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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 T2-B3
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.

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1 Present today as the alternate designated
2 federal officer is Sophie Holiday, our ACMUI
3 coordinator.

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

8 This meeting is being transcribed by the
9 NRC and it may also be transcribed or recorded by
10 others. The meeting was announced in the January
11 27th, 2015 edition of the *Federal Register*, Volume
12 80, pages 4319 through 4320.

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

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

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

3 Our Chairman, Dr. Bruce Thomadsen,
4 therapy medical physicist.

5 CHAIRMAN THOMADSEN: Present.

6 MR. BOLLOCK: Our Vice Chairman, Dr.
7 Philip Alderson, health care administrator.

8 VICE CHAIR ALDERSON: Here.

9 MR. BOLLOCK: Mr. Frank Costello, our
10 Agreement State representative.

11 MEMBER COSTELLO: Here.

12 MR. BOLLOCK: Dr. Vasken Dilsizian, our
13 nuclear cardiologist.

14 MEMBER DILSIZIAN: Present.

15 MR. BOLLOCK: Dr. Ronald Ennis, radiation
16 oncologist.

17 MEMBER ENNIS: Here.

18 MR. BOLLOCK: Dr. Sue Langhorst,
19 radiation safety officer.

20 MEMBER LANGHORST: Here.

21 MR. BOLLOCK: Mr. Steve Mattmuller,
22 radiation pharmacist.

23 MEMBER MATTMULLER: Here.

24 MR. BOLLOCK: Dr. Michael O'Hara, our FDA
25 representative.

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1 MEMBER O'HARA: Present.

2 MR. BOLLOCK: Dr. Christopher Palestro,
3 our nuclear medicine physician.

4 MEMBER PALESTRO: Present.

5 MR. BOLLOCK: Dr. John Suh, radiation
6 oncologist.

7 MEMBER SUH: Here.

8 MR. BOLLOCK: Ms. Laura Weil, our
9 patients' right advocate.

10 MEMBER WEIL: Here.

11 MR. BOLLOCK: And Dr. Pat Zanzonico, our
12 nuclear medicine physicist.

13 MEMBER ZANZONICO: Here.

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

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

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

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1 access the bridge line is 70873#.

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

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

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

25 At this point I'd like to turn the meeting

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1 over to Laura Dudes, Director of the Division of
2 Materials Safety, States, Tribal and Rulemaking
3 Programs for some opening remarks.

4 MS. DUDES: Good morning.

5 ALL: Good morning.

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

8 (Laughter.)

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

12 (Laughter)

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

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

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

25 Doug, although he's been with us since

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1 last February in an acting capacity, I believe, he's
2 now the permanent branch chief for the Medical Safety
3 Branch.

4 Chris Einberg, who was the former branch
5 chief, has graciously taken over our Agreement State
6 Branch, and so he's part of our team still, but he's
7 doing another function for us now.

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

15 (Laughter.)

16 MS. DUDES: But really fantastic news
17 about this change is the person coming in to replace
18 me is someone who has done this job for years and
19 years and years in various capacities. It's Josie
20 Piccone. If I'm not sure if you are familiar with
21 her, but she has an extensive background in both
22 medical, health physics, state and tribal programs,
23 rulemaking, and has done -- even though the division
24 has merged and taken on different functions,
25 truthfully Josie has done all of them. And so that

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1 will be a seamless transition. I know she will be
2 very supportive of the Committee and I think you'll
3 enjoy having her. As I sit here and listen to the
4 presentations and I'm fascinated, interested and
5 getting myself educated, she has a very strong
6 background in this area. So it will be very good for
7 the division.

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

13 (Laughter)

14 MS. DUDES: But anyways, Pamela Henderson
15 should be here with you tomorrow.

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

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1 enjoyed it.

2 With respect to this Committee, I would
3 say that I keep encouraging that as much open
4 dialogue, as much direction as you can give the staff,
5 keep it coming and use the open forums. Use your
6 experience. Bring it here and help the staff craft
7 regulations that are supportive of the public health
8 and safety, supportive of the workers, but not
9 intrusive in the practice of medicine. Those are the
10 most difficult issues that we have on any given day
11 is looking at an event that occurred as a result of
12 a treatment that is doing so much good for an
13 individual and balancing how the staff reacts.

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

24 So I do want to thank you all very much
25 for helping me understand the line between regulatory

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1 and the practice of medicine and teaching me a little
2 bit. I think I'm smarter now. And I know I will
3 actually be a better patient, hopefully, or a patient
4 advocate having had the opportunity to work with you.

5 So with that, I will turn it over to the
6 Chair.

7 CHAIRMAN THOMADSEN: And on behalf of the
8 Committee I can say we've much enjoyed working with
9 you. We've appreciated your openness and your
10 concern. And we will miss you. We wish you well in
11 your new position.

12 MS. DUDES: Thank you.

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

17 (Laughter.)

18 CHAIRMAN THOMADSEN: Is this your first
19 -- you were here last meeting.

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

21 CHAIRMAN THOMADSEN: This is your first
22 meeting. Oh my gosh. Well, welcome definitely to
23 you, too.

24 MEMBER O'HARA: Thank you.

25 CHAIRMAN THOMADSEN: And I hope you, like

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1 everybody else, enjoy the work here.

2 MEMBER O'HARA: I'm sure it will be an
3 experience.

4 CHAIRMAN THOMADSEN: Yes.

5 (Laughter.)

6 CHAIRMAN THOMADSEN: It certainly will be
7 that, yes.

8 We start out with old business and Ms.
9 Holiday.

10 MS. HOLIDAY: Good morning, everyone.
11 As I like to say, I know this is your most favorite
12 part of the meeting when we go over our old
13 recommendations and actions.

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

18 So on the screen we have 2007, and there's
19 nothing different on here than it was in the fall
20 meeting. All these items are included in the current
21 Part 35 rulemaking.

22 So then we can move on to 2008. And in
23 2008 the same thing as last September's meeting. All
24 of these are included in the current Part 35
25 rulemaking with the exception of items 5, 19 and 20.

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1 Those are delayed, meaning they are not included in
2 the current rulemaking.

3 Then we move on to 2009. Same thing as
4 last meeting. These two items are in the current
5 Part 35 rulemaking.

6 2010 is not included in this list because
7 we did close all of those items.

8 For 2011 all of these are included in the
9 Part 35 rulemaking.

10 And then we move on to 2012. There's
11 only one item and that was to say that ACMUI requested
12 the reporting structure be reviewed on an annual
13 basis. Since this is an ongoing item, that just
14 forever stays open on this list. And we will hear
15 about that from me in this meeting.

16 So we move on to 2013. 2013, this was
17 when the Committee worked on providing their comments
18 on the current Part 35 rulemaking. So, all of these
19 are included in the Part 35 rulemaking with the
20 exception of items 21 and 25. Twenty-one has to deal
21 with the germanium/gallium-68 generators, which we
22 will hear from Mr. Mattmuller's subcommittee report
23 later on this afternoon. And item 25 was just to
24 reestablish the Rulemaking Subcommittee. As the
25 Committee is aware, when the current Part 35

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1 rulemaking gets ready to go into the draft final
2 stage, that will come back to the Committee for their
3 review. You will also hear more about the rulemaking
4 status from Ms. Neelum Bhalla later on.

5 So then we move on to 2014. So again for
6 the first item that has to deal with Mr. Mattmuller's
7 subcommittee. Again, we'll hear from them later on
8 today. And for items 10, 11, 12 and 13 this has to
9 deal with the Y-20 Microspheres Medical Event
10 Reporting Criteria Subcommittee report. And staff is
11 currently in the process of reviewing and evaluating
12 those recommendations. As you all are aware, Ms.
13 Cockerham was on rotation during the time, and we
14 have to learn to balance priorities, but we are
15 currently evaluating those recommendations.

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

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

22 Item 19, Dr. Thomadsen formed the
23 subcommittee to address the AMPR for Part 20. The
24 Committee had a public teleconference on December
25 10th, 2014 where we received the subcommittee's

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1 report which was endorsed by the full ACMUI. And
2 that report was received in its final form with the
3 minor comments or changes that were suggested during
4 that public teleconference and distributed in January
5 of this year.

6 Then you move on to item 20. Item 20 had
7 to deal with the time where we had heard about the
8 draft legislation that went to the Appropriations
9 Committee with the Water and Energy Bill. At that
10 time Dr. Thomadsen had asked Dr. Suh and Dr. Welsh,
11 our former ACMUI radiation oncologist, to also work
12 with -- not at that time, but is now our current
13 radiation oncologist, Dr. Ennis, to pair with ASTRO
14 to address providing language to make changes to that
15 bill. That has actually -- let's see, NRC was issued
16 in Section 402 of our appropriations. We were
17 directed to assess our current Part 35.

18 MS. DUDES: Part 37.

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

25 MS. DUDES: Well, I would suggest maybe

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1 that during the meeting if you wanted to reformulate
2 or rethink that action item for a longer-term view
3 -- I think we talked about -- the original draft
4 legislation was challenging and very directive. And
5 now we have a piece of legislation that tells us to
6 see if the source security rule -- do an assessment
7 of it after two years of implementation.

8 But there may be other issues that the
9 Committee would want to consider around the idea of
10 alternative technologies or source security. And I
11 would leave that up to you. You could close that
12 because the appropriations came and the language was
13 very simple. It just said do a two-year assessment
14 of Part 37. Report back to Congress and then direct
15 the GAO to do an audit with an independent.

16 So that sort of addresses the immediate
17 issue. But there are broader issues to source
18 security. And I think more for the medical community
19 in terms of the status of alternative technologies,
20 what's viable for various therapies or diagnostics or
21 blood irradiators. So I would suggest you close that
22 item because it was very specific to language if the
23 Committee believes that to be the case, but consider
24 if there's anything else you would like to pursue
25 over this period of time related to source security.

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1 And I guess it's the viability of alternative
2 technologies, but it's also impacts to the medical
3 community if there were to be a different set of
4 security requirements. So I would just leave that
5 back to you.

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

9 MEMBER LANGHORST: So moved.

10 CHAIRMAN THOMADSEN: We have a motion.
11 Do we have a second?

12 MEMBER COSTELLO: Second.

13 CHAIRMAN THOMADSEN: We have a second.
14 Discussion? Yes, Dr. Langhorst?

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

19 (Laughter.)

20 MEMBER LANGHORST: And, yes, I'd be glad
21 to.

22 (Laughter.)

23 CHAIRMAN THOMADSEN: Okay. That will
24 come up just a little bit later. Any other
25 discussion? You've already volunteered. Dr.

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1 Langhorst?

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

4 (Simultaneous speaking.)

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

7 Hearing none, all in favor, say aye?

8 (Chorus of ayes.)

9 CHAIRMAN THOMADSEN: Opposed, say no.

10 (No response)

11 CHAIRMAN THOMADSEN: Abstentions?

12 (No response)

13 CHAIRMAN THOMADSEN: It passes. We'll
14 close that particular item.

15 MS. HOLIDAY: Excellent. Thank you.
16 Then that brings us to the last item on this chart
17 which is again dealing with the ANPR for Part 20
18 simply to say that the Full Committee endorsed the
19 subcommittee report.

20 Are there any comments or questions or
21 concerns with any of these recommendation action
22 charts?

23 CHAIRMAN THOMADSEN: Dr. Langhorst?

24 MEMBER LANGHORST: I just wanted to
25 clarify on the 2007-2008 when you say things are part

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1 of the Part 35 rulemaking --

2 MS. HOLIDAY: Yes.

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

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

8 MEMBER LANGHORST: Right. Right. And
9 also that while some of your -- you mentioned that
10 some of our recommendations are part of Part 35, they
11 weren't accepted. For instance, the Committee
12 strongly encouraged that all people with board
13 certifications be approved as authorized individuals
14 whenever their board certification happened. And I
15 don't think that was in the proposed Part 35. And
16 also the fact that the parental administration of
17 betas versus alphas, we suggested that not be
18 separated, but it was in the proposed Part 35. So
19 while they were included, they weren't accepted. So
20 I just want to make those --

21 MS. HOLIDAY: I'd also like to respond to
22 that and say so when I say they're included in the
23 current Part 35, it's, as you said, not exactly to
24 say that we have accepted them, but as you know, this
25 is still the draft proposed rule. So it's not final

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1 yet. Staff may send it up as certain way and the
2 Commission may come back and say we don't want it
3 like that. But the Rulemaking Group will address all
4 of the recommendations, all of the comments. So there
5 is -- and Neelam will speak to the Committee later on
6 to tell you that the working group is currently
7 addressing all of the comments that we received. As
8 you all know, the comment period ended November 18th
9 of 2014, so that working group is working very
10 vigorously to address all of the comments that were
11 received.

12 MEMBER LANGHORST: Right. I just wanted
13 to clarify that they were made part of 35, but they
14 weren't all accepted.

15 MS. HOLIDAY: Absolutely. Absolutely.

16 Okay. Are there any other comments,
17 questions or concerns regarding these charts?

18 Doesn't seem to have any. Thank you very
19 much, Ms. Holiday.

20 MS. HOLIDAY: Great. Thank you.

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

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1 MEMBER ZANZONICO: Good morning,
2 everyone. I had several issues that came to mind
3 when I saw this agenda topic. The first is the MIRD
4 Committee of the Society of Nuclear Medicine
5 Molecular Imaging. They're going to be publishing a
6 monograph on alpha particle dosimetry. And it's
7 clear from the literature they compiled and their
8 review that there's a real future for alpha particle
9 emitters in radionuclide therapy. And it struck me
10 that when the Committee was considering the licensing
11 requirements for radium-223 dichloride.

12 My recollection was that we, the NRC,
13 stopped short of the licensing requirements across
14 all alpha particle emitters, but rather restricted
15 what was decided specifically to Xofigo. And I think
16 a broader licensing for all alpha emitters consistent
17 with what was decided for Xofigo should be considered,
18 because I think again there will be a real future for
19 alpha particle emitters in nuclide therapy.

20 CHAIRMAN THOMADSEN: Sophie, can you
21 clarify, was our decision specifically for that
22 particular radiopharmaceutical? I think it was not.

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

24 MEMBER ZANZONICO: I thought there was
25 some discussion to that effect, and correct me if I'm

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1 wrong.

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

4 CHAIRMAN THOMADSEN: Please.

5 DR. HOWE: In the Part 35 rulemaking
6 we're addressing alpha emitters used in nuclear
7 medicine in general. When the Xofigo was looked at,
8 it was looked at in particular because it was the
9 only one. And we were looking at its properties and
10 how it could be used. So I do believe the answer is
11 both. We looked at Xofigo and all of the things that
12 we knew about it, and then we're looking at alpha
13 emitters being used primarily for alpha emitters in
14 a more general term for the rulemaking. Does that
15 answer the question?

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

20 MEMBER ZANZONICO: Understood. So I had
21 several more items.

22 CHAIRMAN THOMADSEN: Yes?

23 MEMBER ZANZONICO: One is the propriety
24 and value of dose tracking. In other words, I guess
25 in Europe they characterize it as a smart card where

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1 the cumulative radiation doses received by patients
2 from diagnostic studies is recorded for some purpose.
3 And I think as you are suggesting or -- we should
4 actively engage the staff in timely issues. And I
5 think this is one that if it's not timely yet, will
6 become timely, the issue of whether there's value,
7 propriety, etcetera, etcetera in a dose tracking
8 practice and so forth. It may be a bit broader than
9 usual topics addressed by the NRC, but I think we
10 have an opportunity to make a statement on it and I
11 would encourage the ACMUI to do so.

12 And perhaps a related issue, there was an
13 editorial several years ago by Hedvig Hricak, who's
14 the chairman of radiology at Memorial, and David
15 Brenner which stopped short of recommending
16 regulatory dose limits for diagnostic imaging
17 procedures. And that might be a companion issue
18 that's worth considering and staking some position
19 on.

20 And the last item which I'll be speaking
21 about, which is disposition of radioactive cadavers
22 following either brachytherapy or radionuclide
23 therapy. And I was struck as I was researching the
24 topic for my talk about how sparse and, for lack of
25 a better term, ill-defined the regulatory guidance is

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1 on the topic. So I presume, or I hope that my talk
2 today will sort of be the initial effort in
3 formulating, for lack of a better term, more helpful
4 guidelines for disposition of radioactive cadavers.
5 When I originally was looking into it I thought it
6 was simply a non-issue, but there's some technical
7 complexities that warrant further attention. So
8 those would be my suggestions in terms of issues to
9 address in the near future.

10 CHAIRMAN THOMADSEN: Thank you very much,
11 Dr. Zanzonico.

12 Do we have other recommendations? Yes,
13 Dr. Mettler.

14 DR. METTLER: Just on the dose tracking
15 issue, if anybody's starting to look into it, of
16 course the National Academy just had a whole workshop
17 on it and they published a whole document on it
18 recently that included radiology and nuclear medicine
19 and everything else. It's got some issues.

20 CHAIRMAN THOMADSEN: Yes.

21 DR. METTLER: The other thing is down the
22 road -- I don't know enough about this, but I've seen
23 research proposals lately about nanotechnologies to
24 go with nuclear medicine therapy. And so people are
25 working on it. And I don't know enough about

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1 nanotechnology to understand exactly what they're
2 doing, but I don't know whether there's any safety
3 issues or regulatory issues that ought to be looked
4 at.

5 CHAIRMAN THOMADSEN: Very good. I'll put
6 that down definitely. We are working on that at
7 Wisconsin. Yes, good topic.

8 Any others? Dr. Langhorst?

9 MEMBER LANGHORST: We will be having a
10 speaker later at this meeting concerning the
11 licensing guidance for Part 35.1000. And that might
12 be something that the Committee would want to take up
13 on some of the older licensing guidance documents to
14 maybe -- if they haven't been brought before us to
15 kind of step through those and see where things stand
16 on those. So that would be my suggestion.

17 CHAIRMAN THOMADSEN: Very good. Thank
18 you.

19 VICE CHAIR ALDERSON: Dr. Alderson here.
20 This is a part where I thought maybe Ms. Langhorst
21 was going to explore what she said a few moments ago,
22 but this issue of source security is an area of great
23 interest to me and I support her interest in that.
24 And I think this Committee shouldn't stop discussing
25 it. Even though the Water and Energy Bill has kind

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1 of made it a set-aside momentarily, I think it's a
2 very important issue to discuss going forward.

3 CHAIRMAN THOMADSEN: Thank you. Any
4 other topics?

5 (No response.)

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

10 That brings us to quite a similar topic
11 talking about new discussion and Dr. Langhorst and
12 Mr. Costello will be talking about the potential for
13 additional topical meetings.

14 MEMBER LANGHORST: Sophie said she would
15 drive my slides, so I appreciate that. And thank you
16 very much.

17 Next slide. So Dr. Thomadsen asked Mr.
18 Costello and Dr. Davis and I to look at creating a
19 proposal to present to you all this meeting on costs
20 and logistics for additional face-to-face meeting
21 and/or maybe a medical regulatory information
22 conference to present. This has been a challenge.
23 We feel we've had some very valuable discussions on
24 what it would take to develop this, but we maybe have
25 not met your expectation at this meeting.

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1 Next slide. We've discussed who would or
2 should be the target audiences for this meeting
3 between the medical community and regulators. And
4 when I say "medical community," I don't mean to leave
5 out the patient community either. I think they're
6 part of the medical community because they are part
7 of that medical treatment/medical diagnostic
8 discussion.

9 Perhaps a good place to start is with the
10 organizations associated with the specialty boards
11 that the NRC recognizes and the regulator who are
12 regularly part of the ACMUI.

13 Next slide, please. And what would be
14 the purpose or objective of such a meeting? We know
15 we want to enhance communications to improve
16 understanding of how the use of radioactive materials
17 and radiation and medicine is different from other
18 uses and how that could or should impact the
19 regulatory controls. Who should decide what would be
20 the specific objective for such a meeting, and would
21 or should each meeting have the same objective?

22 Next slide, please. In some of my
23 previous talks I've mentioned the NRC's regulatory
24 information conference, otherwise known as the RIC,
25 and last week was the 27th annual meeting of the RIC

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1 that takes place every year here in Washington, D.C.
2 This is NRC's largest annual meeting with about 3,000
3 participants from more than 30 countries. This
4 meeting began in the late 1980s and only had a few
5 hundred participants at that point in time. It's
6 taken many years and the commitment by the NRC and
7 the participants to build this meeting and develop
8 its importance and its value to the community. The
9 continued commitment is evident by the fact that you
10 can see there are the next three years' meetings dates
11 up on their Web site so people can plan on, yes, this
12 is when this is going to happen each year. And each
13 year it's held I believe at the Marriott, so close to
14 NRC headquarters.

15 Next slide. The RIC is co-sponsored by
16 the Office of Nuclear Reactor Regulation in the Office
17 of Nuclear Regulatory Research. The meeting's
18 invitation letter states that the program is designed
19 to encourage informal open dialogue about significant
20 NRC ongoing or emerging activities related to the
21 regulation of nuclear power plants and nuclear safety
22 research. Participants have a unique opportunity to
23 interact with their counterparts to gain and share
24 valuable insights and perspectives on safety and
25 security issues facing both the domestic and

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1 international nuclear community.

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

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

18 The meeting is scheduled the same time of
19 the year, August, and moves to different locations.
20 And so you can see a list of where they have been.
21 And this August they'll be in Boston. Thank goodness
22 it wasn't in January.

23 (Laughter.)

24 MEMBER LANGHORST: Attendance for this
25 meeting I think is about around 200, but I was not

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1 able to verify that. But I think it's about that
2 order. NRC supports the meeting and travel expenses
3 for one individual from each Agreement State so that
4 all are represented.

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

13 (Laughter.)

14 MEMBER LANGHORST: And the medical
15 community, while there are various groups out there
16 in the audience, it may not be the best way to do
17 that.

18 NRC conducts rulemaking workshops, but
19 those interactions seem to mostly -- the purpose of
20 those are for information gathering for NRC staff to
21 take back to then make their product. Now there are
22 NRC stakeholder meetings, and that will seem to be
23 focused on one topic like the recent safety culture
24 meetings that happened across the country. And
25 again, NRC kind of takes that back to make their

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1 product. Don't know always how conducive it is for
2 idea exchange. And it's only happening a couple times
3 and then it's done.

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

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

24 I noticed in looking at the RIC, and since
25 putting together our slides I've learned of an example

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1 of an additional meeting that the NRC has developed
2 from the RIC. About 10 years ago the Fuel Cycle
3 Information Exchange meeting started. That's the
4 FCIX. Got to come up with a better acronym than that.

5 (Laughter.)

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

20 So because the RIC was too big for that
21 group and they wanted a more manageable group to
22 discuss their issues, could the NMSS consider
23 sponsoring a similar kind of meeting focused on
24 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
8 medical community have a different idea of why we
9 built it? Would licensees be nervous about bringing
10 up challenges for fear of having their inspector show
11 up the next month to inspect on the issue they raised?
12 I believe that's a definition of a chilling effect or
13 turning oneself into cat food.

14 (Laughter.)

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

25 Next slide, please. As we started we

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

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

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

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1 Next slide, please. So what does ACMUI
2 think? Would you be willing to discuss these types
3 of questions with your professional organizations and
4 your regulators to explore their interest and gather
5 their ideas?

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

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

15 MS. DUDES: Program Directors.

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

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

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

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1 CHAIRMAN THOMADSEN: Thank you, Dr.
2 Langhorst.

3 Do we have comments from the Committee?
4 Yes, Dr. Ennis?

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

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

23 MEMBER LANGHORST: Thank you very much.
24 I appreciate those. One of the things that the OAS
25 does bring is representation from the Agreement

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1 States that regulate licensees within their State.
2 And they're already there. That's one of the things
3 that was attractive in that way. And while there is
4 something to be said about having a meeting always in
5 the same place where you know you can count on it,
6 the OAS does move around the country, and maybe it
7 needs to be planned out a little farther in advance,
8 but that gives other parts of the medical community
9 around the country opportunity to at least be part of
10 that. So that was one of the reasons -- a couple of
11 the reasons why we felt OAS might be a good at least
12 fit to start with.

13 CHAIRMAN THOMADSEN: Mr. Costello?

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

24 Now the NRC has a lead, clearly. NRC
25 develops guidance. NRC develops regulations which

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1 the states piggyback on. But the implementation of
2 that guidance, the implementation of those
3 regulations is also very important. And I think
4 getting feedback from the medical community on how
5 well we're doing in doing that in licensing inspection
6 I think would be useful.

7 CHAIRMAN THOMADSEN: Thank you. Dr.
8 Alderson?

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

16 I also think we should think a little
17 more broadly because ultimately who is it that
18 determines how medical radiation is used? Well,
19 ultimately it's the doctors who order it. And I think
20 that a very important community is the general
21 physician community, and particularly the people who
22 teach tomorrow's physicians.

23 So obviously I bring a bias here. I'm a
24 medical school dean. But just next week I'll be going
25 to the Council of Deans meeting, and if we can reach

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1 into that community, if you could convince deans and
2 people who do medical school clerkship development
3 that are medical students around the country need to
4 learn more about radiation and how it's used in
5 medicine and how they as ordering physicians impact
6 that, I think that would be a tremendous plus.

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

20 CHAIRMAN THOMADSEN: Thank you very much,
21 Philip, for those comments.

22 Other comments? Dr. Mettler?

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

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1 CHAIRMAN THOMADSEN: With the which?

2 DR. METTLER: With the remit of this
3 Committee. In other words, it sounds like a really
4 broad thing that is going to cover everything. And
5 this is medical uses of isotopes.

6 CHAIRMAN THOMADSEN: Correct.

7 DR. METTLER: And then I heard that it
8 was maybe that the Agreement States could get input
9 about how well they're doing or whatever. So just
10 what I've heard around the table I've got three
11 different things that don't sound the same to me, and
12 I was just wondering. Again, it sounds like a really
13 broad issue that I don't quite -- I wasn't sure about
14 the remit, when I read the remit, how this fits.

15 CHAIRMAN THOMADSEN: I think that the
16 -- and please correct me, Dr. Langhorst and Mr.
17 Costello -- I think the concept is that this would
18 help provide the NRC with the input and thoughts from
19 the medical community and provide the medical
20 community with the thoughts of the NRC as to what is
21 needed in regulation. Is that correct?

22 MEMBER LANGHORST: And if you would also
23 include the Agreement States, yes.

24 CHAIRMAN THOMADSEN: Right. Well, as far
25 as talking about our charge, it would be dealing with

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1 the NRC. And I think that's where this came from,
2 how it fits in with what the job of the ACMUI is.

3 Mr. Costello?

4 MEMBER COSTELLO: I think this idea came
5 in large part from Dr. Langhorst's briefing of the
6 Commission last year in which she made the point, a
7 very good point, is that medical is different. The
8 NRC is a very strong technical agency when it comes
9 to nuclear power reactors. In terms of the regulatory
10 agency in that area, it's probably the best in the
11 world, to be honest. However, and our, because I
12 worked for the NRC for many years, our medical
13 background of our staff and the Commission itself is
14 not the same. Not the same. And medical is different
15 because it's such a profound effect on the lives of
16 patients. And correct me if I'm wrong, Sue, but
17 getting more information from the medical community
18 into the NRC, and ultimately all the other regulators,
19 being Agreement States, might mean that we do our job
20 better.

21 In addition, the medical use of
22 radioisotopes is a rapidly changing field. It's
23 always changed during my career in the business, when
24 we didn't have microspheres and who knows what else?
25 And so I think the ACMUI helps the NRC with that

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1 regard, but if we were to meet -- and however we did
2 it. I'm not sure of the best way to do it. And as
3 Sue mentioned in the beginning we have a lot more
4 questions than answers. If we could go to them and
5 talk to them at ASTRO or other meetings. They could
6 come to us. I'm not sure we've got the answer to
7 that. But I'm trying to explain what the purpose of
8 this is.

