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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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PUBLIC MEETING

+ + + + +

THURSDAY,

MARCH 19, 2015

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The meeting was convened in Room T2B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:30 a.m., Bruce R. Thomadsen, Ph.D., ACMUI Chairman, presiding.

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1 MEMBERS PRESENT:

2 BRUCE R. THOMADSEN, Ph.D., Chairman

3 PHILIP O. ALDERSON, M.D., Vice Chairman

4 FRANCIS M. COSTELLO, Agreement State
5 Representative

6 VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

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

8 SUSAN M. LANGHORST, Ph.D., Radiation Safety
9 Officer

10 STEVEN R. MATTMULLER, Nuclear Pharmacist

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

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

14 JOHN J. SUH, M.D., Radiation Oncologist

15 LAURA M. WEIL, Patients' Rights Advocate

16 PAT B. ZANZONICO, Ph.D., Nuclear Medicine
17 Physicist

18 Non-Voting: FRED A. METTLER, JR., M.D.

19

20 NRC STAFF PRESENT:

21 LAURA DUDES, Director, Division of Material
22 Safety, State, Tribal and Rulemaking Programs

23 DOUGLAS BOLLOCK, Designated Federal Officer

24 SOPHIE HOLIDAY, Alternate Designated Federal
25 Officer, ACMUI Coordinator

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1 NRC STAFF PRESENT (CONT'D) :

2 MARYANN ABOGUNDE, NMSS/MSTR/MSEB
3 LUIS BENEVIDES, Ph.D., RES/DSA/RPB
4 JENNIFER BISHOP, RIII/DNMS/MLB
5 MARCIA CARPENTIER, OGC/GCHEA/AGCNRP
6 COLLEEN CASEY, RIII/DNMS/MLB
7 ASHLEY COCKERHAM, NMSS/MSTR/MSEB
8 SAID DAIBES, Ph.D., NMSS/MSTR/MSEB
9 SARA FORSTER, RIII/DNMS/MLB
10 CASSANDRA FRAZIER, RIII/DNMS/MLB
11 SANDRA GABRIEL, Ph.D., NMSS/MSTR/MSEB
12 JOSEPH GIESSNER, RIII/DRP
13 LATISCHA HANSON, RIV/DNMS/NMSB-A
14 MICHELLE HAMMOND, RIV/DNMS/NMSB-B
15 VINCENT HOLAHAN, Ph.D, NMSS/MSTR
16 DONNA-BETH HOWE, Ph.D., NMSS/MSTR/MSEB
17 CARDELIA MAUPIN, NMSS/MSTR/RPMB
18 ANGELA McINTOSH, NMSS/MSTR/MSEB
19 TONY McMURTRAY, NMSS/MSTR/MSLB
20 KEVIN NULL, RIII/DNMS/MLB
21 PATTY PELKE, RIII/DNMS/MLB
22 LYMARI SEPULVEDA, NMSS/MSTR/MSLB
23 SAMI SHERBINI, Ph.D., RES/DSA
24 TOYE SIMMONS, RIII/DNMS/MLB
25 KATIE TAPP, Ph.D, RES/DSA/RPB

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1 NRC STAFF PRESENT (CONT'D):

2 FRANK TRAN, RIII/DNMS/MLB

3 LESTER TRIPP, RI/DNMS/MB

4

5 ALSO PRESENT:

6 BETTE BLANKENSHIP, American Association for
7 Physicists in Medicine

8 SUE BUNNING, Society of Nuclear Medicine and
9 Molecular Imaging

10 PETER CRANE, *unaffilitated*

11 ROBERT DANSEREAU, New York State Department of
12 Health

13 WILLIAM DAVIDSON, University of Pennsylvania

14 LYNNE FAIROBENT, American Association for
15 Physicists in Medicine

16 CAITLIN KUBLER, Society of Nuclear Medicine and
17 Molecular Imaging

18 JOSH MAILMAN, Society of Nuclear Medicine and
19 Molecular Imaging

20 RICHARD MARTIN, American Association for
21 Physicists in medicine

22 MICHAEL PETERS, American College of Radiology

23 DHEREEN PRASAD, Roswell Park Cancer Center

24 MICHAEL SHEETZ, University of Pittsburgh

25

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1 ALSO PRESENT (CONT'D) :

2 CINDY TOMLINSON, American Society for Radiation
3 Oncology

4 RICHARD WAHL, Mallinckrodt Institute of
5 Radiology

6 BIN WANG, Walter Reed National Military Medical
7 Center

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

(8:38 a.m.)

CHAIRMAN THOMADSEN: Thank you one and all for attending.

And I would like to welcome our new member. Dr. Ennis is now official on the Committee. And newly appointed is Dr. Fred Mettler, who'll be taking a position as a diagnostic radiologist.

Welcome. I hope you enjoy your stay with us.

MEMBER METTLER: Thank you.

CHAIRMAN THOMADSEN: And with that, I'll turn it over -- Mr. Bollock, are you the one who is going to be doing the opening?

MR. BOLLOCK: I am.

CHAIRMAN THOMADSEN: Very fine. Please.

MR. BOLLOCK: Thank you. As the Designated Federal Official for this meeting I'm pleased to welcome you to this public meeting of the Advisory Committee on the Medical Uses of Isotopes.

My name is Douglas Bollock. I'm the Branch Chief of the Medical Safety and Events Assessment Branch and I have been designated as the federal officer for this advisory committee in accordance with 10 CFR Part 7.11.

Present today as the alternate designated

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1 federal officer is Sophie Holiday, our ACMUI
2 coordinator.

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

7 This meeting is being transcribed by the
8 NRC and it may also be transcribed or recorded by others.
9 The meeting was announced in the January 27th, 2015
10 edition of the *Federal Register*, Volume 80, pages 4319
11 through 4320.

12 The function of the Committee is to advise
13 the staff on issues or questions that arise on the
14 medical use of byproduct material. The Committee
15 provides counsel to the staff, but does not determine
16 or direct the actual decisions of the staff or the
17 Commission. The NRC solicits the views of the
18 Committee and values their opinion.

19 I request that whenever possible we try to
20 reach a consensus on the procedural issue that we'll
21 discuss today, but I also recognize there may be a
22 minority or dissenting opinions. If you have such
23 opinions, please allow them to be read into the record.

24 At this point I'd like to perform a roll
25 call of the ACMUI members participating today.

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1 Our Chairman, Dr. Bruce Thomadsen, therapy
2 medical physicist.

3 CHAIRMAN THOMADSEN: Present.

4 MR. BOLLOCK: Our Vice Chairman, Dr.
5 Philip Alderson, health care administrator.

6 VICE CHAIR ALDERSON: Here.

7 MR. BOLLOCK: Mr. Frank Costello, our
8 Agreement State representative.

9 MEMBER COSTELLO: Here.

10 MR. BOLLOCK: Dr. Vasken Dilsizian, our
11 nuclear cardiologist.

12 MEMBER DILSIZIAN: Present.

13 MR. BOLLOCK: Dr. Ronald Ennis, radiation
14 oncologist.

15 MEMBER ENNIS: Here.

16 MR. BOLLOCK: Dr. Sue Langhorst, radiation
17 safety officer.

18 MEMBER LANGHORST: Here.

19 MR. BOLLOCK: Mr. Steve Mattmuller,
20 radiation pharmacist.

21 MEMBER MATTMULLER: Here.

22 MR. BOLLOCK: Dr. Michael O'Hara, our FDA
23 representative.

24 MEMBER O'HARA: Present.

25 MR. BOLLOCK: Dr. Christopher Palestro,

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1 our nuclear medicine physician.

2 MEMBER PALESTRO: Present.

3 MR. BOLLOCK: Dr. John Suh, radiation
4 oncologist.

5 MEMBER SUH: Here.

6 MR. BOLLOCK: Ms. Laura Weil, our
7 patients' right advocate.

8 MEMBER WEIL: Here.

9 MR. BOLLOCK: And Dr. Pat Zanzonico, our
10 nuclear medicine physicist.

11 MEMBER ZANZONICO: Here.

12 MR. BOLLOCK: Okay. I've confirmed we
13 have at least six members, and we have a quorum.

14 At the table we also have Dr. Fred Mettler.
15 Dr. Mettler has been selected as the ACMUI diagnostic
16 radiologist. Dr. Mettler is pending his security
17 clearance, but may participate in the meeting; however,
18 he does not have voting rights at this time.

19 I'd like to also add that this meeting is
20 being Web cast, and so other individuals may be watching
21 online. We have a bridge line available and the phone
22 number is (888) 864-0940. The passcode to access the
23 bridge line is 70873#.

24 Individuals who would like to ask a
25 question or make a comment regarding a specific issue

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1 the Committee has discussed should request permission
2 to be recognized by the ACMUI Chairperson, Dr. Bruce
3 Thomadsen. Dr. Thomadsen at his option may entertain
4 comments or questions from members of the public who are
5 participating with us today. Comments and questions
6 are usually addressed by the Committee near the end of
7 the meeting after the Committee has fully discussed the
8 topic. We ask that one person speak at a time as this
9 meeting is also closed-captioned.

10 I'd also like to add hand-outs and agenda
11 for this meeting are available on the NRC's public Web
12 site.

13 At this time I'd ask that everyone on the
14 call is not speaking to place their phones on mute. If
15 you do not have the capability to mute your phone, please
16 press star six to utilize the conference line mute and
17 un-mute functions. I would ask everyone to exercise
18 extreme care to ensure that background noise is kept at
19 a minimum as any stray background noise can be very
20 disruptive in a conference call this large.

21 At this point I'd like to turn the meeting
22 over to Laura Dudes, Director of the Division of
23 Materials Safety, States, Tribal and Rulemaking
24 Programs for some opening remarks.

25 MS. DUDES: Good morning.

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1 ALL: Good morning.

2 MS. DUDES: How's everybody doing? I'm
3 glad I don't have a script.

4 (Laughter.)

5 MS. DUDES: And I often forget that this
6 meeting is being webcast, so when I'm sitting here going
7 like this --

8 (Laughter)

9 MS. DUDES: So I'm trying to say, okay,
10 make sure you're looking attentive at this. And I'm
11 always attentive to the topics that we have here.

12 The change of the seating is a little
13 different, but good. At least we still have some
14 balance of where people used to sit.

15 I want to just confirm, I know the Chair and
16 Doug have welcomed our new members, but also Dr. O'Hara
17 coming in as our FDA representative. I appreciate
18 that. And congratulate Dr. Alderson as our new Vice
19 Chair. So we have had some change since the last
20 meeting.

21 Doug, although he's been with us since last
22 February in an acting capacity, I believe, he's now the
23 permanent branch chief for the Medical Safety Branch.

24 Chris Einberg, who was the former branch
25 chief, has graciously taken over our Agreement State

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1 Branch, and so he's part of our team still, but he's
2 doing another function for us now.

3 Then the other news of change is that this
4 will be my last ACMUI meeting. I have taken a position
5 in Region II in Atlanta. I often tell everyone if
6 you're not aware Sophie has recently relocated to
7 Atlanta, although she still works for us. And I said
8 well, as soon as I found out Sophie was leaving, I had
9 to go to Atlanta as well.

10 (Laughter.)

11 MS. DUDES: But really fantastic news
12 about this change is the person coming in to replace me
13 is someone who has done this job for years and years and
14 years in various capacities. It's Josie Piccone. If
15 I'm not sure if you are familiar with her, but she has
16 an extensive background in both medical, health
17 physics, state and tribal programs, rulemaking, and has
18 done -- even though the division has merged and taken
19 on different functions, truthfully Josie has done all
20 of them. And so that will be a seamless transition. I
21 know she will be very supportive of the Committee and
22 I think you'll enjoy having her. As I sit here and
23 listen to the presentations and I'm fascinated,
24 interested and getting myself educated, she has a very
25 strong background in this area. So it will be very good

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1 for the division.

2 So in opening remarks we've added these
3 open forum parts to the agenda. And this is my last
4 meeting. Unfortunately I won't be able to join you
5 tomorrow. I'm going to get a crown after a root canal,
6 so that's --

7 (Laughter)

8 MS. DUDES: But anyways, Pamela Henderson
9 should be here with you tomorrow.

10 But I feel so lucky to have worked in this
11 division. I told Patty Pelke, who's here from Region
12 III, a few moments ago that I think my life will be so
13 much more linear when I go back to reactors than it has
14 been in the past two years just because any given day,
15 whether it's a brachytherapy treatment or a diagnostic
16 issue or a generator issue that Donna-Beth has taught
17 me all about, patient release, radiography, rulemaking,
18 tribal, your brain shifts gears 10 times a day in this
19 division, and I've truly enjoyed it.

20 With respect to this Committee, I would say
21 that I keep encouraging that as much open dialogue, as
22 much direction as you can give the staff, keep it coming
23 and use the open forums. Use your experience. Bring
24 it here and help the staff craft regulations that are
25 supportive of the public health and safety, supportive

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1 of the workers, but not intrusive in the practice of
2 medicine. Those are the most difficult issues that we
3 have on any given day is looking at an event that
4 occurred as a result of a treatment that is doing so much
5 good for an individual and balancing how the staff
6 reacts.

7 And so this is the Committee that can really
8 influence that. Whether it's comments on Part 20 or
9 Part 35 and where we go, how we resolve those things,
10 this is the committee that has the expertise. And the
11 more early discussions we have -- I've always encouraged
12 the staff don't wait and go create something and then
13 say here, Committee, what do you think? Use, within the
14 FACA process, but use, whether it's teleconferences or
15 subcommittees, to get as much early engagement on issues
16 as possible.

17 So I do want to thank you all very much for
18 helping me understand the line between regulatory and
19 the practice of medicine and teaching me a little bit.
20 I think I'm smarter now. And I know I will actually be
21 a better patient, hopefully, or a patient advocate
22 having had the opportunity to work with you.

23 So with that, I will turn it over to the
24 Chair.

25 CHAIRMAN THOMADSEN: And on behalf of the

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1 Committee I can say we've much enjoyed working with you.
2 We've appreciated your openness and your concern. And
3 we will miss you. We wish you well in your new position.

4 MS. DUDES: Thank you.

5 CHAIRMAN THOMADSEN: And I'll have to
6 apologize to Dr. O'Hara for not introducing you.
7 You're far enough around the table. It seems like
8 you've been here for a while.

9 (Laughter.)

10 CHAIRMAN THOMADSEN: Is this your first
11 -- you were here last meeting.

12 MEMBER O'HARA: It is the first meeting.

13 CHAIRMAN THOMADSEN: This is your first
14 meeting. Oh my gosh. Well, welcome definitely to you,
15 too.

16 MEMBER O'HARA: Thank you.

17 CHAIRMAN THOMADSEN: And I hope you, like
18 everybody else, enjoy the work here.

19 MEMBER O'HARA: I'm sure it will be an
20 experience.

21 CHAIRMAN THOMADSEN: Yes.

22 (Laughter.)

23 CHAIRMAN THOMADSEN: It certainly will be
24 that, yes.

25 We start out with old business and Ms.

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1 Holiday.

2 MS. HOLIDAY: Good morning, everyone.

3 As I like to say, I know this is your most favorite part
4 of the meeting when we go over our old recommendations
5 and actions.

6 So to start off, on the screen and in your
7 handouts -- again as Doug said, there are meeting
8 handouts in the back of the room on my left side behind
9 the lady in blue in case you need a handout.

10 So on the screen we have 2007, and there's
11 nothing different on here than it was in the fall
12 meeting. All these items are included in the current
13 Part 35 rulemaking.

14 So then we can move on to 2008. And in 2008
15 the same thing as last September's meeting. All of
16 these are included in the current Part 35 rulemaking
17 with the exception of items 5, 19 and 20. Those are
18 delayed, meaning they are not included in the current
19 rulemaking.

20 Then we move on to 2009. Same thing as last
21 meeting. These two items are in the current Part 35
22 rulemaking.

23 2010 is not included in this list because
24 we did close all of those items.

25 For 2011 all of these are included in the

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1 Part 35 rulemaking.

2 And then we move on to 2012. There's only
3 one item and that was to say that ACMUI requested the
4 reporting structure be reviewed on an annual basis.
5 Since this is an ongoing item, that just forever stays
6 open on this list. And we will hear about that from me
7 in this meeting.

8 So we move on to 2013. 2013, this was when
9 the Committee worked on providing their comments on the
10 current Part 35 rulemaking. So, all of these are
11 included in the Part 35 rulemaking with the exception
12 of items 21 and 25. Twenty-one has to deal with the
13 germanium/gallium-68 generators, which we will hear
14 from Mr. Mattmuller's subcommittee report later on this
15 afternoon. And item 25 was just to reestablish the
16 Rulemaking Subcommittee. As the Committee is aware,
17 when the current Part 35 rulemaking gets ready to go into
18 the draft final stage, that will come back to the
19 Committee for their review. You will also hear more
20 about the rulemaking status from Ms. Neelum Bhalla later
21 on.

22 So then we move on to 2014. So again for
23 the first item that has to deal with Mr. Mattmuller's
24 subcommittee. Again, we'll hear from them later on
25 today. And for items 10, 11, 12 and 13 this has to deal

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1 with the Y-20 Microspheres Medical Event Reporting
2 Criteria Subcommittee report. And staff is currently
3 in the process of reviewing and evaluating those
4 recommendations. As you all are aware, Ms. Cockerham
5 was on rotation during the time, and we have to learn
6 to balance priorities, but we are currently evaluating
7 those recommendations.

8 You move on to item 17 where Dr. Thomadsen
9 created a task group, if you will, with Mr. Costello and
10 Dr. Langhorst. You will hear from them two
11 presentations after me.

12 And for item 18 we can close that because
13 we're all here at the spring meeting.

14 Item 19, Dr. Thomadsen formed the
15 subcommittee to address the AMPR for Part 20. The
16 Committee had a public teleconference on December 10th,
17 2014 where we received the subcommittee's report which
18 was endorsed by the full ACMUI. And that report was
19 received in its final form with the minor comments or
20 changes that were suggested during that public
21 teleconference and distributed in January of this year.

22 Then you move on to item 20. Item 20 had
23 to deal with the time where we had heard about the draft
24 legislation that went to the Appropriations Committee
25 with the Water and Energy Bill. At that time Dr.

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1 Thomadsen had asked Dr. Suh and Dr. Welsh, our former
2 ACMUI radiation oncologist, to also work with -- not at
3 that time, but is now our current radiation oncologist,
4 Dr. Ennis, to pair with ASTRO to address providing
5 language to make changes to that bill. That has
6 actually -- let's see, NRC was issued in Section 402 of
7 our appropriations. We were directed to assess our
8 current Part 35.

9 MS. DUDES: Part 37.

10 MS. HOLIDAY: Part 37. I'm sorry. Thank
11 you, Laura. So we have been directed to do that
12 assessment. So that I can consider -- item 20 I still
13 would like to keep it open because that means that that
14 bill has not been closed. So it's still out there at
15 this time. Did I say that correctly?

16 MS. DUDES: Well, I would suggest maybe
17 that during the meeting if you wanted to reformulate or
18 rethink that action item for a longer-term view -- I
19 think we talked about -- the original draft legislation
20 was challenging and very directive. And now we have a
21 piece of legislation that tells us to see if the source
22 security rule -- do an assessment of it after two years
23 of implementation.

24 But there may be other issues that the
25 Committee would want to consider around the idea of

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1 alternative technologies or source security. And I
2 would leave that up to you. You could close that
3 because the appropriations came and the language was
4 very simple. It just said do a two-year assessment of
5 Part 37. Report back to Congress and then direct the
6 GAO to do an audit with an independent.

7 So that sort of addresses the immediate
8 issue. But there are broader issues to source
9 security. And I think more for the medical community
10 in terms of the status of alternative technologies,
11 what's viable for various therapies or diagnostics or
12 blood irradiators. So I would suggest you close that
13 item because it was very specific to language if the
14 Committee believes that to be the case, but consider if
15 there's anything else you would like to pursue over this
16 period of time related to source security. And I guess
17 it's the viability of alternative technologies, but
18 it's also impacts to the medical community if there were
19 to be a different set of security requirements. So I
20 would just leave that back to you.

21 CHAIRMAN THOMADSEN: And I think that's
22 reasonable to at least talk about. Right now I would
23 entertain a motion to close that item.

24 MEMBER LANGHORST: So moved.

25 CHAIRMAN THOMADSEN: We have a motion. Do

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1 we have a second?

2 MEMBER COSTELLO: Second.

3 CHAIRMAN THOMADSEN: We have a second.
4 Discussion? Yes, Dr. Langhorst?

5 MEMBER LANGHORST: I think it is a very
6 important topic for this group to take up, and I say that
7 with hesitation because I know who you're going to want
8 to lead that effort.

9 (Laughter.)

10 MEMBER LANGHORST: And, yes, I'd be glad
11 to.

12 (Laughter.)

13 CHAIRMAN THOMADSEN: Okay. That will
14 come up just a little bit later. Any other discussion?
15 You've already volunteered. Dr. Langhorst?

16 MEMBER LANGHORST: I do want to talk about
17 some of the other things, but --

18 (Simultaneous speaking.)

19 CHAIRMAN THOMADSEN: We'll come to those,
20 yes. Any other discussion on this motion?

21 Hearing none, all in favor, say aye?

22 (Chorus of ayes.)

23 CHAIRMAN THOMADSEN: Opposed, say no.

24 (No response)

25 CHAIRMAN THOMADSEN: Abstentions?

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1 (No response)

2 CHAIRMAN THOMADSEN: It passes. We'll
3 close that particular item.

4 MS. HOLIDAY: Excellent. Thank you.
5 Then that brings us to the last item on this chart which
6 is again dealing with the ANPR for Part 20 simply to say
7 that the Full Committee endorsed the subcommittee
8 report.

9 Are there any comments or questions or
10 concerns with any of these recommendation action
11 charts?

12 CHAIRMAN THOMADSEN: Dr. Langhorst?

13 MEMBER LANGHORST: I just wanted to
14 clarify on the 2007-2008 when you say things are part
15 of the Part 35 rulemaking --

16 MS. HOLIDAY: Yes.

17 MEMBER LANGHORST: -- some are not. Like
18 looking at Gamma Knife Perfexion going from 1,000 to
19 600. So those have been delayed.

20 MS. HOLIDAY: Yes, items 5, 19 and 22 on the
21 2008 chart are delayed.

22 MEMBER LANGHORST: Right. Right. And
23 also that while some of your -- you mentioned that some
24 of our recommendations are part of Part 35, they weren't
25 accepted. For instance, the Committee strongly

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1 encouraged that all people with board certifications be
2 approved as authorized individuals whenever their board
3 certification happened. And I don't think that was in
4 the proposed Part 35. And also the fact that the
5 parental administration of betas versus alphas, we
6 suggested that not be separated, but it was in the
7 proposed Part 35. So while they were included, they
8 weren't accepted. So I just want to make those --

9 MS. HOLIDAY: I'd also like to respond to
10 that and say so when I say they're included in the
11 current Part 35, it's, as you said, not exactly to say
12 that we have accepted them, but as you know, this is
13 still the draft proposed rule. So it's not final yet.
14 Staff may send it up as certain way and the Commission
15 may come back and say we don't want it like that. But
16 the Rulemaking Group will address all of the
17 recommendations, all of the comments. So there is
18 -- and Neelam will speak to the Committee later on to
19 tell you that the working group is currently addressing
20 all of the comments that we received. As you all know,
21 the comment period ended November 18th of 2014, so that
22 working group is working very vigorously to address all
23 of the comments that were received.

24 MEMBER LANGHORST: Right. I just wanted
25 to clarify that they were made part of 35, but they

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1 weren't all accepted.

2 MS. HOLIDAY: Absolutely. Absolutely.

3 Okay. Are there any other comments,
4 questions or concerns regarding these charts?

5 Doesn't seem to have any. Thank you very
6 much, Ms. Holiday.

7 MS. HOLIDAY: Great. Thank you.

8 CHAIRMAN THOMADSEN: And now we have time
9 designated for an open forum where the ACMUI will
10 identify topics of concern that we should think about,
11 maybe include in future meetings. Yes, Dr. Zanzonico?

12 MEMBER ZANZONICO: Good morning,
13 everyone. I had several issues that came to mind when
14 I saw this agenda topic. The first is the MIRD
15 Committee of the Society of Nuclear Medicine Molecular
16 Imaging. They're going to be publishing a monograph on
17 alpha particle dosimetry. And it's clear from the
18 literature they compiled and their review that there's
19 a real future for alpha particle emitters in
20 radionuclide therapy. And it struck me that when the
21 Committee was considering the licensing requirements
22 for radium-223 dichloride.

23 My recollection was that we, the NRC,
24 stopped short of the licensing requirements across all
25 alpha particle emitters, but rather restricted what was

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1 decided specifically to Xofigo. And I think a broader
2 licensing for all alpha emitters consistent with what
3 was decided for Xofigo should be considered, because I
4 think again there will be a real future for alpha
5 particle emitters in nuclide therapy.

6 CHAIRMAN THOMADSEN: Sophie, can you
7 clarify, was our decision specifically for that
8 particular radiopharmaceutical? I think it was not.

9 MS. HOLIDAY: If I may direct that --

10 MEMBER ZANZONICO: I thought there was
11 some discussion to that effect, and correct me if I'm
12 wrong.

13 MS. HOLIDAY: If I may direct that to Dr.
14 Howe who's more familiar with radium-223.

15 CHAIRMAN THOMADSEN: Please.

16 DR. HOWE: In the Part 35 rulemaking we're
17 addressing alpha emitters used in nuclear medicine in
18 general. When the Xofigo was looked at, it was looked
19 at in particular because it was the only one. And we
20 were looking at its properties and how it could be used.
21 So I do believe the answer is both. We looked at Xofigo
22 and all of the things that we knew about it, and then
23 we're looking at alpha emitters being used primarily for
24 alpha emitters in a more general term for the
25 rulemaking. Does that answer the question?

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1 CHAIRMAN THOMADSEN: Yes, thank you very
2 much, Dr. Howe. And with that it's definitely a topic
3 we should have on the agenda at least to clarify if it's
4 not done. Yes, thank you.

5 MEMBER ZANZONICO: Understood. So I had
6 several more items.

7 CHAIRMAN THOMADSEN: Yes?

8 MEMBER ZANZONICO: One is the propriety
9 and value of dose tracking. In other words, I guess in
10 Europe they characterize it as a smart card where the
11 cumulative radiation doses received by patients from
12 diagnostic studies is recorded for some purpose. And
13 I think as you are suggesting or -- we should actively
14 engage the staff in timely issues. And I think this is
15 one that if it's not timely yet, will become timely, the
16 issue of whether there's value, propriety, etcetera,
17 etcetera in a dose tracking practice and so forth. It
18 may be a bit broader than usual topics addressed by the
19 NRC, but I think we have an opportunity to make a
20 statement on it and I would encourage the ACMUI to do
21 so.

22 And perhaps a related issue, there was an
23 editorial several years ago by Hedvig Hricak, who's the
24 chairman of radiology at Memorial, and David Brenner
25 which stopped short of recommending regulatory dose

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1 limits for diagnostic imaging procedures. And that
2 might be a companion issue that's worth considering and
3 staking some position on.

4 And the last item which I'll be speaking
5 about, which is disposition of radioactive cadavers
6 following either brachytherapy or radionuclide
7 therapy. And I was struck as I was researching the
8 topic for my talk about how sparse and, for lack of a
9 better term, ill-defined the regulatory guidance is on
10 the topic. So I presume, or I hope that my talk today
11 will sort of be the initial effort in formulating, for
12 lack of a better term, more helpful guidelines for
13 disposition of radioactive cadavers. When I
14 originally was looking into it I thought it was simply
15 a non-issue, but there's some technical complexities
16 that warrant further attention. So those would be my
17 suggestions in terms of issues to address in the near
18 future.

19 CHAIRMAN THOMADSEN: Thank you very much,
20 Dr. Zanzonico.

21 Do we have other recommendations? Yes,
22 Dr. Mettler.

23 DR. METTLER: Just on the dose tracking
24 issue, if anybody's starting to look into it, of course
25 the National Academy just had a whole workshop on it and

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1 they published a whole document on it recently that
2 included radiology and nuclear medicine and everything
3 else. It's got some issues.

4 CHAIRMAN THOMADSEN: Yes.

5 DR. METTLER: The other thing is down the
6 road -- I don't know enough about this, but I've seen
7 research proposals lately about nanotechnologies to go
8 with nuclear medicine therapy. And so people are
9 working on it. And I don't know enough about
10 nanotechnology to understand exactly what they're
11 doing, but I don't know whether there's any safety
12 issues or regulatory issues that ought to be looked at.

13 CHAIRMAN THOMADSEN: Very good. I'll put
14 that down definitely. We are working on that at
15 Wisconsin. Yes, good topic.

16 Any others? Dr. Langhorst?

17 MEMBER LANGHORST: We will be having a
18 speaker later at this meeting concerning the licensing
19 guidance for Part 35.1000. And that might be something
20 that the Committee would want to take up on some of the
21 older licensing guidance documents to maybe -- if they
22 haven't been brought before us to kind of step through
23 those and see where things stand on those. So that
24 would be my suggestion.

25 CHAIRMAN THOMADSEN: Very good. Thank

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1 you.

2 VICE CHAIR ALDERSON: Dr. Alderson here.
3 This is a part where I thought maybe Ms. Langhorst was
4 going to explore what she said a few moments ago, but
5 this issue of source security is an area of great
6 interest to me and I support her interest in that. And
7 I think this Committee shouldn't stop discussing it.
8 Even though the Water and Energy Bill has kind of made
9 it a set-aside momentarily, I think it's a very
10 important issue to discuss going forward.

11 CHAIRMAN THOMADSEN: Thank you. Any
12 other topics?

13 (No response.)

14 CHAIRMAN THOMADSEN: In that case we'll
15 close this part of our discussion, but do keep in mind
16 that these things can come up any time as they rise
17 during the rest of our discussions today.

18 That brings us to quite a similar topic
19 talking about new discussion and Dr. Langhorst and Mr.
20 Costello will be talking about the potential for
21 additional topical meetings.

22 MEMBER LANGHORST: Sophie said she would
23 drive my slides, so I appreciate that. And thank you
24 very much.

25 Next slide. So Dr. Thomadsen asked Mr.

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1 Costello and Dr. Davis and I to look at creating a
2 proposal to present to you all this meeting on costs and
3 logistics for additional face-to-face meeting and/or
4 maybe a medical regulatory information conference to
5 present. This has been a challenge. We feel we've had
6 some very valuable discussions on what it would take to
7 develop this, but we maybe have not met your expectation
8 at this meeting.

9 Next slide. We've discussed who would or
10 should be the target audiences for this meeting between
11 the medical community and regulators. And when I say
12 "medical community," I don't mean to leave out the
13 patient community either. I think they're part of the
14 medical community because they are part of that medical
15 treatment/medical diagnostic discussion.

16 Perhaps a good place to start is with the
17 organizations associated with the specialty boards that
18 the NRC recognizes and the regulator who are regularly
19 part of the ACMUI.

20 Next slide, please. And what would be the
21 purpose or objective of such a meeting? We know we want
22 to enhance communications to improve understanding of
23 how the use of radioactive materials and radiation and
24 medicine is different from other uses and how that could
25 or should impact the regulatory controls. Who should

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1 decide what would be the specific objective for such a
2 meeting, and would or should each meeting have the same
3 objective?

4 Next slide, please. In some of my previous
5 talks I've mentioned the NRC's regulatory information
6 conference, otherwise known as the RIC, and last week
7 was the 27th annual meeting of the RIC that takes place
8 every year here in Washington, D.C. This is NRC's
9 largest annual meeting with about 3,000 participants
10 from more than 30 countries. This meeting began in the
11 late 1980s and only had a few hundred participants at
12 that point in time. It's taken many years and the
13 commitment by the NRC and the participants to build this
14 meeting and develop its importance and its value to the
15 community. The continued commitment is evident by the
16 fact that you can see there are the next three years'
17 meetings dates up on their Web site so people can plan
18 on, yes, this is when this is going to happen each year.
19 And each year it's held I believe at the Marriott, so
20 close to NRC headquarters.

21 Next slide. The RIC is co-sponsored by the
22 Office of Nuclear Reactor Regulation in the Office of
23 Nuclear Regulatory Research. The meeting's invitation
24 letter states that the program is designed to encourage
25 informal open dialogue about significant NRC ongoing or

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1 emerging activities related to the regulation of
2 nuclear power plants and nuclear safety research.
3 Participants have a unique opportunity to interact with
4 their counterparts to gain and share valuable insights
5 and perspectives on safety and security issues facing
6 both the domestic and international nuclear community.

7 For this meeting the regulator is the NRC
8 and the regulated community is somewhat focused on
9 reactor licensees and their associated vendors and
10 interests. There may be talks about radioactive
11 material regulations, but they're limited and again
12 with a focus surrounding reactors. A meeting regarding
13 medical use would not seem to mesh well in this meeting
14 because it would be overwhelmed. Okay?

15 Next slide, please. Another meeting that
16 Mr. Costello and Dr. Daibes and I talked about was the
17 Organization of Agreement States. This meeting is
18 supported by the NRC and already has gathered the
19 regulatory community involved with the medical use of
20 radioactive materials. An additional day might be
21 added to focus on medical us and regulatory control with
22 that group already there.

23 The meeting is scheduled the same time of
24 the year, August, and moves to different locations.
25 And so you can see a list of where they have been. And

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1 this August they'll be in Boston. Thank goodness it
2 wasn't in January.

3 (Laughter.)

4 MEMBER LANGHORST: Attendance for this
5 meeting I think is about around 200, but I was not able
6 to verify that. But I think it's about that order. NRC
7 supports the meeting and travel expenses for one
8 individual from each Agreement State so that all are
9 represented.

10 Next slide, please. Some other meetings
11 and models that we discussed are listed here that either
12 to model after or to tag onto. So we looked at our own
13 ACMUI meeting, maybe adding a third day to a meeting or
14 having a third separate meeting, but then bringing in
15 the Agreement States. They're not represented here.
16 Excuse me. They're represented but --

17 (Laughter.)

18 MEMBER LANGHORST: And the medical
19 community, while there are various groups out there in
20 the audience, it may not be the best way to do that.

