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on the Medical Uses of Isotopes

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UNITED STATES OF AMERICA
 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

SUSAN M. LANGHORST, Radiation Safety Officer

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

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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

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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

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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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C-O-N-T-E-N-T-S

Discuss the Draft ACMUI Radioactive Seed.....7

Localization Subcommittee Report

Discuss Potential Rulemaking to Expand the.....30

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

Adjourn

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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

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1 Coordinator. This announced meeting of the committee
2 is being held in accordance with the rules and
3 regulations of the Federal Advisory Committee Act and
4 the Nuclear Regulatory Commission. This meeting is
5 being transcribed by the NRC. It may also be
6 transcribed or reported by others. The meeting was
7 announced in the June 8th, 2016 edition of the Federal
8 Register, Volume 81, pages 36964 through 36965.

9 The function of the committee is to advise
10 the staff on issues and questions that arise in the
11 medical use of byproduct materials. The committee
12 provides counsel to the staff but does not determine
13 or direct the actual decisions of the staff or the
14 Commission. The NRC solicits the views of the
15 committee and values their opinions.

16 I request that whenever possible, we try
17 to reach a consensus on the issues that will be
18 discussed today, but I also recognize there may be
19 minority or dissenting opinions. If you have such
20 opinions, please allow them to be read into the record.

21 At this point, I'd like to perform a roll
22 call of the ACMUI members participating today. Dr.
23 Phil Alderson?

24 CHAIRMAN ALDERSON: Yes, here.

25 MR. BOLLOCK: Thank you. Dr. Pat

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1 Zanzonico?

2 VICE CHAIRMAN ZANZONICO: Yes.

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

5 MEMBER COSTELLO: Here.

6 MR. BOLLOCK: Thank you. Dr. Vasken

7 Dilsizian?

8 MEMBER DILSIZIAN: Present.

9 MR. BOLLOCK: Thank you. Dr. Ronald

10 Ennis?

11 MEMBER ENNIS: Here.

12 MR. BOLLOCK: Thank you. Dr. Sue

13 Langhorst?

14 MEMBER LANGHORST: Here.

15 MR. BOLLOCK: Thank you. Dr. Darlene

16 Metter?

17 MEMBER METTER: Here.

18 MR. BOLLOCK: Thank you. Dr. Michael

19 O'Hara?

20 MEMBER O'HARA: Here.

21 MR. BOLLOCK: Thank you. Dr. Christopher

22 Palestro?

23 MEMBER PALESTRO: Here.

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

25 (No audible response.)

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1 MR. BOLLOCK: Okay. Ms. Laura Weil?

2 (No audible response.)

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

6 (No audible response.)

7 MR. BOLLOCK: And Mr. Richard Green?

8 MR. GREEN: Here.

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

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

18 DR. HOWE: Dr. Donna-Beth Howe.

19 MS. HOLIDAY: Sophie Holiday.

20 DR. TAPP: Dr. Katie Tapp.

21 (Off mic introduction.)

22 MS. HENDERSON: Pam Henderson.

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

25 MR. WHITED: This is Ryan Whited.

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1 MR. FULLER: Mike Fuller.

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

5 MR. DANSEREAU: Bob Dansereau.

6 MR. GALLAGHAR: Bob Gallagher.

7 MR. GRIFFIN: Phil Griffin.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 I want to take a moment here to thank all

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1 the subcommittee members for all their work on the
2 subcommittee. It has been a wonderful group to work
3 with, and I think we have worked well together and come
4 up with meaningful contributions to this discussion.

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

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

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

24 The specific rationale for why a written
25 directive is not necessary, as stated in our draft in

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1 our report, is -- I'll just read the sentence that we
2 wrote just because that will be relevant in a moment.
3 "The rationale for the working group's recommendation
4 is that a written directive is required for therapeutic
5 procedures. Since this is a diagnostic procedure, a
6 written directive is not necessarily required. After
7 we have submitted this report with further discussions,
8 we have come to the conclusion that the language is
9 imprecise and are going to recommend a modification in
10 which we would recommend, say, that since this is a
11 localization procedure, a written directive is not
12 required." I think that really captures the essence
13 of why this RSL is distinct and a written directive is
14 not necessary.