9 DR. METTLER: I guess what I'm hearing
10 now is that the idea originally was to educate the
11 NRC about how things are different. But what I've
12 heard
13 -- other things are that we have to go out and then
14 educate the rest of the world about other stuff.

15 MEMBER COSTELLO: I think it's more the
16 other way around. And, Sue, correct me, because
17 you're smarter on this than I am, but I think it's
18 supposed to be a two-way exchange. But the medical
19 community really knows their stuff. And I think the
20 ways that medical is different, if we the regulators;
21 I'm speaking as an Agreement State Representative
22 here, and the NRC can learn how do this very difficult
23 job better -- you know, Laura talked about the fine
24 line between the practice of medicine and regulation.
25 Very difficult. Very difficult thing to understand.

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1 And we often don't get it right. And I think that
2 talking to the people on the other side who provide
3 the medical treatments in a system that I think would
4 help us, the regulators, do our job better.

5 Did I get close, Sue?

6 MEMBER LANGHORST: I think you did very
7 well, Frank.

8 MEMBER COSTELLO: Thank you.

9 MEMBER LANGHORST: Thank you. The NRC,
10 the Commission has advisory committees on reactor
11 safeguards, but they felt that it was worthwhile to
12 bring together a group of the industry. And like
13 they say on their Web site, the RIC's meeting states
14 that the program is designed to encourage informal,
15 open dialogue about significant NRC ongoing and
16 emerging activities. I think that's the same reason
17 we're looking at what could be gotten from a medical
18 regulatory issue exchange in bringing together more
19 people who are involved, more regulators who are
20 involved and to explore that opportunity of having
21 those dialogues among the regulators and the medical
22 community.

23 CHAIRMAN THOMADSEN: Dr. Dilsizian?

24 MEMBER DILSIZIAN: Thank you. Great
25 discussions. I think from the physicians'

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1 perspective there are so many meetings that we attend.
2 It would be very hard I think for most physicians,
3 including medical students and deans, to really have
4 another meeting that they would attend. I really
5 like the idea of the outreach. I think that if the
6 NRC goes to the medical meetings, whether it's
7 radiation oncology, radiology, nuclear medicine, that
8 would be fantastic. And you will also get unique
9 input from those individual societies that may be
10 different. And I think the discussion will be better.
11 So that's just a solution. Probably it will be less
12 expensive and being more directed going to the
13 physicians rather than having them come to a meeting.

14 CHAIRMAN THOMADSEN: Thank you very much.
15 Dr. Palestro?

16 MEMBER PALESTRO: That's exactly what I
17 was going to say, that I think that working to improve
18 communication between the medical community and the
19 NRC is an excellent idea. How to implement it can be
20 logistically difficult, but the simplest and maybe
21 the most expedient way of doing it is by having
22 representatives of the NRC attend some of the meetings
23 such as the Society of Nuclear Medicine, maybe ASTRO,
24 RSNA.

25 The Society of Nuclear Medicine has for

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1 several years run one or two sessions at every meeting
2 with representatives from the FDA and there's been
3 good interchange, and obviously has worked very well.
4 So I think a meeting along those lines, or a session
5 incorporated into these sorts of meetings might be
6 the fastest and maybe even most effective way of
7 improving communication.

8 CHAIRMAN THOMADSEN: Thank you, Dr.
9 Palestro.

10 We have a member of the public.

11 MS. FAIROBENT: Thank you, Dr. Thomadsen.
12 Lynne Fairobent with the American Association of
13 Physicists in Medicine. Just a perspective from
14 someone who has attended 24 of the 27 NRC RICs over
15 the years, and probably as an individual who has
16 brought this topic up in a variety of forums over the
17 years being back in medical over the last 15 years.

18 The difference in what a RIC does that
19 the normal communication and outreach -- and NRC does
20 send staff and attends many of the professional
21 society meetings and does interact with us on our
22 grounds. What the RIC or a RIC-like meeting would do
23 is allow the individuals in the medical profession
24 who have to interact on the broad licensee community
25 to interact with NRC on a very informal basis to talk

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1 through issues that are pending that is not able to
2 be done in the same manner once a formal rulemaking
3 is in place, or even in a structured rulemaking round
4 table-type discussion. The RIC is very informal.

5 In many respects tagging it onto the
6 Organization of Agreement States meeting does make a
7 lot of sense. It would be somewhat cost-effective
8 from NRC's perspective because they already pay for
9 one Agreement State regulator to attend that meeting.
10 The other 13 states that are not Agreement States
11 could be reached out to, to also attend. And the
12 reason I'm saying tag it to OAS maybe initially versus
13 the Conference of Radiation Control Program Directors
14 is that although all of the program directors do
15 attend, they're not paid for by NRC. So it's a
16 logistical-type thing.

17 And, yes, I agree we're not going to get
18 as many physicians perhaps that one might like in
19 doing outreach to a medical professional society, but
20 I do think that you're going to get the medical RSOs
21 there, and they are the bulk of the individuals who
22 on a routine basis have to deal with the licensing
23 actions, the interpretations of the regulation.

24 And the reason why it's important that
25 the Agreement States are there, and I think the reason

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1 why it's important for ACMUI's presence to be there,
2 is although ACMUI only advises NRC staff, much of
3 what you do does filter back to the Agreement States
4 and into the programs either through their official
5 representative or when they're looking at adoption of
6 compatible regulations. The levels of compatibility
7 are varied through each of the rule. There are not
8 many that are compatibility A or B that are
9 essentially verbatim to NRC. So the States do have
10 a lot of leeway in the use of medical isotopes.

11 So I do think that until we do one I don't
12 know that we can all say how beneficial it would be.
13 The first couple of RICs were kind of shaky. If you
14 went to the RIC last week or the week before; I forget
15 which week it was, they're blurring, there's a huge
16 difference in the RIC today than the RIC 1 and 2, 26-
17 27 years ago. So I really would like to see an
18 effort. And AAPM is very supportive of involving our
19 membership to this.

20 As one of the few organizations that
21 attends every Organization of Agreement States
22 meeting, until you're there that meeting is very
23 different. That's the one meeting where there is
24 open discussion in a public forum on issues across
25 the board between NRC as a regulator and their partner

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1 State regulators. And it's a very different
2 discussion than the type of discussion at the
3 Conference of Radiation Control Program Directors.

4 CHAIRMAN THOMADSEN: Thank you very much,
5 Ms. Fairbent.

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

9 MEMBER LANGHORST: I think they're open
10 to listen to what the ACMUI would like to pursue. We
11 did not get into cost because we don't have it very
12 well defined. Maybe I could ask Said to bring in his
13 perspective.

14 DR. DAIBES: Good morning. We're
15 currently working on the cost-effective plan and see
16 if we can provide more detail to ACMUI. It's somewhat
17 complicated to simply compare the regular RIC to this
18 idea. So that's why we don't have a very detailed
19 cost analysis yet. We're working on it. We wanted
20 to hear your perspective, and based on your
21 perspective then work on that cost-effective plan to
22 provide you details later.

23 CHAIRMAN THOMADSEN: Okay. Thank you.
24 Dr. Ennis?

25 MEMBER ENNIS: So, I think we need to

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1 sharpen what our goal is and what our target is,
2 following up with Dr. Mettler. If our target is to
3 really help educate the regulators about the medical
4 perspective and medical knowledge, then we really
5 need to tailor it in a way that is a significant
6 physician component.

7 If it's about getting all the regulators
8 together and their RSOs together to talk about how
9 things are being implemented and how that is working,
10 that's a different conversation and a different
11 audience. We just need to decide what's necessary or
12 better. Not the same meeting.

13 CHAIRMAN THOMADSEN: Thank you. Mr.
14 Costello?

15 MEMBER COSTELLO: Said, thanks for that.
16 I lean toward the former. The Agreement States and
17 RSOs talk to each other a lot. We have a lot of
18 opportunities to interchange, sometimes in a happy
19 way, sometimes less so. But the States talk to each
20 other a lot. And, however, what we don't do is hear
21 from physicians a lot. I don't think I've ever been
22 to a meeting of physicians. I've never been to a
23 meeting of physicians, or I've never been to an ASTRO
24 meeting, or an AAPM meeting. I would think more
25 -- don't you agree with me?

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1 I think I'd like to hear from what the
2 physicians have to say, what the medical physicists
3 have to say, what patient advocates have to say.
4 Agreement States and the NRC and RSOs, we talk a lot.
5 We're somewhat the same group of people. You might
6 meet at HPS meetings. Sometimes we change positions
7 and RSOs become regulators and regulators become
8 RSOs. We have the same educational backgrounds and
9 such. Physicians are a very different group and their
10 concerns are very different, as are medical
11 physicists. And I think we need to hear from them,
12 too.

13 CHAIRMAN THOMADSEN: Yes, Dr. Alderson?

14 VICE CHAIR ALDERSON: To follow up on
15 some of my earlier comments, I understand what Dr.
16 Mettler was concerned about and the NRC might be
17 concerned about, and Dr. Thomadsen's issue, are we
18 regulators or educators? Well, I think the NRC is
19 more in the regulations sphere than the education
20 sphere, but I would suggest to you that it's a
21 continuum. Education and regulation are just part of
22 a continuum where the rules are more and more rigid
23 around the people that you're trying to regulate.
24 And so the better informed they are, the more likely
25 you are to have successful regulation.

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1 And I go back again to say somewhere in
2 this; not as the primary focus, but as a spin-off of
3 this effort if you could develop something as simple
4 as a good slide set and give it to people who are
5 going to the Society of Nuclear Medicine or the
6 Council of Deans or other medical meetings and they
7 could talk about the importance of radiation and why
8 it has to be regulated and why people have to know
9 about it, I think you'd make a real contribution.

10 CHAIRMAN THOMADSEN: Dr. Langhorst?

11 MEMBER LANGHORST: I would like to
12 emphasize the word that's used for this fuel cycle
13 group, and it's "exchange." So if we were just
14 wanting physicians to train NRC, we'd be asking you
15 to come in and go to some of their training classes
16 to train them. That's not the purpose of this. The
17 purpose is to exchange ideas about how regulations
18 impact medical use. What is the right balance of
19 we'll say NRC- or Agreement State regulatory control
20 versus practice of medicine. And that is always a
21 moving kind of thing.

22 So I don't think it's just the physicians
23 telling NRC this is what this all means. It's the
24 NRC, it's the Agreement States talking about this is
25 our purpose in regulating. This is our charter. This

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1 is our charge. And we need to work this together to
2 make it a reasonable set of regulations that meet
3 both interests. So I would emphasize the term
4 "exchange."

5 Now, I think it's also an exchange
6 between the organizations. And, no, I don't see this
7 as being a 3,000-member meeting, because I don't think
8 that would help. But it may be key individuals from
9 these organizations, key physicians who maybe are in
10 the leadership of each organization to help us in
11 this effort of exchange of ideas and that NRC
12 continues with its outreach, too, to be out there to
13 talk to each of the groups. So I'll emphasize the
14 word "exchange."

15 CHAIRMAN THOMADSEN: Thank you very much.

16 Ms. Dudes?

17 MS. DUDES: Laura?

18 MEMBER WEIL: The other Laura.

19 CHAIRMAN THOMADSEN: One of the Laura's,
20 please.

21 MEMBER WEIL: Just to play devil's
22 advocate a bit, one could argue that the purpose of
23 this group is to do exactly what you're describing.
24 And I wonder if it might be the most efficient thing
25 for those of us in this group who go to professional

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1 organization meetings to go there, rather than
2 wearing the hat of a member of that professional
3 society, to wear the hat of being a representative of
4 the ACMUI or the NRC and to foster the communication
5 in that context rather than in the context of being
6 the radiation oncologist or an RSO, or whatever, and
7 to bring that information back and to bring
8 information from NRC to the meeting just -- we're
9 already there. And I wonder if that's the first step,
10 to see if we can foster interest in communicating
11 with the NRC that way.

12 CHAIRMAN THOMADSEN: Thank you. Now the
13 other?

14 MS. DUDES: Thank you. Well, I think
15 that it's a good dialogue on this subject and I think
16 it's more than I had expected. And I think you asked
17 how the NRC -- what our thoughts on it are. I think
18 the word that you were talking about, "exchange"
19 -- and I was thinking balance and dialogue. And I
20 think Lynne's right; at OAS we have a good dialogue,
21 not only on the issues of the day, but why we're doing
22 something in a certain way. And often the dialogue
23 on "why" is the most important exchange of seeking
24 to understand what the regulators' objectives versus
25 the physicians' objectives are.

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1 That being said, our goal is to serve our
2 community and to serve the public in terms of what
3 you think is best in terms of information exchange,
4 education, outreach and transparency. We will try
5 and find a way to do that. That's also in the
6 interest of -- financially responsible. Some of
7 these things are more suited to the nuclear material
8 users than others. Like going to the meetings, I
9 think that's a good idea to get to the physicians.

10 But maybe it's not a one-size-fits-all.
11 I mean, maybe you have an outreach plan. Maybe that's
12 what comes out of this as you start talking about
13 what types of things can we do for outreach? And
14 it's not having a meeting a year, but it's what's our
15 plan for the year with the ACMUI, with our own staff
16 to get out to the professional meetings? What are
17 our messages for this year? What are the questions?
18 And keep your communication plan as a living document
19 and update it and look for different ways. Because
20 I mean, budgets are shrinking all around us now, so
21 the fact that we use multiple avenues to achieve a
22 set of agreed upon objectives, I think that's where
23 this conversation is sort of leading us.

24 CHAIRMAN THOMADSEN: Dr. Mettler?

25 DR. METTLER: You know most physicians

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1 are just buried in clinical work from morning until
2 night, and they're not going to -- if they go to a
3 big meeting, they're not going to go to something,
4 sorry, that an NRC person shows up and says I'm here
5 to communicate. I mean, they might go if they know
6 the NRC's about to like do something horrible that's
7 going to shut down their practice.

8 (Laughter.)

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

12 But if you're really thinking about doing
13 something and you want input back, and you want to do
14 it cheaply, I mean one way is to just put an article
15 in the *Journal of Nuclear Medicine* or an editorial or
16 something that says this is what the NRC is fiddling
17 with and does anybody have any comments? I mean,
18 everybody's going to read the *Journal of Nuclear*
19 *Medicine* who's in nuclear medicine and they'll say,
20 a-ha, I read that and here's the six things they're
21 up to and, boom, yes, I'll write them an email. So
22 that doesn't cost any money and you'll get to a lot
23 of people. So, I don't know.

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

25 CHAIRMAN THOMADSEN: Thank you very much.

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1 We have another member of the public.

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

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

19 One other option might be a Webinar
20 series that you can do jointly with the societies.
21 And that way you could reach all the different
22 audiences that you're talking about here and not have
23 to deal with time constraints of physicians and
24 others. And if you attach CME to some of those
25 activities, then that's obviously a good incentive to

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1 participate.

2 CHAIRMAN THOMADSEN: Thank you. Dr. Suh?

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

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

22 Because it's very, very large and the
23 question is do we start small and go to societies and
24 have -- just take radiation oncologists, for
25 instance, a presentation by ASTRO, say we'd like to

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1 have a little special forum for those interested in
2 learning more about the NRC and what it involves,
3 what it entails and what it can perhaps provide for
4 you. Try that forum to see what type of interest we
5 get. And if we can put that out there and we have
6 exactly -- if Ron's the only other person who shows
7 up, then --

8 (Laughter)

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

16 CHAIRMAN THOMADSEN: Thank you, Dr. Suh.
17 Further comments? Yes, Dr. Langhorst?

18 MEMBER LANGHORST: That was why it was
19 difficult to come back with something with cost
20 associated with it, because it is potentially very
21 big, but how do you get that dialogue going?

22 So I really appreciate all the great
23 ideas. And I think I'm showing my age, that I never
24 even thought about Webinar kind of things. So I
25 thought that was a very interesting idea to be

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1 thinking about, too. I like the ideas of perhaps
2 expanding the outreach with various professional
3 societies like maybe a forum. So I really appreciate
4 all your brain power that you've lent to this.

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

16 MEMBER LANGHORST: I will commit us to
17 putting together a list of questions for you all to
18 maybe consider. You may not use all of them, but I
19 will start with our small group to develop those and
20 then send them out to the whole group and get your
21 feedback on whether they meet your needs in discussing
22 with your various groups, and would appreciate
23 feedback on that as we prepare for our fall meeting.

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

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

3 DR. METTLER: Well, thank you very much.

4 MEMBER LANGHORST: Thank you.

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

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

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

14 MS. COCKERHAM: Good morning.

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

19 So, that's going on with Research and,
20 yes, that's on its own path. So, if you want to go
21 to the first slide.

22 So, what I'm going to talk about is
23 Commission direction that we got in 2014 which the
24 research stuff, I believe, we got in 2012, '11, yes,

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1 further back.

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

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

9 Next slide? Thank you.

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

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

20 They gave us direction to develop a
21 website and they wanted it to provide information to
22 relevant medical organizations, patient advocacy
23 groups. And this would enable patients to access
24 clear and consistent information regarding, you know,

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1 what the radioactive iodine is, how it's used in
2 treatment, how to prepare, what to expect, side
3 effects, some basic radiation safety and precautions
4 to take after receiving the treatment and the risk to
5 others.

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

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

16 Next slide, please?

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

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

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

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

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

20 We felt if we put both of them together,
21 everyone has interest in rulemaking and gets very
22 excited about where we might go in rulemaking. So,
23 we felt the guidance would probably not get as much
24 attention and we wouldn't get as much good information

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1 on that side.

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

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

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

24 So, right now, we're in the 60 day comment

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1 period for that.

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

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

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

22 The Federal Register notice is really two
23 documents. One is the Federal Register notice which
24 is not very informative. The second is a supplemental

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

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

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

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

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

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

3 MS. COCKERHAM: Next slide, please?

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

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

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

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

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

24 Next slide, please?

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1 And then 2016 and beyond, we'll have,
2 like Donna-Beth said, we split this into two separate
3 things, guidance and rulemaking. We're going to have
4 a second set of workshops for the rulemaking -- for
5 the potential rulemaking to discuss whether or not we
6 should pursue rulemaking.

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

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

14 Donna-Beth, do you have anything else to
15 add?

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

22 And their data and our data will come
23 back together potentially for future rulemaking and
24 definitely for the guidance development. So, we're

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1 off on divergent paths and then we'll come back
2 together and that's why it's going to take as long as
3 it's going to.

4 CHAIR THOMADSEN: Thank you very much.
5 Questions or comments from the Committee?
6 Yes, Dr. Mettler?

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

8 CHAIR THOMADSEN: That's what you're here
9 for.

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

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

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

24 But, one of the things that came up to me

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1 when you start looking into the gory details of this
2 is about the worst thing you could do after you've
3 had radioiodine is to go kiss a baby because of the
4 saliva and the transfer and the uptake in the kids
5 and the sensitivity of the thyroid and all the rest
6 of that.

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

12 At least, you know, you get the whole
13 list of things but not in any order of particular
14 importance.

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

20 DR. HOWE: You turn the knob around.

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

23 DR. HOWE: Extra rinse then.

24 DR. METTLER: And does that really make

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1 a difference?

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

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

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

17 Some of our other guidance, there's a
18 form that's supposed to be a patient licensee
19 acknowledgment form. That's going to -- what does
20 the physician and the patient talk about in order for
21 the licensee make a good determination on when to
22 release the patient.

23 Because what we're looking at from our
24 study is the patient is the key to radiation safety.

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1 They need to understand what they're getting. They
2 need to understand how they can reduce exposure to
3 others and they need to be able to do things that get
4 reasonable instructions at the end that they can
5 follow. So, that's what we're focusing on this one.

6 The health physics and the calculations
7 and the actual external dose and internal dose are
8 more the subject for the research study.

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

14 You get disagreements. So --

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

19 DR. METTLER: Yes, because if you link to
20 some of these sites, you're going to get information
21 that NRC may not agree with or may have different
22 ideas on.

23 And I'll let you talk about the Society
24 of Nuclear Medicine Guidelines. But, I think there

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1 are issues in there about you can do diagnostic I-131
2 studies and not have to a pregnancy test or anything.

3 CHAIR THOMADSEN: Yes, that is a --

4 MEMBER DILSIZIAN: I mean I was -- you
5 know, I came new to this topic and I was struck how
6 much variability there was among physicians
7 instructing and education of their patients before
8 and after release.

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

14 I was wondering, even though there are
15 documents, guidelines for various societies, would it
16 be under the NRC's umbrella to have a uniform [set
17 of] patient release instructions that physicians can
18 at least read and guide patients so it would be much
19 uniform that variability among the university
20 hospitals versus community hospitals? Would that be
21 under our umbrella?

22 DR. HOWE: That was the gist of the
23 Commission direction that we received was that they
24 were quite concerned about the variability and lack

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1 of clarity. And so that's why they directed us to do
2 what we're going to be doing.

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

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

8 And I think the other thing that I haven't
9 emphasized is that when we go out to collect this
10 information, we are asking for [what's] already
11 existing. We are essentially dependent upon the
12 physicians and the patients to tell us what really
13 works well for you?

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

18 MS. COCKERHAM: When we issue that
19 Federal Register notice, we would want to see that
20 form. Hey, here's an in-house form that we have that
21 works well for us and if we can see all of those
22 forms, that's the information collection that we want
23 to go out and get.

24 DR. HOWE: And we'll have very specific

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1 questions. I'm going to have questions that are more
2 oriented towards the medical community and I'm going
3 to have questions that are more oriented towards the
4 patients so that we can get as wide a set of
5 information as we can.

6 So, I think we're going to try to address
7 those things.

8 CHAIR THOMADSEN: Yes, Dr. Costello?

9 MEMBER COSTELLO: I want to comment on
10 patient instruction.

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

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

17 Now, the safety suggestion to that is,
18 they are going to the landfill and they're buried and
19 never bother anybody again.

20 However, there are some landfills that
21 because of their agreement with their local township
22 or because they incinerate their waste and the
23 township doesn't want radioactive place incinerated
24 for no good technical reason, they're forbidden from

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1 taking radioactive waste.

2 And so, we got a call from a mother whose
3 daughter has thyroid cancer and whose waste set off
4 their alarms and they were contacted by the company
5 that collects their waste and threatened with
6 thousands of dollars in fines or they would simply no
7 longer collect their waste.

8 And so, we try to help, you know, we call
9 up the -- and they don't care. You know? And we say
10 this stuff is exempt. This stuff isn't harmful, all
11 the stuff that you would say if you were talking to
12 them, and they don't care.

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

17 I and this patient went to a very
18 prestigious institution in Columbia. But, as you
19 know, all this is not regulated, it's all exempt and
20 there's not much we can do. They want us to somehow
21 or another to punish the medical institution for not
22 sufficiently instructing what to do with the waste.

23 And to be honest, from a safety point of
24 view, putting patient waste in the trash is probably

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1 the safest thing to do. I'm not sure I want them
2 saving the other I-131 waste and keeping it in
3 wherever who keeps these things.

4 But, in drafting the guidance, okay,
5 please remember that a lot of this stuff is out in
6 trash. A lot of this stuff sets off alarms and very
7 frequently, the patients, remember our cancer
8 patients, have to be dealing with people threatening
9 to fine them or threatening not to pick up the trash
10 anymore because there was iodine left.

11 DR. HOWE: And, Frank, you bring out a
12 really good point. We don't regulate the trash
13 facilities, but many trash facilities around the
14 country, they are afraid of radiation so they put in
15 their contracts, no radioactive waste can go to this
16 transfer point, can go to this landfill. And that's
17 an absolute.

18 MEMBER COSTELLO: We do regulate them,
19 the broader department, and we require them to have
20 detectors. And we issue a lot of DOT exemptions for
21 shipping these things.

22 DR. HOWE: But we don't license
23 landfills.

24 MEMBER COSTELLO: I know, we do.

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1 DR. HOWE: Yes. We don't and many
2 landfills do have this because of the local community,
3 no radioactive waste, no medical waste, no whatever
4 waste they consider harmful.

5 MEMBER COSTELLO: I think it's important
6 that the instruction to the -- the instruction to the
7 patient, at least address this. Since I don't even
8 know what it should say, to be honest. I think
9 throwing it out in the trash is probably the best and
10 safest thing to do, but that mother who had the
11 daughter who had thyroid cancer wasn't seeing things
12 my way.

13 DR. HOWE: And that's one of the elements
14 that is included in the questions that we'll be going
15 out with.

16 CHAIR THOMADSEN: Yes, ma'am?

17 MEMBER WEIL: Many institutions do
18 provide instructions about waste and this just points
19 out the discrepancy of information that patients
20 receive. And it's a wonderful thing that NRC is
21 trying to develop some consistency of guidance for
22 patients in order to address the post-treatment
23 period.

24 I'd like to make the point that I've made

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1 before; this often we get some push back when we talk
2 about NRC intruding upon the practice of medicine by
3 regulating what kind of guidance patients will
4 receive, what kind of information they will receive
5 about dealing with the post-treatment period.

6 And I'd like to say that this is not the
7 practice of medicine, this is post-treatment. This
8 is after treatment. This is public health. This is
9 not intruding in any way upon the administration of
10 the iodine; it's simply trying to protect the public
11 and the patient from mundane stuff like never having
12 their trash picked up again and real radiation
13 exposure to infants.

14 This is different from the practice of
15 medicine.

16 CHAIR THOMADSEN: Thank you very much.

17 Dr. Zanzonico?

18 MEMBER ZANZONICO: Well, that addresses
19 a point I want to bring up.

20 I thought I heard something to the effect
21 that in this brochure or website among the issues
22 that might be addressed would be side effects, what
23 the patient would expect.

24 To me, that is now infringing on practice

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1 of medicine. Frankly, I think I'm very leery of a
2 regulator-sponsored website directly conveying
3 information to patients, especially if it now
4 incorporates issues like side effects and this
5 general concept of what to expect.

6 I mean a physician may decide for very
7 legitimate reasons that side effects that might be
8 considered undesirable might be tolerable under some
9 medical circumstances.

10 So, how does a patient who accesses such
11 a website and sees some information, reconciles what
12 they see there with what their physician may tell
13 them in a specific case under specific circumstances?

14 So, I'm just very leery about that
15 component of such a website or brochure or any public
16 outreach.

17 I feel the most appropriate way would [be
18 to] provide information to physicians and still leave
19 it to the physician to convey that information even
20 with respect to radiation safety practices and dose
21 reduction practices to the physician.

22 I think it's almost unavoidable that no
23 matter how restrictive the NRC may characterize
24 things, that it's going to start infringing on medical

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1 practice and the patient/physician relationship.

2 I mean these are not simple issues and I
3 think physicians need to take more responsibility in
4 conveying this information reliably so forth and so
5 on to patients but it's their responsibility. It's
6 not the regulator's responsibility.

7 DR. HOWE: And I agree with you, Dr.
8 Zanzonico and I think one of the things to keep in
9 mind, the direction that we got from the Commission
10 does take us into practicing medicine but it's done
11 in such a way it's supposed to be a website that the
12 medical community may have a website that addresses
13 a certain issue. And so, we would have a link to
14 that website.

15 It would not be an NRC requirement. It
16 is just a recognition that patients go up on the
17 Internet and look for things and this would bring
18 some links that would go to professional groups and
19 others that might provide information.

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

23 MEMBER ZANZONICO: I think, though, it
24 has to be recognized that just the fact that the NRC

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1 is directing a patient to a website whether they've
2 claimed to have vetted it or not has a certain
3 implication. I mean that's just inevitable.

4 DR. HOWE: Yes, I appreciate that.

5 CHAIR THOMADSEN: Ms. Langhorst?

6 MEMBER LNAGHORST: There's ample
7 precedence for government agencies providing
8 information about drugs and side effects to the
9 public. And this would not be a unique instance.