21 NRC conducts rulemaking workshops, but
22 those interactions seem to mostly -- the purpose of
23 those are for information gathering for NRC staff to
24 take back to then make their product. Now there are NRC
25 stakeholder meetings, and that will seem to be focused

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1 on one topic like the recent safety culture meetings
2 that happened across the country. And again, NRC kind
3 of takes that back to make their product. Don't know
4 always how conducive it is for idea exchange. And it's
5 only happening a couple times and then it's done.

6 Next slide, please. Now, the NRC staff has
7 been doing much in its outreach efforts trying to
8 enhance the communications with medical licensees and
9 regulators, the stakeholder, other regulatory
10 agencies. They're doing this to promote education of
11 themselves on the relevant topics for each of the
12 groups; again an information exchange between licensees
13 and regulators, and trying to encourage the
14 participation of many groups like physicists, RSOs,
15 physicians, scientists, stakeholders and so on. This
16 outreach at professional society meetings and even
17 their participation in providing talks and so on is very
18 important.

19 This outreach effort is good and should
20 continue, but it leaves it to the NRC staff to interpret
21 the overall medical community's consensus on topics.
22 How should different or competing interests be
23 interpreted? Could a medical regulatory issues
24 meeting provide a forum for these kinds of discussions
25 among the medical community?

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1 I noticed in looking at the RIC, and since
2 putting together our slides I've learned of an example
3 of an additional meeting that the NRC has developed from
4 the RIC. About 10 years ago the Fuel Cycle Information
5 Exchange meeting started. That's the FCIX. Got to
6 come up with a better acronym than that.

7 (Laughter.)

8 MEMBER LANGHORST: And that meets in June
9 each year. It's a smaller group. And that meeting is
10 hosted by the Office of Nuclear Material Safety and
11 Safeguards, Division of Fuel Cycle Safety, Safeguards
12 and Environmental Review. This conference, as it's
13 described on its Web site, provides a forum for NRC
14 staff, industry representatives, licensees, and other
15 stakeholders to discuss regulatory issues of neutral
16 interests related to the nuclear fuel cycle including
17 licensing, certification and inspection of nuclear fuel
18 facilities, for uranium conversion and enrichment,
19 nuclear fuel fabrication and de-conversion of depleted
20 uranium tails.

21 So because the RIC was too big for that
22 group and they wanted a more manageable group to discuss
23 their issues, could the NMSS consider sponsoring a
24 similar kind of meeting focused on medical use?

25 Next slide, please. So in discussing the

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1 developments of a medical regulatory information
2 exchange, we kept coming back to baseball. Okay.
3 Maybe that was just me.

4 (Laughter.)

5 MEMBER LANGHORST: But if you build it,
6 will they come?

7 Next slide, please. And would the medical
8 community have a different idea of why we built it?
9 Would licensees be nervous about bringing up challenges
10 for fear of having their inspector show up the next month
11 to inspect on the issue they raised? I believe that's
12 a definition of a chilling effect or turning oneself
13 into cat food.

14 (Laughter.)

15 MEMBER LANGHORST: Next slide, please.
16 So if they hope you build it, will they be more willing
17 to participate? We really came to a conclusion that we
18 need to explore the interest in developing and fostering
19 a medical regulatory information exchange that can
20 include our target audience of regulators in the medical
21 community and built it into a meaningful exchange of
22 ideas that can produce medical use regulations that are
23 more in tune and adaptable to supporting patient care.

24 Next slide, please. As we started we
25 proposed doing the following: Explore with our

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1 regulatory community and our professional
2 organizations their willingness to help develop and
3 participate in a medical regulatory information
4 exchange perhaps added to the annual OAS meeting. OAS,
5 thanks to Mr. Costello and his discussions with them,
6 is willing to explore this idea. But how would such a
7 meeting be sponsored? How should ACMUI be included in
8 the sponsorship of such a meeting?

9 Next slide, please. Are there issues with
10 other organizations or vendors helping to fund this
11 meeting or should this totally be funded by NRC? How
12 long should it be? Maybe we start with one day tagged
13 onto the OAS meeting. What are the kinds of topics that
14 people want to discuss? How would that program be
15 developed? Could a couple of the professional
16 organizations rotate partnership with the OAS, the NRC,
17 the ACMUI on developing a programming chair? How do we
18 all make it worth participating?

19 I believe there needs to be a multi-year
20 commitment made to build such a meeting and
21 participation and to develop products from those
22 meetings so that it gives that exchange traction to
23 prove its worth and its value.

24 Next slide, please. So what does ACMUI
25 think? Would you be willing to discuss these types of

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1 questions with your professional organizations and your
2 regulators to explore their interest and gather their
3 ideas?

4 I've had an opportunity to speak with some
5 folks already. I discussed this topic with the NCRP PAC
6 4 members; that's the group that is radiation protection
7 and medicine, when they met on Sunday, and they were
8 interested and supportive.

9 I'm working with the American Association
10 of Physicists in Medicine to discuss this topic at the
11 May CRCPD meeting. That's Council on Radiation
12 Protection Control.

13 MS. DUDES: Program Directors.

14 MEMBER LANGHORST: Thank you very much.
15 That's why I always say CRCPD.

16 I also hope to discuss this topic at the
17 Health Physics Society meeting in July with the medical
18 health physics section.

19 Would you all be willing to then provide
20 Frank, Said, myself with your feedback from your
21 professional organizations? And we are willing to keep
22 exploring this concept and then report back to you at
23 the fall ACMUI meeting. Thank you very much.

24 CHAIRMAN THOMADSEN: Thank you, Dr.
25 Langhorst.

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1 Do we have comments from the Committee?
2 Yes, Dr. Ennis?

3 MEMBER ENNIS: So I think I would support
4 the idea. I think it would be good to try it for a few
5 years and see if it gets some traction, just based on
6 the other examples you gave where they seem to have
7 fulfilled a role for groups that are similar to us, but
8 not ones that we could dovetail with. Certainly I'd be
9 happy to contact ASTRO and find out what their interest
10 would be. I think making it collaborative, as you said,
11 with all the organizations you listed on one of the
12 slides from the design going forward would make it most
13 likely to be successful.

14 I'm not sure dovetailing with OAS would be
15 as good, because that's one of a dozen stakeholders, so
16 to speak. And maybe something that's more maybe
17 NRC-based or maybe certainly for convenience like the
18 day after an ACMUI meeting or right before might be
19 better. Those are my thoughts.

20 MEMBER LANGHORST: Thank you very much. I
21 appreciate those. One of the things that the OAS does
22 bring is representation from the Agreement States that
23 regulate licensees within their State. And they're
24 already there. That's one of the things that was
25 attractive in that way. And while there is something

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1 to be said about having a meeting always in the same
2 place where you know you can count on it, the OAS does
3 move around the country, and maybe it needs to be planned
4 out a little farther in advance, but that gives other
5 parts of the medical community around the country
6 opportunity to at least be part of that. So that was
7 one of the reasons -- a couple of the reasons why we felt
8 OAS might be a good at least fit to start with.

9 CHAIRMAN THOMADSEN: Mr. Costello?

10 MEMBER COSTELLO: Yes, when you were
11 talking about the RIC a point you made was that the NRC
12 is the sole regulator. Well, that's certainly not true
13 for medical use of radioisotopes. I mean, Agreement
14 States have pushing 90 percent of the licensees in the
15 United States that they regulate. So I think I'm not
16 saying it has to be at the OAS meeting, annual meeting,
17 but involving the OAS I think is an important thing to
18 do because you get the actual regulators there.

19 Now the NRC has a lead, clearly. NRC
20 develops guidance. NRC develops regulations which the
21 states piggyback on. But the implementation of that
22 guidance, the implementation of those regulations is
23 also very important. And I think getting feedback from
24 the medical community on how well we're doing in doing
25 that in licensing inspection I think would be useful.

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1 CHAIRMAN THOMADSEN: Thank you. Dr.
2 Alderson?

3 VICE CHAIR ALDERSON: I'd first of all like
4 to compliment Dr. Langhorst and Mr. Costello on this
5 initiative. I think this is extremely important.
6 During my still relatively short time here, from the
7 very first meeting I was thinking about things like
8 this, and it never quite came into focus. So I strongly
9 support what you're talking about.

10 I also think we should think a little more
11 broadly because ultimately who is it that determines how
12 medical radiation is used? Well, ultimately it's the
13 doctors who order it. And I think that a very important
14 community is the general physician community, and
15 particularly the people who teach tomorrow's
16 physicians.

17 So obviously I bring a bias here. I'm a
18 medical school dean. But just next week I'll be going
19 to the Council of Deans meeting, and if we can reach into
20 that community, if you could convince deans and people
21 who do medical school clerkship development that are
22 medical students around the country need to learn more
23 about radiation and how it's used in medicine and how
24 they as ordering physicians impact that, I think that
25 would be a tremendous plus.

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1 Now they won't come to a one-day meeting.
2 You'll have to go to them, and you may only get an hour.
3 But I think you could make a real impact by getting those
4 sorts of people to think about medical radiation. And
5 then beyond that to even be more aggressive, I'd have
6 to turn to Laura Weil, but ultimately the public. I
7 mean, there's this mysticism that surrounds radiation
8 and its uses in anything, but particularly in medicine
9 because that impacts them. And ultimately if you could
10 eventually develop some sort of approach that could at
11 least help demystify this issue to the public, I think
12 it would also be useful.

13 CHAIRMAN THOMADSEN: Thank you very much,
14 Philip, for those comments.

15 Other comments? Dr. Mettler?

16 DR. METTLER: As a new person I'm a little
17 confused. So how does this fit in with the remit of this
18 Committee?

19 CHAIRMAN THOMADSEN: With the which?

20 DR. METTLER: With the remit of this
21 Committee. In other words, it sounds like a really
22 broad thing that is going to cover everything. And this
23 is medical uses of isotopes.

24 CHAIRMAN THOMADSEN: Correct.

25 DR. METTLER: And then I heard that it was

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1 maybe that the Agreement States could get input about
2 how well they're doing or whatever. So just what I've
3 heard around the table I've got three different things
4 that don't sound the same to me, and I was just
5 wondering. Again, it sounds like a really broad issue
6 that I don't quite -- I wasn't sure about the remit, when
7 I read the remit, how this fits.

8 CHAIRMAN THOMADSEN: I think that the
9 -- and please correct me, Dr. Langhorst and Mr. Costello
10 -- I think the concept is that this would help provide
11 the NRC with the input and thoughts from the medical
12 community and provide the medical community with the
13 thoughts of the NRC as to what is needed in regulation.
14 Is that correct?

15 MEMBER LANGHORST: And if you would also
16 include the Agreement States, yes.

17 CHAIRMAN THOMADSEN: Right. Well, as far
18 as talking about our charge, it would be dealing with
19 the NRC. And I think that's where this came from, how
20 it fits in with what the job of the ACMUI is.

21 Mr. Costello?

22 MEMBER COSTELLO: I think this idea came in
23 large part from Dr. Langhorst's briefing of the
24 Commission last year in which she made the point, a very
25 good point, is that medical is different. The NRC is

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1 a very strong technical agency when it comes to nuclear
2 power reactors. In terms of the regulatory agency in
3 that area, it's probably the best in the world, to be
4 honest. However, and our, because I worked for the NRC
5 for many years, our medical background of our staff and
6 the Commission itself is not the same. Not the same.
7 And medical is different because it's such a profound
8 effect on the lives of patients. And correct me if I'm
9 wrong, Sue, but getting more information from the
10 medical community into the NRC, and ultimately all the
11 other regulators, being Agreement States, might mean
12 that we do our job better.

13 In addition, the medical use of
14 radioisotopes is a rapidly changing field. It's always
15 changed during my career in the business, when we didn't
16 have microspheres and who knows what else? And so I
17 think the ACMUI helps the NRC with that regard, but if
18 we were to meet -- and however we did it. I'm not sure
19 of the best way to do it. And as Sue mentioned in the
20 beginning we have a lot more questions than answers. If
21 we could go to them and talk to them at ASTRO or other
22 meetings. They could come to us. I'm not sure we've
23 got the answer to that. But I'm trying to explain what
24 the purpose of this is.

25 DR. METTLER: I guess what I'm hearing now

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1 is that the idea originally was to educate the NRC about
2 how things are different. But what I've heard
3 -- other things are that we have to go out and then
4 educate the rest of the world about other stuff.

5 MEMBER COSTELLO: I think it's more the
6 other way around. And, Sue, correct me, because you're
7 smarter on this than I am, but I think it's supposed to
8 be a two-way exchange. But the medical community
9 really knows their stuff. And I think the ways that
10 medical is different, if we the regulators; I'm speaking
11 as an Agreement State Representative here, and the NRC
12 can learn how do this very difficult job better -- you
13 know, Laura talked about the fine line between the
14 practice of medicine and regulation. Very difficult.
15 Very difficult thing to understand. And we often don't
16 get it right. And I think that talking to the people
17 on the other side who provide the medical treatments in
18 a system that I think would help us, the regulators, do
19 our job better.

20 Did I get close, Sue?

21 MEMBER LANGHORST: I think you did very
22 well, Frank.

23 MEMBER COSTELLO: Thank you.

24 MEMBER LANGHORST: Thank you. The NRC,
25 the Commission has advisory committees on reactor

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1 safeguards, but they felt that it was worthwhile to
2 bring together a group of the industry. And like they
3 say on their Web site, the RIC's meeting states that the
4 program is designed to encourage informal, open
5 dialogue about significant NRC ongoing and emerging
6 activities. I think that's the same reason we're
7 looking at what could be gotten from a medical
8 regulatory issue exchange in bringing together more
9 people who are involved, more regulators who are
10 involved and to explore that opportunity of having those
11 dialogues among the regulators and the medical
12 community.

13 CHAIRMAN THOMADSEN: Dr. Dilsizian?

14 MEMBER DILSIZIAN: Thank you. Great
15 discussions. I think from the physicians' perspective
16 there are so many meetings that we attend. It would be
17 very hard I think for most physicians, including medical
18 students and deans, to really have another meeting that
19 they would attend. I really like the idea of the
20 outreach. I think that if the NRC goes to the medical
21 meetings, whether it's radiation oncology, radiology,
22 nuclear medicine, that would be fantastic. And you
23 will also get unique input from those individual
24 societies that may be different. And I think the
25 discussion will be better. So that's just a solution.

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1 Probably it will be less expensive and being more
2 directed going to the physicians rather than having them
3 come to a meeting.

4 CHAIRMAN THOMADSEN: Thank you very much.
5 Dr. Palestro?

6 MEMBER PALESTRO: That's exactly what I
7 was going to say, that I think that working to improve
8 communication between the medical community and the NRC
9 is an excellent idea. How to implement it can be
10 logistically difficult, but the simplest and maybe the
11 most expedient way of doing it is by having
12 representatives of the NRC attend some of the meetings
13 such as the Society of Nuclear Medicine, maybe ASTRO,
14 RSNA.

15 The Society of Nuclear Medicine has for
16 several years run one or two sessions at every meeting
17 with representatives from the FDA and there's been good
18 interchange, and obviously has worked very well. So I
19 think a meeting along those lines, or a session
20 incorporated into these sorts of meetings might be the
21 fastest and maybe even most effective way of improving
22 communication.

23 CHAIRMAN THOMADSEN: Thank you, Dr.
24 Palestro.

25 We have a member of the public.

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1 MS. FAIROBENT: Thank you, Dr. Thomadsen.
2 Lynne Fairobent with the American Association of
3 Physicists in Medicine. Just a perspective from
4 someone who has attended 24 of the 27 NRC RICs over the
5 years, and probably as an individual who has brought
6 this topic up in a variety of forums over the years being
7 back in medical over the last 15 years.

8 The difference in what a RIC does that the
9 normal communication and outreach -- and NRC does send
10 staff and attends many of the professional society
11 meetings and does interact with us on our grounds. What
12 the RIC or a RIC-like meeting would do is allow the
13 individuals in the medical profession who have to
14 interact on the broad licensee community to interact
15 with NRC on a very informal basis to talk through issues
16 that are pending that is not able to be done in the same
17 manner once a formal rulemaking is in place, or even in
18 a structured rulemaking round table-type discussion.
19 The RIC is very informal.

20 In many respects tagging it onto the
21 Organization of Agreement States meeting does make a lot
22 of sense. It would be somewhat cost-effective from
23 NRC's perspective because they already pay for one
24 Agreement State regulator to attend that meeting. The
25 other 13 states that are not Agreement States could be

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1 reached out to, to also attend. And the reason I'm
2 saying tag it to OAS maybe initially versus the
3 Conference of Radiation Control Program Directors is
4 that although all of the program directors do attend,
5 they're not paid for by NRC. So it's a logistical-type
6 thing.

7 And, yes, I agree we're not going to get as
8 many physicians perhaps that one might like in doing
9 outreach to a medical professional society, but I do
10 think that you're going to get the medical RSOs there,
11 and they are the bulk of the individuals who on a routine
12 basis have to deal with the licensing actions, the
13 interpretations of the regulation.

14 And the reason why it's important that the
15 Agreement States are there, and I think the reason why
16 it's important for ACMUI's presence to be there, is
17 although ACMUI only advises NRC staff, much of what you
18 do does filter back to the Agreement States and into the
19 programs either through their official representative
20 or when they're looking at adoption of compatible
21 regulations. The levels of compatibility are varied
22 through each of the rule. There are not many that are
23 compatibility A or B that are essentially verbatim to
24 NRC. So the States do have a lot of leeway in the use
25 of medical isotopes.

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1 So I do think that until we do one I don't
2 know that we can all say how beneficial it would be. The
3 first couple of RICs were kind of shaky. If you went
4 to the RIC last week or the week before; I forget which
5 week it was, they're blurring, there's a huge difference
6 in the RIC today than the RIC 1 and 2, 26- 27 years ago.
7 So I really would like to see an effort. And AAPM is
8 very supportive of involving our membership to this.

9 As one of the few organizations that
10 attends every Organization of Agreement States meeting,
11 until you're there that meeting is very different.
12 That's the one meeting where there is open discussion
13 in a public forum on issues across the board between NRC
14 as a regulator and their partner State regulators. And
15 it's a very different discussion than the type of
16 discussion at the Conference of Radiation Control
17 Program Directors.

18 CHAIRMAN THOMADSEN: Thank you very much,
19 Ms. Fairbent.

20 I have one question. As you were having
21 your discussions were you able to assess the interest
22 that the NRC has in this type of a program?

23 MEMBER LANGHORST: I think they're open to
24 listen to what the ACMUI would like to pursue. We did
25 not get into cost because we don't have it very well

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1 defined. Maybe I could ask Said to bring in his
2 perspective.

3 DR. DAIBES: Good morning. We're
4 currently working on the cost-effective plan and see if
5 we can provide more detail to ACMUI. It's somewhat
6 complicated to simply compare the regular RIC to this
7 idea. So that's why we don't have a very detailed cost
8 analysis yet. We're working on it. We wanted to hear
9 your perspective, and based on your perspective then
10 work on that cost-effective plan to provide you details
11 later.

12 CHAIRMAN THOMADSEN: Okay. Thank you.
13 Dr. Ennis?

14 MEMBER ENNIS: So, I think we need to
15 sharpen what our goal is and what our target is,
16 following up with Dr. Mettler. If our target is to
17 really help educate the regulators about the medical
18 perspective and medical knowledge, then we really need
19 to tailor it in a way that is a significant physician
20 component.

21 If it's about getting all the regulators
22 together and their RSOs together to talk about how
23 things are being implemented and how that is working,
24 that's a different conversation and a different
25 audience. We just need to decide what's necessary or

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1 better. Not the same meeting.

2 CHAIRMAN THOMADSEN: Thank you. Mr.
3 Costello?

4 MEMBER COSTELLO: Said, thanks for that.
5 I lean toward the former. The Agreement States and RSOs
6 talk to each other a lot. We have a lot of opportunities
7 to interchange, sometimes in a happy way, sometimes less
8 so. But the States talk to each other a lot. And,
9 however, what we don't do is hear from physicians a lot.
10 I don't think I've ever been to a meeting of physicians.
11 I've never been to a meeting of physicians, or I've never
12 been to an ASTRO meeting, or an AAPM meeting. I would
13 think more -- don't you agree with me?

14 I think I'd like to hear from what the
15 physicians have to say, what the medical physicists have
16 to say, what patient advocates have to say. Agreement
17 States and the NRC and RSOs, we talk a lot. We're
18 somewhat the same group of people. You might meet at
19 HPS meetings. Sometimes we change positions and RSOs
20 become regulators and regulators become RSOs. We have
21 the same educational backgrounds and such. Physicians
22 are a very different group and their concerns are very
23 different, as are medical physicists. And I think we
24 need to hear from them, too.

25 CHAIRMAN THOMADSEN: Yes, Dr. Alderson?

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1 VICE CHAIR ALDERSON: To follow up on some
2 of my earlier comments, I understand what Dr. Mettler
3 was concerned about and the NRC might be concerned
4 about, and Dr. Thomadsen's issue, are we regulators or
5 educators? Well, I think the NRC is more in the
6 regulations sphere than the education sphere, but I
7 would suggest to you that it's a continuum. Education
8 and regulation are just part of a continuum where the
9 rules are more and more rigid around the people that
10 you're trying to regulate. And so the better informed
11 they are, the more likely you are to have successful
12 regulation.

13 And I go back again to say somewhere in
14 this; not as the primary focus, but as a spin-off of this
15 effort if you could develop something as simple as a good
16 slide set and give it to people who are going to the
17 Society of Nuclear Medicine or the Council of Deans or
18 other medical meetings and they could talk about the
19 importance of radiation and why it has to be regulated
20 and why people have to know about it, I think you'd make
21 a real contribution.

22 CHAIRMAN THOMADSEN: Dr. Langhorst?

23 MEMBER LANGHORST: I would like to
24 emphasize the word that's used for this fuel cycle
25 group, and it's "exchange." So if we were just wanting

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1 physicians to train NRC, we'd be asking you to come in
2 and go to some of their training classes to train them.
3 That's not the purpose of this. The purpose is to
4 exchange ideas about how regulations impact medical
5 use. What is the right balance of we'll say NRC- or
6 Agreement State regulatory control versus practice of
7 medicine. And that is always a moving kind of thing.

8 So I don't think it's just the physicians
9 telling NRC this is what this all means. It's the NRC,
10 it's the Agreement States talking about this is our
11 purpose in regulating. This is our charter. This is
12 our charge. And we need to work this together to make
13 it a reasonable set of regulations that meet both
14 interests. So I would emphasize the term "exchange."

15 Now, I think it's also an exchange between
16 the organizations. And, no, I don't see this as being
17 a 3,000-member meeting, because I don't think that would
18 help. But it may be key individuals from these
19 organizations, key physicians who maybe are in the
20 leadership of each organization to help us in this
21 effort of exchange of ideas and that NRC continues with
22 its outreach, too, to be out there to talk to each of
23 the groups. So I'll emphasize the word "exchange."

24 CHAIRMAN THOMADSEN: Thank you very much.

25 Ms. Dudes?

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1 MS. DUDES: Laura?

2 MEMBER WEIL: The other Laura.

3 CHAIRMAN THOMADSEN: One of the Laura's,
4 please.

5 MEMBER WEIL: Just to play devil's
6 advocate a bit, one could argue that the purpose of this
7 group is to do exactly what you're describing. And I
8 wonder if it might be the most efficient thing for those
9 of us in this group who go to professional organization
10 meetings to go there, rather than wearing the hat of a
11 member of that professional society, to wear the hat of
12 being a representative of the ACMUI or the NRC and to
13 foster the communication in that context rather than in
14 the context of being the radiation oncologist or an RSO,
15 or whatever, and to bring that information back and to
16 bring information from NRC to the meeting just -- we're
17 already there. And I wonder if that's the first step,
18 to see if we can foster interest in communicating with
19 the NRC that way.

20 CHAIRMAN THOMADSEN: Thank you. Now the
21 other?

22 MS. DUDES: Thank you. Well, I think that
23 it's a good dialogue on this subject and I think it's
24 more than I had expected. And I think you asked how the
25 NRC -- what our thoughts on it are. I think the word

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1 that you were talking about, "exchange" -- and I was
2 thinking balance and dialogue. And I think Lynne's
3 right; at OAS we have a good dialogue, not only on the
4 issues of the day, but why we're doing something in a
5 certain way. And often the dialogue on "why" is the
6 most important exchange of seeking to understand what
7 the regulators' objectives versus the physicians'
8 objectives are.

9 That being said, our goal is to serve our
10 community and to serve the public in terms of what you
11 think is best in terms of information exchange,
12 education, outreach and transparency. We will try and
13 find a way to do that. That's also in the interest of
14 -- financially responsible. Some of these things are
15 more suited to the nuclear material users than others.
16 Like going to the meetings, I think that's a good idea
17 to get to the physicians.

18 But maybe it's not a one-size-fits-all. I
19 mean, maybe you have an outreach plan. Maybe that's
20 what comes out of this as you start talking about what
21 types of things can we do for outreach? And it's not
22 having a meeting a year, but it's what's our plan for
23 the year with the ACMUI, with our own staff to get out
24 to the professional meetings? What are our messages
25 for this year? What are the questions? And keep your

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1 communication plan as a living document and update it
2 and look for different ways. Because I mean, budgets
3 are shrinking all around us now, so the fact that we use
4 multiple avenues to achieve a set of agreed upon
5 objectives, I think that's where this conversation is
6 sort of leading us.

7 CHAIRMAN THOMADSEN: Dr. Mettler?

8 DR. METTLER: You know most physicians are
9 just buried in clinical work from morning until night,
10 and they're not going to -- if they go to a big meeting,
11 they're not going to go to something, sorry, that an NRC
12 person shows up and says I'm here to communicate. I
13 mean, they might go if they know the NRC's about to like
14 do something horrible that's going to shut down their
15 practice.

16 (Laughter.)

17 DR. METTLER: But I mean, they're just
18 typically going to go to some other part of the meeting.

19 But if you're really thinking about doing
20 something and you want input back, and you want to do
21 it cheaply, I mean one way is to just put an article in
22 the *Journal of Nuclear Medicine* or an editorial or
23 something that says this is what the NRC is fiddling with
24 and does anybody have any comments? I mean,
25 everybody's going to read the *Journal of Nuclear*

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1 *Medicine* who's in nuclear medicine and they'll say,
2 a-ha, I read that and here's the six things they're up
3 to and, boom, yes, I'll write them an email. So that
4 doesn't cost any money and you'll get to a lot of people.
5 So, I don't know.

6 MS. DUDES: That's good. Thank you.

7 CHAIRMAN THOMADSEN: Thank you very much.
8 We have another member of the public.

9 MR. PETERS: Yes, Mike Peters, American
10 College of Radiology. I just want to point out, go on
11 record in saying that NRC is certainly one of the best
12 in the Federal Government at stakeholder outreach, and
13 they do a lot of the things already that you guys are
14 talking about here, so it might be worthwhile to explore
15 what they already do within their existing outreach
16 activities.

17 But the other thing that I wanted to point
18 out is the example of another agency called the Office
19 of National Coordinator for HIT in HHS. And what they
20 do is they have an online forum where they do informal
21 requests for comment when a pressing issue comes up.
22 And the casual nature of it allows them to not have to
23 notice in the *Federal Register* or do something more
24 formal, but it allows them to reach out to various
25 communities.

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1 One other option might be a Webinar series
2 that you can do jointly with the societies. And that
3 way you could reach all the different audiences that
4 you're talking about here and not have to deal with time
5 constraints of physicians and others. And if you
6 attach CME to some of those activities, then that's
7 obviously a good incentive to participate.

8 CHAIRMAN THOMADSEN: Thank you. Dr. Suh?

9 MEMBER SUH: So first I want to thank Sue
10 and Frank for putting this together. I think it's a
11 very timely topic.

12 Just to kind of emphasize what Laura
13 mentioned, I think one of the things I'm hearing, just
14 because there's a lot of differing opinions of what this
15 should look like, is what is the 'why' behind doing this?
16 It's still not clear to me. Is it an exchange of ideas
17 with the physicians, the public, other stakeholders,
18 the societies, or is it more general dialogue or
19 exchange, as Sue put it, among the various programs, is
20 it to educate? I think one of the things that I think
21 is going to be very important to put some teeth behind
22 this "what" is the clear objective of what we're trying
23 to accomplish here? I think this is a good starting
24 point. There's a lot of good discussion, but right now
25 it's a little nebulous to me in terms of what is the clear

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1 direction we want to take this.

2 Because it's very, very large and the
3 question is do we start small and go to societies and
4 have -- just take radiation oncologists, for instance,
5 a presentation by ASTRO, say we'd like to have a little
6 special forum for those interested in learning more
7 about the NRC and what it involves, what it entails and
8 what it can perhaps provide for you. Try that forum to
9 see what type of interest we get. And if we can put that
10 out there and we have exactly -- if Ron's the only other
11 person who shows up, then --

12 (Laughter)

13 MEMBER SUH: On the other hand, if there's
14 a lot of people who show up because there's various
15 topics that are of concern to them, then I think you have
16 a more -- actually, I think the 'why' question I think
17 is very important right now. I think it's a good
18 starting point, but I'm hearing a lot of different
19 things right now.

20 CHAIRMAN THOMADSEN: Thank you, Dr. Suh.
21 Further comments? Yes, Dr. Langhorst?

22 MEMBER LANGHORST: That was why it was
23 difficult to come back with something with cost
24 associated with it, because it is potentially very big,
25 but how do you get that dialogue going?

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1 So I really appreciate all the great ideas.
2 And I think I'm showing my age, that I never even thought
3 about Webinar kind of things. So I thought that was a
4 very interesting idea to be thinking about, too. I like
5 the ideas of perhaps expanding the outreach with various
6 professional societies like maybe a forum. So I really
7 appreciate all your brain power that you've lent to
8 this.

9 CHAIRMAN THOMADSEN: Thank you very much.
10 And thank both of you for the work you've put into this.
11 I think I would ask you not to step down yet, but to take
12 some of the suggestions that have come out of this
13 discussion and come back to this group with a more
14 refined and complete recommendation of where you think
15 we should go considering all the possibilities of a
16 one-day meeting in conjunction with some other meeting
17 or going in a more limited way to some of the various
18 meetings that will be out there to have a less formal
19 exchange of ideas.

20 MEMBER LANGHORST: I will commit us to
21 putting together a list of questions for you all to maybe
22 consider. You may not use all of them, but I will start
23 with our small group to develop those and then send them
24 out to the whole group and get your feedback on whether
25 they meet your needs in discussing with your various

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1 groups, and would appreciate feedback on that as we
2 prepare for our fall meeting.

3 DR. METTLER: But you'll articulate
4 exactly what the problem is that you're fixing?

5 CHAIRMAN THOMADSEN: I think that's the
6 first order of business, yes.

7 Well, thank you very much.

8 MEMBER LANGHORST: Thank you.

9 CHAIRMAN THOMADSEN: At this time we are
10 scheduled for a break. We will be back here at 10:15.

11 (Whereupon, the above-entitled matter went
12 off the record at 10:00 a.m. and resumed at 10:15 a.m.)

13 CHAIR THOMADSEN: Now I think we have an
14 update from a potential research project that the NRC
15 has been discussing with us on patient release. And Ms.
16 Cockerham and Dr. Howe will be presenting.

17 MS. COCKERHAM: Good morning.

18 Quick point of clarification, there is a
19 research project going on with patient release, but that
20 is over in Research; this isn't it. I want to talk to
21 you about something a little bit different.

22 So, that's going on with Research and, yes,
23 that's on its own path. So, if you want to go to the
24 first slide.

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1 So, what I'm going to talk about is
2 Commission direction that we got in 2014 which the
3 research stuff, I believe, we got in 2012, '11, yes,
4 further back.

5 So, this is the most recent Commission
6 direction which they basically added on. So, in
7 addition to what you're doing in research space, please
8 look at these things as well.

9 So, I'm going to go over the current status,
10 sort of what we're looking at this year and then where
11 we're going on a path forward.

12 Next slide? Thank you.

13 So, the tasks that we have now are to -- so
14 this is April 2014, the Commission gave staff direction
15 to verify assumptions made concerning the patient
16 release guidance. And one thing they wanted us to look
17 at is, could we have a brochure?

18 And is this an NRC brochure? Is this
19 something that a professional society or organization
20 has already created that we endorse? You know, let's
21 look into could we have a small pamphlet that has
22 information on patient release.

23 They gave us direction to develop a website
24 and they wanted it to provide information to relevant

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1 medical organizations, patient advocacy groups. And
2 this would enable patients to access clear and
3 consistent information regarding, you know, what the
4 radioactive iodine is, how it's used in treatment, how
5 to prepare, what to expect, side effects, some basic
6 radiation safety and precautions to take after
7 receiving the treatment and the risk to others.

8 They also wanted us to look at guidelines
9 and to develop a standard set of guidelines that
10 licensees can use to provide instructions to patients.
11 And they said that this could be done in conjunction with
12 updates to our guidance and the main two guidance
13 documents we have are Regulatory Guide 8.39 and
14 NUREG-1556, Volume 9.

15 Then they also wanted us to look at the
16 potential for rulemaking and, like I mentioned, the
17 guidance, we would update that.

18 Next slide, please?

19 So, I'm going to turn it over to Donna-Beth.
20 Right now, I'm the Project Manager for this, so I'm
21 looking at the big picture, where we are on a multi-year
22 time line and Donna-Beth is doing the technical lead
23 pieces and worked specifically most recently on the OMB
24 clearance that we need in order to get this information

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1 to do the project.

2 So, I'm going to turn it over to Dr. Howe.

3 DR. HOWE: So, the Commission asked us to
4 a lot of things. And when they asked to do it, they
5 asked us to go out and get as much information from as
6 broad a stakeholder representation as we could, which
7 would be patients, patient advocacy group, physicians,
8 Agreement States, NRC licensees, professional
9 societies and all people that would be interested in the
10 administration of I-131.

11 Well, you can't just out and ask people for
12 information. If you're part of the Federal Government,
13 you have to ask permission from the Office of Management
14 and Budget (OMB). So, we needed to get an OMB
15 clearance.

16 The other thing we did is we split the
17 project into two parts. We looked at the guidance part
18 and we looked at the rulemaking part and we split it so
19 that the first part we're going to tackle is going to
20 be the guidance part; and later, we're going to be
21 tackling the rulemaking.