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

23 And this is something that our
24 subcommittee discussed at length, and regarding the
25 radiologists part of the regulation, we are aware that

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1 there are radiologists whose training makes them
2 eligible to be authorized users under 290, but there
3 are some that are not. However, even those who have
4 substantial education through the medical residency
5 training in radiation protection, radiation biology,
6 and other related subjects, such that we do feel for
7 a low-risk procedure such as RSL, an 80-hour training
8 would be reasonable to expect that they would then have
9 requisite knowledge, understanding, capabilities to be
10 authorized users for this procedure.

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

21 Regarding the next topic in terms of
22 medical event reporting, so the working group has
23 modified our definitions of medical events in two ways.
24 It has eliminated the possibility of a medical event
25 if the seeds were left in place for more than 20 percent

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1 longer than the intended amount of time. The rationale
2 for this is quite reasonable in the sense that a few
3 hour delay, if the RSLs were put in the same day, could
4 turn into a 20 percent error, but that clearly is not
5 medically relevant.

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

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

24 The last issue is the one regarding advice
25 regarding nursing, breastfeeding, for women who have

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1 the radioactive seeds in place. We had advised that
2 patients be specifically advised not to breastfeed
3 while seeds are in place, and only after they've been
4 removed, and that if a seed were to rupture, they ought
5 to be advised not to breastfeed for ten half-lives.

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

19 Those are the issues where it's really
20 impinging on medical practice. This is really a
21 radiation safety issue that ought to be told to
22 everyone, and coupling that with the fact that we do
23 feel that it would not be surprising for many involved
24 to not be quite aware of the enhanced sensitivity of
25 children, babies, to radioactivity and the possibility

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1 of very delayed effects on them, and may easily assume
2 that if it's safe for the mother, it's safe for the baby.
3 And because of that possible fallacy, we think it is
4 important that such a warning be given.

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

9 (No audible response.)

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

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

14 MEMBER ENNIS: Yes, please, Sue.

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

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

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

25 MEMBER LANGHORST: Okay. That shows up

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1 at the beginning and at the end --

2 MEMBER ENNIS: Yes.

3 MEMBER LANGHORST: -- of your --

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

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

8 MEMBER ENNIS: Okay. Thank you.

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

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

21 The surgeon more than likely is not a
22 radiologist and more than likely wouldn't want to be
23 an authorized user, and I agree with the subcommittee
24 that a surgeon who has no radiology background should
25 not be allowed to become an authorized user with only

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1 40 hours of -- or, excuse me, 80 hours of total training
2 for this procedure. I don't think that is going to
3 limit this procedure in any way if that change is made,
4 as you guys have -- have recommended.

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

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

17 So that's my question for the
18 subcommittee.

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

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

25 On the breastfeeding, if you have a

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1 ruptured seed, I would think that the precaution would
2 be to completely eliminate breastfeeding rather than
3 just breastfeeding in the one breast because of the
4 potential of the radioactive material going throughout
5 the mother's body. So I would recommend that you not
6 just say for that breast, but that breastfeeding be
7 ceased totally.

8 That is all I had to add. Thank you.

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

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

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

23 MEMBER METTER: This is Darlene. I
24 agree.

25 MEMBER ENNIS: Okay. I should make an

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1 additional comment that we -- the subcommittee actually
2 changed its own recommendation regarding the
3 breastfeeding issue in the following way: in the
4 initial subcommittee report, we talked about ten
5 half-lives of no breastfeeding, but in the -- just for
6 practical purposes and simplicity, we modified that in
7 our new subcommittee report to say this -- for this
8 child.

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

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

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

18 One additional concern I have regarding
19 the explantation that is significantly delayed due to
20 a patient's failure to present for the explantation
21 procedure, in order for patient intervention to be a
22 reasonable reason for not designating the delayed
23 explantation as a medical event, I think there should
24 be a requirement that there's documentation that all
25 appropriate education was provided to the patient

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1 regarding the necessity of timely explantation, and
2 that should be something that can be found and -- and
3 documented in order for patient intervention to be used
4 as a rationale for not designating a medical event.

5 MEMBER ENNIS: So Laura, could you maybe
6 just articulate that a little more specifically, what
7 you would like to specifically require in the medical
8 record as a demonstration of that education?

9 (No audible response.)

10 MEMBER ENNIS: Hello?

11 (No audible response.)