10 CHAIR THOMADSEN: Thank you.

11 Dr. Palestro?

12 MEMBER PALESTRO: Yes, I certainly agree
13 with Pat Zanzonico's comments and I would express
14 previously my reservations to Donna-Beth. We've even
15 been back and forth on this about establishing a
16 website and providing links.

17 I think a potential, more than a
18 potential, like a real problem is that you establish
19 these links, you're going to find that some of the
20 websites, you're actually give contradictory
21 information and I think that creates its own set of
22 problems.

23 And I'm inclined to also agree with Pat,
24 at least if I understand what he was saying correctly,

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1 I think that the NRC should be establishing the
2 regulations and it should be up to the medical
3 community to identify ways to meet them, to satisfy
4 them, not be provided that.

5 CHAIR THOMADSEN: Thank you, Dr.
6 Palestro.

7 Dr. Alderson?

8 VICE CHAIR ALDERSON: I don't disagree
9 with anything that the other speakers have said and
10 I share their concerns.

11 I just want to make a comment that we've
12 all read in many publications about how patients are
13 using the Internet more and more and more all the
14 time and wise people have described that growing use
15 as disruptive to the practice of medicine.

16 So, although I share the concerns, I
17 don't think we can ignore the fact that the patients
18 are going to be out there, they're going to be looking
19 at all these things and, in some way, we have some
20 kind of responsibility to be aware of that and to try
21 to respond to it. It's a big problem but it's not
22 going away.

23 CHAIR THOMADSEN: Thank you, Dr.
24 Alderson.

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1 Can I ask, when would the input from the
2 ACMUI be the most useful in this process? Would it
3 be most useful before you hold the stakeholder
4 meetings? After you get some of the input? When you
5 think it would be efficacious for us to give advice?

6 DR. HOWE: I think certainly ACMUI
7 members attending the stakeholder meetings would be
8 good. We will be collecting the information from the
9 public and then we will be processing it and we'll be
10 processing into some kind of final product.

11 And we would be bringing in the ACMUI as
12 we're reviewing those final -- bringing those final
13 products together to finalize them.

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

18 CHAIR THOMADSEN: When do you expect that
19 you'd be doing the processing?

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

24 I've got probably about 30 days to

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1 process that information which I think is much more
2 limited and then go back to OMB for the actual request
3 for the clearance. They've got 60 days to act on the
4 request.

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

10 In that 60 day time period while the
11 public is commenting on the actual questions is, I
12 think, when we will be holding our stakeholder
13 meetings.

14 MS. COCKERHAM: So, later this year.

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

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

21 DR. HOWE: I think the next meeting is
22 probably about the right time frame. Things could go
23 a little faster. If they do, we could always --

24 CHAIR THOMADSEN: Have a telephone

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1 conference.

2 DR. HOWE: -- have a telephone
3 conference.

4 CHAIR THOMADSEN: Dr. Ennis?

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

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

15 And the tension that exists between our
16 perspective, perhaps, or the scientific community
17 perspective, that it's not an issue.

18 And the public's anxiety about
19 radioactivity, and this is a recurring theme that
20 maybe we need to be dealing with that more than the
21 particular -- or in addition to at least, or maybe
22 more than the particulars of one particular scenario.

23 CHAIR THOMADSEN: And, I'll just say that
24 has been an ongoing issue that is precisely what we

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1 do. We always have to deal with those issues. It's
2 not something we can deal with once for and all and
3 say we're done.

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

9 Dr. Mettler?

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

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

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

23 But, in your -- the two questions I have
24 is, is the collection and processing of this, I know

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

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

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

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

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

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1 dose from those patients when they go to sites other
2 than, say, their home?

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

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

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

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

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

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

24 DR. HOWE: I was a CA note.

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

6 DR. HOWE: One of the Commission
7 questions was, well, how is NRC racking up against
8 the 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
13 could 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
17 of 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
21 in the first place.

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

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

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

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

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

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

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

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

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

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1 Ms. Dudes?

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

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

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

20 I don't know if I'd know to go to the
21 Nuclear Regulatory Commission if I was having an I-
22 131 treatment.

23 But I think the fundamental is what do
24 you do? It's don't kiss a baby, right? What do you

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1 do with your waste? Keep and make sure that if you're
2 this, that you have enough time before the treatment
3 to make the arrangements that you need to do.

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

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

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

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

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1 I am worried about us being the
2 brochures/website experts. And it's so confusing.
3 But and comments like, keep your website to here's
4 the things you should know post-treatment for public
5 health and safety and other things and for your safety
6 as opposed to here's the impacts of I-131. That
7 should be in the medical journals and such.

8 So, I mean, so I would encourage everyone
9 to stay very active and communicative and directive
10 and taking positions or the staff. That's what the
11 ACMUI is for.

12 CHAIR THOMADSEN: Dr. Langhorst?

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

18 So, that includes Tc-99m, PET scans,
19 Xofigo, microspheres, everything.

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

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

24 MEMBER WEIL: Oh, see, I didn't mean to

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1 catch this. That's not me.

2 Thank you for that comment because I
3 think it's really important. I mean I recently had
4 a Tc-99 scan and nobody told me not to go near my
5 pregnant daughter. Now, I knew but there should be
6 information about that on a website that's accessible
7 post-treatment for patients who have questions, who
8 may not get the information that they need from their
9 clinician.

10 CHAIR THOMADSEN: Thank you very much.

11 Any other comments from the Committee?

12 Hearing none, thank you very much, Ms.
13 Cockerham, Dr. Howe.

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

16 DR. GABRIEL: Good morning.

17 ACMUI requested to discuss patient
18 intervention at this meeting and I was asked to open
19 the discussion by providing some background
20 information and the history of NRC's use of the term
21 patient intervention.

22 Next slide, please?

23 Let's start with NRC's current definition
24 of patient intervention and then go back to trace the

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1 history of this concept.

2 NRC's medical regulation, 10 CFR Part 35
3 includes definitions of terms in Section 35.2. This
4 slide shows the current definition of patient
5 intervention and intentional or unintentional actions
6 by the patient such as dislodging or removing
7 treatment devices or prematurely terminating the
8 administration.

9 Next slide?

10 The current regulation uses the medical
11 event to describe deviations from intended
12 administrations that need to be reported to the NRC.

13 The older term, misadministration, was
14 first introduced in 1980. The concept of patient
15 intervention was acknowledged in 1980, although the
16 term was not added to the regulation until 2002.

17 Next slide?

18 The requirement to report
19 misadministrations was added to Part 35 in 1980 and
20 after the final rule was published, the NRC received
21 a number of questions from licensees about the
22 definition of misadministration.

23 In response to these questions, NRC
24 issued a letter with a series of questions and answers

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1 illustrating what constituted a misadministration.

2 And then, the slide shows a question and
3 answer that may involve the first use of the term
4 patient intervention.

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

12 And the response was that patient
13 intervention in the treatment plan is not a
14 misadministration. So, it appears that the term
15 patient intervention pertained to patient behavior
16 that was not under the control of the licensee.

17 Next slide?

18 The next major rulemaking was the 1992
19 Quality Management Rule. The rule did not address
20 patient intervention. Another clarifying letter with
21 sample questions and answers was sent to licensees by
22 this time, there were no examples involving patient
23 intervention.

24 In documents the NRC files from error

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1 indicate that NRC made determinations of patient
2 intervention on a case-by-case basis. So, there was
3 no public addressing on the concept.

4 Next slide, please?

5 The next major proposed rule was issued
6 in 1998 and SOC stands for Statements of
7 Consideration. And the Statements of Consideration
8 for the proposed rule discussed patient intervention
9 as a problem area in misadministration reporting.
10 So, attention is starting to be paid to this.

11 The terms misadministration and medical
12 event are both used in this document. This was the
13 proposed rule that changed the terminology to medical
14 event.

15 And this slide includes in the second
16 bullet a quote from the Federal Register notice. It
17 starts with the language licensee is expected to act
18 reasonably in accordance with prevailing standards of
19 care to prevent a medical event.

20 It continues, in cases where patient
21 intervention is probable, the licensee should take
22 reasonable actions to avoid a medical event such as
23 using extra sutures in the case of a temporary
24 brachytherapy treatment, extra taping or more

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1 frequent checks by nursing staff.

2 So, it appears that the term patient
3 intervention still pertained to behavioral actions on
4 the part of the patient.

5 It was also noted in this document that,
6 in some cases, the licensee might be able to
7 anticipate that patient intervention was likely to
8 occur and there might be steps that the licensee could
9 take to prevent the undesired patient behavior.

10 Next slide, please?

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

18 The Federal Register notice for the
19 proposed rule specifically asked for public comment
20 on whether a patient intervention was adequately
21 addressed by proposed changes.

22 Next slide, please?

23 The final rule corresponding to the 1998
24 proposed rule was issued in 2002. The Statements of

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1 Consideration for the final rule stated that the
2 phrase, "that could have been reasonably prevented
3 by the licensee" was deleted. The deletion was in
4 response to comments from the public that this phrase
5 was ambiguous, subjective and infringed on the
6 practice of medicine.

7 The Statements of Consideration also
8 described a new requirement that was added for
9 licensees to report events caused by patient
10 intervention if they resulted in serious
11 consequences.

12 The description of serious consequences
13 was unintended permanent functional damage as
14 determined by a physician.

15 Next slide, please?

16 The same Statements of Consideration also
17 presented the definition of patient intervention, the
18 same one that's in effect today and that I described
19 at the beginning of my presentation that is
20 intentional or unintentional actions by the patient
21 such as dislodging or removing treatment devices or
22 prematurely terminating the administration.

23 And finally, the Statements of
24 Consideration reiterated the expectation for

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1 licensees to act reasonably to prevent patient
2 intervention that could result in medical events.

3 Next slide?

4 The 2002 final rule includes the version
5 of the medical event-reporting requirement 10 CFR
6 35.3045 that remains in effect today. And Section
7 35.3045(a) introduces the medical event reporting
8 requirements and excludes reporting of events
9 resulting from patient intervention.

10 Next slide?

11 When you move to the next section,
12 35.3045(b) also mentions patient intervention. It
13 states that under some circumstances, medical events
14 resulting from patient intervention do need to be
15 reported. A report is required if the event resulting
16 from patient intervention results in or is expected
17 to result in unintended permanent functional damage
18 to an organ or physiological system.

19 The determination of unintended permanent
20 functional damage is to be made by a physician.

21 Next slide, please?

22 So, I wanted to provide some examples for
23 this presentation and I searched historical NRC
24 records for formal case reviews that evaluated

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1 whether patient intervention was the cause of a
2 misadministration or medical event.

3 The most common types of cases that I
4 found were those in which the patient removed a
5 brachytherapy applicator before the conclusion of the
6 treatment of a patient in motion accidentally caused an
7 implant ribbon or an applicator to become dislodged.

8 Many, but not all, of those case reviews
9 concluded that patient intervention was the cause of
10 the misadministration or medical event.

11 However, in some of the cases, a
12 determination was made that while patient
13 intervention may have been a contributing factor,
14 there were reasonable steps the licensee could have
15 taken to avoid the event or react more appropriately
16 when it was identified.

17 There was one unusual case in which,
18 after administration of an I-131 capsule, the patient
19 surreptitiously removed the capsule and concealed it.
20 The determination was that the patient actions in
21 removing the capsule were consistent with the
22 definition of patient intervention and the reporting
23 exclusion in 25.3405(a) could be used.

24 Next slide, please?

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1 The most recent communication issued by
2 the NRC about patient information was an Information
3 Notice in 2006 related to gamma stereotactic
4 radiosurgery treatments. Two cases were described in
5 which patient movement caused the head frame to be
6 displaced resulting in dose to an unintended site.

7 And if you're interested in the details
8 of those two cases, I can refer you to the Information
9 Notice itself.

10 Next slide?

11 The Information Notice noted that both
12 licensees believed it was not necessary to report a
13 medical event because they viewed the patient
14 movement as patient intervention.

15 However, the NRC disagreed and viewed the
16 events as resulting primarily from issues with the
17 patient equipment set up.

18 The NRC suggested a number of actions
19 that licensees should consider taking to avoid
20 medical events caused by patient intervention for all
21 treatment modalities, not just for gamma stereotactic
22 radiosurgery treatments.

23 Next slide?

24 So, finally, as you know, a major Part 35

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1 rulemaking is currently under way and the proposed
2 rule this time did not make any changes regarding
3 patient intervention.

4 On the slide are some definitions and
5 this concludes my presentation.

6 MEMBER COSTELLO: Thank you, Sandy.

7 Bruce, before you start, any questions
8 for Sandy?

9 CHAIR THOMADSEN: Dr. Mettler?

10 DR. METTLER: It said that it's when --
11 it has to be reported when it results in permanent
12 functional damage. How does taking out an applicator
13 result in permanent functional damage?

14 DR. GABRIEL: That would be an example of
15 a case that likely would not result in permanent
16 functional damage.

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

20 DR. GABRIEL: That's what the rule says,
21 however, considering the case examples, it looks like
22 in a number of cases similar to that that the NRC has
23 formally evaluated. The determination was made that
24 patient intervention was a contributing factor but

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1 not --

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

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

4 MEMBER COSTELLO: Let me interrupt.

5 I think that precisely if the NRC has
6 determined, I guess, that if the institution could
7 have anticipated that the patient would remove it and
8 taken steps to make that more difficult or unlikely,
9 then it would still be a medical event.

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

12 MEMBER COSTELLO: I don't think it says
13 that. I think it says even if there is a patient
14 intervention, if it causes medical damage, it's a
15 medical event.

16 DR. METTLER: If it doesn't?

17 MEMBER COSTELLO: If it does.

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

20 MEMBER COSTELLO: It could still be a
21 medical event. It meets the definition of a medical
22 event and it doesn't meet the definition of patient
23 intervention.

24 If there's permanent damage, even if

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1 there is patient intervention, it's still a medical
2 event. But that's pretty rare.

3 DR. GABRIEL: Thank you for answering
4 that question.

5 MEMBER COSTELLO: I can't help myself,
6 Sandy.

7 Did I do okay?

8 DR. GABRIEL: Yes.

9 MEMBER COSTELLO: Any other questions for
10 Sandy that you can answer?

11 Okay. Next slide, please? Oh, let's go
12 back to that slide.

13 Some of you may recall when we had the
14 subcommittee that was looking into guidance for
15 microspheres, in particular, looking for guidance
16 initially involving shunting to the GI tract then we
17 expanded it somewhat further than that.

18 There was a lot of discussion amongst our
19 group about patient intervention. So, if the --
20 basically we came to the conclusion if the treatment
21 put the spheres in the right place but due to the
22 patient's anatomy it went to the wrong place that we
23 would then consider that not to be a medical event.
24 Because what more could the doctor and the medical

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1 team have done?

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

7 And that wasn't my recollection of what
8 the NRC meant by patient intervention, that that was
9 more of a type of passive patient intervention rather
10 than active patient intervention.

11 And that troubled, because I think that
12 the NRC and its Advisory Committee, it's important
13 that they mean the same thing by words like patient
14 intervention. That we don't have a situation where
15 the ACMUI's advising the NRC in a particular case,
16 let's say. And say, well, that's not a medical event
17 because of patient intervention and we're meaning
18 different things by that phrase.

19 Now, I'm not advocating a particular
20 definition; I'm not. I want to call this both to the
21 attention of the Committee and to the attention of
22 the NRC so we can become aligned and mean the same
23 thing about the same words.

24 Okay, go the next slide, please? Thank

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1 you.

2 The NRC basically has viewed patient
3 intervention as actions by the patient, behavioral
4 actions rather than physiological phenomena, how to
5 put together a pubic arch in an inconvenient place
6 or, you know, vascular systems to go the wrong way or
7 the patient just body is not cooperating so that when
8 the medical team does everything according to their
9 procedures, the outcome is not what was intended.

10 So, by my past experience was that if the
11 anatomy result and sources coming to the wrong place,
12 that that would not constitute a medical patient
13 intervention.

14 But it's clear to me that overwhelming
15 the Committee felt that if the doctor did everything
16 right and the team did everything right and sources
17 went to the wrong place, that's not a medical event.

18 Next slide, please?

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

23 So, if you wrote me on patient
24 intervention, I scoured my emails and I tried to

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1 capture your thoughts because I wanted to accurately
2 reflect what I believe the Committee's thoughts are.
3 Okay?

4 However, I don't remember whose comments
5 are whose, you know, maybe if you recognize your
6 comment you could raise your hand.

7 One is there's another case of regulatory
8 terms not being in alignment with connotative and
9 denotative meaning. Basically, what we're
10 recognizing here is, we the NRC, will tell the medical
11 industry or tell people, medical events are not --
12 they're not violations, you know, they're just
13 medical events.

14 But I think, and the physicians kind of
15 try, you know, when they hear medical event, they
16 think that they -- it's saying they did something
17 wrong. That's not always the case, I think, from the
18 NRC point of view. But, I think clearly medical
19 practitioners see it that way.

20 And as this email you sent me, what does
21 actions -- what does intentional or unintentional
22 mean?

23 Next slide?

24 I have too many words in this slide, so

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1 I hope you all can read this.

2 Look at all these various things that can
3 occur within the patient, changing flows so the
4 results that things get, you know, the seeds or the
5 microspheres go to the wrong place. These are -- and
6 it carries all the suboptimal treatment. But again,
7 once again, when the doctor and his team stop the
8 treating part, everything was going fine from their
9 point of view and then a person's body intervened.

10 Another couple of these occurrences are
11 not the fault of the patient. There's no meaning to
12 saying it's the patient's fault unless the patient
13 gets up and walks off the table or pulls out a tube
14 or something, nor the AU, nor the administering
15 physician or team.

16 And the question they ask is, what can be
17 done in reporting such things when the person's
18 anatomy causes it? What can be done in the future to
19 avoid medical events? Okay?

20 Now, I want to remind you what Sandy
21 talked about what the NRC's view of patient
22 intervention. That doesn't capture those type of
23 events.

24 Next slide, please?

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1 If during the injection of microspheres,
2 the patient's artery contracts and you have
3 microspheres going into the GI tract, the thought of
4 my ACMUI colleague was that, too, would be patient
5 intervention. But I'm telling you I believe that
6 historically, that would not meet the definition of
7 patient intervention as interpreted by the NRC.

8 I'll repeat, I'm not trying to argue
9 whether that should be patient intervention or not.
10 Okay? I don't know. But, I don't want to have this
11 misalignment between the Committee and the NRC, which
12 maybe that is and then lung shunt fraction and so
13 forth.

14 Next slide, please?

15 As I said, the NRC and its Advisory
16 Committee seem to be misaligned on patient
17 intervention. I'm going to go further than that. I
18 think it's even a misalignment on medical events in
19 general. And I think that the Committee basically
20 believes that the doctor did a good job and couldn't
21 have done any better. That's not a medical event.

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

24 You don't want to have miscommunication

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1 between the Committee and the NRC when we're using
2 the same words that have different meanings behind
3 them.

4 And the last question is, does whether
5 the Authorized User medical team did something wrong,
6 is that the sole determination of whether there's a
7 medical event?

8 If the Authorized User and the team did
9 everything according to protocols, should that be
10 considered to be a medical event?

11 So, I want to have this discussion today,
12 that's the last slide, to call this, I think it's
13 this misalignment to the attention of the Committee
14 and to the attention of the NRC so we can resolve it.

15 Perhaps we could have a subcommittee to
16 be the committee recommending an interpretation of a
17 medical event of a patient interpretation.

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

23 I'm better on, you know, why's and what's
24 than how's. But I would leave it to the Committee

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1 working with the NRC to come up with a good how to
2 resolve it because I don't think the present situation
3 is a good one.

4 Thank you.

5 CHAIR THOMADSEN: Thank you very much.

6 Comments from the Committee? I'll guess
7 we'll start around the table.

8 Dr. Ennis?

9 MEMBER ENNIS: So, kind of more of a
10 general comment but reflecting on this. So, one of
11 my other hats in life I spent a good amount of time
12 scholarly understanding of the development of Jewish
13 law. And if you study the law, any kind of law really
14 applies, words, even when they're black letter, often
15 change meaning over time in the community.

16 And as long as everyone is in agreement,
17 it works and it's not necessarily a problem.

18 So, again, I don't know how NRC feels,
19 but the fact that everyone many years ago felt the
20 phrase meant one thing and now everyone feels the
21 phrase means something a little bit more because we've
22 gotten a little more sophisticated medically or we've
23 broadened our understanding, to me, it's not
24 necessarily a problem unless there's some kind of

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1 clash.

2 MEMBER COSTELLO: Thank you. It's a very
3 good question.

4 Is there any representative from the OGC
5 here today?

6 MS. HOUSEMAN: Yes.

7 MEMBER COSTELLO: Hello. I understand
8 you're new to us.

9 MS. HOUSEMAN: Yes.

10 MEMBER COSTELLO: I think
11 congratulations.

12 From my previous life, okay, such
13 questions often wind up being resolved by attorneys,
14 for better or worse. Okay?

15 However, I think that the meaning of
16 patient intervention within the NRC, perhaps, has not
17 evolved while the meaning of it in the medical
18 community has and I believe that to other people.

19 But, I think that's a true statement. I
20 think that, you know, we're going back -- how far did
21 you -- 1992?

22 DR. GABRIEL: 1980.

23 MEMBER COSTELLO: 1980. You know, a lot
24 has changed, a lot of modalities have come along. We

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1 weren't talking microspheres in 1980, you're talking,
2 you know, Cobalt and Cesium and gynecological
3 implants or something.

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

8 And so, right now, if the Committee says,
9 this is not an event because of patient intervention,
10 the NRC understands something fundamentally
11 different.

12 CHAIR THOMADSEN: Thank you.

13 MEMBER COSTELLO: A full evolution of.

14 MEMBER DILSIZIAN: Great discussion.

15 So, to me, these are the words, patient
16 intervention and the other key words that said
17 behavioral actions, intentional or unintentional.

18 MEMBER COSTELLO: Right.

19 MEMBER DILSIZIAN: So, and I understand
20 the evolution. So, if I were to say to you, patient
21 intervention, that is one, instead of putting
22 behavioral actions parenthesis intentional or
23 unintentional.

24 If we say intentional behavioral, because

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1 behavior is doing something intentional or
2 unintentional action due to anatomy or physiology, I
3 think that would clearer. Isn't it?

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

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

8 MEMBER COSTELLO: It'd be clearer but
9 different.

10 MEMBER DILSIZIAN: Yes.

11 MEMBER COSTELLO: It'd be clearer but
12 different.

13 MEMBER DILSIZIAN: Yes.

14 MEMBER COSTELLO: I'm sure it's unclear
15 now.

16 MEMBER DILSIZIAN: Yes.

17 MEMBER COSTELLO: But that might be
18 better.

19 MEMBER DILSIZIAN: Yes.

20 CHAIR THOMADSEN: Dr. Weil.

21 MEMBER WEIL: No.

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

23 MEMBER WEIL: But I do appreciate the
24 promotion, honorary, whatever.

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

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

10 But the other thing is the one that's
11 unintentional, the one where patient anatomy or
12 patient behavior is the driving factor for the
13 failure, then there's a problem with the therapeutic
14 modality.

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

20 MEMBER COSTELLO: If I could respond to
21 that.

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

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1 One thing that's supposed to happen is
2 you're supposed to report it to your regulator and if
3 your regulator's agree it's [a] mistake, like
4 ourselves, we then report to the NRC.

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

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

18 So that's doing -- I think it's going to
19 be in the wholesale level. But, we're doing more
20 than that, we're telling the patient and telling the
21 patient isn't for the intention of what did we learn
22 about this modality, it's telling the patient what
23 happened.

24 And these are very different things. And

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

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

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

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

20 Dr. Mettler?

21 DR. METTLER: Yes, the simple -- I mean
22 this is nothing new. We inject patients with x, they
23 have an allergy. Boom, something is bad. Doctor did
24 everything fine.

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

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

12 You're going to report every
13 radiosensitive patient as a misadministration? No.

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

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

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

21 DR. METTLER: But if it's due to patient
22 physiology of that particular patient, all you want
23 to do is not do it to that patient again.

24 MEMBER COSTELLO: My point is the absence

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1 of fault; I think the NRC's point of view is not a
2 reason not to make it a medical event.

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

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

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

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

21 Other comments?

22 Not hearing comments, I'd like to name a
23 subcommittee to look into this issue and report back
24 to the whole Committee with a proposed statement of

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1 what we consider a reasonable definition of patient
2 intervention.

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

8 Any comments?

9 Good. Yes?

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

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

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

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1 operating experience and trending and, you know, is
2 there things out there that we should be communicating
3 to the broader community?

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

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

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

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

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

18 DR. GABRIEL: Of course.

19 CHAIR THOMADSEN: Very fine.

20 Dr. Alderson?

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

24 One of the problems with this whole

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1 discussion, I believe, is that term patient
2 intervention and what that means.

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

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

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

19 CHAIR THOMADSEN: Dr. Langhorst?

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

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

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

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

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

22 So, the definition you're talking about,
23 I think, would capture more of the things we're
24 talking about although, as you know, rulemaking is

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1 very difficult and slow. I don't know how we could
2 treat this in guidance space, I just don't know. But,
3 you know, that's for the Committee and the NRC to
4 figure out.

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

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

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

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

24 MEMBER COSTELLO: And perhaps we need a

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1 rule that says that because that's really -- because
2 we don't have one.

3 CHAIR THOMADSEN: Well, thank you and --
4 oh, whoops, we have a comment from Ms. Holiday.

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

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

12 CHAIR THOMADSEN: John Suh.

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

15 Thank you.

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

18 MEMBER LANGHORST: I'm good.

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

22 (Whereupon, the above-entitled matter
23 went off the record at 11:39 a.m. and resumed at 1:03
24 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
5 a member of the public who wanted to make a comment
6 on the topic earlier in the session, but there was a
7 technical problem apparently with the bridge line at
8 that point.

9 Are you on the line?

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

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

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

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

21 MR. CRANE: Which report was that?

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

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1 MR. CRANE: What year was it released?

2 DR. METTLER: About six years ago.

3 MR. CRANE: Was that ICRP 94 on doses for
4 patients?

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

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

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

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

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

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

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1 CHAIR THOMADSEN: Well, thank you very
2 much for those comments, Mr. Crane.

3 MR. CRANE: Thank you, Dr. Thomadsen and
4 members of the Committee.

5 CHAIR THOMADSEN: And Dr. Mettler?

6 DR. METTLER: That report was ICRP 94
7 that was published in 2004.

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

13 CHAIR THOMADSEN: Thank you.

14 MR. CRANE: Goodbye, thank you.

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

17 MS. COCKERHAM: Sure can. Do you want to
18 go to the first slide. I'm sorry some of you can't
19 read this. Sorry it's so small. It's another multi-
20 year project that we've got going on. And so I just
21 kind of wanted to bring you up to date with where we
22 are on revising the guidance. And initially, we had
23 a comment from -- when we did Revision 2 back when we
24 put the NARM rule through, we opened up the volume

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1 and they only made changes for NARM. And during that
2 comment period, we received comments that were not
3 necessarily related to NARM and so those comments
4 were rolled over to be considered now for Revision 3.

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

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

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1 So you're not going to get a redline
2 strikeout because if you did, the entire document
3 would be red. But at least you can see here was the
4 issue, you know, if it's a mobile medical license,
5 and then here's how we resolved it, go see Section
6 8.4 and then you can go read Section 8.4 to see what
7 changes were made.

