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on the Medical Uses of Isotopes
Open Session

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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

+ + + + +

MEETING

+ + + + +

WEDNESDAY,

APRIL 26, 2017

+ + + + +

The meeting was convened in room T2-B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:00 a.m., Philip Alderson, M.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

PHILIP O. ALDERSON, M.D., Chairman

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

VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

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

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

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

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

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

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JOHN H. SUH, M.D., Radiation Oncologist

LAURA M. WEIL, Patients' Rights Advocate

NON-VOTING: ZOUBIR OUHIB

NON-VOTING: RICHARD GREEN

NRC STAFF PRESENT:

DANIEL COLLINS, Director, Division of Material
Safety, State, Tribal and Rulemaking Programs

JOSEPH NICK, Acting Deputy Director, Division of
Material Safety, State, Tribal and Rulemaking
Programs (MSTR)

DOUGLAS BOLLOCK, ACMUI Designated Federal
Officer

MICHELLE SMETHERS, ACMUI Alternate Designated
Federal Officer and ACMUI Coordinator

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

MICHAEL FULLER, NMSS/MSTR/MSEB

VINCENT HOLAHAN, Ph.D., NMSS/MSTR

SOPHIE HOLIDAY, NMSS/MSTR/MSEB

ESTHER HOUSEMAN, OGC/GCLR/RMR

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

MANUEL JIMENEZ, NRR/DRA/ARCB

MINH-THUY NGUYEN, RES/DSA/RPB

GRETCHEN RIVERA-CAPELLA, NMSS/MSTR/MSEB

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

TORRE TAYLOR, NMSS/MSTR/RPMB

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IRENE WU, NMSS/MSTR/SMPB

MEMBERS OF THE PUBLIC PRESENT:

BETTE BLANKENSHIP, American Association of
Physicists in Medicine (AAPM)

MICHAEL CALLAHAN, CCMSC Corp

ALEX FLIRT, Affiliation unknown

CATHERINE GILMORE-LAWLESS, Elekta

DESIREE KENNEDY, Elekta

CAITLIN KUBLER, Society of Nuclear Medicine and
Molecular Imaging (SNMMI)

SUSAN LOHMAN, Elekta

RICHARD MARTIN, American Association of
Physicists in Medicine (AAPM)

AVI OLER, Spectrum Pharmaceuticals

MICHAEL PETERS, American College of Radiology

JOSEPHINE PICCONE, Independent

CRAIG PIERCY, American Nuclear Society (ANS)

GLORIA ROMANELLI, American College of Radiology
(ACR)

MICHAEL STEWART, Walter Reed National Military
Medical Center

CINDY TOMLINSON, American Society for Radiation
Oncology

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

2 8:04 a.m.

3 CHAIRMAN ALDERSON: Before we start into
4 the usual series of events, I certainly want to
5 acknowledge the fact Frank Costello is no longer with
6 us. A great colleague. I'm sure that most of you know,
7 having read in the emails that have gone back and forth
8 from the organization, that probably next fall at the
9 autumn meeting there will be a more formal recognition
10 of Frank and his work. His family is potentially
11 planning to be here at that time. So we will not do a
12 formal recognition of Frank today.

13 But suffice it for those of you who've read
14 the information, I didn't realize that for 30 years,
15 Frank worked for the NRC. And he was engaged with
16 Agreement State issues in Region 1.

17 But then he went to Pennsylvania where he
18 became their representative to the Agreement States
19 group. And then he came here to this particular
20 committee and brought that tremendous expertise of his,
21 that willingness to always get engaged in the
22 discussions in a Frank way, but in a very good way,

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1 because he really knew the regulations and knew how the
2 organization worked. So he was always valuable. Even
3 when he was on the phone and not sitting here personally
4 he was valuable because of all he could bring.

5 So I look forward to -- and I'm sure all of
6 you do, too, to next fall when we'll be able to recognize
7 him in a more formal way. And I might suggest that just
8 for a moment, just for a moment we have a moment of
9 silence out of respect for Frank, and then we'll turn
10 it over to Doug and go on with the regular meeting.

11 (Moment of silence.)

12 CHAIRMAN ALDERSON: Thank you very much
13 and thanks to Frank for all he did for all of us.

14 Doug, the meeting is yours.

15 MR. BOLLOCK: Okay. Thank you, Dr.
16 Alderson.

17 Okay. Good morning, everyone. As the
18 designated federal officer for this meeting I'm pleased
19 to welcome you to the public meeting of the Advisory
20 Committee on the Medical Uses of Isotopes. My name is
21 Doug Bollock. I'm the Branch Chief of the Medical
22 Safety and Events Assessment Branch and I have been
23 designated as the federal officer for this advisory
24 committee in accordance with 10 CFR Part 7.11.

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1 Present today as the alternate designated
2 federal officer is Michelle Smethers, our ACMUI
3 Coordinator.

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

8 This meeting is being transcribed by the NRC and
9 may also be transcribed or recorded by others.

10 The meeting was announced in the February
11 27, 2017 edition of the *Federal Register*, Volume 82,
12 pages 11950 through 11951.

13 The function of the Committee is to advise
14 the staff on issues and questions that arise on the
15 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 opinions.

20 I request that whenever possible we try to
21 reach consensus on the various issues we'll discuss
22 today, but I also recognize there may be minority or
23 dissenting opinions. If you have such opinions, please
24 allow them to be read into the 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 Chairman, Dr. Philip Alderson, healthcare
4 administrator?

5 CHAIRMAN ALDERSON: Here.

6 MR. BOLLOCK: Thank you. Our vice
7 chairman, Dr. Pat Zanzonico, nuclear medicine
8 physicist?

9 VICE CHAIR ZANZONICO: Here.

10 MR. BOLLOCK: Thank you. Our nuclear
11 cardiologist, Dr. Vasken Dilsizian?

12 MEMBER DILSIZIAN: Here.

13 MR. BOLLOCK: Thank you. Our radiation
14 oncologist Dr. Ronald Ennis?

15 MEMBER ENNIS: Here.

16 MR. BOLLOCK: Thank you. Radiation
17 safety officer, Dr. Sue Langhorst?

18 MEMBER LANGHORST: Here.

19 MR. BOLLOCK: Thank you. Our diagnostic
20 radiologist, Dr. Darlene Metter?

21 MEMBER METTER: Here.

22 MR. BOLLOCK: Thank you. Our FDA
23 representative, Dr. Michael O'Hara?

24 MEMBER O'HARA: Here.

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1 MR. BOLLOCK: Thank you. Nuclear
2 medicine physician, Dr. Christopher Palestro?

3 MEMBER PALESTRO: Here.

4 MR. BOLLOCK: Thank you. Radiation
5 oncologist, Dr. John Suh?

6 MEMBER SUH: Here.

7 MR. BOLLOCK: Thank you. And our
8 patients' rights advocate, Ms. Laura Weil?

9 MEMBER WEIL: Here.

10 MR. BOLLOCK: Thank you. All right. I
11 confirm that we have -- a quorum is met of at least six
12 members.

13 Also at the table we have Mr. Zoubir Ouhib
14 and Mr. Richard Green. Mr. Zoubir Ouhib has been
15 selected as the ACMUI therapy medical physicist and Dr.
16 Richard Green has been selected as the ACMUI nuclear
17 pharmacist. Both Mr. Ouhib and Mr. Green are pending
18 security clearance but may participate in the meeting,
19 however, they do not have voting rights at this time.

20 I'd also like to add that this meeting is
21 being web cast, so other individuals may be watching on
22 line. We have a bridge line available, and that phone
23 number is (888) 711-9833. The pass code to access this
24 bridge line is 93680 followed by the pound sign.

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1 I'd just like to make a side note that we
2 have, as recently as yesterday afternoon, had
3 difficulties with the web cast. I believe the server
4 went down. Our technical staff, the NRC technical
5 staff did a wonderful job of getting it back up for this
6 morning, but if there are issues, I'd please encourage
7 people to make note of the bridge line, because they
8 still will be able to participate through that. So
9 again, the bridge line number is (888) 711-9833 and the
10 pass code is 93680 followed by the pound sign.

11 Individuals who'd like to ask a question or
12 make a comment regarding a specific issue the Committee
13 has discussed should request permission to be
14 recognized by the ACMUI Chairperson, Dr. Philip
15 Alderson. Dr. Alderson, at his option, may entertain
16 comments or questions from members of the public who are
17 participating with us today. Comments and questions
18 are usually addressed by the Committee near the end of
19 the presentation after the Committee has fully
20 discussed the topic. We ask that one person speak at
21 a time as this meeting is also closed captioned.

22 I'd also like to add the handouts and agenda
23 for this meeting are available at NRC's public web site.

24 At this time I'd ask everyone on the call

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1 who is not speaking to place their phones on mute. If
2 you do not have the capability to mute your phone, please
3 press star 6 to utilize the conference line mute and
4 un-mute functions.

5 At this point I'd like to turn the meeting
6 over to Dr. -- to Mr. Dan Collins, Director of the
7 Division of Material Safety, State, Tribal and
8 Rulemaking Programs for some opening remarks.

9 MR. COLLINS: All right. Thank you, Doug.
10 And I am not a doctor, but thank you and welcome to all
11 of the members of the ACMUI. I appreciate you taking
12 time out of your busy schedules and traveling to meet
13 with us today. And those of you who had painful Uber
14 experiences, we especially thank you.

15 So just by way of some opening remarks I'd
16 like to thank you members, all of the members for all
17 of the hard work that you do to support the important
18 work that's being done by the Committee in support of
19 the NRC and our regulatory functions. We wouldn't be
20 successful without your input, so thank you.

21 Just in terms of some -- before I get to some
22 organizational changes, I also thank you, Dr. Alderson,
23 for your kind words regarding Frank Costello. As you
24 noted, he was a long-time NRC employee and added great

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1 value in everything he touched, and he will be missed.
2 So I also look forward to the meeting in the fall where
3 we can recognize him more formally.

4 In terms of some other organizational
5 changes, just for folks' awareness in case you haven't
6 heard, we do have a new chairman at the NRC. Kristine
7 Svinicki was designated to be the chairman of the NRC
8 by President Donald J. Trump on January 23rd, 2017. She
9 began as a commissioner at the NRC on March 20th, 2008,
10 and so she has a long history with the Commission, but
11 she is now the chairman and the former chairman Stephen
12 Burns remains on the Commission as a commissioner.

13 Within the Office of Nuclear Material
14 Safety, State, Tribal and Rulemaking Programs, not the
15 office, the Division of Material Safety, State, Tribal
16 and Rulemaking Programs, we have had some changes. Pam
17 Henderson, who was my deputy, retired on March 31st, and
18 we are in the process of identifying her replacement.

19 Also, some of you may know that Mike Fuller
20 will be retiring effective May 5th. So we will hate to
21 see him go, but we appreciate everything that Mike has
22 done for the medical team and for the support of ACMUI.

23 You'll be missed, Mike.

24 We will be backfilling for him, but we're

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1 not far enough along in the process to make any
2 announcements at this point. But that will be
3 forthcoming fairly soon.

4 Within the ACMUI many of you know Dr.
5 Langhorst will be rotating off of ACMUI in September of
6 this year.

7 So, doctor, thank you for everything you've
8 done for us.

9 We have identified her replacement and I
10 sent out an email on this to everybody this morning.
11 Mr. Michael Sheetz has been selected to fill the
12 radiation safety officer position once Dr. Langhorst's
13 term ends in September. Mr. Sheetz will be joining us
14 for this meeting over the bridge line and we hope to have
15 him here present in the fall.

16 For those of you who haven't had an
17 opportunity to check your emails, just by -- and for the
18 other members of the public who are listening, just by
19 way of a little bit of short background for Mr. Sheetz,
20 he's currently serving as the director of the University
21 of Pittsburgh's Radiation Safety Office and as the
22 radiation safety officer for the University of
23 Pittsburgh and the University of Pittsburgh Medical
24 Center.

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1 He is a clinical assistant professor of
2 radiology in the University of Pittsburgh's School of
3 Medicine where he provides ongoing clinical teaching
4 and research support. He holds a bachelor's degree in
5 biological science and health planning and
6 administration from Pennsylvania State University and
7 a master's degree in radiation health from the
8 University of Pittsburgh's Graduate School of Public
9 Health.

10 He is board certified. He received his
11 board certification in comprehensive health physics
12 from the American Board of Health Physics in 1988 and
13 his board certification in medical health physics from
14 the American Board of Medical Physics in 2003.

15 So we welcome him to the ACMUI and we look
16 forward to hopefully a speedy clearance process for him
17 so he can formally join the --

18 (Laughter.)

19 MR. COLLINS: So, always hold out hope,
20 right?

21 In terms of some other things going on, the
22 members of the ACMUI all know this, but for members of
23 the public who may be listening, there will be an open
24 Commission meeting with the ACMUI tomorrow morning at

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1 10:00 in the NRC Commission Hearing Room. So members
2 of the public will be able to attend that or listen in.

3 Other activities going on. With respect
4 to patient release, I see on the agenda that you are
5 going to get a more fulsome update from Dr. Donna-Beth
6 Howe this afternoon. But other things going on with
7 respect to patient release, the NRC did publish a
8 *Federal Register* notice in -- on April 11th of this year
9 entitled, "Patient Release Programs." And that was
10 requesting public comments on the NRC's Patient Release
11 Programs. Specifically we're seeking input from the
12 public on whether additional or alternate criteria are
13 needed and whether to clarify the NRC's current patient
14 release requirements. And that information will be
15 used to help develop some recommendations that the staff
16 will be sending up to the Commission in the December time
17 frame of this year.

18 So we had a public meeting yesterday on
19 that, and that was the meeting that Doug referenced
20 where we had some challenges with the webinar, or with
21 the web cast. And then there's another public meeting
22 that's scheduled for May 23rd, which will also be here
23 at headquarters, and that will be again seeking
24 additional input from members of the public on that

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1 issue. But as I said, Dr. Donna-Beth Howe will be
2 providing additional updates to the ACMUI this
3 afternoon.

4 With regard to rulemaking, the Part 35
5 rulemaking is still with the Commission. We are hoping
6 to get the final vote within the next month or so, and
7 Torre Taylor will be providing a brief update for you
8 tomorrow afternoon.

9 We'll also be providing for you an update
10 on the Agency's Category 3 Source Security
11 Accountability Initiatives that we've previously
12 talked about, but Irene Wu, who's the project manager,
13 will be here today to give you an update on where that
14 all stands. And we recognize that there are some
15 important considerations from both the practitioners
16 and the public's perspectives regarding the Source
17 Security and Accountability Initiatives, so look
18 forward to that discussion.

19 In terms of other ACMUI upcoming vacancies,
20 we will be, as I said, working to backfill for Frank.
21 And then additionally the staff is going to be looking
22 at those positions on the ACMUI that are due to rotate
23 off within the next year and working on the succession
24 planning for that.

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1 And at this time I will turn the meeting
2 back over to Dr. Alderson. But before I do that, just
3 my apologies, I am triple-booked this morning, so I'm
4 not going to be able to stay for it all, but you're in
5 good hands with Doug and the rest of his team.

6 So with that, Dr. Alderson, the meeting is
7 -- I'll turn the meeting back over to you.

8 CHAIRMAN ALDERSON: Thank you very much,
9 Mr. Collins. Any other comments related to anything
10 that -- questions on anything that's been said here?

11 (No audible response.)

12 CHAIRMAN ALDERSON: Well, then we're into
13 the old business segment of the agenda and Michelle
14 Smethers will bring us up to date.

15 MS. SMETHERS: Thanks, Dr. Alderson.
16 It's nice to be here with all of you. For those of you
17 in the back who don't know me, I'm Michelle Smethers and
18 I'm the ACMUI coordinator. During this portion, the
19 next portion of our agenda, we'll be going through the
20 old business, as we do in all meetings, where we recap
21 actions and recommendations put forth by the Committee
22 and noting any changes.

23 So beginning with 2007. Okay. So all
24 items listed in 2007 are open as -- sorry. All items

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1 in 2007 listed as open are included in the current Part
2 35 rulemaking, and open and delayed means they will be
3 considered in future rulemaking.

4 Moving onto 2008. Again, just like 2007
5 all items listed as open are included in the current Part
6 35 rulemaking, and open and delayed means they will be
7 considered in future rulemaking.

8 2009. The two items listed in 2009 are
9 both included in the current Part 35 rulemaking.

10 Moving onto 2010. 2010 is not included
11 because all actions and recommendations were previously
12 closed.

13 2011. Items 11, 13, 14 and 15 are included
14 in the Part 35 rulemaking. And then Dan touched on
15 this. Items 1 and 16 have to do with the patient release
16 criteria, and both of these items are pending because
17 there's a patient release effort going on at the NRC in
18 the Office of Nuclear Material Safety and Safeguards.
19 So as he mentioned, there was a public meeting yesterday
20 and there will be another to seek feedback and comments
21 on May 23rd. So that is pending and will stay on there.

22 Lastly, item 6 is the indefinite action
23 item, the open action item from the Committee to review
24 its reporting structure, and I will be reviewing that

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1 later in the meeting. So that stays on there.

2 Moving to 2012. All 2012 items were closed
3 in the last -- in the March 2016 meeting, so there's
4 nothing for 2012.

5 2013. Items 1 through 13 are part of the
6 current Part 35 rulemaking. Some of these charts are
7 less exciting than others. Okay.

8 Moving onto 2014, all items were closed as
9 well during the October 2016 fall meeting.

10 For 2015 item 7 is still listed as open as
11 this is an ongoing effort and we are waiting on staff's
12 review and evaluation to revise the NRC's abnormal
13 occurrence criteria policy statement. Item's 12
14 through 15 have been part of an ongoing effort. You
15 will hear a presentation tomorrow morning from Dr.
16 Dilsizian regarding the Patient Intervention
17 Subcommittee's recommendations on the definition of
18 patient intervention.

19 And item 22. Like item 7, item 22 has to
20 do with NRC's ongoing efforts with the abnormal
21 occurrence criteria policy statement.

22 For 2016 -- we're going to move onto 2016.
23 Items 1 through 15 all deal with the Part 35 rulemaking
24 Subcommittee report that had the recommendations

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1 related to the draft final rule. The Part 35 rulemaking
2 package, as you've heard, is sitting with the Commission
3 for vote. And we'll hear from Ms. Torre Taylor tomorrow
4 afternoon for a brief update.