22 We felt if we put both of them together,
23 everyone has interest in rulemaking and gets very
24 excited about where we might go in rulemaking. So, we

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1 felt the guidance would probably not get as much
2 attention and we wouldn't get as much good information
3 on that side.

4 So, I drafted a straw Federal Register
5 notice for the questions that we want to go out and ask
6 because when you're doing OMB guidance, you don't really
7 start at the beginning, you start at the end. And once
8 you start at the end, you know what kind of questions
9 you're going to ask, then you know what you have to go
10 out with and you back it up to where you're asking OMB
11 for permission.

12 So, for the straw Federal Register notice,
13 I went to Ms. Weil and I went to Dr. Palestro because
14 they are nuclear medicine physicians and are patient
15 advocates to see where I could improve on the straw-man
16 and I got very good input from both of them.

17 So, then I drafted up the Federal Register
18 notice and the Federal Register notice was published
19 March 3rd. The public has 60 days to respond. This
20 Federal Register notice is not the questions, it is just
21 has NRC -- is NRC looking for the right information?
22 Are we going about it in the right manner? Are we doing
23 it in an efficient manner? And have we estimated the
24 burden on the public to respond to the future Federal

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1 Register notice?

2 So, right now, we're in the 60 day comment
3 period for that.

4 OMB has started a new process and that is
5 that while we're in the 60 day comment period, NRC has
6 to go out to nine individuals, and in this case an
7 individual can be a person, it can be a licensee, it can
8 be a professional group, it can be any entity, and ask
9 them the same four questions that we're asking in the
10 Federal Register notice that we just published in March.

11 And that is, is NRC collecting information?
12 Do they need the information? Is there a better way of
13 collecting it? Have they estimated the burden
14 correctly?

15 And so, I'm in the process of going out to
16 nine individuals. I've got an individual that
17 represents patients. I've got a patient advocacy
18 group. I've got small clinical facilities around the
19 country, both in Agreement States and NRC States that
20 I'm going to be going to. And I've got one private
21 practice physician in the middle of the country that I'm
22 going to be going to and asking them to evaluate.

23 The Federal Register notice is really two
24 documents. One is the Federal Register notice which is

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1 not very informative. The second is a supplemental
2 statement. And the supplemental statement is an
3 extraction from the future Federal Register notice that
4 I'm going to be putting out. And it essentially states
5 why we need the information in general terms what we're
6 going to be asking but not the specific questions.

7 And so, we're going to be asking the public
8 in this 60-day comment period to see, look at that
9 abbreviated information and give us comments back on it.

10 And then we will take that information,
11 we'll put it together into our final package, going to
12 OMB and hopefully getting OMB's approval for us to go
13 out with the final Federal Register.

14 OMB has 60 days to respond once we put our
15 information together and put in our formal request, they
16 have 60 days to respond.

17 So, I've got 60 days now for the public to
18 comment; that ends May 4th. It'll take us a little bit
19 of time to take the comments and put them together and
20 prepare the final package. And then OMB has another 60
21 days after that. So, probably about three months later
22 is where we may be able to publish our Federal Register
23 if everything goes well.

24 At this point, I'll turn it back to Ashley.

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1 MS. COCKERHAM: Next slide, please?

2 So, as Donna-Beth just said, we're in this
3 first green bullet here - in the 60 day period for the
4 OMB clearance. It's the publication that they've put
5 out saying "is this reasonable?"

6 And we'll do what Donna-Beth mentioned;
7 we'll have the 60 days, 60 days again for them to look
8 at it and then once we actually issue the Federal
9 Register notice that will be out for 60 days for public
10 comments.

11 And then about the time that that's
12 happening is when we'll also start our workshops. And
13 those workshops will be to collect the information that
14 is requested in the Federal Register notice.

15 So, those two will be complementary and
16 then we'll have several workshops over several months
17 throughout the country and this year, we're also going
18 to be drafting the website and I know that a draft of
19 the website will go to the ACMUI for review and for input
20 and then before anything is finalized.

21 So, that's what's going on for this year.

22 Next slide, please?

23 And then 2016 and beyond, we'll have, like
24 Donna-Beth said, we split this into two separate things,

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1 guidance and rulemaking. We're going to have a second
2 set of workshops for the rulemaking -- for the potential
3 rulemaking to discuss whether or not we should pursue
4 rulemaking.

5 And after that, we'll collect all of that
6 information, put it in a Commission paper, send it up
7 to the Commission for a vote and they'll tell us whether
8 or not to pursue rulemaking. You guys know how that
9 process goes: proposed rule, final rule.

10 And we would also be revising the Reg.
11 Guides to complement any rulemaking that's necessary.

12 Donna-Beth, do you have anything else to
13 add?

14 DR. HOWE: I think in this point to bring
15 back the research project because one reason that we're
16 looking out so far in 2016 and even out to 2019 is that
17 there's a -- Research has got a project going on patient
18 release and they're collecting data in a totally
19 different perspective.

20 And their data and our data will come back
21 together potentially for future rulemaking and
22 definitely for the guidance development. So, we're off
23 on divergent paths and then we'll come back together and
24 that's why it's going to take as long as it's going to.

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1 CHAIR THOMADSEN: Thank you very much.
2 Questions or comments from the Committee?
3 Yes, Dr. Mettler?

4 DR. METTLER: I'm sorry to be a pest.

5 CHAIR THOMADSEN: That's what you're here
6 for.

7 DR. METTLER: So, I actually wrote the ICRP
8 document on patient release. And when we were doing
9 that, the thing that impressed me is when I went back
10 to look at some of the scientific underlying issues
11 about guidance and saying, well, just where did this
12 come from?

13 Like, you have to, I don't know, flush the
14 toilet twice. It's like, really? Did somebody
15 actually ever figure this out? And does it really make
16 any difference?

17 And I mean I went all the way into figuring
18 out where the sewage went and how much the sewage workers
19 were exposed and did it get into the trout and, you know,
20 so on.

21 But, one of the things that came up to me
22 when you start looking into the gory details of this is
23 about the worst thing you could do after you've had
24 radioiodine is to go kiss a baby because of the saliva

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1 and the transfer and the uptake in the kids and the
2 sensitivity of the thyroid and all the rest of that.

3 And that a bunch of the guidelines that are
4 out there are interesting but they have virtually no
5 biological effect. And some of the things that
6 probably have the biggest biological effect somehow
7 don't really seem to get much attention.

8 At least, you know, you get the whole list
9 of things but not in any order of particular importance.

10 And so, I always ask, well, that's just like
11 rinse your laundry twice. Well, I mean I try. I went
12 home and looked at my washer, right? It's like, okay,
13 so I run it through and it's done. Now, how the hell
14 do I hit rinse again?

15 DR. HOWE: You turn the knob around.

16 DR. METTLER: No, not on the digital
17 computer one, I'm sorry, it doesn't work that way.

18 DR. HOWE: Extra rinse then.

19 DR. METTLER: And does that really make a
20 difference?

21 But so, I think some of this stuff that's
22 out there, if you're going to put it on a website and
23 make guidelines, somebody better have some underlying
24 data.

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1 DR. HOWE: Dr. Mettler, just to kind of
2 respond on that. The website information is going to
3 be -- we've been directed to make that information more
4 like what does the patient need to know before the
5 treatment? What is I-131? What is the I-131
6 treatment? What is the preparation?

7 A lot of things in practice in medicine and
8 all they want us to do is to be able to have a patient
9 go to one site and find links to other sites that will
10 provide them with information. So, that's kind of the
11 focus of the website.

12 Some of our other guidance, there's a form
13 that's supposed to be a patient licensee acknowledgment
14 form. That's going to -- what does the physician and
15 the patient talk about in order for the licensee make
16 a good determination on when to release the patient.

17 Because what we're looking at from our
18 study is the patient is the key to radiation safety.
19 They need to understand what they're getting. They
20 need to understand how they can reduce exposure to
21 others and they need to be able to do things that get
22 reasonable instructions at the end that they can follow.
23 So, that's what we're focusing on this one.

24 The health physics and the calculations and

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1 the actual external dose and internal dose are more the
2 subject for the research study.

3 DR. METTLER: The thing about links,
4 though, if you link, for example, to the Society of
5 Nuclear Medicine Guidelines, and you just start looking
6 at stuff like, do I need a pregnancy test? Yes or no
7 for x amount of radioiodine.

8 You get disagreements. So --

9 DR. HOWE: And we'll have to deal with that
10 when -- well, we'll see because it may be the Commission
11 wants clear and consistent guidance. And the reality
12 is probably not clear, not consistent.

13 DR. METTLER: Yes, because if you link to
14 some of these sites, you're going to get information
15 that NRC may not agree with or may have different ideas
16 on.

17 And I'll let you talk about the Society of
18 Nuclear Medicine Guidelines. But, I think there are
19 issues in there about you can do diagnostic I-131
20 studies and not have to a pregnancy test or anything.

21 CHAIR THOMADSEN: Yes, that is a --

22 MEMBER DILSIZIAN: I mean I was -- you
23 know, I came new to this topic and I was struck how much
24 variability there was among physicians instructing and

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1 education of their patients before and after release.

2 And my role is also a nuclear medicine
3 physician, so I do give I-131. And as I was giving a
4 patient release forms and instructions, I realized that
5 we all have our own, you know, in-house produced forms.

6 I was wondering, even though there are
7 documents, guidelines for various societies, would it
8 be under the NRC's umbrella to have a uniform [set of]
9 patient release instructions that physicians can at
10 least read and guide patients so it would be much uniform
11 that variability among the university hospitals versus
12 community hospitals? Would that be under our umbrella?

13 DR. HOWE: That was the gist of the
14 Commission direction that we received was that they were
15 quite concerned about the variability and lack of
16 clarity. And so that's why they directed us to do what
17 we're going to be doing.

18 DR. DILSIZIAN: Will we, at the end, have
19 a document that would be uniform? Is that the goal?

20 DR. HOWE: That is the goal. I don't know
21 whether it is achievable or not. I mean we won't know
22 until we get the information in.

23 And I think the other thing that I haven't
24 emphasized is that when we go out to collect this

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1 information, we are asking for [what's] already
2 existing. We are essentially dependent upon the
3 physicians and the patients to tell us what really works
4 well for you?

5 And then we'll take that, we aren't asking
6 anybody to develop anything new, we're just saying,
7 physicians, what really works well for you? Let us
8 know, share it.

9 MS. COCKERHAM: When we issue that Federal
10 Register notice, we would want to see that form. Hey,
11 here's an in-house form that we have that works well for
12 us and if we can see all of those forms, that's the
13 information collection that we want to go out and get.

14 DR. HOWE: And we'll have very specific
15 questions. I'm going to have questions that are more
16 oriented towards the medical community and I'm going to
17 have questions that are more oriented towards the
18 patients so that we can get as wide a set of information
19 as we can.

20 So, I think we're going to try to address
21 those things.

22 CHAIR THOMADSEN: Yes, Dr. Costello?

23 MEMBER COSTELLO: I want to comment on
24 patient instruction.

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1 A problem that comes up, and maybe it's
2 unique to Pennsylvania, I don't know, is that
3 Pennsylvania has a lot of radiation detectors at trash
4 transfer stations, landfills and such.

5 And we get two or three cases a week of them
6 being set off by I-131 patients.

7 Now, the safety suggestion to that is, they
8 are going to the landfill and they're buried and never
9 bother anybody again.

10 However, there are some landfills that
11 because of their agreement with their local township or
12 because they incinerate their waste and the township
13 doesn't want radioactive place incinerated for no good
14 technical reason, they're forbidden from taking
15 radioactive waste.

16 And so, we got a call from a mother whose
17 daughter has thyroid cancer and whose waste set off
18 their alarms and they were contacted by the company that
19 collects their waste and threatened with thousands of
20 dollars in fines or they would simply no longer collect
21 their waste.

22 And so, we try to help, you know, we call
23 up the -- and they don't care. You know? And we say
24 this stuff is exempt. This stuff isn't harmful, all the

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1 stuff that you would say if you were talking to them,
2 and they don't care.

3 And we're talking to the mother of the
4 patient who was very angry and she was angry because no
5 one had given her any instructions with regard to what
6 to do with waste. Okay?

7 I and this patient went to a very
8 prestigious institution in Columbia. But, as you know,
9 all this is not regulated, it's all exempt and there's
10 not much we can do. They want us to somehow or another
11 to punish the medical institution for not sufficiently
12 instructing what to do with the waste.

13 And to be honest, from a safety point of
14 view, putting patient waste in the trash is probably the
15 safest thing to do. I'm not sure I want them saving the
16 other I-131 waste and keeping it in wherever who keeps
17 these things.

18 But, in drafting the guidance, okay, please
19 remember that a lot of this stuff is out in trash. A
20 lot of this stuff sets off alarms and very frequently,
21 the patients, remember our cancer patients, have to be
22 dealing with people threatening to fine them or
23 threatening not to pick up the trash anymore because
24 there was iodine left.

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1 DR. HOWE: And, Frank, you bring out a
2 really good point. We don't regulate the trash
3 facilities, but many trash facilities around the
4 country, they are afraid of radiation so they put in
5 their contracts, no radioactive waste can go to this
6 transfer point, can go to this landfill. And that's an
7 absolute.

8 MEMBER COSTELLO: We do regulate them, the
9 broader department, and we require them to have
10 detectors. And we issue a lot of DOT exemptions for
11 shipping these things.

12 DR. HOWE: But we don't license landfills.

13 MEMBER COSTELLO: I know, we do.

14 DR. HOWE: Yes. We don't and many
15 landfills do have this because of the local community,
16 no radioactive waste, no medical waste, no whatever
17 waste they consider harmful.

18 MEMBER COSTELLO: I think it's important
19 that the instruction to the -- the instruction to the
20 patient, at least address this. Since I don't even know
21 what it should say, to be honest. I think throwing it
22 out in the trash is probably the best and safest thing
23 to do, but that mother who had the daughter who had
24 thyroid cancer wasn't seeing things my way.

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1 DR. HOWE: And that's one of the elements
2 that is included in the questions that we'll be going
3 out with.

4 CHAIR THOMADSEN: Yes, ma'am?

5 MEMBER WEIL: Many institutions do provide
6 instructions about waste and this just points out the
7 discrepancy of information that patients receive. And
8 it's a wonderful thing that NRC is trying to develop some
9 consistency of guidance for patients in order to address
10 the post-treatment period.

11 I'd like to make the point that I've made
12 before; this often we get some push back when we talk
13 about NRC intruding upon the practice of medicine by
14 regulating what kind of guidance patients will receive,
15 what kind of information they will receive about dealing
16 with the post-treatment period.

17 And I'd like to say that this is not the
18 practice of medicine, this is post-treatment. This is
19 after treatment. This is public health. This is not
20 intruding in any way upon the administration of the
21 iodine; it's simply trying to protect the public and the
22 patient from mundane stuff like never having their trash
23 picked up again and real radiation exposure to infants.

24 This is different from the practice of

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1 medicine.

2 CHAIR THOMADSEN: Thank you very much.

3 Dr. Zanzonico?

4 MEMBER ZANZONICO: Well, that addresses a
5 point I want to bring up is a fight.

6 I thought I heard something to the effect
7 that in this brochure or website among the issues that
8 might be addressed would be side effects, what the
9 patient would expect.

10 To me, that is now infringing on practice
11 of medicine. Frankly, I think I'm very leery of a
12 regulator-sponsored website directly conveying
13 information to patients, especially if it now
14 incorporates issues like side effects and this general
15 concept of what to expect.

16 I mean a physician may decide for very
17 legitimate reasons that side effects that might be
18 considered undesirable might be tolerable under some
19 medical circumstances.

20 So, how does a patient who accesses such a
21 website and sees some information, reconciles what they
22 see there with what their physician may tell them in a
23 specific case under specific circumstances?

24 So, I'm just very leery about that

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1 component of such a website or brochure or any public
2 outreach.

3 I feel the most appropriate way would [be
4 to] provide information to physicians and still leave
5 it to the physician to convey that information even with
6 respect to radiation safety practices and dose
7 reduction practices to the physician.

8 I think it's almost unavoidable that no
9 matter how restrictive the NRC may characterize things,
10 that it's going to start infringing on medical practice
11 and the patient/physician relationship.

12 I mean these are not simple issues and I
13 think physicians need to take more responsibility in
14 conveying this information reliably so forth and so on
15 to patients but it's their responsibility. It's not
16 the regulator's responsibility.

17 DR. HOWE: And I agree with you, Dr.
18 Zanzonico and I think one of the things to keep in mind,
19 the direction that we got from the Commission does take
20 us into practicing medicine but it's done in such a way
21 it's supposed to be a website that the medical community
22 may have a website that addresses a certain issue. And
23 so, we would have a link to that website.

24 It would not be an NRC requirement. It is

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1 just a recognition that patients go up on the Internet
2 and look for things and this would bring some links that
3 would go to professional groups and others that might
4 provide information.

5 So, we aren't intending to get into the
6 practice of medicine but it looks like it for this
7 website. So, how it turns out, I don't know.

8 MEMBER ZANZONICO: I think, though, it has
9 to be recognized that just the fact that the NRC is
10 directing a patient to a website whether they've claimed
11 to have vetted it or not has a certain implication. I
12 mean that's just inevitable.

13 DR. HOWE: Yes, I appreciate that.

14 CHAIR THOMADSEN: Ms. Langhorst?

15 MEMBER LNAGHORST: There's ample
16 precedence for government agencies providing
17 information about drugs and side effects to the public.
18 And this would not be a unique instance.

19 CHAIR THOMADSEN: Thank you.

20 Dr. Palestro?

21 MEMBER PALESTRO: Yes, I certainly agree
22 with Pat Zanzonico's comments and I would express
23 previously my reservations to Donna-Beth. We've even
24 been back and forth on this about establishing a website

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1 and providing links.

2 I think a potential, more than a potential,
3 like a real problem is that you establish these links,
4 you're going to find that some of the websites, you're
5 actually give contradictory information and I think
6 that creates its own set of problems.

7 And I'm inclined to also agree with Pat, at
8 least if I understand what he was saying correctly, I
9 think that the NRC should be establishing the
10 regulations and it should be up to the medical community
11 to identify ways to meet them, to satisfy them, not be
12 provided that.

13 CHAIR THOMADSEN: Thank you, Dr. Palestro.
14 Dr. Alderson?

15 VICE CHAIR ALDERSON: I don't disagree
16 with anything that the other speakers have said and I
17 share their concerns.

18 I just want to make a comment that we've all
19 read in many publications about how patients are using
20 the Internet more and more and more all the time and wise
21 people have described that growing use as disruptive to
22 the practice of medicine.

23 So, although I share the concerns, I don't
24 think we can ignore the fact that the patients are going

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1 to be out there, they're going to be looking at all these
2 things and, in some way, we have some kind of
3 responsibility to be aware of that and to try to respond
4 to it. It's a big problem but it's not going away.

5 CHAIR THOMADSEN: Thank you, Dr. Alderson.

6 Can I ask, when would the input from the
7 ACMUI be the most useful in this process? Would it be
8 most useful before you hold the stakeholder meetings?
9 After you get some of the input? When you think would
10 be efficacious for us to give advice?

11 DR. HOWE: I think certainly ACMUI members
12 attending the stakeholder meetings would be good. We
13 will be collecting the information from the public and
14 then we will be processing it and we'll be processing
15 into some kind of final product.

16 And we would be bringing in the ACMUI as
17 we're reviewing those final -- bringing those final
18 products together to finalize them.

19 So, I think your input should be both in the
20 public meetings and also as we've collected the
21 information, we processed it, we'll be coming back to
22 you with what we find.

23 CHAIR THOMADSEN: When do you expect that
24 you'd be doing the processing?

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1 DR. HOWE: Well, roughly, if I've got
2 through the 4th of May for people to comment on should
3 NRC be collecting this information and if the burden
4 correct...?

5 I've got probably about 30 days to process
6 that information which I think is much more limited and
7 then go back to OMB for the actual request for the
8 clearance. They've got 60 days to act on the request.

9 So, that kind of puts us into maybe
10 August/September when we would publish the Federal
11 Register asking the public to provide its input on these
12 different questions. And they've got 60 days to
13 comment.

14 In that 60 day time period while the public
15 is commenting on the actual questions is, I think, when
16 we will be holding our stakeholder meetings.

17 MS. COCKERHAM: So, later this year.

18 DR. HOWE: So, it's going to be probably
19 maybe even late summer.

20 CHAIR THOMADSEN: So, it sounds like we may
21 be would be naming a subcommittee at the next meeting.
22 That nothing would happening between now and then that
23 we would really be commenting on.

24 DR. HOWE: I think the next meeting is

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1 probably about the right time frame. Things could go
2 a little faster. If they do, we could always --

3 CHAIR THOMADSEN: Have a telephone
4 conference.

5 DR. HOWE: -- have a telephone
6 conference.

7 CHAIR THOMADSEN: Dr. Ennis?

8 MEMBER ENNIS: So, I haven't been on the
9 Committee that long, so I want to kind of -- it seems
10 like the core issue here, and my question really is, is
11 this a repeating theme? And, if so, what would I think
12 about it in that way?

13 What we do with situations where the
14 medical information, scientific information, would
15 suggest we essentially have nonissues and yet, the
16 public or portions of the public want to be more strict
17 than that.

18 And the tension that exists between our
19 perspective, perhaps, or the scientific community
20 perspective, that it's not an issue.

21 And the public's anxiety about
22 radioactivity, and this is a recurring theme that maybe
23 we need to be dealing with that more than the particular
24 -- or in addition to at least, or maybe more than the

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1 particulars of one particular scenario.

2 CHAIR THOMADSEN: And, I'll just say that
3 has been an ongoing issue that is precisely what we do.
4 We always have to deal with those issues. It's not
5 something we can deal with once for and all and say we're
6 done.

7 It perennially comes up and it's not going
8 to go away because the public has their perceptions,
9 scientists may have theirs. This isn't unique to
10 radiation and both have to be accounted for.

11 Dr. Mettler?

12 DR. METTLER: So, one of the things I ran
13 into when I was doing this ICRP thing was all the
14 different countries who are right next to each other had
15 different regulations.

16 So, the Germans wanted to keep everybody in
17 a hospital for a week and they were collecting all the
18 urine for, you know, I don't know, 30 days and storing
19 it. And the French were just letting them out.

20 So, all the patients we've got on the train
21 going from Germany to France, getting treated and coming
22 back, end of discussion. I mean that's the whole
23 practice - just went that way.

24 But, in your -- the two questions I have is,

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1 is the collection and processing of this, I know IAEA
2 has a whole thing out on patient release and are you
3 going to take into account other things like that when
4 you put this all together or are you just going to take
5 the database and then work from the database?

6 Or are you actually going to try and
7 interact with the other things out there and saying,
8 well, we're going to actually -- this is what IAEA
9 recommends but we're not going to do it because or we're
10 going to something?

11 The second question I have was, a bunch of
12 us, I don't how many in the room, have gotten calls from
13 people saying there's an RFP out on a Request for
14 Proposals and I guess there is contracts or grants to
15 find out how many patients are released from each
16 hospital and yadda, yadda, yadda.

17 So, is that -- that's an NRC thing that
18 there's these groups out there that are collecting
19 information from various institutions and then they're
20 going to feed back to NRC?

21 DR. HOWE: NRC has two projects going right
22 now. One project is a contract based project that the
23 Office of Research is managing and they're going out and
24 looking at where do patients go after they're released?

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1 And what is the expected radiation dose from those
2 patients when they go to sites other than, say, their
3 home?

4 So, that may be what you have heard about.
5 That contract is already been let. So, there's a
6 contractor in place and they are working at going
7 through the different steps of the contract and
8 collecting information. And that is separate and
9 distinct from what Ashley and I are talking about.

10 DR. METTLER: Right, but knowing those
11 things, I assume it's going to take two years.

12 DR. HOWE: And that's why --

13 MS. COCKERHAM: And so we are saying
14 they're going to feed that together. Yes, they'll feed
15 back.

16 DR. HOWE: And that's why we talk about the
17 fact that when we go to guidance, it's going to be
18 several years out because we have to get that
19 information back.

20 MS. COCKERHAM: To address your first part
21 about the international practices and different things.
22 That was part of the Commission direction and I believe
23 it's Sophie that put that together and it's already gone
24 back up. Was a CA note?

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1 DR. HOWE: I was a CA note.

2 MS. COCKERHAM: CA note. So, we did do a
3 survey and collected information as voluntary and it was
4 from many other countries and we put that information
5 together and transmit that back to the Commission.

6 DR. HOWE: One of the Commission questions
7 was, well, how is NRC racking up against the
8 international community?

9 DR. METTLER: Well, the interesting part
10 of that is when I was doing this ICRP stuff, I looked
11 all around the world and we decided that what the NRC
12 had in place was the most reasonable thing that we could
13 find.

14 So, the ICRP report is, in fact,
15 essentially based on NRC guidance and we got that
16 through the international community. And it's sort of
17 where the IAEA stuff came out of a lot of it.

18 And then, Congress came back and said,
19 well, how come you guys aren't up with the ICRP, not
20 knowing that the ICRP basically was using your stuff in
21 the first place.

22 DR. HOWE: No, we saw a lot of fingerprints
23 on the ICRP. But the equality is that when we went back
24 and collected the international data there were some

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1 countries that had just recently, after the ICRP and way
2 after NRC went to its things, had changed their patient
3 release and they were getting much more conservative.
4 So, they weren't necessarily moving in the NRC
5 direction, they were moving back in the other direction.

6 So, I think it's a wide open field out
7 there.

8 CHAIR THOMADSEN: Yes, originally, I had
9 hoped that all the patient release stuff would have been
10 settled while I was on this Committee. Then I was
11 hoping before I retired, but it sounds like now I'm
12 hoping it's done before I die.

13 DR. HOWE: Yes, you know, it's just
14 2016-plus on my slide. Like, I'm not even putting a
15 date right now.

16 MEMBER COSTELLO: And you're still being
17 an optimist.

18 DR. HOWE: Well, to tell you the truth, I
19 think we're passing 2019 dates.

20 MS. COCKERHAM: Yes, I was hesitant to even
21 put that on the slide.

22 CHAIR THOMADSEN: Ashley, your child will
23 take over.

24 Ms. Dudes?

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1 MS. DUDES: Well, I appreciate the
2 dialogue on this and I think there's a lot of common
3 ground. This is one of those topics where we absolutely
4 need the ACMUI and lock step guiding and directing the
5 staff as we're going through this project.

6 I'm also very leery about us having a
7 website because, although I did go on a website one day,
8 Donna-Beth gave me a video to watch someone [who] had
9 I-131 treatment.

10 And then I went on looking for information
11 about what do I do? And I was all over the map. And
12 I thought, well, and I'm not clear that the regulator
13 should be telling the patient about the side effects.
14 But, perhaps, if you could have some fundamental agreed
15 upon guidelines with the experts, that would be very
16 useful. I'm not sure I'd go the NRC necessarily.

17 I don't know if I'd know to go to the Nuclear
18 Regulatory Commission if I was having an I-131
19 treatment.

20 But I think the fundamental is what do you
21 do? It's don't kiss a baby, right? What do you do with
22 your waste? Keep and make sure that if you're this,
23 that you have enough time before the treatment to make
24 the arrangements that you need to do.

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1 I mean you know, you get a simple procedure
2 done and you're uncomfortable and you're challenged. I
3 mean this is a lot more complicated and you have to take
4 some precautions.

5 And I like the fact that you're talking
6 about, hey, we should have a standard set of guidance
7 and forms. But ACMUI can tell us that and we don't have
8 to wait until 2019.

9 I mean it's great to have an endorsement and
10 once we're getting information back from our
11 solicitation, if there's a form that we can get out and
12 say, hey, this is what we think is the right thing. Tell
13 us, because, you know, I worry when we have these
14 multi-year projects that, you know, the staff keeps
15 working and then other life goes on, members change.

16 And as much early direction as we can get
17 and participation, and I know you talked about a
18 subcommittee at the next meeting and that would be great
19 so that there's an ongoing dialogue and really
20 directive.

21 I am worried about us being the
22 brochures/website experts. And it's so confusing.
23 But and comments like, keep your website to here's the
24 things you should know post-treatment for public health

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1 and safety and other things and for your safety as
2 opposed to here's the impacts of I-131. That should be
3 in the medical journals and such.

4 So, I mean, so I would encourage everyone
5 to stay very active and communicative and directive and
6 taking positions or the staff. That's what the ACMUI
7 is for.

8 CHAIR THOMADSEN: Dr. Langhorst?

9 MEMBER LANGHORST: Whenever we talk
10 patient release, it always comes to I-131. But I just
11 want to remind the Committee that patient release
12 applies to all radiopharmaceuticals, isotopes and so
13 on.

14 So, that includes Tc-99m, PET scans,
15 Xofigo, microspheres, everything.

16 So, one guidance does not fit all those
17 situations. So, I know we always come back to I-131,
18 but I just want to remind everyone that aspect of it.

19 CHAIR THOMADSEN: Dr. Weil? I'm sorry.

20 MEMBER WEIL: Oh, see, I didn't mean to
21 catch this. That's not me.

22 Thank you for that comment because I think
23 it's really important. I mean I recently had a Tc-99
24 scan and nobody told me not to go near my pregnant

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1 daughter. Now, I knew but there should be information
2 about that on a website that's accessible
3 post-treatment for patients who have questions, who may
4 not get the information that they need from their
5 clinician.

6 CHAIR THOMADSEN: Thank you very much.

7 Any other comments from the Committee?

8 Hearing none, thank you very much, Ms.
9 Cockerham, Dr. Howe.

10 This brings us to patient intervention,
11 which will be Dr. Gabriel and Mr. Costello.

12 DR. GABRIEL: Good morning.

13 ACMUI requested to discuss patient
14 intervention at this meeting and I was asked to open the
15 discussion by providing some background information and
16 the history of NRC's use of the term patient
17 intervention.

18 Next slide, please?

19 Let's start with NRC's current definition
20 of patient intervention and then go back to trace the
21 history of this concept.

22 NRC's medical regulation, 10 CFR Part 35
23 includes definitions of terms in Section 35.2. This
24 slide shows the current definition of patient

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1 intervention and intentional or unintentional actions
2 by the patient such as dislodging or removing treatment
3 devices or prematurely terminating the administration.

4 Next slide?

5 The current regulation uses the medical
6 event to describe deviations from intended
7 administrations that need to be reported to the NRC.

8 The older term, misadministration, was
9 first introduced in 1980. The concept of patient
10 intervention was acknowledged in 1980, although the
11 term was not added to the regulation until 2002.

12 Next slide?

13 The requirement to report
14 misadministrations was added to Part 35 in 1980 and
15 after the final rule was published, the NRC received a
16 number of questions from licensees about the definition
17 of misadministration.

18 In response to these questions, NRC issued
19 a letter with a series of questions and answers
20 illustrating what constituted a misadministration.

21 And then, the slide shows a question and
22 answer that may involve the first use of the term patient
23 intervention.

24 So, the question asked if the

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1 misadministration has occurred when the patient stops
2 attending treatment sessions and the total dose is not
3 delivered? And this was in era where cobalt-60
4 teletherapy was in wider use than it is today. So,
5 that's likely the kind of scenario this question was
6 addressing.

7 And the response was that patient
8 intervention in the treatment plan is not a
9 misadministration. So, it appears that the term
10 patient intervention pertained to patient behavior that
11 was not under the control of the licensee.

12 Next slide?

13 The next major rulemaking was the 1992
14 Quality Management Rule. The rule did not address
15 patient intervention. Another clarifying letter with
16 sample questions and answers was sent to licensees by
17 this time, there were no examples involving patient
18 intervention.

19 In documents the NRC files from error
20 indicate that NRC made determinations of patient
21 intervention on a case by case basis. So, there was no
22 public addressing on the concept.

23 Next slide, please?

24 The next major proposed rule was issued in

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1 1998 and SOC stands for Statements of Consideration.
2 And the Statements of Consideration for the proposed
3 rule discussed patient intervention as a problem area
4 in misadministration reporting. So, attention is
5 starting to be paid to this.

6 The terms misadministration and medical
7 event are both used in this document. This was the
8 proposed rule that changed the terminology to medical
9 event.

10 And this slide includes in the second
11 bullet a quote from the Federal Register notice. It
12 starts with the language licensee is expected to act
13 reasonably in accordance with prevailing standards of
14 care to prevent a medical event.

15 It continues, in cases where patient
16 intervention is probable, the licensee should take
17 reasonable actions to avoid a medical event such as
18 using extra sutures in the case of a temporary
19 brachytherapy treatment, extra taping or more frequent
20 checks by nursing staff.

21 So, it appears that the term patient
22 intervention still pertained to behavioral actions on
23 the part of the patient.

24 It was also noted in this document that, in

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1 some cases, the licensee might be able to anticipate
2 that patient intervention was likely to occur and there
3 might be steps that the licensee could take to prevent
4 the undesired patient behavior.

5 Next slide, please?

6 This 1998 proposed rule included language
7 to incorporate the concept of patient intervention.
8 The proposed wording included an exception from
9 reporting for, and I'll quote the phrase,
10 "administrations resulting from a direct intervention
11 of a patient that could not have reasonably been
12 prevented by the licensee."

13 The Federal Register notice for the
14 proposed rule specifically asked for public comment on
15 whether a patient intervention was adequately addressed
16 by proposed changes.

17 Next slide, please?

18 The final rule corresponding to the 1998
19 proposed rule was issued in 2002. The Statements of
20 Consideration for the final rule stated that the phrase,
21 "that could have been reasonably prevented by the
22 licensee" was deleted. The deletion was in response to
23 comments from the public that this phrase was ambiguous,
24 subjective and infringed on the practice of medicine.

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1 The Statements of Consideration also
2 described a new requirement that was added for licensees
3 to report events caused by patient intervention if they
4 resulted in serious consequences.

5 The description of serious consequences
6 was unintended permanent functional damage as
7 determined by a physician.

8 Next slide, please?

9 The same Statements of Consideration also
10 presented the definition of patient intervention, the
11 same one that's in effect today and that I described at
12 the beginning of my presentation that is intentional or
13 unintentional actions by the patient such as dislodging
14 or removing treatment devices or prematurely
15 terminating the administration.