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

20 Now at the same time, we have the Part 35
21 rule going on, the rulemaking is going. And Donna-
22 Beth has been working on that, Sandy Gabriel as well,
23 and they've been making changes to the guidance,
24 basically in parallel. So they're making changes to

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1 pages. I'm making changes to pages and if you look,
2 the bottom time line is the rulemaking time line.
3 Their guidance went out for comments, so it's already
4 been published. They're ahead of us in that sense.
5 So once they resolve all of their comments and they
6 have final language, I'll take that final language if
7 you look out into 2016 and put that into the document
8 that I'm working on. So we will have one final
9 document at the end. It will all come together, but
10 we're sort of working in parallel on them right now.
11 So I kind of tried to lay out a picture of where we
12 are, where we're trucking along and where we want to
13 be in the end.

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

24 CHAIR THOMADSEN: Thank you very much.

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1 Comments, questions? Yes, Dr. Zanzonico.

2 MEMBER ZANZONICO: So the first one is
3 the NUREG revision time line? Did I understand that
4 correctly?

5 MS. COCKERHAM: They're both revisions to
6 the same document. The first line is the working
7 group that I'm working on which is anything except
8 for rulemaking. So if it's not a rulemaking change
9 -- you know there's changes being made to Part 35
10 right now. So they need to update the guidance with
11 that. That's being done by a different working group
12 which is the second line. So my working group is on
13 the top time line which was the "everything else,
14 catch all."

15 MEMBER ZANZONICO: Thank you.

16 CHAIR THOMADSEN: Dr. Langhorst.

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

20 MS. COCKERHAM: Just my group.

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

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

3 MEMBER LANGHORST: Yes.

4 MS. COCKERHAM: So anything you comment
5 on there will come back to me, the last box on the
6 bottom row where it says final rule and guidance
7 published. Theirs is going to get published and
8 really be a done deal and then I'm going to take any
9 of those changes and wrap it back up into mine.

10 MEMBER LANGHORST: But it's in the same
11 document?

12 MS. COCKERHAM: Same documents.

13 MEMBER LANGHORST: I don't know that I
14 understand that. I'll trust.

15 MS. COCKERHAM: We have direction from
16 the Commission that when we put out a new rule, we
17 have to have guidance to accompany it. So we have to
18 work with what we have right now.

19 MEMBER LANGHORST: And I absolutely love
20 that. Thank you so very much. So I'm just trying to
21 figure out what we are going to be looking at what
22 changes may still -- have you already added their
23 changes?

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

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1 MEMBER LANGHORST: Okay. I think that's
2 very confusing. Sorry.

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

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

8 MS. COCKERHAM: Right.

9 DR. HOWE: When we put it in final form,
10 it will come back to the ACMUI for its review and
11 then when it's ready to be actually published, after
12 you have reviewed it and made your comments, we'll
13 resolve whatever comments we have, then it will go
14 out for the public and to Ashley and Ashley will then
15 incorporate it. So you will have a chance to see it,
16 see the Part 35 changes to the guidance, as well as
17 things that Ashley is talking about.

18 MEMBER LANGHORST: But we will probably
19 see that in two separate iterations.

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

22 MEMBER LANGHORST: Okay.

23 MS. COCKERHAM: What we didn't want to do
24 is hold back any work that I could be doing on other

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1 changes, waiting on them to finish all the rule stuff,
2 and so that's why we thought if we did it in parallel,
3 we're making a little more time.

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

7 MS. COCKERHAM: We've had a couple of
8 little notes and I have just been able to note, like
9 oh, this would be Part 35 rulemaking. We'll make
10 sure we add it to the discussion. So I have them
11 noted.

12 MEMBER LANGHORST: Okay.

13 MS. COCKERHAM: No major conflicts.

14 MEMBER LANGHORST: I think that will be
15 helpful.

16 CHAIR THOMADSEN: Any other comments?

17 MEMBER LANGHORST: Just to let everyone
18 know, it is a 512 page document, so I just want to
19 you know.

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

22 MEMBER LANGHORST: I like it already.

23 MS. COCKERHAM: One of my big purposes of
24 this was to sort of change the format, the layout,

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1 how it flows and condense where we can. And so we
2 have taken a big step to do that.

3 MEMBER LANGHORST: Okay, great. Thank
4 you.

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

7 MS. COCKERHAM: Thank you.

8 CHAIR THOMADSEN: And now we have Dr.
9 Howe with our medical events.

10 DR. HOWE: Well, good afternoon. This
11 is my yearly presentation on the status of medical
12 events and I will give you all an overview of what
13 we've had reported to us during -- I think it's
14 through Fiscal Year 2014, during Fiscal Year 2014.

15 And then there will be a working group of
16 the ACMUI who will probably come back in the fall and
17 give its presentation on what it thinks about the
18 medical events. And the two were not supposed to be
19 identical. I give you the overview. I go through in
20 depth on kind of scanning the top of it and we're
21 hoping that in that overview, you'll see some areas
22 that you think you'd like to delve into deeper. And
23 you will eventually -- we will be giving you a copy
24 of the NMED reports that I pulled up. And in those

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1 NMED reports, at the bottom of each event, you'll see
2 references and so ACMUI may want to go into some of
3 those references and try to get additional
4 information or come back and ask the NRC to get
5 additional information. So the intent is not to
6 duplicate things in the spring and in the fall.

7 First slide. The biggest thing I want
8 you to see here, we have a lot of discussion about
9 medical events and how bad it is for physicians to
10 have medical events and medical licensees. I want
11 you to know that only 46 medical events last year.
12 It's not a big number. It's not a statistically
13 significant number and it's not a big number.

14 And I always try give you a perspective
15 of where were we last year and this has no statistical
16 significance. It's just to give you just a view.
17 Last year there were about 43 medical events. I've
18 broken it down by modalities so that you can see where
19 things shift from year to year. We very rarely ever
20 get a diagnostic nuclear medicine medical event. And
21 why is that? That's because when we introduced --
22 either the radiopharmacy rule or the quality
23 management rule, we changed the definition of medical
24 event. For diagnostic, we put a threshold of 5 rem

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1 whole body, 50 rem to an organ. Very few diagnostic
2 procedures will trip that threshold. So we have very
3 few, maybe once every two or three years and we
4 generally have the same diagnostic medical event each
5 time.

6 And you'll see the 300s, pretty much the
7 same. We had a decrease in 400s. We have much fewer
8 prostate brachytherapy medical events this year. Six
9 hundred stayed about the same, but the distribution
10 changed a little. And the largest numbers are always
11 in 35.1000 because that's where the yttrium-90
12 microspheres are and that is a very difficult
13 procedure to give in accordance with a written
14 directive because of the mechanics of the device.

15 So if I can have the next slide?

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

21 We have about 150,000 therapeutic
22 procedures. We had 45 this past year. That's 1 in
23 3,000. We've always been told that roughly the
24 percent of human error is about 1 times 10^{-4} , which is

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1 1 in 10,000, so it's right in the human error realm.

2 Next slide.

3 So now we'll start going through the
4 different modalities. 35.200 are our diagnostic
5 nuclear medicine procedures. Things that do not
6 require a written directive, so these are all your
7 cardiac scans, your technetium scans, etcetera.
8 Generally, if we have a medical event in 35.200, it's
9 because somebody eluded the generator and gave the
10 entire generator elution to one patient or in this
11 particular case, they had a multi-dose vial and they
12 gave the whole vial to one patient. And by giving
13 them 140 millicuries instead of 20 millicuries, they
14 got a whole body dose of 6 to 7 centigray. So this
15 is what we normally expect to see when have a
16 diagnostic medical event. We don't have one very
17 often. Generally, they are on weekends or at night
18 when you've got multi-dose vials or generator
19 elution.

20 Next slide.

21 I've got three -- we normally call them
22 therapy nuclear medicine, but because you've got the
23 diagnostic whole body I-131 scans in here, we just
24 call it unsealed material, requiring a written

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1 directive. And we've got three of them. Normally,
2 they're all I-131. We have quite a bit of variety
3 this time. We have a samarium one in which they --
4 this may be one that I want to go back and look a
5 little harder at because the description was that
6 they gave it in the skin as opposed to intravenous
7 and that could be because they missed the vein and
8 therefore it went under the skin or it could be they
9 deliberately tried to deliver into the skin or the
10 arm or somewhere. So I'll have to go back and see,
11 because if it was they missed the vein, we've already
12 made a determination those are not medical events.
13 But I'll have to go back and check on that.

14 The radium-223, that was a comedy of
15 errors. It was where one error gets promulgated and
16 another error is made and the end result is the
17 patient gets exactly what the patient should have
18 gotten. The hospital has its written directives,
19 written out primarily in millicuries and so when they
20 went to give the radium-223 because radium-223 is
21 given primarily in microcuries, they wrote the number
22 for microcuries, but they put it in a block that had
23 millicuries. And so the written directive is for
24 millicuries. What was administered was the correct

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1 dosage in microcuries. So that's two errors make a
2 right. So that was not one with any significance
3 other than procedures are now being changed so that
4 they are very aware that when they see radium-223,
5 they're going to have to use a different form that
6 has microcuries so the written directive does
7 correspond with what's given.

8 Next slide.

9 We have our I-131 patient. This was
10 probably one of our more interesting medical events.
11 A patient came in. They gave the patient the wrong
12 identification bracelet. The patient wasn't supposed
13 to get I-131. They moved the patient along, gave the
14 administration and then the authorized user had not
15 bothered to identify the patient by any other means.
16 So this is a clear example of where they're programmed
17 to ensure the patient gets what they are supposed to
18 get failed in multiple areas. And it's human factors
19 1 and 2. So that was -- and the end result was this
20 patient got 728 centigray to the thyroid.

21 Next slide.

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

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1 MEMBER COSTELLO: Going back to that,
2 what was the consequence to the patient?

3 DR. HOWE: They said the consequence --
4 they didn't --

5 MEMBER COSTELLO: It just looked like a
6 big dose is all.

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

8 MEMBER COSTELLO: That would be
9 hypothyroid.

10 DR. HOWE: Yes, there are going to be
11 effects.

12 MEMBER COSTELLO: Thank you.

13 DR. HOWE: So we have one gynecological
14 one and we have four prostates. So this is four
15 medical events in 35.400 - is a pretty low number.

16 So let's go to the next slide.

17 This is a case where the applicator
18 became dislodged during the treatment. The treatment
19 should have lasted the 63 hours. They believe the
20 applicator was dislodged at 49 hours. The inner thigh
21 received a higher dose than it was supposed to be
22 received. To be a medical event, it has to be over
23 50 rem or 50 centigray, certainly that. It has to be
24 over 50 percent of what it should have gotten and in

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1 this case it is. So this is the medical event.

2 Next slide.

3 So prostate brachytherapy. We're always
4 going to have prostate brachytherapy medical events.
5 One reason we probably will always have it is there
6 is confusion in ordering air kerma units when they
7 need millicurie or ordering millicurie when they need
8 air kerma. So this is one that we've seen before.
9 They've ordered in the wrong units. So you ordered
10 millicuries instead of air kerma.

11 The second prostate brachytherapy medical
12 event was when some of the seeds were inadvertently
13 implanted into scar tissue and therefore the prostate
14 didn't receive the full dose that it was supposed to
15 receive.

16 Next slide.

17 Then we have the ultrasound issues.
18 We're almost always going to have medical events
19 because of this reason. People, the physicians, and
20 the urologists, and the oncologists don't necessarily
21 see the prostate. They see another anatomical area,
22 generally the penile bulb. They insert all of the
23 seeds and it's not until they take an image later
24 that they find they were not in the right location.

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1 So you can pretty much tell these because they're
2 always about 2.5 to 3.5 centimeters from where the
3 target tissue should have been. So both of those
4 were due to ultrasound issues.

5 Next slide.

6 Now we've got the 35.600. We had both
7 HDR and Gamma Knife this time. I had a difficult
8 time trying to break down the HDRs for you. First of
9 all, there were a number of different target areas
10 that were being treated, but also there were a number
11 of different reasons for the errors. So in this
12 particular slide, you'll see the different target
13 areas. They had scanned a bronchial, one not
14 designated. It was probably pelvic. It was one
15 designated pelvic and then three OBGYN cases and then
16 we have one Gamma Knife.

17 So the next slide shows the reason for
18 the errors. Wrong site, wrong patient, decay
19 correction, right patient, wrong treatment plan,
20 source retraction, wrong dwell time, wrong
21 interpretation of dose per fraction. Some of these
22 are common human errors that we've seen many times
23 before.

24 So let's take a look at the wrong site

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1 ones. We had an OBGYN case where for three of the
2 treatments they gave 700 centigray per fraction and
3 they realized that they had given the treatment later.
4 They realized they had given it 10 centimeters short
5 of the intended treatment site, so they ended up with
6 radiation burns to the patient's thigh and labia. So
7 that one had medical consequences.

8 The next slide was a bronchial and in
9 this case they had two different segments. One
10 segment used a simple catheter. The other used a
11 centering catheter. One of the segments wasn't
12 delivered correctly. So they discovered the error in
13 the first fraction so they gave the second treatment,
14 which I think is the center catheter was nine
15 centimeters from where it should have been delivered.

16 Next slide.

17 We have another OBGYN. They had three
18 fractions and when they checked to make sure the
19 positioning of the vaginal cylinder on the first
20 fraction, they realized that it wasn't where they
21 thought it should be. They attributed that to special
22 patient anatomy, something that you guys would have
23 called patient intervention.

24 However, when they went to give the

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1 second fraction and they checked the x-ray, they found
2 out it went exactly where they thought it have gone
3 on the first time. So they had an error in the first
4 delivery and they were able to deliver the next
5 fractions the way they were intended in the written
6 directive. So in the first one they delivered 900
7 centigray to the wrong treatment site. And so it
8 really wasn't patient intervention. It was
9 positioning issues.

10 On the next slide, this is where we have
11 the wrong patient. And this one was to the skin.
12 They were looking at the correct site. They were
13 looking at the right applicator, but they used the
14 wrong patient's treatment plan. So they delivered
15 the wrong dose to the wrong place. And the area
16 adjacent to where the dose was got about 2,300
17 centigray to a single point. We don't normally see
18 where they use the right target, the right applicator,
19 but they use the wrong treatment plan. So that one
20 is a little bit different from what we normally see.

21 The next slide.

22 This one is a little hard to explain.
23 For some reason, they believed that they needed to
24 put a decay correction for the source into the HDR

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1 treatment plan and did not realize that the HDR
2 treatment plan already accounted for decay
3 correction. Therefore, they had doubled decay
4 correction and they gave too much radiation because
5 the time window was much longer than it should have
6 been. I think this is about the first one I've ever
7 seen that's been this. It kind of sounds like
8 somebody was not familiar with the treatment plans or
9 a new physicist. I don't know exactly why.

10 The next slide.

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

19 Next slide.

20 In this particular case, they had started
21 the procedure. They went to the first dwell location.
22 When they went to the second dwell location, they
23 experienced a resistance and the HDR did exactly what
24 it was supposed to do. It retracted. It would not

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1 go back out. So they tried new tubes. That didn't
2 work. The dummy wire source wouldn't transverse, so
3 they had to abandon this particular procedure.

4 Next slide.

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

17 Next slide.

18 Okay, this one we've seen, this type of
19 event happen before. You've got three fractions of
20 500 centigray each. And when they set up the
21 treatment plan instead of saying 3 times 500, they
22 divide 500 by 3. And so the patient got much less
23 than they were supposed to get because they did the
24 fractions, the dose delivered on each fraction was

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1 too low.

2 Next slide.

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

18 Now next slide.

19 Now we get to 35.1000. And if you
20 remember correctly, there are 46 medical events
21 total. Over half of them are in 35.1000. The
22 majority of them in 35.1000 are in the yttrium-90
23 microspheres. What's interesting on the 35.1000
24 medical events this time is that we did have a

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1 Perfixion and a seed localization medical event.

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

14 The next slide.

15 The seed localization. This is supposed
16 to be a diagnostic procedure. In this case, the
17 licensee received two seeds. They had two markers.
18 One marker was for a benign biopsy. They had two
19 seeds, so they put one seed in the benign biopsy site
20 and they put one seed in the cancer site. So that
21 was unintended dose that was for two days' duration
22 until they explanted the seed and so they received 61
23 centigray to a half centimeter volume.

24 The next slide.

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

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

20 The second one was in the gastric fundus.
21 They prescribed microspheres to the right lobe. They
22 stopped when they identified unexpected shunting and
23 they delivered a little over 1,000 rads to the gastric
24 fundus.

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1 Our next event, this was an overdose of
2 13,000 centigray or rads. This is a 10,000 centigray
3 or rads to the lung. In this case, the -- no, have
4 I got the right one? No. Okay. Sorry about that.

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

14 Next slide.

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

22 The next one, the microspheres were in
23 the tubing near the stopcock valve, but in that case,
24 the device was not defective, but the spheres got

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

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

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

13 The next slide.

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

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

20 And the next slide.

21 You had two different under doses. You
22 had a split dose. Each one of them had its own
23 written directive and they didn't realize until they
24 got to the very end that there was blockage in the

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1 delivery system and that neither one of the procedures
2 received the microspheres that they should have
3 received.

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

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

24 And then the last one for the SirSpheres

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

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

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

21 Next slide.

22 In this case, they couldn't properly
23 position the catheter into Segment IV. But they went
24 ahead and delivered it and when they did deliver the

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1 dose, very little went into Segment IV. About half
2 of the dose went to Segment IV and the other half
3 went to the right lobe.

4 Next slide.

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

10 Next slide.

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

19 Next slide.

20 So in this case, 20 percent remained in
21 the vial. Didn't get into the tubing. The one below
22 it, 44 percent under dose. The targeting vessel was
23 flowing slowly. The microspheres settled out prior
24 to reaching the target. The 73 percent under dose,

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1 they had the wrong catheter and they had kinking. We
2 had a lot of cases where they identified a particular
3 catheter brand as having issues for multiple
4 licensees. I didn't bring that with the catheter
5 brand before the ACMUI because we don't know that
6 there aren't other catheters out that they just didn't
7 name the brand on. But this was one of those.

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

18 My last slide is a GliaSite. Probably
19 we'll have to do a little bit more checking on this
20 one to make sure that it is a medical event. In this
21 particular case, the balloon didn't inflate correctly
22 because they put a three-way stopcock on that they
23 were not supposed to use. It's not part of the
24 GliaSite packet. And they put the stopcock on the

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1 wrong position and so the ion tracks didn't go into
2 the balloon to load the balloon up. So we have to
3 check. This may or may not be a medical event
4 depending on whether the patient received the dose.
5 If they didn't receive a dose, then it won't be a
6 medical event, but we don't know exactly where the
7 syringe was in relationship to the patient. So it
8 could have been close enough to give a dose, but the
9 wrong treatment site.

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

13 CHAIR THOMADSEN: Thank you very much,
14 Dr. Howe. Comments and questions from the committee?
15 Questions? Yes, Dr. Zanzonico.

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

23 DR. HOWE: I don't think we have a sense
24 of that. We do inspections. Some of the medical

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1 events that are identified come up as a result of
2 inspection because the inspectors, although they're
3 not specifically going to say where are the medical
4 events you didn't report, that comes up in the
5 discussion of how your program is doing. And so we
6 have identified a number of medical events that were
7 not identified by the licensee. And that happens
8 every year.

9 MEMBER ZANZONICO: But I presume it's not
10 a huge excess?

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

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

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

18 DR. HOWE: I think they figured out that
19 there was a kink in the catheter going out and that
20 the HDR device did what it was supposed to do. It
21 could not send the source out so it retracted it.
22 And when they tried the same thing with the dummy
23 source, it wouldn't go out either so it retracted.
24 So it was in that connector going into the patient

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1 where the problem was located.

2 MEMBER O'HARA: Thank you.

3 CHAIR THOMADSEN: Yes, Dr. Mettler.

4 DR. METTLER: You alluded that there
5 might be a problem with a catheter from a vendor, a
6 particular manufacturer. Is there some way that your
7 information on such things gets to the FDA?

8 DR. HOWE: Yes. We have an NRC-FDA MOU
9 and we can share that information freely with the FDA
10 and we also have certain people in the FDA that have
11 access to our database.

12 DR. METTLER: So that routinely happens.

13 DR. HOWE: I haven't shared this
14 particular one, but I can send information over.
15 That's a good point.

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

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

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

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1 MEMBER LANGHORST: I think it's important
2 to note that when you say that you don't know some of
3 the information, sometimes it's not reported by the
4 Agreement State as opposed to by the licensee. And
5 also do all Agreement States report their events to
6 the NMED database?

7 DR. HOWE: All Agreement States report
8 their medical events to the NRC and they get into the
9 NMED database.

10 CHAIR THOMADSEN: Or at least they're
11 supposed to.

12 MS. DUDES: And that's where I was at. I
13 actually thank the Committee because both of you asked
14 the questions that I was going to pose back to the
15 Committee.

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

24 We use our IMPEP process to audit the

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1 programs to assure that they're trying to put those
2 things into NMED and report, make the reports.

3 We have been trying to do some webinars
4 and training for Agreement State inspectors and NRC
5 inspectors on when you're out how do you look for
6 medical events and it's not necessarily that you're
7 out there looking for the event, but how would you
8 spot one? Because I don't think that's -- it's a
9 more studied type of skill.

10 Each year we do report to our Commission,
11 okay, here is the status of the program. Here is the
12 number of events. I always feel a little odd in that
13 I don't have a sense of okay, 45 out of 150,000
14 therapeutic and then God knows how many diagnostic
15 which I think the threshold there, that's a little
16 different. But I was going to pose to the Committee
17 who practices and sees, is this -- would you expect
18 this? But you were asking us the question, so I'm
19 curious what others think because the Commission and
20 I, in my reporting, well, 45 out of 150,000.

21 CHAIR THOMADSEN: Mr. Costello.

22 MEMBER COSTELLO: A couple of years ago,
23 I gave a talk at OAS and it was about microspheres
24 medical events and I broke them down by State. I did

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1 this because we had so many. And some States that
2 are huge, perhaps the biggest State, starts with a C,
3 had fewer, had similar events as Idaho.

4 To get events reported, my view, it's not
5 for us to find them on inspections. It's a very hard
6 thing for us to do. To rely on us finding them on
7 inspections is really not realistic.

8 MS. DUDES: Right.

9 MEMBER COSTELLO: What I do ask for
10 inspections, I ask licensees, well, how did they know
11 this was a medical event? You know, is that
12 something, do they evaluate their treatments? Do
13 they think about it? Because if they're not being
14 noticed by the licensees, the chances are they're not
15 going to be noticed. I mean think of the events that
16 are described up there. By and large, inspectors
17 aren't going to find those. Licensees have to notice
18 those.

19 And so at least -- I know it was in
20 Pennsylvania, I encouraged people just ask a simple
21 question. If trained in modality, just pick a
22 modality. If you had a medical event, how would you
23 know it? And sometimes you get very good answers.
24 Sometimes not as good. I think the best a regulator

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1 can do is to remind a licensee that it's a licensee's
2 responsibility to report medical events because we
3 the States are really not well positioned to identify
4 them ourselves.

5 CHAIR THOMADSEN: Thank you. Dr.
6 Mettler.

7 DR. METTLER: The IAEA has struggled with
8 your question for a long time, especially about
9 radiation therapies, and everything else. And I
10 think in general, most people feel that accident
11 reports are somewhere between 10 and 30 percent of
12 what's actually happening, especially since they
13 generally have to be self-reported.

14 DR. HOWE: And I think Laura brought up
15 a point and Frank brought up an excellent point. If
16 the licensee doesn't recognize it, then it's going to
17 be more difficult to report. Every once in a while,
18 and he's right, the inspectors aren't there to
19 identify unidentified medical events, but as they're
20 asking questions they may trigger something in the
21 licensee that they remember.

22 I've also gone through a number of years
23 and looked at the Agreement State response. And many
24 times when I'm going through this all of a sudden I

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1 will see a huge number of medical events from a given
2 State. I know that State just had an IMPEP, and so
3 they were asked well, how are your medical events
4 doing? And then they look and either they received
5 them and they didn't pass them on or for some other
6 reason. So we tend to -- and that's one reason that
7 I always present the medical event talk as to what
8 was recorded in the fiscal year, not what happened in
9 the fiscal year because that way if I've got medical
10 events that were identified late, they're going to be
11 captured. If the State is late in getting them in,
12 they're going to be captured. So it gives you the
13 most complete picture by identifying those things
14 reported in that particular year.

15 CHAIR THOMADSEN: Dr. Zanzonico.

16 MEMBER ZANZONICO: Just to address your
17 question, I'm Chairman of the Radiation Committee at
18 Memorial, which presumably sees all of the medical
19 events. And we like to think we're very self-critical
20 in terms of what constitutes a report on medical
21 event. And I would say across all modalities, no
22 more than one to two a year with many years having
23 none. And that's a very large number of procedures
24 across modalities. So I think it's at least

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1 qualitatively consistent with a very low ME rate
2 that's reported here.

3 CHAIR THOMADSEN: Dr. Weil.

4 MEMBER WEIL: It's fine.

5 CHAIR THOMADSEN: I think we're going to
6 have to live with that one.

7 MEMBER WEIL: Just two points, one in
8 response to Dr. Zanzonico, but you're at Memorial.

9 MEMBER ZANZONICO: Yes.

10 MEMBER WEIL: Okay, so enough said there.
11 I wonder if there's any transparency or coordination
12 among other entities that collect this kind of data
13 like CMS and State health departments in terms of
14 what get called different things by different
15 agencies. In this instance, medical events, medical
16 errors or unanticipated outcomes. Do you know? CMS
17 collects a bunch of stuff about unusual occurrences.
18 And NRC is collecting stuff. Is there any
19 coordination between those two entities?

20 DR. HOWE: I don't believe we have any
21 coordination between the two. In many cases, it's
22 because our definition is pretty well defined and
23 it's here and their definition may be something else
24 than over there. We do communicate back and forth

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1 with FDA. If they see something that they think we
2 need to know about, they let us know. If we see
3 something we think they need to know about, we let
4 them know. So we do have that coordination going.

5 CHAIR THOMADSEN: Dr. Langhorst.

6 MEMBER LANGHORST: I think last year when
7 we were talking about the various groups that are
8 trying to gather these types of information and near
9 misses and so on, that there was a move maybe to make
10 some of the NMED data public. Is there -- what's the
11 status of that? Because again, it's always good to
12 learn from others' errors.

13 MR. BOLLOCK: We evaluated that at a
14 public meeting and did quite a bit of outreach and
15 there was not a lot of interest.

16 MEMBER LANGHORST: Okay.

17 MR. BOLLOCK: From the public for that.

18 MEMBER LANGHORST: Okay.

19 MR. BOLLOCK: It was -- so we made a
20 decision based upon the fact that there are publicly-
21 available yearly reports that give the numbers, the
22 statistics that are available from NMED and there are
23 other ways if you have questions on that, you can
24 reach out to us or the states for specific questions,

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1 but we felt that that was enough.

2 MEMBER LANGHORST: Okay.

3 CHAIR THOMADSEN: Mr. Costello.

4 MEMBER COSTELLO: Two points. One on the
5 public NMED. I think it would be fair to say that
6 because of public NMED there is very open hostility
7 from Agreement States on public NMED. More than
8 disinterest. I can talk to anybody who was talking
9 about that, but there are reasons why the States are
10 not crazy about that idea.

11 And the second about medical events, at
12 least in our State, they generally are reported on
13 the better institutions. The better institutions,
14 the stronger programs are more likely to identify
15 medical events. Okay? That doesn't mean, I don't
16 think that they have more of them. In fact, being
17 aware of the program, I think they'd like to have
18 less of them, but in fact, they're the ones who report
19 them fairly religiously. Other places, during
20 inspections I ask, might be less likely to do it than
21 the really strong programs.