5 And then for item 16 we will hear from Dr.
6 Palestro later this afternoon for an update on the work
7 done by the Training and Experience for All Modalities
8 Subcommittee.

9 Item 24 was an ACMUI action to reach out to
10 professional organizations to encourage interactions
11 and communications between professional organizations,
12 the NRC and the ACMUI. And I believe Dr. Alderson will
13 report briefly on this to the Commission tomorrow.

14 Would you like to keep this on the chart?
15 I think last meeting we decided that moving forward we
16 would, but --

17 (Simultaneous speaking.)

18 CHAIRMAN ALDERSON: Yes, I would. And
19 before tomorrow's meeting I want to review with people
20 exactly who's meeting with whom and when so we can convey
21 that to the Commission.

22 MS. SMETHERS: Great. Yes, we can do that
23 later today.

24 And for item -- are we on -- let's see, item

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1 38 was brought to the attention of the ACMUI last meeting
2 by Dr. Zanzonico during the open forum of the fall 2016
3 ACMUI meeting. The open forum provides ACMUI the
4 opportunity to identify medical topics of interest for
5 further discussion, so Dr. Alderson requested that this
6 topic be discussed at this spring meeting to appoint a
7 subcommittee that will report on the nursing mother
8 guidelines for the fall 2017 meeting.

9 Item 39. Item 39 was the Committee
10 recommendation that staff issue a generic communication
11 or information notice regarding tubing issues such as
12 kinking, connection, hub, etcetera, during the
13 administration of Y-90 microsphere brachytherapy. And
14 staff is still looking into this, so this remains on the
15 list.

16 Item 41 was an action to reestablish the
17 Patient Intervention Subcommittee, and the
18 subcommittee's new charge was to make a recommendation
19 on what the definition of patient intervention should
20 be. As I mentioned, Dr. Dilsizian, chair of the
21 Subcommittee, will be reporting tomorrow morning.

22 Items 42 and 43. The working group is
23 developing a draft revision for the licensing guidance,
24 which it intends to send out for public comment this

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1 summer.

2 And items 44 through 52 all pertain to the
3 NorthStar Medical Radioisotopes RadioGenix Moly-99
4 Tech-99 Generator System Licensing Guidance. And
5 these items are still open since the comment resolution
6 work is still in progress.

7 Lastly, item 25 was an ACMUI action to hold
8 the spring 2017 meeting. And since we are all here and
9 holding this meeting, I would like to request that this
10 action be closed.

11 CHAIRMAN ALDERSON: Are there questions or
12 comments before we vote on that request? Yes?

13 MEMBER LANGHORST: Oh, on the request
14 of --

15 CHAIRMAN ALDERSON: To approve. Please,
16 go ahead. Make your comment.

17 MEMBER LANGHORST: I'm sorry. What was
18 the request? To approve for what?

19 MS. SMETHERS: To close the action --

20 MEMBER LANGHORST: Oh, yes.

21 MS. SMETHERS: -- to hold this meeting.

22 MEMBER LANGHORST: That was not my comment
23 on that.

24 CHAIRMAN ALDERSON: Not your comment?

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1 MEMBER LANGHORST: Sorry.

2 CHAIRMAN ALDERSON: Would you like to make
3 another comment?

4 MEMBER LANGHORST: I'll wait until we --

5 CHAIRMAN ALDERSON: You'll wait?

6 MEMBER LANGHORST: -- decide on that.

7 CHAIRMAN ALDERSON: Very good. Are there
8 any other people who would like to comment on this
9 particular action?

10 (No audible response.)

11 CHAIRMAN ALDERSON: Hearing none, let's
12 vote. All in favor?

13 (Chorus of aye.)

14 CHAIRMAN ALDERSON: Unanimous. Thank
15 you.

16 MS. SMETHERS: Okay. Thank you.

17 CHAIRMAN ALDERSON: Now, Dr. Langhorst?

18 MEMBER LANGHORST: Yes, thank you. I did
19 have a question on the item. So with so many items being
20 closed for Part 35, will they all still remain on the
21 list and be discussed as closed next time? Because I
22 think the Committee may want to really be careful in
23 looking through each of those items to make sure nothing
24 is lost that was not part of the Part 35 change, but that

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1 the Committee feels is important to keep in the
2 forefront.

3 MS. SMETHERS: Yes, we can keep them on
4 there and discuss them next meeting before moving them
5 from the list.

6 CHAIRMAN ALDERSON: Okay.

7 MEMBER LANGHORST: That might take a
8 little more time.

9 MS. SMETHERS: Yes. Yes.

10 MEMBER LANGHORST: So, thank you.

11 CHAIRMAN ALDERSON: Good. Thank you.

12 Other comments?

13 (No audible response.)

14 CHAIRMAN ALDERSON: All right. Hearing
15 none, Ms. Smethers, thank you for --

16 MR. BOLLOCK: Thank you.

17 CHAIRMAN ALDERSON: -- doing this part of
18 the agenda.

19 And that brings us to the part of the agenda
20 called open forum. And this is a time when something
21 just like Dr. Langhorst just discussed can actually be
22 discussed, such as any medical topics of interest for
23 further discussion that people would like to talk about
24 before we get into the actual presentations. So the

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1 floor is open at this time for any such items.

2 Dr. Zanzonico?

3 VICE CHAIR ZANZONICO: Yes, good morning.
4 We went through a lot of time and effort and thought,
5 and so did the NRC staff, on the -- waiving the Disposal
6 Funding Plan for the germanium-68/gallium-68
7 generator. And I've gotten informal inquiries,
8 feedback from various individuals saying that at least
9 some of the Agreement States are still requiring
10 disposal plan funding to the point where some
11 institutions are not going to do gallium-68 studies,
12 unfortunately.

13 And again, these were informal
14 comments/inquiries. I don't know their accuracy and I
15 don't know exactly what was told to various institutions
16 and how the various institutions responded and so forth
17 and so on, but it seemed there was so much effort and
18 so much unanimity of the value of the gallium-68
19 radiopharmaceuticals and the impropriety of the
20 Disposal Funding Plan requirement as originally
21 appeared that it seemed we should somehow address that,
22 because you seem to be going backwards to some extent
23 after all of that. So I just wanted to bring that to
24 everyone's attention and perhaps discuss what could be

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1 done to remediate that situation.

2 CHAIRMAN ALDERSON: Yes, Mr. Green?

3 MEMBER GREEN: I have personal knowledge
4 of that with our licenses. While the financial -- the
5 decommissioning funding plan has been exempted if you
6 ask for it and follow all the requirements that were
7 specified in the guidance, some states are still
8 requiring the financial assurances warranty bond, which
9 doesn't make sense because to get it back to the
10 manufacturer is an \$85 FedEx charge but to put a couple
11 \$100,000 down on a financial assurances warranty bond
12 doesn't make sense. So part of it was I made a pathway,
13 but part of it's still unclear and some states are
14 requiring that warranty -- financial assurances
15 warranty bond.

16 MR. BOLLOCK: And I can address all this.
17 Are there any other comments from the Committee or
18 questions that I -- they'd like me to address in this
19 area? And I can touch on all the points that both Dr.
20 Zanzonico and Mr. Green have brought up.

21 So the issue that was brought to us was the
22 decommissioning funding plan was too expensive, and
23 -- expensive and extensive is what we heard. So we
24 brought -- so we looked at that, went through how could

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1 we get rid of the decommissioning funding plan, because
2 they can -- this is something that needs to be updated.
3 It can be very difficult to -- to get a decommissioning
4 funding plan for just -- just to have these generators,
5 which is what can happen.

6 So, and it's not just -- some the states
7 actually are -- in order for us to allow our license
8 -- our regions to allow licenses with exemptions to the
9 decommissioning funding plan there was still a
10 requirement for funding assurance, essentially the bond
11 that Mr. Green was talking about. That actually is our
12 requirement and some of the states' requirements.

13 Some of the other issues are some of the
14 other states because they do not have to follow our
15 exemptions, our exemption comes from our office
16 director to the regional administrators that license
17 NRC licensees. They don't necessarily have to follow
18 exactly how we deal with decommissioning financial
19 assurance. So there are some differences state to
20 state and we are aware of that.

21 There was also some confusion whether the
22 financial assurance was still required or not based upon
23 our exemption. And as Mr. Green brought up, the fact
24 that if you just ship it back, that's -- it's a very cheap

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1 thing, however, in order to kind of shift the -- I was
2 -- and so I have explained this to the Commission.

3 I believe I said this in front of -- at an
4 ACMUI meeting previously. We got rid of the financial
5 -- the decommissioning funding plan, but we shifted the
6 -- there is no -- there's a zero sum safety change. The
7 licensees are still required to have that bond so that
8 they can't -- so that we know they can ship it back
9 without any of that -- the financial discussions back
10 and forth.

11 We had originally looked at other options,
12 and that would -- from manufacturers to pay for it, get
13 it into the book. So we did look at other options, but
14 what we had last summer when we worked through this, the
15 information we had, that is the end result where the
16 exemption was leaving some sort of financial assurance.

17 Unfortunately, our financial assurances
18 are set in our regulations that 100 and -- I think it's
19 a \$125,000 bond for -- it would -- practically equates
20 to one or two generators. And then more than two
21 generators it is -- or, no, it's 250,000 and then 1.25
22 million for more than two generators is -- is what it
23 comes down to. So that's not right.

24 And as Mr. Green -- we realize practically

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1 you're shipping back a little generator and what does
2 that cost and why does the bond -- unfortunately, we're
3 working within our bounds on the information that we
4 have to keep -- to allow us to not just on a safety basis
5 and a legal basis be able to allow exemptions.

6 We did just receive -- I believe this is
7 publicly available knowledge. We did receive a
8 petition for rulemaking to open up the Part 30 table that
9 requires the decommissioning financial assurance. And
10 one of the specific isotopes they want to add to the
11 table which could basically allow for us to address all
12 this in rulemaking, in a petition for rulemaking is the
13 germanium-68.

14 So we are -- we were working on a direct
15 final rule to address this instead of going by
16 exemption, and we believe now that we may -- still in
17 process, but there is a petition for us to just open up
18 the table and address this issue. So there will be time
19 available or opportunities available in the future to
20 bring up all of these points for us to make a change in
21 the regulations to allow easier access without
22 financial assurance, essentially a bond of some sort
23 even with the exemption or a decommissioning funding
24 plan.

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1 CHAIRMAN ALDERSON: So I'm sure that
2 everyone's happy to know that there is ongoing progress.
3 A couple of questions might be useful.

4 Dr. Zanzonico, do you know in terms of the
5 states that are still requiring this -- there's
6 something like 37 Agreement States. How many states or
7 what proportion of the states are still requiring some
8 sort of bond? Is this a big problem or is it only a few
9 states?

10 VICE CHAIR ZANZONICO: Again, the
11 information I received is just anecdotal, sort of a
12 semi-hysterical email.

13 CHAIRMAN ALDERSON: From one of the
14 Committee members.

15 VICE CHAIR ZANZONICO: Well, no, just from
16 users out in the field. And I believe they identified
17 two different states.

18 CHAIRMAN ALDERSON: Two?

19 VICE CHAIR ZANZONICO: But for the people
20 in those states it's a big --

21 (Simultaneous speaking.)

22 CHAIRMAN ALDERSON: Yes, it's a big
23 number. Absolutely.

24 MR. COLLINS: And just to be -- it's not

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1 just the states. Those states are following NRC -- our
2 exemption -- still requires the bond. It was -- the
3 issue was the decommissioning financial
4 -- decommissioning funding plan, because that -- there
5 are other requirements for that. That was the issue,
6 get rid of that. While we still have -- it's a step down
7 in our regulations of requirements based upon the amount
8 of certain isotopes. So we -- again, based on the
9 information that we had last year we were able to exempt
10 the decommissioning funding plan, however, when we took
11 a step down we were still requiring that, financial
12 assurance was still required.

13 Mike, do you have anything to add? Mike
14 Fuller.

15 MR. FULLER: Yes, thanks, Doug. Thank
16 you, Dr. Alderson.

17 The one thing I'd like to point out; and
18 this is something I think is kind of in the details and
19 folks don't always recognize, our requirements are for
20 decommissioning financial assurance. People
21 sometimes confuse that with decontamination. And so
22 it's not just the cost. We talk about this being a
23 relatively closed system and the potential for
24 contamination is pretty low. Everyone would agree to

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1 that.

2 But when it comes to decommissioning what
3 we're talking about is actually removing something from
4 a license and/or actually terminating a license. And
5 so our rules are pretty straightforward and pretty clear
6 that there needs to be financial assurance in place;
7 this is the way that we've done it for many, many years,
8 that ensures that folks have the funding in place to
9 properly decommission and then ultimately terminate a
10 license.

11 We haven't had a lot of these situations,
12 but we've had situations where people, even some medical
13 facilities have gone bankrupt and someone comes in and
14 padlocks doors and there is radioactive material on
15 site. And so in situations like that there needs to be
16 some financial instrument in place to ensure that means
17 can be -- I mean that steps can be taken to have that
18 material removed appropriately and properly and
19 disposed of or returned to someone. And sometimes that
20 costs some money.

21 And as Doug mentioned, our funding levels
22 under our financial assurance requirements are really
23 set in stone. Everyone would agree that it probably
24 doesn't cost that much money. But again, this is a

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1 default. If we can get the table updated to an
2 appropriate value for germanium-68, that will tend to
3 alleviate a lot of this.

4 But just wanted to caution folks don't just
5 think of decommissioning -- I mean, don't -- yes, don't
6 just think of decommissioning as decontamination or
7 cleaning up something. It's probably not likely to be
8 contaminated. It has to do more with decommissioning
9 a license or decommissioning a facility and ultimately
10 terminating a license. So keep that in mind, too, as
11 we discuss this.

12 CHAIRMAN ALDERSON: So again, I think that
13 most people would be happy that there is some progress
14 that the NRC is discussing this. I would certainly
15 advocate that -- and we've discussed this many other
16 times, that this -- these discussions be as timely as
17 possible.

18 Pat, do you want to make any more comments?

19 VICE CHAIR ZANZONICO: Yes, I think -- and
20 I understand the regulatory constraints; and they're
21 not unreasonable and so forth, but clearly there's some
22 confusion among users that's significantly affecting
23 patient care and so forth. So I think at the very least
24 there needs to be some formal document, some formal

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1 release from the NRC clarifying exactly what is and is
2 not required at the moment and what the path forward is,
3 because otherwise I think this confusion is going to
4 persist.

5 MR. BOLLOCK: Yes, and we are actually
6 addressing that because we -- even amongst our -- the
7 other states that want to follow our exemption or
8 something similar. So we -- there's some -- we're going
9 to add one clarifying line to the actual guidance, but
10 then our methods, or communicating our exemption
11 guidance, that confused people because it didn't have
12 all the details. And having the cover sheet that set
13 the actual information didn't get specifically to the
14 point of you still have some financial assurance if -- in
15 the case that Mike said -- an organization went
16 -- bankrupt.

17 So I'm sure you can send these things back
18 or decommission the site. So there was some confusion
19 in that because that didn't get into those details. And
20 that is an important detail. So we are updating that.
21 And that -- I mean, that -- we are very shortly will be
22 sending that out to try to clarify that amongst the
23 regulators.

24 CHAIRMAN ALDERSON: So Dr. Daibes from the

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1 NRC has a comment and then Dr. Ennis has a comment.

2 DR. DAIBES: Said Daibes. Yes, adding to
3 what our branch chief just added, we have three
4 documents in concurrence. It's apparent there's a
5 potential confusion out there with respect to when you
6 request the exemption for the DFP. People were under
7 the impression that that was exempting financial
8 assurance. And we're working with that confusion. So
9 we have something specifically addressing that concern.
10 It's pretty close to being a final product. And that
11 will actually do what needs to be done out there with
12 respect to clarifying.

13 We have updated guidance and we have
14 updated the memo to add those clarifications so people
15 are not under that impression. So our initiatives will
16 potentially exempt DFP, but we cannot assume that it's
17 going to exempt all financial assurance requirements.
18 And that's very explicitly defined in our new documents
19 coming out. So I wanted to add that.

20 CHAIRMAN ALDERSON: Dr. Ennis?

21 MEMBER ENNIS: Thank you. So I'm not
22 surprised there's confusion because I was misunderstood
23 what we had done. So how much would it actually cost
24 an institution to have that bond in place?

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1 MR. BOLLOCK: We -- Said and I have kind of
2 ballparked that, like just looking at it. I mean, this
3 is just us on Google, right? And it was within hundreds
4 of dollars or a thousand dollar a year insurance --

5 DR. DAIBES: Can I add --

6 MR. BOLLOCK: Yes.

7 DR. DAIBES: Yes, Said Daibes. So we went
8 out and we were checking this. Five hundred dollars to
9 actually get a bond that will provide the assurance you
10 need in order to access this financial assurance bond.
11 Four, five hundred bucks.

12 MEMBER ENNIS: Okay. So to me then that's
13 reassuring that we did accomplish something.

14 (Laughter.)

15 MEMBER ENNIS: That seems like a
16 reasonable price.

17 (Simultaneous speaking.)

18 MEMBER ENNIS: And then -- and but again,
19 I mean, it's important to hear from someone who has the
20 practice. So, Mr. Green?

21 MR. GREEN: Yes, it's roughly two percent
22 per annum of the bond amount, but the organization that
23 I'm employed by has 22 sites that currently possess
24 germanium generators. And it's not just the per annum

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1 amount that you pay to the financial institution for the
2 instrument. It's the process of going through your
3 bank and treasury departments and so on to create all
4 the paperwork and all the lawyers involved to do all
5 that. But I'm happy to see that we have a short term
6 solution to dispel the confusion that exists and I hope
7 we have a long-term solution by changing a value on a
8 table.

9 CHAIRMAN ALDERSON: Yes, Dr. Ennis?

10 MEMBER ENNIS: Just one thought. When we
11 get to the issue of the table, I'm a little concerned;
12 and this is something we had talked about, there may be
13 another isotope next week. And two weeks from now or
14 a year from now yet another isotope. And if we're going
15 to go back to rulemaking to change the table every time,
16 that's not an ideal solution. So I don't know if we
17 could be more creative about figuring out and
18 anticipating what might be coming in a more generic kind
19 of way.