16 And finally, the Statements of
17 Consideration reiterated the expectation for licensees
18 to act reasonably to prevent patient intervention that
19 could result in medical events.

20 Next slide?

21 The 2002 final rule includes the version of
22 the medical event reporting requirement 10 CFR 35.3045
23 that remains in effect today. And Section 35.3045(a)
24 introduces the medical event reporting requirements and

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1 excludes reporting of events resulting from patient
2 intervention.

3 Next slide?

4 When you move to the next section,
5 35.3045(b) also mentions patient intervention. It
6 states that under some circumstances, medical events
7 resulting from patient intervention do need to be
8 reported. A report is required if the event resulting
9 from patient intervention results in or is expected to
10 result in unintended permanent functional damage to an
11 organ or physiological system.

12 The determination of unintended permanent
13 functional damage is to be made by a physician.

14 Next slide, please?

15 So, I wanted to provide some examples for
16 this presentation and I searched historical NRC records
17 for formal case reviews that evaluated whether patient
18 intervention was the cause of a misadministration or
19 medical event.

20 The most common types of cases that I found
21 were those in which the patient removed a brachytherapy
22 applicator before the conclusion of the treatment of a
23 patient in motion accidentally caused an implant ribbon
24 or an applicator to become dislodged.

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1 Many, but not all, of those case reviews
2 concluded that patient intervention was the case of the
3 misadministration or medical event.

4 However, in some of the cases, a
5 determination was made that while patient intervention
6 may have been a contributing factor, there were
7 reasonable steps the licensee could have taken to avoid
8 the event or react more appropriately when it was
9 identified.

10 There was one unusual case in which, after
11 administration of an I-131 capsule, the patient
12 surreptitiously removed the capsule and concealed it.
13 The determination was that the patient actions in
14 removing the capsule were consistent with the
15 definition of patient intervention and the reporting
16 exclusion in 25.3405(a) could be used.

17 Next slide, please?

18 The most recent communication issued by the
19 NRC about patient information was an Information Notice
20 in 2006 related to gamma stereotactic radiosurgery
21 treatments. Two cases were described in which patient
22 movement caused the head frame to be displaced resulting
23 in dose to an unintended site.

24 And if you're interested in the details of

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1 those two cases, I can refer you to the Information
2 Notice itself.

3 Next slide?

4 The Information Notice noted that both
5 licensees believed it was not necessary to report a
6 medical event because they viewed the patient movement
7 as patient intervention.

8 However, the NRC disagreed and viewed the
9 events as resulting primarily from issues with the
10 patient equipment set up.

11 The NRC suggested a number of actions that
12 licensees should consider taking to avoid medical
13 events caused by patient intervention for all treatment
14 modalities, not just for gamma stereotactic
15 radiosurgery treatments.

16 Next slide?

17 So, finally, as you know, a major Part 35
18 rulemaking is currently under way and the proposed rule
19 this time did not make any changes regarding patient
20 intervention.

21 On the slide are some definitions and this
22 concludes my presentation.

23 MEMBER COSTELLO: Thank you, Sandy.

24 Bruce, before you start, any questions for

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1 Sandy?

2 CHAIR THOMADSEN: Dr. Mettler?

3 DR. METTLER: It said that it's when -- it
4 has to be reported when it results in permanent
5 functional damage. How does taking out an applicator
6 result in permanent functional damage?

7 DR. GABRIEL: That would be an example of
8 a case that likely would not result in permanent
9 functional damage.

10 DR. METTLER: So, anything that they pull
11 out that's an under exposure is not a misadministration
12 and doesn't need to be reported?

13 DR. GABRIEL: That's what the rule says,
14 however, considering the case examples, it looks like
15 in a number of cases similar to that that the NRC has
16 formally evaluated. The determination was made that
17 patient intervention was a contributing factor but not
18 --

19 DR. METTLER: But see, that's what --

20 DR. GABRIEL: -- but not the major cause.

21 MEMBER COSTELLO: Let me interrupt.

22 I think that precisely if the NRC has
23 determined, I guess, that if the institution could have
24 anticipated that the patient would remove it and taken

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1 steps to make that more difficult or unlikely, then it
2 would still be a medical event.

3 DR. METTLER: But it doesn't -- it said
4 it's a medical event if it causes permanent damage.

5 MEMBER COSTELLO: I don't think it says
6 that. I think it says even if there is a patient
7 intervention, if it causes medical damage, it's a
8 medical event.

9 DR. METTLER: If it doesn't?

10 MEMBER COSTELLO: If it does.

11 DR. METTLER: It is does? Yes, if it
12 doesn't cause permanent damage.

13 MEMBER COSTELLO: It could still be a
14 medical event. It meets the definition of a medical
15 event and it doesn't meet the definition of patient
16 intervention.

17 If there's permanent damage, even if there
18 is patient intervention, it's still a medical event.
19 But that's pretty rare.

20 DR. GABRIEL: Thank you for answering that
21 question.

22 MEMBER COSTELLO: I can't help myself,
23 Sandy.

24 Did I do okay?

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1 DR. GABRIEL: Yes.

2 MEMBER COSTELLO: Any other questions for
3 Sandy that you can answer?

4 Okay. Next slide, please? Oh, let's go
5 back to that slide.

6 Some of you may recall when we had the
7 subcommittee that was looking into guidance for
8 microspheres, in particular, looking for guidance
9 initially involving shunting to the GI tract then we
10 expanded it somewhat further than that.

11 There was a lot of discussion amongst our
12 group about patient intervention. So, if the --
13 basically we came to the conclusion if the treatment put
14 the spheres in the right place but due to the patient's
15 anatomy it went to the wrong place that we would then
16 consider that not to be a medical event. Because what
17 more could the doctor and the medical team have done?

18 Well, and I heard that expressed for any of
19 people and we'll get to that later on the slides. Well,
20 as I think most everybody here, I don't know about the
21 audience, knows I worked for the NRC like forever, even
22 when Sandy was there.

23 And that wasn't my recollection of what the
24 NRC meant by patient intervention, that that was more

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1 of a type of passive patient intervention rather than
2 active patient intervention.

3 And that troubled, because I think that the
4 NRC and its Advisory Committee, it's important that they
5 mean the same thing by words like patient intervention.
6 That we don't have a situation where the ACMUI's
7 advising the NRC in a particular case, let's say. And
8 say, well, that's not a medical event because of patient
9 intervention and we're meaning different things by that
10 phrase.

11 Now, I'm not advocating a particular
12 definition, I'm not. I want to call this both to the
13 attention of the Committee and to the attention of the
14 NRC so we can become aligned and mean the same thing
15 about the same words.

16 Okay, go the next slide, please? Thank
17 you.

18 The NRC basically has viewed patient
19 intervention as actions by the patient, behavioral
20 actions rather than physiological phenomena, how to put
21 together a pubic arch in an inconvenient place or, you
22 know, vascular systems to go the wrong way or the patient
23 just body is not cooperating so that when the medical
24 team does everything according to their procedures, the

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1 outcome is not what was intended.

2 So, by my past experience was that if the
3 anatomy result and sources coming to the wrong place,
4 that that would not constitute a medical patient
5 intervention.

6 But it's clear to me that overwhelming the
7 Committee felt that if the doctor did everything right
8 and the team did everything right and sources went to
9 the wrong place, that's not a medical event.

10 Next slide, please?

11 So, in preparing for this, is I want to
12 think, how could I express what I heard from the
13 Committee on patient intervention? And thankfully,
14 the Committee told me in many emails and things.

15 So, if you wrote me on patient
16 intervention, I scoured my emails and I tried to capture
17 your thoughts because I wanted to accurately reflect
18 what I believe the Committee's thoughts are. Okay?

19 However, I don't remember whose comments
20 are whose, you know, maybe if you recognize your comment
21 you could raise your hand.

22 One is there's another case of regulatory
23 terms not being in alignment with connotative and
24 denotative meaning. Basically, what we're recognizing

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1 here is, we the NRC, will tell the medical industry or
2 tell people, medical events are not -- they're not
3 violations, you know, they're just medical events.

4 But I think, and the physicians kind of try,
5 you know, when they hear medical event, they think that
6 they -- it's saying they did something wrong. That's
7 not always the case, I think, from the NRC point of view.
8 But, I think clearly medical practitioners see it that
9 way.

10 And as this email you sent me, what does
11 actions -- what does intentional or unintentional mean?

12 Next slide?

13 I have too many words in this slide, so I
14 hope you all can read this.

15 Look at all these various things that can
16 occur within the patient, changing flows so the results
17 that things get, you know, the seeds or the microspheres
18 go to the wrong place. These are -- and it carries all
19 the suboptimal treatment. But again, once again, when
20 the doctor and his team stop the treating part,
21 everything was going fine from their point of view and
22 then a person's body intervened.

23 Another couple of these occurrences are not
24 the fault of the patient. There's no meaning to saying

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1 it's the patient's fault unless the patient gets up and
2 walks off the table or pulls out a tube or something,
3 nor the AU, nor the administering physician or team.

4 And the question they ask is, what can be
5 done in reporting such things when the person's anatomy
6 causes it? What can be done in the future to avoid
7 medical events? Okay?

8 Now, I want to remind you what Sandy talked
9 about what the NRC's view of patient intervention.
10 That doesn't capture those type of events.

11 Next slide, please?

12 If during the injection of microspheres,
13 the patient's artery contracts and you have
14 microspheres going into the GI tract, the thought of my
15 ACMUI colleague was that, too, would be patient
16 intervention. But I'm telling you I believe that
17 historically, that would not meet the definition of
18 patient intervention as interpreted by the NRC.

19 I'll repeat, I'm not trying to argue
20 whether that should be patient intervention or not.
21 Okay? I don't know. But, I don't want to have this
22 misalignment between the Committee and the NRC, which
23 maybe that is and then lung shunt fraction and so forth.

24 Next slide, please?

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1 As I said, the NRC and its Advisory
2 Committee seem to be misaligned on patient
3 intervention. I'm going to go further than that. I
4 think it's even a misalignment on medical events in
5 general. And I think that the Committee basically
6 believes that the doctor did a good job and couldn't have
7 done any better. That's not a medical event.

8 And I don't believe historically, that the
9 NRC is seeing it that way.

10 You don't want to have miscommunication
11 between the Committee and the NRC when we're using the
12 same words that have different meanings behind them.

13 And the last question is, does whether the
14 Authorized User medical team did something wrong, is
15 that the sole determination of whether there's a medical
16 event?

17 If the Authorized User and the team did
18 everything according to protocols, should that be
19 considered to be a medical event?

20 So, I want to have this discussion today,
21 that's the last slide, to call this, I think it's this
22 misalignment to the attention of the Committee and to
23 the attention of the NRC so we can resolve it.

24 Perhaps we could have a subcommittee to be

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1 the committee recommending an interpretation of a
2 medical event of a patient interpretation.

3 It's a challenge because we're talking
4 about black letter regulation. I mean 35.2, I guess,
5 is the definition of patient intervention. It's there
6 and I don't know if changing guidance can change that.

7 I'm better on, you know, why's and what's
8 than how's. But I would leave it to the Committee
9 working with the NRC to come up with a good how to resolve
10 it because I don't think the present situation is a good
11 one.

12 Thank you.

13 CHAIR THOMADSEN: Thank you very much.

14 Comments from the Committee? I'll guess
15 we'll start around the table.

16 Dr. Ennis?

17 MEMBER ENNIS: So, kind of more of a
18 general comment but reflecting on this. So, one of my
19 other hats in life I spent a good amount of time
20 scholarly understanding of the development of Jewish
21 law. And if you study the law, any kind of law really
22 applies, words, even when they're black letter, often
23 change meaning over time in the community.

24 And as long as everyone is in agreement, it

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1 works and it's not necessarily a problem.

2 So, again, I don't know how NRC feels, but
3 the fact that everyone many years ago felt the phrase
4 meant one thing and now everyone feels the phrase means
5 something a little bit more because we've gotten a
6 little more sophisticated medically or we've broadened
7 our understanding, to me, it's not necessarily a problem
8 unless there's some kind of clash.

9 MEMBER COSTELLO: Thank you. It's a very
10 good question.

11 Is there any representative from the OGC
12 here today?

13 MS. HOUSEMAN: Yes.

14 MEMBER COSTELLO: Hello. I understand
15 you're new to us.

16 MS. HOUSEMAN: Yes.

17 MEMBER COSTELLO: I think
18 congratulations.

19 From my previous like, okay, such questions
20 often wind up being resolved by attorneys, for better
21 or worse. Okay?

22 However, I think that the meaning of
23 patient intervention within the NRC, perhaps, has not
24 evolved while the meaning of it in the medical community

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1 has and I believe that to other people.

2 But, I think that's a true statement. I
3 think that, you know, we're going back -- how far did
4 you -- 1992?

5 DR. GABRIEL: 1980.

6 MEMBER COSTELLO: 1980. You know, a lot
7 has changed, a lot of modalities have come along. We
8 weren't talking microspheres in 1980, you're talking,
9 you know, Cobalt and Cesium and gynecological implants
10 or something.

11 But, it's a lot more complicated now than
12 it was then. And perhaps, perhaps, our understanding
13 of that term should change, but it hasn't changed yet.

14 And so, right now, if the Committee says,
15 this is not an event because of patient intervention,
16 the NRC understands something fundamentally different.

17 CHAIR THOMADSEN: Thank you.

18 MEMBER COSTELLO: A full evolution of.

19 MEMBER DILSIZIAN: Great discussion.

20 So, to me, these are the words, patient
21 intervention and the other key words that said
22 behavioral actions, intentional or unintentional.

23 MEMBER COSTELLO: Right.

24 MEMBER DILSIZIAN: So, and I understand

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1 the evolution. So, if I were to say to you, patient
2 intervention, that is one, instead of putting
3 behavioral actions parenthesis intentional or
4 unintentional.

5 If we say intentional behavioral, because
6 behavior is doing something intentional or
7 unintentional action due to anatomy or physiology, I
8 think that would clearer. Isn't it?

9 MEMBER COSTELLO: If that's what the
10 decision is to do. I mean much clearer.

11 MEMBER DILSIZIAN: Yes, it's a medical
12 event, but see, the point is --

13 MEMBER COSTELLO: It'd be clearer but
14 different.

15 MEMBER DILSIZIAN: Yes.

16 MEMBER COSTELLO: It'd be clearer but
17 different.

18 MEMBER DILSIZIAN: Yes.

19 MEMBER COSTELLO: I'm sure it's unclear
20 now.

21 MEMBER DILSIZIAN: Yes.

22 MEMBER COSTELLO: But that might be
23 better.

24 MEMBER DILSIZIAN: Yes.

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1 CHAIR THOMADSEN: Dr. Weil.

2 MEMBER WEIL: No.

3 CHAIR THOMADSEN: Ms. Weil, I'm sorry.

4 MEMBER WEIL: But I do appreciate the
5 promotion, honorary, whatever.

6 I think what we -- it's important to know
7 why you're collecting the data before you define the
8 terms that will drive the data.

9 And it seems to me that there are two
10 different things here that should be captured. One is,
11 is this particularly therapeutic or diagnostic modality
12 creating a lot of medical events that harm patients? Is
13 there a particular practitioner or a group of
14 practitioners that harming the patients?

15 But the other thing is the one that's
16 unintentional, the one where patient anatomy or patient
17 behavior is the driving factor for the failure, then
18 there's a problem with the therapeutic modality.

19 And there are different things that you
20 want to collect and we're trying to lump them in one
21 category of medical event which doesn't make sense
22 because they each have meaning and they should be looked
23 at separately.

24 MEMBER COSTELLO: If I could respond to

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1 that.

2 Medical event, if you look what's supposed
3 to happen when there is medical event, it'll tell you
4 something of the purpose of it.

5 One thing that's supposed to happen is
6 you're supposed to report it to your regulator and if
7 your regulator's agree it's [a] mistake, like
8 ourselves, we then report to the NRC.

9 Another thing you'd have to do is you have
10 to tell the referring physician and the patient. Okay?
11 And if the patient, for whatever reasons it's not safe
12 for the patient to tell us, you tell the physician, the
13 family maybe you're looking.

14 So, these are two different things.
15 You're doing on the wholesale level what you're telling
16 the regulator does. And the regulator can process
17 those. I think the next speaker we're going to have a
18 review of medical events. Well, we're not going to be
19 focusing as much on the individual events, well, what
20 did we learn from these? You know, what's it tell us
21 about the modality?

22 So that's doing -- I think it's going to be
23 in the wholesale level. But, we're doing more than
24 that, we're telling the patient and telling the patient

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1 isn't for the intention of what did we learn about this
2 modality, it's telling the patient what happened.

3 And these are very different things. And
4 a physician can respond to me. I think the concern
5 normally about something being called a medical event
6 when it shouldn't be, let's say, is not so much notifying
7 the regulator, it's talking to the patient who may have
8 had a perfectly good treatment and telling them they
9 didn't have a perfectly good patient.

10 And, I'll tell you, as a cancer patient
11 myself, the last thing I want to hear [when] I'm treated
12 is that didn't really go right. That helped.

13 CHAIR THOMADSEN: One comment on the two
14 purposes. One thing about identifying problems in the
15 procedures could come from reporting the incidents to
16 an incident reporting database. They don't have to
17 rise to the level of an event.

18 Well, that's right, there are reasons why
19 people should want to and there is diminishing reasons
20 why they don't want to. But that's where that data
21 would be better coming from.

22 Dr. Mettler?

23 DR. METTLER: Yes, the simple -- I mean
24 this is nothing new. We inject patients with x, they

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1 have an allergy. Boom, something is bad. Doctor did
2 everything fine.

3 Yes, it gets reported, like you said, to a
4 database so the FDA says, so many of these happen and
5 it gets put in the patient chart so nobody injects him
6 with it again.

7 But if you start going after -- if you just
8 think about where you would go with this as a
9 misadministration kind of bit, there are patients in
10 radiotherapy who are radio sensitive. And you go along
11 and all of a sudden, whoops, they're having a reaction
12 you didn't expect. So, they've got some permanent
13 damage. It's not the doctor's fault.

14 You're going to report every radio
15 sensitive patient as a misadministration? No.

16 So, I think you don't want to go there.

17 MEMBER COSTELLO: Let me pick up on the
18 words you used there and I think is a source of some of
19 this issue, and that's the word fault. Okay?

20 I believe the NRC, if asked, would say that
21 a medical event can be nobody's fault. It's not medical
22 fault, they're not looking for fault.

23 DR. METTLER: But if it's due to patient
24 physiology of that particular patient, all you want to

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1 do is not do it to that patient again.

2 MEMBER COSTELLO: My point is the absence
3 of fault; I think the NRC's point of view is not a reason
4 not to make it a medical event.

5 However, I think, and correct me, that if
6 I am the physician, the Authorized User, it's all about
7 fault. Okay? I'm having to report this treatment that
8 went badly to the NRC and tell the patient, it goes on
9 the websites and it's made public, I think that
10 somebody's going to think I was at fault. It's only
11 human.

12 Again, I'm not proposing a solution to this
13 because I don't know. But, what I know is not good is
14 the status quo where the Committee and the NRC look on
15 a very important term, patient intervention, ultimately
16 medical event, you know, why do we report these things
17 differently? And I want us to be in alignment.

18 What we're going with, I'll leave up to the
19 Committee.

20 CHAIR THOMADSEN: Thank you for thinking
21 of us.

22 Other comments?

23 Not hearing comments, I'd like to name a
24 subcommittee to look into this issue and report back to

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1 the whole Committee with a proposed statement of what
2 we consider a reasonable definition of patient
3 intervention.

4 And I would ask Dr. Dilsizian to chair the
5 committee, if he's willing. I recommend Dr. Ennis, Mr.
6 Costello, Dr. Suh, Dr. Alderson to sit on that committee
7 and if Ms. Weil would also join that committee, I think
8 that be useful.

9 Any comments?

10 Good. Yes?

11 MS. DUDES: I think that I will get a hook
12 from both sides of my staff when I raise this issue, but
13 so you talk about the common definition of patient
14 intervention. If there's a little discussion, again,
15 it goes back to Ms. Weil's point about what are you doing
16 with the information?

17 So, we have this phrase, medical event, and
18 it's defined in our procedures. But then there's the
19 usefulness of operating experience that helps you
20 identify trends and other things.

21 And is there another way to get to that
22 level of detail where there is no fault assigned? But
23 it's still -- because I would agree with Frank that I
24 think that if the staff believes, we like that a medical

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1 event, there is no fault, but we use it as operating
2 experience and trending and, you know, is there things
3 out there that we should be communicating to the broader
4 community?

5 CHAIR THOMADSEN: And as I said, that was
6 in the presentations we had at the last meeting,
7 discussions of reporting systems that are out there. I
8 think that's pretty much their job. I mean they're
9 completely blameless, so to speak.

10 And it might be very likely to get more
11 information than what you would get in reporting events,
12 a medical event, according to our definition.

13 And I would also ask Dr. Gabriel, would you
14 be the staff contact for that? Would that be
15 appropriate?

16 DR. GABRIEL: I will turn to my boss.

17 CHAIR THOMADSEN: Since you've already
18 done the research on this.

19 DR. GABRIEL: Of course.

20 CHAIR THOMADSEN: Very fine.

21 Dr. Alderson?

22 VICE CHAIR ALDERSON: Yes, I have a
23 question that will help Dr. Dilsizian and the rest of
24 of us as we go forward.

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1 One of the problems with this whole
2 discussion, I believe, is that term patient
3 intervention and what that means.

4 So, in the regulations of the NRC, are we
5 allowed to, among the things, recommend that that term
6 be done away with? Is that within the scope of our
7 recommendations?

8 MS. DUDES: You can recommend. Whatever
9 the Committee comes to with an independent -- I mean that
10 you are our Advisory Committee. I mean understanding
11 that when we go down that road, that we get into
12 rulemaking space. But I think Part 35, given the
13 evolution of medicine we'll be in a perpetual state of
14 updates. So, absolutely.

15 How expeditiously we would get that
16 definition change? I don't know, but absolutely. I
17 don't think you should -- this Committee should not feel
18 constrained about what they can recommend to the staff
19 given the expertise there.

20 CHAIR THOMADSEN: Dr. Langhorst?

21 MEMBER LANGHORST: As a radiation safety
22 officer who has gone through medical events, from a
23 licensee's point of view, it is an onerous thing to
24 defend to yourself against guilty until proven

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1 innocent.

2 The patient intervention part of it allows
3 the medical licensee to not have to report it to the NRC
4 because the NRC, I understand, medical event to them is
5 an event involving medical application, let's look at
6 it.

7 But it isn't how we feel on defending
8 ourselves and it's very seldom that the licensee is
9 exonerated.

10 I've had it happen one time because it's
11 always something about procedures or whatever. And so,
12 you are -- it is a big deal when you have to report a
13 medical event. And you're -- whether it is a medical
14 event or not, it stays on the website forever.

15 MEMBER COSTELLO: As far as deleting
16 patient intervention, you would have to replace it with
17 something else or you would make it worse because then
18 there'd be no such thing as patient intervention even
19 if the patient does get off the table or pulls out the
20 applicator from HDR, that'd still be a medical event.

21 So, the definition you're talking about, I
22 think, would capture more of the things we're talking
23 about although, as you know, rulemaking is very
24 difficult and slow. I don't know how we could treat

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1 this in guidance space, I just don't know. But, you
2 know, that's for the Committee and the NRC to figure out.

3 If rulemaking weren't so hard, we could do
4 a lot of things better, you know?

5 MS. DUDES: Yes, but there are things we
6 can do in the interim. You know, if there's an agreed
7 upon path forward, I think there's a lot of things that
8 we can do to ease that.

9 MEMBER LANGHORST: And again, it's that
10 position of what should be regulated and what should be
11 practice of medicine. And there are a lot of things
12 that we, as medical professionals, have to really review
13 when something like this happens with a patient that NRC
14 doesn't necessarily have to be part of.

15 I mean I think as long as NRC understands
16 that there are other mechanisms that are used to look
17 at what the problem was, how to learn as much as you can
18 from it and minimize it happening for future patients
19 or for that patient, that's a continual thing that
20 changes and I think is worth a look at, too.

21 MEMBER COSTELLO: And perhaps we need a
22 rule that says that because that's really -- because we
23 don't have one.

24 CHAIR THOMADSEN: Well, thank you and --

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1 oh, whoops, we have a comment from Ms. Holiday.

2 MS. HOLIDAY: I'd just like to confirm on
3 March 19th Dr. Thomadsen formed a subcommittee to review
4 and evaluate the phrase patient intervention.

5 Dr. Dilsizian has been appointed as the
6 Chair. Additional members include Dr. Ennis, Mr.
7 Costello, Dr. Alderson, Ms. Weil and is that Dr. John
8 Suh or Dr. Sue Langhorst?

9 CHAIR THOMADSEN: John Suh.

10 MS. HOLIDAY: Okay, Dr. John Suh and your
11 NRC contact person is Dr. Sandy Gabriel.

12 Thank you.

13 CHAIR THOMADSEN: Not that I wouldn't want
14 to invite Dr. Sue Langhorst.

15 MEMBER LANGHORST: I'm good.

16 CHAIR THOMADSEN: And if there's no other
17 comments or clarifications, we'll stand adjourned until
18 after lunch at 1:00 we'll resume promptly.

19 (Whereupon, the above-entitled matter went
20 off the record at 11:39 a.m. and resumed at 1:03 p.m.)

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1 A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

2 (1:03 p.m.)

3 CHAIR THOMADSEN: We'll reconvene, after
4 lunch, and before we start with the agenda, we have a
5 member of the public who wanted to make a comment on the
6 topic earlier in the session, but there was a technical
7 problem apparently with the bridge line at that point.

8 Are you on the line?

9 MR. CRANE: I am. And I will identify
10 myself. I'm Peter Crane, retired NRC.

11 CHAIR THOMADSEN: Very fine. And you want
12 to make comments and you have three minutes, please.

13 MR. CRANE: Thank you, Dr. Thomadsen.
14 First, my question for Dr. Mettler, when he refers to
15 an ICRP report that he wrote, is that the forthcoming
16 ICRP 128? And if so, is it possible to obtain a copy?

17 DR. METTLER: No, it's not that report.
18 It was an earlier one.

19 MR. CRANE: Which report was that?

20 DR. METTLER: I'd have to look up the
21 number, but it's about release of patients. I can get
22 you a copy.

23 MR. CRANE: What year was it released?

24 DR. METTLER: About six years ago.

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1 MR. CRANE: Was that ICRP 94 on doses for
2 patients?

3 DR. METTLER: I can look it up for you.

4 MR. CRANE: Okay, well, thank you. What I
5 wanted to say is I wanted to commend the staff for its
6 very conscientious and thorough work in implementing
7 the Commission's SRM. The staff does what the
8 Commission directs in the SRM. I hear some discontent
9 from members of the committee with the SRM, but you know
10 that's out of the staff's hands.

11 There was a comment from Dr. Howe about how
12 this comes down to the patients. It's all about the
13 patients. I think that's quite right and that's the
14 path down which the Commission went with the rule change
15 of 1997.

16 Previously, we could -- we, the NRC, could
17 give our directive to licensees over whom we had some
18 control. We're now dealing with the fact that we have
19 transferred a lot of control into the hands of patients,
20 their discretion, their knowledge, their conscience, et
21 cetera. And that puts us in the position of having to
22 educate them.

23 I agree with Dr. Weil that there is lots of
24 precedence for giving directives to the public, package

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1 inserts, CDC guidance, it's all over the place. And I
2 want to say I think the importance of getting guidance
3 out there is underlined by this recent petition for
4 rulemaking filed by Dr. Marcus who is the origin of the
5 patient release rule change of 1997 where she says that
6 fetuses ought to be able to get as much radiation as a
7 worker in a nuclear facility and that it's important to
8 remove these limitations, remove the preferential
9 treatment for women, children, and fetuses. And why do
10 we want to remove the limits on the public so that they
11 can have the hormetic benefits of radiation? So if you
12 have one person out there who believes in ALARA and
13 keeping radiation rates down and another person who
14 thinks that it's beneficial to get radiation and you can
15 see the great, great gap in the kind of guidance that
16 goes out.

17 And I think that the NRC is doing the right
18 and responsible thing in trying to provide guidance that
19 will be useful to everybody and that has buy-off from
20 the medical community as well. And that concludes what
21 I have to say.

22 CHAIR THOMADSEN: Well, thank you very
23 much for those comments, Mr. Crane.

24 MR. CRANE: Thank you, Dr. Thomadsen and

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1 members of the Committee.

2 CHAIR THOMADSEN: And Dr. Mettler?

3 DR. METTLER: That report was ICRP 94 that
4 was published in 2004.

5 MR. CRANE: Okay. I have ICRP 94. I'm
6 not sure I read it in quite the same terms you do,
7 although certainly the risk to children from saliva is
8 emphasized in that. Thank you very much and I'll sign
9 off at this point.

10 CHAIR THOMADSEN: Thank you.

11 MR. CRANE: Goodbye, thank you.

12 CHAIR THOMADSEN: Goodbye. Ms.
13 Cockerham, would you like to tell us about 1556.

14 MS. COCKERHAM: Sure can. Do you want to
15 go to the first slide. I'm sorry some of you can't read
16 this. Sorry it's so small. It's another multi-year
17 project that we've got going on. And so I just kind of
18 wanted to bring you up to date with where we are on
19 revising the guidance. And initially, we had a comment
20 from -- when we did Revision 2 back when we put the NARM
21 rule through, we opened up the volume and they only made
22 changes for NARM. And during that comment period, we
23 received comments that were not necessarily related to
24 NARM and so those comments were rolled over to be

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1 considered now for Revision 3.

2 So we looked at all of those comments. We
3 also looked at comments received from regulatory staff
4 and the public since the last publication of Revision
5 2. And we also looked at all of the updated references
6 to know the ICRP, NRCR, all of those documents get
7 updated and so we took a look at all of those to say are
8 we in line with those, can we adopt those as a part of
9 this guidance as well?

10 So for time line right now, we're in the
11 green box. I sent the document a few weeks ago to the
12 steering committee and so they're looking at all of the
13 changes that have been made and they should be getting
14 back to me here at the end of this month. And then at
15 that time, the document will come to the ACMUI. So
16 you'll see a new version of NUREG-1556, Volume 9, and
17 I have basically a whole list of comments that have been
18 received in an Excel chart and then to the right of it,
19 it says how we've resolved it. And then there are
20 changes throughout the document.

21 So you're not going to get a redline
22 strikeout because if you did, the entire document would
23 be red. But at least you can see here was the issue,
24 you know, if it's a mobile medical license, and then

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1 here's how we resolved it, go see Section 8.4 and then
2 you can go read Section 8.4 to see what changes were
3 made.

4 So we're trucking along. It's 2015. The
5 top row is the working group that I'm leading and we're
6 in steering committee. Also, our legal counsel is
7 taking a look at the document. And then after the ACMUI
8 has their 60-day review which I expect they will have
9 in the summer, we'll do a comment resolution, wrap all
10 those comments into the document and actually publish
11 it for public comment, so it will go out again. And
12 we'll do comment resolution again. We'll have tech
13 editing and it will go for final management review and
14 then we'll eventually publish the document.

15 Now at the same time, we have the Part 35
16 rule going on, the rulemaking is going. And Donna-Beth
17 has been working on that, Sandy Gabriel as well, and
18 they've been making changes to the guidance, basically
19 in parallel. So they're making changes to pages. I'm
20 making changes to pages and if you look, the bottom time
21 line is the rulemaking time line. Their guidance went
22 out for comments, so it's already been published.
23 They're ahead of us in that sense. So once they resolve
24 all of their comments and they have final language, I'll

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1 take that final language if you look out into 2016 and
2 put that into the document that I'm working on. So we
3 will have one final document at the end. It will all
4 come together, but we're sort of working in parallel on
5 them right now. So I kind of tried to lay out a picture
6 of where we are, where we're trucking along and where
7 we want to be in the end.

8 So my last slide is just that what I
9 mentioned, the significant changes that actually went
10 into this revision, what were we looking at. I know Dr.
11 Langhorst's name popped up several times. There were
12 letters from her and various NRC staff members, our
13 regional licensing staff, and inspection staff. If
14 they come across things and say hey, could we say this
15 differently or could we say it better in our guidance?
16 Could we be more clear? We made all of those changes.

17 CHAIR THOMADSEN: Thank you very much.
18 Comments, questions? Yes, Dr. Zanzonico.

19 MEMBER ZANZONICO: So the first one is the
20 NUREG revision time line? Did I understand that
21 correctly?

22 MS. COCKERHAM: They're both revisions to
23 the same document. The first line is the working group
24 that I'm working on which is anything except for

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1 rulemaking. So if it's not a rulemaking change -- you
2 know there's changes being made to Part 35 right now.
3 So they need to update the guidance with that. That's
4 being done by a different working group which is the
5 second line. So my working group is on the top time line
6 which was the "everything else, catch all."

7 MEMBER ZANZONICO: Thank you.

8 CHAIR THOMADSEN: Dr. Langhorst.

9 MEMBER LANGHORST: And so what you think
10 [is] you may be giving us this summer is that just your
11 group's working on it or will it be everything?

12 MS. COCKERHAM: Just my group.

13 MEMBER LANGHORST: Okay. And so then will
14 we see it again when it's all put together or we've
15 already seen it because it went out with the Part 35
16 proposed rulemaking?

17 MS. COCKERHAM: You've seen what went out
18 for the Part 35 proposed rulemaking.

19 MEMBER LANGHORST: Yes.

20 MS. COCKERHAM: So anything you comment on
21 there will come back to me, the last box on the bottom
22 row where it says final rule and guidance published.
23 Theirs is going to get published and really be a done
24 deal and then I'm going to take any of those changes and

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1 wrap it back up into mine.

2 MEMBER LANGHORST: But it's in the same
3 document?

4 MS. COCKERHAM: Same documents.

5 MEMBER LANGHORST: I don't know that I
6 understand that. I'll trust.

7 MS. COCKERHAM: We have direction from the
8 Commission that when we put out a new rule, we have to
9 have guidance to accompany it. So we have to work with
10 what we have right now.

11 MEMBER LANGHORST: And I absolutely love
12 that. Thank you so very much. So I'm just trying to
13 figure out what we are going to be looking at what
14 changes may still -- have you already added their
15 changes?