22 CHAIR THOMADSEN: Dr. O'Hara.

23 MEMBER O'HARA: The medical device-
24 reporting database, it's called MAUDE, if any of you

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1 have ever looked at it, it's public. Part of it is
2 public. It doesn't contain proprietary information
3 on specifics about the products. It's undergoing
4 some changes right now. They're changing how it
5 operates. They're going to change the searching
6 abilities of it. And it's gone through a few name
7 changes, too. At one point in time it was going to
8 be called ISIS, but one of the biggest things that
9 has to do with radiological devices is that all of
10 the medical device reporting comes into the same
11 division, the Division of Radiological Health. It
12 doesn't sound like a big change, but it is because
13 the Division of Radiological Health clears or
14 approves devices for the market. And now the same
15 group that clears or approves devices for the market
16 now gets the medical device reports and does the
17 compliance activities with device sponsors. And
18 that's only been a relatively recent occurrence about
19 two years. So there are some changes that are going
20 on with that. Just thought I would --

21 CHAIR THOMADSEN: Thank you. Comments or
22 questions for the committee? Dr. Suh?

23 MEMBER SUH: In terms of the medical
24 events, do you sense that the human errors are the

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1 same human errors year after year after year? We're
2 hearing common themes of wrong dose, wrong site, wrong
3 patient which in my mind these should be really never
4 events. If you do the proper time out or are properly
5 trained, the authorized user takes the time to
6 visualize what's going on, is present, that shouldn't
7 occur.

8 And one of the things I just noticed is
9 that you kind of hear the same story over and over.
10 I don't think it's necessarily the purview of the NRC
11 to just go and regulate medicine, but somehow I think
12 if physicians and others are educated on what's going
13 on, perhaps it will increase the awareness. I can
14 tell you, just being on the committee, it's definitely
15 opened my eyes in terms of how a patient can be seen
16 at a radiation oncology department. So we have really
17 increased kind of our right versus right, identifying
18 correct patient, making sure we electronically
19 document time outs for every single patient because
20 we want to really minimize any of these occurrences
21 from occurring.

22 DR. HOWE: I'll tell you that back in the
23 1980s when we brought in the misadministration rule
24 which is the precursor to the medical event rule in

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1 1980, they decided that they would try to do something
2 to reduce the number of misadministrations and they
3 would do it two prong. NRC would do a two-prong
4 approach. One would be rulemaking to capture simple
5 human errors and how can we prevent some of the more
6 common simple human errors.

7 And the second part would be to go after
8 quality control of devices and so what they found was
9 probably 90 percent of the medical events are simple
10 human error. And we had a rule that was implemented
11 in 1992 called the quality management rule. Many
12 core parts of that rule are still in the regulations
13 and they found out that the most simple human errors
14 that attributed to most of the medical events were
15 identifying the patient. So we had a requirement to
16 use two different methods to identify the patient.

17 In 2002, we dropped back on the
18 prescriptive nature of that and you just have to
19 identify the patient. The second was the written
20 directive because there were many, many things coming
21 across on the telephone that weren't being recorded
22 correctly. So we went to a written directive. And
23 so those two things. And you will have heard a common
24 thread in here where some people were not looking at

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1 the written directive. The one doing the treatment
2 plan for the Gamma Knife knew or the Perfexion, knew
3 the patient always got treated on the right side and
4 went and set it up for the right and didn't bother to
5 look at what the physician wrote.

6 So you're right. A lot of these are the
7 same type of human errors, happening in different
8 locations because they are in some respects the
9 easiest human errors to make and it's really difficult
10 to eliminate them, but we try with a written directive
11 and we also tried with the patient identification.

12 And now, we are adding in the new proposed
13 35 requirement to evaluate administrations to make
14 sure you don't have medical events. So we're trying
15 to get to those issues. So I don't think I was
16 helpful, but I'm just trying to tell you, we've
17 recognized that was an issue all along and continues
18 to be an issue.

19 MEMBER SUH: It's just you see common
20 themes.

21 DR. HOWE: Yes. And it's frustrating
22 because we see the same thing happening over and over.

23 CHAIR THOMADSEN: Mr. Costello.

24 MEMBER COSTELLO: Another thing I'll say,

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1 there's a course that they give called the root cause
2 course for investigating. One of the things you
3 learned is be skeptical when human error is always
4 given as the reason because sometimes a little
5 probing, you can find out why the human error
6 occurred. It could be a training issue. It could be
7 a procedure issue. It could be a working condition
8 issue.

9 It could be a lot of things, but the
10 easiest thing is the patient, if you're an inspector
11 looking into it is say well, the person identified
12 was the wrong patient; it must have been a human
13 error. Well, maybe, but maybe a little deeper looking
14 into what happened you can find out the person had
15 worked so many hours, tired, or the person who was
16 doing the job hadn't got trained or the procedures
17 were bad. Sometimes human error is just sort of a
18 quick, glib answer that the inspector can take and be
19 done and write up the report. I'm just saying, as an
20 inspector, if you spend some more time interviewing
21 people and interviewing the person who made the error,
22 you might find out that there are deeper causes.

23 DR. HOWE: Also, another thing I would
24 point out in the root cause is many of the accepted

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1 changes are training, but in fact, if you really
2 looked at the human error it's more than training.

3 CHAIR THOMADSEN: And from human error
4 analysis, you almost always find that there's never
5 a root cause. There's always multiple root causes of
6 these things. You're absolutely right, training is
7 not a particularly effective treatment for these
8 problems.

9 Other comments from the committee? In
10 that case, thank you very much.

11 DR. HOWE: Thank you.

12 CHAIR THOMADSEN: We are way ahead of
13 schedule at the moment. And as always, because there
14 are people who may be coming in to listen to certain
15 topics who are expecting it to be at certain times we
16 really can't just go ahead. So we are going to be on
17 a break now until 3:30 when we will talk about
18 radioactive seed localization.

19 (Whereupon, the above-entitled matter
20 went off the record at 2:12 p.m. and resumed at 3:30
21 p.m.)

22 CHAIR THOMADSEN: We are ready to
23 continue on the topic we were just discussing of
24 medical events, that we need to renew the Subcommittee

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1 that reviews the medical events this Committee each
2 year because we have lost a couple of the members
3 from that Subcommittee.

4 And so, the new Subcommittee will be
5 Steve Mattmuller and Pat Zanzonico, John Suh, myself,
6 Michael O'Hara, Ron Ennis. And I think that it is
7 it.

8 Is there anybody who was on the Committee
9 last time that I have forgotten?

10 MS. HOLIDAY: Dr. Palestro.

11 CHAIR THOMADSEN: Oh, Dr. Palestro.
12 Thank you. Right. There we go. I think that is the
13 Committee then.

14 MEMBER LANGHORST: I have been on it in
15 the past, but I am good with not being on.

16 CHAIR THOMADSEN: How many do we have?
17 That would be too many, I think.

18 MEMBER LANGHORST: Right.

19 MS. HOLIDAY: So, by practice,
20 Subcommittees should have six members or less. This
21 is not a Subcommittee that makes recommendations per
22 se. The Subcommittee just presents information on
23 medical events. I think it is fine if you have more
24 than six members.

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1 CHAIR THOMADSEN: I think you're on it.
2 Congratulations.

3 (Laughter.)

4 Is there anybody who wants to speak up?

5 (Laughter.)

6 MS. HOLIDAY: I have Dr. Ennis, Dr.
7 O'Hara, yourself, Dr. Palestro, Dr. Langhorst. Who
8 was the sixth person?

9 CHAIR THOMADSEN: Dr. Suh.

10 MS. HOLIDAY: Dr. Suh. Okay. So, that
11 is six people.

12 CHAIR THOMADSEN: And Dr. Zanzonico.

13 MS. HOLIDAY: Thank you.

14 CHAIR THOMADSEN: Yes. We will name the
15 people who aren't on that Committee.

16 (Laughter.)

17 Well, I think we are ready to proceed
18 with our schedule here. It is a pleasure to introduce
19 Michael Sheetz from the University of Pittsburgh to
20 talk about radiation safety and regulatory issues of
21 radioactive seed localization of non-topical lesions.

22 MR. SHEETZ: Thank you. I would like to
23 thank the members from the NRC and the ACMUI for
24 giving me this opportunity to speak on radioactive

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1 seed localization, or RSL.

2 I must admit that, when I first heard of
3 RSL, I thought to myself, why would anyone want to
4 implant a seed in a patient just to localize a lesion
5 for surgical removal? And then, I learned of the
6 benefits that this technique has with respect to
7 patient care. And so, I have become a proponent or
8 a supporter of this procedure, as evidenced by my
9 presence here.

10 Next slide, please.

11 RSL was developed in the late 1990s, the
12 first clinical trials occurring in 2001. I would
13 say, up until the last several years, most
14 institutions adopting this procedure have been large
15 medical institutions with broad scope licenses.

16 We initiated our RSL program in 2011. We
17 now have one of the most active programs I think in
18 the country. We are implanting over 100 seeds or 100
19 procedures per month at six different locations.

20 We have also sponsored several RSL
21 workshops or seminars, one-day seminars for
22 institutions interested in starting a program. Mayo
23 Clinic has been offering RSL workshops for several
24 years, and most recently, both MD Anderson and

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1 Memorial Sloan Kettering are offering RSL workshops.
2 And so, it has gained more attention and interest.

3 From my employment with the workshops,
4 conversations with colleagues, presentations I have
5 done at professional meetings, the feedback I am
6 getting is that, primarily from limited scope
7 licensees, is that strict compliance with the NRC
8 licensing guidance document makes it difficult to
9 establish a program, and some have even given up.

10 And so, my purpose here today is to try
11 to point where certain revisions and changes to the
12 licensing guidance can make it more relevant to the
13 procedure, make it less burdensome for institutions
14 trying to initiate a program, and allow entries to
15 access of this beneficial procedure to patients.

16 Next slide.

17 The medical background, advances in
18 technology and screening mammography have led to
19 increased detection of microscopic breast lesions.
20 The traditional method of pinpointing these areas of
21 concerns is where a localization breast biopsy
22 procedure where a radiologist places a thin guide
23 wire into the area of concern, using ultrasound or
24 mammography. The surgeon, then, removes the tissue

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1 around the guidewire and sends it to pathology for
2 analysis.

3 Alternative technique, RSL, in this
4 procedure a radiologist a radioactive seed in the
5 area of concern, again under ultrasonic or
6 mammographic guidance. The surgeon then uses a gamma
7 probe to locate where the seed and the lesion is for
8 extraction. There have been a number of studies and
9 publications showing benefits of RSL over the wire
10 localization procedure.

11 Next slide.

12 An example of the wire localization
13 procedure with the image on the left, the radiologist
14 places a needle to the center lesion and, then,
15 inserts a guide wire with a barb on the tip to hold
16 it in place. The wire extends outside the skin of
17 the breast. The patient then goes to surgery, where
18 the surgeon makes an incision at or near the
19 protruding wire and uses it to guide the excision of
20 the tissue. On the right is an image of the excised
21 tissue with the wire still attached. These two
22 procedures are performed on the same day.

23 Some of the disadvantage of wire
24 localization is that it can pull out; it becomes

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1 lodged and gets transected during surgery. The
2 surgeon needs to use the wire as his or her point of
3 entry in the surgical procedure. There is patient
4 discomfort, and there are time delays in scheduling
5 between the radiological procedure and the surgical
6 procedure.

7 Next slide, please.

8 With RSL and iodine-125, seed is used
9 which is the same type as that that is used for
10 brachytherapy such as in prostate implants. The seed
11 is now available in sterile, pre-loaded, 18-gauge
12 needles. These packaged seed assemblies are
13 available from two different vendors with full FDA
14 approval for the localization procedure. So, it is
15 no longer an off-label use of a brachytherapy source.

16 Initially, it was an off-label use, and
17 institutions had to buy seasoned bulk and load their
18 own. Now they have let the approval for this
19 procedure, at least from two institutions.

20 The average activity that is used in the
21 seed is around 200 microcuries, although that ranges
22 from about 75 to 300 microcuries. At the bottom you
23 can see what the assembled device looks like. There
24 is an 18-gauge needle with a stainless steel sleeve

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1 around for shielding the radiation from the seed.
2 There is a blue spacer that holds the stylet that is
3 inside the needle in place. And then, the seed is
4 secured in the needle with bone wax, so it doesn't
5 fall out the tip.

6 Next slide, please.

7 The seed is implanted at the center of
8 the lesion by a radiologist under ultrasonic or
9 mammographic guidance by advancing the needle to the
10 center of the lesion. Then, the stylet is used to
11 push the seed out and deploy it into the breast.

12 Once positioned, the seed cannot be
13 repositioned, and then once it is in place, there is
14 a very rare incidence of this seed migrating, even if
15 it is left in for several days.

16 Next slide, please.

17 Immediately following that, a mammogram
18 is taken to verify the implant location. We also
19 perform a survey at this time, or actually before the
20 mammogram, where we will take a GM Survey Meter and
21 we will hold it up to the breast, so that we get a
22 single and confirmed that the seed has been implanted.
23 And then, we will also survey the implant tray and
24 the implant area, so that we make sure we do not

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1 detect any activity therein.

2 The patient is released with instructions
3 to return for the scheduled surgery, usually within
4 five days. We do not provide any radiation safety
5 guidance to these patients, as it is not required;
6 they are releasable and the exposure from these
7 patients is very, very low.

8 Next slide, please.

9 On the day of surgery, the surgeon uses
10 a gamma probe to localize the seed. This is the same
11 instrument that the surgeon uses for sentinel lymph
12 node biopsy with technetium-99m sulfur colloid.

13 The device is set on an I-125 window, so
14 it 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
18 seed is located and where the lesion is located in
19 the breast, and thereby choose the best approach in
20 how they want to excise this tissue.

21 Most of these patients also have
22 technetium sulfur colloid onboard for a sentinel node
23 biopsy. Typically, the seed is removed first, and
24 the sentinel node biopsy is performed after with the

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1 axillary resection.

2 Next slide, please.

3 The gamma probe that is used provides
4 audio feedback and it guides the excision during the
5 whole process. Once the seed and tissue is removed,
6 the surgeon will put the probe up to the tissue, make
7 sure they get a strong signal indicating that the
8 seed is present, and they will take the probe and put
9 it into 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,
15 but also to confine the margins and confirm that all
16 the suspicious tissue has been completely removed.
17 The specimen is then transported to pathology for
18 seed removal. However, some institutions at this
19 point actually have the surgeon removing the seed
20 from the specimen.

21 Next slide, please.

22 In pathology, the pathologist or
23 pathology assistant will use the same gamma probe to
24 scan the specimen and locate where the seed is

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1 positioned within the specimen. They will then
2 section the specimen into grade-thin 4-millimeter,
3 5-millimeter slices.

4 Next slide, please.

5 Once the seed is visualized in one of the
6 sections, they will use reverse-action tweezers to
7 remove it. The seed is, then, typically placed in
8 some type of container labeled with an Rx or tracking
9 number.

10 There is also, then, a survey performed
11 of the remaining tissue specimen to make sure there
12 is no activity in it. The seeds are, then, disposed
13 of either through decay-in-storage or some
14 institutions will actually disinfect the seed at this
15 point and return it to the manufacturer.

16 Next slide, please.

17 Some studies show a reduced incidence in
18 positive margins. With a positive margin, that means
19 that there is still cancerous tissue close to the
20 edge or at the edge of the tissue sample that was
21 removed. It requires a repeat surgery. Repeat
22 surgery positive margin incident rates vary greatly
23 from surgeon to surgeon and institution to
24 institution, but they are somewhere in the range of

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1 5 to 20 percent. So, it is not insignificant as far
2 as this repeat rate and requiring new surgery.

3 With RSL, the surgeon can approach the
4 lesion from an angle. And so, this results in better
5 cosmetic outcomes. There is less pain and discomfort
6 for the patient, because once the seed is implanted,
7 the patient doesn't feel anything.

8 And one of the largest advantages is that
9 it decouples the radiology procedure from the
10 surgical procedure. And so, delays in the breast
11 center don't, then, cause delays piling up in the
12 surgery center. Also, too, it allows for first-
13 morning surgeries now; whereas, before that would not
14 be possible.

15 Next slide, please.

16 RSL is covered under 35.1000 since it
17 really doesn't fit in any of the other medical use
18 categories. The NRC issued licensing guidance for
19 RSL in 2006. To my knowledge, it has not been revised
20 since then.

21 At that time, it was an off-use of the
22 same seeds used for brachytherapy. So, it makes sense
23 that the focus of the initial guidance would be to
24 view this as a therapy procedure. However, even

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1 though RSL uses the same seed as that used for
2 brachytherapy, albeit at a lower activity, this is a
3 localization procedure performed that is very similar
4 to the technetium-99m sulfur colloid localization for
5 sentinel lymph nodes under 35.200. It should be noted
6 that RSL is the only non-therapeutic procedure
7 addressed under 35.1000.

8 There are also certain regulatory
9 requirements in Part 35 that will apply to RSL, such
10 as patient release, leak tests, decay, and disposal
11 of seeds, instrument calibration, and so forth. So,
12 there are other regulations still in Part 35 that are
13 applicable and don't need to be addressed in the
14 licensing guidance.

15 Next slide, please.

16 I feel that the main issues to be
17 addressed with respect to how RSL is performed and
18 was being required in the licensing guidance are the
19 training and experience requirements for the AU and
20 individuals working the supervision of the AU; the
21 need for a written directive; radiation surveys and
22 their documentation; what would constitute a medical
23 event for RSL; survey instruments used for this
24 procedure and their calibration requirements, and

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1 commitments to certain safety precautions in Part 35
2 that may not be directly applicable to radioactive
3 seed localization.

4 Next slide, please.

5 In the guidance document, an individual
6 qualifies to be an AU for RSL if they meet the
7 requirements in 35.490 for manual brachytherapy or a
8 radiation oncologist. However, this procedure is not
9 performed by radiation oncologists, as they are
10 neither trained nor credentialed to perform this
11 procedure.

12 For a radiologist to be qualified as an
13 Authorized User, they must meet the requirements in
14 35.290 for unsealed sources and be supervised in three
15 cases by a 490-approved Authorized User. I would
16 question whether it is appropriate for an individual
17 to supervise casework for an implant procedure that
18 they themselves do not perform.

19 There is a requirement for participation
20 in three cases by the Authorized User. This can be
21 difficult to obtain in institutions that are just
22 starting out with the procedure where no one is an
23 Authorized User. And so, then, who becomes the
24 supervisor?

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1 Also, it is not practical for the person
2 attempting to be an Authorized User to go to another
3 institution where RSL is licensed because most likely
4 they will not have clinical privileges there to
5 perform that procedure under an Authorized User at
6 that other site.

7 Consideration should be given to
8 accepting observance of cases to meet this three-case
9 requirement or attendance to an RSL workshop to meet
10 this requirement, or consideration should also be
11 given to removing the three-case requirement to be an
12 AU, as there is little or no precedent for it for any
13 other localization procedure or any other non-
14 therapeutic procedure.

15 The guidance document also requires the
16 Authorized User to have experience in the surgical
17 incision and seed removal. While the AU should be
18 knowledgeable in the procedures that the surgeon is
19 performing and the pathologist is performing, again,
20 they cannot perform these procedures as they are
21 neither trained in that nor credentialed to perform
22 those. I know of one Agreement State where they were
23 insisting for the AU to get this work experience and
24 actually perform these procedures.

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1 In the same sense, the surgeons that are
2 working under the supervision of the Authorized User,
3 in the guidance document it wants them to have
4 training or preparation in implanting the seeds.
5 Again, I will say surgeons are not qualified to
6 prepare and implant seeds. And so, while they should
7 be knowledgeable in the implant procedure, they
8 themselves can't have actually hands-on work
9 experience performing that.

10 Several statements in the guidance
11 document imply that only an Authorized User implant
12 seeds. As I have previously explained, the RSL
13 procedure involves three different components. One,
14 implanting a radioactive seed in a patient under
15 mammographic or ultrasonic guidance by a radiologist.
16 Two, surgical removal of a target lesion and seed
17 from the patient by a surgeon. And three, removing
18 the seed from the tissue specimen by a pathologist or
19 pathology assistant.

20 Therefore, many, if not all, of these
21 procedures with RSL are being performed by
22 individuals working under the supervision of the AU.
23 And so, this should include a radiologist who is not
24 an AU, but has appropriate training experience to

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1 implant seeds. Radiologists, by training, implant
2 clips to mark biopsy sites. They implant wires for
3 the localization procedure. And so, implanting a
4 radioactive seed is an equivalent procedure for
5 radiologists.

6 Next slide, please.

7 The procedure does not meet the
8 requirements for written directive as identified
9 35.40(a). The sources are not intended to deliver a
10 therapeutic dose for palliative, curative treatments.

11 It would take nine days to deliver a dose
12 of 50 rem at 1 centimeter from the seed with a 200-
13 microcurie seed. While this is not a therapeutic
14 dose, it is the dose threshold for a medical event.

15 Also, the documentation requirements for
16 written directive in 35.40(b) sets demanded by the
17 therapy simply are not applicable to the radioactive
18 seed localization procedure. If a non-AU implants
19 the seed, they would not be permitted to sign the
20 written directive.

21 It may be appropriate to require a
22 prescription to document the isotope ascribed implant
23 site total number and activity of seeds implanted,
24 time range of scheduled surgery date, and the name of

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1 the approved radiologist who implanted the seed.

2 Next slide, please.

3 Now I have previously explained surveys
4 are performed after the seed implant with a GM Survey
5 Meter, and in the surgery environment and in the
6 pathology environment, surveys are performed with the
7 gamma probe. Documentation is usually maintained as
8 part of a checklist and not as a separate survey
9 document.

10 Also, it should be noted that, if one
11 tried to perform surveys on the OR, in pathology,
12 with a GM or a thin crystal sodium iodide detector,
13 that there will be interference from technetium if
14 the sentinel node biopsy procedure was performed.

15 If a confirmatory radiograph was obtained
16 following the implant, should this be allowed to
17 substitute for radiation survey, as it will visualize
18 and confirm the location of the seed and even if it
19 was damaged? Similarly, a radiographic image taken
20 of the specimen after it has been surgically removed
21 from the patient could substitute for a radiation
22 survey. So, there are different means and avenues to
23 accomplish this.

24 Next slide, please.

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1 Consideration needs to be given as to
2 what criteria would result in a medical event with
3 RSL procedures. A dose threshold of 50 rem to tissue
4 is unlikely. From the chart, you can see that the
5 dose at 1 centimeter from a 200-microcurie seed would
6 only be 28 rads if left in for five days.

7 Once you realize that when the seed and
8 tissue is removed, there are several centimeters of
9 tissue surrounding the seed that is excised, and so,
10 the dose further out to the tissue that is remaining
11 in the patient would be much less. In this case, at
12 five days at 3 centimeters from the seed, the dose
13 would be down to 2 rads.

14 There is no prescribed dose for radiation
15 seed localization. There is an activity range of the
16 seeds to be implanted.

17 As far as implant time, it is based on a
18 recommendation that we want to perform the surgery
19 within a certain amount of time. If the patient does
20 not return for the surgery -- I know there was a
21 discussion on this earlier, on what constitutes
22 patient intervention -- but there are two different
23 situations.

24 One which has occurred is the patient is

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1 implanted with the seed and they come down with the
2 flu, and so, they can't come back within five days
3 because they don't want to do the surgery. So, the
4 surgery is delayed for two or three weeks. I would
5 contend that that would be patient intervention. It
6 is out of anybody's control and they are going to
7 recover the seed later.

8 If the patient refuses to come back to
9 have the seed removed, then you may question, was
10 there reasonable instruction to the patient to ensure
11 that they would return? And so, I am not advocating
12 any particular stance on what constitutes a medical
13 event. I am just throwing out different situations
14 that need to be thought-through and better defined on
15 what constitutes a medical event for RSL.

16 And there was one case where the seed was
17 intentionally left in the patient because of the
18 location of the seed where it had migrated into a
19 highly-vascularly area. And so, certainly, you would
20 expect that to qualify as a medical event and being
21 reported. So, I am not saying there are no medical
22 event reporting criteria for RSL.

23 Next slide, please.

24 There are three main radiation meters

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1 used for RSL, the thin crystal sodium iodide and GM
2 Survey Meters and the gamma probe. The guidance
3 document recommends a survey instrument with a thin
4 crystal sodium iodide; reverse-surveys are performed.
5 While this is certainly the instrument of choice for
6 trying to locate a lost seed, if you don't know where
7 it is and no other activity is around, the GM Survey
8 Meter works great on the implant side, again, checking
9 that the seed has been implanted in the patient,
10 checking the seed is in the needle. And the gamma
11 probe works fantastic in the OR environment as far as
12 locating the seed and, again, double-checking it is
13 not in the patient. And again, it is the same with
14 pathology. So, consideration should be given for the
15 other instruments.

16 Most gamma probes do not require any
17 routine annual calibration. They only have a system
18 check when the instrument is turned on. So, they
19 don't fit the normal calibration requirements in
20 35.60 and, in fact, the thin crystal sodium iodide
21 detector does not fit the instrument calibration
22 requirements in 35.60 as it typically reads out in
23 counts per minute and not mR per hour.

24 Next slide, please.

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1 There is a section in the guidance
2 document for a commitment to certain safety
3 procedures for RSL. There is a commitment to verify
4 the activity prior to seed implant using a calibrated
5 instrument. There should be allowance now for
6 allowing vendor verification of the seed activity.

7 There is a commitment requested to
8 provide annual training on topics described in
9 35.410. This training is for personnel caring for
10 patients who have been implanted with brachytherapy
11 seeds and cannot be released into 35.75. These topics
12 are not applicable to RSL, and these patients are
13 released under 35.75.

14 If a licensee uses the radioactive seeds
15 that are currently approved by FDA for this procedure,
16 a custom evaluation of its use, off-label use, is not
17 required.

18 Also, there is a lot of emphasis on
19 routine monitoring before, during, and after all uses
20 of the seeds to ensure rapid identification and
21 remediation of a broken or a leaking seed, and
22 emergency procedures and responding to sources that
23 may rupture, retrieval of leaking/cut sources,
24 contamination control, and decontamination of the

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1 patient to carry out.

2 These seeds have been used for RSL
3 procedures for over a decade and thousands of
4 procedures, and without one case ever being reported
5 of a cut or leaking seed implanted in patient. There
6 have been seeds cut on the removal side, in pathology,
7 but not on the implant side.

8 And so, while there needs to be
9 appropriate instrumentation, procedures and response
10 for cut or leaking sources, it should be realized
11 that this is a very rare occurrence, and that the
12 response by the same as that for
13 contamination/decontamination in nuclear medicine.

14 Personnel are wearing personnel
15 protective clothing on the implant and the surgical
16 and the pathology side. So, there is personal
17 protection. And any contamination of items would
18 likely be contained with the bio-hazardous
19 containment system.

20 Next slide, please.

21 The guidance document may want to
22 consider or have consideration for other procedures,
23 have those events. One of these would be loss of the
24 radioactive seed, implanting a radioactive seed in

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1 the wrong patient or the wrong location, inability to
2 locate an implanted seed during surgery, and there's
3 been a planted seed in the patient but the patient
4 does not return for the scheduled surgery. We have
5 actually experienced three of the four.

6 Next slide, please.

7 So, in conclusion, I believe that the RSL
8 procedure provides significant clinical and patient
9 care advantages over the standard wire localization
10 technique. Strict compliance with NRC licensing
11 guidance document makes it very difficult for limited
12 scope licensees to implement this procedure. State
13 regulators are not likely to vary from the stated
14 guidance without specific approval from the NRC.

15 And I believe certain revisions to the
16 guidance document can make it more relevant to the
17 way the procedure is performed, make it less
18 burdensome for institutions to establish an RSL
19 program, and allow increased access to this
20 beneficial procedure for patients, while maintaining
21 a high level of safety.