20 MR. BOLLOCK: That's a very good point and
21 we are aware of it and that is our plan -- we're in the
22 process. That is actually part of the discussion we had
23 on Monday of this week, that we recognize exactly that.
24 So our first step would be to solicit that. What other

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1 isotopes are out there that aren't in the tables that
2 are used for medical or for other uses, industrial, that
3 can show the need. So that would be the first step and
4 we are aware of that.

5 CHAIRMAN ALDERSON: Yes, one final comment
6 on this. Dr. Langhorst?

7 MEMBER LANGHORST: I have a couple
8 comments, if that's okay, Dr. Alderson.

9 CHAIRMAN ALDERSON: Please.

10 MEMBER LANGHORST: For people doing
11 financial assurance -- and just a reminder that
12 decommissioning funding planning is when you have a lot
13 of activity and you have to design how much financial
14 assurance you have for your given license. That's
15 where the DFP comes in. There's NUREG-1757 that is very
16 good in telling licensees what are the ways they can get
17 this financial assurance. So a bond is one way, but
18 there are other options. And so licensees should
19 explore that NUREG-1757.

20 The change in the table -- this is a Part
21 30, Appendix B table, which is the old table from Part
22 20 before it was updated in the early 1990s. The table
23 in Part 20 could be referenced instead of this table.

24 Now if you're changing that -- the proposed

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1 -- or the request for rulemaking was to change the table,
2 is that correct? So that has lots of implications.
3 And it won't go quickly because a lot of people may no
4 longer need to do decommissioning funding planning to
5 do their financial assurance, but maybe it might change
6 others to require that decommissioning funding
7 planning. So that's not a quick fix. So I would hope
8 that NRC keeps going on its proposed plan to have like
9 a footnote on the table for germanium-68.

10 And the isotopes that are in this table are
11 ones that are greater than 120-day half-life. So that
12 leaves out a lot of medical use isotopes because a lot
13 of them are a lot less -- lower half-lives. So I just
14 wanted to make a few of those comments that -- thank you.

15 CHAIRMAN ALDERSON: Mr. Bollock wants to
16 follow that up.

17 MR. BOLLOCK: I just -- and so the -- that
18 direct fund rule with the footnote that we talked about,
19 we're working on that.

20 MEMBER LANGHORST: Yes.

21 MR. BOLLOCK: And actually we're very far
22 along. That's not going to be -- that will still
23 require some financial assurance --

24 MEMBER LANGHORST: Right.

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1 MR. BOLLOCK: -- so it does not alleviate
2 the bond or that level of financial assurance that
3 currently is in our exemption. So if you want further
4 changes, we -- the -- so for our -- at least our NRC
5 licensees there is no -- there would be no change in the
6 -- in what we're doing with the direct final rule. So
7 I just want to make that be known and be clear to you
8 all so you understand that.

9 CHAIRMAN ALDERSON: Okay. Thank you.

10 Is there anything else on this subject?
11 Yes?

12 MEMBER OUHIB: Just a general comment. Do
13 we have a timeline at this point, because there are users
14 sitting out there thinking, well, what do I do now, or
15 how long do I have to wait to make some changes and so
16 on and so forth?

17 MR. BOLLOCK: So --

18 MEMBER OUHIB: So, I mean I know you have
19 some corrective actions and so on and so forth.

20 MR. BOLLOCK: So your options now would be
21 follow the rules as is, which is a decommissioning
22 funding plan, which is -- can take a lot -- this is
23 -- well, it's expensive to come up with one and
24 everything, but if your plan was it costs us \$85 to send

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1 back these generators, we only need \$1,000 of assurance
2 to -- for four of them, then that's one option.

3 Or if you're an NRC licensee, request the
4 exemption. You have some sort of financial assurance
5 at our levels. And then the other specific
6 requirements to get that exemption, which is just that
7 you have a contract, that when our generator is expired,
8 we ship it back. And that's -- those -- so those right
9 now are the two current options. If we -- even with a
10 direct final rule change for the -- to the footnote to
11 the table, it would still be that for NRC's licensees.
12 So I want to be clear on that.

13 To make a change to lower the values, lower
14 that bond rate, make it even easier would take
15 -- and that has always -- that would take a more
16 extensive change to the table now. We are further along
17 the lines when it comes to germanium, but as Dr. Ennis
18 pointed out and we understand, we're not just going to
19 open a table for just that.

20 There are other -- there could be other
21 uses, other isotopes that could be useful to the medical
22 community that we want to know about and also include
23 those so that we're not doing this all over again with
24 those other isotopes.

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1 CHAIRMAN ALDERSON: So, Dr. Daibes, you
2 had a final comment?

3 DR. DAIBES: Yes, Said Daibes. I just
4 want to add that when you request the exemption, there's
5 two requirements you need to satisfy, one of them being
6 the legally binding agreement with the distributor that
7 will be supplying that generator. And our memo and
8 guidance has specifics on the components that a legally
9 binding agreement will need to have in order to comply
10 with the NRC's regs. And the other component is a
11 financial assurance certificate for the corresponding
12 amount of financial assurance based on the level of
13 activity or generators you're requesting. So those are
14 the two, just clarifying, to answer your question.

15 CHAIRMAN ALDERSON: Thank you. I think
16 we'll draw this discussion to a close. I think it's
17 been a very good discussion. Ultimately a lot of these
18 issues are going to relate to the specific venue or the
19 territory in which you work and what that hospital or
20 that state is willing to do. So I think we've gotten
21 a good background on what some of the issues will be.
22 So thank you very much to all of you who have
23 participated in this discussion.

24 We are a little bit behind time, not badly

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1 behind time. Is there another issue for the open forum
2 that people feel they need to bring forward at this time?

3 (No audible response.)

4 CHAIRMAN ALDERSON: Hearing none, I think
5 that we're ready then to move onto the next part of the
6 agenda, which is the -- the representatives from Elekta
7 will discuss the physical presence requirement for the
8 Leksell Gamma Knife Icon. So there they come.

9 MS. LOHMAN: Good morning. I'm Susan
10 Lohman from Elekta and I have worked for Elekta for two
11 decades. Prior to that worked in a clinical setting
12 with Leksell Gamma Knife.

13 What I do for Elekta is clinical training
14 and application support. In the role of application
15 support and clinical training I participate at the
16 training centers here in the United States that train
17 customers that are new to Gamma Knife or that will be
18 upgrading a Gamma Knife, as well as on-site training,
19 both for the equipment itself, the machine, and planning
20 software. With the experience that I've had I've
21 probably observed greater than 2,000 Gamma Knife cases,
22 either participating as a clinician while I was working
23 as a nurse or in my role with Elekta.

24 The presentation today is going to include

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1 four parts: The first is a brief introduction to Elekta
2 as a company. The second is information about the Gamma
3 Knife technology, recognizing that there are various
4 degrees of familiarity with Gamma Knife. The third
5 portion of the presentation will focus on the importance
6 to the patient and the public for access to Gamma Knife
7 treatment and the physical presence requirement. And
8 finally, specific language that is being requested in
9 a modification to the physical presence requirement.

10 As a corporate overview, Elekta is a
11 medical technology company that is global in its
12 presence. Elekta has -- developed Gamma Knife at the
13 beginning with a physician who was striving to improve
14 patient care. Over the 30-year history of Elekta,
15 Elekta has been focused on improving the quality of
16 patient treatments through advances in technology and
17 additions such as imaging and improvement of treatment
18 planning.

19 With all of this Elekta is a
20 well-established cancer care partner in over 6,000
21 hospitals worldwide with 1.5 million people being
22 treated with an Elekta solution every day -- I'm sorry,
23 every year. And then every day greater than 140,000
24 patients are touched by some sort of Elekta solution,

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1 whether it be with treatment, treatment planning or with
2 an electronic medical record as follow-up.

3 The Gamma Knife has been through an
4 evolution over these past 30 years. It is a machine
5 designed to specifically treat intracranial lesions,
6 and those intracranial lesions or diseases are often
7 things that are considered inoperable. They cannot be
8 reached with a surgeon's scalpel. The machine uses
9 cobalt-60 sealed sources as its source of radiation for
10 treatment. It is considered a gold standard in
11 radiosurgery. It treats very small locations as well
12 as lesions in critical locations.

13 If you look at the picture on the top left
14 of the screen, that represents a -- it's a picture of
15 a tumor that is being -- had been planned with Leksell
16 Gamma Knife. The yellow line represents the treatment
17 margin of that tumor. And the two green lines represent
18 a steep dose fall-off, minimal amount of tissue being
19 affected by the radiation that is being used to treat
20 the target.

21 The small red circles that you see in there
22 are our isocenters or the points at which the radiation
23 is focused throughout the treatment. And I believe in
24 this specific treatment there were 20-some isocenters

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1 used. So different positions at the focal point of the
2 machine during the treatment.

3 It uses 192 sealed cobalt sources in its
4 treatment. Each one of these beams individually are
5 not strong enough to affect the tissue, to have any
6 negative effects on tissue, however, as these beams
7 converge to a single point is where it becomes effective
8 in treating abnormal tissue.

9 There are very few moving parts to the Gamma
10 Knife. The sealed sources which are represented by the
11 red dots on the screen are on a plate that moves
12 longitudinally over the collimator body. This
13 collimator body is drilled with different size channels
14 for the beams to pass through, and those channels are
15 what will collimate the beams to one of three different
16 sizes: 4-millimeter diameter, 8- millimeter diameter of
17 a 16-millimeter diameter. Because we're using
18 cobalt-60 sealed sources, the output from the machine
19 is stable and known throughout the life of the machine.

20 The patient positioning device is the
21 entire couch on which the patient lies. That is
22 calibrated to the focal point of the Gamma Knife
23 treatment unit. The patient is attached to the
24 positioning device through an apparatus, either a

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1 stereotactic frame attached to their head rigidly or
2 through mask fixation with an interface to the patient
3 positioning couch.

4 There are expanding clinical applications
5 for Gamma Knife treatment. When Gamma Knife first
6 began the large majority of treatments were vascular
7 diseases, however, over the years that percentage has
8 changed and now the majority of treatments that you see
9 being performed by a Gamma Knife are for malignant
10 disease, many of these being brain metastases as
11 patients are being better cared for, advances in
12 medications throughout the cancer care spectrum, seeing
13 more patients with metastases living longer and having
14 more metastases.

15 So there are greater than a million
16 patients treated worldwide with Gamma Knife, 80,000 of
17 those annually, and there are over 2,500 peer-reviewed
18 papers attesting to the efficacy and safety of the Gamma
19 Knife.

20 Over 30 years the technology has changed
21 tremendously for Gamma Knife from a completely manual
22 system to a fully automated system for patient
23 positioning. The first Gamma Knife was a Leksell Gamma
24 Knife Model U, and that was in 1987, which happens to

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1 be the very first model of Gamma Knife that I worked
2 with. And this was a fully manual system.

3 The helmet that you see, the collimator, which is
4 the silver portion immediately around the patient head
5 -- there were four helmets, each with 201 collimators
6 in it that would go -- retract back into the machine and
7 line up with the cobalt sources to deliver treatment.
8 These helmets had to be changed manually using a hoist
9 that was brought alongside the bed, attached to the
10 helmet, lifted off of the machine and moved to a storage
11 table in order to change the helmets.

12 In addition, the coordinates for each one
13 of the isocenters needed to be set manually by the
14 treatment team on the stereotactic frame. So three
15 coordinates: X, Y and Z. So a total of six coordinates
16 for every isocenter. All of this manual intervention
17 left a lot of room for human error.

18 So the next model of Gamma Knife changed the
19 configuration of the collimator helmet, but that was
20 really the change there.

21 In 1999 Elekta released the Model C Gamma
22 Knife, and this was where automation began to come into
23 the picture with Gamma Knife. There was an electronic
24 transfer of the treatment plan, the coordinates for each

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1 isocenter between the Gamma Knife and the planning
2 system. There was also a sensor for the helmet that was
3 in place so that it was no longer left totally to the
4 user to make sure that the helmet was the correct one.
5 The sensor would tell you if the helmet that was on the
6 machine is the one that you had planned to use.

7 Shortly after that there was an upgrade to
8 the Gamma Knife C that included an automatic positioning
9 system, which was an interface between the helmet and
10 the patient's stereotactic frame which is attached to
11 their head. And this would move the patient between
12 isocenters. There were some coordinates that still
13 needed to be set manually for some isocenters. Others
14 were set automatically. So it was a combination
15 between your manual and automatic.

16 The next model was a fully automated
17 system. The helmets have been removed. The
18 collimator body replaces the helmets. The collimator
19 body is inside the treatment unit, is stationary and the
20 earlier picture where I showed the cobalt sources in red
21 on plates that move over the collimator body all
22 contained inside this unit. The transfer between the
23 planning system and the treatment unit is all
24 electronic. It is a fully automated positioning system

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1 where the entire patient body moves, not just the
2 patient head, as you move from isocenter to isocenter.
3 There is an integrated QA to the machine for simplicity
4 and quality.

5 The version of Gamma Knife that we're
6 really focusing on today though is the latest released
7 model, which is a Gamma Knife Icon. And the -- with the
8 benefit of improved technology, the ability to treat a
9 large number of patients with larger lesions over a
10 series of multiple sessions.

11 The visible changes between Gamma Knife
12 Perfexion and Gamma Knife Icon are pointed out here.
13 The first one is the ability to use a mask instead of
14 a frame for immobilization. The second is the addition
15 of a cone-beam CT. And the last is the addition of a
16 camera and tracking system for motion management.

17 The planning system has advanced so that it
18 integrates real time information about the patient
19 positioning immediately before beginning the treatment
20 where the patient position can be evaluated, how the
21 dose distribution looks at that time for that position.

22 Once the planning has been completed, the
23 positioning has been reviewed, the dose distribution
24 reviewed and approved by the authorized user, we then

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1 move into the treatment. And there is a limit set on
2 the amount of movement that is acceptable, and that's
3 a very small amount of movement: 0.5 millimeters to 3
4 millimeters. That is continuously monitored
5 throughout the treatment through the use of an infrared
6 camera and reference frame. The threshold that is set,
7 if it's surpassed, the machine goes into a safe mode or
8 beam-off position without user interface. That is
9 built into the machine.

10 This next slide -- yes, I'm sorry.

11 CHAIRMAN ALDERSON: Yes, this is Dr.
12 Alderson. When that -- when you go into that beam off
13 is there an alarm that sounds or is there some sort of
14 a notification that goes out?

15 MS. LOHMAN: Yes, there is. There -- on
16 the console itself there is a color change of the
17 representation of the sectors that show they are in a
18 beam-off position. There's also an indicator light
19 that will flash that tells you that the beam is off. And
20 then there's a -- if I go back to that slide, the graph
21 representation that's on the bottom left of the slide,
22 the blue line represents the tracking that's being done
23 of the patient. The red line is representative of the
24 threshold. So you can also visually see if that

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1 threshold has been surpassed. What you
2 can't see on this slide is that there are numbers in the
3 top right corner of that screen that's on the monitor
4 at the console that gives a numerical value for how far
5 off of baseline the patient is. So it doesn't only
6 monitor that they go out of threshold. It also monitors
7 how far off of baseline they are in submillimeters.

8 CHAIRMAN ALDERSON: Thank you.

9 MS. LOHMAN: Yes.

10 Yes?

11 MEMBER ENNIS: The infrared tracking is
12 specifically tracking what?

13 MS. LOHMAN: What it's tracking is the
14 position of patient by way of a marker on their nose that
15 is relative to four -- if I may for just a second -- these
16 lines coming in here represent the eye of the camera.
17 And what it's looking at are four sensors, infrared
18 sensors that are built into that mask holder. So the
19 patient is affixed to that mask holder. The camera is
20 monitoring the position of the four fixed reflectors and
21 any movement of the patient relative to those
22 reflectors.

23 MEMBER ENNIS: So the patient position is
24 essentially by the single point on the tip of the nose?

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1 MS. LOHMAN: Correct.

2 MEMBER ENNIS: So and what, do you stick
3 something on their nose?

4 MS. LOHMAN: Yes, a reflective marker
5 is --

6 MEMBER ENNIS: How big is that marker?

7 MS. LOHMAN: Approximately three
8 millimeters in diameter.

9 MEMBER ENNIS: And how is it attached to
10 the nose?

11 MS. LOHMAN: It's a sticker and it sits on
12 the tip of the patient's nose.

13 MEMBER ENNIS: And --

14 MS. LOHMAN: So with the configuration of
15 these four reference points any movement of the
16 patient's nose will be monitored in all directions, not
17 just linearly.

18 MEMBER ENNIS: Well, you probably just
19 have --

20 (Simultaneous speaking.)

21 MS. LOHMAN: Well, you also have rotation
22 because it's where this one hits. So if the marker
23 rotates even, its position relative to the fixed points
24 changes.

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1 CHAIRMAN ALDERSON: Thank you. Let's go
2 ahead with the --

3 (Simultaneous speaking.)

4 MS. LOHMAN: Certainly. As I mentioned,
5 this next slide to my taste is a little bit too salesy,
6 but there is one point on it which I do want to draw your
7 attention to, and that is the last one, which is safety
8 through integration. There is a high level of safety
9 built into the Gamma Knife with continuously quality
10 control, with continuous self-monitoring that's built
11 into the system, sensors that are triple-sensored, that
12 there is redundancy in each and every movement of the
13 device.

14 Gamma Knife has an impeccable safety
15 record. Between the eight years of 2006 and 2014 there
16 has been a review of these medical event records to the
17 NRC. Of the 105,000 patients treated during that time
18 in the United States there were only 17 event records
19 submitted. Of those 17, one of them resulted in user
20 intervention to stop a treatment, and that was because
21 it was identified that the wrong site had been planned.
22 It had nothing to do with the machine itself. It was
23 during the planning process that there was an error made
24 which was identified during treatment.

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1 In addition to the NRC records, Elekta also
2 looked at global reports available to us for that same
3 time period. And what we found is that the need for the
4 authorized user or authorized medical physicist; and
5 those terms vary in different parts of the world, was
6 for intervention to take place in 0.004 percent of
7 treatments that were performed during that time making
8 this the safest therapeutic technology available for
9 radiation.

10 One of the major concerns for Elekta as well
11 as others is the minimization of radiation to the
12 public, and the Gamma Knife is designed to give very low
13 dose to surrounding tissue as well as to other body
14 tissue during the treatment. And this is documented in
15 peer-reviewed papers that have looked at the scientific
16 evidence with -- between treatments with Gamma Knife and
17 other technology available in the market.

