the materials for the meeting and then answer any questions you have on this proposed rulemaking. I want to emphasize at this point, this is only a staff proposal to the Commission.

There's a new process for doing this. It is called a rulemaking plan SECY paper, and that resulted from a Commission SRM that came out this past

February, so writing this rulemaking plan SECY paper to propose this rulemaking on 10 CFR 30.35, the Commission will have, you know, an opportunity to weigh in and tell us whether they want us to proceed.

So in terms of background, we're talking about 10 CFR 30.35, which is titled Financial Assurance and Recordkeeping for Decommissioning. That regulation requires a fixed dollar amount of financial assurance or a decommissioning funding plan, or a DFP, for licensees that possess byproduct material with a half-life greater than 120 days and at activity levels that are above certain thresholds.

The regulations don't require financial assurance for a majority of the IEA Category 1 and 2 as well as lower category radioactive sealed sources, and in fact, the threshold values for radionuclides that are in the back of Part 30, the threshold for sealed material is seven orders of magnitude higher than for unsealed material, and so for many radionuclides, the threshold level for a Category 1 source, including cesium-137 and cobalt-60, there are no financial assurance requirements. So things like blood irradiators, Gamma Knives, et cetera, at this point, there's no financial assurance required for licensees that only have those types of sources.

This issue has been highlighted by a number of groups over the past five to ten years. Some of them include the Government Accountability Office, the Radiation Source Protection and Security Task Force, the Low-Level Waste Forum Disused Sources Working Group, all of them have put out reports over the past five years basically saying this is an issue that NRC should look at, that, you know, it may contribute to, you know, disused sources, you know, not being disposed of in a timely way.

And so because of that, we decided to take a look at it, and we proposed to the Commission in September of 2014 that it was time to look at the issue because a couple of those reports had come out in 2014, and we received a Commission SRM to do so at that time.

End-of-life cost for these sources, and in particular, you know, some of the higher activity sealed sources, can be quite significant, and it can be unpredictable. The cost includes steps like interim storage, packaging and conditioning, transportation to disposal site or the other -- you know, another type of disposition option such as return to supplier or reuse or recycling.

NRC does not currently require licensee to declare when the sealed sources in their possession are

disused, and we also don't require them to provide for prompt disposition of those sources once they're disused. And, you know, in some cases, if a licensee has not planned for end-of-life cost for these sources, it can represent a significant financial burden, I mean, on the order of a few hundred thousand dollars or even more.

For some of the sources, disposal may not even be a viable option. For example, some of the higher-activity cesium-137 sources may be greater than Class C, and right now, you know, there is no commercial disposition option for greater than Class C sources. In general cobalt-60 would not have that problem. Cobalt-60 would not be greater than Class C, but in a lot of cases, the waste acceptance criteria for the disposal sites don't allow those high activity sealed cobalt-60 sources.

And so because of that, you know, licensees may just choose to indefinitely store these things long-term as the most practical and cost-effective management option.

So as I mentioned, you know, we raised this issue to the Commission in September of 2014. We received a Commission SRM that directed us to conduct this, what's called a scoping study, kind of look at the

issue and decide, you know, where the staff would recommend the Commission go, and so we initiated the scoping study to determine whether additional financial planning requirements are necessary for end-of-life management of some byproduct material, and in particular, these higher activity radioactive sealed sources.

And so we issued a Federal Register Notice, or an FRN, last August, on August the 3rd, to solicit comments from stakeholders. The comment period closed on October the 19th, and we received 11 comment letters from a range of federal and state agencies, organizations such as the Low-Level Waste Forum and the Organization of Agreement States, a couple of industry groups, and members of the public.

We also convened a public meeting and a webinar on October the 7th, 2015 to gather stakeholder feedback, and we had about 35 participants in that meeting.

And so in the materials that you received in advance of this meeting, we -- we documented the scoping study in a SECY paper that was issued April the 7th. That was SECY-16-006, and that paper is publicly available on the NRC website.