22 Thank you.

23 CHAIR THOMADSEN: Thank you.

24 Comments from the Committee?

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1 Dr. Costello? Mr. Costello?

2 MEMBER COSTELLO: Well, Sue promoted me
3 to being a doctor earlier. So, I appreciate that.

4 What are the barriers to the radiologist
5 being approved?

6 MR. SHEETZ: If they are boarded in
7 radiology from 2007 forward, they would meet the
8 requirements. But, if they are boarded prior to that,
9 they would have to fill out the preceptor statement
10 and document all of the training experience.

11 MEMBER COSTELLO: So, I was looking at
12 your slide on Authorized Users. They wouldn't need
13 to be supervised in three cases by a 35.490 Authorized
14 User, right, because they would be an Authorized User
15 if they were a radiologist?

16 MR. SHEETZ: No, if you are a radiologist
17 and you have equivalent training for 35.200, you still
18 need to be supervised in three cases by 490 or another
19 Authorized User who is already approved for RSL. So,
20 your 35.200 training experience criteria does not
21 qualify you to be an Authorized User alone.

22 MEMBER COSTELLO: Because that is what
23 the guidance says? Okay. This isn't 35.400 use;
24 this is 35.1000 use. But they chose to use 35.490

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1 as --

2 MR. SHEETZ: Correct, in this space, and
3 understandably so, because at that time it was an
4 off-label use of a brachytherapy source.

5 MEMBER COSTELLO: Okay.

6 MR. SHEETZ: I am not arguing that, but
7 that is part of my reason for changing the focus.

8 MEMBER COSTELLO: Thank you.

9 CHAIR THOMADSEN: Other comments?
10 Dr. Suh?

11 MEMBER SUH: Do you have a rough sense of
12 how many centers use this technique, this radioactive
13 seed localization technique?

14 MR. SHEETZ: From conversations with one
15 of the largest distributors, it is that they have 40
16 clients.

17 MEMBER SUH: Forty clients?

18 MR. SHEETZ: Yes, in the country.

19 MEMBER SUH: Do you have a broad sense of
20 like how many cases per year in the U.S. that they
21 do?

22 MR. SHEETZ: I do not have an idea of how
23 many cases in the U.S. So, we are doing 1200, or
24 whatever. Memorial Sloan Kettering is doing, in

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1 fact, actually more than we are. They are doing a
2 lot. I would say Mayo is probably close, third. So,
3 it is times several thousands [of] cases per year.

4 MEMBER ZANZONICO: Right, and the only
5 incident in thousands, one seed was cut in pathology?

6 MR. SHEETZ: I think the broad scope
7 licensees have been doing this and they are the main
8 user of this. But now, I think because of the
9 articles that have come out, it is limited scope
10 licensees that are trying to add this procedure, and
11 this is where the difficulties come in.

12 It is really driven by the surgeons. The
13 surgeons love this. It is not driven by the
14 radiologists. It is driven by the surgeons.

15 CHAIR THOMADSEN: Ms. Weil?

16 MEMBER WEIL: Where do you get the data
17 that this is a preferable procedure for patients from
18 the point of view of discomfort?

19 MR. SHEETZ: Anecdotally, from patients
20 that we have done both the wire and the seed. And
21 so, this is the response back to the
22 mammography/breast care imaging tech, that "Oh, wow,
23 this seed was a piece of cake. This was great. I
24 wish I had had this before as opposed to the wire."

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1 MEMBER WEIL: And why do you have a
2 mammogram immediately post-seed implant?

3 CHAIR THOMADSEN: It works with a wire
4 with a hook on the end.

5 MR. SHEETZ: Sure.

6 MEMBER WEIL: But do you do the
7 mammogram? Do you have to --

8 MR. SHEETZ: Uh-hum.

9 MEMBER WEIL: Yes?

10 MR. SHEETZ: Yes, there is still imaging
11 with the wire.

12 MEMBER WEIL: Never mind.

13 (Laughter.)

14 CHAIR THOMADSEN: Okay. Dr. Ennis?

15 MEMBER ENNIS: Could you share more
16 specifics about the purported advantages? There is,
17 of course, no data, no real information about how
18 much margins are better, how much pain is better,
19 whatever the purported benefits.

20 MR. SHEETZ: I didn't really want to get
21 into that. There are a number of studies. Some show
22 advantages. Some show the procedures to be
23 equivalent. But the numbers are small with all these
24 studies. So, I don't think the verdict is out yet.

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1 MEMBER ENNIS: Okay. So, at this point,
2 is it fair to say the real advantage is the logistics
3 for the surgeon?

4 MR. SHEETZ: Yes, that is the primary
5 driver for it, yes.

6 CHAIR THOMADSEN: Dr. Dilsizian?

7 MEMBER DILSIZIAN: Great presentation. I
8 just have many medical questions, just to help me to
9 understand.

10 Usually, the biopsy, if it is malignant,
11 then, you go in and put in the seed, correct?

12 MR. SHEETZ: Yes, they would do the
13 imaging; they would see a suspicious tissue. They
14 would do a needle biopsy.

15 MEMBER DILSIZIAN: First?

16 MR. SHEETZ: And then, they would drop a
17 clip. Okay.

18 MEMBER DILSIZIAN: You mean you wouldn't
19 wait until the official biopsy comes?

20 MR. SHEETZ: Yes.

21 MEMBER DILSIZIAN: For instance, first,
22 you do the biopsy.

23 MR. SHEETZ: You do a needle biopsy.

24 MEMBER DILSIZIAN: If it is malignant,

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1 then you go in and put in a beaker, right? I mean,
2 you wouldn't just put it in if it is cystic abnormal?

3 MR. SHEETZ: Well, if there is suspicious
4 tissue, they will do a needle biopsy, and then, they
5 drop a clip, a marker clip, where they took the
6 biopsy. And then, pathology does an analysis on the
7 tissue, the needle biopsy.

8 MEMBER DILSIZIAN: Right.

9 MR. SHEETZ: And if that is cancerous or
10 it is suspicious and they say, "We want to remove
11 it," then, the patient comes back and either gets a
12 wire or a seed for surgical removal of that tissue.

13 MEMBER DILSIZIAN: Okay. So, now it is
14 malignancy and you are putting in a seed. My question
15 is two-fold. One, you said that it would interfere
16 with sentinel imaging, which if it is malignant, I
17 mean, it seems to me that sentinel node would be an
18 important quality assessment. Is that correct? Do
19 you say that this would interfere or not with the
20 sentinel technetium assessment?

21 MR. SHEETZ: No, this does not interfere
22 with the sentinel node --

23 MEMBER DILSIZIAN: It doesn't?

24 MR. SHEETZ: Because the gamma probe has

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1 windows for technetium and windows for the
2 Iodine-125.

3 MEMBER DILSIZIAN: Sure.

4 MR. SHEETZ: Where I said it would be a
5 problem or interference is if somebody used one of
6 the other sodium iodide detector instruments to try
7 to survey for I-125, and if there was technetium there
8 for the sentinel node, they would get a signal from
9 that.

10 MEMBER DILSIZIAN: I see. Okay. Thank
11 you.

12 MR. SHEETZ: And so, they would not be
13 able to serve the I-125.

14 CHAIR THOMADSEN: Mr. Costello?

15 MEMBER COSTELLO: You mentioned strict
16 compliance; it is difficult, particularly to limited
17 scope licensees. What particular changes in the
18 guidance would you recommend?

19 MR. SHEETZ: Consideration of everything
20 that I have stated here before you.

21 MEMBER COSTELLO: Well, for example, for
22 an Authorized User how would we change that?

23 MR. SHEETZ: You could still have an
24 Authorized User, either as a 490-approved radiation

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1 oncologist or the 35.200, but not require the case
2 requirements.

3 MEMBER COSTELLO: Okay.

4 MR. SHEETZ: They just have to be
5 knowledgeable in the radioactive seed localization
6 process from implant to surgical removal, to
7 extraction, to inventories and surveys. Because they
8 would be, then, the Authorized Users. Everybody else
9 would, then, be performing the procedure, the
10 radiologist, the breast care radiologist, and the
11 surgeon and the pathologist, they would all be working
12 under the supervision of the Authorized User.

13 DR. METTLER: At the end of the day, this
14 is just the same as doing a sentinel lymph node. I
15 mean, the surgeon has to chase it around. He has got
16 to take it out. The pathologist has got to play with
17 it.

18 MR. SHEETZ: Right.

19 DR. METTLER: And it is unsealed with the
20 sentinel lymph node. This is sealed.

21 MR. SHEETZ: And most radiologists who
22 perform the injection for sentinel lymph node are
23 performing it under the supervision of your nuclear
24 medicine physician. And we actually now have trained

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1 our surgeons to perform the sentinel lymph node
2 injections on the OR if the patient is put under
3 anesthesia, to eliminate that pain. And so, the
4 surgeons are actually performing sentinel lymph node
5 injections under the supervision of the Nuclear
6 Medicine Authorized User. So, this is no different.
7 So, you have an Authorized user, but, then, a lot of
8 the work is being performed by individuals under their
9 supervision.

10 MEMBER COSTELLO: And I think you
11 suggested that you don't need a written directive for
12 this?

13 MR. SHEETZ: The written directive is not
14 necessary.

15 MEMBER COSTELLO: But you also suggested
16 that medical events are still possible?

17 MR. SHEETZ: That is correct. That is
18 possible. Again, I am not advocating anything. I
19 can see certain situations where a seed is left in.

20 MEMBER COSTELLO: And you ascribe it.

21 MR. SHEETZ: And ascribe it.

22 VICE CHAIR ALDERSON: So, I have a
23 question which some of the people who use this
24 procedure now widely can perhaps answer and, then, a

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1 comment.

2 So, the question is, in institutions like
3 your own, like Sloan Kettering, where this has begun
4 to be used widely, it is judged by those physicians
5 and the people involved that it is so much better?
6 Has it replaced the wire? That is the first question.
7 Has it replaced the wire?

8 MEMBER ZANZONICO: At Sloan Kettering, as
9 far as I know, it has replaced it. It is the standard
10 now. There are some instances where they still use
11 the wire, but that is my understanding.

12 MR. SHEETZ: Yes, it has essentially
13 replaced it.

14 VICE CHAIR ALDERSON: Okay.

15 MR. SHEETZ: Except for a very rare
16 occurrence.

17 VICE CHAIR ALDERSON: All right. So,
18 that's good. I mean, that suggests that a lot of
19 knowledgeable people who use this think it is a good
20 thing to do. I have no experience with this technique
21 at all.

22 MEMBER ZANZONICO: There is a lot of
23 enthusiasm, as you said, among the surgeons.

24 VICE CHAIR ALDERSON: Right. So, I am

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1 going to mention a concern that will make you think
2 I am extremely conservative, and this knowledgeable
3 body can say, "Eh, forget about it now."

4 But I understand that the radiation range
5 is small. The thing I am concerned about, or that my
6 conservatism makes me be concerned about, is it is
7 radiation. So, this is a relatively new procedure
8 now. So, we haven't had much time. But, if in a few
9 years some women come back and they have a new cancer
10 and it is somewhere in the region of where they had
11 the radioactive seed localization before, are some of
12 our legal friends going to go after this, the same
13 way they went after asbestos, and make it into
14 something we turn around and say, "We wish we had
15 never done that."?

16 Now that is, again, probably
17 extraordinarily conservative, but we haven't had much
18 time yet. So, anyway, I thought I should say it.

19 MR. SHEETZ: In response to that, I think
20 if you look at the dose to the tissue that is
21 remaining after the seed and the lesion have been
22 excised, the radiation dose to that tissue is on the
23 order of two view mammogram.

24 VICE CHAIR ALDERSON: Okay.

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1 MR. SHEETZ: So, it is very low.

2 VICE CHAIR ALDERSON: So, it is just a
3 couple hundred millirems, yes. All right. That is a
4 good answer.

5 CHAIR THOMADSEN: Other comments?

6 Yes, Mr. Bollock.

7 MR. BOLLOCK: Thank you.

8 I would just like to add that the NRC and
9 the Organization of Agreement States are forming a
10 working group to update the guidance. Actually, Ms.
11 Holiday is part of the working group, along with a
12 representative from the States of New York and Utah.
13 And we have one other NRC staff that hasn't been
14 identified yet. But we are going to do that,
15 hopefully, begin that in April.

16 CHAIR THOMADSEN: Begin that in April and
17 finishing it when?

18 (Laughter.)

19 MR. BOLLOCK: If somebody can help me out
20 with what's the estimate?

21 MS. HOLIDAY: Well, in all honesty, I
22 can't really put a timeframe on it. It really does
23 depend on deliberations and discussions of that
24 working group. April is actually when we are hoping

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1 to kick off the working group. We are still waiting
2 to identify one additional member. And then, of
3 course, you have to work around people's schedules.
4 We are approaching summer vacation.

5 But I would just like to remind the
6 Committee, with our most recent 35.1000 device, that
7 is part of the toolkit, that only took us nine months
8 to develop guidance. But that doesn't mean that we
9 could be done in nine months. It could be earlier.
10 It could be later. But I don't want to put a
11 definitive number on that.

12 CHAIR THOMADSEN: My question has the
13 intention of, when would you have to have this
14 Committee's input in order to have it considered in
15 the discussions?

16 MR. BOLLOCK: Yes, again, that would be
17 dependent upon when the working group finishes their
18 deliberations. So, I mean, it would be a guess, but
19 it wouldn't be the next meeting. It would be after
20 some few months at least, if they begin next month,
21 that they would be ready to turn it over to ACMUI to
22 review.

23 CHAIR THOMADSEN: Thank you.

24 Yes, Dr. Mettler?

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1 DR. METTLER: So, can you tell me how
2 this is any different from a sentinel lymph node other
3 than it is a sealed source in terms of hazard or
4 anything else?

5 MR. SHEETZ: And my viewpoint is it is no
6 different.

7 MEMBER ZANZONICO: The one tact that
8 strikes me is in the event -- and again, it would be
9 patient intervention. A patient doesn't return. You
10 are talking about considerably higher local radiation
11 doses apropos the point that Dr. Alderson raised. I
12 mean, the doses would be much less than a sentinel
13 lymph node.

14 But those aren't trivial if they are
15 local. It depends upon the volume for your
16 calculation.

17 MR. SHEETZ: But these are the same seeds
18 that are used for brachytherapy at three to five times
19 greater activity where 50 to 100 are implanted in the
20 prostate, and it is not infrequent for one to migrate
21 to the lungs or the bladder or become dislodged
22 somewhere else in the body and remain there until
23 they decay away.

24 DR. METTLER: Plus, the people pee them

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1 out.

2 MR. SHEETZ: So, a single left in the
3 body is not going to cause any extra --

4 MEMBER ZANZONICO: No, I don't disagree.
5 I am just playing devil's advocate.

6 MR. SHEETZ: Yes.

7 MEMBER ENNIS: Well, it would depend on
8 where it was. I mean, if it was right under the skin,
9 it actually would, a superficial region.

10 MR. SHEETZ: Okay.

11 MEMBER ENNIS: And if the patient didn't
12 return, they would have an ulcer and it would be a
13 problem.

14 CHAIR THOMADSEN: Ms. Weil?

15 MEMBER WEIL: I just have to put this out
16 there. From listening to this, it sounds like the
17 primary driver for this particular therapy is that it
18 is extremely convenient for the surgical schedule
19 because it doesn't have to be done in tandem with the
20 radiologist doing a localization with a wire. There
21 isn't that proximity in time that has to be factored
22 into it.

23 If that is the primary reason for the
24 popularity of this particular procedure, it would be

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1 nice to have more data about its satisfaction levels
2 for patients as opposed to satisfaction for the
3 clinicians involved.

4 CHAIR THOMADSEN: Dr. Langhorst?

5 MEMBER LANGHORST: But this discussion is
6 really a request to update NRC's licensing guidance
7 for this. It is not to make any changes and, hey,
8 everybody needs to have this. It is to update a 2006
9 guidance document, with the many years -- I mean,
10 this has been used for 10 years now -- with the
11 current way of doing it. And so, that is what is
12 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
18 particular 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

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1 make the incision to remove the lesion, as opposed to
2 having to follow the wire in. So, there is definitely
3 cosmetic outcomes by using the seed because they don't
4 have to follow the wire. They can come where it is
5 not going 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
10 big driver for this.

11 And the positive margins and reduced
12 volume of tissue, and all that, it is probably
13 equivalent.

14 VICE CHAIR ALDERSON: I have a follow-up
15 question.

16 CHAIR THOMADSEN: Yes, go ahead.

17 VICE CHAIR ALDERSON: And I was reading
18 your slides to see if it was here and I just missed
19 it. So, say it again. What are the specific changes
20 that you seek in the guidance? It just says here you
21 want the guidance to be changed. What are the
22 specific changes that you seek?

23 MR. SHEETZ: The primary one would be the
24 training and experience requirements for the

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1 Authorized User. Maybe discontinuing three cases or
2 allow them to observe cases or allow them to attend
3 a workshop and they would automatically qualify as an
4 Authorized User, whether they are 35.200- or 35.400-
5 approved.

6 Recognition that radiologists with
7 training in the procedure can implant the seeds under
8 the supervision of an Authorized User because the
9 guidance document right now implies that only an
10 Authorized User implant seeds. And some institutions
11 are following that. They looked at that and
12 said -- and some regulators are requiring that. So,
13 they won't allow a radiologist to implant the seed
14 under the supervision of an Authorized User. That
15 means everybody has to become an Authorized User.

16 VICE CHAIR ALDERSON: So, those are those
17 are the only two things you see?

18 MR. SHEETZ: No. The other was the
19 elimination of a written directive requirement.

20 VICE CHAIR ALDERSON: Yes, no written
21 directive.

22 MR. SHEETZ: And the other was my third-
23 to-the-last slide on the commitments that are
24 required in the guidance documents for other

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1 regulations in 35 that really are inapplicable; you
2 know, 35.410, and things of that nature.

3 VICE CHAIR ALDERSON: I see. And do you
4 believe, in addition to a radiologist being able to
5 implant under the direction of an AU, what about
6 surgeons? Can they do it under an AU?

7 MR. SHEETZ: Do the surgical procedure?

8 VICE CHAIR ALDERSON: Do the
9 implantation?

10 MR. SHEETZ: No, they don't have the
11 training to implant seeds nor would they be medically
12 credentialed. A surgeon can't implant a seed in a
13 hospital.

14 MEMBER WEIL: They remove them.

15 MR. SHEETZ: They remove them.

16 DR. METTLER: But, in one sentence, if
17 you had that one sentence, it would be: treat this
18 procedure just like you treat a sentinel node
19 procedure; everything the same?

20 MR. SHEETZ: Yes.

21 DR. METTLER: Excepting if they don't
22 come back to get this thing taken out, though. Other
23 than that, everything is the same. In fact, let's
24 say it is at least sealed as opposed to unsealed.

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1 MR. SHEETZ: Well, it would fit perfectly
2 under 35.200 except it is sealed.

3 MEMBER COSTELLO: The one medical
4 event -- I'm sorry -- that you described where
5 basically you couldn't remove the seed because of
6 where it was located, if I recall, right?

7 MR. SHEETZ: I'm sorry? What?

8 MEMBER COSTELLO: The one medical event
9 that you referred to --

10 MR. SHEETZ: Yes, yes, right.

11 MEMBER COSTELLO: -- if that had happened
12 with technetium, would that have been a medical event?

13 MR. SHEETZ: I'm not sure what you mean
14 by technetium. The sentinel node injection stays
15 there or --

16 MEMBER DILSIZIAN: No, the exposure.

17 MEMBER COSTELLO: Okay.

18 MR. SHEETZ: The exposure?

19 MEMBER COSTELLO: As far as the exposure.
20 So, the exposure in a case with these was hot, turned
21 out to be hot, or would have been --

22 MR. SHEETZ: If left in indefinitely or
23 for a certain period of time, correct.

24 MEMBER COSTELLO: Right.

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1 MR. SHEETZ: This is a long half-life.

2 MEMBER COSTELLO: So, the doses can be
3 higher here if they stay there longer, assuming they
4 can't get them out?

5 MR. SHEETZ: Correct. As I said, it
6 would be nine days for 50 rads at 170.

7 MEMBER COSTELLO: Right.

8 DR. METTLER: But, at the end of the day,
9 if you infiltrate an FDG dose, you know, you have got
10 local doses of the same amount.

11 MEMBER COSTELLO: Thinking infiltration,
12 Think as an acceptor for infiltration, right?

13 DR. METTLER: Yes, I mean in terms of
14 biological events.

15 MEMBER COSTELLO: Sure.

16 MR. SHEETZ: And I am not arguing that if
17 the seed is left in or a patient doesn't return, that
18 that shouldn't be reported as a medical event.

19 MEMBER COSTELLO: What I struggle with
20 is, conceptually, possibly having a medical event
21 without the written directive, because the two are
22 linked together.

23 CHAIR THOMADSEN: Mr. Mattmuller?

24 MEMBER MATTMULLER: Well, I would say

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1 that is not possible because, for example, we had
2 where the patient was accidentally injected with a
3 full multi-dose vial of, I think it was technetium
4 NBP, and there was no written directive for that
5 diagnostic procedure. But, yet, still a medical
6 event occurred.

7 MEMBER COSTELLO: Thank you.

8 CHAIR THOMADSEN: Now any other comments?

9 MS. THOMAS: Are you asking for comments
10 on the bridge line?

11 CHAIR THOMADSEN: Yes, on the issue of
12 breast localization with radioactive sources.

13 Okay. I would like to name a
14 Subcommittee to develop recommendations on the issues
15 raised by this presentation. So, it would be making
16 recommendations on radioactive seed localization to
17 present to this Committee. The timeline would be
18 before the next Committee meeting. We may have to
19 have a conference call, depending on how quickly the
20 working group is getting together and discussing
21 this. Whether or not the presentation would be before
22 the next Committee meeting is irrelevant. The work
23 needs to be done quickly.

24 And I would like to ask Dr. Ennis to be

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1 the Chair of that Committee. I would like Dr.
2 Alderson to also be on that Committee and Mr. Costello
3 to be on that Committee.

4 Do we have volunteers who would like to
5 be on that Committee as well?

6 Dr. Zanzonico. I would like to name Dr.
7 Mettler as soon as he gets his final approval and
8 clearances, and whatever.

9 It should happen before the Committee
10 makes its report.

11 Any other comments on that?

12 MEMBER COSTELLO: Could you go through
13 those names again, please?

14 CHAIR THOMADSEN: Dr. Ennis, Dr.
15 Alderson, Mr. Costello, Dr. Zanzonico, and Dr.
16 Mettler conditionally. I think that is what I said.

17 Okay. No other comments on this topic?

18 Yes?

19 MEMBER LANGHORST: I just want to make
20 mention as to how Mr. Sheetz came to give us this
21 talk. He reached out to the NRC to ask about the
22 licensing guidance. NRC's staff was fabulous in
23 trying to direct him to the right place. I know we
24 talked with Mr. Costello and, eventually, it came to

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1 me. My name is on there just because I tried to help
2 facilitate this.

3 But I really want to encourage the people
4 who listen to our Committee meetings, who read our
5 transcripts, and so on, that you have available to
6 you an opportunity to suggest topics and even come
7 talk to us.

8 I really appreciate Mr. Sheetz's efforts
9 in educating me on this process because we do not do
10 it at Washington University at this point in time.
11 And I really appreciate him coming out to talk to us
12 about this.

13 CHAIR THOMADSEN: Dr. Mettler?

14 DR. METTLER: A great presentation.

15 MR. SHEETZ: Thank you.

16 DR. METTLER: You must have a library of
17 references that might be in PDF format about all of
18 this? If you could get it forward --

19 MR. SHEETZ: I certainly can.

20 CHAIR THOMADSEN: Thank you. Thank you
21 very much.

22 MR. SHEETZ: Thank you very much. I
23 appreciate it.

24 MS. HOLIDAY: Dr. Thomadsen?

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1 CHAIR THOMADSEN: Yes?

2 MS. HOLIDAY: Is this okay? I just
3 wanted to make one comment. I just wanted to say
4 this is a prime example of -- I know we have said it
5 before -- but for all items that are licensed under
6 35.1000, there is that caveat where all these guidance
7 documents are located that there is an opportunity
8 for the general public, staff, anyone, if you feel
9 that there should be changes, that you can contact us
10 to let us know. Because these are essentially living,
11 breathing documents.

12 As we all know, microspheres guidance
13 document has undergone several revisions, as I am
14 sure we will go under another revision with this most
15 recent Subcommittee report that we received at the
16 last meeting.

17 So, as Mr. Sheetz indicated, this
18 guidance document was created in 2006. As time goes
19 on, we learn more about what these modalities can do.
20 If there is stuff that we had in there before that is
21 no longer applicable or if there is stuff that should
22 be in there, help us help the medical community. That
23 is what we rely on you for; that is what we rely on
24 the medical community to tell us. We can't do our

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1 jobs if you don't tell us.

2 Thank you.

3 CHAIR THOMADSEN: Thank you. Point well
4 taken. Thank you very much.

5 And now, to round out the day, we have
6 Mr. Mattmuller to tell us about germanium/gallium
7 generators and their decommissioning.

8 MEMBER MATTMULLER: Good afternoon,
9 everyone.

10 I am Steve Mattmuller, and I will be
11 presenting our Subcommittee report. But, first, I
12 just wanted to make a couple of general comments on
13 comments I have already heard today that I really
14 appreciated.

15 Laura's initial comments reminding us of
16 our responsibility to help advise/guide the NRC for
17 appropriate regulations, so they are perfect for
18 medical care and patient care and don't interfere
19 with patient care.

20 Also, I really appreciated the comment
21 Dr. Mettler made, and then confirmed by Dr. Thomadsen,
22 that we are to be pests to the NRC, if need be the
23 case.

24 (Laughter.)

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1 DR. METTLER: Advice.

2 MEMBER MATTMULLER: Advice? It sounded
3 like "pests" over here on this side of the room.

4 DR. METTLER: It reminds me of my
5 children. What I said wasn't necessarily what I
6 meant, and what you heard wasn't what I said.

7 (Laughter.)

8 MEMBER MATTMULLER: Okay. So, first of
9 all, I would like to review why germanium and
10 gallium-68 are so important to the field of nuclear
11 medicine, the charges to the Subcommittee, and its
12 responses to the charges.

13 Next slide, please.

14 So, here's a comparison, images of a PET
15 drug versus a spec drug. You can see the dramatic
16 advantages the PET drug offers of the gallium-68 DOTA
17 on the right versus the older spec agent, indium-111
18 DTPA octreotide on the left.

19 Greater image quality, greater diagnostic
20 sensitivity and accuracy. There is actually faster
21 imaging time. The gallium-68 image can be acquired
22 in one day for the patient versus the two days it
23 takes for the indium study. And there is also a lower
24 radiation dose.

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1 Another exciting developing for the
2 gallium-68 right in pharmaceuticals is the relative
3 ease of how you can substitute, you can bring in a
4 therapeutic radionuclide such as lutetium-177 into
5 the very same molecule. So, then, you actually
6 transform a very sensitive, specific diagnostic drug
7 into a very sensitive, specific therapeutic drug.
8 And they call this aspect theragnostics, the
9 combinations of a diagnostic/therapeutic drug.

10 For this type of drug, for the DOTAs, in
11 particular, they call this peptide receptor
12 radionuclide therapy, or PRRT.

13 Next slide, please.

14 So, here is a list of most, not all, of
15 the different areas where gallium-68 is now being
16 used or under investigation. So, you might ask, how
17 big is this iceberg really, especially in today's
18 years or time zones and climate change? But it is
19 big.

20 As an example, last weekend was the Third
21 World Congress of Theragnostics Gallium-68 and PRRT
22 held last weekend in Baltimore. This is the first
23 time it has met here in the U.S., as especially in
24 Europe, gallium-68 use is mainstream; whereas, in the

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1 U.S. it is still investigational.