18 The efficacy and safety has been reported
19 repeatedly. The 2,500 peer-reviewed papers on Gamma
20 Knife represent over 74 percent of the literature
21 available for stereotactic radiosurgery of the brain.
22 This efficacy and safety is part of what has made the
23 Gamma Knife the gold standard for treatment with
24 radiosurgery of intracranial lesions.

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1 Based on the long safety record of Leksell
2 Gamma Knife, the technology to not only deliver precise
3 and accurate treatment with high normal tissue sparing,
4 but also built-in safety features incorporated into the
5 machine, Elekta is making a request for modification to
6 the physical presence requirement.

7 The current requirement is that a licensee
8 shall for gamma stereotactic radiosurgery units require
9 an authorized user and an authorized medical physicist
10 to be physically present throughout all patient
11 treatments involving the unit. And "physically
12 present" is defined as within hearing distance of normal
13 voice. And practically what this means in the clinical
14 setting is that the authorized user and authorized
15 medical physicist need to be at the console area of the
16 Gamma Knife.

17 In order to increase patient access to care
18 providers -- cancer is increasing both in the United
19 States as well as worldwide. The incidence has grown
20 exponentially. And in order to make care more
21 accessible to patients, we feel that releasing the
22 authorized user from being present at the console for
23 the entire duration of the treatment would be a benefit
24 to the patient population as a whole.

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1 The proposed change that Elekta is
2 respectfully requesting consideration of is we will
3 have an authorized user and authorized medical
4 physicist physically present during the initiation of
5 all treatments involving the unit. The authorized
6 medical physicist will be physically present throughout
7 all patient treatments involving the unit. the
8 authorized user will be physically present in the
9 department during patient treatment and immediately
10 available to come to the treatment room to respond to
11 an emergency.

12 That's a lot of verbiage, so we've split it
13 into two columns of the current requirement as well as
14 the requested requirement.

15 So at the console at the initiation of
16 treatment we are not requesting any change. Both the
17 authorized user and authorized medical physicist be
18 present. However, throughout the treatment course
19 we're asking that the authorized medical physicist
20 remain present, however, that the authorized user be
21 allowed to be away from the immediate area of the
22 console, but still immediately available within the
23 department in the case of a medical emergency.

24 The rationale for keeping the medical

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1 physicist at the console. The medical physicist is
2 really the one who knows the most about the machine
3 itself, and its machine safety as well as patient safety
4 that is a concern. And the patient safety comes from
5 the safety of the machine. The physicist does the
6 commissioning, they do the QA throughout the year. If
7 there's any troubleshooting that needs to be done with
8 the machine, it's done by the physicist. So the
9 physicist is the most prepared to respond to any
10 emergency with the machine.

11 If we look at physical presence
12 requirements throughout the radiosurgery world, the
13 physical presence requirements on the Leksell Gamma
14 Knife are the most restrictive. For linear accelerator
15 stereotactic radiosurgery, there is no physical
16 presence requirement.

17 In the middle of that, with the ViewRay
18 Guided System there is a requirement for an authorized
19 user or authorized medical physicist to be present in
20 the department. The modification that we are
21 requesting will keep Gamma Knife as the most restricted,
22 however, it will allow the radiation oncologist, the
23 authorized user, to step away from the console. It's
24 the -- Gamma Knife is the most integrated technology,

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1 but the most restrictive.

2 And with that, I thank you for your
3 attention and allowing us to present this today and will
4 open for questions.

5 CHAIRMAN ALDERSON: Excellent. Thank you
6 very much.

7 Questions? Comments about this
8 presentation? Dr. Zanzonico?

9 VICE CHAIR ZANZONICO: Thank you very
10 much. That was very, very helpful. I'm not personally
11 familiar with this technology, so some of my questions
12 -- I'm a little naïve.

13 For a typical treatment what is the
14 duration of the treatment? What kind of dose rates are
15 we discussing?

16 MS. LOHMAN: Well, with cobalt decay, to
17 give a dose rate, when a Gamma Knife machine is first
18 loaded, it's a new machine, new cobalt, the dose rate
19 is typically around 3.4 Gray per minute. The decay of
20 cobalt is 5.26 years, so as time goes on the treatment
21 becomes longer for the same indication, the exact same
22 plan.

23 Treatments range anywhere from 30 minutes
24 to 3 to 4 hours. A simple metastasis with the largest

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1 size collimation might be a 20-minute treatment. A
2 very complex meningioma or arteriovenous malformation
3 or a patient with 15, 20 or even 30 metastases could be
4 as long as 3 or 4 hours.

5 VICE CHAIR ZANZONICO: Because the point
6 I'm getting at is sort of what is the tolerance in
7 responding to a catastrophic failure? In other words,
8 is it the order of minutes or less or longer in terms
9 of avoiding some really damaging mis-irradiation of
10 normal tissue? Because obviously the real value of
11 this technology is its spatial precision.

12 MS. LOHMAN: Yes.

13 VICE CHAIR ZANZONICO: And that's sort of
14 a double-sided coin --

15 MS. LOHMAN: Yes.

16 VICE CHAIR ZANZONICO: -- that if there was
17 some failure, it wouldn't take much of a failure to
18 over-radiate some nearby sensitive structures. So
19 that was the question I was trying to get at, is sort
20 of the response time relative to delivery of some
21 potentially damaging radiation to a normal part of the
22 brain.

23 MS. LOHMAN: The response time to minimize
24 that would be seconds. It would require -- and in most

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1 instances it would be the authorized medical physicist
2 entering the room, removing the back cover of the
3 machine and manually retracting the sector that was in
4 a treatment position as opposed to in a safe position.
5 That whole process takes less than maybe two minutes,
6 the longest part being getting through the door into the
7 treatment room.

8 VICE CHAIR ZANZONICO: And so that motion
9 tracking system --

10 MS. LOHMAN: Yes.

11 VICE CHAIR ZANZONICO: -- if the patient
12 for example had a seizure and some violent head
13 motion --

14 MS. LOHMAN: Yes.

15 VICE CHAIR ZANZONICO: -- I mean, that
16 wouldn't cause the system to fail-safe and
17 automatically shut down?

18 MS. LOHMAN: No. What it would do is as
19 soon as that seizure began and the patient moved out of
20 tolerance -- and forgive me, I'm going to go into sort
21 of a little bit of detail to better answer your question.
22 If the patient is above that tolerance for three
23 seconds, the sectors automatically go to a blocked
24 position, which means radiation is not being delivered.

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1 If after 30 seconds the patient does not return to under
2 the threshold, the sectors go home, which is a totally
3 retracted position, and the couch comes out.

4 If didn't want to wait that 30 seconds for
5 that to happen, could press a pause button at the console
6 which would send the sectors home and bring the couch
7 out, at the same time allowing entry into the room in
8 a safe condition for the users.

9 CHAIRMAN ALDERSON: And what you've
10 described is just true of the Icon, is that correct?

11 MS. LOHMAN: Yes, the motion management,
12 the tracking is only available with the Icon.

13 CHAIRMAN ALDERSON: Right, I just wanted
14 to make that clarification because I think they're
15 asking for a change with relationship to the Icon. But
16 there are lots of other Gamma Knives out there that
17 aren't Icons, and what we're discussing doesn't apply
18 to them. They still need the more rigorous approach.

19 Yes, Dr. Palestro?

20 MEMBER PALESTRO: Thank you. I have two
21 questions for you and they're sort of related. And
22 again, like Dr. Zanzonico, I'm not familiar with this
23 sort of equipment. But you indicate that the
24 authorized user; the requested change, should be

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1 immediately available in the department.

2 MS. LOHMAN: Correct.

3 MEMBER PALESTRO: Okay. My first
4 question is how is "immediately" defined? To me it's
5 sort of a general term as written. There may be an
6 implied or an understood definition.

7 And my second question sort of goes along
8 with that: "is immediately available in the
9 department." Initially or at least on first glance
10 that sounds reasonable except when you think about
11 departments that are scattered on multiple floors and
12 in sometimes multiple buildings.

13 MS. LOHMAN: Yes.

14 MEMBER PALESTRO: So how is that
15 addressed?

16 MS. LOHMAN: Okay. So to answer the first
17 part of the question, the "immediately available in the
18 department," what Elekta visualizes that as; and I
19 believe many of the Gamma Knife users would visualize
20 that as, is they could be doing a consult, they could
21 be evaluating a plan for a patient to be treated
22 somewhere else, they could be taking phone calls in
23 their office, that if a page went out overhead, Dr.
24 Authorized User, please report to Gamma Knife, they

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1 could drop what they were doing and respond. They
2 wouldn't be in the middle of a brachytherapy procedure
3 or another procedure that they could not just drop what
4 they were doing and walk away.

5 In regards to multiple departments spread
6 over various parts of the hospital or various floors,
7 the vision that Elekta has is that the Radiation
8 Oncology Department would be a single floor, a single
9 location, not spread out over multiple floors, multiple
10 facilities.

11 CHAIRMAN ALDERSON: Dr. Ouhib has a
12 question.

13 MEMBER OUHIB: Yes, this is Zoubir Ouhib.
14 I think the importance is really what is the role of the
15 authorized users in this treatment itself?

16 MS. LOHMAN: Yes.

17 MEMBER OUHIB: And so, let's take a look at
18 two scenarios. There is a device malfunction. Source
19 stuck for instance.

20 MS. LOHMAN: Correct.

21 MEMBER OUHIB: Okay? Or there is a
22 medical situation, an emergency with a patient. So I
23 think my first question is that who actually is involved
24 in the patient's set up at the very beginning?

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1 MS. LOHMAN: Okay. So involved in the
2 patient set up at the very beginning varies. There are
3 requirements, regulations that dictate that, but then
4 there are also others who participate depending on
5 individual centers that are not regulated that they have
6 to be there. So by regulation the physicist and the
7 radiation oncologist, authorized user and authorized
8 medical physicist, have to be there, have to be
9 involved.

10 And then depending on what center you're
11 talking about the neurosurgeon may be involved in the
12 patient's set up, nursing staff may be involved in the
13 patient's set up, and in a few centers in the United
14 States a radiation therapist involved in the patient's
15 set up. But those three individuals are specific to
16 institutions not regulated as such.

17 MEMBER OUHIB: Right, but to get to the
18 details of it, because this is what will determine why
19 and what. Okay. So we have a patient that comes in the
20 room. The patient will lay on the couch and there's the
21 set up. Does the therapist and the medical physicist
22 get involved in positioning the patient at that point
23 or does the authorized users must be present? What I'm
24 getting to is that in the event that the whole set up

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1 has to be dismantled --

2 MS. LOHMAN: Yes.

3 MEMBER OUHIB: -- in an urgent manner, can
4 the medical physicist and the therapist and the nurse
5 be able to do that without the intervention of the
6 authorized user --

7 (Simultaneous speaking.)

8 MS. LOHMAN: Absolutely.

9 MEMBER OUHIB: Okay.

10 MS. LOHMAN: Yes.

11 MEMBER OUHIB: So in that event --

12 MS. LOHMAN: To clarify that, the release
13 from the unit is a single latch which is sensed.
14 Soit's a
15 depress-a-button-turn-a-latch-all-in-one-movement
16 which will release the patient's head from the
17 positioning device.

18 MEMBER OUHIB: Okay. And then the patient
19 can be taken out of the room?

20 MS. LOHMAN: Yes.

21 MEMBER OUHIB: Okay. That's great. And
22 in the event of a source stuck, we know that the
23 authorized user is not going to intervene in that
24 situation. That will be the role of the medical

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1 physicist?

2 MS. LOHMAN: Correct.

3 MEMBER OUHIB: I think what I'm trying to
4 get at here is that what is it that's really critical
5 from the authorized user to actually be present by the
6 unit itself? And in both situations, it doesn't seem
7 to be as critical as one might think. However, there
8 is a need of the authorized user to be present in the
9 department or whatever should a medical situation occur
10 to basically care for that patient. But that patient
11 could be rolled out of that room, taken out to a special
12 room or whatever and then be evaluated and so on and so
13 forth.

14 MS. LOHMAN: Yes.

15 MEMBER OUHIB: That was really all my
16 point. Thank you.

17 MS. LOHMAN: That is correct. Thank you.

18 CHAIRMAN ALDERSON: Dr. Ennis has a
19 comment.

20 MEMBER ENNIS: So you alluded to multiple
21 sites or multiple isocenter types of treatment. So --

22 MS. LOHMAN: Yes.

23 MEMBER ENNIS: -- I have not had the
24 privilege of working with a Gamma Knife very much. I

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1 have LINAC-based SRS.

2 MS. LOHMAN: Yes.

3 MEMBER ENNIS: So when that's done within
4 a Gamma Knife do you physically have to move the patient
5 to a new isocenter position?

6 MS. LOHMAN: No, that is now fully
7 automated.

8 MEMBER ENNIS: So what does that mean?

9 MS. LOHMAN: So --

10 MEMBER ENNIS: So you do a repeat cone-beam
11 CT or you do --

12 MS. LOHMAN: No. The --

13 (Simultaneous speaking.)

14 MEMBER ENNIS: -- at the beginning?

15 MS. LOHMAN: The patient is positioned on
16 the patient positioning device.

17 MEMBER ENNIS: Yes.

18 MS. LOHMAN: All of the information is
19 electronically fed from the planning system to the Gamma
20 Knife console. The console then controls movement of
21 the positioning device. So the head is rigidly fixed
22 to the positioning device, and the positioning device
23 is what will move to change the isocenters. So the user
24 intervention in setting up a patient is to lie the

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1 patient down on the couch, affix either the stereotactic
2 frame or the mask into the positioning interface.

3 There's a graphical interface that is
4 visible in the room for things such as a timeout to
5 identify the patient position, correct site, all of
6 those, and interlocks, that side rails are in place,
7 that it is -- the correct gamma angle, the tilt of the
8 patient's head in the unit, etcetera, is all interfaced
9 electronically.

10 And so once the patient is positioned on the
11 treatment table, all of the other changes are made
12 computerized.

13 MEMBER ENNIS: So --

14 (Simultaneous speaking.)

15 MS. LOHMAN: So the user is sitting at the
16 console --

17 MEMBER ENNIS: Right.

18 MS. LOHMAN: -- watching the computer move
19 the patient.

20 MEMBER ENNIS: So it's then treating a
21 left-sided brain metastasis and then a right-sided one?

22 MS. LOHMAN: Yes.

23 MEMBER ENNIS: Does the patient's body
24 move?

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1 MS. LOHMAN: Correct.

2 MEMBER ENNIS: The patient's body moves?

3 MS. LOHMAN: So the whole couch will
4 move --

5 MEMBER ENNIS: Okay. And how does that
6 verify -- who verifies that that's happened correctly?

7 MS. LOHMAN: It's -- it -- on the -- at the
8 Gamma Knife console there is a display of what the
9 coordinates are that are planned as well as what the
10 current position is.

11 MEMBER ENNIS: Yes. And --

12 MS. LOHMAN: And so --

13 MEMBER ENNIS: -- with your proposal --

14 MS. LOHMAN: -- it's a visual --

15 MEMBER ENNIS: -- the authorized user
16 would not necessarily need to be there to check that?

17 MS. LOHMAN: Correct. Yes.

18 MEMBER ENNIS: Would need to be to check
19 the first set up --

20 MS. LOHMAN: Would need to check the set up
21 --

22 MEMBER ENNIS: -- the first --

23 MS. LOHMAN: -- of the patient --

24 MEMBER ENNIS: At the first --

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1 (Simultaneous speaking.)

2 MS. LOHMAN: -- so that they're
3 positioned, yes.

4 MEMBER ENNIS: But not later on?

5 MS. LOHMAN: Correct.

6 MEMBER ENNIS: And what would --

7 MS. LOHMAN: If --

8 MEMBER ENNIS: -- be the logical
9 difference between the first set up and making sure that
10 first position is correct --

11 MS. LOHMAN: Yes.

12 MEMBER ENNIS: -- and --

13 MS. LOHMAN: It's --

14 MEMBER ENNIS: -- why the second position
15 doesn't need the same --

16 (Simultaneous speaking.)

17 MS. LOHMAN: It's not necessarily making
18 -- it's not making sure that the first position is
19 correct. It's making sure that the patient is
20 correctly positioned on the treatment couch. So it's
21 not the movement of the couch that we're talking about
22 at the initiation of treatment. It's that the patient
23 is correctly set up on the treatment couch.

24 MEMBER ENNIS: Yes. And the cone-beam CT,

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1 that would be done to check the alignment? In your
2 proposal even the first one would not need to be checked
3 by the authorized user?

4 MS. LOHMAN: That is done before the
5 initiation of treatment.

6 MEMBER ENNIS: Right. No, I understand
7 that.

8 MS. LOHMAN: So if --

9 MEMBER ENNIS: But I'm saying from your --
10 (Simultaneous speaking.)

11 MS. LOHMAN: It -- no, it does need to be
12 checked by the authorized user.

13 MEMBER ENNIS: But then why would only the
14 first one need to be --

15 (Simultaneous speaking.)

16 MS. LOHMAN: Because a cone-beam CT is only
17 done before the initiation of treatment.

18 MEMBER ENNIS: And then you just rely on
19 the technology to make the shifts correctly?

20 MS. LOHMAN: The shifts are done through
21 the couch and any patient movement out of position from
22 where they were at the time that the cone-beam CT was
23 acquired is monitored by the patient tracking -- the
24 high-definition, correct. Correct. Yes.

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1 MEMBER ENNIS: Okay. So it's really
2 relying a lot on this nose marker and --

3 (Simultaneous speaking.)

4 MS. LOHMAN: Correct. If at any time that
5 marker not only moves, but becomes invisible or any of
6 the reference positions become invisible, the patient
7 changes position of their arm and the blanket is up and
8 blocks visualization, it will stop treatment. It has
9 to see all four markers and a consistent relationship
10 of the marker on the patient to the four reference
11 markers.

12 CHAIRMAN ALDERSON: So before we get into
13 too many micro-details of exactly how people do this,
14 I'd like to point out that what they're asking for, the
15 authorized user is going to be in the department. Could
16 be the contiguous department. And so the NRC doesn't
17 want to regulate medical practice, so the NRC isn't
18 going to say, well, the authorized user has to be here,
19 there or somewhere else. If he's in the department, he
20 or she, they'll practice medicine.