12 MEMBER ENNIS: Hello?

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

14 MEMBER ENNIS: Oh, okay.

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

22 There should be a check-off where, you
23 know, information has been provided to the patient
24 about the necessity for presenting on such-and-such a
25 date for explantation, and the reasons for that

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1 explanation. Is that clearer?

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

5 VICE CHAIRMAN ZANZONICO: This is Pat. I
6 think that is fairly reasonable. I think the -- the
7 patient would be given any number of instructions or
8 follow-up instructions, as they would for any sort of
9 procedure, and -- and including among that a statement
10 to the effect that it's important that the patient
11 return to have the seeds removed, for, among other
12 reasons, avoiding a larger-than-necessary radiation
13 dose, and I don't think that's an unreasonable point
14 to include in -- in information given to the patient.

15 MEMBER ENNIS: Thank you.

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

18 MEMBER ENNIS: Okay. Me too.

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

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

23 MEMBER ENNIS: Go ahead, Sophie.

24 MS. HOLIDAY: When you guys were talking
25 about modifying the report in terms of the safety

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1 precautions where you said that breastfeeding should
2 be eliminated altogether, are you trying to modify the
3 sentence that says "Patients should be advised not to
4 breastfeed from a breast into which one or more
5 radioactive seeds have been implanted and not yet
6 removed," and the other sentence, or just the one
7 regarding the leaking seed?

8 MEMBER ENNIS: Just regarding the leaking
9 seeds.

10 MS. HOLIDAY: Okay. Thank you.

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

13 MR. GREEN: This is Richard Green. May I
14 --

15 MEMBER ENNIS: Sure.

16 MR. GREEN: -- pose a question?

17 MEMBER ENNIS: Yes.

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

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1 MEMBER ENNIS: So the way I would read it
2 would be as follows: the prior wording was rationale
3 for the written -- the working group's --
4 recommendation is that a written directive is required
5 for therapeutic procedures. Since this is a
6 diagnostic procedure, written directive is not
7 necessarily required.

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

15 MR. GREEN: My --

16 MEMBER ENNIS: Yes?

17 MR. GREEN: My concern -- my concern was
18 --

19 MEMBER ENNIS: Go ahead.

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

25 MEMBER ENNIS: Right, exactly --

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1 MR. GREEN: -- so --

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

8 MR. GREEN: Which would fit under 35 Part
9 200, just imagining and localization procedures for
10 which written directive is not required?

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

13 MR. GREEN: Right.

14 MEMBER ENNIS: Right.

15 MS. HOLIDAY: So it's --

16 MR. GREEN: It -- yes. Okay.

17 MEMBER ENNIS: Yes.

18 MR. GREEN: Thank you.

19 MEMBER COSTELLO: This is Frank.
20 Strictly speaking, it's not 35 - 200 because there are
21 other things that you put in that category. This is
22 35 - 1000. But it has similarity to 35 - 200.

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

25 (No audible response.)

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

3 MEMBER METTER: This is Darlene.

4 MEMBER ENNIS: Yes, Darlene?

5 MEMBER METTER: You know on the part when
6 -- about consent before the medical event and the
7 patient didn't return? Perhaps Rich we could add it
8 in that last sentence, where it says the subcommittee
9 report supports a position that a medical event has not
10 occurred in the event patient fails to return for the
11 surgical removal procedure despite informed consent
12 and risk -- I mean, and with procedure risk, considering
13 this to be an instance of patient intervention, we
14 should actually kind of add that to the part there
15 because I think that is, like it was said, it is
16 important to --

17 MEMBER ENNIS: Right.

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

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

23 Thank you. Any other questions or
24 comments?

25 (No audible response.)

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

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

8 (No audible response.)

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

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

25 So with those modifications to the report,

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1 I believe Dr. Alderson we can --

2 CHAIRMAN ALDERSON: Yes.

3 MEMBER ENNIS: -- have a vote on --

4 CHAIRMAN ALDERSON: Yes --

5 MEMBER ENNIS: -- on the report?

6 CHAIRMAN ALDERSON: -- so would the
7 subcommittee like to make a motion for a vote on this
8 report? And I'd remind everyone that no second is
9 needed because this is coming from a subcommittee.

10 MEMBER ENNIS: We would.

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

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

16 (Chorus of ayes.)

17 CHAIRMAN ALDERSON: Are any opposed?
18 State aye.

19 (No audible response.)