16 MS. COCKERHAM: No. They'll stay out.

17 MEMBER LANGHORST: Okay. I think that's
18 very confusing. Sorry.

19 MS. COCKERHAM: That's why I've created
20 two totally different time lines.

21 DR. HOWE: This is Dr. Howe. When we have
22 our guidance, you've already seen our guidance once.

23 MS. COCKERHAM: Right.

24 DR. HOWE: When we put it in final form, it

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1 will come back to the ACMUI for its review and then when
2 it's ready to be actually published, after you have
3 reviewed it and made your comments, we'll resolve
4 whatever comments we have, then it will go out for the
5 public and to Ashley and Ashley will then incorporate
6 it. So you will have a chance to see it, see the Part
7 35 changes to the guidance, as well as things that Ashley
8 is talking about.

9 MEMBER LANGHORST: But we will probably
10 see that in two separate iterations.

11 DR. HOWE: You will definitely see the Part
12 35 one in a different iteration.

13 MEMBER LANGHORST: Okay.

14 MS. COCKERHAM: What we didn't want to do
15 is hold back any work that I could be doing on other
16 changes, waiting on them to finish all the rule stuff,
17 and so that's why we thought if we did it in parallel,
18 we're making a little more time.

19 MEMBER LANGHORST: Do you feel like there
20 is anything that you may be working on that's impacted
21 by them, vice versa, in the coordination of the --

22 MS. COCKERHAM: We've had a couple of
23 little notes and I have just been able to note, like oh,
24 this would be Part 35 rulemaking. We'll make sure we

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1 add it to the discussion. So I have them noted.

2 MEMBER LANGHORST: Okay.

3 MS. COCKERHAM: No major conflicts.

4 MEMBER LANGHORST: I think that will be
5 helpful.

6 CHAIR THOMADSEN: Any other comments?

7 MEMBER LANGHORST: Just to let everyone
8 know, it is a 512 page document, so I just want to you
9 know.

10 MS. COCKERHAM: You will be happy to know
11 that it has been condensed down to 300 and some pages.

12 MEMBER LANGHORST: I like it already.

13 MS. COCKERHAM: One of my big purposes of
14 this was to sort of change the format, the layout, how
15 it flows and condense where we can. And so we have taken
16 a big step to do that.

17 MEMBER LANGHORST: Okay, great. Thank
18 you.

19 CHAIR THOMADSEN: Any other comments?
20 Hearing none, thank you very much, Ms. Cockerham.

21 MS. COCKERHAM: Thank you.

22 CHAIR THOMADSEN: And now we have Dr. Howe
23 with our medical events.

24 DR. HOWE: Well, good afternoon. This is

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1 my yearly presentation on the status of medical events
2 and I will give you all an overview of what we've had
3 reported to us during -- I think it's through Fiscal Year
4 2014, during Fiscal Year 2014.

5 And then there will be a working group of
6 the ACMUI who will probably come back in the fall and
7 give its presentation on what it thinks about the
8 medical events. And the two were not supposed to be
9 identical. I give you the overview. I go through in
10 depth on kind of scanning the top of it and we're hoping
11 that in that overview, you'll see some areas that you
12 think you'd like to delve into deeper. And you will
13 eventually -- we will be giving you a copy of the NMED
14 reports that I pulled up. And in those NMED reports,
15 at the bottom of each event, you'll see references and
16 so ACMUI may want to go into some of those references
17 and try to get additional information or come back and
18 ask the NRC to get additional information. So the
19 intent is not to duplicate things in the spring and in
20 the fall.

21 First slide. The biggest thing I want you
22 to see here, we have a lot of discussion about medical
23 events and how bad it is for physicians to have medical
24 events and medical licensees. I want you to know that

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1 only 46 medical events last year. It's not a big
2 number. It's not a statistically significant number
3 and it's not a big number.

4 And I always try give you a perspective of
5 where were we last year and this has no statistical
6 significance. It's just to give you just a view. Last
7 year there were about 43 medical events. I've broken
8 it down by modalities so that you can see where things
9 shift from year to year. We very rarely ever get a
10 diagnostic nuclear medicine medical event. And why is
11 that? That's because when we introduced -- either the
12 radiopharmacy rule or the quality management rule, we
13 changed the definition of medical event. For
14 diagnostic, we put a threshold of 5 rem whole body, 50
15 rem to an organ. Very few diagnostic procedures will
16 trip that threshold. So we have very few, maybe once
17 every two or three years and we generally have the same
18 diagnostic medical event each time.

19 And you'll see the 300s, pretty much the
20 same. We had a decrease in 400s. We have much fewer
21 prostate brachytherapy medical events this year. Six
22 hundred stayed about the same, but the distribution
23 changed a little. And the largest numbers are always
24 in 35.1000 because that's where the yttrium-90

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1 microspheres are and that is a very difficult procedure
2 to give in accordance with a written directive because
3 of the mechanics of the device.

4 So if I can have the next slide?

5 To put it in perspective, we really don't
6 have anything that you compare on the diagnostic events
7 because even though the denominator is very, very tall,
8 the threshold is very, very high, so we expect to see
9 maybe one every two or three years.

10 We have about 150,000 therapeutic
11 procedures. We had 45 this past year. That's 1 in
12 3,000. We've always been told that roughly the percent
13 of human error is about 1 times 10^{-4} which is 1 in 10,000,
14 so it's right in the human error realm.

15 Next slide.

16 So now we'll start going through the
17 different modalities. 35,200 are our diagnostic
18 nuclear medicine procedures. Things that do not
19 require a written directive, so these are all your
20 cardiac scans, your technetium scans, etcetera.
21 Generally, if we have a medical event in 35,200, it's
22 because somebody eluded the generator and gave the
23 entire generator elution to one patient or in this
24 particular case, they had a multi-dose vial and they

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1 gave the whole vial to one patient. And by giving them
2 140 millicuries instead of 20 millicuries, they got a
3 whole body dose of 6 to 7 centigray. So this is what
4 we normally expect to see when have a diagnostic medical
5 event. We don't have one very often. Generally, they
6 are on weekends or at night when you've got multi-dose
7 vials or generator elution.

8 Next slide.

9 I've got three -- we normally call them
10 therapy nuclear medicine, but because you've got the
11 diagnostic whole body I-131 scans in here, we just call
12 it unsealed material, requiring a written directive.
13 And we've got three of them. Normally, they're all
14 I-131. We have quite a bit of variety this time. We
15 have a samarium one in which they -- this may be one that
16 I want to go back and look a little harder at because
17 the description was that they gave it in the skin as
18 opposed to intravenous and that could be because they
19 missed the vein and therefore it went under the skin or
20 it could be they deliberately tried to deliver into the
21 skin or the arm or somewhere. So I'll have to go back
22 and see, because if it was they missed the vein, we've
23 already made a determination those are not medical
24 events. But I'll have to go back and check on that.

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1 The radium-223, that was a comedy of
2 errors. It was where one error gets promulgated and
3 another error is made and the end result is the patient
4 gets exactly what the patient should have gotten. The
5 hospital has its written directives, written out
6 primarily in millicuries and so when they went to give
7 the radium-223 because radium-223 is given primarily in
8 microcuries, they wrote the number for microcuries, but
9 they put it in a block that had millicuries. And so the
10 written directive is for millicuries. What was
11 administered was the correct dosage in microcuries. So
12 that's two errors make a right. So that was not one with
13 any significance other than procedures are now being
14 changed so that they are very aware that when they see
15 radium-223, they're going to have to use a different
16 form that has microcuries so the written directive does
17 correspond with what's given.

18 Next slide.

19 We have our I-131 patient. This was
20 probably one of our more interesting medical events. A
21 patient came in. They gave the patient the wrong
22 identification bracelet. The patient wasn't supposed
23 to get I-131. They moved the patient along, gave the
24 administration and then the authorized user had not

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1 bothered to identify the patient by any other means. So
2 this is a clear example of where they're programmed to
3 ensure the patient gets what they are supposed to get
4 failed in multiple areas. And it's human factors 1 and
5 2. So that was -- and the end result was this patient
6 got 728 centigray to the thyroid.

7 Next slide.

8 These are our sealed source manual
9 brachytherapy medical events. We normally [get] a few
10 gynecological ones and most of them are prostate.

11 MEMBER COSTELLO: Going back to that, what
12 was the consequence to the patient?

13 DR. HOWE: They said the consequence --
14 they didn't --

15 MEMBER COSTELLO: It just looked like a big
16 dose is all.

17 DR. HOWE: It's a big dose.

18 MEMBER COSTELLO: That would be
19 hypothyroid.

20 DR. HOWE: Yes, there are going to be
21 effects.

22 MEMBER COSTELLO: Thank you.

23 DR. HOWE: So we have one gynecological one
24 and we have four prostates. So this is four medical

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1 events in 35.400 - is a pretty low number.

2 So let's go to the next slide.

3 This is a case where the applicator became
4 dislodged during the treatment. The treatment should
5 have lasted the 63 hours. They believe the applicator
6 was dislodged at 49 hours. The inner thigh received a
7 higher dose than it was supposed to be received. To be
8 a medical event, it has to be over 50 rem or 50 centigray,
9 certainly that. It has to be over 50 percent of what
10 it should have gotten and in this case it is. So this
11 is the medical event.

12 Next slide.

13 So prostate brachytherapy. We're always
14 going to have prostate brachytherapy medical events.
15 One reason we probably will always have it is there is
16 confusion in ordering air kerma units when they need
17 millicurie or ordering millicurie when they need air
18 kerma. So this is one that we've seen before. They've
19 ordered in the wrong units. So you ordered millicuries
20 instead of air kerma.

21 The second prostate brachytherapy medical
22 event was when some of the seeds were inadvertently
23 implanted into scar tissue and therefore the prostate
24 didn't receive the full dose that it was supposed to

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1 receive.

2 Next slide.

3 Then we have the ultrasound issues. We're
4 almost always going to have medical events because of
5 this reason. People, the physicians, and the
6 urologists, and the oncologists don't necessarily see
7 the prostate. They see another anatomical area,
8 generally the penile bulb. They insert all of the seeds
9 and it's not until they take an image later that they
10 find they were not in the right location. So you can
11 pretty much tell these because they're always about 2.5
12 to 3.5 centimeters from where the target tissue should
13 have been. So both of those were due to ultrasound
14 issues.

15 Next slide.

16 Now we've got the 35.600. We had both HDR
17 and Gamma Knife this time. I had a difficult time
18 trying to break down the HDRs for you. First of all,
19 there were a number of different target areas that were
20 being treated, but also there were a number of different
21 reasons for the errors. So in this particular slide,
22 you'll see the different target areas. They had
23 scanned a bronchial, one not designated. It was
24 probably pelvic. It was one designated pelvic and then

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1 three OBGYN cases and then we have one Gamma Knife.

2 So the next slide shows the reason for the
3 errors. Wrong site, wrong patient, decay correction,
4 right patient, wrong treatment plan, source retraction,
5 wrong dwell time, wrong interpretation of dose per
6 fraction. Some of these are common human errors that
7 we've seen mNY times before.

8 So let's take a look at the wrong site ones.
9 We had an OBGYN case where for three of the treatments
10 they gave 700 centigray per fraction and they realized
11 that they had given the treatment later. They realized
12 they had given it 10 centimeters short of the intended
13 treatment site, so they ended up with radiation burns
14 to the patient's thigh and labia. So that one had
15 medical consequences.

16 The next slide was a bronchial and in this
17 case they had two different segments. One segment used
18 a simple catheter. The other used a centering
19 catheter. One of the segments wasn't delivered
20 correctly. So they discovered the error in the first
21 fraction so they gave the second treatment which I think
22 is the center catheter was nine centimeters from where
23 it should have been delivered.

24 Next slide.

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1 We have another OBGYN. They had three
2 fractions and when they checked to make sure the
3 positioning of the vaginal cylinder on the first
4 fraction, they realized that it wasn't where they
5 thought it should be. They attributed that to special
6 patient anatomy, something that you guys would have
7 called patient intervention.

8 However, when they went to give the second
9 fraction and they checked the x-ray, they found out it
10 went exactly where they thought it have gone on the first
11 time. So they had an error in the first delivery and
12 they were able to deliver the next fractions the way they
13 were intended in the written directive. So in the first
14 one they delivered 900 centigray to the wrong treatment
15 site. And so it really wasn't patient intervention.
16 It was positioning issues.

17 On the next slide, this is where we have the
18 wrong patient. And this one was to the skin. They were
19 looking at the correct site. They were looking at the
20 right applicator, but they used the wrong patient's
21 treatment plan. So they delivered the wrong dose to the
22 wrong place. And the area adjacent to where the dose
23 was got about 2,300 centigray to a single point. We
24 don't normally see where they use the right target, the

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1 right applicator, but they use the wrong treatment plan.
2 So that one is a little bit different from what we
3 normally see.

4 The next slide.

5 This one is a little hard to explain. For
6 some reason, they believed that they needed to put a
7 decay correction for the source into the HDR treatment
8 plan and did not realize that the HDR treatment plan
9 already accounted for decay correction. Therefore,
10 they had doubled decay correction and they gave too much
11 radiation because the time window was much longer than
12 it should have been. I think this is about the first
13 one I've ever seen that's been this. It kind of sounds
14 like somebody was not familiar with the treatment plans
15 or a new physicist. I don't know exactly why.

16 The next slide.

17 We have another wrong treatment plan. In
18 this case they've got the right patient. The patient
19 had two different fractions, but the fractions were
20 slightly different and so when the patient came back for
21 the second fraction they used the treatment plan for the
22 first fraction. And so that put it in the wrong place.
23 And they received about 700 centigray or 60 percent of
24 the dose went to the planned volume.

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1 Next slide.

2 In this particular case, they had started
3 the procedure. They went to the first dwell location.
4 When they went to the second dwell location, they
5 experienced a resistance and the HDR did exactly what
6 it was supposed to do. It retracted. It would not go
7 back out. So they tried new tubes. That didn't work.
8 The dummy wire source wouldn't transverse, so they had
9 to abandon this particular procedure.

10 Next slide.

11 And this is where we have a dwell time. And
12 they didn't specify where this particular treatment
13 site was. So before the third of six fractions, they
14 realized that for two of the fractions, they hadn't used
15 the correct dwell position. And they didn't give us a
16 lot more information than this. So the corrective
17 action was that they were now going to check the catheter
18 measurements and do a checklist. So you get the feeling
19 that they put the wrong catheter in. That's why they
20 had the wrong dwell times and that was the reason for
21 the medical event.

22 Next slide.

23 Okay, this one we've seen, this type of
24 event happen before. You've got three fractions of 500

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1 centigray each. And when they set up the treatment plan
2 instead of saying 3 times 500, they divide 500 by 3. And
3 so the patient got much less than they were supposed to
4 get because they did the fractions, the dose delivered
5 on each fraction was too low.

6 Next slide.

7 This was a Gamma Knife. This was pretty
8 interesting. They had two patients coming. The first
9 patient was going to be a very long treatment. The
10 second patient was not going to be quite as long. They
11 were similar. They put the head frames on. They
12 decided not to treat the long treatment patient. So
13 that meant the first patient that should have been
14 treated was not getting treated that day. But they
15 didn't communicate that information to the nurses. And
16 so when they went to do the treatment, they got the wrong
17 patient and so they gave the patient the second
18 patient's treatment. So they realized they made a
19 mistake about two minutes into the treatment and they
20 stopped the treatment. So it was for the wrong
21 treatment site.

22 Now next slide.

23 Now we get to 35.1000. And if you remember
24 correctly, there are 46 medical events total. Over

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1 half of them are in 35.1000. The majority of them in
2 35.1000 are in the yttrium-90 microspheres. What's
3 interesting on the 35.1000 medical events this time is
4 that we did have a Perfexion and a seed localization
5 medical event.

6 So if we go to the first slide, so this is
7 another human error. There should have been a clear
8 written directive. The person that was doing -- the
9 treatment planner, knew the patient. Knew the patient
10 had problems on the right side. Somehow did not see the
11 doctor's instructions that this was to be treated on the
12 left side and went ahead and set it up on the right side.
13 And they were -- luckily they caught it about 1.7 minutes
14 into a 19-minute treatment and they realized it was on
15 the wrong side. And approximately 1800 centigray was
16 given for the wrong treatment site.

17 The next slide.

18 The seed localization. This is supposed
19 to be a diagnostic procedure. In this case, the
20 licensee received two seeds. They had two markers.
21 One marker was for a benign biopsy. They had two seeds,
22 so they put one seed in the benign biopsy site and they
23 put one seed in the cancer site. So that was unintended
24 dose that was for two days' duration until they

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1 explanted the seed and so they received 61 centigray to
2 a half centimeter volume.

3 The next slide.

4 Now we'll start with the microspheres.
5 Sometimes we have more SirSpheres medical events.
6 Sometimes we have more TheraSpheres medical events.
7 This time it was SirSpheres treatment. So SirSpheres,
8 we got 15 medical events. They are wrong site, written
9 directive problems, three-way stopcock, bubbles,
10 contamination, transfer error, occluded/kinked
11 catheters, that's normally why we see problems, so there
12 are six of those. It's the largest group. Or no
13 information at all provided.

14 So let's start. The first one is the
15 duodenal ulcer. In the first of three treatments, they
16 discovered a duodenal lesion and the ulcer developed,
17 it seems to be as a result of the microspheres migrating
18 to the stomach. They did a biopsy. They picked up the
19 microspheres in the site of the ulcer. And they
20 attributed it to aberrant hepatic arterial vasculature
21 supplying the stomach. So that's one of our shunting
22 types of errors.

23 The second one was in the gastric fundus.
24 They prescribed microspheres to the right lobe. They

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1 stopped when they identified unexpected shunting and
2 they delivered a little over 1,000 rads to the gastric
3 fundus.

4 Our next event, this was an overdose of
5 13,000 centigray or rads. This is a 10,000 centigray
6 or rads to the lung. In this case, the -- no, have I
7 got the right one? No. Okay. Sorry about that.

8 This is one where the authorized user
9 provided the radiopharmacist with an incorrect version
10 of the written directive. The pharmacist filled it.
11 They didn't recognize the problem. And they attributed
12 it to failure to follow all procedures and that they had
13 defeated normal checks and balances that would have
14 identified the incorrect dosage. So that was a dosage
15 error. We very rarely see a dosage error like this.

16 Next slide.

17 I think from here on we'll see under doses.
18 The first one was a 45 percent under dose where most of
19 the yttrium stayed in and around a three-way stopcock.
20 They sent it back to the manufacturer and they
21 determined the three-way stopcock was defective. So
22 that was a defective device.

23 The next one, the microspheres were in the
24 tubing near the stopcock valve, but in that case, the

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1 device was not defective, but the spheres got held up
2 at the valve. And their solution was to use dextrose
3 and not saline for the flushing. We hadn't heard that
4 one before.

5 The next slide. Seventy-five percent
6 under dose. The technologist noticed bubbles in the
7 administration line and stopped the procedure.

8 The next one is 44. They had elevated
9 readings in the catheter vial interface and they saw
10 coagulation of microspheres. And in this case they
11 actually had contamination of the physician's gloves
12 and the table. So they had more than just the spheres
13 sticking in one place.

14 The next slide.

15 Thirty-four percent. There was an error
16 in transferring the microspheres from the delivery vial
17 which was shipped in to the dosing vial.

18 The next one is larger than expected among
19 of microspheres remained in the needle and didn't reach
20 the patient.

21 And the next slide.

22 You had two different under doses. You had
23 a split dose. Each one of them had its own written
24 directive and they didn't realize until they got to the

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1 very end that there was blockage in the delivery system
2 and that neither one of the procedures received the
3 microspheres that they should have received.

4 The next dose, the catheter was clogged
5 halfway through the procedure. They removed it. They
6 replaced it. And then they were able to deliver the
7 remaining administration, but they lost a significant
8 amount into the catheter.

9 Next one.

10 We have an under dose. They were
11 delivering to the same lobe but through two different
12 arterial pathways. And they never managed to get the
13 microspheres through the second part. They looked at
14 it. They had a short arterial segment. They had an
15 acute angle and as a result they had kinking and folding
16 of the tube.

17 Next slide. They had blockage. They
18 determined it wasn't a problem with the administration
19 kit, but that they had significant kinks, bends, and
20 clots and other blockages at the catheter tip and then
21 they had a 32 percent under dose where the bolus just
22 couldn't be pushed through. And they didn't provide
23 additional information.

24 And then the last one for the SirSpheres was

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1 a 38 percent under dose, but there was no information
2 provided as to why they believe they had 38 percent under
3 dose.

4 So the next one is the TheraSpheres. There
5 were nine TheraSphere medical events, two to the wrong
6 site, one reflux of precipitation out, one dose error,
7 one remained in the vial, one settled out of kink.

8 In the first slide, we have a shunting
9 issue. There were two tumors on the right and the left
10 lobes. They tested for shunting with the right hepatic
11 artery, but they didn't test for shunting on the left
12 hepatic artery. The lobe that they treated was the left
13 hepatic artery and there was more shunting from the left
14 hepatic artery than there was from the right for a factor
15 of ten. So they had expected to receive 370 centigray
16 to the lung. They received 3,450 centigray to the lung
17 and this patient died five months later and the cause
18 of death was acute respiratory distress syndrome.

19 Next slide.

20 In this case, they couldn't properly
21 position the catheter into Segment IV. But they went
22 ahead and delivered it and when they did deliver the
23 dose, very little went into Segment IV. About half of
24 the dose went to Segment IV and the other half went to

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1 the right lobe.

2 Next slide.

3 We had a reflux and precipitation out where
4 it was 24 percent under dose. There was reduced flow
5 rate during the administration and I think that caused
6 the precipitation of microspheres along the outflow
7 tube.

8 Next slide.

9 They were 20 percent under the written
10 directive. They reviewed the treatment plan, but in
11 this particular case, there was a change in the written
12 directive from a normal treatment plan to one where they
13 wanted less activity. So when they reviewed the
14 treatment plan, they didn't verify that the standard
15 activity was not what was being prescribed.

16 Next slide.

17 So in this case, 20 percent remained in the
18 vial. Didn't get into the tubing. The one below it,
19 44 percent under dose. The targeting vessel was
20 flowing slowly. The microspheres settled out prior to
21 reaching the target. The 73 percent under dose, they
22 had the wrong catheter and they had kinking. We had a
23 lot of cases where they identified a particular catheter
24 brand as having issues for multiple licensees. I

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1 didn't bring that with the catheter brand before the
2 ACMUI because we don't know that there aren't other
3 catheters out that they just didn't name the brand on.
4 But this was one of those.

5 Twenty-three percent under on the next
6 slide. The microspheres adhered to the connector one
7 inch, in the first inch of the manufacturer's supplied
8 tubing. The next one, there was kinking in the delivery
9 catheter. It created blockage. They got a thinner,
10 more flexible catheter walls and small, internal
11 catheter diameter were the contributing factors. So I
12 think we're getting to the point where they're pushing
13 the edge of the envelope and ending up with more catheter
14 issues than anything else.

15 My last slide is a GliaSite. Probably
16 we'll have to do a little bit more checking on this one
17 to make sure that it is a medical event. In this
18 particular case, the balloon didn't inflate correctly
19 because they put a three-way stopcock on that they were
20 not supposed to use. It's not part of the GliaSite
21 packet. And they put the stopcock on the wrong position
22 and so the ion tracks didn't go into the balloon to load
23 the balloon up. So we have to check. This may or may
24 not be a medical event depending on whether the patient

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1 received the dose. If they didn't receive a dose, then
2 it won't be a medical event, but we don't know exactly
3 where the syringe was in relationship to the patient.
4 So it could have been close enough to give a dose, but
5 the wrong treatment site.

6 So that is the conclusion of the medical
7 events. We had a wide variety of them. Some of the
8 causes and root causes were things we've seen before.

9 CHAIR THOMADSEN: Thank you very much, Dr.
10 Howe. Comments and questions from the committee?
11 Questions? Yes, Dr. Zanzonico.

12 MEMBER ZANZONICO: Inevitably, these kind
13 of self-reporting systems under estimate the actual
14 incidents in this case of medical events. I know it's
15 an unfair question, but do you have any sense of what
16 percentage of medical events are actually being
17 reported? In other words, what is the under reporting
18 rate?

19 DR. HOWE: I don't think we have a sense of
20 that. We do inspections. Some of the medical events
21 that are identified come up as a result of inspection
22 because the inspectors, although they're not
23 specifically going to say where are the medical events
24 you didn't report, that comes up in the discussion of

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1 how your program is doing. And so we have identified
2 a number of medical events that were not identified by
3 the licensee. And that happens every year.

4 MEMBER ZANZONICO: But I presume it's not
5 a huge excess?

6 DR. HOWE: It's not a huge number at all.

7 CHAIR THOMADSEN: Yes, Dr. O'Hara.

8 MEMBER O'HARA: The medical event that
9 would involve the remote after-loader where the source
10 wasn't doing -- it wasn't moving in and out as it should,
11 was it ever determined was that a device failure?

12 DR. HOWE: I think they figured out that
13 there was a kink in the catheter going out and that the
14 HDR device did what it was supposed to do. It could not
15 send the source out so it retracted it. And when they
16 tried the same thing with the dummy source, it wouldn't
17 go out either so it retracted. So it was in that
18 connector going into the patient where the problem was
19 located.

20 MEMBER O'HARA: Thank you.

21 CHAIR THOMADSEN: Yes, Dr. Mettler.

22 DR. METTLER: You alluded that there might
23 be a problem with a catheter from a vendor, a particular
24 manufacturer. Is there some way that your information

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1 on such things gets to the FDA?

2 DR. HOWE: Yes. We have an NRC-FDA MOU and
3 we can share that information freely with the FDA and
4 we also have certain people in the FDA that have access
5 to our database.

6 DR. METTLER: So that routinely happens.

7 DR. HOWE: I haven't shared this
8 particular one, but I can send information over.
9 That's a good point.

10 CHAIR THOMADSEN: And is it clear that
11 those catheters do get bent in the patient as the patient
12 moves around? No. It's not clear. Dr. Langhorst.

13 MEMBER LANGHORST: Dr. Howe, do you have a
14 sense of how many of these reported medical events are
15 through Agreement States rather than NRC?

16 DR. HOWE: That is data that I could
17 obtain, but it is not one that I focus on.

18 MEMBER LANGHORST: I think it's important
19 to note that when you say that you don't know some of
20 the information, sometimes it's not reported by the
21 Agreement State as opposed to by the licensee. And also
22 do all Agreement States report their events to the NMED
23 database?

24 DR. HOWE: All Agreement States report

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1 their medical events to the NRC and they get into the
2 NMED database.

3 CHAIR THOMADSEN: Or at least they're
4 supposed to.

5 MS. DUDES: And that's where I was at. I
6 actually thank the Committee because both of you asked
7 the questions that I was going to pose back to the
8 Committee.

9 I can tell you that the majority of events
10 that we get are from Agreement States. And that's just
11 a numbers issue. They have the majority of the
12 licensees. And so as we're preparing for our annual
13 action review meeting and you look at the abnormal
14 occurrences that we report to Congress, all of those
15 events come from Agreement States. We encourage and
16 they're supposed to put the data into NMED.

17 We use our IMPEP process to audit the
18 programs to assure that they're trying to put those
19 things into NMED and report, make the reports.

20 We have been trying to do some webinars and
21 training for Agreement State inspectors and NRC
22 inspectors on when you're out how do you look for medical
23 events and it's not necessarily that you're out there
24 looking for the event, but how would you spot one?

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1 Because I don't think that's -- it's a more studied type
2 of skill.

3 Each year we do report to our Commission,
4 okay, here is the status of the program. Here is the
5 number of events. I always feel a little odd in that
6 I don't have a sense of okay, 45 out of 150,000
7 therapeutic and then God knows how many diagnostic which
8 I think the threshold there, that's a little different.
9 But I was going to pose to the Committee who practices
10 and sees, is this -- would you expect this? But you were
11 asking us the question, so I'm curious what others think
12 because the Commission and I, in my reporting, well, 45
13 out of 150,000.

14 CHAIR THOMADSEN: Mr. Costello.

15 MEMBER COSTELLO: A couple of years ago, I
16 gave a talk at OAS and it was about microspheres medical
17 events and I broke them down by State. I did this
18 because we had so many. And some States that are huge,
19 perhaps the biggest State, starts with a C, had fewer,
20 had similar events as Idaho.

21 To get events reported, my view, it's not
22 for us to find them on inspections. It's a very hard
23 thing for us to do. To rely on us finding them on
24 inspections is really not realistic.

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1 MS. DUDES: Right.

2 MEMBER COSTELLO: What I do ask for
3 inspections, I ask licensees, well, how did they know
4 this was a medical event? You know, is that something,
5 do they evaluate their treatments? Do they think about
6 it? Because if they're not being noticed by the
7 licensees, the chances are they're not going to be
8 noticed. I mean think of the events that are described
9 up there. By and large, inspectors aren't going to find
10 those. Licensees have to notice those.

11 And so at least -- I know it was in
12 Pennsylvania, I encouraged people just ask a simple
13 question. If trained in modality, just pick a
14 modality. If you had a medical event, how would you
15 know it? And sometimes you get very good answers.
16 Sometimes not as good. I think the best a regulator can
17 do is to remind a licensee that it's a licensee's
18 responsibility to report medical events because we the
19 States are really not well positioned to identify them
20 ourselves.

21 CHAIR THOMADSEN: Thank you. Dr.
22 Mettler.

23 DR. METTLER: The IAEA has struggled with
24 your question for a long time, especially about

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1 radiation therapies, and everything else. And I think
2 in general, most people feel that accident reports are
3 somewhere between 10 and 30 percent of what's actually
4 happening, especially since they generally have to be
5 self-reported.

6 DR. HOWE: And I think Laura brought up a
7 point and Frank brought up an excellent point. If the
8 licensee doesn't recognize it, then it's going to be
9 more difficult to report. Every once in a while, and
10 he's right, the inspectors aren't there to identify
11 unidentified medical events, but as they're asking
12 questions they may trigger something in the licensee
13 that they remember.

14 I've also gone through a number of years and
15 looked at the Agreement State response. And many times
16 when I'm going through this all of a sudden I will see
17 a huge number of medical events from a given State. I
18 know that State just had an IMPEP, and so they were asked
19 well, how are your medical events doing? And then they
20 look and either they received them and they didn't pass
21 them on or for some other reason. So we tend to -- and
22 that's one reason that I always present the medical
23 event talk as to what was recorded in the fiscal year,
24 not what happened in the fiscal year because that way

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1 if I've got medical events that were identified late,
2 they're going to be captured. If the State is late in
3 getting them in, they're going to be captured. So it
4 gives you the most complete picture by identifying those
5 things reported in that particular year.

6 CHAIR THOMADSEN: Dr. Zanzonico.

7 MEMBER ZANZONICO: Just to address your
8 question, I'm Chairman of the Radiation Committee at
9 Memorial which presumably sees all of the medical
10 events. And we like to think we're very self-critical
11 in terms of what constitutes a report on medical event.
12 And I would say across all modalities, no more than one
13 to two a year with many years having none. And that's
14 a very large number of procedures across modalities.
15 So I think it's at least qualitatively consistent with
16 a very low ME rate that's reported here.

17 CHAIR THOMADSEN: Dr. Weil.

18 MEMBER WEIL: It's fine.

19 CHAIR THOMADSEN: I think we're going to
20 have to live with that one.

21 MEMBER WEIL: Just two points, one in
22 response to Dr. Zanzonico, but you're at Memorial.

23 MEMBER ZANZONICO: Yes.

24 MEMBER WEIL: Okay, so enough said there.

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1 I wonder if there's any transparency or coordination
2 among other entities that collect this kind of data like
3 CMS and State health departments in terms of what get
4 called different things by different agencies. In this
5 instance, medical events, medical errors or
6 unanticipated outcomes. Do you know? CMS collects a
7 bunch of stuff about unusual occurrences. And NRC is
8 collecting stuff. Is there any coordination between
9 those two entities?

10 DR. HOWE: I don't believe we have any
11 coordination between the two. In many cases, it's
12 because our definition is pretty well defined and it's
13 here and their definition may be something else than
14 over there. We do communicate back and forth with FDA.
15 If they see something that they think we need to know
16 about, they let us know. If we see something we think
17 they need to know about, we let them know. So we do have
18 that coordination going.

19 CHAIR THOMADSEN: Dr. Langhorst.

20 MEMBER LANGHORST: I think last year when
21 we were talking about the various groups that are trying
22 to gather these types of information and near misses and
23 so on, that there was a move maybe to make some of the
24 NMED data public. Is there -- what's the status of

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1 that? Because again, it's always good to learn from
2 others' errors.

3 MR. BOLLOCK: We evaluated that at a public
4 meeting and did quite a bit of outreach and there was
5 not a lot of interest.

6 MEMBER LANGHORST: Okay.

7 MR. BOLLOCK: From the public for that.

8 MEMBER LANGHORST: Okay.

9 MR. BOLLOCK: It was -- so we made a
10 decision based upon the fact that there are
11 publicly-available yearly reports that give the
12 numbers, the statistics that are available from NMED and
13 there are other ways if you have questions on that, you
14 can reach out to us or the states for specific questions,
15 but we felt that that was enough.

16 MEMBER LANGHORST: Okay.

17 CHAIR THOMADSEN: Mr. Costello.

18 MEMBER COSTELLO: Two points. One on the
19 public NMED. I think it would be fair to say that
20 because of public NMED there is very open hostility from
21 Agreement States on public NMED. More than
22 disinterest. I can talk to anybody who was talking
23 about that, but there are reasons why the States are not
24 crazy about that idea.

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1 And the second about medical events, at
2 least in our State, they generally are reported on the
3 better institutions. The better institutions, the
4 stronger programs are more likely to identify medical
5 events. Okay? That doesn't mean, I don't think that
6 they have more of them. In fact, being aware of the
7 program, I think they'd like to have less of them, but
8 in fact, they're the ones who report them fairly
9 religiously. Other places, during inspections I ask,
10 might be less likely to do it than the really strong
11 programs.