21 But the fact is that they're asking for some
22 latitude to allow that authorized user, not the
23 physicist, to be steps away or down the hall or somewhere
24 else because their system in the ICON will regulate

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1 that. So I just wanted to make that clear to everyone,
2 yes.

3 Yes, Laura? Ms. Weil?

4 MEMBER WEIL: I have a question, two
5 questions.

6 MS. LOHMAN: Yes.

7 MEMBER WEIL: The error that was
8 discovered where it was a planning error --

9 MS. LOHMAN: Yes.

10 MEMBER WEIL: -- 1 out of 105,000 cases --

11 MS. LOHMAN: Yes.

12 MEMBER WEIL: -- who discovered that error
13 and at what point?

14 MS. LOHMAN: It was the physician that
15 discovered that error during dictation when they were
16 comparing the -- in doing the dictation --

17 MEMBER WEIL: Yes.

18 MS. LOHMAN: -- was reading both the
19 patient history and the treatment protocol and realized
20 that one said right, the other said left.

21 MEMBER WEIL: So that physician was
22 present?

23 MS. LOHMAN: Was not present. It was
24 someone that was not at the console but made the call

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1 to the Gamma Knife console where the authorized user was
2 to say we need to stop treatment. We're on the wrong
3 side.

4 MEMBER WEIL: Okay.

5 MS. LOHMAN: And that may not be the exact
6 verbiage, but that's --

7 MEMBER WEIL: Okay.

8 MS. LOHMAN: -- the gist of it.

9 MEMBER WEIL: That's helpful. Thank you.

10 MS. LOHMAN: Yes.

11 MEMBER WEIL: And had a physician not been
12 present at the console when that call was made, the
13 physicist --

14 MS. LOHMAN: Physicist, nurse,
15 therapist --

16 MEMBER WEIL: -- could have --

17 MS. LOHMAN: -- would have pushed the pause
18 button which would have interrupted the treatment and
19 brought the patient out of the treatment unit --

20 MEMBER WEIL: Okay.

21 MS. LOHMAN: -- and closed the --

22 (Simultaneous speaking.)

23 MEMBER WEIL: The other question I have,
24 you talk about this relaxation of the regulations would

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1 increase patient access --

2 MS. LOHMAN: Yes.

3 MEMBER WEIL: -- to this particular
4 intervention. Are you aware that there's a delay in
5 access or are either of your radiation oncologists aware
6 that there's any delay that patients experience because
7 of the regulation that's current?

8 MS. LOHMAN: It's not the delay in
9 treatment. It's allowing the radiation oncologists to
10 be available to see more patients during the course of
11 a day. So the access that we're talking about is the
12 patient population as a whole, not necessarily patients
13 who will or are even candidates for Gamma Knife
14 treatments, but access for the public population, those
15 who have been diagnosed with a cancer to see the
16 availability of a radiation oncologist to see them in
17 a timely manner.

18 CHAIRMAN ALDERSON: Yes, Dr. Langhorst?

19 MEMBER LANGHORST: Thank you.

20 Ms. Weil, I wanted to let you know in our
21 case our physicians could be looking at our next Gamma
22 Knife patient and getting them prepared for their
23 treatment. And so that's why they would be outside this
24 patient's treatment, to get prepared for the next

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1 patient, to make that a more timely and a better flow,
2 a process for the treatment.

3 And we have many people in the Gamma Knife
4 facility to respond to emergencies. And so when Dr.
5 Zanzonico was asking about if there's a stuck source or
6 whatever, the physicist, yes, can go in and pull those
7 sources, but that's not the only response. The
8 therapist, the nurse, they're all trained to -- I mean,
9 I as a radiation safety officer am trained to know how
10 to disconnect the couch, pull it out and get the patient
11 out of there. So there's a lot of different things that
12 happen and it doesn't require the authorized user to be
13 physically present, because there's a lot of the team
14 right there to be able to respond to those situations.

15 I had one question. When you have longer
16 treatments --

17 MS. LOHMAN: Yes.

18 MEMBER LANGHORST: -- patients may ask
19 please stop right now, and so maybe they need to get up
20 and move a little bit, do you propose that the authorized
21 user come back to make sure that positioning again
22 happens correctly?

23 MS. LOHMAN: Yes, because that would be an
24 initiation of treatment.

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1 MEMBER LANGHORST: Okay.

2 MS. LOHMAN: It's an interrupted
3 treatment --

4 MEMBER LANGHORST: Right.

5 MS. LOHMAN: -- but it would be initiating
6 treatment at that time.

7 MEMBER LANGHORST: Okay. I think that
8 would need to be clarified, too, because that was a
9 question I had, and I think that's the right way that
10 it needs to go.

11 MS. LOHMAN: Yes.

12 MEMBER LANGHORST: Thank you.

13 CHAIRMAN ALDERSON: Dr. Ouhib?

14 MEMBER OUHIB: Yes, so you have multiple
15 isocenters.

16 MS. LOHMAN: Yes.

17 MEMBER OUHIB: Is there verification of
18 the second isocenter is correctly placed by the
19 authorized user?

20 MS. LOHMAN: The --

21 MEMBER OUHIB: I mean, is -- I guess the
22 question is there any imaging at that point --

23 MS. LOHMAN: There is not.

24 (Simultaneous speaking.)

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1 MEMBER OUHIB: -- to another?

2 MS. LOHMAN: There is not. The planning
3 is done. The patient is fixed. We're not moving
4 -- we're not repositioning the patient on the treatment
5 unit. The patient is positioned and the whole couch is
6 moving. And so what's being detected is the movement
7 of the couch to the next isocenter. There's not a
8 specific patient intervention to get from isocenter to
9 isocenter.

10 The way that Gamma Knife works is there is
11 a fixed focal point of the machine and the patient,
12 whatever is prescribed as the isocenter. The X, Y and
13 Z coordinate, by way of stereotactic space, is moved to
14 that isocenter.

15 MEMBER OUHIB: I understand. So I'm
16 assuming that couch shift is being tested on a daily
17 basis or --

18 MS. LOHMAN: Absolutely.

19 MEMBER OUHIB: -- prior to each patient?

20 MS. LOHMAN: It is tested on a daily basis
21 and it is monitored throughout the patient treatment
22 with triple sensors that -- there's one sensor that
23 monitors it. There's a sensor -- a second sensor that
24 monitors it and then a third sensor that monitors the

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1 activity of both of the previous sensors. So the
2 movement of the couch is triple monitored in the machine
3 itself. And any variation at submillimeter increments
4 will cause a pause of the treatment. It would cause the
5 couch to come out and it would report it as an error,
6 movement surveillance error.

7 MEMBER OUHIB: Right, but are there
8 watchdogs monitoring the accuracy of the couch itself
9 at the same time in the system?

10 MS. LOHMAN: Yes. Yes, those sensors are
11 what are monitoring the movement of the couch to
12 submillimeter accuracy.

13 MEMBER OUHIB: All right.

14 CHAIRMAN ALDERSON: Are there any final
15 questions on this? Yes, Dr. Metter?

16 MEMBER METTER: Thank you for your very
17 nice presentation. I don't know much about it either,
18 but my question relates to medical events.

19 MS. LOHMAN: Yes.

20 MEMBER METTER: What were the other 16
21 issues you mentioned? Were there any trends?

22 MS. LOHMAN: The other 16, the majority of
23 those that were reported were planning errors or errors
24 in imaging which resulted in a mis-definition of

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1 stereotactic space. And by that I mean when the patient
2 was imaged in the MR or CT Department, an indicator box
3 which provides fiducial markers to set up to define
4 stereotactic space was misplaced. It was not attached
5 appropriately.

6 There was one instance that the patient
7 actually moved. They were able to dislodge the frame,
8 but it was discovered at the end of the treatment. So
9 there were 17 different targets being treated. Between
10 targets 16 and 17 there was a request by the patient
11 for a break. The break was given. Medication was
12 given. Treatment was resumed. During that last
13 target the patient did move quite a bit in the unit and
14 at the end of treatment when they went to remove the
15 stereotactic frame, it was loose. So they don't know
16 if there was actually any misadministration as a result
17 of that, but it was noted that the frame was loose, which
18 meant it could have shifted slightly on the patient's
19 head.

20 MEMBER METTER: So then the other things
21 you mentioned didn't apply then, or didn't kick in to
22 stop the treatment?

23 MS. LOHMAN: That was on an older model of
24 the Gamma Knife.

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1 MEMBER METTER: Okay.

2 MS. LOHMAN: That -- there have been, that
3 I'm aware of, no incidences reported with Gamma Knife
4 Icon.

5 CHAIRMAN ALDERSON: Ms. Holiday has a
6 comment.

7 MS. HOLIDAY: Hi, Sophie Holiday. I just
8 have two questions for you. The first is when you went
9 through your presentation you quoted how many
10 treatments were performed worldwide with the Gamma
11 Knife System.

12 MS. LOHMAN: Yes.

13 MS. HOLIDAY: Are you aware of how many
14 treatments have occurred in the U.S. with the Icon unit?

15 MS. LOHMAN: Let me -- Catherine
16 Gilmore-Lawless is here as a consultant for Elekta.

17 And do you have that -- I know there was
18 information available as of four months ago. Do you
19 happen to know what that number was?

20 MS. GILMORE-LAWLESS: I think we only have
21 it for -- the global number is over 2,000.

22 MS. LOHMAN: Okay. Thank you.

23 CHAIRMAN ALDERSON: Global number is over
24 2,000 in case people didn't hear that.

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1 MS. HOLIDAY: Thank you. And then another
2 question or point of clarification is it's my
3 understanding that with the Leksell Gamma Knife Icon
4 unit, while there is a thermoplastic mask that can be
5 used as a frameless option, not with the frame, and it's
6 coupled with the cone-beam CT and the high-definition
7 motion management system --

8 MS. LOHMAN: Yes.

9 MS. HOLIDAY: -- the Icon also has the
10 ability to operate with the frame.

11 MS. LOHMAN: That is --

12 MS. HOLIDAY: So that means the Icon can
13 use the mask, which as you've heard will detect if there
14 is any position difference through the HDMM system,
15 however, if the Icon is used with the frame, you do not
16 use the HDMM system. So I just wanted to clarify that
17 for the Committee.

18 CHAIRMAN ALDERSON: Well, I'm going to
19 have to ask a follow-up question then. If you're using
20 it with a frame -- by the way, patients don't want to
21 use the frame. The frame is uncomfortable. This move
22 to a mask is a big positive step in the right direction.
23 But are you saying that if they're using the frame
24 there's no automatic cutoff like there is here?

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1 MS. LOHMAN: There is not motion
2 tracking --

3 CHAIRMAN ALDERSON: There is not?

4 MS. LOHMAN: -- with use of the frame. The
5 frame is considered a rigid device.

6 CHAIRMAN ALDERSON: I see.

7 MS. LOHMAN: It's a rigid fixation to the
8 skull, to bone of the patient. So they're not going to
9 be able to move within that frame unless there is an
10 issue as such where a frame becomes loose. And that
11 you'll -- is not going to be -- that would not be
12 something that could be detected --

13 (Simultaneous speaking.)

14 CHAIRMAN ALDERSON: Well, then it might be
15 necessary in any change in wording to specify an Icon
16 system using the mask specifically. All right.

17 Yes?

18 MEMBER LANGHORST: I would like to ask how
19 the presence of an authorized user would prevent that.
20 It wouldn't and it wouldn't deter the response to any
21 emergency. And so I believe this works well on the
22 Perfexion unit also. So --

23 CHAIRMAN ALDERSON: But the only thing
24 being requested is for the Icon, correct?

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1 MS. LOHMAN: Correct.

2 CHAIRMAN ALDERSON: Correct.

3 MEMBER LANGHORST: But for the Icon only
4 with the mask --

5 MS. LOHMAN: No, for --

6 MEMBER LANGHORST: -- or for the Icon
7 total?

8 MS. LOHMAN: -- Icon Gamma Knife
9 radiosurgery.

10 MEMBER LANGHORST: Yes.

11 CHAIRMAN ALDERSON: Yes.

12 MEMBER LANGHORST: So I think that --

13 CHAIRMAN ALDERSON: We're about 14 minutes
14 over. Is there a final -- I don't -- if there's a
15 burning question, you can ask it, but other than that
16 I would suggest that you hold the questions now just in
17 view of the other important items we have to discuss.

18 Yes, Dr. Suh?

19 MEMBER SUH: Yes, so, Susan --

20 CHAIRMAN ALDERSON: That will be the last
21 comment.

22 MEMBER SUH: So, Susan, thanks for an
23 excellent presentation. There is no question that
24 Elekta should be very proud of the safety record that

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1 the Gamma Knife has had over the many decades, that it's
2 really been a pioneer in terms of how to make treatments
3 more accessible to patients in terms of delivery. And
4 with the current version of the Icon, it's been an
5 advance, there's no question, with the mask-based
6 system.

7 But in terms of the physical presence
8 requirement, it is something that I would be open to,
9 although the language would need to be very strict about
10 what physical presence involves. As you know, where I
11 used -- where our former Gamma Knife center was it was
12 a 10-minute walk to the department. So although
13 technically I could say that it was within -- physically
14 within the department, it's 10 minutes for me to respond
15 because -- and that's if I ran on a good day.

16 MS. LOHMAN: Right.

17 MEMBER SUH: So that language would need to
18 be modified. And again, that's where it's going to be
19 a little difficult in terms of how prescriptive it would
20 be. And what's that distance? Is it 100 meters? Is
21 it 200 meters? Because there's no question, the safety
22 record is something that is -- think about 108,000 cases
23 and 17 safety reported events from an 8-year period.
24 That's very, very impressive. And I think it's very

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1 important that whatever change that any committee or
2 anyone else advises -- I think you want to try to uphold
3 that really high bar in terms of safety and quality,
4 because when patients think about Gamma Knife surgery,
5 the first thing that comes to mind is this is a very,
6 very precise treatment.

7 MS. LOHMAN: Yes.

8 CHAIRMAN ALDERSON: Well, I'd like to
9 thank Ms. Lohman for her excellent, excellent
10 presentation. I think we will ask later for a
11 subcommittee to review what's been discussed here,
12 particularly with some of our radiation oncologists on
13 that committee and to come back to us at a later date
14 with their own recommendations.

15 But thank you very much.

16 MS. LOHMAN: Thank you.

17 CHAIRMAN ALDERSON: Appreciate that.

18 We'll move on now to the next presentation,
19 which is from Dr. Wu of the NRC on the status update on
20 Source Security and Accountability Initiatives.

21 DR. WU: Hi. Good morning, everybody.
22 Thank you so much for the opportunity to come and speak
23 to you today about Source Security and Accountability
24 Initiatives here at the NRC. I will be focusing my

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1 presentation on specifically the Category 3 Source
2 Security and Accountability Initiatives going on.

3 Again, I'm Irene Wu. I am a project
4 manager here at the NRC in the Office of Nuclear Material
5 Safety and Safeguards and I am the co-chair of the
6 Category 3 Source Security and Accountability Working
7 Group that is leading the effort on this initiative.

8 So before I go into what exactly the working
9 group's been looking at and those activities, I did want
10 to give some background on how we got here. So since
11 the events of September 11th the NRC has been enhancing
12 the security and accountability of radioactive sources
13 that pose a threat to the public, and these enhancements
14 have been focused on the most dangerous sources, those
15 with International Atomic Energy Agency Category 1 and
16 2 quantities of radioactive materials. The NRC has
17 considered expanding these enhancements to Category 3
18 sources in the past, and most recently in 2009, but
19 concluded that the existing requirements provide
20 adequate protection.

21 As I will discuss, as a result of recent
22 events involving NRC and the Agreement States, the
23 Commission directed staff to provide recommendations on
24 whether it is necessary to revise NRC regulations or

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1 processes governing source protection and
2 accountability of Category 3 materials to continue to
3 ensure adequate protection of public health and safety.

4 So what are Category 3 sources and what type
5 of activities involve their use? Category 3 sources,
6 if not safely managed or securely protected, could cause
7 permanent injury to a person who handled them or was
8 otherwise in contact with them for some hours.
9 Category 3 sources are those containing a quantity of
10 radioactive material equal to or greater than 1/10th of
11 the Category 2 thresholds, but less than the Category
12 2 thresholds.

13 These sources have a wide variety of uses
14 in industry, medicine and research and include
15 applications such as fixed industrial gauges, high dose
16 rate brachytherapy sources, plutonium pacemakers,
17 research reactor start-up and certain well logging
18 sources. Category 3 sources are also being used by
19 governmental agencies in security screening at ports
20 and cargo terminals. The number of Category 1 through
21 Category 3 NRC and Agreement State licensees affected
22 by this reevaluation could exceed about 5,000.

23 So in 2007 the Government Accountability
24 Office, or GAO, conducted an investigation into the

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1 NRC's Materials Licensing Program. Using a fictitious
2 company, GAO attempted to obtain radioactive materials
3 licenses from one NRC regional office and one Agreement
4 State. GAO was successful in one of two attempts to
5 obtain a radioactive materials license and used the
6 original license in an altered version to place orders
7 for radioactive material in portable gauges. The
8 investigation demonstrated that GAO could have acquired
9 an aggregated Category 3 quantity of material, although
10 I'll make clear that at no point in the investigation
11 were radioactive materials actually shipped to the
12 fictitious company.

13 After the 2007 investigation the NRC and
14 Agreement States made a number of significant changes
15 to strengthen the licensing and regulatory processes to
16 prevent individuals who have malevolent intent from
17 obtaining a radioactive materials license.

18 Later in 2007 staff submitted an action
19 plan to the Commission to address recommendations for
20 enhancing NRC and Agreement State inspection and
21 licensing programs with respect to source security
22 oversight. The Commission approved the staff's action
23 plan which included consideration of expanding the
24 National Source Tracking System, or the NSTS, to include

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1 Category 3 sources plus a subset of high-end Category
2 4 sources. This proposed rule on the expansion of NSTS
3 was published in the *Federal Register* in April 2008.

4 In January of 2009 licensees began
5 reporting Category 1 and 2 source information to the
6 NSTS. Staff requested to further -- to defer further
7 expansion of the National Source Tracking System that
8 would have included Category 3 sources to allow staff
9 to monitor the operation of NSTS for one year to apply
10 any resulting insights to inform the decision on -- the
11 Commission's decision on system expansion.