So in terms of the results of this scoping study, you know, it was a pretty broad study. You know,

we didn't go -- you know, have time or resources to drill deeply into all of the technical issues, but we kind of provided an overview, about 40 pages in length, to just survey all of the issues that impact decision-making on this particular topic.

We looked at current NRC regulations and guidance, both internal and external reports that had been generated on this topic, and also the stakeholder feedback that we received through our FRN and our public meeting. You know, some of the issues include, you know, there are a variety of different financial assurance methods that can be used, funding mechanisms. There's an issue in terms of compatibility with Agreement State requirements. You know, currently, the compatibility levels for 10 CFR 30.35 are such that states can go beyond NRC requirements if they wish, and some of them have on this issue. States like Florida and Texas and Illinois have more stringent financial assurance requirements than 10 CFR 30.35 currently requires.

We also looked at a number of relevant domestic and international activities like availability of new disposal capacity; issues related to transportation containers, which can be problematic for some of the higher-activity sources -- they're

called Type B transportation containers, and there has been an issue with the availability of those over the past several years; the NRC's revised Branch Technical Position on concentration averaging, which might be applied to allow higher activity sources to be disposed of if, again, the disposal sites can look at, you know, the NRC's concentration averaging BTP and adjust their waste acceptance criteria accordingly to possibly allow disposal of sources that have not been allowed to this point.

CRCPD is also looking at this issue, and they have developed some -- some suggested state regulations on financial surety, and so we -- we're on the CRCPD group that's developed those suggested state regs, and we have communicated with them because our efforts are very similar.

And we have also interfaced a lot with the National Nuclear Security Agency, NNSA. They run two programs right now that address disposition of these sources. One is called the Off-Site Source Recovery Project, which deals with the higher activity Category 1 and 2 sources, and they also run what's called the SCTR Program, the Source Collection and Threat Reduction Program.

And basically, you know, they run those

programs to help folks that have these sources and want to disposition them but either don't have the funds to do so or, you know, for the higher-activity ones, again, there -- there may not be a disposition pathway, and so NNSA has been in the business of helping come pick these sources up, either store them, some of them are stored at -- at the Los Alamos site. Some of them go for disposal in the State of Nevada.

But NNSA has highlighted to us that, you know, that is a business they are not sure they can remain in in the long term, you know, due to funding issues and -- and other issues, so they -- you know, as part of their comments to us in response to our FRN, they highlighted that, you know, it would be their preference that licensees, you know, assume a greater role in providing for the disposition and end-of-life management of these sources.

So we noted in our scoping study that we agree with the assessments that we received from numerous stakeholders that providing financial assurance for source disposition supports overall safety and security goals. It helps facilitate timely disposition of disused sources, and it helps ensure that the full cost of using radioactive sealed sources is appropriately considered by licensees.

But our scoping study also recognizes that we do have regulations in place, the current NRC regulations, that ensure safe and secure management of sealed sources, and if we implemented new financial assurance requirements, you know, that will impose additional regulatory costs, and it could have the potential to adversely affect beneficial uses of radioactive material.

So the outcome of our SECY paper, SECY-16-0046, was that we recommended the financial assurance requirements in 10 CFR 30.35 be expanded to include all byproduct material Category 1 and 2 radioactive sealed sources that are currently tracked in the National Source Tracking System, and again, as I mentioned up front, so we're preparing this new vehicle called a rulemaking plan SECY paper, which is due by the end of this fiscal year, to further evaluate potentially changing 10 CFR 30.35.

We will provide that paper to the Commission, and the Commission will make a decision and tell us whether they'd like us to proceed or not. We made this recommendation, you know, to focus on the Category 1 and 2 sources really because we felt it, you know, made sense to focus on the highest -- the sources of highest risk significance right now. We do think

that having financial assurance for these sources will reduce the likelihood that some licensees will be unprepared for end-of-life disposition costs. It may help reduce the use of long-term storage as a management option, and we feel it's -- you know, it's complementary to the NRC's existing safety and security regulatory framework.

The rulemaking plan SECY paper, there is a template that was submitted to Congress that provides a variety of different aspects that -- that you have to look at, and some of those aspects include costs and benefits of the proposed rulemaking; potential cumulative effects of regulation; Agreement State considerations; you also look at what other regulatory options are out there, other than rulemaking, that might address the issue.