2 The boat is at the tip of the iceberg.
3 It is used to image somatostatin receptors found in
4 neuroendocrine tumors, or NETs, N-E-T. And as stated
5 by Dr. Zanzonico in a past meeting, the DOTAs are
6 really just the tip of the iceberg. Also, in the
7 U.S. they are the closest to be acquiring FDA
8 approval.

9 In the middle of the iceberg -- I hope
10 you can see it -- is prostate imaging using an agent
11 PSMA. That is also getting a lot of attention
12 worldwide. Again, great images and a much larger
13 patient population. It would be my prediction as the
14 next drug after the DOTAs to receive FDA approval.

15 And at the base, which is maybe a little
16 bit hard to read -- I'm sorry -- are the
17 theragnostics. Again, the development of therapeutic
18 drugs from the diagnostic drug.

19 Next, please.

20 This is our source of the gallium-68, the
21 generator. The parent radionuclide is germanium-68,
22 a solid on a dry column about the size of my little
23 finger. The germanium-68 decays to the daughter
24 radionuclide gallium-68. To remove it, one elutes

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1 the column by passing dilute hydrochloric acid
2 through the column and it is a collection vial. But
3 germanium-68 is left behind on the column; the
4 gallium-68 collects in the vial.

5 Now, even though she is a pre-K teacher,
6 my daughter assured me that no one could go wrong
7 with show and tell.

8 (Laughter.)

9 So, this is an actual prototype of the
10 Eckart & Ziegler generator. This is what we are
11 talking about. It is very small. It requires no
12 power, no electrical cord, no batteries. There are
13 no moving parts. It is rather kind of boring. It
14 just sits in a lead-shielded area.

15 This helps explain why the previous image
16 of the iceberg is so big. PET radionuclides have
17 terrific imaging advantages over spec radionuclides.
18 But most of the PET radionuclides need a cyclotron
19 just to produce them, and cyclotrons are big and
20 expensive. Actually, you would need a room about the
21 size of this meeting room for a cyclotron, its support
22 areas, and chemistry areas, and quality control
23 areas.

24 You might think of this little generator

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1 as a mini-cyclotron in a box, but it has regulatory
2 issues -- and that is why we are really here -- as
3 the germanium-68, the parent radionuclide, triggers
4 a decommissioning funding plan.

5 Next slide, please.

6 And here it is for a decommissioning fund
7 plan in part 35.35. "Each applicant for a specific
8 license authorizing the possession and use of
9 unsealed byproduct material" -- and, currently, the
10 germanium is considered unsealed -- "with a half-life
11 greater than 120 days" -- it does have a half-life of
12 271 days -- "and in quantities exceeding 10 to the
13 fifth times the applicable quantity set forth in
14 Appendix B," it meets these three conditions and you
15 need to get a DFP for your gallium generator or for
16 any radionuclide.

17 Briefly, a DFP describes what happens to
18 the facility after it closes, after you lose or
19 terminate your possess license. Equipment,
20 structures, and portions of the facility containing
21 radioactive contaminants will be removed or
22 decontaminated to a level that permits release of the
23 property. Basically, it has to be cleaned-up to the
24 original background levels.

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1 So, a DFP is very extensive and expensive
2 to create, to get approved, and also to fund. And it
3 is a continuous burden, as it needs to be reviewed,
4 resubmitted, and reapproved every three years for as
5 long as the license is active. It is a big burden.
6 It requires a lot of man-hours and a lot in terms of
7 financial assurance.

8 Next slide, please.

9 This really is a curious regulatory
10 situation for us, as we have two identically labeled
11 appendices in 10 CFR, quantities of licensed material
12 requiring labeling, but they contain two different
13 lists. Appendix C in Part 20 has over 600
14 radionuclides, and B in Part 30 has less than 200.
15 Appendix C, you might guess, is the newer version of
16 the two.

17 And for the first two radionuclides that
18 we are all familiar with, F-18 and molybdenum-99, the
19 two appendices have the same values. But the problem
20 is our germanium-68. There is a boundary of 10
21 microcuries in Appendix C, but there is no value
22 listed for germanium in B. And this is the missing
23 piece of our regulatory puzzle.

24 So, from the previous regulation, it says

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1 you take this number, list it in B, multiply it by 10
2 to the fifth power, and that is your limit for
3 activity to determine whether or not you have to get
4 a DFP.

5 But, without a value in the appendix, you
6 have to use the default-level value of 0.1
7 microcuries, which, when you do the math, gives you
8 a limit of only 10 millicuries. That is a problem
9 because these are typically 50-millicurie-sized
10 generators.

11 It gets more curious. The last time
12 Appendix B was amended was 1980. But check out these
13 two redesignations, which means it gets moved, not
14 amended, but just to a different part in the
15 regulations.

16 From 1991 to 1993, this was a transition
17 period for the implementation of the then-newly-
18 revised Part 20. So, we have the new Appendix C and
19 the new version of Part 20, and Appendix B from Part
20 30 gets moved over to Part 20 as the old version.
21 So, during these two years, there are two versions of
22 Appendix C, an old and a new, and there is no version
23 of B in Part 30. That amended Part 30 to say, if you
24 need to calculate a DFP, then look for your value in

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1 the old Appendix C in Part 20.

2 In 1993, the transition period is over.
3 So, it is just a new version of Part 20 is valid, and
4 the old version of C is moved back to Part 30 and
5 becomes Appendix B again. So, here to the old and,
6 then, back.

7 Unfortunately, with all this, which is
8 not clear why that happened, there still isn't a value
9 for germanium-68. So, it is puzzling because we are
10 not sure why. At one point, they had a reference in
11 Part 30 to say, if you need this value, go to Appendix
12 C. Why they didn't keep that I don't know. Or why,
13 then, they moved the old Appendix C from 20 back to
14 become Appendix B again of Part 30, why that appendix
15 wasn't revised and amended to include a value for
16 germanium-68?

17 So, another part of the puzzle is in 2005,
18 when the definition of byproduct material is expanded
19 to include accelerator-produced radionuclides such as
20 the PET radionuclides F-18 and germanium-68. This is
21 the original occurrence when there were a couple of
22 licensees that had gallium generators in 2004, and in
23 2005 they were told, "You now have to have a DFP."

24 But, overall, trying to figure this out,

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1 this rabbit hole of regulations, I am still not 100-
2 percent sure what really happened to our core value.
3 As best as I can say, it was an unintentional omission
4 for B or, as you might say, it got lost in
5 translation.

6 Next slide, please.

7 So, the charges given to the Committees
8 were to evaluate the cost of a DFP, to provide
9 examples of regulatory relief, and to evaluate how a
10 DFP might affect future clinical use of gallium-68.

11 Next slide, please.

12 So, the first attempt was to try to figure
13 out what does a DFP cost. Several large commercial
14 nuclear pharmacy firms were contacted, and we also
15 found a couple of health physics consultants on the
16 internet who advertised their DFP experience and
17 expertise. We contacted them also, asked for an
18 estimate on what it would cost to prepare or fund a
19 DFP for a medical license, not a firm number, just an
20 estimate. We heard nothing from nobody.

21 So, I thought, all right, I will just try
22 to do it myself. You know, a do-it-yourself attitude.
23 How hard could it be, right?

24 (Laughter.)

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1 And this slide is actually a little bit
2 inaccurate because it just lists one volume of
3 NUREG-1757. After I prepared this slide, I actually
4 found two more volumes of this guide and, ironically,
5 is titled "Consolidated". And the three guides total
6 1,349 pages of guidance.

7 So, the DFP covers, as I have said before,
8 not just the use of germanium-68, but all uses of
9 radioactive material at all locations under the
10 license. So, a hospital, if they have a cyclotron,
11 PET chemistry areas, PET spec imaging areas, a hot
12 lab with a technetium generator, satellite imaging
13 sites within the building, outside of the department,
14 or satellite imaging areas outside at different
15 locations in the town, local area, or even in another
16 hospital with its own nuclear medicine department, if
17 those are all under the same license, as is the case
18 at my hospital, they all have to be considered in the
19 formation/calculation of the DFP.

20 Or, for a commercial nuclear pharmacy, a
21 number of them have cyclotrons and PET chemistry
22 areas. That would dramatically increase their cost
23 for a DFP.

24 In fact, that did happen in 2004. There

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1 was a commercial pharmacy that had a cyclotron and
2 had a gallium-68 generator for research. When they
3 were told to get a DFP, they looked into it, but it
4 is going to cost them \$15 to \$20 thousand a year every
5 year. So, they got rid of the generator.

6 So, our charge is about a question asked.
7 It is really a very expensive question to answer.
8 And it is also very unreasonable to expect anyone to
9 do this on a voluntary basis. So, in hindsight, I am
10 now not at all surprised that I didn't hear from any
11 of those other firms. So, this may be pictured as an
12 RSO as he tries to push a round through a square hole.

13 Next slide, please.

14 We do, however, have a very detailed
15 narrative from an RSO as he tried to prepare a DFP
16 for a large, multi-site university-based hospital.
17 In the next couple of slides, the quotations marks
18 all are comments from this RSO.

19 Next. Yes.

20 "Resource demands go far beyond the cost
21 associated with the generation and maintenance of a
22 financial assurance instrument itself, which can be
23 in the thousands of dollars in creation fees and more
24 thousands in annual maintenance fees. It is a very

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1 expensive effort to prepare it."

2 He had to review the regulations and
3 guidance, all 1,349 pages. He had to review research,
4 the historical use for all buildings and locations,
5 obtain cost estimates for the various actions
6 required that required any decommissioning process,
7 calculate person-hour involvement for all man-hour
8 costs related to these actions, and determine and
9 estimate waste disposal cost, time demands for the
10 creation of the worksheets and spreadsheets, writing
11 and compiling a plan for related internal and external
12 communications.

13 Next, please.

14 His initial estimate, substantial cost in
15 manpower from the Operations and Safety Office. He
16 calculated 140 hours. So, it sounds maybe somewhat
17 manageable.

18 But, then, he soon adds -- next,
19 please -- "I'm probably underestimating this. He
20 sums up his experience as "extensive and expensive".

21 Next slide, please.

22 There are also significant manpower costs
23 to the institution for other areas involved, such as
24 risk management, insurance, finance, facilities,

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1 administration, and legal.

2 Next, please.

3 Once submitted, the DFP has to go to the
4 State, in his case, to be approved. And he states,
5 "This puts significant resource demands on regulatory
6 agencies related to review an ultimate approval of
7 the DFP." So, I think that is a pretty insightful
8 observation on his part. A DFP also puts a big demand
9 on states, who already have very limited resources in
10 dealing with radioactive material licensees.

11 Next, please.

12 For example, the State's initial review
13 resulted in comments that required yet additional
14 demands that he estimated cost them an additional 30
15 person-hours.

16 And that, ultimately, for his
17 institution, financial assurances owed of \$1.125
18 million.

19 In addition, this burden still doesn't
20 end because, if they go this route, they still have
21 to revise, resubmit, and get it reapproved every three
22 years.

23 So, what happened at this institution?
24 Ultimately, they decided the DFP was going to cost

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1 too much. So, they didn't do it. So, they had to
2 scale-back their research plans to use a used
3 generator smaller than 10 millicuries in size, so
4 they wouldn't have the DFP.

5 But all their research is limited to just
6 imaging in smaller animals, mice, rats, versus what
7 they had initially planned to do was image in
8 patients, research subjects.

9 So, trying to push a round ball through
10 a square hole does have consequences. That's clear.

11 Many hospitals will not have the in-house
12 expertise to deal with the DFP issue. And if they do
13 have to pursue DFP Planning, they will likely need to
14 hire consultants, adding further to their costs, one
15 more additional potential barrier in cost. A RSO
16 really understands what it takes to prepare a DFP for
17 a medical institution.

18 The restrictive aspects arising from the
19 current Part 30 situation may, therefore, prevent or
20 deter use of promising imaging agents for patients
21 due to the decommissioning funding burden. This
22 concern is exactly our concern.

23 Next, please.

24 So, the little RSO has given up on the

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1 ball, and now he is thinking about our second charge,
2 regulatory relief.

3 The simplest and best way would be to add
4 the same value of 10 microcuries for germanium-68
5 that exist in Appendix C, Part 20, to Appendix B,
6 Part 30. A simple solution, as both appendices have
7 the same title, "Quantities of Radioactive Material
8 that Require Labeling," but how?

9 Perhaps the best would be using a Direct
10 Final Rulemaking or DFR, and these can be used for
11 noncontroversial rulemaking, as this issue would
12 certainly be. Its advantage is that it takes much
13 less time than a typical rulemaking of 10 to 12 years.

14 However, from the DFR guidance, it
15 typically deals with safety or security concerns.
16 So, this really isn't a safety concern or a security
17 concern. This is a patient concern.

18 Since the unintentional omission of a
19 value in Appendix B for germanium, a DFP is now
20 required for the possession of a generator. And the
21 cost of a DFP can be a prohibitive financial barrier
22 to the license and will deter the safe and effective
23 use of gallium in patients.

24 The next slide, please.

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1 On the upside, fortunately, DFR guidance
2 is much shorter than DFP guidance, but there are five
3 questions we have to answer.

4 The first question is, what has happened,
5 what has changed that causes the current regulation
6 or policy to be insufficient? Appendix B has actually
7 been unchanged since 1980. What has changed is the
8 recent dramatic increase in the use of gallium-68.
9 Remember the iceberg.

10 Next, please.

11 Suzanne said this succinctly: increase
12 in the use of gallium-68.

13 Next, please.

14 What information causes the NRC to
15 question the current regulation or policy? We are
16 now very aware of the man-hour and financial burden
17 of a DFP and how this has already deterred the use of
18 gallium in research and more than likely will deter
19 the use of gallium-68 in clinical patients.

20 A nuclear pharmacy and a contract
21 research organization stopped their research after
22 2005. And more recently, a large university hospital
23 curtailed their research use.

24 Next, please.

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1 So, to answer this, a DFP's deleterious
2 effects.

3 Next, please.

4 The third question is, what is the
5 regulatory insufficiency or gap that needs to be
6 addressed?

7 Next, please.

8 The missing value in Appendix B.

9 In '93, why in 30.35 wasn't the reference
10 to Appendix C, Part 20, kept, as it would have
11 referenced the new version of the appendix? Or why
12 wasn't Appendix B, Part 30, amended to be consistent
13 with the new C -- they had the same title -- with the
14 value for germanium-68?

15 Next, please.

16 So, the fourth question is, why does the
17 insufficiency or gap warrant being addressed? The
18 FDA and the NRC are both responsible for the
19 regulation of radiopharmaceuticals, but this
20 responsibility has to be balanced, in that on one
21 side of this responsibility is to ensure the safe and
22 effective use, but the other side's responsibility is
23 to avoid creating artificial barriers and unnecessary
24 barriers to the use of these drugs.

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1 Next, please.

2 Patient access. The last question,
3 please. Why is a change needed if there is no gap to
4 be addressed?

5 Next, please.

6 The gap does exist and it has very
7 expensive consequences.

8 Next slide, please.

9 So, still thinking about alternates and
10 guidance, and I really think a DFR would be the best
11 route, but if the NRC wants a choice, what if the NRC
12 were to reconsider this generator as a sealed source
13 within a device? As such, we could avoid the DFP
14 requirements.

15 So, if you looked at the current sealed
16 source device guidance -- next, please -- which is
17 NUREG-1556, it could fit as a custom sealed source or
18 device. As a custom, what is attractive here in the
19 guidance, if it stays under 200 millicuries, which it
20 could, and if the reviewer decides applicant has
21 training and experience to handle the material in
22 unsealed -- that is not a typo -- unsealed form, one
23 would not have to rely on the intrinsic safety of the
24 sealed source to demonstrate compliance. It just

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1 sits there. That is all it does.

2 Next, please.

3 Or it could fit under a sealed source and
4 device for medical uses. Now, currently, in guidance
5 for medical use, it says the device has to have one
6 of four types of FDA approval, and it won't have any
7 of these four types.

8 But this is NRC guidance, not FDA
9 guidance. So, it could be revised to include the
10 generator as a medical source device.

11 If the guidance is revised, it is now a
12 sealed source device where it could fit in the
13 regulations. It could fit under 32.74, and I
14 expressly want to read in Section (a)(2)(iii) where
15 "results of the prototype testing demonstrate that
16 the source of the device will maintain its integrity
17 under stresses likely" -- and that is underlined;
18 emphasis has been added -- "to be encountered in
19 normal use." So, unlike a sealed seed that is
20 implanted into a patient, a much more stressful
21 environment than what this will ever encounter. This
22 sits in a box.

23 Or, it could also fit under 35.1000,
24 "Other Medical Uses of Byproduct Material or

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1 Radiation from Byproduct Material". It is definitely
2 another.

3 Next slide, please.

4 So, let's address our last charge, effect
5 on clinical care because of a regulatory quirk, an
6 unintentional omission.

7 Next, please.

8 We know of a DFP's negative effect on
9 three licensees already in regards to research, the
10 most recent, a large, university-based hospital. And
11 we really can't say it any better than the RSO.

12 Next, please.

13 To paraphrase him: may prevent or deter
14 use due to the DFP's funding burden.

15 And as a reminder, we are getting closer
16 to clinical use here in the U.S. The DOTAs, which
17 are used in NET patients, one of the DOTAs is already
18 in active discussions with the FDA to determine the
19 best pathway forward for approval, and you might
20 remember, as an orphan drug, this is not uncommon for
21 the FDA to assist sponsors for these orphan drugs.

22 So, it is really not a question of if
23 there will be an approved gallium-68 drug, but really
24 a question of when. The zebra ribbon, the NET patient

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1 groups use it for public awareness and as a metaphor
2 for the difficulty they experience in getting their
3 disease diagnosed. If you hear hoof beats, it may
4 not be a horse, but a zebra.

5 Next, please.

6 NET cancers are very difficult to
7 diagnose. After the onset of symptoms, which are
8 often non-specific and vague, a diagnosis can take an
9 average of three to seven years. It would be tragic
10 for patients in the U.S. who are suffering from
11 neuroendocrine disease to be given one more burden
12 in coping with their disease.

13 So, while this issue may not be safety-
14 significant in a traditional NRC way, i.e., a risk of
15 people or to the environment, I can guarantee you it
16 is very significant to the patients who suffer with
17 neuroendocrine disease.

18 Next, please.

19 I have added this web address to remind
20 us why we are here, as sometimes it is lost to get in
21 the regulations we come across. I urge you to check
22 this out at a later time.

23 It is from a NET patient support group,
24 and there are pictures of patients holding out

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1 placards with a number on it, and the number
2 represents how long it took them to get a correct
3 diagnosis. It is really pretty sobering, especially
4 in this day and age of modern medicine.

5 The NRC does have a responsibility, and
6 that is not to be burden to these or to any other
7 patients.

8 One more time, please. Thank you.

9 So, three cold facts to remember about
10 our iceberg: the drugs will be the first of the
11 gallium-68 drugs here in the U.S. to be approved.
12 Worldwide interest is a big driving force. There
13 will be more gallium-68 drugs approved in the future,
14 and it is time for the NRC to act now and not later.

15 And at the base, again, the large
16 potential for theragnostic or therapeutic drugs is
17 also driving interesting in gallium-68.

18 Next slide, please.

19 So, to summarize, to evaluate the cost of
20 a DFP, it is prohibitive. It is very expensive just
21 to create a DFP. They are specific to license. No
22 two will be alike.

23 Next, please.

24 Relief.

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1 Next, please.

2 A DFR, a Direct Final Ruling, or revised
3 guidance.

4 Next, please.

5 Will the future clinical use of new
6 radiopharmaceuticals be affected? Yes, it will, of
7 course.

8 First, the neuroendocrine tumor patients
9 will be affected, and then, more than likely, the
10 prostate cancer patients.

11 And really, I should put our little RSO
12 figure at the top, as his narrative and his experience
13 was invaluable for preparing this report, especially
14 his final words of "may prevent or deter use due to
15 the DFP funding burden".

16 We believe the NRC needs to act so as to
17 avoid the consequences of an unintentional omission
18 in the regulations from becoming an unintentional
19 burden on patient care. To eliminate this burden, we
20 would recommend that the NRC should notify the
21 licensees as soon as possible, stating that
22 "Regulatory relief from a DFP requirement for a
23 gallium-68 generator is now in progress. It will no
24 longer be required. Effective immediately, no

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1 licensee will be required to submit a DFP for a
2 gallium-68 generator."

3 Thank you.

4 CHAIR THOMADSEN: Thank you very much,
5 Mr. Mattmuller.

6 Comments from the Committee?

7 Yes?

8 MEMBER ZANZONICO: I just have a
9 question. You had mentioned that a DFP is not
10 isotope-specific. In other words, you have a DFP
11 covering all the isotopes in an institution?

12 MEMBER MATTMULLER: Right. In
13 everybody's situation right now, the DFP is triggered
14 by the possession of the gallium generator. But,
15 once you need a DFP, it, then, covers all
16 radionuclides, all locations under that license.

17 MEMBER ZANZONICO: So, that is why it
18 escalates the cost?

19 MEMBER MATTMULLER: Right, right, right.
20 It would be a much different situation if it was just
21 the box that is sits in.

22 MEMBER ZANZONICO: And one other
23 question. There is no other regulatory vehicle, like
24 a surety bond or such a thing as that in place of an

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1 actual DFP? Or are they the same thing?

2 MEMBER MATTMULLER: The surety bond is
3 the financial assurance portion --

4 MEMBER ZANZONICO: Okay.

5 MEMBER MATTMULLER: -- of the DFP.

6 MEMBER ZANZONICO: So, that would be a
7 component of the DFP?

8 MEMBER MATTMULLER: It is a component of
9 it, right.

10 MEMBER ZANZONICO: That is all part of
11 it?

12 MEMBER MATTMULLER: Right.

13 CHAIR THOMADSEN: Mr. Costello?

14 MEMBER COSTELLO: There are a number of
15 elements. There is the cost estimate in which the
16 RSO had talked about he looked at all the labs that
17 had isotopes of a half-life longer than 120 days and
18 you get their area and look at their history, and so
19 forth. And you develop a cost estimate.

20 Then, you have the Decommissioning
21 Funding Plan, which is how you are going to fund the
22 cost estimate. And then, you have the instruments.
23 So, you are talking about a surety bond or whatever
24 it is. These are all the instruments to fund the

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1 Decommissioning Funding Plan.

2 CHAIR THOMADSEN: Thank you very much.

3 Dr. Mettler?

4 DR. METTLER: You keep saying this was an
5 unintentional omission.

6 MEMBER MATTMULLER: I believe so.

7 DR. METTLER: How do you know that? You
8 know, there are people who have been in the NRC
9 forever, I hear.

10 (Laughter.)

11 I mean, somebody did this. And so, there
12 must be some memory out there.

13 MEMBER COSTELLO: Remember that the
14 purpose of this table, this table has been back in
15 Part 20 since the dawn of time, I mean, probably back
16 to the fifties, okay? It is a safety purpose. Okay?
17 It is telling you what qualities of radioactive
18 material are required to be labeled.

19 The purpose where these tables were
20 shaded, there was no requirement for financial
21 assurance. Okay? It was just to cite what has to
22 put a label on that bottle, or whatever. Basically,
23 that was considered to be a small quantity, a not-
24 very-hazardous quantity.

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1 And so, if financial assurance came
2 along, they didn't want to be reinventing the wheel
3 and come up with their own table. So, they said,
4 "Oh, we'll use that table as a multiplier of that
5 table." I think the lowest multiplier is 1,000 times,
6 which you get your certain amount of financial
7 assurance, and you have to have 10,000 times and
8 100,000 times, okay?

9 The purpose of the table, nothing to do
10 with 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
16 not financial assurance. It is telling universities
17 or whatever when they have to label things. By and
18 large, they are all the same.

19 Of course, back in 1980, or whenever,
20 there was no energy jurisdiction. If there had been,
21 we 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

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1 a little bit of insight about there were some
2 discussions, 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
6 was understood, I mean, I don't even remember the
7 part about 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
10 use the old values while implementation was happening
11 with the new Part 20 because licensees had the option
12 to implement it at any given point in time, I think,
13 within a two-year period.

14 But, at the end of that two years, you
15 assumed that that Part 30 table would, then, switch
16 to reference the new Part 20 Appendix C. But,
17 instead, it got put back into Part 30 and,
18 unfortunately, in that Federal Register the Part 30
19 table was not reprinted. It just referenced it, and
20 then, it appeared in the next year's Code of Federal
21 Regulations. So, that table wasn't reprinted as the
22 old table in Part 30 in that Federal Register of the
23 change of the final Part 20.

24 This also confusing, and I have been

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1 confused by it as we have been reviewing it, because
2 I thought a mistake was made, but then, no, it wasn't
3 a mistake. But it certainly is goofy.

4 DR. METTLER: Okay. Well, in any case, I
5 haven't heard for sure that it was unintended. I
6 haven't heard the proof that it was unintentional.

7 But, be that as it may, the next question
8 I would have is, if one isotope got lost, are there
9 other isotopes that have gotten lost? I'm sure there
10 are. I mean, how many isotopes are there in the Part
11 20 version?

12 MEMBER MATTMULLER: It is 600.

13 MEMBER COSTELLO: And how many in the
14 Part 30 version?

15 MEMBER MATTMULLER: Less than 200.

16 (Laughter.)

17 I mean, but the question would be, of
18 those 400, which have applications to nuclear
19 medicine for either diagnosis -- well, if they are
20 going to have a half-life greater than 270 days, they
21 were thinking therapy or such.

22 MEMBER COSTELLO: A hundred and twenty
23 days is like financial assurance. But maybe there
24 are isotopes in there that aren't being used now that

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1 sometime in the future could be. I don't know.

2 DR. METTLER: Well, yes. I mean, it
3 seems to me, if you are missing one that became
4 useful, there might be other ones that are missing
5 that could become useful. If you are going to fix
6 this, why fix it for just one as opposed the other
7 potential issues?

8 MEMBER COSTELLO: I totally agree.

9 CHAIR THOMADSEN: Dr. Langhorst?

10 MEMBER LANGHORST: Fixing it would mean
11 rulemaking, and our children here around the table
12 could be discussing this. I think the relief right
13 now that is needed is for one identified isotope and
14 the encouragement to get this fixed on a wider basis
15 for future isotopes used in medicine would be helpful.

16 DR. METTLER: Okay, but it seems to me,
17 rather than calling this sealed source or whatever,
18 the simplest thing to do is say you need a number
19 that is going to get you to 50 in this table, period.

20 MEMBER COSTELLO: And take the number
21 from the other table, and they're good.

22 MEMBER MATTMULLER: If you take the
23 number from the newer version, from Appendix C, that
24 will give us a limit of 100 millicuries, which is

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1 twice the value of a 50-millicurie generator.

2 DR. METTLER: And what would it take to
3 put the number from that table into this table? Or,
4 I mean, that doesn't need a rule. That just needs
5 somebody in the Commission to go do it.

6 (Laughter.)

7 DR. HOWE: It requires rulemaking.

8 MEMBER MATTMULLER: To address your other
9 concerns --

10 CHAIR THOMADSEN: Yes?

11 MEMBER MATTMULLER: -- I also serve on
12 the Isotope Committee for the Society of Nuclear
13 Medicine and Molecular Imaging. To be honest, most
14 of the time we do talk about this little radionuclide
15 called molybdenum-99.

16 But this is where this issue came up a
17 couple of years ago with germanium. To my knowledge,
18 this is the only one on our radar screen, so to speak,
19 that has an almost-immediate medical/clinical use
20 that is going to be held back because of the DFP.