12 This request for deferral was not approved
13 by the Commission, so in June of 2009 staff requested
14 approval of the final rule amending Part 20 and Part 32
15 to expand the reporting to the NSTS to include Category
16 3 sources. The Commission did not reach a decision on
17 the proposed rulemaking and that final rule was not
18 approved as a result of a split 2-2 vote.

19 Some of the Commission votes indicated that
20 a further expansion of NSTS should be based upon a
21 vulnerability assessment built off of an interagency
22 risk study for sources and that the original
23 recommendation lacked a risk-informed foundation for
24 the proposed regulatory action.

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1 So moving forward, in December of 2014
2 Congress passed and President Obama signed the
3 Consolidated and Further Continuing Appropriations Act
4 of 2015 that included a requirement for NRC to conduct
5 an assessment of the security requirements in 10 CFR
6 Part 37. This assessment, referred to as the Program
7 Review of Part 37, was expanded to encompass an
8 evaluation of nine review areas which are listed on the
9 slide related to the implementation of the security
10 requirements in the rule.

11 These areas included the results of
12 inspections conducted of NRC licensees in the first two
13 years of the rule implementation as well as an
14 evaluation of events reported under the provisions of
15 the rule. The Program Review also included
16 consideration of the definition of "aggregation" as it
17 applies to well logging sources and an evaluation of
18 enhanced tracking and accounting of radioactive
19 sources. The results of the Program Review were
20 documented in a report that was sent to Congress in
21 December of 2016. A second report was prepared by staff
22 summarizing the detailed findings of the Part 37 Program
23 Review Team.

24 In the same Appropriations Act, Congress

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1 required GAO to lead an independent review of NRC and
2 Agreement States' Part 37 implementation upon the
3 conclusion of NRC's Program Review and provide a
4 separate report to Congress by the end of 2018.

5 So that brings us to the most recent GAO
6 licensing audit and investigation.

7 So in 2014 GAO initiated another audit of
8 the Materials Licensing Program to determine whether
9 the licensing vulnerabilities identified back in its
10 2007 investigation had been addressed by the NRC and
11 Agreement States. As part of its audit GAO conducted
12 an investigation that again attempted to obtain
13 radioactive materials licenses from one NRC regional
14 office and two separate Agreement States using
15 fictitious companies.

16 This investigation went beyond the 2007
17 investigation in its sophistication and planning such
18 that GAO rented storefront space to demonstrate each
19 fictitious company's legitimacy during pre-licensing
20 visits. The GAO was successful in one of three attempts
21 and acquired a license for a Category 3 well logging
22 source. GAO was subsequently able to place an order for
23 one Category 3 source and then alter the license and
24 place an order for a second Category 3 source.

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1 The investigation demonstrated that GAO
2 could have acquired an aggregated Category 2 quantity
3 of material, although at no point again in this
4 investigation were radioactive materials actually
5 shipped to the fictitious company.

6 On July 15th, 2016 the GAO published its
7 final report for the material licensing audit and
8 investigation entitled, "Nuclear Security: NRC has
9 Enhanced the Controls of Dangerous Radioactive
10 Materials, But Vulnerabilities Remain," and this report
11 made three recommendations, which are listed on this
12 slide: They are they were to include Category 3 sources
13 in the National Source Tracking System and add Agreement
14 State Category 3 licenses to the Web-Based Licensing
15 System, or WBL.

16 Second was to require that transfers of
17 Category 3 quantities of radioactive materials confirm
18 the validity of a would-be purchaser's radioactive
19 materials license with the appropriate regulatory
20 authority or use NRC's License Verification System, or
21 LVS, before transferring any Category 3 quantities of
22 licensed materials.

23 And lastly, consider requiring that an
24 on-site security review be conducted for all unknown

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1 applicants of Category 3 licenses to verify that each
2 applicant is prepared to implement the required
3 security measures before taking possession of licensed
4 radioactive materials.

5 Once notified of GAO's audit and
6 investigation in October of 2015, the NRC and Agreement
7 States took a number of immediate and long-term actions.
8 The immediate actions included the conduct of
9 self-assessments of licenses issued to unknown
10 applicants. Refresher training was developed and
11 provided via webinars on the use of pre-licensing
12 guidance and conduct of site visits for all NRC regional
13 and Agreement State inspectors and license reviewers.

14 In January of 2016 we stood up two NRC
15 Agreement State working groups and they were commenced
16 to evaluate vulnerabilities identified as a result of
17 this GAO investigation. One of the working groups
18 considered enhancements to the pre-licensing guidance,
19 while the second working group evaluated the need for
20 enhancements to existing requirements or guidance for
21 the license verification and source tracking beyond the
22 Category 1 and 2 thresholds.

23 The working groups were also tasked with
24 evaluating the GAO final report. The working groups

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1 completed their reports back in October of 2016 and a
2 steering committee evaluated those recommendations
3 that were made by those two working groups. The two
4 reports and the recommendations produced by the working
5 group will play a key role -- and they do play a key role
6 in the Category 3 source accountability reevaluation.

7 So now to the work that my working group is
8 leading. So given the Agency's operating experience
9 with higher-risk sources and response to the GAO
10 findings, on October 18th of 2016 the Commission issued
11 a staff requirements memorandum on the proposed staff
12 reevaluation of Category 3 source accountability.
13 That SRM issued directed staff to take specific actions
14 to evaluate whether it's necessary to revise NRC
15 regulations or processes governing source protection
16 and accountability. The SRM also required the
17 submission of a notation vote paper that is slated to
18 go to the Commission in August of 2017.

19 And the evaluation has to include these
20 nine tasks, and they are: to evaluate the pros and cons,
21 different methods of verification of a license's
22 validity, evaluating the pros and cons of including
23 Category 3 sources in NSTS, looking at the GAO
24 recommendations and assess any additional options for

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1 addressing those recommendations, a vulnerability
2 assessment or threat analysis, a regulatory impact
3 analysis of the accrued benefits and costs of any
4 recommended changes, any potential actions that don't
5 require any rulemaking and that can be monitored through
6 the Integrated Materials Performance Evaluation
7 Program, an assessment of the risk of aggregation of
8 Category 3 sources into a Category 2 quantity,
9 collaboration with affected stakeholders, getting that
10 stakeholder feedback, and then lastly any other factors
11 to inform the Commission decision.

12 As previously noted, it hasn't been since
13 2009 that we've really looked at enhancing Category 3
14 source security and accountability, but as you can see
15 from these tasks this reevaluation is a bit different
16 from past efforts in its scope. Not only will the
17 reevaluation build off of the efforts resulting from the
18 recent GAO investigation, but it will integrate the
19 recently completed comprehensive program review of Part
20 37 and the current threat landscape.

21 And then the last task that's included on
22 that slide speaks to the Commission's desire for a real
23 -- a broad and comprehensive assessment.

24 So to conduct this reevaluation of Category

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1 3 source security and accountability we stood up an NRC
2 and Agreement State Working Group to evaluate and make
3 recommendations. The working group took the nine tasks
4 on the previous slide and broke those down and then
5 grouped them into four activities, as you see on the
6 slide. And all of these task are underway. The
7 working group recommendations will be documented, as I
8 said before, in a notation vote paper to the Commission
9 in August of 2017. Clearly a significant amount of work
10 has been done already and there's still left to be done
11 in the coming months, so I'll give you an update
12 especially on the stakeholder feedback piece.

13 In February of 2017 NRC also did provide the
14 Commission with an information paper to update them on
15 the source security and accountability activities.
16 That's SECY-17-025. And included in that information
17 paper were the recommendations from the two previous
18 working groups formed in response to the findings and
19 recommendations by the GAO materials licensing audit
20 and secondly the initiation of this current working
21 group looking at Category 3 source security and
22 accountability, and then also potential strategies for
23 addressing rulemaking activities affected by materials
24 licensees.

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1 So on that last note about rulemaking
2 activities I did want to include a diagram for you to
3 see; and it is quite complicated, that would summarize
4 the various materials security activities over the last
5 few years that I've been mentioning and how they'll be
6 integrated into this current Category 3 reevaluation.

7 The red box on the left highlights our
8 activities in response to the GAO audit, where the box
9 on the right highlights -- the orange box on the right
10 highlights the Part 37 Program Review. The middle or
11 yellow box summarizes the Category 3 source security and
12 accountability activities.

13 Some recommendations from our GAO and Part
14 37 reviews identified enhancements of our licensing and
15 inspection guidance training and oversight
16 responsibilities. These recommendations will be
17 integrated into our Inspection, Licensing and oversight
18 Programs and implemented in the future.

19 The GAO and Part 37 reviews also identified
20 the need for changes to the NRC rules and regulations.
21 The Commission will have to approve the commencement of
22 work on the regulations and development of their
23 regulatory basis, which is seen in that little blue box
24 in the middle.

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1 The NRC recognizes the impact for making
2 multiple changes to the regulations over a short period
3 of time and the cumulative effect that it will have on
4 licensees and the Agreement States. So we'll look for
5 ways to bundle any changes to the regulations together.
6 Any rulemaking activities associated with these
7 activities and these initiatives will likely occur
8 beyond 2017, but most important however is that any
9 rulemaking that -- will require input from the regulated
10 community and the Agreement States.

11 So the main enhancements under
12 consideration by this working group are listed here on
13 the slide. And here's -- the first -- the items here
14 are ones that are currently required for Category 1 and
15 2 sources. So we're looking to see if they -- the
16 questions that we asked in our *Federal Register* notice
17 and in all of our outreach efforts were asked whether
18 or not that -- we should expand what's being done for
19 Category 1 and 2 licenses to Category 3 licenses and
20 Category 3 sources.

21 It's important to note that the focus of the
22 working group is source accountability and license
23 verification for Category 3 sources and not all the
24 security areas required from Category 1 and 2 sources.

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1 However, as previously noted the Commission did direct
2 the staff to not limit the scope of this assessment, but
3 for it to be very comprehensive.

4 So this slide just depicts what is
5 currently being done for Category 1 and 2 licenses and
6 to show how license verification -- how it ties to the
7 other systems I've mentioned: the National Source
8 Tracking System and the Web-Based Licensing System.
9 And we've been using this diagram in our outreach
10 efforts to demonstrate what is being done for Category
11 1 and 2 and let people see if that is something that they
12 would want us to expand for Category 3.

13 So an important aspect of this Category 3
14 reevaluation was and is to solicit input from the
15 affected regulatory community, many of whom have not
16 been subject to enhanced security and accountability
17 requirements. So we published a *Federal Register*
18 notice back in January of 2017 which contains specific
19 questions for stakeholders to consider regarding
20 Category 3 sources. We received 54 comment letters in
21 response to that *Federal Register* notice. And to
22 facilitate feedback on that we also held four public
23 meetings and two webinars that were transcribed.

24 In addition to those efforts we wrote

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1 articles that were published in the CRCPD, Health
2 Physics Society, and the NMSS Newsletter, as well as
3 gave presentations to industry groups and professional
4 organizations like the AAPM to solicit feedback.
5 And the comment period, we had a 60-day comment period
6 on that *Federal Register* notice and that closed back on
7 March 10th.

8 There were 22 questions in that *Federal*
9 *Register* notice that were separated into seven sections
10 that were based on topics and applicability to relevant
11 stakeholders. The seven sections included general
12 questions related to license verification involving
13 transfers of Category 3 sources, general questions
14 related to the inclusion of Category 3 sources in NSTS,
15 and then again questions related to
16 -- more specific to Agreement States, related to license
17 verification and inclusion of Category 3 sources in
18 NSTS, and then sort of another category of questions.

19 So at the time that I had to finish these
20 slides for this I didn't -- we hadn't -- I don't -- the
21 comment period closed, but we hadn't fully gone through
22 all the analysis of the comments that we received. So
23 I included this general slide to be able to talk with
24 you on what we observed in the comments. So

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1 in general; and I'll step through it first on the
2 comments that we received regarding license
3 verification of Category 3 source -- Category 3
4 quantities of radioactive material.

5 In this area majority of people were
6 against expanding license verification, or in this case
7 sort of limiting the license verification options to
8 just having to do those through the LVS or the regulatory
9 authority. In general we heard from stakeholders that
10 they were happy with the existing method of being able
11 to exchange paper licenses with one another and then to
12 be able to -- and then not to have to then do the extra
13 step of going through the regulatory authority.

14 We did hear specifically from -- let me find
15 my notes here, hold on, give me a second -- from specific
16 medical licensees as well as we did hear from several
17 non-governmental organizations that you would be
18 interested in. AAPM being one, the American College of
19 Radiology and the American Society of Radiation
20 Oncology. And for the medical licensees that we heard
21 from, as well as those NGOs, they mostly again said no
22 for expanding LVS to include Category 3 licenses.

23 In terms of comments received regarding
24 Category 3 sources in the NSTS, again the specific

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1 medical licensees and the NGOs that we heard from were
2 against tracking Category 3 sources in NSTS. Most of
3 the arguments for why they didn't feel that that was
4 necessary was if there would be no added security or
5 safety benefit and there would be a high burden to do
6 that additional tracking.

7 Comments received regarding enhancing
8 physical security requirements for Category 3 sources,
9 again as we expected we did hear from medical licensees
10 and the medical NGOs on this and they did not want us
11 to take Part 37 security requirements and apply them to
12 licensees with just Category 3 sources, again for the
13 same reasons that it would be a huge cost, a financial
14 burden, they would have to ramp up staffing.

15 And then we did hear some aspects of how
16 -- that this -- that having to implement all this and
17 then the higher costs would essentially take away from
18 patient care. It could cause some licensees to stop
19 offering certain medical care. So we are incorporating
20 and reviewing these comments and taking them into
21 consideration for working group recommendations.

22 And then lastly, we did have some questions
23 on whether Category 3 sources covered under a general
24 license -- if that should be prohibited, if those should

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1 be considered switched from a general license to a
2 specific license. And medical licensees and the NGOs
3 were mostly silent on this. The only -- the few
4 comments that we did get from them were that if NRC did
5 choose to expand Part 37 to apply to Category 3 licenses
6 that they felt that those Category 3 devices that
7 contained -- that were covered under a general license
8 should be then converted to a specific license.

9 So again, we're taking all these comments
10 right now into consideration as part of the working
11 group and formulating recommendations.

12 So next steps. Like I said, we are -- we
13 finished reviewing all of the comments we've received
14 from letters and all of the comments in our public
15 meetings and webinars and we're preparing comment
16 resolution documents that will be part of the Commission
17 paper. We've identified some gaps with our current
18 regulations and guidance and are looking at the changes
19 or enhancements needed to close those gaps.

20 We have done a lot of work on the
21 vulnerability and threat assessment piece. And we are
22 also making a lot of headway on the cost-benefit
23 analysis. The cost-benefit analysis, although
24 somewhat similar to what's done for rulemaking, will

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1 focus on the working group recommendations and the
2 various options. And that will be done at a much higher
3 level. Again, if this proceeds to -- when this -- if
4 this proceeds to rulemaking, then there will be a much
5 more detailed cost-benefit analysis included with that.

6 And then finally, as I've mentioned several
7 times, staff is preparing a Commission paper with its
8 recommendation, and that's due to the Commission in
9 August.

10 So I just wanted to end with my contact
11 information. Duncan White, who is also on the working
12 group. We also have a web page that has links to our
13 working group charter, the transcripts and meeting
14 summaries from all of the public meetings that we've
15 had. So we tried to do all this to help facilitate
16 stakeholder feedback and keep all stakeholders
17 informed.

18 CHAIRMAN ALDERSON: Well, thank you very
19 much for this report. And I have a couple of questions
20 that I'd like to put on the table and then open it up
21 for everyone else.

22 I think this is an important activity. I
23 am surprised -- but my first question is; and I'm unaware
24 of this, are any members of the ACMUI on the working

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1 group that is looking at this question?

2 DR. WU: No, so the working group is made
3 up of NRC and Agreement State staff. So it's -- there's
4 no members from ACMUI.

5 CHAIRMAN ALDERSON: And it's all staff? I
6 mean, the Agreement State people that are on are staff
7 in those Agreement States. NRC staff --

8 (Simultaneous speaking.)

9 MS. LOHMAN: Right, so ours -- the
10 Agreement State representatives we have, we have one
11 that is a supervisor of their Radioactive Material
12 Program, and then the other one is staff --

13 CHAIRMAN ALDERSON: I see.

14 MS. LOHMAN: -- from two different
15 Agreement State.

16 CHAIRMAN ALDERSON: All right. So the
17 second question, it's a corollary and I'm going to be
18 the one -- probably all of you sitting around the table
19 at your fingertips know what all the Category 3 sources
20 are that are used in medicine. Your chairman does not.
21 And so I'm going to ask you to tell us what these sources
22 are, most of these sources are. Perhaps Dr. Langhorst
23 will tell us what those are --

24 (Laughter.)

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1 CHAIRMAN ALDERSON: -- because she has her
2 hand up.

3 MEMBER LANGHORST: Thank you.

4 CHAIRMAN ALDERSON: And that will give all
5 of us a little better idea of what impact we might be
6 talking about.

7 Dr. Langhorst, would you like to help with
8 this question?

9 MEMBER LANGHORST: Thank you very much.
10 I'd be more than happy to help with this question.

11 So currently if there are no changes in the
12 Part 20 table of what sources are required for NSTS
13 tracking, it will only impact HDR sources.

14 CHAIRMAN ALDERSON: HDR radiotherapy
15 sources?

16 MEMBER LANGHORST: Yes, so the high-dose
17 remote afterloader sources.

18 So the other sources used in medicine; and
19 I hear Ms. Weil asking about cobalt, those are already
20 Category 1 and Category 2 sources that are already
21 covered. So the inclusion of Category 3 sources only
22 impacts HDR sources at this point in time.

23 CHAIRMAN ALDERSON: So at this point in
24 time what we would call diagnostic radionuclides would

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1 not be impacted?

2 MEMBER LANGHORST: That's correct.

3 CHAIRMAN ALDERSON: And what about blood
4 irradiators?

5 MEMBER LANGHORST: Those are already more
6 than likely Category 1 or Category 2 sources.

7 CHAIRMAN ALDERSON: They are already
8 Category 1 or Category 2 sources?

9 DR. WU: Right, so they are already
10 complying with the license verification requirements in
11 Part 37 and the NSTS source tracking requirements in
12 Part 20.