And so, again, we'll submit that to the Commission at the end of the fiscal year, and they will tell us whether or not they would like us to proceed.

On the final page of my handout, you know, one question we often received was well what about the lower-category sealed sources, you know, the IAEA Category 3 and below? And so I wanted to just address, you know, why we decided to focus on Category 1 and 2 sources at this time. You know, again, those are the

sources that have the highest risk significance. They are generally the most likely sources to have challenges in finding a disposition pathway, and the cost is likely to be higher for those sources compared to other source categories.

You know, and also, in terms of implementation, you know, there are about 76,000 or 77,000 of these sources that are tracked right now in the NSTS, and those are held by about 1400 NRC and Agreement State licensees. You know, it is going to take some resources and be a complex undertaking to implement this, and we really felt like, you know, the most prudent use of both our resources and Agreement State resources would be to focus on the Category 1 and 2 sources now before we consider going down to the lower category sources.

And, you know, there was a SECY paper that was written several years ago that looked at numbers of these sources, and basically, if you went down to Category 3 sources, you would essentially double the number of sources and the number of licensees that would be affected, so it would essentially double the task if you -- if you went to the lower category sources.

But, you know, if we decide to do so in the future, certainly, implementing this for Cat 1 and 2

sources would help us make sure we're effective and efficient if we decided to further expand financial assurance requirements in the future, and again, as I mentioned, Agreement States have the option now, if they wish, to have more stringent financial assurance, and some of them do go even below the Category 1 and 2 sources, and so until we would put rulemaking in place, which would take several years, the Agreement State could continue to do that.

So that concludes my remarks in terms of it's an overview of the scoping study and -- and where we're going from here. I would be happy to answer any questions the committee might have.

CHAIRMAN ALDERSON: Well thank you Mr. Whitehead and Mr. Schaffner for informing us about the -- your intent to pursue this rulemaking, which I think is -- is important, an important subject. We look forward to learning more about this.

Are there questions that members of the ACMUI would like to ask?

MEMBER COSTELLO: Hey, this is Frank Costello.

CHAIRMAN ALDERSON: Yes, go ahead, Frank.

MEMBER COSTELLO: Okay. I just have a comment. I would like to express my strong support of

this effort. Here in Pennsylvania, we've had a number of cases since we became an Agreement State in 2008. We had a Gamma Knife be abandoned by the licensee and the landlord, you know, because they weren't paying the rent, you know, drilled locks to gain access. We had very recently a blood irradiator used for research, used for the same purpose.

And it becomes a real challenge to try to come up with a, you know, significant amount of funds. A lot of money is necessary to dispose of these things. So I think that it is particularly unfortunate when these Cat 1, Cat 2 facilities are in leased space because, you know, the landlord always in some way has access to the facility, so I -- I encourage your work, and I think you can think about the Cat 3 and lower another time. I think getting Cat 1 and Cat 2 now is an important thing to do. Thank you.

MR. WHITEHEAD: Thank you.

CHAIRMAN ALDERSON: Thank --

MR. WHITEHEAD: Thank you, Frank.

CHAIRMAN ALDERSON: -- you, Frank. Any other comments?

VICE CHAIRMAN ZANZONICO: This is Pat. I have a general question, and it may just reflect my ignorance of this whole area, but wouldn't this be

impacted, and isn't it impacted, by this sort of more general issue of long-term disposal of -- of radioactivity in general? And -- and would -- I am not -- I am not articulating this well, but wouldn't that need some sort of national consideration, a national plan for disposal of -- of radioactivity? Wouldn't that need to be incorporated in some sense in a -- a source disposal program? Or am I off base on this and thinking about something that's not really relevant?

MR. WHITEHEAD: Well, I think it absolutely is relevant, and, you know, the challenge with the disposal landscape right now, you know, the -- the low-level waste disposal landscape in the United States, is it is always changing, and it is difficult to predict where it is going to be, you know, three years, five years, ten years from now, you know.