12 CHAIR THOMADSEN: Dr. O'Hara.

13 MEMBER O'HARA: The medical device
14 reporting database, it's called MAUDE, if any of you
15 have ever looked at it, it's public. Part of it is
16 public. It doesn't contain proprietary information on
17 specifics about the products. It's undergoing some
18 changes right now. They're changing how it operates.
19 They're going to change the searching abilities of it.
20 And it's gone through a few name changes, too. At one
21 point in time it was going to be called ISIS, but one
22 of the biggest things that has to do with radiological
23 devices is that all of the medical device reporting
24 comes into the same division, the Division of

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1 Radiological Health. It doesn't sound like a big
2 change, but it is because the Division of Radiological
3 Health clears or approves devices for the market. And
4 now the same group that clears or approves devices for
5 the market now gets the medical device reports and does
6 the compliance activities with device sponsors. And
7 that's only been a relatively recent occurrence about
8 two years. So there are some changes that are going on
9 with that. Just thought I would --

10 CHAIR THOMADSEN: Thank you. Comments or
11 questions for the committee? Dr. Suh?

12 MEMBER SUH: In terms of the medical
13 events, do you sense that the human errors are the same
14 human errors year after year after year? We're hearing
15 common themes of wrong dose, wrong site, wrong patient
16 which in my mind these should be really never events.
17 If you do the proper time out or are properly trained,
18 the authorized user takes the time to visualize what's
19 going on, is present, that shouldn't occur.

20 And one of the things I just noticed is that
21 you kind of hear the same story over and over. I don't
22 think it's necessarily the purview of the NRC to just
23 go and regulate medicine, but somehow I think if
24 physicians and others are educated on what's going on,

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1 perhaps it will increase the awareness. I can tell you,
2 just being on the committee, it's definitely opened my
3 eyes in terms of how a patient can be seen at a radiation
4 oncology department. So we have really increased kind
5 of our right versus right, identifying correct patient,
6 making sure we electronically document time outs for
7 every single patient because we want to really minimize
8 any of these occurrences from occurring.

9 DR. HOWE: I'll tell you that back in the
10 1980s when we brought in the misadministration rule
11 which is the precursor to the medical event rule in 1980,
12 they decided that they would try to do something to
13 reduce the number of misadministrations and they would
14 do it two prong. NRC would do a two-prong approach.
15 One would be rulemaking to capture simple human errors
16 and how can we prevent some of the more common simple
17 human errors.

18 And the second part would be to go after
19 quality control of devices and so what they found was
20 probably 90 percent of the medical events are simple
21 human error. And we had a rule that was implemented in
22 1992 called the quality management rule. Many core
23 parts of that rule are still in the regulations and they
24 found out that the most simple human errors that

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1 attributed to most of the medical events were
2 identifying the patient. So we had a requirement to use
3 two different methods to identify the patient.

4 In 2002, we dropped back on the
5 prescriptive nature of that and you just have to
6 identify the patient. The second was the written
7 directive because there were many, many things coming
8 across on the telephone that weren't being recorded
9 correctly. So we went to a written directive. And so
10 those two things. And you will have heard a common
11 thread in here where some people were not looking at the
12 written directive. The one doing the treatment plan
13 for the Gamma Knife knew or the Perfexion, knew the
14 patient always got treated on the right side and went
15 and set it up for the right and didn't bother to look
16 at what the physician wrote.

17 So you're right. A lot of these are the
18 same type of human errors, happening in different
19 locations because they are in some respects the easiest
20 human errors to make and it's really difficult to
21 eliminate them, but we try with a written directive and
22 we also tried with the patient identification.

23 And now, we are adding in the new proposed
24 35 requirement to evaluate administrations to make sure

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1 you don't have medical events. So we're trying to get
2 to those issues. So I don't think I was helpful, but
3 I'm just trying to tell you, we've recognized that was
4 an issue all along and continues to be an issue.

5 MEMBER SUH: It's just you see common
6 themes.

7 DR. HOWE: Yes. And it's frustrating
8 because we see the same thing happening over and over.

9 CHAIR THOMADSEN: Mr. Costello.

10 MEMBER COSTELLO: Another thing I'll say,
11 there's a course that they give called the root cause
12 course for investigating. One of the things you
13 learned is be skeptical when human error is always given
14 as the reason because sometimes a little probing, you
15 can find out why the human error occurred. It could be
16 a training issue. It could be a procedure issue. It
17 could be a working condition issue.

18 It could be a lot of things, but the easiest
19 thing is the patient, if you're an inspector looking
20 into it is say well, the person identified was the wrong
21 patient; it must have been a human error. Well, maybe,
22 but maybe a little deeper looking into what happened you
23 can find out the person had worked so many hours, tired,
24 or the person who was doing the job hadn't got trained

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1 or the procedures were bad. Sometimes human error is
2 just sort of a quick, glib answer that the inspector can
3 take and be done and write up the report. I'm just
4 saying, as an inspector, if you spend some more time
5 interviewing people and interviewing the person who
6 made the error, you might find out that there are deeper
7 causes.

8 DR. HOWE: Also, another thing I would
9 point out in the root cause is many of the accepted
10 changes are training, but in fact, if you really looked
11 at the human error it's more than training.

12 CHAIR THOMADSEN: And from human error
13 analysis, you almost always find that there's never a
14 root cause. There's always multiple root causes of
15 these things. You're absolutely right, training is not
16 a particularly effective treatment for these problems.

17 Other comments from the committee? In
18 that case, thank you very much.

19 DR. HOWE: Thank you.

20 CHAIR THOMADSEN: We are way ahead of
21 schedule at the moment. And as always, because there
22 are people who may be coming in to listen to certain
23 topics who are expecting it to be at certain times we
24 really can't just go ahead. So we are going to be on

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1 a break now until 3:30 when we will talk about
2 radioactive seed localization.

3 (Whereupon, the above-entitled matter went
4 off the record at 2:12 p.m. and resumed at 3:30 p.m.)

5 CHAIR THOMADSEN: We are ready to continue
6 on the topic we were just discussing of medical events,
7 that we need to renew the Subcommittee that reviews the
8 medical events this Committee each year because we have
9 lost a couple of the members from that Subcommittee.

10 And so, the new Subcommittee will be Steve
11 Mattmuller and Pat Zanzonico, John Suh, myself, Michael
12 O'Hara, Ron Ennis. And I think that it is it.

13 Is there anybody who was on the Committee
14 last time that I have forgotten?

15 MS. HOLIDAY: Dr. Palestro.

16 CHAIR THOMADSEN: Oh, Dr. Palestro.
17 Thank you. Right. There we go. I think that is the
18 Committee then.

19 MEMBER LANGHORST: I have been on it in the
20 past, but I am good with not being on.

21 CHAIR THOMADSEN: How many do we have?
22 That would be too many, I think.

23 MEMBER LANGHORST: Right.

24 MS. HOLIDAY: So, by practice,

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1 Subcommittees should have six members or less. This is
2 not a Subcommittee that makes recommendations per se.
3 The Subcommittee just presents information on medical
4 events. I think it is fine if you have more than six
5 members.

6 CHAIR THOMADSEN: I think you're on it.
7 Congratulations.

8 (Laughter.)

9 Is there anybody who wants to speak up?

10 (Laughter.)

11 MS. HOLIDAY: I have Dr. Ennis, Dr. O'Hara,
12 yourself, Dr. Palestro, Dr. Langhorst. Who was the
13 sixth person?

14 CHAIR THOMADSEN: Dr. Suh.

15 MS. HOLIDAY: Dr. Suh. Okay. So, that is
16 six people.

17 CHAIR THOMADSEN: And Dr. Zanzonico.

18 MS. HOLIDAY: Thank you.

19 CHAIR THOMADSEN: Yes. We will name the
20 people who aren't on that Committee.

21 (Laughter.)

22 Well, I think we are ready to proceed with
23 our schedule here. It is a pleasure to introduce
24 Michael Sheetz from the University of Pittsburgh to talk

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1 about radiation safety and regulatory issues of
2 radioactive seed localization of non-topical lesions.

3 MR. SHEETZ: Thank you. I would like to
4 thank the members from the NRC and the ACMUI for giving
5 me this opportunity to speak on radioactive seed
6 localization, or RSL.

7 I must admit that, when I first heard of
8 RSL, I thought to myself, why would anyone want to
9 implant a seed in a patient just to localize a lesion
10 for surgical removal? And then, I learned of the
11 benefits that this technique has with respect to patient
12 care. And so, I have become a proponent or a supporter
13 of this procedure, as evidenced by my presence here.

14 Next slide, please.

15 RSL was developed in the late 1990s, the
16 first clinical trials occurring in 2001. I would say,
17 up until the last several years, most institutions
18 adopting this procedure have been large medical
19 institutions with broad scope licenses.

20 We initiated our RSL program in 2011. We
21 now have one of the most active programs I think in the
22 country. We are implanting over 100 seeds or 100
23 procedures per month at six different locations.

24 We have also sponsored several RSL

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1 workshops or seminars, one-day seminars for
2 institutions interested in starting a program. Mayo
3 Clinic has been offering RSL workshops for several
4 years, and most recently, both MD Anderson and Memorial
5 Sloan Kettering are offering RSL workshops. And so, it
6 has gained more attention and interest.

7 From my employment with the workshops,
8 conversations with colleagues, presentations I have
9 done at professional meetings, the feedback I am getting
10 is that, primarily from limited scope licensees, is that
11 strict compliance with the NRC licensing guidance
12 document makes it difficult to establish a program, and
13 some have even given up.

14 And so, my purpose here today is to try to
15 point where certain revisions and changes to the
16 licensing guidance can make it more relevant to the
17 procedure, make it less burdensome for institutions
18 trying to initiate a program, and allow entries to
19 access of this beneficial procedure to patients.

20 Next slide.

21 The medical background, advances in
22 technology and screening mammography have led to
23 increased detection of microscopic breast lesions.
24 The traditional method of pinpointing these areas of

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1 concerns is where a localization breast biopsy
2 procedure where a radiologist places a thin guide wire
3 into the area of concern, using ultrasound or
4 mammography. The surgeon, then, removes the tissue
5 around the guidewire and sends it to pathology for
6 analysis.

7 Alternative technique, RSL, in this
8 procedure a radiologist a radioactive seed in the area
9 of concern, again under ultrasonic or mammographic
10 guidance. The surgeon then uses a gamma probe to locate
11 where the seed and the lesion is for extraction. There
12 have been a number of studies and publications showing
13 benefits of RSL over the wire localization procedure.

14 Next slide.

15 An example of the wire localization
16 procedure with the image on the left, the radiologist
17 places a needle to the center lesion and, then, inserts
18 a guide wire with a barb on the tip to hold it in place.
19 The wire extends outside the skin of the breast. The
20 patient then goes to surgery, where the surgeon makes
21 an incision at or near the protruding wire and uses it
22 to guide the excision of the tissue. On the right is an
23 image of the excised tissue with the wire still
24 attached. These two procedures are performed on the

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1 same day.

2 Some of the disadvantage of wire
3 localization is that it can pull out; it becomes lodged
4 and gets transected during surgery. The surgeon needs
5 to use the wire as his or her point of entry in the
6 surgical procedure. There is patient discomfort, and
7 there are time delays in scheduling between the
8 radiological procedure and the surgical procedure.

9 Next slide, please.

10 With RSL and iodine-125, seed is used which
11 is the same type as that that is used for brachytherapy
12 such as in prostate implants. The seed is now available
13 in sterile, pre-loaded, 18-gauge needles. These
14 packaged seed assemblies are available from two
15 different vendors with full FDA approval for the
16 localization procedure. So, it is no longer an
17 off-label use of a brachytherapy source.

18 Initially, it was an off-label use, and
19 institutions had to buy seasoned bulk and load their
20 own. Now they have let the approval for this procedure,
21 at least from two institutions.

22 The average activity that is used in the
23 seed is around 200 microcuries, although that ranges
24 from about 75 to 300 microcuries. At the bottom you can

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1 see what the assembled device looks like. There is an
2 18-gauge needle with a stainless steel sleeve around for
3 shielding the radiation from the seed. There is a blue
4 spacer that holds the stylet that is inside the needle
5 in place. And then, the seed is secured in the needle
6 with bone wax, so it doesn't fall out the tip.

7 Next slide, please.

8 The seed is implanted at the center of the
9 lesion by a radiologist under ultrasonic or
10 mammographic guidance by advancing the needle to the
11 center of the lesion. Then, the stylet is used to push
12 the seed out and deploy it into the breast.

13 Once positioned, the seed cannot be
14 repositioned, and then once it is in place, there is a
15 very rare incidence of this seed migrating, even if it
16 is left in for several days.

17 Next slide, please.

18 Immediately following that, a mammogram is
19 taken to verify the implant location. We also perform
20 a survey at this time, or actually before the mammogram,
21 where we will take a GM Survey Meter and we will hold
22 it up to the breast, so that we get a single and confirmed
23 that the seed has been implanted. And then, we will
24 also survey the implant tray and the implant area, so

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1 that we make sure we do not detect any activity therein.

2 The patient is released with instructions
3 to return for the scheduled surgery, usually within five
4 days. We do not provide any radiation safety guidance
5 to these patients, as it is not required; they are
6 releasable and the exposure from these patients is very,
7 very low.

8 Next slide, please.

9 On the day of surgery, the surgeon uses a
10 gamma probe to localize the seed. This is the same
11 instrument that the surgeon uses for sentinel lymph node
12 biopsy with technetium-99m sulfur colloid.

13 The device is set on an I-125 window, so it
14 can detect the photon energies of the I-125. The
15 detector has a collimator on it, so it can look at it
16 as a focused beam of radiation coming from the seed.
17 And so, the surgeon can see in 3-dimension where the seed
18 is located and where the lesion is located in the breast,
19 and thereby choose the best approach in how they want
20 to excise this tissue.

21 Most of these patients also have technetium
22 sulfur colloid onboard for a sentinel node biopsy.
23 Typically, the seed is removed first, and the sentinel
24 node biopsy is performed after with the axillary

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1 resection.

2 Next slide, please.

3 The gamma probe that is used provides audio
4 feedback and it guides the excision during the whole
5 process. Once the seed and tissue is removed, the
6 surgeon will put the probe up to the tissue, make sure
7 they get a strong signal indicating that the seed is
8 present, and they will take the probe and put it into
9 the cavity to confirm that they don't see any
10 radioactivity and there is no activity left back into
11 the patient.

12 Next slide, please.

13 At this point, a specimen radiograph is
14 taken not only to confirm the presence of the seed, but
15 also to confine the margins and confirm that all the
16 suspicious tissue has been completely removed. The
17 specimen is then transported to pathology for seed
18 removal. However, some institutions at this point
19 actually have the surgeon removing the seed from the
20 specimen.

21 Next slide, please.

22 In pathology, the pathologist or pathology
23 assistant will use the same gamma probe to scan the
24 specimen and locate where the seed is positioned within

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1 the specimen. They will then section the specimen into
2 grade-thin 4-millimeter, 5-millimeter slices.

3 Next slide, please.

4 Once the seed is visualized in one of the
5 sections, they will use reverse-action tweezers to
6 remove it. The seed is, then, typically placed in some
7 type of container labeled with an Rx or tracking number.

8 There is also, then, a survey performed of
9 the remaining tissue specimen to make sure there is no
10 activity in it. The seeds are, then, disposed of either
11 through decay-in-storage or some institutions will
12 actually disinfect the seed at this point and return it
13 to the manufacturer.

14 Next slide, please.

15 Some studies show a reduced incidence in
16 positive margins. With a positive margin, that means
17 that there is still cancerous tissue close to the edge
18 or at the edge of the tissue sample that was removed.
19 It requires a repeat surgery. Repeat surgery positive
20 margin incident rates vary greatly from surgeon to
21 surgeon and institution to institution, but they are
22 somewhere in the range of 5 to 20 percent. So, it is
23 not insignificant as far as this repeat rate and
24 requiring new surgery.

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1 With RSL, the surgeon can approach the
2 lesion from an angle. And so, this results in better
3 cosmetic outcomes. There is less pain and discomfort
4 for the patient, because once the seed is implanted, the
5 patient doesn't feel anything.

6 And one of the largest advantages is that
7 it decouples the radiology procedure from the surgical
8 procedure. And so, delays in the breast center don't,
9 then, cause delays piling up in the surgery center.
10 Also, too, it allows for first-morning surgeries now;
11 whereas, before that would not be possible.

12 Next slide, please.

13 RSL is covered under 35.1000 since it
14 really doesn't fit in any of the other medical use
15 categories. The NRC issued licensing guidance for RSL
16 in 2006. To my knowledge, it has not been revised since
17 then.

18 At that time, it was an off-use of the same
19 seeds used for brachytherapy. So, it makes sense that
20 the focus of the initial guidance would be to view this
21 as a therapy procedure. However, even though RSL uses
22 the same seed as that used for brachytherapy, albeit at
23 a lower activity, this is a localization procedure
24 performed that is very similar to the technetium-99m

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1 sulfur colloid localization for sentinel lymph nodes
2 under 35.200. It should be noted that RSL is the only
3 non-therapeutic procedure addressed under 35.1000.

4 There are also certain regulatory
5 requirements in Part 35 that will apply to RSL, such as
6 patient release, leak tests, decay, and disposal of
7 seeds, instrument calibration, and so forth. So, there
8 are other regulations still in Part 35 that are
9 applicable and don't need to be addressed in the
10 licensing guidance.

11 Next slide, please.

12 I feel that the main issues to be addressed
13 with respect to how RSL is performed and was being
14 required in the licensing guidance are the training and
15 experience requirements for the AU and individuals
16 working the supervision of the AU; the need for a written
17 directive; radiation surveys and their documentation;
18 what would constitute a medical event for RSL; survey
19 instruments used for this procedure and their
20 calibration requirements, and commitments to certain
21 safety precautions in Part 35 that may not be directly
22 applicable to radioactive seed localization.

23 Next slide, please.

24 In the guidance document, an individual

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1 qualifies to be an AU for RSL if they meet the
2 requirements in 35.490 for manual brachytherapy or a
3 radiation oncologist. However, this procedure is not
4 performed by radiation oncologists, as they are neither
5 trained nor credentialed to perform this procedure.

6 For a radiologist to be qualified as an
7 Authorized User, they must meet the requirements in
8 35.290 for unsealed sources and be supervised in three
9 cases by a 490-approved Authorized User. I would
10 question whether it is appropriate for an individual to
11 supervise casework for an implant procedure that they
12 themselves do not perform.

13 There is a requirement for participation in
14 three cases by the Authorized User. This can be
15 difficult to obtain in institutions that are just
16 starting out with the procedure where no one is an
17 Authorized User. And so, then, who becomes the
18 supervisor?

19 Also, it is not practical for the person
20 attempting to be an Authorized User to go to another
21 institution where RSL is licensed because most likely
22 they will not have clinical privileges there to perform
23 that procedure under an Authorized User at that other
24 site.

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1 Consideration should be given to accepting
2 observance of cases to meet this three-case requirement
3 or attendance to an RSL workshop to meet this
4 requirement, or consideration should also be given to
5 removing the three-case requirement to be an AU, as
6 there is little or no precedent for it for any other
7 localization procedure or any other non-therapeutic
8 procedure.

9 The guidance document also requires the
10 Authorized User to have experience in the surgical
11 incision and seed removal. While the AU should be
12 knowledgeable in the procedures that the surgeon is
13 performing and the pathologist is performing, again,
14 they cannot perform these procedures as they are neither
15 trained in that nor credentialed to perform those. I
16 know of one Agreement State where they were insisting
17 for the AU to get this work experience and actually
18 perform these procedures.

19 In the same sense, the surgeons that are
20 working under the supervision of the Authorized User,
21 in the guidance document it wants them to have training
22 or preparation in implanting the seeds. Again, I will
23 say surgeons are not qualified to prepare and implant
24 seeds. And so, while they should be knowledgeable in

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1 the implant procedure, they themselves can't have
2 actually hands-on work experience performing that.

3 Several statements in the guidance
4 document imply that only an Authorized User implant
5 seeds. As I have previously explained, the RSL
6 procedure involves three different components. One,
7 implanting a radioactive seed in a patient under
8 mammographic or ultrasonic guidance by a radiologist.
9 Two, surgical removal of a target lesion and seed from
10 the patient by a surgeon. And three, removing the seed
11 from the tissue specimen by a pathologist or pathology
12 assistant.

13 Therefore, many, if not all, of these
14 procedures with RSL are being performed by individuals
15 working under the supervision of the AU. And so, this
16 should include a radiologist who is not an AU, but has
17 appropriate training experience to implant seeds.
18 Radiologists, by training, implant clips to mark biopsy
19 sites. They implant wires for the localization
20 procedure. And so, implanting a radioactive seed is an
21 equivalent procedure for radiologists.

22 Next slide, please.

23 The procedure does not meet the
24 requirements for written directive as identified

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1 35.40(a). The sources are not intended to deliver a
2 therapeutic dose for palliative, curative treatments.

3 It would take nine days to deliver a dose
4 of 50 rem at 1 centimeter from the seed with a
5 200-microcurie seed. While this is not a therapeutic
6 dose, it is the dose threshold for a medical event.

7 Also, the documentation requirements for
8 written directive in 35.40(b) sets demanded by the
9 therapy simply are not applicable to the radioactive
10 seed localization procedure. If a non-AU implants the
11 seed, they would not be permitted to sign the written
12 directive.

13 It may be appropriate to require a
14 prescription to document the isotope ascribed implant
15 site total number and activity of seeds implanted, time
16 range of scheduled surgery date, and the name of the
17 approved radiologist who implanted the seed.

18 Next slide, please.

19 Now I have previously explained surveys are
20 performed after the seed implant with a GM Survey Meter,
21 and in the surgery environment and in the pathology
22 environment, surveys are performed with the gamma
23 probe. Documentation is usually maintained as part of
24 a checklist and not as a separate survey document.

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1 Also, it should be noted that, if one tried
2 to perform surveys on the OR, in pathology, with a GM
3 or a thin crystal sodium iodide detector, that there
4 will be interference from technetium if the sentinel
5 node biopsy procedure was performed.

6 If a confirmatory radiograph was obtained
7 following the implant, should this be allowed to
8 substitute for radiation survey, as it will visualize
9 and confirm the location of the seed and even if it was
10 damaged? Similarly, a radiographic image taken of the
11 specimen after it has been surgically removed from the
12 patient could substitute for a radiation survey. So,
13 there are different means and avenues to accomplish
14 this.

15 Next slide, please.

16 Consideration needs to be given as to what
17 criteria would result in a medical event with RSL
18 procedures. A dose threshold of 50 rem to tissue is
19 unlikely. From the chart, you can see that the dose at
20 1 centimeter from a 200-microcurie seed would only be
21 28 rads if left in for five days.

22 Once you realize that when the seed and
23 tissue is removed, there are several centimeters of
24 tissue surrounding the seed that is excised, and so, the

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1 dose further out to the tissue that is remaining in the
2 patient would be much less. In this case, at five days
3 at 3 centimeters from the seed, the dose would be down
4 to 2 rads.

5 There is no prescribed dose for radiation
6 seed localization. There is an activity range of the
7 seeds to be implanted.

8 As far as implant time, it is based on a
9 recommendation that we want to perform the surgery
10 within a certain amount of time. If the patient does
11 not return for the surgery -- I know there was a
12 discussion on this earlier, on what constitutes patient
13 intervention -- but there are two different situations.

14 One which has occurred is the patient is
15 implanted with the seed and they come down with the flu,
16 and so, they can't come back within five days because
17 they don't want to do the surgery. So, the surgery is
18 delayed for two or three weeks. I would contend that
19 that would be patient intervention. It is out of
20 anybody's control and they are going to recover the seed
21 later.

22 If the patient refuses to come back to have
23 the seed removed, then you may question, was there
24 reasonable instruction to the patient to ensure that

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1 they would return? And so, I am not advocating any
2 particular stance on what constitutes a medical event.
3 I am just throwing out different situations that need
4 to be thought-through and better defined on what
5 constitutes a medical event for RSL.

6 And there was one case where the seed was
7 intentionally left in the patient because of the
8 location of the seed where it had migrated into a
9 highly-vascularly area. And so, certainly, you would
10 expect that to qualify as a medical event and being
11 reported. So, I am not saying there are no medical
12 event reporting criteria for RSL.

13 Next slide, please.

14 There are three main radiation meters used
15 for RSL, the thin crystal sodium iodide and GM Survey
16 Meters and the gamma probe. The guidance document
17 recommends a survey instrument with a thin crystal
18 sodium iodide; reverse-surveys are performed. While
19 this is certainly the instrument of choice for trying
20 to locate a lost seed, if you don't know where it is and
21 no other activity is around, the GM Survey Meter works
22 great on the implant side, again, checking that the seed
23 has been implanted in the patient, checking the seed is
24 in the needle. And the gamma probe works fantastic in

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1 the OR environment as far as locating the seed and,
2 again, double-checking it is not in the patient. And
3 again, it is the same with pathology. So,
4 consideration should be given for the other
5 instruments.

6 Most gamma probes do not require any
7 routine annual calibration. They only have a system
8 check when the instrument is turned on. So, they don't
9 fit the normal calibration requirements in 35.60 and,
10 in fact, the thin crystal sodium iodide detector does
11 not fit the instrument calibration requirements in
12 35.60 as it typically reads out in counts per minute and
13 not mR per hour.

14 Next slide, please.

15 There is a section in the guidance document
16 for a commitment to certain safety procedures for RSL.
17 There is a commitment to verify the activity prior to
18 seed implant using a calibrated instrument. There
19 should be allowance now for allowing vendor
20 verification of the seed activity.

21 There is a commitment requested to provide
22 annual training on topics described in 35.410. This
23 training is for personnel caring for patients who have
24 been implanted with brachytherapy seeds and cannot be

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1 released into 35.75. These topics are not applicable
2 to RSL, and these patients are released under 35.75.

3 If a licensee uses the radioactive seeds
4 that are currently approved by FDA for this procedure,
5 a custom evaluation of its use, off-label use, is not
6 required.

7 Also, there is a lot of emphasis on routine
8 monitoring before, during, and after all uses of the
9 seeds to ensure rapid identification and remediation of
10 a broken or a leaking seed, and emergency procedures and
11 responding to sources that may rupture, retrieval of
12 leaking/cut sources, contamination control, and
13 decontamination of the patient to carry out.

14 These seeds have been used for RSL
15 procedures for over a decade and thousands of
16 procedures, and without one case ever being reported of
17 a cut or leaking seed implanted in patient. There have
18 been seeds cut on the removal side, in pathology, but
19 not on the implant side.

20 And so, while there needs to be appropriate
21 instrumentation, procedures and response for cut or
22 leaking sources, it should be realized that this is a
23 very rare occurrence, and that the response by the same
24 as that for contamination/decontamination in nuclear

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1 medicine.

2 Personnel are wearing personnel protective
3 clothing on the implant and the surgical and the
4 pathology side. So, there is personal protection.
5 And any contamination of items would likely be contained
6 with the bio-hazardous containment system.

7 Next slide, please.

8 The guidance document may want to consider
9 or have consideration for other procedures, have those
10 events. One of these would be loss of the radioactive
11 seed, implanting a radioactive seed in the wrong patient
12 or the wrong location, inability to locate an implanted
13 seed during surgery, and there's been a planted seed in
14 the patient but the patient does not return for the
15 scheduled surgery. We have actually experienced three
16 of the four.

17 Next slide, please.

18 So, in conclusion, I believe that the RSL
19 procedure provides significant clinical and patient
20 care advantages over the standard wire localization
21 technique. Strict compliance with NRC licensing
22 guidance document makes it very difficult for limited
23 scope licensees to implement this procedure. State
24 regulators are not likely to vary from the stated

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1 guidance without specific approval from the NRC.

2 And I believe certain revisions to the
3 guidance document can make it more relevant to the way
4 the procedure is performed, make it less burdensome for
5 institutions to establish an RSL program, and allow
6 increased access to this beneficial procedure for
7 patients, while maintaining a high level of safety.

8 Thank you.

9 CHAIR THOMADSEN: Thank you.

10 Comments from the Committee?

11 Dr. Costello? Mr. Costello?

12 MEMBER COSTELLO: Well, Sue promoted me to
13 being a doctor earlier. So, I appreciate that.

14 What are the barriers to the radiologist
15 being approved?

16 MR. SHEETZ: If they are boarded in
17 radiology from 2007 forward, they would meet the
18 requirements. But, if they are boarded prior to that,
19 they would have to fill out the preceptor statement and
20 document all of the training experience.

21 MEMBER COSTELLO: So, I was looking at your
22 slide on Authorized Users. They wouldn't need to be
23 supervised in three cases by a 35.490 Authorized User,
24 right, because they would be an Authorized User if they

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1 were a radiologist?

2 MR. SHEETZ: No, if you are a radiologist
3 and you have equivalent training for 35.200, you still
4 need to be supervised in three cases by 490 or another
5 Authorized User who is already approved for RSL. So,
6 your 35.200 training experience criteria does not
7 qualify you to be an Authorized User alone.

8 MEMBER COSTELLO: Because that is what the
9 guidance says? Okay. This isn't 35.400 use; this is
10 35.1000 use. But they chose to use 35.490 as --

11 MR. SHEETZ: Correct, in this space, and
12 understandably so, because at that time it was an
13 off-label use of a brachytherapy source.

14 MEMBER COSTELLO: Okay.

15 MR. SHEETZ: I am not arguing that, but
16 that is part of my reason for changing the focus.

17 MEMBER COSTELLO: Thank you.

18 CHAIR THOMADSEN: Other comments?

19 Dr. Suh?

20 MEMBER SUH: Do you have a rough sense of
21 how many centers use this technique, this radioactive
22 seed localization technique?

23 MR. SHEETZ: From conversations with one
24 of the largest distributors, it is that they have 40

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1 clients.

2 MEMBER SUH: Forty clients?

3 MR. SHEETZ: Yes, in the country.

4 MEMBER SUH: Do you have a broad sense of
5 like how many cases per year in the U.S. that they do?

6 MR. SHEETZ: I do not have an idea of how
7 many cases in the U.S. So, we are doing 1200, or
8 whatever. Memorial Sloan Kettering is doing, in fact,
9 actually more than we are. They are doing a lot. I
10 would say Mayo is probably close, third. So, it is
11 times several thousands [of] cases per year.

12 MEMBER ZANZONICO: Right, and the only
13 incident in thousands, one seed was cut in pathology?

14 MR. SHEETZ: I think the broad scope
15 licensees have been doing this and they are the main user
16 of this. But now, I think because of the articles that
17 have come out, it is limited scope licensees that are
18 trying to add this procedure, and this is where the
19 difficulties come in.

20 It is really driven by the surgeons. The
21 surgeons love this. It is not driven by the
22 radiologists. It is driven by the surgeons.

23 CHAIR THOMADSEN: Ms. Weil?

24 MEMBER WEIL: Where do you get the data

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1 that this is a preferable procedure for patients from
2 the point of view of discomfort?

3 MR. SHEETZ: Anecdotally, from patients
4 that we have done both the wire and the seed. And so,
5 this is the response back to the mammography/breast care
6 imaging tech, that "Oh, wow, this seed was a piece of
7 cake. This was great. I wish I had had this before as
8 opposed to the wire."

9 MEMBER WEIL: And why do you have a
10 mammogram immediately post-seed implant?

11 CHAIR THOMADSEN: It works with a wire with
12 a hook on the end.

13 MR. SHEETZ: Sure.

14 MEMBER WEIL: But do you do the mammogram?
15 Do you have to --

16 MR. SHEETZ: Uh-hum.

17 MEMBER WEIL: Yes?

18 MR. SHEETZ: Yes, there is still imaging
19 with the wire.

20 MEMBER WEIL: Never mind.

21 (Laughter.)

22 CHAIR THOMADSEN: Okay. Dr. Ennis?

23 MEMBER ENNIS: Could you share more
24 specifics about the purported advantages? There is, of

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1 course, no data, no real information about how much
2 margins are better, how much pain is better, whatever
3 the purported benefits.

4 MR. SHEETZ: I didn't really want to get
5 into that. There are a number of studies. Some show
6 advantages. Some show the procedures to be equivalent.
7 But the numbers are small with all these studies. So,
8 I don't think the verdict is out yet.

9 MEMBER ENNIS: Okay. So, at this point,
10 is it fair to say the real advantage is the logistics
11 for the surgeon?

12 MR. SHEETZ: Yes, that is the primary
13 driver for it, yes.

14 CHAIR THOMADSEN: Dr. Dilsizian?

15 MEMBER DILSIZIAN: Great presentation. I
16 just have many medical questions, just to help me to
17 understand.

18 Usually, the biopsy, if it is malignant,
19 then, you go in and put in the seed, correct?

20 MR. SHEETZ: Yes, they would do the
21 imaging; they would see a suspicious tissue. They
22 would do a needle biopsy.

23 MEMBER DILSIZIAN: First?

24 MR. SHEETZ: And then, they would drop a

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1 clip. Okay.

2 MEMBER DILSIZIAN: You mean you wouldn't
3 wait until the official biopsy comes?

4 MR. SHEETZ: Yes.

5 MEMBER DILSIZIAN: For instance, first,
6 you do the biopsy.

7 MR. SHEETZ: You do a needle biopsy.

8 MEMBER DILSIZIAN: If it is malignant,
9 then you go in and put in a beaker, right? I mean, you
10 wouldn't just put it in if it is cystic abnormal?

11 MR. SHEETZ: Well, if there is suspicious
12 tissue, they will do a needle biopsy, and then, they drop
13 a clip, a marker clip, where they took the biopsy. And
14 then, pathology does an analysis on the tissue, the
15 needle biopsy.

16 MEMBER DILSIZIAN: Right.

17 MR. SHEETZ: And if that is cancerous or it
18 is suspicious and they say, "We want to remove it," then,
19 the patient comes back and either gets a wire or a seed
20 for surgical removal of that tissue.

21 MEMBER DILSIZIAN: Okay. So, now it is
22 malignancy and you are putting in a seed. My question
23 is two-fold. One, you said that it would interfere with
24 sentinel imaging, which if it is malignant, I mean, it

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1 seems to me that sentinel node would be an important
2 quality assessment. Is that correct? Do you say that
3 this would interfere or not with the sentinel technetium
4 assessment?