13 CHAIRMAN ALDERSON: Good. Thank you very
14 much. That's good context. Given that context, Dr.
15 Ouhib would like to --

16 (Simultaneous speaking.)

17 MEMBER OUHIB: Yes, keep in mind on the HDR
18 itself -- now if you have two sources present there of
19 12 curies, now you are in a different category.

20 CHAIRMAN ALDERSON: Yes, Dr. Langhorst?

21 MEMBER LANGHORST: And usually you
22 wouldn't have two sources that are at their maximum.

23 MEMBER OUHIB: Right, just to be aware of
24 it.

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1 MEMBER LANGHORST: But I do have a couple
2 questions, if I may?

3 CHAIRMAN ALDERSON: Please.

4 MEMBER LANGHORST: Ms. Wu, I thank you and
5 your working group's efforts and in particular the
6 seeking of stakeholder comments. I mean, I know that
7 takes a lot and I really appreciate -- and especially
8 with you being under such a tight deadline.

9 My first question is do licensees have
10 access to the License Verification System?

11 DR. WU: So currently those who are subject
12 to Part 37, the license verification requirements, that
13 are mostly Category 1 and 2, they can apply for access.
14 And we go through a credentialing process of determining
15 whether they need to have access. We have had instances
16 where lower category licensees who can't aggregate to
17 a Category 2 quantity have applied for access and we've
18 denied them in those cases because they don't have a need
19 to get access to LVS. But, yes, there are licensees
20 currently right now who have access to LVS.

21 CHAIRMAN ALDERSON: And are those
22 licensees mostly the vendors, because I understood I
23 couldn't get access.

24 DR. WU: So, yes, they are mostly

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1 licensees. Agreement State and regulated community do
2 have access, but they have a different view when they
3 log in. Like myself, when I log in, I see a different
4 view than when a licensee goes in.

5 MEMBER LANGHORST: And if a licensee does
6 not have that access, what's the way that they have to
7 do to verify this as far as Part 37 goes and what you're
8 considering?

9 DR. WU: Okay. Yes, so we prefer them to
10 use the online License Verification System, but we
11 recognize that a lot of licensees will opt to use the
12 manual process, the alternative method, for many
13 different reasons. Right now we have licensees who
14 either are not comfortable -- they did not want to use
15 the computer-based system. Either they don't have a
16 frequency of transfers that would warrant them to then
17 go through that full credentialing process and have yet
18 another password to remember.

19 So for them, they use -- we have a form, Form
20 749, which is available on our web site. And what they
21 would do is they would complete the top portion. Basic
22 information. What -- their information, what
23 licensee that they are trying to perform the license
24 verification on. And then it is submitted to our help

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1 desk that we have for all of our IT-based systems to then
2 follow through the rest of the process, send that to the
3 regulatory authority for the actual license
4 verification.

5 MEMBER LANGHORST: And so are Agreement
6 States set up to be able to do this in a timely manner?

7 DR. WU: Yes, currently Agreement States
8 are -- we work closely with the Agreement State
9 partners. And this process has been working pretty
10 well with us, the help desk sending it to them or getting
11 to the NRC person responsible for doing that portion of
12 the verification.

13 MEMBER LANGHORST: In your vulnerability
14 assessment that you all are working on will that be
15 available to the public or any portion of it available
16 to the public?

17 DR. WU: So the majority of the
18 vulnerability assessment piece and that appendix to the
19 Commission paper will likely be OOU, official use only.
20 We will try our best to include language in the
21 Commission paper that will talk to our methodology, what
22 we looked at to then make a conclusion on the current
23 threat landscape.

24 MEMBER LANGHORST: And will your

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1 vulnerability assessment also consider what is the
2 negative impact of now including Category 3 sources on
3 Category 1 and Category 2 source security and tracking?
4 Because my understanding is there will be a great many
5 more reporting and requirements on Category 3 sources,
6 and I'm concerned that that overwhelms the 1 and 2
7 Category sources.

8 DR. WU: Yes, we did get a lot of that
9 feedback. Mostly the vulnerability assessment is
10 looking at existing vulnerability assessments and
11 inspection and licensing experience with regulated
12 entities and then current threat information. So the
13 feedback we got from a lot of folks on the effects of
14 the Category -- all these additional sources and
15 licensees and how it could affect Category 1 and 2, it
16 will be taken in consideration most likely separate from
17 the vulnerability assessment, but again will be a piece
18 of our analysis.

19 MEMBER LANGHORST: I encourage you to look
20 at that. I thank you very much.

21 CHAIRMAN ALDERSON: Good.

22 Yes, Dr. Ennis?

23 MEMBER ENNIS: So I think that was a great
24 overview, so I have a really good understanding of

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1 what's going on and good luck with kind of balancing all
2 those risks.

3 Just I think -- just so people know, HDR is
4 used -- just people from a medical perspective what
5 would be at risk potentially for patients is it's a
6 curative treatment. It's included for the curative
7 treatment for several cancers, mainly cancer of the
8 cervix, cancer of the uterus, and in many centers
9 prostate cancer.

10 So, and the other key thing about our field
11 and access issues are that these treatments are usually
12 done at least a few times and travel barriers become a
13 big issue. So right now there are centers throughout
14 the country that use this on a regular basis but not all
15 day, every day. And if there are financial barriers to
16 them having this start to make it financially not
17 viable, they will not really be able to offer it and they
18 will turn to alternatives that are not as successful.
19 But that's just -- that's what's at risk if we
20 over-regulate. Even if technically it's still legal,
21 we could end up harming our friends and colleagues by
22 making these unavailable.

23 I note that the GAO sting both times was
24 only on the issue of getting into the game, and I'm

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1 wondering if that really just needs to be the focus.
2 It's great that you're doing the whole overview, but it
3 does bring to my mind whether the issue is only we need
4 to really, really careful on how we vet people to let
5 them in, but the system itself, once you're in is
6 healthy.

7 DR. WU: Right, so -- and that is a good
8 point and we did hear that in a lot of stakeholder
9 comments. So the working group has really been
10 focusing on several vulnerabilities that sort of GAO
11 exposed or that as a working group we've talked about,
12 and that is sort of the first one, the ability to obtain
13 a valid license using a fictitious company.

14 Then there's the other ones which were -- which
15 I think more of our analysis is geared towards, and
16 that's the ability to alter a valid license to obtain
17 more than authorized or falsifying a license to obtain
18 radioactive materials illicitly or say just
19 counterfeiting a license outright.

20 And then there's the vulnerability of being
21 able to accumulate and aggregate Category 3 sources to
22 a Category 2 quantity.

23 And then lastly there's that whole general
24 license issue where you have -- here you have

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1 specifically licensed Category 3 sources that go
2 through pre-licensing and oversight and
3 accountability, but then there's this whole other
4 subset of generally licensed devices with the same
5 Category 3 sources in them that don't have any
6 pre-licensing or accountability or oversight.

7 So I think this group is focused on those
8 latter vulnerabilities, but a lot of work has been done
9 and is going to be done to address that first
10 vulnerability. So this is -- so we are looking at that
11 as an aspect of this.

12 CHAIRMAN ALDERSON: Yes, Dr. Ouhib?

13 MEMBER OUHIB: That takes me back to your
14 first question is that should there be some sort of
15 subcommittee to -- from the ACMUI to actually look at
16 this particular issue and make some recommendation?

17 CHAIRMAN ALDERSON: You would like to
18 comment on that question or are you --

19 MEMBER OUHIB: Well, no, I'm addressing
20 -- yes, basically should we have a subcommittee? I'm
21 not aware of any within the ACMUI --

22 (Simultaneous speaking.)

23 CHAIRMAN ALDERSON: So I'll give you
24 -- since I raised the question, I'll give you a quick

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1 answer. And then I believe Mr. Green was next and then
2 Dr. Langhorst.

3 I believe that if this -- if and when this
4 activity begins to extend to the point where sources
5 that are medically relevant -- and perhaps HDR is now,
6 but when sources that are medically relevant are
7 involved, then someone from a medical perspective,
8 potentially from this committee, should be involved in
9 those discussions. So that would be my opening answer.

10 So Mr. Green was next and then we'll go to
11 Dr. Langhorst.

12 MEMBER GREEN: Thank you, Dr. Alderson.
13 Yes, I think you and I are in the same camp, not knowing
14 exactly where the Category 2s and Category 3s cut off,
15 and HDR I think is one that we can all agree is probably
16 in Category 3.

17 But I'm currently aware of at least 10
18 commercial nuclear pharmacies that have 100-millicurie
19 or so cesium-137 sources for survey meter calibrations,
20 and there may be likewise medical institutions who do
21 their own meter calibrations and pocket dosimeter
22 calibrations. And that's within the commercial
23 nuclear pharmacy or in the hospital setting. Plus
24 there's all the private physicist practices that do

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1 meter calibrations. It's not medically related, but we
2 all have to have our machines -- our Geiger counters
3 function to do our medical operations. So it's I think
4 partially involved as well.

5 CHAIRMAN ALDERSON: Right. It's of
6 concern.

7 Dr. Langhorst?

8 MEMBER LANGHORST: So my first response is
9 to Zoubir's question. I think once the process of what
10 the NRC and Agreement States recommendations are, then
11 if there's anything needed for regulatory change,
12 that's where we need to have our subcommittee. I don't
13 think there's anything we can add more that -- what we
14 will at this meeting before that.

15 If the Part 20 table gets changed, the
16 potential of including high-activity moly-tech
17 generators are there, and that will impact nuclear
18 pharmacies, so that's another question that I have.
19 And I believe that the cesium irradiators that you're
20 talking about for meter calibration is below the
21 Category 3 level.

22 And, Ms. Wu, you can --

23 DR. WU: Yes.

24 MEMBER LANGHORST: -- chime in on that. I

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1 believe -- because, yes, I don't believe that those are
2 included in Category 3.

3 DR. WU: Yes, the threshold for cesium
4 would be 2.7 curies, or 0.1 terabecquerels. Mostly
5 when we did our stakeholder outreach we did hear that
6 it was primarily HDRs.

7 MEMBER LANGHORST: Yes. Thank you.

8 CHAIRMAN ALDERSON: Do we have other
9 questions or comments on this subject?

10 (No audible response.)

11 CHAIRMAN ALDERSON: Well, seeing none, I
12 want to thank you again for an excellent report. I
13 believe that the issue remains an open issue for the
14 ACMUI because we want to keep informed and know how this
15 might extend. And if and when it does, then we would
16 appreciate the ACMUI being brought into the
17 discussions.

18 DR. WU: Thank you.

19 CHAIRMAN ALDERSON: Thanks very much.

20 All right. We are at two minutes -- no,
21 we're actually a little bit behind on break time. The
22 break was supposed to begin at 10:15.

23 So, Mr. Bollock, are we in position to go
24 ahead and have a brief break now?

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1 MR. BOLLOCK: Yes, I think it might be a
2 good time to give everyone a break, and at your
3 discretion for how long you want to give --

4 CHAIRMAN ALDERSON: Well, I think that --

5 MR. BOLLOCK: -- but we are about 12
6 minutes behind.

7 CHAIRMAN ALDERSON: Let's say that instead
8 of having a 15-minute break, we'll have a 10-minute
9 break. And so we'll be back here and we'll begin the
10 next session at 10:40.

11 MR. BOLLOCK: Thank you.

12 CHAIRMAN ALDERSON: Thank you.

13 (Whereupon, the above-entitled matter went
14 off the record at 10:27 a.m. and resumed at 10:42 a.m.)

15 CHAIRMAN ALDERSON: All right, well, I
16 think we're ready to reconvene at this particular time.
17 And the issues are Dr. Howe, Dr. Langhorst are going to
18 talk to us about medical related events.

19 Before we begin, I do want to say that after
20 that last excellent session on source security that I
21 spoke to Mr. Bullock and to Ms. Wu, and suggested, and
22 they agreed, that at our meeting in the fall, with a date
23 still to be determined, that we will get a brief update
24 report from Ms. Wu on the status of the source security

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1 issue and its relationship to the ACMUI.

2 Okay, we're ready for the next report. Dr.
3 Howe.

4 DR. HOWE: Thank you, Dr. Alderson. So
5 I'll be talking about the status of medical events for
6 FY2016. And just to put it into perspective that
7 medical events are a very small number. There are many,
8 many diagnostic events that are performed every year,
9 and there are many, many therapeutic events that are
10 performed every year.

11 And in the past, the ACMUI has asked for
12 kind of a perspective, where have we come from and where
13 are we going. So this time, I decided to give you about
14 a six-year perspective, to start with the number of
15 medical events back in 2011 and carry through to 2016.

16 So we've gone from 58, we dropped to 48, we
17 dropped to 43. You can see in this slide that there's
18 a distribution of them most, there's an increase in the
19 2000 -- in the 35.1000, and there were a fair number of
20 35.400.

21 And then if you look at the last three
22 years, we hit 46, we're up to 57, and now this year we're
23 at 50. And you'll see that we've shifted, so we don't
24 have as many in 35.400.

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1 We still have a fair number in 35.600,
2 although that changes on a daily basis. And most of our
3 growth is in 35.1000. And you'll see, as I go through
4 the 35.1000s, most of the 35.1000s are in the yttrium-90
5 microspheres.

6 So that's how we have progressed through
7 the last six years.

8 CHAIRMAN ALDERSON: That's excellent.
9 And by the way, I think this committee asked for that
10 sort of trending summary, and I thank the NRC for
11 providing it.

12 DR. HOWE: Thank you, Dr. Alderson. So
13 let's look at 35.200. This is the imaging and
14 mobilization. We generally have very few imaging and
15 mobilization medical events, because you have a
16 threshold of 50 rem to a given organ, or five rem whole
17 body.

18 And so, as expected, the medical events
19 that we have for technetium-99m are where people have
20 given multi-dose vials to a single patient, and that
21 would be our first one we're talking here. The staff
22 member failed to verify the dosage. And the licensee
23 has decided that it's no longer going to use multi-dose
24 vials, and that they will only be ordering uni-dose

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1 vials from the pharmacy.

2 We had another case which was slightly
3 different, and that's where an intravenous port leaked.
4 And because of the leakage, you had technetium on the
5 skin, and the skin exposure exceeded the limits.

6 You also had failure to verify the dosage.
7 So in this case, they were looking for a filtered sulfur
8 colloid for a lymphoscintigraphy. They got an
9 unfiltered sulfur colloid significantly higher in
10 activity, 2.4 millicuries instead of a half to one
11 millicurie. And you ended up with over 50 rem to the
12 skin.

13 And in this case, the technologist has now
14 had retraining, and this will be a verbal confirmation
15 of activity and type of procedure so they end up with
16 the right radiopharmaceutical in the right form.

17 And the final one is the wrong patient,
18 wrong drug. In this case, they were supposed to get a
19 lymphoscintigraphy, and at a half a millicurie.
20 Instead, they got a bone scan injected into the
21 lymphoscintigraphy site at 30 millicuries.

22 And so you had in excess of the reporting
23 requirements here. And the technologist failed to
24 verify patient identity. It was the same as on the

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1 dosage. So you had a number of events here. One, wrong
2 patient, wrong radiopharmaceutical, and then you exceed
3 the limits.

4 So those are our four imaging and
5 mobilization medical events.

6 The next group of medical events are
7 35.300, which are unsealed material requiring a written
8 directive. We had four of those. We had a
9 distribution between samarium-153, radium-223, and
10 iodine-131.

11 For samarium-153, they were supposed to
12 give three gigabecquerels. They gave three
13 gigabecquerels instead of 2.48, so they have an
14 overdose. And the dosage from the pharmacy was not
15 correctly calculated for patient's weight. So the
16 written directive was one thing, and what came from the
17 pharmacy was different.

18 And for radium-223, they administered 119
19 microcuries instead of 87. The issue was the 119 was
20 for the wrong patient. And because you're therapeutic,
21 you automatically exceed the limits. Then they
22 administered 99 microcuries instead of 980.

23 I think it's clear from this that most
24 radium-223 administrations are down in the 99-100

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1 microcurie level, and that the authorized user in the
2 written directive wrote the wrong number. And so it is
3 a good thing that they administered 99 microcuries and
4 they did not administer the 980 microcuries.

5 So the technician failed to observe the
6 difference between the calibrated activity and the
7 prescribed. That probably wasn't a bad thing is this
8 particular case. And they do believe that the
9 authorized user intended to prescribe 98, but got the
10 wrong value.

11 So they're going to list the activities for
12 radium-223 in microcuries now, instead of millicuries,
13 which is what they normally use for other procedures.

14 Iodine-131, they administered roughly less
15 than half of the dose. Typical cause, two capsules,
16 only one of them was delivered. They did not check to
17 make sure that it was two capsules and that there was
18 still a capsule left in the vial.

19 And they didn't realize he had a capsule
20 left in the vial until they were ready to send the empty
21 vial back to the commercial pharmacy. So they've now
22 revised their procedures for transferring of
23 radioactive materials so they can catch these things
24 quicker.

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1 And moving on to 35.400, we have only six
2 medical events last year. One is gynecological and
3 five are prostate. The five prostate ones, we had
4 multiple patients involved in a few of the cases. For
5 the gynecological, they administered roughly half of
6 the dose to the treatment site.

7 There was a crimped applicator in the lead
8 pig during transport, so they interpreted the
9 resistance during the application is that they had the
10 source in the right place. And then they found out
11 later that it was not, and so the dose to the lower rectum
12 and the vaginal areas received more dose than expected.

13 For the prostate, we had one licensee with
14 two events in 15 patients. And actually, both of the
15 -- this is one licensee. They had two different medical
16 events. One medical event identified in 2016 involved
17 two patients in the post-implant imaging, and they
18 received 66% of prescribed dose and 71%.

19 And as a result of that being found in
20 inspection, they went back and looked at their previous
21 records from 2006 up to 2011. And they discovered they
22 had an additional 13 patients that had medical events
23 where the administration differed by more than 20%.

24 We had a prostate where the ultrasound

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1 images were confusing, and so they didn't get the
2 brachytherapy sources into the prostate gland at all.

3 Then we had a human error where the dose was
4 60, about 70% of the intended, the target. And another
5 one with human error was, the activity was about 59%
6 intended.