For example, you know, in recent years, we have seen the opening of the Waste Control Specialists site in Texas, which has, you know, provided some additional options for disposal of certain materials that hadn't been available to this point.

You know, in general, I think, you know, for sources, you know -- if a source is greater than Class C waste, which again, some of the cesium-137 sources are, you know, right now, there is no commercial

disposal pathway, and DOE is charged with developing such a pathway, but for the other -- you know, for Class A, B, and C low-level waste, you know, we would hope that the marketplace, you know, would help develop solutions, you know, that would allow disposal pathways to be available, you know.

Again, one of many factors is, as I mentioned, the, you know, NRC's new Branch Technical Position on concentration averaging. They actually looked at a scenario in that BTP for a cesium-137 source, I believe, and, you know, using new scientific methods, you know, and depending on disposal site characteristics, what that BTP says basically is, you know, you've got to raise the threshold for cesium-137 disposal significantly higher than -- than NRC would have allowed in the past, but what we hope is, you know, disposal sites -- you know, but even though NRC is saying that, a disposal site can still through their waste acceptance criteria exclude, you know, whatever kind of material they wish, and a lot of them -- a lot of the sealed sources, you know, they just -- the waste acceptance criteria for the site won't allow them to be disposed of.

You know, that is a problem. NRC, you know, we can try to influence, but you know, it really

-- a lot of it is beyond our control. I mean Jim, if you're on the call, you might have some input that would be helpful on that topic.

MR. SCHAFFNER: I think you've pretty well covered it, but I mean, you know, clearly low-level waste disposal has been a challenge for 30-some years, and because of the compact system, and, as Ryan mentioned, the waste acceptance criteria, you know, it's sort of an artificial system that we're -- we're kind of up against, and, you know, we -- we discuss a lot of this in the scoping study that Ryan alluded to, but I think getting back to the gentleman's original point, it -- you know, there are several significant challenges.

CHAIRMAN ALDERSON: Are there other comments or questions?

MEMBER ENNIS: Yes, this is Ron. I have a few questions.

CHAIRMAN ALDERSON: Yes, Ron, go ahead.

MEMBER ENNIS: Thank you.

First, has -- have -- has anyone's health been hurt by these sources that have not been disposed of in the way that would have -- that they should have ideally been done?

MR. WHITEHEAD: In the United States, I

mean, I am not aware of a case where there was like, you know, an accidental exposure that resulted in health consequences, but there are examples where companies have gone bankrupt, you know, or otherwise haven't had the means to properly manage the disposition of the sources, and therefore, another entity has had to come in and bail them out.

MEMBER ENNIS: Right, understood, but I just want to have a good like context and framework. So we're not talking about a health risk to the American population, at least -- maybe in theory, but in practice, there's not been health issues, more financial issues and management and properties and all those kind of things? Not that that's not important, but I wanted to clarify that.

MR. SCHAFFNER: But actually, if I could just interject, Ron?

MEMBER ENNIS: Yes.

MR. SCHAFFNER: There have been instances of -- of improperly discarded sources being picked up by -- by just random members of the general public in other countries and numbers of people dying as a result, so -- so there is that -- it is more than a risk in principle, though as far as I know as well, it has not occurred in the United States.

MEMBER ENNIS: Right, right. So could you also just for a moment expand on the states -- you said some states have actually gone ahead and moved in this direction, I guess, so would you mind just giving a little more detail what the states have done and when they did it, how long ago they've done that?

MR. WHITEHEAD: Yes, I mean, I can give you a, you know, a high-level picture, and Jim can --

MEMBER ENNIS: Yes.

MR. WHITEHEAD: -- Jim can help. And we -- this is an issue that we do talk about in the SECY paper. We highlight I believe three states: State of Florida, State of Texas, and State of Illinois.

Florida in particular has an interesting risk-based calculation that they use. So when a -- when one of their licensees, you know, proposes to acquire, they -- you know, they're getting a license for these sources, there are a number of parameters that, you know, they have to stay in. I think some of them are like what -- of course, what type of source is it? What's the activity? What's the isotope? What kind of facility is it going to be used in? And they have like a multiplier that accounts for these factors and -- and then that equation says therefore you owe so much, you know, dollars in financial assurance.

