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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

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

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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 or
13 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 to
17 reach a consensus on the issues that will be discussed
18 today, but I also recognize there may be minority or
19 dissenting opinions. If you have such opinions, please
20 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. WHITEHEAD: This is Ryan Whitehead.

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

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 are
9 participating with us today. Comments and questions
10 are usually addressed by the committee near the end of
11 the meeting after the committee has fully discussed the
12 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 I
2 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 of
9 -- and the community of practitioners who were ready to
10 see the localization request to the NRC for modification
11 or adjustments to the current guidance. Our
12 subcommittee presented its report in the fall, and I'll
13 just briefly highlight some of those issues just to give
14 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 be
22 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 product
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 a
15 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 of
21 neutrality, it was felt that he ought not continue to
22 serve as a member of the subcommittee, and he has been
23 replaced by Dr. Darlene Metter for the current report.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7 (No audible response.)

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

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

12 MEMBER ENNIS: Yes, please, Sue.

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

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

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

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

25 MEMBER ENNIS: Yes.

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1 MEMBER LANGHORST: -- of your --

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

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

6 MEMBER ENNIS: Okay. Thank you.

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

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

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

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

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

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

15 So that's my question for the subcommittee.

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

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

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

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

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

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

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

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

20 MEMBER METTER: This is Darlene. I agree.

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

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

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

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

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

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

25 MEMBER ENNIS: So Laura, could you maybe

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

4 (No audible response.)

5 MEMBER ENNIS: Hello?

6 (No audible response.)

7 MEMBER ENNIS: Hello?

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

9 MEMBER ENNIS: Oh, okay.

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

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

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

25 VICE CHAIRMAN ZANZONICO: This is Pat. I

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

10 MEMBER ENNIS: Thank you.

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

13 MEMBER ENNIS: Okay. Me too.

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

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

18 MEMBER ENNIS: Go ahead, Sophie.

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

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

3 MEMBER ENNIS: Just regarding the leaking
4 seeds.

5 MS. HOLIDAY: Okay. Thank you.

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

8 MR. GREEN: This is Richard Green. May I
9 --

10 MEMBER ENNIS: Sure.

11 MR. GREEN: -- pose a question?

12 MEMBER ENNIS: Yes.

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

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

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1 written directive is not necessarily required.

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

9 MR. GREEN: My --

10 MEMBER ENNIS: Yes?

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

12 MEMBER ENNIS: Go ahead.

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

18 MEMBER ENNIS: Right, exactly --

19 MR. GREEN: -- so --

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

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1 MR. GREEN: Which would fit under 35 Part
2 200, just imagining and localization procedures for
3 which written directive is not required?

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

6 MR. GREEN: Right.

7 MEMBER ENNIS: Right.

8 MS. HOLIDAY: So it's --

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

10 MEMBER ENNIS: Yes.

11 MR. GREEN: Thank you.

12 MEMBER COSTELLO: This is Frank.
13 Strictly speaking, it's not 35 200 because there are
14 other things that you put in that category. This is 35
15 1000. But it has similarity to 35 200.

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

18 (No audible response.)

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

21 MEMBER METTER: This is Darlene.

22 MEMBER ENNIS: Yes, Darlene?

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

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

10 MEMBER ENNIS: Right.

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

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

16 Thank you. Any other questions or
17 comments?

18 (No audible response.)

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

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

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1 (No audible response.)

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

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

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

20 CHAIRMAN ALDERSON: Yes.

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

22 CHAIRMAN ALDERSON: Yes --

23 MEMBER ENNIS: -- on the report?

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

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

3 MEMBER ENNIS: We would.

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

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

9 (Chorus of ayes.)

10 CHAIRMAN ALDERSON: Are any opposed?
11 State aye.

12 (No audible response.)

13 CHAIRMAN ALDERSON: Are there any
14 abstentions?

15 (No audible response.)

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

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

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

25 We are moving on now to the second subject.

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

3 MR. WHITEHEAD: Yes, Ryan Whitehead is
4 here.

5 CHAIRMAN ALDERSON: Good. I will turn the
6 meeting over to Mr. Whitehead to provide the committee
7 with an overview of the potential rulemaking to the
8 expanded financial assurance requirements in 10 CFR
9 30.35 for certain radioactive byproduct materials.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19 And so in the materials that you received
20 in advance of this meeting, we -- we documented the
21 scoping study in a SECY paper that was issued April the
22 7th. That was SECY-16-006, and that paper is publicly
23 available on the NRC website.

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

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

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

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

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

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

17 And we have also interfaced a lot with the
18 National Nuclear Security Agency, NNSA. They run two
19 programs right now that address disposition of these
20 sources. One is called the Off-Site Source Recovery
21 Project, which deals with the higher activity Category
22 1 and 2 sources, and they also run what's called the SCTR
23 Program, the Source Collection and Threat Reduction
24 Program.

25 And basically, you know, they run those

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

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

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

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

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

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

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

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

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

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

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

6 You know, and also, in terms of
7 implementation, you know, there are about 76,000 or
8 77,000 of these sources that are tracked right now in
9 the NSTS, and those are held by about 1400 NRC and
10 Agreement State licensees. You know, it is going to
11 take some resources and be a complex undertaking to
12 implement this, and we really felt like, you know, the
13 most prudent use of both our resources and Agreement
14 State resources would be to focus on the Category 1 and
15 2 sources now before we consider going down to the lower
16 category sources.

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

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

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

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

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

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

21 MEMBER COSTELLO: Hey, this is Frank
22 Costello.

23 CHAIRMAN ALDERSON: Yes, go ahead, Frank.

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

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

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

18 MR. WHITEHEAD: Thank you.

19 CHAIRMAN ALDERSON: Thank --

20 MR. WHITEHEAD: Thank you, Frank.

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

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

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

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

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

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

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

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

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

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

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

15 CHAIRMAN ALDERSON: Are there other
16 comments or questions?

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

19 CHAIRMAN ALDERSON: Yes, Ron, go ahead.

20 MEMBER ENNIS: Thank you.

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

25 MR. WHITEHEAD: In the United States, I

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

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

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

18 MEMBER ENNIS: Yes.

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

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

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

9 MEMBER ENNIS: Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12 You talked about 70,000 roughly sources and
13 1400 licensees.

14 MR. WHITEHEAD: Yes.

15 CHAIRMAN ALDERSON: Was that for Category
16 1 and 2 sealed sources?

17 MR. WHITEHEAD: Yes, that --

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

20 MR. WHITEHEAD: I believe -- you know, I
21 just heard somebody that helps manage that system --
22 well, Sophie probably knows as well. I think the
23 current number for NSTS is around 77,000 Category 1 and
24 2 sources that are tracked.

25 CHAIRMAN ALDERSON: Good. All right,

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1 thank you.

2 Do people on the ACMUI have additional
3 questions?

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

6 CHAIRMAN ALDERSON: Okay. Sue, go ahead.

7 MEMBER LANGHORST: Okay.

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

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

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

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

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

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

25 So, you know, those details will be worked

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

9 MEMBER LANGHORST: Thank you very much for
10 that.

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

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

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1 year, 2016.

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

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

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

17 (No audible response.)

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

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

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1 MS. HOLIDAY: Dr. Alderson?

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

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

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

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

14 (Pause.)

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

18 (No audible response.)

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

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

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

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

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

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