20 CHAIRMAN ALDERSON: Are there any
21 abstentions?

22 (No audible response.)

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

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1 you, Dr. Ennis.

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

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

7 We are moving on now to the second subject.
8 Is Ryan Whited or Jim Schaffner on the call, the NRC
9 people?

10 MR. WHITED: Yes, Ryan Whited is here.

11 CHAIRMAN ALDERSON: Good. I will turn
12 the meeting over to Mr. Whited to provide the committee
13 with an overview of the potential rulemaking to the
14 expanded financial assurance requirements in 10 CFR
15 30.35 for certain radioactive byproduct materials.

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

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

23 We are going to take probably ten minutes
24 to just kind of walk you through the handout materials
25 that Sophie has included in the materials for the

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1 meeting and then answer any questions you have on this
2 proposed rulemaking. I want to emphasize at this
3 point, this is only a staff proposal to the Commission.

4 There's a new process for doing this. It
5 is called a rulemaking plan SECY paper, and that
6 resulted from a Commission SRM that came out this past
7 February, so writing this rulemaking plan SECY paper
8 to propose this rulemaking on 10 CFR 30.35, the
9 Commission will have, you know, an opportunity to weigh
10 in and tell us whether they want us to proceed.

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

19 The regulations don't require financial
20 assurance for a majority of the IEA Category 1 and 2
21 as well as lower category radioactive sealed sources,
22 and in fact, the threshold values for radionuclides
23 that are in the back of Part 30, the threshold for sealed
24 material is seven orders of magnitude higher than for
25 unsealed material, and so for many radionuclides, the

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1 threshold level for a Category 1 source, including
2 cesium-137 and cobalt-60, there are no financial
3 assurance requirements. So things like blood
4 irradiators, Gamma Knives, et cetera, at this point,
5 there's no financial assurance required for licensees
6 that only have those types of sources.

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

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

22 End-of-life cost for these sources, and in
23 particular, you know, some of the higher activity
24 sealed sources, can be quite significant, and it can
25 be unpredictable. The cost includes steps like

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1 interim storage, packaging and conditioning,
2 transportation to disposal site or the other -- you
3 know, another type of disposition option such as return
4 to supplier or reuse or recycling.

5 NRC does not currently require licensee to
6 declare when the sealed sources in their possession are
7 disused, and we also don't require them to provide for
8 prompt disposition of those sources once they're
9 disused. And, you know, in some cases, if a licensee
10 has not planned for end-of-life cost for these sources,
11 it can represent a significant financial burden, I
12 mean, on the order of a few hundred thousand dollars
13 or even more.

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

24 And so because of that, you know, licensees
25 may just choose to indefinitely store these things

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1 long-term as the most practical and cost-effective
2 management option.

3 So as I mentioned, you know, we raised this
4 issue to the Commission in September of 2014. We
5 received a Commission SRM that directed us to conduct
6 this, what's called a scoping study, kind of look at
7 the issue and decide, you know, where the staff would
8 recommend the Commission go, and so we initiated the
9 scoping study to determine whether additional
10 financial planning requirements are necessary for
11 end-of-life management of some byproduct material, and
12 in particular, these higher activity radioactive
13 sealed sources.

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

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

25 And so in the materials that you received

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1 in advance of this meeting, we -- we documented the
2 scoping study in a SECY paper that was issued April the
3 7th. That was SECY-16-006, and that paper is publicly
4 available on the NRC website.

5 So in terms of the results of this scoping
6 study, you know, it was a pretty broad study. You know,
7 we didn't go -- you know, have time or resources to drill
8 deeply into all of the technical issues, but we kind
9 of provided an overview, about 40 pages in length, to
10 just survey all of the issues that impact
11 decision-making on this particular topic.

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

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1 requires.

2 We also looked at a number of relevant
3 domestic and international activities like
4 availability of new disposal capacity; issues related
5 to transportation containers, which can be problematic
6 for some of the higher-activity sources -- they're
7 called Type B transportation containers, and there has
8 been an issue with the availability of those over the
9 past several years; the NRC's revised Branch Technical
10 Position on concentration averaging, which might be
11 applied to allow higher activity sources to be disposed
12 of if, again, the disposal sites can look at, you know,
13 the NRC's concentration averaging BTP and adjust their
14 waste acceptance criteria accordingly to possibly
15 allow disposal of sources that have not been allowed
16 to this point.