They're the only state I know that has a risk-based calculation system like that. I don't know when it was originally put in place. The -- Texas -- and Jim, can you help me out with Texas? I think you're a little more familiar with that than I am.

MR. SCHAFFNER: Well, to that, Ryan, I am -- I -- you know, I don't have access to that right now, so we can get -- get back to them on that.

MR. WHITEHEAD: Okay. You know, it is -- it is not a recent phenomenon. It's not something that has only been in place the past few years. I know there was a 2010 report, inter-agency report that was done that NRC headed, that also used the State of Texas as an example. They have some feature that's called I believe a universal fund as well where they essentially tax their -- some of their materials licensees, and they have a fund set aside for situations where you have an orphan source or a licensee that goes bankrupt or you otherwise need a state to help come in and manage the disposition of the source.

MEMBER ENNIS: Got it. Right. Okay. So -- and then I guess a -- well, a couple more comments.

So it would seem that the idea of turning towards the licensee would be from some rationale, well, the licensee benefitted for all the years of the source,

or hoped to at least, so he or she or that entity ought to kind of bear -- bear that cost, and there's certainly a rationale for that, but of course, if we stop and think about it a little bit, who benefits, at least within the medical space, from these sources, the benefit is quite broad.

There is the company that sells the source, the company that embeds it into its equipment that sells -- that then sells it, you know, as a -- as a treatment machine for something or a blood irradiator. There's members of the public who benefit from -- or the patients that benefit from the blood irradiation or the Gamma Knife or the high dose rate treatments.

Then there's the physicians who practice who get to bill Medicare, et cetera, for that. Then there's the hospitals or the facilities. So how do we reasonably spread out that cost if we feel like we need to? I don't know, to my mind, that targeting specifically one group within all of those is a -- is an appropriate way to kind of spread out the -- the cost.

CHAIRMAN ALDERSON: I would interject here that I think that is an excellent, detailed analysis you have provided. I don't think that we're here today to go into that level of discussion. We're certainly not going to solve this problem today, and a number of those

things, you know, have occurred to several of us, so I hope we can continue this.

MR. SCHAFFNER: It's a legitimate point, and it's something we recognize that would have to be teased out in the development of the regulatory basis during the rulemaking.

CHAIRMAN ALDERSON: Good, thank you. I wanted to ask just a specific question about something you said. I'm the one that has to go over these transcripts, and so I want to be sure I got this correctly.

You talked about 70,000 roughly sources and 1400 licensees.

MR. WHITEHEAD: Yes.

CHAIRMAN ALDERSON: Was that for Category 1 and 2 sealed sources?

MR. WHITEHEAD: Yes, that --

CHAIRMAN ALDERSON: It was. Okay. Thank you very much. I've got that clear.

MR. WHITEHEAD: I believe -- you know, I just heard somebody that helps manage that system -- well, Sophie probably knows as well. I think the current number for NSTS is around 77,000 Category 1 and 2 sources that are tracked.

CHAIRMAN ALDERSON: Good. All right,

thank you.

Do people on the ACMUI have additional questions?

MEMBER LANGHORST: This is Sue Langhorst. I have a couple.

CHAIRMAN ALDERSON: Okay. Sue, go ahead.

MEMBER LANGHORST: Okay.

In the NRC regulations regarding financial assurance and recordkeeping for decommissioning, that's in 30.35, the item (a) is split into two parts. The first part deals with unsealed byproduct material, and then the second part is what you've been speaking on regarding sealed sources.

Through that section of the regulations, they pretty much keep those separated. So a clarification that I am seeking is if you have these 1400 licensees who need to do a decommissioning funding plan for their sealed sources, would that be limited only to those sealed sources, and would not require them to then also sweep up their unsealed sources into that decommissioning funding plan?

MR. SCHAFFNER: Well, it would all have to be included, but as Ryan mentioned earlier, there is a seven-order-of-magnitude difference between a threshold for financial assurance for unsealed

byproduct material and sealed byproduct material. So, you know, arguably, the unsealed material is probably under a financial assurance umbrella now.