21 MEMBER COSTELLO: As some people have
22 seen my emails on this, okay, I say it is not the
23 "what" or the "why" that we are talking about; it
24 is the "how". I mean the "why" is very clear and the

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1 "what" is very clear. The question is, what
2 regulatory mechanism gets us from here to there the
3 fastest?

4 It is really an NRC question. You know,
5 it is their rulemaking process. It is their
6 everything process. But it should be whatever is
7 fastest to make that number say 100 should be taken.

8 DR. WAHL: Hi. This is Dr. Wahl. I am
9 calling in. May I comment?

10 CHAIR THOMADSEN: Yes, please.

11 DR. WAHL: Yes. I'm Richard Wahl. I'm
12 Director of the Mallinckrodt Institute of Radiology
13 in St. Louis. I am a nuclear medicine physician and
14 radiologist.

15 I have looked at the discussion. I just
16 wanted to reiterate what Mr. Mattmuller has said. I
17 was a Co-Chair of the Third World Gallium Congress
18 this past Thursday, Friday, and Saturday in
19 Baltimore. We had over 200 scientific registrants
20 and an additional 70 patient participants with
21 neuroendocrine tumors.

22 From that meeting, it is abundantly clear
23 that the gallium-68 radioisotope will play an
24 important and growing role in patients with

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1 neuroendocrine tumors and likely prostate cancer, as
2 he pointed out.

3 And the neuroendocrine tumors are an
4 orphan indication. And the patent position on some
5 of the agents is not so clear. But it is quite clear
6 that it is a very limited market. The FDA has
7 recognized this and provided some regulatory relief
8 specific to orphan drugs.

9 Clearly, the requirement for DFP for a
10 drug that is not used in very many patients is a huge
11 burden on academic medical centers or whoever has to
12 install the generators, perhaps commercial
13 pharmacies.

14 But these stands clearly are better than
15 what we have available now. And interestingly, the
16 radiation death to patients from these particular
17 types of standards are substantially lower than from
18 the currently-available tests. The results are more
19 accurate and the patients have the results more
20 quickly and they are likely cheaper.

21 There are many good things and many
22 reasons to have this technology available.
23 Certainly, I don't think the NRC would want us not to
24 have the methodologies available. And this relief in

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1 some way from the DFP for the germanium generators
2 appears logical and appropriate using methods that
3 you can best figure out, but it needs to be done
4 expeditiously.

5 I had such a system up and using it in
6 patients at Johns Hopkins, where I worked until a few
7 months ago. I have recently moved to St. Louis, and
8 we would like to get this going here. We are working
9 on it, but the cost of a DFP will be a barrier to our
10 implementing this, even at a large academic center.

11 So, I just wanted to reiterate how
12 medically important this is and how there are so many
13 barriers already; we really don't need one more to
14 prevent patients from receiving this isotope.

15 Thank you.

16 CHAIR THOMADSEN: Thank you very much.

17 We also have another caller who wanted to
18 make a comment.

19 Josh Mailman, are you on the line?

20 MR. MAILMAN: Yes, I am on the line. I
21 am Josh Mailman. I am the Chair of Patient Advocacy
22 for the Society of Nuclear Medicine, and I also run
23 501(c)(3) nonprofit for neuroendocrine support in
24 Northern California.

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1 And I wanted to echo Dr. Wahl's comments
2 as well and also say that, while the incidence is
3 rare, the prevalence is actually much more widespread
4 than we think of. We have 150,000 patients in the
5 United States that are living with neuroendocrine
6 tumors.

7 With the very short half-life of
8 gallium-68, it will mean that the gallium-68 will
9 need to be produced near where the patients are as
10 opposed to having it shipped in, like we are currently
11 doing with indium-111. So, it will be of great
12 patient benefit to have it near where the patients
13 live and not just at certain compounding pharmacies
14 or pharmacies that can send things out to different
15 centers. So, it is challenging if it is just going
16 to be at a couple of very large centers around the
17 United States and not have access at the regional
18 locations as well.

19 CHAIR THOMADSEN: Thank you very much.

20 I think we have a comment here.

21 MS. BUNNING: Okay, thank you.

22 I am Sue Bunning. I am with the Society
23 of Nuclear Medicine and Molecular Imaging.

24 I think everything pretty much has been

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1 said. I want to thank the Committee that has looked
2 at this. This is a very important issue to the
3 Society.

4 I think, Steve, you mentioned the
5 Committee within SNMMI that has been working on this.
6 He's right, this is the only isotope that has been
7 brought to our attention. We are hearing a lot on
8 this issue.

9 The Theragnostic Congress last week, I
10 also had the pleasure of attending it. And Dr. Wahl
11 is right, there were about 300 folks there. In
12 addition to the patients asking often, "Okay, what's
13 happening at the FDA to get this through," we receive
14 a lot of questions about why do we still have to keep
15 going to Europe.

16 And the patients often encounter problems
17 with their travel. I think Josh on the phone could
18 fill you in on some of those.

19 But they want to see this widely used in
20 the United States. Right now, I believe there are
21 approximately 10 or 11 centers that are under IND.
22 But our hope is that this gets widely distributed
23 throughout the United States and the patients will
24 have access to this.

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1 So, thank you. We support the work that
2 you are doing, and thank you very much for letting me
3 speak.

4 CHAIR THOMADSEN: Thank you.

5 I think the case has made that we should
6 try to do something about this. And I will put it to
7 the NRC: what would be the most efficacious way to
8 address the issue?

9 MR. BOLLOCK: Yes, that is a tough one to
10 answer, which would be the fastest. I mean, there
11 are options. There are multiple options. Petitions
12 for rulemaking. There are requests for relief from
13 the DFP and giving the reasons why. And, yes, us
14 going through and changing our guidance documents. I
15 don't know which one has the shortest timeline. A
16 lot depends on what is the process and how much we
17 have backing any opposition, especially for the
18 rulemaking, any opposition.

19 CHAIR THOMADSEN: Mr. Mattmuller, you had
20 a comment?

21 MEMBER MATTMULLER: Right. So, I would
22 like to ask, is it possible that why don't we let
23 staff figure out what is the preferred route they
24 would like to go to get relief? Can the Commissioners

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1 put out a notice saying that relief is coming and,
2 effective immediately, you no longer have to pay
3 attention to DFP requirements, as in the future it
4 won't be required?

5 MR. BOLLOCK: We do have a few options.
6 I know I can think of one option.

7 Sophie, do you want to chime-in?

8 MS. HOLIDAY: I just want to say, as the
9 Subcommittee knows, I was the appointed NRC contact
10 person for this Subcommittee. And so, while the
11 Subcommittee was doing their research, and Dr.
12 Langhorst made the trail on all the old Federal
13 Register notices, I did speak to some of our
14 counterparts here.

15 Originally, it was believed that there
16 was an omission. Some staff had believed that was
17 the case; other staff did not.

18 So, I think it would be inappropriate to
19 expect for the Commission to issue something to say,
20 "We will grant relief immediately." Because, just
21 like anything, you have to do your research very
22 thoroughly before you go out and do anything like
23 that.

24 It is also like when NRC publishes

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1 Regulatory Issue Summaries or Information Notices,
2 you can't just do it on a whim. You have to make
3 sure you are putting out the correct information.

4 So, Sophie's suggest would be for the
5 Committee to put forth a recommendation. And that
6 way, we can say the ACMUI has made this
7 recommendation. And that would give us the language
8 that we need to go forth and say, "Hey, given what
9 our priorities are, how can we fit this in? Because
10 we have heard from the ACMUI. We have heard from
11 members of the public. We have heard from
12 professional organizations regarding this generator.
13 What do we do now?" So, that would be my suggestion.

14 MEMBER COSTELLO: Can the NRC recommend
15 to the Committee what we can recommend to you for the
16 "how"? Because we don't know the "how" as well as
17 you folks do.

18 MR. BOLLOCK: Right, and, I mean, the
19 "how" would be -- you could recommend to us to find
20 out what our options are, and then --

21 MEMBER COSTELLO: We can do that now.

22 (Laughter.)

23 MR. BOLLOCK: That's right. Like I said,
24 I mean, there are options.

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1 MEMBER COSTELLO: I don't know a "how,"
2 but --

3 CHAIR THOMADSEN: Dr. Langhorst?

4 MEMBER LANGHORST: A question I have on
5 the request for relief, is that a licensee-by-
6 licensee request or --

7 MR. BOLLOCK: I believe so. I believe it
8 is licensee-to-licensee, unless we did come up -- I
9 know Sophie mentioned the RIS, Regulatory Information
10 Summary -- unless we saw a number of those or a group
11 got together and put it in. That may be a pathway
12 that we would like to take.

13 MEMBER COSTELLO: And the solution has to
14 work in the Agreement State, which is where the
15 licensees are.

16 MR. BOLLOCK: Uh-hum.

17 MS. HOLIDAY: I would also like to point
18 out that at the last meeting Ms. Dudes, she did a lot
19 of contribution for the discussions that took place.
20 And she said, in order for us to move forward with
21 any type of action, we need to know how many potential
22 licensees does this affect. And without us knowing,
23 to say, "Oh, there are three institutions that this
24 impacts," NRC wouldn't necessarily, to be efficient,

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1 we wouldn't just say, "Here's a blanket exemption."
2 But, if it is only three, then those three individual
3 institutions may get relief on an individual basis.
4 It is kind of like when we do exemptions. It is on
5 a case-by-case basis.

6 But, if we do truly believe that it is
7 affecting a wide range of licensees, we have to be
8 able to make that justification. Similar to how we
9 do our rulemakings, a regulatory basis has to be
10 formed.

11 CHAIR THOMADSEN: Right, although we do
12 have the problem that, if you are looking at how many
13 licensees this may affect, you are not getting any
14 data on those people who would be licensees but are
15 being deterred by the current regulations.

16 MS. HOLIDAY: Right.

17 MEMBER MATTMULLER: Right. It is sort of
18 like a-chicken-or-an-egg question. But the three I
19 mentioned were involved in research. And so,
20 technically, we don't have an approved drug yet. So,
21 we don't know about the official effect on clinical
22 use.

23 And I attended the meeting last weekend,
24 too. If you see the interest that these new drugs

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1 generate, you know it is going to happen. So, when
2 it does happen, I would hate to see this requirement
3 slow it down.

4 CHAIR THOMADSEN: Dr. O'Hara?

5 MEMBER O'HARA: So, the drug isn't
6 cleared, isn't approved by CDER yet?

7 MEMBER MATTMULLER: Not yet, no.

8 MEMBER O'HARA: Is there an indication
9 where it is in the review?

10 MEMBER MATTMULLER: I don't know the
11 exact answer to that question.

12 MEMBER O'HARA: Yes. I was just
13 wondering.

14 MEMBER MATTMULLER: Yes.

15 MEMBER O'HARA: Because once CDER would
16 approve it, approve the drug, my estimation would be
17 there would be a lot more demand.

18 MEMBER MATTMULLER: Right. Of course.
19 In the DOTAs' advantage, in their corner, I mean,
20 they have extensive data. They have been used for
21 over a decade in Europe. So, there is a lot of safety
22 and efficacy data already generated for the drug.
23 So, it is not like they are reinventing the wheel for
24 the data to support the application.

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1 CHAIR THOMADSEN: The big rush will come
2 when CMS approves it.

3 Yes, Dr. Langhorst?

4 MEMBER LANGHORST: So, you don't have
5 any -- do you think in a year? It could happen next
6 month? You really don't know?

7 MEMBER MATTMULLER: That's a question I
8 would to love ask the FDA representative to answer.

9 MEMBER O'HARA: And I can't answer it.

10 MEMBER MATTMULLER: So, no, no.

11 MEMBER O'HARA: I can't answer it now.

12 MEMBER LANGHORST: Right. And even if he
13 could, he couldn't.

14 (Laughter.)

15 MEMBER MATTMULLER: Well, that is a whole
16 other issue, yes.

17 MEMBER LANGHORST: A recommendation that
18 I might suggest is that we have an ACMUI
19 teleconference soon, like in the next two months,
20 that NRC staff can come back and provide us with what
21 are the "how's" that we can follow.

22 CHAIR THOMADSEN: I think that is a good
23 idea, but I will amend that to suggest that the
24 Committee go back to work, and maybe based on European

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1 experience, try to come up with an estimated number
2 of potential licensees that there may be who would
3 want to do this.

4 And with the support staff member -- do
5 you have a support staff member yet?

6 MEMBER MATTMULLER: Yes, Sophie.

7 MEMBER LANGHORST: Sophie is that support
8 staff.

9 MEMBER MATTMULLER: Of course.

10 CHAIR THOMADSEN: With the help of your
11 support staff person, consider the possible remedial
12 actions that could be taken to provide relief, to
13 make a recommendation to this Committee. So that,
14 when we do have our call, we have something to work
15 with, rather than just start talking.

16 Ms. Weil?

17 MEMBER WEIL: Would it also make sense to
18 have statements from the related professional
19 societies supporting the changes that we are
20 suggesting, to add those to our recommendation?

21 CHAIR THOMADSEN: Oh, I will ask Mr.
22 Bollock. Should they bother with that now?

23 MR. BOLLOCK: Well, I think the more
24 people you have behind it, it gives more weight to

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1 the broad scope. And so, three licensees -- if there
2 is more interest --

3 CHAIR THOMADSEN: Dr. Mettler?

4 DR. METTLER: Me knowing nothing about
5 the process, so if three groups ask for
6 exemption -- is that what you are calling it? -- and
7 they got it -- well, first, I don't know how difficult
8 it is to apply for an exemption and get it. But, if
9 you did that and got it, regardless of all this other
10 process of trying to figure out what is going to
11 happen in the future, the door would be cracked open
12 already. And it would seem to me that would make the
13 rest of the process go a lot quicker later.

14 So, do you see what I'm saying? I mean,
15 I just don't know how difficult it is to get the
16 exemption. But, once one person has the exemption or
17 two --

18 CHAIR THOMADSEN: Ms. Cockerham, do you
19 have a comment on that?

20 MS. COCKERHAM: Yes, just a general
21 comment. Just from being around for a little while,
22 I don't see OGC in the audience here, but they will
23 not regulate by exemption. That is not a model that
24 we use.

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1 And so, the idea that the door would be
2 cracked open and, then, the others could follow, it
3 would be case-by-case and it wouldn't necessarily be
4 based on precedent. And they are very, very hesitant
5 to let us -- like I said, that is wide open, like we
6 will not regulate by exemption. They will prefer
7 that we go rulemaking or --

8 CHAIR THOMADSEN: Mr. Costello?

9 MEMBER COSTELLO: I believe that one of
10 the institutions that thought about using it is in
11 Pennsylvania. And they did, in fact, ask us for an
12 exemption, and we said no, not me personally,
13 but -- (laughter) -- me, institutionally, said no.

14 If the NRC grants an exemption to one of
15 its licensees, I think that would make the Agreement
16 States much more comfortable in granting exemptions.
17 But, if the NRC has never granted an exemption, it
18 would be highly unlikely that we are going to be on
19 the cutting edge of exemption-granting.

20 (Laughter.)

21 CHAIR THOMADSEN: Thank you for that
22 comment.

23 Do we have any other comments?

24 (No response.)

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1 In that case, maybe what we also might do
2 is, at our closing when we find dates for our next
3 meeting, we also find a date for the conference call
4 covering this, while we are all here. I think that
5 will make Sophie's life a little easier.

6 Yes?

7 MS. THOMAS: I'm on the phone line.

8 CHAIR THOMADSEN: Yes?

9 MS. THOMAS: Are you open for public
10 comment?

11 CHAIR THOMADSEN: On this topic?

12 MS. THOMAS: This is Ruth Thomas.

13 CHAIR THOMADSEN: Yes?

14 MS. THOMAS: And I have been listening
15 with interest. I would like to ask for -- I am afraid
16 it has to be hard copy because I don't have a
17 computer -- but I would like to have either a
18 transcript or the information that has been presented
19 today, so that this can be made available to members
20 of the public.

21 CHAIR THOMADSEN: I think that that can
22 be arranged. Usually, the transcripts are reviewed
23 and approved within, I think, 90 days of the meeting.

24 Is there a way for her to leave a

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1 telephone number or an address with somebody?

2 MS. THOMAS: Well, this last part seems
3 like it was going into a new area, and the gentleman
4 that presented that, is he going to be making that
5 available?

6 CHAIR THOMADSEN: I'm sorry, what did you
7 just ask? Is he going to be what? Oh, are your
8 slides available?

9 MS. THOMAS: The gentleman that came
10 on -- I didn't catch his name -- and presented this
11 different idea.

12 CHAIR THOMADSEN: Uh-hum. Could we get
13 the hard copy of the slides along with the transcript
14 sent?

15 MS. HOLIDAY: Yes. Ms. Thomas, I know
16 that you have my contact information. So, please
17 feel free to call me.

18 But, for everyone that is listening in,
19 all of the handouts, which includes the meeting slides
20 for all of the presenters, the meeting transcript,
21 and the meeting summary are posted onto the ACMUI
22 meetings web page, which you can access through
23 nrc.gov. And if you do a search for "ACMUI" or even
24 if you go to Google and you just type in "ACMUI

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1 meeting," the link will pop up very quickly.

2 MS. THOMAS: Well, thank you very much.
3 I appreciate that.

4 MS. HOLIDAY: You're welcome.

5 CHAIR THOMADSEN: Certainly.

6 MR. MAILMAN: Just so you know, this is
7 Josh Mailman again.

8 Your actual web page went dead about 10
9 minutes ago, in case anyone is there. Actually, I
10 see that it is connection lost.

11 Thank you.

12 CHAIR THOMADSEN: Thank you. But you
13 have been able to be on the telephone line, it sounds
14 like? Is that true?

15 MR. MAILMAN: Yes, the telephone line
16 stayed alive. So, I have been on both.

17 CHAIR THOMADSEN: Okay. Thank you for
18 that information.

19 Any other comments? Hearing none -- yes?

20 MR. BOLLOCK: I just want to add -- and
21 this is on a personal safety basis -- with the
22 forecast for tomorrow, the potential snow in the
23 morning, so there is a potential for a mix of snow
24 and rain; there is the possibility that the government

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1 will have a two-hour delay. But we will still be
2 able to start on time at 8:30 tomorrow morning.

3 And just a note for all of you here who
4 have traveled, be careful, be safe out there.

5 CHAIR THOMADSEN: Thank you for that
6 warning.

7 (Laughter.)

8 Any other announcements?

9 Yes?

10 MEMBER COSTELLO: Move to adjourn.

11 CHAIR THOMADSEN: What's that?

12 MEMBER COSTELLO: Move to adjourn.

13 CHAIR THOMADSEN: We're going to, then,
14 adjourn until 8:30 tomorrow morning, where we plan on
15 meeting promptly.

16 (Whereupon, at 5:28 p.m., the meeting
17 adjourned, to reconvene the following day, Friday,
18 March 20, 2015, at 8:30 a.m.)

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STATEMENT OF PETER CRANE TO THE ADVISORY COMMITTEE ON THE MEDICAL USES
OF ISOTOPES

MEETING OF MARCH 19, 2015, NRC HEADQUARTERS, ROCKVILLE, MARYLAND

March 18, 2015

To the Committee:

I appreciate the opportunity to submit this statement to the Committee, as it prepares for its meetings on March 19 and 20, 2015. I look forward to hearing the staff's report on the progress of the continuing studies, under contract to NRC, on radiation doses attributable to patients released under 10 CFR 35.75, the Patient Release Rule.

Through the RADSAFE online bulletin board, I recently learned that Dr. Carol S. Marcus, a former member of this Committee, filed a petition for rulemaking with the NRC on February 9, 2015.¹ I urge the members of the Committee and other concerned persons in the NRC community to give this document close attention. Not only is it of interest in and of itself, its extremism serves to illuminate the intellectual underpinnings of the Patient Release Rule, which derives from an earlier petition for rulemaking from Dr. Marcus, filed in 1990 and later amended. Regrettably, the Commission did not then appreciate the extent to which Dr. Marcus's views deviated from the mainstream.

Dr. Marcus begins by attacking the Linear No-Dose Threshold Theory (LNT). So far so good, one might say; the LNT is admittedly a theory which remains to be proven. Dr. Marcus goes beyond that, however, to disparage the expertise of bodies that advocate the LNT (she mentions "NCRP, ICRP, IAEA, and NAS-NRC's BEIR Committee"²) and the integrity of the "army of regulators at NRC, EPA, FDA, as well as DOE [who] would be unbudgeted if the LNT disappeared." She reveals herself as a passionate advocate of the "hormesis" theory, and cites with approval the claims of Professor Edward Calabrese that the LNT was based on "amazing misconduct by the nation's leading geneticists in mid-twentieth century."³ She informs us that "the attitude of today's regulators is reminiscent of the Catholic Church at the time of Galileo. ... [T]he Church threatened to torture Galileo to death unless he rescinded his point of view. ... [W]hile today's regulators do not have the tools of torture available that the Catholic Church used, today's regulators will certainly destroy careers for regulatory violations of questionable importance."

I will leave it to those currently employed by NRC to decide whether they deserve comparison

¹ It can be found online at:
<http://radiationeffects.org/wp-content/uploads/2015/03/Hormesis-Petition-to-NRC-02-09-15.pdf>

² "NRC" in this context stands for the National Research Council.

³ Anyone with an interest in unusual conspiracy theories can read Dr. Calabrese's views in an interview in which he asserts that the LNT was a deliberate lie, launched in the 1946 Nobel Prize acceptance speech of Dr. Hermann Muller.
http://www.21stcenturysciencetech.com/Articles_2011/Fall-2011/Interview_Calabrese.pdf

to torturers. I certainly didn't feel that way in my 23 years at the agency.

Next, Dr. Marcus reviews the scientific data: the Hiroshima and Nagasaki survivors, nuclear power plant workers, tuberculosis patients given fluoroscopes, radium watch dial painters, hyperthyroidism patients treated with I-131, persons exposed to radiation from the explosion of a nuclear fuel reprocessing plant in Russia in 1957, persons exposed to radiation from accidentally recycled cobalt-60 sources in Taiwan, and Americans exposed to low levels of radon in their homes. Again and again she finds a hormetic effect.

This reader of the petition immediately wondered, how will she deal with Chernobyl, which has caused over 7000 cases of thyroid cancer to date? The answer: it didn't happen. She writes:

The affected population in the former Soviet Union was followed for increased cancer incidence. According to UNSCEAR 2000b [citation omitted] and the United Nations Chernobyl Forum in 2006, except for thyroid cancers in the highly contaminated areas, there was no increased incidence of leukemias or solid tumors, and no evidence of increased genetic diseases. The increase in thyroid cancers was found in children under the age of 15 years in 1987, the year after the accident. However, the radiation doses were too low to have caused this, and there was no dose-response relationship. In addition, the timing was off – the mean latent period for radiation induced thyroid cancer is about 28 years [citing the UNSCEAR 2000b report.] However, the increase was highly likely due to a mass screening effect [citation omitted]. Occult thyroid cancer is actually extremely common.... [petition at p. 6.]

The mainstream view of the Chernobyl data, of course, is that the appearance of so many thyroid cancers so soon after the accident (the first cluster of cases showed up near Minsk, Belarus, in about 1991, as I recall) was an indication that I-131 was more carcinogenic, when inhaled or ingested by the young, than previously suspected. Previously, the latency period was believed to be much longer. Dr. Marcus turns this on its head, however, arguing that since the latency period is much longer (a mean of 28 years, she says), the cancers found in 2000 and 2006 had to have some cause other than radiation, and can be attributed to better screening. Does that argument hold up? I will focus on just one part of the question: latency periods. Let us look, for example, at "Latency Period of Thyroid Neoplasia After Radiation Exposure," an article published in the journal *Annals of Surgery* in 2004.⁴ It found, based on a relatively small sample, that the mean latency period for papillary thyroid cancer associated with external radiation was approximately 30 years, whereas the mean latency period for

⁴<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1356259/>
Ann Surg. 2004 Apr; 239(4): 536–543.
[Latency Period of Thyroid Neoplasia After Radiation Exposure](#)
Shoichi Kikuchi, MD, PhD, Nancy D. Perrier, MD, Philip Ituarte, PhD, MPH, Allan E. Siperstein, MD, Quan-Yang Duh, MD, and Orlo H. Clark, MD

post-Chernobyl cancer, associated with internal radiation, was about six years.

This is not the place for a detailed discussion of the Chernobyl data – I only learned of Dr. Marcus’s petition yesterday, and the Committee’s meeting is tomorrow – but there is ample scientific evidence that the post-Chernobyl thyroid cancers were caused by internal radiation exposure, and that there is a linear dose-response relationship. See, e.g., Risk of thyroid cancer after exposure to ¹³¹I in childhood, Cardis E et al., J. Natl Cancer Inst., 2005 May 18;97(10): 724-32.⁵

Finally, we come to Dr. Marcus’s proposed solution. Rather than characterize it, I will reproduce it in full:

- 1) Worker doses should remain at present levels, with allowance of up to 100 mSv (10 rem) effective dose per year if the doses are chronic.
- 2) ALARA should be removed entirely from the regulations, as it makes no sense to decrease radiation doses that are not only harmless but may be hormetic.
- 3) Public doses should be raised to worker doses, as these low doses may be hormetic. Why deprive the public of the benefits of low dose radiation?
- 4) End differential doses to pregnant women, embryos and fetuses, and children under 18 years of age.

⁵ Abstract

BACKGROUND:

After the Chernobyl nuclear power plant accident in April 1986, a large increase in the incidence of childhood thyroid cancer was reported in contaminated areas. Most of the radiation exposure to the thyroid was from iodine isotopes, especially ¹³¹I. We carried out a population-based case-control study of thyroid cancer in Belarus and the Russian Federation to evaluate the risk of thyroid cancer after exposure to radioactive iodine in childhood and to investigate environmental and host factors that may modify this risk.

METHODS:

We studied 276 case patients with thyroid cancer through 1998 and 1300 matched control subjects, all aged younger than 15 years at the time of the accident. Individual doses were estimated for each subject based on their whereabouts and dietary habits at the time of the accident and in following days, weeks, and years; their likely stable iodine status at the time of the accident was also evaluated. Data were analyzed by conditional logistic regression using several different models. All statistical tests were two-sided.

RESULTS:

A strong dose-response relationship was observed between radiation dose to the thyroid received in childhood and thyroid cancer risk ($P < .001$). For a dose of 1 Gy, the estimated odds ratio of thyroid cancer varied from 5.5 (95% confidence interval [CI] = 3.1 to 9.5) to 8.4 (95% CI = 4.1 to 17.3), depending on the risk model. A linear dose-response relationship was observed up to 1.5-2 Gy. The risk of radiation-related thyroid cancer was three times higher in iodine-deficient areas (relative risk [RR] = 3.2, 95% CI = 1.9 to 5.5) than elsewhere. Administration of potassium iodide as a dietary supplement reduced this risk of radiation-related thyroid cancer by a factor of 3 (RR = 0.34, 95% CI = 0.1 to 0.9, for consumption of potassium iodide versus no consumption).

CONCLUSION:

Exposure to (¹³¹I) in childhood is associated with an increased risk of thyroid cancer. Both iodine deficiency and iodine supplementation appear to modify this risk. These results have important public health implications: stable iodine supplementation in iodine-deficient populations may substantially reduce the risk of thyroid cancer related to radioactive iodines in case of exposure to radioactive iodines in childhood that may occur after radiation accidents or during medical diagnostic and therapeutic procedures.

It is safe to say that if the United States of America were to change its radiation protection regulations to allow children, fetuses, and pregnant woman to receive as much radiation as a worker in a nuclear facility, on grounds that we do not want to deprive them of the hormetic benefits of radiation, this country and the NRC in particular would, in the world radiation community, be laughingstocks.

Thank you.

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1356259/>