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

23 And we have also interfaced a lot with the
24 National Nuclear Security Agency, NNSA. They run two
25 programs right now that address disposition of these

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1 sources. One is called the Off-Site Source Recovery
2 Project, which deals with the higher activity Category
3 1 and 2 sources, and they also run what's called the
4 SCTR Program, the Source Collection and Threat
5 Reduction Program.

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

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

24 So we noted in our scoping study that we
25 agree with the assessments that we received from

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1 numerous stakeholders that providing financial
2 assurance for source disposition supports overall
3 safety and security goals. It helps facilitate timely
4 disposition of disused sources, and it helps ensure
5 that the full cost of using radioactive sealed sources
6 is appropriately considered by licensees.

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

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

25 We will provide that paper to the

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1 Commission, and the Commission will make a decision and
2 tell us whether they'd like us to proceed or not. We
3 made this recommendation, you know, to focus on the
4 Category 1 and 2 sources really because we felt it, you
5 know, made sense to focus on the highest -- the sources
6 of highest risk significance right now. We do think
7 that having financial assurance for these sources will
8 reduce the likelihood that some licensees will be
9 unprepared for end-of-life disposition costs. It may
10 help reduce the use of long-term storage as a management
11 option, and we feel it's -- you know, it's complementary
12 to the NRC's existing safety and security regulatory
13 framework.

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

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

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1 On the final page of my handout, you know,
2 one question we often received was well what about the
3 lower-category sealed sources, you know, the IAEA
4 Category 3 and below? And so I wanted to just address,
5 you know, why we decided to focus on Category 1 and 2
6 sources at this time. You know, again, those are the
7 sources that have the highest risk significance. They
8 are generally the most likely sources to have
9 challenges in finding a disposition pathway, and the
10 cost is likely to be higher for those sources compared
11 to other source categories.

12 You know, and also, in terms of
13 implementation, you know, there are about 76,000 or
14 77,000 of these sources that are tracked right now in
15 the NSTS, and those are held by about 1400 NRC and
16 Agreement State licensees. You know, it is going to
17 take some resources and be a complex undertaking to
18 implement this, and we really felt like, you know, the
19 most prudent use of both our resources and Agreement
20 State resources would be to focus on the Category 1 and
21 2 sources now before we consider going down to the lower
22 category sources.

23 And, you know, there was a SECY paper that
24 was written several years ago that looked at numbers
25 of these sources, and basically, if you went down to

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1 Category 3 sources, you would essentially double the
2 number of sources and the number of licensees that would
3 be affected, so it would essentially double the task
4 if you -- if you went to the lower category sources.

5 But, you know, if we decide to do so in the
6 future, certainly, implementing this for Cat 1 and 2
7 sources would help us make sure we're effective and
8 efficient if we decided to further expand financial
9 assurance requirements in the future, and again, as I
10 mentioned, Agreement States have the option now, if
11 they wish, to have more stringent financial assurance,
12 and some of them do go even below the Category 1 and
13 2 sources, and so until we would put rulemaking in
14 place, which would take several years, the Agreement
15 State could continue to do that.

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

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

25 Are there questions that members of the

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1 ACMUI would like to ask?

2 MEMBER COSTELLO: Hey, this is Frank
3 Costello.

4 CHAIRMAN ALDERSON: Yes, go ahead, Frank.

5 MEMBER COSTELLO: Okay. I just have a
6 comment. I would like to express my strong support of
7 this effort. Here in Pennsylvania, we've had a number
8 of cases since we became an Agreement State in 2008.
9 We had a Gamma Knife be abandoned by the licensee and
10 the landlord, you know, because they weren't paying the
11 rent, you know, drilled locks to gain access. We had
12 very recently a blood irradiator used for research,
13 used for the same purpose.

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

24 MR. WHITED: Thank you.

25 CHAIRMAN ALDERSON: Thank --

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1 MR. WHITED: Thank you, Frank.

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

4 VICE CHAIRMAN ZANZONICO: This is Pat. I
5 have a general question, and it may just reflect my
6 ignorance of this whole area, but wouldn't this be
7 impacted, and isn't it impacted, by this sort of more
8 general issue of long-term disposal of -- of
9 radioactivity in general? And -- and would -- I am not
10 -- I am not articulating this well, but wouldn't that
11 need some sort of national consideration, a national
12 plan for disposal of -- of radioactivity? Wouldn't
13 that need to be incorporated in some sense in a -- a
14 source disposal program? Or am I off base on this and
15 thinking about something that's not really relevant?