5 MR. SHEETZ: No, this does not interfere
6 with the sentinel node --

7 MEMBER DILSIZIAN: It doesn't?

8 MR. SHEETZ: Because the gamma probe has
9 windows for technetium and windows for the Iodine-125.

10 MEMBER DILSIZIAN: Sure.

11 MR. SHEETZ: Where I said it would be a
12 problem or interference is if somebody used one of the
13 other sodium iodide detector instruments to try to
14 survey for I-125, and if there was technetium there for
15 the sentinel node, they would get a signal from that.

16 MEMBER DILSIZIAN: I see. Okay. Thank
17 you.

18 MR. SHEETZ: And so, they would not be able
19 to serve the I-125.

20 CHAIR THOMADSEN: Mr. Costello?

21 MEMBER COSTELLO: You mentioned strict
22 compliance; it is difficult, particularly to limited
23 scope licensees. What particular changes in the
24 guidance would you recommend?

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1 MR. SHEETZ: Consideration of everything
2 that I have stated here before you.

3 MEMBER COSTELLO: Well, for example, for
4 an Authorized User how would we change that?

5 MR. SHEETZ: You could still have an
6 Authorized User, either as a 490-approved radiation
7 oncologist or the 35.200, but not require the case
8 requirements.

9 MEMBER COSTELLO: Okay.

10 MR. SHEETZ: They just have to be
11 knowledgeable in the radioactive seed localization
12 process from implant to surgical removal, to
13 extraction, to inventories and surveys. Because they
14 would be, then, the Authorized Users. Everybody else
15 would, then, be performing the procedure, the
16 radiologist, the breast care radiologist, and the
17 surgeon and the pathologist, they would all be working
18 under the supervision of the Authorized User.

19 DR. METTLER: At the end of the day, this
20 is just the same as doing a sentinel lymph node. I mean,
21 the surgeon has to chase it around. He has got to take
22 it out. The pathologist has got to play with it.

23 MR. SHEETZ: Right.

24 DR. METTLER: And it is unsealed with the

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1 sentinel lymph node. This is sealed.

2 MR. SHEETZ: And most radiologists who
3 perform the injection for sentinel lymph node are
4 performing it under the supervision of your nuclear
5 medicine physician. And we actually now have trained
6 our surgeons to perform the sentinel lymph node
7 injections on the OR if the patient is put under
8 anesthesia, to eliminate that pain. And so, the
9 surgeons are actually performing sentinel lymph node
10 injections under the supervision of the Nuclear
11 Medicine Authorized User. So, this is no different.
12 So, you have an Authorized user, but, then, a lot of the
13 work is being performed by individuals under their
14 supervision.

15 MEMBER COSTELLO: And I think you
16 suggested that you don't need a written directive for
17 this?

18 MR. SHEETZ: The written directive is not
19 necessary.

20 MEMBER COSTELLO: But you also suggested
21 that medical events are still possible?

22 MR. SHEETZ: That is correct. That is
23 possible. Again, I am not advocating anything. I can
24 see certain situations where a seed is left in.

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1 MEMBER COSTELLO: And you ascribe it.

2 MR. SHEETZ: And ascribe it.

3 VICE CHAIR ALDERSON: So, I have a question
4 which some of the people who use this procedure now
5 widely can perhaps answer and, then, a comment.

6 So, the question is, in institutions like
7 your own, like Sloan Kettering, where this has begun to
8 be used widely, it is judged by those physicians and the
9 people involved that it is so much better? Has it
10 replaced the wire? That is the first question. Has it
11 replaced the wire?

12 MEMBER ZANZONICO: At Sloan Kettering, as
13 far as I know, it has replaced it. It is the standard
14 now. There are some instances where they still use the
15 wire, but that is my understanding.

16 MR. SHEETZ: Yes, it has essentially
17 replaced it.

18 VICE CHAIR ALDERSON: Okay.

19 MR. SHEETZ: Except for a very rare
20 occurrence.

21 VICE CHAIR ALDERSON: All right. So,
22 that's good. I mean, that suggests that a lot of
23 knowledgeable people who use this think it is a good
24 thing to do. I have no experience with this technique

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1 at all.

2 MEMBER ZANZONICO: There is a lot of
3 enthusiasm, as you said, among the surgeons.

4 VICE CHAIR ALDERSON: Right. So, I am
5 going to mention a concern that will make you think I
6 am extremely conservative, and this knowledgeable body
7 can say, "Eh, forget about it now."

8 But I understand that the radiation range
9 is small. The thing I am concerned about, or that my
10 conservatism makes me be concerned about, is it is
11 radiation. So, this is a relatively-new procedure now.
12 So, we haven't had much time. But, if in a few years
13 some women come back and they have a new cancer and it
14 is somewhere in the region of where they had the
15 radioactive seed localization before, are some of our
16 legal friends going to go after this, the same way they
17 went after asbestos, and make it into something we turn
18 around and say, "We wish we had never done that."?

19 Now that is, again, probably
20 extraordinarily conservative, but we haven't had much
21 time yet. So, anyway, I thought I should say it.

22 MR. SHEETZ: In response to that, I think
23 if you look at the dose to the tissue that is remaining
24 after the seed and the lesion have been excised, the

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1 radiation dose to that tissue is on the order of two view
2 mammogram.

3 VICE CHAIR ALDERSON: Okay.

4 MR. SHEETZ: So, it is very low.

5 VICE CHAIR ALDERSON: So, it is just a
6 couple hundred millirems, yes. All right. That is a
7 good answer.

8 CHAIR THOMADSEN: Other comments?

9 Yes, Mr. Bollock.

10 MR. BOLLOCK: Thank you.

11 I would just like to add that the NRC and
12 the Organization of Agreement States are forming a
13 working group to update the guidance. Actually, Ms.
14 Holiday is part of the working group, along with a
15 representative from the States of New York and Utah.
16 And we have one other NRC staff that hasn't been
17 identified yet. But we are going to do that, hopefully,
18 begin that in April.

19 CHAIR THOMADSEN: Begin that in April and
20 finishing it when?

21 (Laughter.)

22 MR. BOLLOCK: If somebody can help me out
23 with what's the estimate?

24 MS. HOLIDAY: Well, in all honesty, I can't

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1 really put a timeframe on it. It really does depend on
2 deliberations and discussions of that working group.
3 April is actually when we are hoping to kick off the
4 working group. We are still waiting to identify one
5 additional member. And then, of course, you have to
6 work around people's schedules. We are approaching
7 summer vacation.

8 But I would just like to remind the
9 Committee, with our most recent 35.1000 device, that is
10 part of the toolkit, that only took us nine months to
11 develop guidance. But that doesn't mean that we could
12 be done in nine months. It could be earlier. It could
13 be later. But I don't want to put a definitive number
14 on that.

15 CHAIR THOMADSEN: My question has the
16 intention of, when would you have to have this
17 Committee's input in order to have it considered in the
18 discussions?

19 MR. BOLLOCK: Yes, again, that would be
20 dependent upon when the working group finishes their
21 deliberations. So, I mean, it would be a guess, but it
22 wouldn't be the next meeting. It would be after some
23 few months at least, if they begin next month, that they
24 would be ready to turn it over to ACMUI to review.

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1 CHAIR THOMADSEN: Thank you.

2 Yes, Dr. Mettler?

3 DR. METTLER: So, can you tell me how this
4 is any different from a sentinel lymph node other than
5 it is a sealed source in terms of hazard or anything
6 else?

7 MR. SHEETZ: And my viewpoint is it is no
8 different.

9 MEMBER ZANZONICO: The one tact that
10 strikes me is in the event -- and again, it would be
11 patient intervention. A patient doesn't return. You
12 are talking about considerably higher local radiation
13 doses apropos the point that Dr. Alderson raised. I
14 mean, the doses would be much less than a sentinel lymph
15 node.

16 But those aren't trivial if they are local.
17 It depends upon the volume for your calculation.

18 MR. SHEETZ: But these are the same seeds
19 that are used for brachytherapy at three to five times
20 greater activity where 50 to 100 are implanted in the
21 prostate, and it is not infrequent for one to migrate
22 to the lungs or the bladder or become dislodged
23 somewhere else in the body and remain there until they
24 decay away.

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1 DR. METTLER: Plus, the people pee them
2 out.

3 MR. SHEETZ: So, a single left in the body
4 is not going to cause any extra --

5 MEMBER ZANZONICO: No, I don't disagree.
6 I am just playing devil's advocate.

7 MR. SHEETZ: Yes.

8 MEMBER ENNIS: Well, it would depend on
9 where it was. I mean, if it was right under the skin,
10 it actually would, a superficial region.

11 MR. SHEETZ: Okay.

12 MEMBER ENNIS: And if the patient didn't
13 return, they would have an ulcer and it would be a
14 problem.

15 CHAIR THOMADSEN: Ms. Weil?

16 MEMBER WEIL: I just have to put this out
17 there. From listening to this, it sounds like the
18 primary driver for this particular therapy is that it
19 is extremely convenient for the surgical schedule
20 because it doesn't have to be done in tandem with the
21 radiologist doing a localization with a wire. There
22 isn't that proximity in time that has to be factored into
23 it.

24 If that is the primary reason for the

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1 popularity of this particular procedure, it would be
2 nice to have more data about its satisfaction levels for
3 patients as opposed to satisfaction for the clinicians
4 involved.

5 CHAIR THOMADSEN: Dr. Langhorst?

6 MEMBER LANGHORST: But this discussion is
7 really a request to update NRC's licensing guidance for
8 this. It is not to make any changes and, hey, everybody
9 needs to have this. It is to update a 2006 guidance
10 document, with the many years -- I mean, this has been
11 used for 10 years now -- with the current way of doing
12 it. And so, that is what is being brought to our --

13 MEMBER WEIL: Yes, this presentation,
14 though, is about how wonderful this is, not about -- I
15 mean, it is about both things. It is about a
16 recommendation for changing guidance or a request for
17 that, but it is also about how terrific this particular
18 procedure is.

19 CHAIR THOMADSEN: Yes?

20 MR. SHEETZ: I agree with you; one of the
21 main benefits is the decoupling of the scheduling
22 conflicts.

23 The second is that the surgeons can see
24 where the seed is. And so, they can choose where to make

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1 the incision to remove the lesion, as opposed to having
2 to follow the wire in. So, there is definitely cosmetic
3 outcomes by using the seed because they don't have to
4 follow the wire. They can come where it is not going
5 to be as revealing.

6 And so, even the surgeons that were not
7 onboard with this early on, once they started, they
8 said, "Okay, this was great because I can get better
9 cosmetic outcomes." So, I think that is the second big
10 driver for this.

11 And the positive margins and reduced volume
12 of tissue, and all that, it is probably equivalent.

13 VICE CHAIR ALDERSON: I have a follow-up
14 question.

15 CHAIR THOMADSEN: Yes, go ahead.

16 VICE CHAIR ALDERSON: And I was reading
17 your slides to see if it was here and I just missed it.
18 So, say it again. What are the specific changes that
19 you seek in the guidance? It just says here you want
20 the guidance to be changed. What are the specific
21 changes that you seek?

22 MR. SHEETZ: The primary one would be the
23 training and experience requirements for the Authorized
24 User. Maybe discontinuing three cases or allow them to

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1 observe cases or allow them to attend a workshop and they
2 would automatically qualify as an Authorized User,
3 whether they are 35.200- or 35.400-approved.

4 Recognition that radiologists with
5 training in the procedure can implant the seeds under
6 the supervision of an Authorized User because the
7 guidance document right now implies that only an
8 Authorized User implant seeds. And some institutions
9 are following that. They looked at that and said -- and
10 some regulators are requiring that. So, they won't
11 allow a radiologist to implant the seed under the
12 supervision of an Authorized User. That means
13 everybody has to become an Authorized User.

14 VICE CHAIR ALDERSON: So, those are those
15 are the only two things you see?

16 MR. SHEETZ: No. The other was the
17 elimination of a written directive requirement.

18 VICE CHAIR ALDERSON: Yes, no written
19 directive.

20 MR. SHEETZ: And the other was my
21 third-to-the-last slide on the commitments that are
22 required in the guidance documents for other
23 regulations in 35 that really are inapplicable; you
24 know, 35.410, and things of that nature.

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1 VICE CHAIR ALDERSON: I see. And do you
2 believe, in addition to a radiologist being able to
3 implant under the direction of an AU, what about
4 surgeons? Can they do it under an AU?

5 MR. SHEETZ: Do the surgical procedure?

6 VICE CHAIR ALDERSON: Do the implantation?

7 MR. SHEETZ: No, they don't have the
8 training to implant seeds nor would they be
9 medically-credentialed. A surgeon can't implant a
10 seed in a hospital.

11 MEMBER WEIL: They remove them.

12 MR. SHEETZ: They remove them.

13 DR. METTLER: But, in one sentence, if you
14 had that one sentence, it would be: treat this
15 procedure just like you treat a sentinel node procedure;
16 everything the same?

17 MR. SHEETZ: Yes.

18 DR. METTLER: Excepting if they don't come
19 back to get this thing taken out, though. Other than
20 that, everything is the same. In fact, let's say it is
21 at least sealed as opposed to unsealed.

22 MR. SHEETZ: Well, it would fit perfectly
23 under 35.200 except it is sealed.

24 MEMBER COSTELLO: The one medical

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1 event -- I'm sorry -- that you described where basically
2 you couldn't remove the seed because of where it was
3 located, if I recall, right?

4 MR. SHEETZ: I'm sorry? What?

5 MEMBER COSTELLO: The one medical event
6 that you referred to --

7 MR. SHEETZ: Yes, yes, right.

8 MEMBER COSTELLO: -- if that had happened
9 with technetium, would that have been a medical event?

10 MR. SHEETZ: I'm not sure what you mean by
11 technetium. The sentinel node injection stays there
12 or --

13 MEMBER DILSIZIAN: No, the exposure.

14 MEMBER COSTELLO: Okay.

15 MR. SHEETZ: The exposure?

16 MEMBER COSTELLO: As far as the exposure.
17 So, the exposure in a case with these was hot, turned
18 out to be hot, or would have been --

19 MR. SHEETZ: If left in indefinitely or for
20 a certain period of time, correct.

21 MEMBER COSTELLO: Right.

22 MR. SHEETZ: This is a long half-life.

23 MEMBER COSTELLO: So, the doses can be
24 higher here if they stay there longer, assuming they

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1 can't get them out?

2 MR. SHEETZ: Correct. As I said, it would
3 be nine days for 50 rads at 170.

4 MEMBER COSTELLO: Right.

5 DR. METTLER: But, at the end of the day,
6 if you infiltrate an FDG dose, you know, you have got
7 local doses of the same amount.

8 MEMBER COSTELLO: Thinking infiltration,
9 Think as an acceptor for infiltration, right?

10 DR. METTLER: Yes, I mean in terms of
11 biological events.

12 MEMBER COSTELLO: Sure.

13 MR. SHEETZ: And I am not arguing that if
14 the seed is left in or a patient doesn't return, that
15 that shouldn't be reported as a medical event.

16 MEMBER COSTELLO: What I struggle with is,
17 conceptually, possibly having a medical event without
18 the written directive, because the two are linked
19 together.

20 CHAIR THOMADSEN: Mr. Mattmuller?

21 MEMBER MATTMULLER: Well, I would say that
22 is not possible because, for example, we had where the
23 patient was accidentally injected with a full
24 multi-dose vial of, I think it was technetium NBP, and

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1 there was no written directive for that diagnostic
2 procedure. But, yet, still a medical event occurred.

3 MEMBER COSTELLO: Thank you.

4 CHAIR THOMADSEN: Now any other comments?

5 MS. THOMAS: Are you asking for comments on
6 the bridge line?

7 CHAIR THOMADSEN: Yes, on the issue of
8 breast localization with radioactive sources.

9 Okay. I would like to name a Subcommittee
10 to develop recommendations on the issues raised by this
11 presentation. So, it would be making recommendations
12 on radioactive seed localization to present to this
13 Committee. The timeline would be before the next
14 Committee meeting. We may have to have a conference
15 call, depending on how quickly the working group is
16 getting together and discussing this. Whether or not
17 the presentation would be before the next Committee
18 meeting is irrelevant. The work needs to be done
19 quickly.

20 And I would like to ask Dr. Ennis to be the
21 Chair of that Committee. I would like Dr. Alderson to
22 also be on that Committee and Mr. Costello to be on that
23 Committee.

24 Do we have volunteers who would like to be

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1 on that Committee as well?

2 Dr. Zanzonico. I would like to name Dr.
3 Mettler as soon as he gets his final approval and
4 clearances, and whatever.

5 It should happen before the Committee makes
6 its report.

7 Any other comments on that?

8 MEMBER COSTELLO: Could you go through
9 those names again, please?

10 CHAIR THOMADSEN: Dr. Ennis, Dr. Alderson,
11 Mr. Costello, Dr. Zanzonico, and Dr. Mettler
12 conditionally. I think that is what I said.

13 Okay. No other comments on this topic?

14 Yes?

15 MEMBER LANGHORST: I just want to make
16 mention as to how Mr. Sheetz came to give us this talk.
17 He reached out to the NRC to ask about the licensing
18 guidance. NRC's staff was fabulous in trying to direct
19 him to the right place. I know we talked with Mr.
20 Costello and, eventually, it came to me. My name is on
21 there just because I tried to help facilitate this.

22 But I really want to encourage the people
23 who listen to our Committee meetings, who read our
24 transcripts, and so on, that you have available to you

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1 an opportunity to suggest topics and even come talk to
2 us.

3 I really appreciate Mr. Sheetz's efforts in
4 educating me on this process because we do not do it at
5 Washington University at this point in time. And I
6 really appreciate him coming out to talk to us about
7 this.

8 CHAIR THOMADSEN: Dr. Mettler?

9 DR. METTLER: A great presentation.

10 MR. SHEETZ: Thank you.

11 DR. METTLER: You must have a library of
12 references that might be in PDF format about all of this?
13 If you could get it forward --

14 MR. SHEETZ: I certainly can.

15 CHAIR THOMADSEN: Thank you. Thank you
16 very much.

17 MR. SHEETZ: Thank you very much. I
18 appreciate it.

19 MS. HOLIDAY: Dr. Thomadsen?

20 CHAIR THOMADSEN: Yes?

21 MS. HOLIDAY: Is this okay? I just wanted
22 to make one comment. I just wanted to say this is a
23 prime example of -- I know we have said it before -- but
24 for all items that are licensed under 35.1000, there is

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1 that caveat where all these guidance documents are
2 located that there is an opportunity for the general
3 public, staff, anyone, if you feel that there should be
4 changes, that you can contact us to let us know.
5 Because these are essentially living, breathing
6 documents.

7 As we all know, microspheres guidance
8 document has undergone several revisions, as I am sure
9 we will go under another revision with this most recent
10 Subcommittee report that we received at the last
11 meeting.

12 So, as Mr. Sheetz indicated, this guidance
13 document was created in 2006. As time goes on, we learn
14 more about what these modalities can do. If there is
15 stuff that we had in there before that is no longer
16 applicable or if there is stuff that should be in there,
17 help us help the medical community. That is what we
18 rely on you for; that is what we rely on the medical
19 community to tell us. We can't do our jobs if you don't
20 tell us.

21 Thank you.

22 CHAIR THOMADSEN: Thank you. Point
23 well-taken. Thank you very much.

24 And now, to round out the day, we have Mr.

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1 Mattmuller to tell us about germanium/gallium
2 generators and their decommissioning.

3 MEMBER MATTMULLER: Good afternoon,
4 everyone.

5 I am Steve Mattmuller, and I will be
6 presenting our Subcommittee report. But, first, I just
7 wanted to make a couple of general comments on comments
8 I have already heard today that I really appreciated.

9 Laura's initial comments reminding us of
10 our responsibility to help advise/guide the NRC for
11 appropriate regulations, so they are perfect for
12 medical care and patient care and don't interfere with
13 patient care.

14 Also, I really appreciated the comment Dr.
15 Mettler made, and then confirmed by Dr. Thomadsen, that
16 we are to be pests to the NRC, if need be the case.

17 (Laughter.)

18 DR. METTLER: Advice.

19 MEMBER MATTMULLER: Advice? It sounded
20 like "pests" over here on this side of the room.

21 DR. METTLER: It reminds me of my children.
22 What I said wasn't necessarily what I meant, and what
23 you heard wasn't what I said.

24 (Laughter.)

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1 MEMBER MATTMULLER: Okay. So, first of
2 all, I would like to review why germanium and gallium-68
3 are so important to the field of nuclear medicine, the
4 charges to the Subcommittee, and its responses to the
5 charges.

6 Next slide, please.

7 So, here's a comparison, images of a PET
8 drug versus a spec drug. You can see the dramatic
9 advantages the PET drug offers of the gallium-68 DOTA
10 on the right versus the older spec agent, indium-111
11 DTPA octreotide on the left.

12 Greater image quality, greater diagnostic
13 sensitivity and accuracy. There is actually faster
14 imaging time. The gallium-68 image can be acquired in
15 one day for the patient versus the two days it takes for
16 the indium study. And there is also a lower radiation
17 dose.

18 Another exciting developing for the
19 gallium-68 right in pharmaceuticals is the relative
20 ease of how you can substitute, you can bring in a
21 therapeutic radionuclide such as lutetium-177 into the
22 very same molecule. So, then, you actually transform
23 a very sensitive, specific diagnostic drug into a very
24 sensitive, specific therapeutic drug. And they call

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1 this aspect theranostics, the combinations of a
2 diagnostic/therapeutic drug.

3 For this type of drug, for the DOTAs, in
4 particular, they call this peptide receptor
5 radionuclide therapy, or PRRT.

6 Next slide, please.

7 So, here is a list of most, not all, of the
8 different areas where gallium-68 is now being used or
9 under investigation. So, you might ask, how big is this
10 iceberg really, especially in today's years or time
11 zones and climate change? But it is big.

12 As an example, last weekend was the Third
13 World Congress of Theranostics Gallium-68 and PRRT held
14 last weekend in Baltimore. This is the first time it
15 has met here in the U.S., as especially in Europe,
16 gallium-68 use is mainstream; whereas, in the U.S. it
17 is still investigational.

18 The boat is at the tip of the iceberg. It
19 is used to image somatostatin receptors found in
20 neuroendocrine tumors, or NETs, N-E-T. And as stated
21 by Dr. Zanzonico in a past meeting, the DOTAs are really
22 just the tip of the iceberg. Also, in the U.S. they are
23 the closest to be acquiring FDA approval.

24 In the middle of the iceberg -- I hope you

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1 can see it -- is prostate imaging using an agent PSMA.
2 That is also getting a lot of attention worldwide.
3 Again, great images and a much larger patient
4 population. It would be my prediction as the next drug
5 after the DOTAs to receive FDA approval.

6 And at the base, which is maybe a little bit
7 hard to read -- I'm sorry -- are the theranostics.
8 Again, the development of therapeutic drugs from the
9 diagnostic drug.

10 Next, please.

11 This is our source of the gallium-68, the
12 generator. The parent radionuclide is germanium-68, a
13 solid on a dry column about the size of my little finger.
14 The germanium-68 decays to the daughter radionuclide
15 gallium-68. To remove it, one elutes the column by
16 passing dilute hydrochloric acid through the column and
17 it is a collection vial. But germanium-68 is left
18 behind on the column; the gallium-68 collects in the
19 vial.

20 Now, even though she is a pre-K teacher, my
21 daughter assured me that no one could go wrong with show
22 and tell.

23 (Laughter.)

24 So, this is an actual prototype of the

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1 Eckart & Ziegler generator. This is what we are talking
2 about. It is very small. It requires no power, no
3 electrical cord, no batteries. There are no moving
4 parts. It is rather kind of boring. It just sits in
5 a lead-shielded area.

6 This helps explain why the previous image
7 of the iceberg is so big. PET radionuclides have
8 terrific imaging advantages over spec radionuclides.
9 But most of the PET radionuclides need a cyclotron just
10 to produce them, and cyclotrons are big and expensive.
11 Actually, you would need a room about the size of this
12 meeting room for a cyclotron, its support areas, and
13 chemistry areas, and quality control areas.

14 You might think of this little generator as
15 a mini-cyclotron in a box, but it has regulatory
16 issues -- and that is why we are really here -- as the
17 germanium-68, the parent radionuclide, triggers a
18 decommissioning funding plan.

19 Next slide, please.

20 And here it is for a decommissioning fund
21 plan in part 35.35. "Each applicant for a specific
22 license authorizing the possession and use of unsealed
23 byproduct material" -- and, currently, the germanium is
24 considered unsealed -- "with a half-life greater than

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1 120 days" -- it does have a half-life of 271 days -- "and
2 in quantities exceeding 10 to the fifth times the
3 applicable quantity set forth in Appendix B," it meets
4 these three conditions and you need to get a DFP for your
5 gallium generator or for any radionuclide.

6 Briefly, a DFP describes what happens to
7 the facility after it closes, after you lose or
8 terminate your possess license. Equipment,
9 structures, and portions of the facility containing
10 radioactive contaminants will be removed or
11 decontaminated to a level that permits release of the
12 property. Basically, it has to be cleaned-up to the
13 original background levels.

14 So, a DFP is very extensive and expensive
15 to create, to get approved, and also to fund. And it
16 is a continuous burden, as it needs to be reviewed,
17 resubmitted, and reapproved every three years for as
18 long as the license is active. It is a big burden. It
19 requires a lot of man-hours and a lot in terms of
20 financial assurance.

21 Next slide, please.

22 This really is a curious regulatory
23 situation for us, as we have two identically-labeled
24 appendices in 10 CFR, quantities of licensed material

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1 requiring labeling, but they contain two different
2 lists. Appendix C in Part 20 has over 600
3 radionuclides, and B in Part 30 has less than 200.
4 Appendix C, you might guess, is the newer version of the
5 two.

6 And for the first two radionuclides that we
7 are all familiar with, F-18 and molybdenum-99, the two
8 appendices have the same values. But the problem is our
9 germanium-68. There is a boundary of 10 microcuries in
10 Appendix C, but there is no value listed for germanium
11 in B. And this is the missing piece of our regulatory
12 puzzle.

13 So, from the previous regulation, it says
14 you take this number, list it in B, multiply it by 10
15 to the fifth power, and that is your limit for activity
16 to determine whether or not you have to get a DFP.

17 But, without a value in the appendix, you
18 have to use the default-level value of 0.1 microcuries,
19 which, when you do the math, gives you a limit of only
20 10 millicuries. That is a problem because these are
21 typically 50-millicurie-sized generators.

22 It gets more curious. The last time
23 Appendix B was amended was 1980. But check out these
24 two redesignations, which means it gets moved, not

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1 amended, but just to a different part in the
2 regulations.

3 From 1991 to 1993, this was a transition
4 period for the implementation of the then-newly-revised
5 Part 20. So, we have the new Appendix C and the new
6 version of Part 20, and Appendix B from Part 30 gets
7 moved over to Part 20 as the old version. So, during
8 these two years, there are two versions of Appendix C,
9 an old and a new, and there is no version of B in Part
10 30. That amended Part 30 to say, if you need to
11 calculate a DFP, then look for your value in the old
12 Appendix C in Part 20.

13 In 1993, the transition period is over.
14 So, it is just a new version of Part 20 is valid, and
15 the old version of C is moved back to Part 30 and becomes
16 Appendix B again. So, here to the old and, then, back.

17 Unfortunately, with all this, which is not
18 clear why that happened, there still isn't a value for
19 germanium-68. So, it is puzzling because we are not
20 sure why. At one point, they had a reference in Part
21 30 to say, if you need this value, go to Appendix C. Why
22 they didn't keep that I don't know. Or why, then, they
23 moved the old Appendix C from 20 back to become Appendix
24 B again of Part 30, why that appendix wasn't revised and

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1 amended to include a value for germanium-68?

2 So, another part of the puzzle is in 2005,
3 when the definition of byproduct material is expanded
4 to include accelerator-produced radionuclides such as
5 the PET radionuclides F-18 and germanium-68. This is
6 the original occurrence when there were a couple of
7 licensees that had gallium generators in 2004, and in
8 2005 they were told, "You now have to have a DFP."

9 But, overall, trying to figure this out,
10 this rabbit hole of regulations, I am still not
11 100-percent sure what really happened to our core value.
12 As best as I can say, it was an unintentional omission
13 for B or, as you might say, it got lost in translation.

14 Next slide, please.

15 So, the charges given to the Committees
16 were to evaluate the cost of a DFP, to provide examples
17 of regulatory relief, and to evaluate how a DFP might
18 affect future clinical use of gallium-68.

19 Next slide, please.

20 So, the first attempt was to try to figure
21 out what does a DFP cost. Several large commercial
22 nuclear pharmacy firms were contacted, and we also found
23 a couple of health physics consultants on the internet
24 who advertised their DFP experience and expertise. We

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1 contacted them also, asked for an estimate on what it
2 would cost to prepare or fund a DFP for a medical
3 license, not a firm number, just an estimate. We heard
4 nothing from nobody.

5 So, I thought, all right, I will just try
6 to do it myself. You know, a do-it-yourself attitude.
7 How hard could it be, right?

8 (Laughter.)

9 And this slide is actually a little bit
10 inaccurate because it just lists one volume of
11 NUREG-1757. After I prepared this slide, I actually
12 found two more volumes of this guide and, ironically,
13 is titled "Consolidated". And the three guides total
14 1,349 pages of guidance.

15 So, the DFP covers, as I have said before,
16 not just the use of germanium-68, but all uses of
17 radioactive material at all locations under the
18 license. So, a hospital, if they have a cyclotron, PET
19 chemistry areas, PET spec imaging areas, a hot lab with
20 a technetium generator, satellite imaging sites within
21 the building, outside of the department, or satellite
22 imaging areas outside at different locations in the
23 town, local area, or even in another hospital with its
24 own nuclear medicine department, if those are all under

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1 the same license, as is the case at my hospital, they
2 all have to be considered in the formation/calculation
3 of the DFP.

4 Or, for a commercial nuclear pharmacy, a
5 number of them have cyclotrons and PET chemistry areas.
6 That would dramatically increase their cost for a DFP.

7 In fact, that did happen in 2004. There
8 was a commercial pharmacy that had a cyclotron and had
9 a gallium-68 generator for research. When they were
10 told to get a DFP, they looked into it, but it is going
11 to cost them \$15 to \$20 thousand a year every year. So,
12 they got rid of the generator.

13 So, our charge is about a question asked.
14 It is really a very expensive question to answer. And
15 it is also very unreasonable to expect anyone to do this
16 on a voluntary basis. So, in hindsight, I am now not
17 at all surprised that I didn't hear from any of those
18 other firms. So, this may be pictured as an RSO as he
19 tries to push a round through a square hole.

20 Next slide, please.

21 We do, however, have a very detailed
22 narrative from an RSO as he tried to prepare a DFP for
23 a large, multi-site university-based hospital. In the
24 next couple of slides, the quotations marks all are

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1 comments from this RSO.

2 Next. Yes.

3 "Resource demands go far beyond the cost
4 associated with the generation and maintenance of a
5 financial assurance instrument itself, which can be in
6 the thousands of dollars in creation fees and more
7 thousands in annual maintenance fees. It is a very
8 expensive effort to prepare it."

9 He had to review the regulations and
10 guidance, all 1,349 pages. He had to review research,
11 the historical use for all buildings and locations,
12 obtain cost estimates for the various actions required
13 that required any decommissioning process, calculate
14 person-hour involvement for all man-hour costs related
15 to these actions, and determine and estimate waste
16 disposal cost, time demands for the creation of the
17 worksheets and spreadsheets, writing and compiling a
18 plan for related internal and external communications.

19 Next, please.

20 His initial estimate, substantial cost in
21 manpower from the Operations and Safety Office. He
22 calculated 140 hours. So, it sounds maybe somewhat
23 manageable.

24 But, then, he soon adds -- next,

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1 please -- "I'm probably underestimating this. He sums
2 up his experience as "extensive and expensive".

3 Next slide, please.

4 There are also significant manpower costs
5 to the institution for other areas involved, such as
6 risk management, insurance, finance, facilities,
7 administration, and legal.

8 Next, please.

9 Once submitted, the DFP has to go to the
10 State, in his case, to be approved. And he states,
11 "This puts significant resource demands on regulatory
12 agencies related to review an ultimate approval of the
13 DFP." So, I think that is a pretty insightful
14 observation on his part. A DFP also puts a big demand
15 on states who already have very limited resources in
16 dealing with radioactive material licensees.

17 Next, please.

18 For example, the State's initial review
19 resulted in comments that required yet additional
20 demands that he estimated cost them an additional 30
21 person-hours.

22 And that, ultimately, for his institution,
23 financial assurances owed of \$1.125 million.

24 In addition, this burden still doesn't end

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1 because, if they go this route, they still have to
2 revise, resubmit, and get it reapproved every three
3 years.

4 So, what happened at this institution?
5 Ultimately, they decided the DFP was going to cost too
6 much. So, they didn't do it. So, they had to
7 scale-back their research plans to use a used generator
8 smaller than 10 millicuries in size, so they wouldn't
9 have the DFP.

10 But all their research is limited to just
11 imaging in smaller animals, mice, rats, versus what they
12 had initially planned to do was image in patients,
13 research subjects.

14 So, trying to push a round ball through a
15 square hole does have consequences. That's clear.

16 Many hospitals will not have the in-house
17 expertise to deal with the DFP issue. And if they do
18 have to pursue DF Planning, they will likely need to hire
19 consultants, adding further to their costs, one more
20 additional potential barrier in cost. A RSO really
21 understands what it takes to prepare a DFP for a medical
22 institution.

23 The restrictive aspects arising from the
24 current Part 30 situation may, therefore, prevent or

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1 deter use of promising imaging agents for patients due
2 to the decommissioning funding burden. This concern is
3 exactly our concern.

4 Next, please.

5 So, the little RSO has given up on the ball,
6 and now he is thinking about our second charge,
7 regulatory relief.

8 The simplest and best way would be to add
9 the same value of 10 microcuries for germanium-68 that
10 exist in Appendix C, Part 20, to Appendix B, Part 30.
11 A simple solution, as both appendices have the same
12 title, "Quantities of Radioactive Material that Require
13 Labeling," but how?

14 Perhaps the best would be using a Direct
15 Final Rulemaking or DFR, and these can be used for
16 noncontroversial rulemaking, as this issue would
17 certainly be. Its advantage is that it takes much less
18 time than a typical rulemaking of 10 to 12 years.