MEMBER LANGHORST: I would say not necessarily, and a decommissioning funding plan that deals only with these sealed sources is going to be much more contained than if the licensee who doesn't have enough unsealed byproduct material to warrant a decommissioning funding plan -- that's going to be a whole larger scope for those licensees, so I encourage you to look at that probably unintended consequence to make sure that you're not requiring a licensee to now include all of their radioactive unsealed sources as part of this decommissioning funding plan.

MR. WHITEHEAD: Well, I mean, I can tell you, you know, our -- our starting point, you know, and I think folks who have been involved in rulemakings know, you know, sometimes you can't predict three years after you start a rulemaking where you're going to end up, but, you know, our opening proposition is that we would modify 30.35 to require financial assurance, you know, only for the Cat 1 and 2 sources for which it is not currently required. I mean, that is kind of the boundary we've drawn around our recommendation.

So, you know, those details will be worked

out in the technical basis for the rule, and, you know, through the whole three-year rulemaking process, but, you know, I wouldn't envision, you know, just because, you know, a licensee has a Cat 1 or 2 source that they now have to provide financial assurance for that they would have to do a comprehensive decommissioning funding plan if they hadn't had to do -- you know, for unsealed material, if they hadn't had to do that prior.

MEMBER LANGHORST: Thank you very much for that.

The other question I have that -- actually I guess it's a -- it's a suggestion that I have that you look at too, as you're developing this, excuse me, is the NRC's capability to do these timely reviews of the decommissioning funding plans and these financial assurances. For those of you who don't know, a licensee is required to update the decommissioning funding plan every three years and when they renew their license, and the license for which I am the radiation safety officer here, our last approved decommissioning funding plan was sent in in September of 2009.

We since have sent in an updated decommissioning funding plan in December of 2010, again in February of 2013 when we renewed our license, and we most recently sent in a -- an update in February of this

year, 2016.

And NRC has not been able to review and give us their approval of our decommissioning funding plan, so I strongly encourage you to address what kind of resources the NRC is going to need to be made available to their staff to review all these decommissioning funding plans' financial assurances. Thank you.

MR. WHITEHEAD: That's a very good comment and something that we have highlighted, you know, will be an issue, but not just for NRC, but for Agreement States as well, and -- and actually, I think it was the Organization of Agreement States also recognized that in their letter response to us as part of the scoping study, so thank you for that comment.

CHAIRMAN ALDERSON: Good comment. Other questions or comments from the ACMUI?

(No audible response.)

CHAIRMAN ALDERSON: Hearing none, thank you Mr. Whitehead and Mr. Schaffner for telling us about this important topic and where you're headed. I am sure we'll be talking about this again at future ACMUI calls or in our meetings.

So we want to -- I want to thank all the committee members for their engagement today and for working hard on these issues --

MS. HOLIDAY: Dr. Alderson?

CHAIRMAN ALDERSON: -- and thank -- yes?

MS. HOLIDAY: It's Sophie. Do you want to possibly open it up to see if any people on the phone have any questions?

CHAIRMAN ALDERSON: Sure. Are there any people on the public phone who would like to have questions or comments about this?

THE OPERATOR: Once again, to ask a question over the phone lines, please press star 1. Make sure your phone is unmuted, and record your name at the prompt. And it will just be a moment while folks queue up.

(Pause.)

THE OPERATOR: Once again, for any questions over the phone lines, press star 1 and record your name.

(No audible response.)

THE OPERATOR: At this time, I am showing no questions.

CHAIRMAN ALDERSON: Well, good. Thank you. Thanks to everyone and all the attendees. Does NRC have any closing remarks that they would like to add?

MR. BOLLOCK: Hi, Dr. Alderson. There are no closing remarks from the NRC. Thank you.

CHAIRMAN ALDERSON: All right. Well, I again want to thank everybody for this engaging discussion today, and we are adjourned. Have a great weekend.

(Whereupon, the above-entitled matter went off the record at 4:13 p.m.)