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

23 For example, you know, in recent years, we
24 have seen the opening of the Waste Control Specialists
25 site in Texas, which has, you know, provided some

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1 additional options for disposal of certain materials
2 that hadn't been available to this point.

3 You know, in general, I think, you know,
4 for sources, you know -- if a source is greater than
5 Class C waste, which again, some of the cesium-137
6 sources are, you know, right now, there is no commercial
7 disposal pathway, and DOE is charged with developing
8 such a pathway, but for the other -- you know, for Class
9 A, B, and C low-level waste, you know, we would hope
10 that the marketplace, you know, would help develop
11 solutions, you know, that would allow disposal pathways
12 to be available, you know.

13 Again, one of many factors is, as I
14 mentioned, the, you know, NRC's new Branch Technical
15 Position on concentration averaging. They actually
16 looked at a scenario in that BTP for a cesium-137
17 source, I believe, and, you know, using new scientific
18 methods, you know, and depending on disposal site
19 characteristics, what that BTP says basically is, you
20 know, you've got to raise the threshold for cesium-137
21 disposal significantly higher than -- than NRC would
22 have allowed in the past, but what we hope is, you know,
23 disposal sites -- you know, but even though NRC is
24 saying that, a disposal site can still through their
25 waste acceptance criteria exclude, you know, whatever

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1 kind of material they wish, and a lot of them -- a lot
2 of the sealed sources, you know, they just -- the waste
3 acceptance criteria for the site won't allow them to
4 be disposed of.

5 You know, that is a problem. NRC, you
6 know, we can try to influence, but you know, it really
7 -- a lot of it is beyond our control. I mean Jim, if
8 you're on the call, you might have some input that would
9 be helpful on that topic.

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

21 CHAIRMAN ALDERSON: Are there other
22 comments or questions?

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

25 CHAIRMAN ALDERSON: Yes, Ron, go ahead.

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1 MEMBER ENNIS: Thank you.

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

6 MR. WHITED: In the United States, I mean,
7 I am not aware of a case where there was like, you know,
8 an accidental exposure that resulted in health
9 consequences, but there are examples where companies
10 have gone bankrupt, you know, or otherwise haven't had
11 the means to properly manage the disposition of the
12 sources, and therefore, another entity has had to come
13 in and bail them out.

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

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

24 MEMBER ENNIS: Yes.

25 MR. SCHAFFNER: There have been instances

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1 of -- of improperly discarded sources being picked up
2 by -- by just random members of the general public in
3 other countries and numbers of people dying as a result,
4 so -- so there is that -- it is more than a risk in
5 principle, though as far as I know as well, it has not
6 occurred in the United States.

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

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

15 MEMBER ENNIS: Yes.

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

20 Florida in particular has an interesting
21 risk-based calculation that they use. So when a --
22 when one of their licensees, you know, proposes to
23 acquire, they -- you know, they're getting a license
24 for these sources, there are a number of parameters
25 that, you know, they have to stay in. I think some of

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1 them are like what -- of course, what type of source
2 is it? What's the activity? What's the isotope?
3 What kind of facility is it going to be used in? And
4 they have like a multiplier that accounts for these
5 factors and -- and then that equation says therefore
6 you owe so much, you know, dollars in financial
7 assurance.

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

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

16 MR. WHITED: Okay. You know, it is -- it
17 is not a recent phenomenon. It's not something that
18 has only been in place the past few years. I know there
19 was a 2010 report, inter-agency report that was done
20 that NRC headed, that also used the State of Texas as
21 an example. They have some feature that's called I
22 believe a universal fund as well where they essentially
23 tax their -- some of their materials licensees, and they
24 have a fund set aside for situations where you have an
25 orphan source or a licensee that goes bankrupt or you

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1 otherwise need a state to help come in and manage the
2 disposition of the source.

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

5 So it would seem that the idea of turning
6 towards the licensee would be from some rationale,
7 well, the licensee benefitted for all the years of the
8 source, or hoped to at least, so he or she or that entity
9 ought to kind of bear -- bear that cost, and there's
10 certainly a rationale for that, but of course, if we
11 stop and think about it a little bit, who benefits, at
12 least within the medical space, from these sources, the
13 benefit is quite broad.