19 However, from the DFR guidance, it
20 typically deals with safety or security concerns. So,
21 this really isn't a safety concern or a security
22 concern. This is a patient concern.

23 Since the unintentional omission of a value
24 in Appendix B for germanium, a DFP is now required for

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1 the possession of a generator. And the cost of a DFP
2 can be a prohibitive financial barrier to the license
3 and will deter the safe and effective use of gallium in
4 patients.

5 The next slide, please.

6 On the upside, fortunately, DFR guidance is
7 much shorter than DFP guidance, but there are five
8 questions we have to answer.

9 The first question is, what has happened,
10 what has changed that causes the current regulation or
11 policy to be insufficient? Appendix B has actually
12 been unchanged since 1980. What has changed is the
13 recent dramatic increase in the use of gallium-68.
14 Remember the iceberg.

15 Next, please.

16 Suzanne said this succinctly: increase in
17 the use of gallium-68.

18 Next, please.

19 What information causes the NRC to question
20 the current regulation or policy? We are now very aware
21 of the man-hour and financial burden of a DFP and how
22 this has already deterred the use of gallium in research
23 and more than likely will deter the use of gallium-68
24 in clinical patients.

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1 A nuclear pharmacy and a contract research
2 organization stopped their research after 2005. And
3 more recently, a large university hospital curtailed
4 their research use.

5 Next, please.

6 So, to answer this, a DFP's deleterious
7 effects.

8 Next, please.

9 The third question is, what is the
10 regulatory insufficiency or gap that needs to be
11 addressed?

12 Next, please.

13 The missing value in Appendix B.

14 In '93, why in 30.35 wasn't the reference
15 to Appendix C, Part 20, kept, as it would have referenced
16 the new version of the appendix? Or why wasn't Appendix
17 B, Part 30, amended to be consistent with the new
18 C -- they had the same title -- with the value for
19 germanium-68?

20 Next, please.

21 So, the fourth question is, why does the
22 insufficiency or gap warrant being addressed? The FDA
23 and the NRC are both responsible for the regulation of
24 radiopharmaceuticals, but this responsibility has to be

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1 balanced, in that on one side of this responsibility is
2 to ensure the safe and effective use, but the other
3 side's responsibility is to avoid creating artificial
4 barriers and unnecessary barriers to the use of these
5 drugs.

6 Next, please.

7 Patient access. The last question,
8 please. Why is a change needed if there is no gap to
9 be addressed?

10 Next, please.

11 The gap does exist and it has very expensive
12 consequences.

13 Next slide, please.

14 So, still thinking about alternates and
15 guidance, and I really think a DFR would be the best
16 route, but if the NRC wants a choice, what if the NRC
17 were to reconsider this generator as a sealed source
18 within a device? As such, we could avoid the DFP
19 requirements.

20 So, if you looked at the current sealed
21 source device guidance -- next, please -- which is
22 NUREG-1556, it could fit as a custom sealed source or
23 device. As a custom, what is attractive here in the
24 guidance, if it stays under 200 millicuries, which it

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1 could, and if the reviewer decides applicant has
2 training and experience to handle the material in
3 unsealed -- that is not a typo -- unsealed form, one
4 would not have to rely on the intrinsic safety of the
5 sealed source to demonstrate compliance. It just sits
6 there. That is all it does.

7 Next, please.

8 Or it could fit under a sealed source and
9 device for medical uses. Now, currently, in guidance
10 for medical use, it says the device has to have one of
11 four types of FDA approval, and it won't have any of
12 these four types.

13 But this is NRC guidance, not FDA guidance.
14 So, it could be revised to include the generator as a
15 medical source device.

16 If the guidance is revised, it is now a
17 sealed source device where it could fit in the
18 regulations. It could fit under 32.74, and I expressly
19 want to read in Section (a)(2)(iii) where "results of
20 the prototype testing demonstrate that the source of the
21 device will maintain its integrity under stresses
22 likely" -- and that is underlined; emphasis has been
23 added -- "to be encountered in normal use." So, unlike
24 a sealed seed that is implanted into a patient, a much

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1 more stressful environment than what this will ever
2 encounter. This sits in a box.

3 Or, it could also fit under 35.1000, "Other
4 Medical Uses of Byproduct Material or Radiation from
5 Byproduct Material". It is definitely another.

6 Next slide, please.

7 So, let's address our last charge, effect
8 on clinical care because of a regulatory quirk, an
9 unintentional omission.

10 Next, please.

11 We know of a DFP's negative effect on three
12 licensees already in regards to research, the most
13 recent, a large, university-based hospital. And we
14 really can't say it any better than the RSO.

15 Next, please.

16 To paraphrase him: may prevent or deter
17 use due to the DFP's funding burden.

18 And as a reminder, we are getting closer to
19 clinical use here in the U.S. The DOTAs which are used
20 in NET patients, one of the DOTAs is already in active
21 discussions with the FDA to determine the best pathway
22 forward for approval, and you might remember, as an
23 orphan drug, this is not uncommon for the FDA to assist
24 sponsors for these orphan drugs.

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1 So, it is really not a question of if there
2 will be an approved gallium-68 drug, but really a
3 question of when. The zebra ribbon, the NET patient
4 groups use it for public awareness and as a metaphor for
5 the difficulty they experience in getting their disease
6 diagnosed. If you hear hoof beats, it may not be a
7 horse, but a zebra.

8 Next, please.

9 NET cancers are very difficult to diagnose.
10 After the onset of symptoms, which are often
11 non-specific and vague, a diagnosis can take an average
12 of three to seven years. It would be tragic for
13 patients in the U.S. who are suffering from
14 neuroendocrine disease to be given one more burden in
15 coping with their disease.

16 So, while this issue may not be
17 safety-significant in a traditional NRC way, i.e., a
18 risk of people or to the environment, I can guarantee
19 you it is very significant to the patients who suffer
20 with neuroendocrine disease.

21 Next, please.

22 I have added this web address to remind us
23 why we are here, as sometimes it is lost to get in the
24 regulations we come across. I urge you to check this

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1 out at a later time.

2 It is from a NET patient support group, and
3 there are pictures of patients holding out placards with
4 a number on it, and the number represents how long it
5 took them to get a correct diagnosis. It is really
6 pretty sobering, especially in this day and age of
7 modern medicine.

8 The NRC does have a responsibility, and
9 that is not to be burden to these or to any other
10 patients.

11 One more time, please. Thank you.

12 So, three cold facts to remember about our
13 iceberg: the drugs will be the first of the gallium-68
14 drugs here in the U.S. to be approved. Worldwide
15 interest is a big driving force. There will be more
16 gallium-68 drugs approved in the future, and it is time
17 for the NRC to act now and not later.

18 And at the base, again, the large potential
19 for theranostic or therapeutic drugs is also driving
20 interesting in gallium-68.

21 Next slide, please.

22 So, to summarize, to evaluate the cost of
23 a DFP, it is prohibitive. It is very expensive just to
24 create a DFP. They are specific to license. No two

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1 will be alike.

2 Next, please.

3 Relief.

4 Next, please.

5 A DFR, a Direct Final Ruling, or revised
6 guidance.

7 Next, please.

8 Will the future clinical use of new
9 radiopharmaceuticals be affected? Yes, it will, of
10 course.

11 First, the neuroendocrine tumor patients
12 will be affected, and then, more than likely, the
13 prostate cancer patients.

14 And really, I should put our little RSO
15 figure at the top, as his narrative and his experience
16 was invaluable for preparing this report, especially
17 his final words of "may prevent or deter use due to the
18 DFP funding burden".

19 We believe the NRC needs to act so as to
20 avoid the consequences of an unintentional omission in
21 the regulations from becoming an unintentional burden
22 on patient care. To eliminate this burden, we would
23 recommend that the NRC should notify the licensees as
24 soon as possible stating that "Regulatory relief from

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1 a DFP requirement for a gallium-68 generator is now in
2 progress. It will no longer be required. Effective
3 immediately, no licensee will be required to submit a
4 DFP for a gallium-68 generator."

5 Thank you.

6 CHAIR THOMADSEN: Thank you very much, Mr.
7 Mattmuller.

8 Comments from the Committee?

9 Yes?

10 MEMBER ZANZONICO: I just have a question.
11 You had mentioned that a DFP is not isotope-specific.
12 In other words, you have a DFP covering all the isotopes
13 in an institution?

14 MEMBER MATTMULLER: Right. In
15 everybody's situation right now, the DFP is triggered
16 by the possession of the gallium generator. But, once
17 you need a DFP, it, then, covers all radionuclides, all
18 locations under that license.

19 MEMBER ZANZONICO: So, that is why it
20 escalates the cost?

21 MEMBER MATTMULLER: Right, right, right.
22 It would be a much different situation if it was just
23 the box that is sits in.

24 MEMBER ZANZONICO: And one other question.

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1 There is no other regulatory vehicle, like a surety bond
2 or such a thing as that in place of an actual DFP? Or
3 are they the same thing?

4 MEMBER MATTMULLER: The surety bond is the
5 financial assurance portion --

6 MEMBER ZANZONICO: Okay.

7 MEMBER MATTMULLER: -- of the DFP.

8 MEMBER ZANZONICO: So, that would be a
9 component of the DFP?

10 MEMBER MATTMULLER: It is a component of
11 it, right.

12 MEMBER ZANZONICO: That is all part of it?

13 MEMBER MATTMULLER: Right.

14 CHAIR THOMADSEN: Mr. Costello?

15 MEMBER COSTELLO: There are a number of
16 elements. There is the cost estimate in which the RSO
17 had talked about he looked at all the labs that had
18 isotopes of a half-life longer than 120 days and you get
19 their area and look at their history, and so forth. And
20 you develop a cost estimate.

21 Then, you have the Decommissioning Funding
22 Plan, which is how you are going to fund the cost
23 estimate. And then, you have the instruments. So, you
24 are talking about a surety bond or whatever it is.

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1 These are all the instruments to fund the
2 Decommissioning Funding Plan.

3 CHAIR THOMADSEN: Thank you very much.

4 Dr. Mettler?

5 DR. METTLER: You keep saying this was an
6 unintentional omission.

7 MEMBER MATTMULLER: I believe so.

8 DR. METTLER: How do you know that? You
9 know, there are people who have been in the NRC forever,
10 I hear.

11 (Laughter.)

12 I mean, somebody did this. And so, there
13 must be some memory out there.

14 MEMBER COSTELLO: Remember that the
15 purpose of this table, this table has been back in Part
16 20 since the dawn of time, I mean, probably back to the
17 fifties, okay? It is a safety purpose. Okay? It is
18 telling you what qualities of radioactive material are
19 required to be labeled.

20 The purpose where these tables were shaded,
21 there was no requirement for financial assurance.
22 Okay? It was just to cite what has to put a label on
23 that bottle, or whatever. Basically, that was
24 considered to be a small quantity, a not-very-hazardous

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1 quantity.

2 And so, if financial assurance came along,
3 they didn't want to be reinventing the wheel and come
4 up with their own table. So, they said, "Oh, we'll use
5 that table as a multiplier of that table." I think the
6 lowest multiplier is 1,000 times, which you get your
7 certain amount of financial assurance, and you have to
8 have 10,000 times and 100,000 times, okay?

9 The purpose of the table, nothing to do with
10 financial assurance. My question from the very
11 beginning when we talked about this is, you have the
12 table in Part 20 and the table in Part 30 both saying,
13 you know, what the requirements are. Why have two
14 tables?

15 The original purpose of those tables is not
16 financial assurance. It is telling universities or
17 whatever when they have to label things. By and large,
18 they are all the same.

19 Of course, back in 1980, or whenever, there
20 was no energy jurisdiction. If there had been, we
21 wouldn't be having this problem, but there wasn't.

22 DR. METTLER: But, still, everybody is
23 sure that it was unintentionally --

24 MEMBER COSTELLO: Sure, I think you have a

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1 little bit of insight about there were some discussions,
2 maybe not?

3 MEMBER LANGHORST: As an RSO that went
4 through the new Part 20 implementation in the early
5 1990s -- I believe I was nine years old then -- it was
6 understood, I mean, I don't even remember the part about
7 Part 30 and that table changing.

8 But, in going back and re-reading that
9 Federal Register, I understood why the NRC wanted to use
10 the old values while implementation was happening with
11 the new Part 20 because licensees had the option to
12 implement it at any given point in time, I think, within
13 a two-year period.

14 But, at the end of that two years, you
15 assumed that that Part 30 table would, then, switch to
16 reference the new Part 20 Appendix C. But, instead, it
17 got put back into Part 30 and, unfortunately, in that
18 Federal Register the Part 30 table was not reprinted.
19 It just referenced it, and then, it appeared in the next
20 year's Code of Federal Regulations. So, that table
21 wasn't reprinted as the old table in Part 30 in that
22 Federal Register of the change of the final Part 20.

23 This also confusing, and I have been
24 confused by it as we have been reviewing it, because I

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1 thought a mistake was made, but then, no, it wasn't a
2 mistake. But it certainly is goofy.

3 DR. METTLER: Okay. Well, in any case, I
4 haven't heard for sure that it was unintended. I
5 haven't heard the proof that it was unintentional.

6 But, be that as it may, the next question
7 I would have is, if one isotope got lost, are there other
8 isotopes that have gotten lost? I'm sure there are. I
9 mean, how many isotopes are there in the Part 20 version?

10 MEMBER MATTMULLER: It is 600.

11 MEMBER COSTELLO: And how many in the Part
12 30 version?

13 MEMBER MATTMULLER: Less than 200.

14 (Laughter.)

15 I mean, but the question would be, of those
16 400, which have applications to nuclear medicine for
17 either diagnosis -- well, if they are going to have a
18 half-life greater than 270 days, they were thinking
19 therapy or such.

20 MEMBER COSTELLO: A hundred and twenty
21 days is like financial assurance. But maybe there are
22 isotopes in there that aren't being used now that
23 sometime in the future could be. I don't know.

24 DR. METTLER: Well, yes. I mean, it seems

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1 to me, if you are missing one that became useful, there
2 might be other ones that are missing that could become
3 useful. If you are going to fix this, why fix it for
4 just one as opposed the other potential issues?

5 MEMBER COSTELLO: I totally agree.

6 CHAIR THOMADSEN: Dr. Langhorst?

7 MEMBER LANGHORST: Fixing it would mean
8 rulemaking, and our children here around the table could
9 be discussing this. I think the relief right now that
10 is needed is for one identified isotope and the
11 encouragement to get this fixed on a wider basis for
12 future isotopes used in medicine would be helpful.

13 DR. METTLER: Okay, but it seems to me,
14 rather than calling this sealed source or whatever, the
15 simplest thing to do is say you need a number that is
16 going to get you to 50 in this table, period.

17 MEMBER COSTELLO: And take the number from
18 the other table, and they're good.

19 MEMBER MATTMULLER: If you take the number
20 from the newer version, from Appendix C, that will give
21 us a limit of 100 millicuries, which is twice the value
22 of a 50-millicurie generator.

23 DR. METTLER: And what would it take to put
24 the number from that table into this table? Or, I mean,

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1 that doesn't need a rule. That just needs somebody in
2 the Commission to go do it.

3 (Laughter.)

4 DR. HOWE: It requires rulemaking.

5 MEMBER MATTMULLER: To address your other
6 concerns --

7 CHAIR THOMADSEN: Yes?

8 MEMBER MATTMULLER: -- I also serve on the
9 Isotope Committee for the Society of Nuclear Medicine
10 and Molecular Imaging. To be honest, most of the time
11 we do talk about this little radionuclide called
12 molybdenum-99.

13 But this is where this issue came up a
14 couple of years ago with germanium. To my knowledge,
15 this is the only one on our radar screen, so to speak,
16 that has an almost-immediate medical/clinical use that
17 is going to be held back because of the DFP.

18 MEMBER COSTELLO: As some people have seen
19 my emails on this, okay, I say it is not the "what" or
20 the "why" that we are talking about; it is the "how".
21 I mean the "why" is very clear and the "what" is very
22 clear. The question is, what regulatory mechanism gets
23 us from here to there the fastest?

24 It is really an NRC question. You know, it

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1 is their rulemaking process. It is their everything
2 process. But it should be whatever is fastest to make
3 that number say 100 should be taken.

4 DR. WAHL: Hi. This is Dr. Wahl. I am
5 calling in. May I comment?

6 CHAIR THOMADSEN: Yes, please.

7 DR. WAHL: Yes. I'm Richard Wahl. I'm
8 Director of the Mallinckrodt Institute of Radiology in
9 St. Louis. I am a nuclear medicine physician and
10 radiologist.

11 I have looked at the discussion. I just
12 wanted to reiterate what Mr. Mattmuller has said. I was
13 a Co-Chair of the Third World Gallium Congress this past
14 Thursday, Friday, and Saturday in Baltimore. We had
15 over 200 scientific registrants and an additional 70
16 patient participants with neuroendocrine tumors.

17 From that meeting, it is abundantly clear
18 that the gallium-68 radioisotope will play an important
19 and growing role in patients with neuroendocrine tumors
20 and likely prostate cancer, as he pointed out.

21 And the neuroendocrine tumors are an orphan
22 indication. And the patent position on some of the
23 agents is not so clear. But it is quite clear that it
24 is a very limited market. The FDA has recognized this

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1 and provided some regulatory relief specific to orphan
2 drugs.

3 Clearly, the requirement for DFP for a drug
4 that is not used in very many patients is a huge burden
5 on academic medical centers or whoever has to install
6 the generators, perhaps commercial pharmacies.

7 But these stands clearly are better than
8 what we have available now. And interestingly, the
9 radiation death to patients from these particular types
10 of standards are substantially lower than from the
11 currently-available tests. The results are more
12 accurate and the patients have the results more quickly
13 and they are likely cheaper.

14 There are many good things and many reasons
15 to have this technology available. Certainly, I don't
16 think the NRC would want us not to have the methodologies
17 available. And this relief in some way from the DFP for
18 the germanium generators appears logical and
19 appropriate using methods that you can best figure out,
20 but it needs to be done expeditiously.

21 I had such a system up and using it in
22 patients at Johns Hopkins, where I worked until a few
23 months ago. I have recently moved to St. Louis, and we
24 would like to get this going here. We are working on

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1 it, but the cost of a DFP will be a barrier to our
2 implementing this, even at a large academic center.

3 So, I just wanted to reiterate how
4 medically important this is and how there are so many
5 barriers already; we really don't need one more to
6 prevent patients from receiving this isotope.

7 Thank you.

8 CHAIR THOMADSEN: Thank you very much.

9 We also have another caller who wanted to
10 make a comment.

11 Josh Mailman, are you on the line?

12 MR. MAILMAN: Yes, I am on the line. I am
13 Josh Mailman. I am the Chair of Patient Advocacy for
14 the Society of Nuclear Medicine, and I also run
15 501(c)(3) nonprofit for neuroendocrine support in
16 Northern California.

17 And I wanted to echo Dr. Wahl's comments as
18 well and also say that, while the incidence is rare, the
19 prevalence is actually much more widespread than we
20 think of. We have 150,000 patients in the United States
21 that are living with neuroendocrine tumors.

22 With the very short half-life of
23 gallium-68, it will mean that the gallium-68 will need
24 to be produced near where the patients are as opposed

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1 to having it shipped in, like we are currently doing with
2 indium-111. So, it will be of great patient benefit to
3 have it near where the patients live and not just at
4 certain compounding pharmacies or pharmacies that can
5 send things out to different centers. So, it is
6 challenging if it is just going to be at a couple of very
7 large centers around the United States and not have
8 access at the regional locations as well.

9 CHAIR THOMADSEN: Thank you very much.

10 I think we have a comment here.

11 MS. BUNNING: Okay, thank you.

12 I am Sue Bunning. I am with the Society of
13 Nuclear Medicine and Molecular Imaging.

14 I think everything pretty much has been
15 said. I want to thank the Committee that has looked at
16 this. This is a very important issue to the Society.

17 I think, Steve, you mentioned the Committee
18 within SNMMI that has been working on this. He's right,
19 this is the only isotope that has been brought to our
20 attention. We are hearing a lot on this issue.

21 The Theranostic Congress last week, I also
22 had the pleasure of attending it. And Dr. Wahl is
23 right, there were about 300 folks there. In addition
24 to the patients asking often, "Okay, what's happening

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1 at the FDA to get this through," we receive a lot of
2 questions about why do we still have to keep going to
3 Europe.

4 And the patients often encounter problems
5 with their travel. I think Josh on the phone could fill
6 you in on some of those.

7 But they want to see this widely used in the
8 United States. Right now, I believe there are
9 approximately 10 or 11 centers that are under IND. But
10 our hope is that this gets widely distributed throughout
11 the United States and the patients will have access to
12 this.

13 So, thank you. We support the work that
14 you are doing, and thank you very much for letting me
15 speak.

16 CHAIR THOMADSEN: Thank you.

17 I think the case has made that we should try
18 to do something about this. And I will put it to the
19 NRC: what would be the most efficacious way to address
20 the issue?

21 MR. BOLLOCK: Yes, that is a tough one to
22 answer, which would be the fastest. I mean, there are
23 options. There are multiple options. Petitions for
24 rulemaking. There are requests for relief from the DFP

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1 and giving the reasons why. And, yes, us going through
2 and changing our guidance documents. I don't know
3 which one has the shortest timeline. A lot depends on
4 what is the process and how much we have backing any
5 opposition, especially for the rulemaking, any
6 opposition.

7 CHAIR THOMADSEN: Mr. Mattmuller, you had
8 a comment?

9 MEMBER MATTMULLER: Right. So, I would
10 like to ask, is it possible that why don't we let staff
11 figure out what is the preferred route they would like
12 to go to get relief? Can the Commissioners put out a
13 notice saying that relief is coming and, effective
14 immediately, you no longer have to pay attention to DFP
15 requirements, as in the future it won't be required?

16 MR. BOLLOCK: We do have a few options. I
17 know I can think of one option.

18 Sophie, do you want to chime-in?

19 MS. HOLIDAY: I just want to say, as the
20 Subcommittee knows, I was the appointed NRC contact
21 person for this Subcommittee. And so, while the
22 Subcommittee was doing their research, and Dr.
23 Langhorst made the trail on all the old Federal Register
24 notices, I did speak to some of our counterparts here.

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1 Originally, it was believed that there was
2 an omission. Some staff had believed that was the case;
3 other staff did not.

4 So, I think it would be inappropriate to
5 expect for the Commission to issue something to say, "We
6 will grant relief immediately." Because, just like
7 anything, you have to do your research very thoroughly
8 before you go out and do anything like that.

9 It is also like when NRC publishes
10 Regulatory Issue Summaries or Information Notices, you
11 can't just do it on a whim. You have to make sure you
12 are putting out the correct information.

13 So, Sophie's suggest would be for the
14 Committee to put forth a recommendation. And that way,
15 we can say the ACMUI has made this recommendation. And
16 that would give us the language that we need to go forth
17 and say, "Hey, given what our priorities are, how can
18 we fit this in? Because we have heard from the ACMUI.
19 We have heard from members of the public. We have heard
20 from professional organizations regarding this
21 generator. What do we do now?" So, that would be my
22 suggestion.

23 MEMBER COSTELLO: Can the NRC recommend to
24 the Committee what we can recommend to you for the "how"?

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1 Because we don't know the "how" as well as you folks do.

2 MR. BOLLOCK: Right, and, I mean, the "how"
3 would be -- you could recommend to us to find out what
4 our options are, and then --

5 MEMBER COSTELLO: We can do that now.

6 (Laughter.)

7 MR. BOLLOCK: That's right. Like I said,
8 I mean, there are options.

9 MEMBER COSTELLO: I don't know a "how,"
10 but --

11 CHAIR THOMADSEN: Dr. Langhorst?

12 MEMBER LANGHORST: A question I have on the
13 request for relief, is that a licensee-by-licensee
14 request or --

15 MR. BOLLOCK: I believe so. I believe it
16 is licensee-to-licensee, unless we did come up -- I know
17 Sophie mentioned the RIS, Regulatory Information
18 Summary -- unless we saw a number of those or a group
19 got together and put it in. That may be a pathway that
20 we would like to take.

21 MEMBER COSTELLO: And the solution has to
22 work in the Agreement State, which is where the
23 licensees are.

24 MR. BOLLOCK: Uh-hum.

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1 MS. HOLIDAY: I would also like to point
2 out that at the last meeting Ms. Dudes, she did a lot
3 of contribution for the discussions that took place.
4 And she said, in order for us to move forward with any
5 type of action, we need to know how many potential
6 licensees does this affect. And without us knowing, to
7 say, "Oh, there are three institutions that this
8 impacts," NRC wouldn't necessarily, to be efficient, we
9 wouldn't just say, "Here's a blanket exemption." But,
10 if it is only three, then those three individual
11 institutions may get relief on an individual basis. It
12 is kind of like when we do exemptions. It is on a
13 case-by-case basis.

14 But, if we do truly believe that it is
15 affecting a wide range of licensees, we have to be able
16 to make that justification. Similar to how we do our
17 rulemakings, a regulatory basis has to be formed.

18 CHAIR THOMADSEN: Right, although we do
19 have the problem that, if you are looking at how many
20 licensees this may affect, you are not getting any data
21 on those people who would be licensees but are being
22 deterred by the current regulations.

23 MS. HOLIDAY: Right.

24 MEMBER MATTMULLER: Right. It is sort of

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1 like a-chicken-or-an-egg question. But the three I
2 mentioned were involved in research. And so,
3 technically, we don't have an approved drug yet. So,
4 we don't know about the official effect on clinical use.

5 And I attended the meeting last weekend,
6 too. If you see the interest that these new drugs
7 generate, you know it is going to happen. So, when it
8 does happen, I would hate to see this requirement slow
9 it down.

10 CHAIR THOMADSEN: Dr. O'Hara?

11 MEMBER O'HARA: So, the drug isn't
12 cleared, isn't approved by CDER yet?

13 MEMBER MATTMULLER: Not yet, no.

14 MEMBER O'HARA: Is there an indication
15 where it is in the review?

16 MEMBER MATTMULLER: I don't know the exact
17 answer to that question.

18 MEMBER O'HARA: Yes. I was just
19 wondering.

20 MEMBER MATTMULLER: Yes.

21 MEMBER O'HARA: Because once CDER would
22 approve it, approve the drug, my estimation would be
23 there would be a lot more demand.

24 MEMBER MATTMULLER: Right. Of course.

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1 In the DOTAs' advantage, in their corner, I mean, they
2 have extensive data. They have been used for over a
3 decade in Europe. So, there is a lot of safety and
4 efficacy data already generated for the drug. So, it
5 is not like they are reinventing the wheel for the data
6 to support the application.

7 CHAIR THOMADSEN: The big rush will come
8 when CMS approves it.

9 Yes, Dr. Langhorst?

10 MEMBER LANGHORST: So, you don't have
11 any -- do you think in a year? It could happen next
12 month? You really don't know?

13 MEMBER MATTMULLER: That's a question I
14 would to love ask the FDA representative to answer.

15 MEMBER O'HARA: And I can't answer it.

16 MEMBER MATTMULLER: So, no, no.

17 MEMBER O'HARA: I can't answer it now.

18 MEMBER LANGHORST: Right. And even if he
19 could, he couldn't.

20 (Laughter.)

21 MEMBER MATTMULLER: Well, that is a whole
22 other issue, yes.

23 MEMBER LANGHORST: A recommendation that I
24 might suggest is that we have an ACMUI teleconference

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1 soon, like in the next two months, that NRC staff can
2 come back and provide us with what are the "how's" that
3 we can follow.

4 CHAIR THOMADSEN: I think that is a good
5 idea, but I will amend that to suggest that the Committee
6 go back to work, and maybe based on European experience,
7 try to come up with an estimated number of potential
8 licensees that there may be who would want to do this.

9 And with the support staff member -- do you
10 have a support staff member yet?

11 MEMBER MATTMULLER: Yes, Sophie.

12 MEMBER LANGHORST: Sophie is that support
13 staff.

14 MEMBER MATTMULLER: Of course.

15 CHAIR THOMADSEN: With the help of your
16 support staff person, consider the possible remedial
17 actions that could be taken to provide relief, to make
18 a recommendation to this Committee. So that, when we
19 do have our call, we have something to work with, rather
20 than just start talking.

21 Ms. Weil?

22 MEMBER WEIL: Would it also make sense to
23 have statements from the related professional societies
24 supporting the changes that we are suggesting, to add

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1 those to our recommendation?

2 CHAIR THOMADSEN: Oh, I will ask Mr.
3 Bollock. Should they bother with that now?

4 MR. BOLLOCK: Well, I think the more people
5 you have behind it, it gives more weight to the broad
6 scope. And so, three licensees -- if there is more
7 interest --

8 CHAIR THOMADSEN: Dr. Mettler?

9 DR. METTLER: Me knowing nothing about the
10 process, so if three groups ask for exemption -- is that
11 what you are calling it? -- and they got it -- well,
12 first, I don't know how difficult it is to apply for an
13 exemption and get it. But, if you did that and got it,
14 regardless of all this other process of trying to figure
15 out what is going to happen in the future, the door would
16 be cracked open already. And it would seem to me that
17 would make the rest of the process go a lot quicker
18 later.

19 So, do you see what I'm saying? I mean, I
20 just don't know how difficult it is to get the exemption.
21 But, once one person has the exemption or two --

22 CHAIR THOMADSEN: Ms. Cockerham, do you
23 have a comment on that?

24 MS. COCKERHAM: Yes, just a general

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1 comment. Just from being around for a little while, I
2 don't see OGC in the audience here, but they will not
3 regulate by exemption. That is not a model that we use.

4 And so, the idea that the door would be
5 cracked open and, then, the others could follow, it
6 would be case-by-case and it wouldn't necessarily be
7 based on precedent. And they are very, very hesitant
8 to let us -- like I said, that is wide open, like we will
9 not regulate by exemption. They will prefer that we go
10 rulemaking or --

11 CHAIR THOMADSEN: Mr. Costello?

12 MEMBER COSTELLO: I believe that one of the
13 institutions that thought about using it is in
14 Pennsylvania. And they did, in fact, ask us for an
15 exemption, and we said no, not me personally,
16 but -- (laughter) -- me, institutionally, said no.

17 If the NRC grants an exemption to one of
18 its licensees, I think that would make the Agreement
19 States much more comfortable in granting exemptions.
20 But, if the NRC has never granted an exemption, it would
21 be highly unlikely that we are going to be on the cutting
22 edge of exemption-granting.

23 (Laughter.)

24 CHAIR THOMADSEN: Thank you for that

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1 comment.

2 Do we have any other comments?

3 (No response.)

4 In that case, maybe what we also might do
5 is, at our closing when we find dates for our next
6 meeting, we also find a date for the conference call
7 covering this, while we are all here. I think that will
8 make Sophie's life a little easier.

9 Yes?

10 MS. THOMAS: I'm on the phone line.

11 CHAIR THOMADSEN: Yes?

12 MS. THOMAS: Are you open for public
13 comment?

14 CHAIR THOMADSEN: On this topic?

15 MS. THOMAS: This is Ruth Thomas.

16 CHAIR THOMADSEN: Yes?

17 MS. THOMAS: And I have been listening with
18 interest. I would like to ask for -- I am afraid it has
19 to be hard copy because I don't have a computer -- but
20 I would like to have either a transcript or the
21 information that has been presented today, so that this
22 can be made available to members of the public.

23 CHAIR THOMADSEN: I think that that can be
24 arranged. Usually, the transcripts are reviewed and

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1 approved within, I think, 90 days of the meeting.

2 Is there a way for her to leave a telephone
3 number or an address with somebody?

4 MS. THOMAS: Well, this last part seems
5 like it was going into a new area, and the gentleman that
6 presented that, is he going to be making that available?

7 CHAIR THOMADSEN: I'm sorry, what did you
8 just ask? Is he going to be what? Oh, are your slides
9 available?

10 MS. THOMAS: The gentleman that came
11 on -- I didn't catch his name -- and presented this
12 different idea.

13 CHAIR THOMADSEN: Uh-hum. Could we get
14 the hard copy of the slides along with the transcript
15 sent?

16 MS. HOLIDAY: Yes. Ms. Thomas, I know
17 that you have my contact information. So, please feel
18 free to call me.

19 But, for everyone that is listening in, all
20 of the handouts, which includes the meeting slides for
21 all of the presenters, the meeting transcript, and the
22 meeting summary are posted onto the ACMUI meetings web
23 page, which you can access through nrc.gov. And if you
24 do a search for "ACMUI" or even if you go to Google and

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1 you just type in "ACMUI meeting," the link will pop up
2 very quickly.

3 MS. THOMAS: Well, thank you very much. I
4 appreciate that.

5 MS. HOLIDAY: You're welcome.

6 CHAIR THOMADSEN: Certainly.

7 MR. MAILMAN: Just so you know, this is
8 Josh Mailman again.

9 Your actual web page went dead about 10
10 minutes ago, in case anyone is there. Actually, I see
11 that it is connection lost.

12 Thank you.

13 CHAIR THOMADSEN: Thank you. But you have
14 been able to be on the telephone line, it sounds like?
15 Is that true?

16 MR. MAILMAN: Yes, the telephone line
17 stayed alive. So, I have been on both.

18 CHAIR THOMADSEN: Okay. Thank you for
19 that information.

20 Any other comments? Hearing none -- yes?

21 MR. BOLLOCK: I just want to add -- and this
22 is on a personal safety basis -- with the forecast for
23 tomorrow, the potential snow in the morning, so there
24 is a potential for a mix of snow and rain; there is the

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1 possibility that the government will have a two-hour
2 delay. But we will still be able to start on time at
3 8:30 tomorrow morning.

4 And just a note for all of you here who have
5 traveled, be careful, be safe out there.

6 CHAIR THOMADSEN: Thank you for that
7 warning.

8 (Laughter.)

9 Any other announcements?

10 Yes?

11 MEMBER COSTELLO: Move to adjourn.

12 CHAIR THOMADSEN: What's that?

13 MEMBER COSTELLO: Move to adjourn.

14 CHAIR THOMADSEN: We're going to, then,
15 adjourn until 8:30 tomorrow morning, where we plan on
16 meeting promptly.

17 (Whereupon, at 5:28 p.m., the meeting
18 adjourned, to reconvene the following day, Friday,
19 March 20, 2015, at 8:30 a.m.)

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