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

21 Then there's the physicians who practice
22 who get to bill Medicare, et cetera, for that. Then
23 there's the hospitals or the facilities. So how do we
24 reasonably spread out that cost if we feel like we need
25 to? I don't know, to my mind, that targeting

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1 specifically one group within all of those is a -- is
2 an appropriate way to kind of spread out the -- the cost.

3 CHAIRMAN ALDERSON: I would interject
4 here that I think that is an excellent, detailed
5 analysis you have provided. I don't think that we're
6 here today to go into that level of discussion. We're
7 certainly not going to solve this problem today, and
8 a number of those things, you know, have occurred to
9 several of us, so I hope we can continue this.

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

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

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

21 MR. WHITED: Yes.

22 CHAIRMAN ALDERSON: Was that for Category
23 1 and 2 sealed sources?

24 MR. WHITED: Yes, that --

25 CHAIRMAN ALDERSON: It was. Okay.

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1 Thank you very much. I've got that clear.

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

7 CHAIRMAN ALDERSON: Good. All right,
8 thank you.

9 Do people on the ACMUI have additional
10 questions?

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

13 CHAIRMAN ALDERSON: Okay. Sue, go ahead.

14 MEMBER LANGHORST: Okay.

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

21 Through that section of the regulations,
22 they pretty much keep those separated. So a
23 clarification that I am seeking is if you have these
24 1400 licensees who need to do a decommissioning funding
25 plan for their sealed sources, would that be limited

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1 only to those sealed sources, and would it not require
2 them to then also sweep up their unsealed sources into
3 that decommissioning funding plan?

4 MR. SCHAFFNER: Well, it would all have to
5 be included, but as Ryan mentioned earlier, there is
6 a seven-order-of-magnitude difference between a
7 threshold for financial assurance for unsealed
8 byproduct material and sealed byproduct material. So,
9 you know, arguably, the unsealed material is probably
10 under a financial assurance umbrella now.

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

22 MR. WHITED: Well, I mean, I can tell you,
23 you know, our -- our starting point, you know, and I
24 think folks who have been involved in rulemakings know,
25 you know, sometimes you can't predict three years after

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1 you start a rulemaking where you're going to end up,
2 but, you know, our opening proposition is that we would
3 modify 30.35 to require financial assurance, you know,
4 only for the Cat 1 and 2 sources for which it is not
5 currently required. I mean, that is kind of the
6 boundary we've drawn around our recommendation.

7 So, you know, those details will be worked
8 out in the technical basis for the rule, and, you know,
9 through the whole three-year rulemaking process, but,
10 you know, I wouldn't envision, you know, just because,
11 you know, a licensee has a Cat 1 or 2 source that they
12 now have to provide financial assurance for that they
13 would have to do a comprehensive decommissioning
14 funding plan if they hadn't had to do -- you know, for
15 unsealed material, if they hadn't had to do that prior.

16 MEMBER LANGHORST: Thank you very much for
17 that.

18 The other question I have that -- actually
19 I guess it's a -- it's a suggestion that I have that
20 you look at too, as you're developing this, excuse me,
21 is the NRC's capability to do these timely reviews of
22 the decommissioning funding plans and these financial
23 assurances. For those of you who don't know, a
24 licensee is required to update the decommissioning
25 funding plan every three years and when they renew their

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1 license, and the license for which I am the radiation
2 safety officer here, our last approved decommissioning
3 funding plan was sent in in September of 2009.

4 We since have sent in an updated
5 decommissioning funding plan in December of 2010, again
6 in February of 2013 when we renewed our license, and
7 we most recently sent in a -- an update in February of
8 this year, 2016.

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

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

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

24 (No audible response.)

25 CHAIRMAN ALDERSON: Hearing none, thank

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1 you Mr. Whited and Mr. Schaffner for telling us about
2 this important topic and where you're headed. I am
3 sure we'll be talking about this again at future ACMUI
4 calls or in our meetings.

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

8 MS. HOLIDAY: Dr. Alderson?

9 CHAIRMAN ALDERSON: -- and thank -- yes?

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

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

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

21 (Pause.)

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

25 (No audible response.)

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

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

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

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

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

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