7 And moving on to 35.600, these are your high
8 dose remote afterloaders, your gamma knives, and your
9 teletherapy units. As expected, we don't have a
10 teletherapy unit medical event here. We probably only
11 have one teletherapy unit left in the country that's
12 used in medical treatment.

13 We had six medical events, they were all HDR
14 units, and in some cases, we had multiple medical events
15 for one facility. So we'll look -- and they range from
16 the bronchus to the mandible to the gynecologic to
17 prostate.

18 So for the bronchus, we had three patients.
19 And in the three patients, you had fractions that were
20 delivered to the wrong treatment site. And you had
21 three fractions that were not delivered to the treatment
22 site at all.

23 And in this case, there was a problem with
24 the adaptor piece being used when it wasn't supposed to

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1 be. And it was a case of an Elekta HDR-type unit with
2 the adaptors that weren't supposed to be used for that
3 unit. So part of the corrective action was Elekta was
4 going to update the user's manual to warn about this
5 adaptor.

6 And they were going to put a warning sticker
7 on the applicator packaging and improve the use of
8 training. And we did follow up on that, and they did
9 take all of those actions. So it was a question of
10 incompatibility between old tubes and new tubes in this
11 adaptor being used.

12 For the mandible, they used a treatment
13 planning time for another patient, so this would be kind
14 of the wrong patient. And they've decided to have a
15 time-out policy to confirm who the patient is, what the
16 treatment information is, and they hope that will
17 prevent them from having future medical events.

18 Gynecologically, we had two events. The
19 first patient reported to the primary care physician
20 with skin burns on the legs, so that's the first that
21 the radiation oncologists were informed that they had
22 an issue.

23 And they thought that the second of three
24 fractions was delivered incorrectly. And they

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1 attributed it to human error, using the wrong transfer
2 tube, and applicator interface.

3 The second one was -- have I got that one
4 right? No, okay. The second one was an equipment
5 problem. Prior to using the third channel, there was
6 friction. It was detected in the applicator check
7 cable. The check cable was drawn and the treatment was
8 stopped.

9 So that's a good point, you're taking the
10 right medical action. But you have a medical event.
11 So they prescribed 600 rad during the tandem ovoid, and
12 the applicator was permanently removed from use because
13 of its problems.

14 And then we had two prostates. There was
15 equipment failure. And in this particular case, both
16 of the medical events reported under the prostate HDR
17 are from the same licensee.

18 The first event happened on, and I'm not
19 sure, I don't have the month. But essentially on the
20 16th of the month. And there were equipment errors,
21 friction, at the catheter site, so they had to replace,
22 it's actually this one, they had to replace the V-block
23 and the opto-pair. And then they tested the next day,
24 and it was operating.

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1 And then about four to five days later, they
2 had another medical event, and that medical event gave
3 the same error codes, the same issues. And they brought
4 the manufacturer in. They had to replace a lot more
5 parts. So it was equipment failure that wasn't totally
6 corrected the first time. Both of these were the same
7 licensee.

8 In 35.1000, we have 30 medical events. We
9 have three medical events from the Perfexion. We have
10 one from seed localization, and we have 26 evenly
11 distributed between TheraSpheres and SIR-Spheres for
12 the yttrium-90 microspheres.

13 For the Perfexion, they got the wrong
14 treatment site. They had a new frame adaptor. They
15 didn't realize that the frame adaptor could be locked,
16 but in the wrong position. And so when they pulled the
17 patient out finally, they realized there was a maximum
18 of two centimeters in one plane of deviation from where
19 the treatment should have been.

20 They looked at it, it was a non-keyed
21 design, so that it wasn't just one way that the head
22 adaptor could fit into the head frame. So it fit in
23 incorrectly. And the difference in clamping forces was
24 not noticed by the licensee. And also, the operator did

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1 not follow the instructions.

2 The second Perfexion was a dose to an
3 unintended site. And the treatment was stopped out of
4 15 and 16 sites to re-sedate the patient, so obviously
5 this patient needed to be sedated in order to get the
6 procedure.

7 And they stopped it, they re-sedated him,
8 and after they started the 16th one, the patient awoke
9 and moved significantly. And the frame was out of
10 position when the patient was removed from the unit. So
11 they believe the frame moved during the treatment.

12 And then we had one on human error where
13 they did the incorrect positioning of the isocenter.
14 It should have been on the left side of the brain. It
15 was given to the right side. It was given to the left
16 side, it should have been given to the right side.

17 And now they're going to look at their
18 procedures and make sure their procedures are correct.
19 And they didn't identify it until the treatment was
20 completed.

21 And in our radioactive seed localization,
22 there was a patient that was given seeds to a location.
23 She had a stroke in the interim days, and so they made
24 medical decision not to bring her back to take out the

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1 seeds.

2 We have since modified our radioactive seed
3 localization guidance so that if the patient doesn't
4 return for a given reason, it would not be a medical
5 event. But this happened before that, so this is a
6 medical event. And these are the expected doses to
7 whole body and to the breast.

8 And now we start the microsphere. So for,
9 and these are evenly distributed between TheraSpheres
10 and SIR-Spheres, and there's a little bit of difference
11 between what the causes are. But most of the causes are
12 very similar.

13 There's the wrong site, wrong volume
14 determination, there were catheter issues, there was a
15 radiation detector problems, the modified apparatus,
16 unusual resistance, materials remained in the waste and
17 delivery system.

18 And in both cases, I have one where there
19 was no description or reason for the medical event,
20 just, there is a medical event.

21 So, let's look at the wrong site. In this
22 case, they had a previously treated segment IV, the left
23 lobe. They hadn't treated the right lobe. They
24 concluded that the catheter moved from patient movement

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1 or breathing, but they didn't perform a fluoroscopy
2 contrast image immediately prior to the treatment to
3 verify the catheter was in the right position.

4 And so they determined that there was a
5 medical event to segment IV. And they ended up with
6 hepatic and tumor necrosis.

7 And in the next one, they administered 88%
8 more than they prescribed. It was to the wrong lobe
9 because they displaced the catheter and failed to verify
10 its position during administration. There were
11 inadequate procedures and insufficient training, and
12 they'll use additional imaging techniques to verify
13 catheter placement.

14 Volume determination. In this case, an
15 image was taken prior to administration that showed a
16 smaller liver volume that was used to determine the
17 amount of the Y-90 administered. But there was also
18 changed work flow, so a second review of the liver volume
19 showed that the liver volume was larger, so they had a
20 medical event.

21 In this one, the catheter, the
22 post-apparatus readings were much higher than expected.
23 Most of the activity remained within the catheter. The
24 catheter representative thought the catheter apparatus

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1 may not have been fully extended, so there are some
2 questions whether it was a catheter issue. And then
3 they've determined to use a different and newer catheter
4 product.

5 In this one, there was radiation meter,
6 we've got three of them with radiation meter problems.
7 In this case, they administered 64%, their electronic
8 dosimetry that was attached to the treatment device had
9 fluctuating readings but no low battery warning. The
10 dosimetry readings indicated that all the microspheres
11 had been administered, but in reality, 36% of the
12 activity remained.

13 The dosimeter was checked and it had a low
14 battery warning. For their corrective actions,
15 they're going to change the batteries in the dosimeter
16 prior to each administration.

17 Another cause with radiation meter. They
18 administered 71%, stasis was not reached, but the
19 radiation survey meter indicated that all of the
20 microspheres had been delivered. So they thought the
21 patient had received the entire dose. But when they
22 went back and did the waste measurement, they found that
23 4,000 rads were in the waste.

24 And another one where there was

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1 administered 62%. At the completion of the radiation
2 survey, once again, they had an indication that all of
3 the microspheres had been delivered. But when they
4 took the delivery kit back to the hot lab for further
5 evaluation, they discovered that 34% of the dose was
6 still in the vial.

7 And modified apparatus. In this case, the
8 authorized user observed air in the delivery system, and
9 he added a three-way stopcock to the system to collect
10 the air.

11 And then the radiation surveys indicated
12 that all of the microspheres had been given. However,
13 significant activity was found within the container
14 when they measured it afterwards. And they concluded
15 that the three-way stopcock interfered with the
16 administration.

17 Unusual resistance. They administered
18 only 25% of the activity during two separate
19 administrations. They got unusual resistance during
20 both procedures. They unsuccessfully attempt to clear
21 the line, and efforts to complete the administration
22 experience both times. And then the administrations
23 were terminated.

24 The delivery sets were from the same lot,

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1 and both doses of microspheres came from the same lot.
2 So they believe they had a problem with the catheters.

3 Unusual resistance, another one. They
4 administered 76%, the resistance in the tubing was felt
5 during administration. The tubing was disconnected,
6 it was flushed with saline, and then it was reattached.
7 And in the end, 24% of radioactivity was in the waste.

8 And now we have really no reason given for
9 what the medical events were, other than the fact that
10 when they made the final measurements of the waste
11 containers, they discovered most of the activity, or a
12 medical event amount of activity, was still left in the
13 waste delivery system.

14 The first one was 50% of the activity, and
15 so it was determined at completion. The other one with
16 74% of the activity was given. And they attributed this
17 one to human error, and they're going to provide new
18 training to personnel.

19 And then I've got one in which there was
20 absolutely no description of any kind. But the patient
21 only received 15% of the intended administration.

22 Now, moving on to SIR-Spheres, we have
23 slightly different generic reasons. Dose calculation
24 error, wrong site, apparatus tubing, catheter crimping

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1 included, catheter displaced, vials, no description or
2 reason. We have 13 of these.

3 So for the dose calculation error, they
4 administered 643 megabecquerels instead of 499. That
5 was 29% more than prescribed. The technologist
6 miscalculated the dosage required.

7 The second one, they administered 77-78% of
8 the intended dose. The authorized user forgot to
9 change the lung and liver estimated doses from the
10 precalculation worksheet, and so the instructions.
11 And their corrective actions is they're going to draw
12 slightly more microspheres than prescribed to account
13 for amounts that they routinely see in the waste.

14 Wrong site. They delivered to the left
15 lobe instead of the right lobe. They didn't really give
16 a reason why it went to the wrong lobe, but they
17 administered it to the wrong lobe, so. And they
18 attributed it to failure to follow procedures.

19 The apparatus tubing, I got one of these.
20 In this case, they administered 0.74 gigabecquerels
21 versus 95 gigabecquerels. A large amount of the
22 microspheres were found in the tubing. No resistance
23 was felt, and stasis was not reached. And they believe
24 there was a long time period between the microsphere

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1 preparation and the patient administration.

2 And they believe that contributed to the
3 cause. So they have decided to draw a little bit more
4 activity than they have in the beginning, and to do the
5 drawing closer to when they give the administration.

6 They administered only three percent of the
7 intended dose. They encountered back pressure, and
8 they terminated the procedure. They saw microsphere
9 clumping.

10 They believe there was improper
11 manufacturer preparation of microspheres, and
12 occlusion of the microcatheters used, or collection of
13 air in a three-way stopcock. So they had multiple
14 things they thought could have gone wrong.

15 Then we have catheter displacement. The
16 microspheres ended up in the patient's catheter chucks
17 and on the floor. They attributed it to patient
18 movement that displaced the catheter in the patient, and
19 disabled treatment to the desired liver.

20 But, and their corrective action now will
21 be that when a patient moves during treatment, they're
22 going to stop the administration and make sure that the
23 catheters are in place.

24 Let's see, catheter issues continued.

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1 They concluded that the misadministration was caused by
2 a clogged catheter. The second case, there was
3 significant resistance. Here, we've named the
4 catheter manufacturer, Surefire Microcatheter.

5 They had low flow in the catheter or target
6 vessels that may allow distal accumulation in the
7 microspheres in the catheter. They've decided to use
8 vasodilators during the administration to give proper
9 infusion in the future.

10 Vial issues. In this case, they
11 administered 44%. There was a small plug of
12 microspheres were noticed at the bottom of the dose
13 vial. And they attributed this to lack of experience
14 with microspheres.

15 They didn't mix the dose as close as
16 possible to the delivery time, and they weren't doing
17 routine agitation of the vial, and they weren't
18 adjusting the position of the inlet tube to ensure
19 maximum agitation. So they attributed it to lack of
20 experience for their part.

21 Another vial issue, residual activity.
22 Adhered to the top of the vial. And they concluded
23 either the needle was not inserted far enough into the
24 vial, or agitation of the vial during administration

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1 caused the microspheres to go up to the top. So their
2 corrective is to increase the amount of activity to make
3 up for the microspheres that don't get through to the
4 tubing.

5 Another vial issue, 74% was given, residual
6 activity remained in the vial. And then they
7 administered ten percent of the intended. There was a
8 puncture site in the V-vial rubber stopper that was
9 leaking.

10 They couldn't stop the leak with a
11 dermabond, which is manufacturer-recommended glue. So
12 they aborted their procedure. I don't know if this is
13 FDA-accepted or not. And so, once again, they're going
14 to go, well, they're going to go to a higher gauge,
15 smaller lumen needles, hopefully to prevent the
16 puncture site issue.

17 And then I have one case where there was no
18 description and no reason given, where they
19 administered a little less than 80% of the prescribed
20 dose. And that concludes my portion of the
21 presentation.

22 CHAIRMAN ALDERSON: All right, so we have
23 questions. Ms. Weil.

24 MS. WEIL: So how is it possible, since

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1 medical event recording and reporting is required, how
2 is it possible that some licensees submit no
3 information, or no information about corrective
4 actions? Is there no review and going back to the
5 licensee to require the necessary info?

6 DR. HOWE: When we get these reports, if
7 they're inadequate, we do go back and ask, and the
8 agreement states go back and ask. But sometimes you
9 just don't get any information. And it's a matter of
10 compatibility.

11 I don't believe this is the same level of
12 compatibility that you have for other parts of the
13 regulation. They have to be kind of equal, but they
14 don't have to be identical.

15 MS. WEIL: It sort of defeats the purpose
16 of reporting medical events.

17 DR. HOWE: And that was one of the issues
18 that the commissioners brought up during the last
19 rulemaking on permanent implant brachytherapy. They
20 wanted medical event reporting to be a category B, which
21 would mean all of the criteria would be the same across
22 the NRC and the states.

23 But the final resolution, we haven't
24 resolved that rule yet, but we did not take it to a

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1 category B. So it is an issue that continues.

2 CHAIRMAN ALDERSON: Dr. Langhorst.

3 DR. LANGHORST: I just want to remind you
4 that these reports come from the NMED database. And so
5 when there isn't information in there, it could be it's
6 not been updated.

7 And so it doesn't mean that the licensee
8 hasn't provided that information necessarily. I would
9 guess, and I'll ask, that NRC-reported events get
10 updated, I would assume? That's not a rhetorical
11 question, but a question to the NRC staff.

12 PARTICIPANT: Yes.

13 DR. LANGHORST: They said yes. Good.
14 But agreement states may not go back and fill in the
15 information. So please don't think that it's totally
16 because they're not getting cooperation from the
17 licensees. That may not be the case.

18 CHAIRMAN ALDERSON: Dr. Ouhib had a
19 comment, and Dr. Dilsizian.

20 DR. OUHIB: Yeah, I just, a couple of
21 comments. First of all, the AAPM is actually looking
22 at this, having some consistency in reporting. There's
23 a task group right now that is actually working on that.

24 I know for a fact that I brought up this

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1 issue about a year ago, that I said that, because I have
2 looked at 13 years of medical event, and while looking
3 at them, was like, there's something that's got to be
4 done here.

5 And I had proposed that we should have some
6 sort of a form that has to be done across the board. And
7 if you don't fill out that form, your reporting event
8 is incomplete, and it's still sitting on your desk that
9 you have to do this, this, and this and this.

10 And that's really very important.
11 Regardless of what the AAPM does, in my opinion, and I
12 could be one of the few, that I think we ought to have
13 some consistency and have very obvious items that we
14 need to know for one purpose: to improve patient safety.

15 CHAIRMAN ALDERSON: Yes, Dr. Dilsizian.

16 DR. DILSIZIAN: Thanks. I was curious
17 with the center that had the prostate post-implant
18 decrease the prescribed dose, two patients, and then
19 subsequently they reviewed back and identified 13
20 patients in previous years.

21 Now, I find this very interesting because,
22 you know, we're balancing both medical errors and
23 medical events and punitive versus reporting, that's
24 been our discussion. Yet, you know, a center like this,

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1 where there was more than one event or error, really
2 going back and identifying that there were actually 13
3 or 12 patients, I think this is important.

4 And I was wondering, in this case, I guess
5 the inspector identified it and went backwards. And
6 when should a center who does more than one or two
7 events, we should do a retrospective to identify how
8 often it happens, and what corrective action should we
9 take? Not being punitive, but really being corrective.

10 DR. HOWE: Normally what happens is, if we
11 get multiple medical events reported from a facility,
12 the regulatory body will go back and say, what is the
13 state of condition? Did you have more? Is this the tip
14 of the iceberg, or is this isolated?

15 And so they'll ask the licensee to go back
16 and check their records to see if they had others. And
17 so in the last medical event reporting, we've had,
18 especially back about the time of the VA prostate
19 implant issues, you will see a lot of facilities that
20 went back and discovered more.

21 They were identified, maybe on inspection,
22 because they hadn't really, the licensee hadn't
23 identified them. And then they were asked for the
24 extended condition and they went back and --

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1 DR. DILSIZIAN: What would be typical
2 corrective action? Is there any, just education, or is
3 there any financial also impacts? Because I know MDE
4 here has financial penalties for things that, you know,
5 go wrong. I just was wondering.

6 DR. HOWE: A medical event is not a
7 violation. But you could have violations that lead to
8 medical events. So if you have violations that lead to
9 medical events, then there is the possibility, if there
10 are a large number of medical events or more than you
11 expect, a civil penalty.

12 Generally, we look at the licensee's
13 corrective actions, and the licensee's corrective
14 actions are normally training and normally a time-out
15 to make sure they have the right patient, they have the
16 right materials, depending on what their issue is. So
17 it goes both ways.

18 CHAIRMAN ALDERSON: Dr. Ouhib.

19 DR. OUHIB: Can I just comment on that, and
20 I'm assuming you're talking about the prostate cases,
21 is that correct? Yeah, obviously, a lot of those cases,
22 when you apply the new rule, most likely will not be a
23 medical event. This was based on the D90 and so on and
24 so forth.

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1 So when it moves to activity-based, you
2 know, we have seen, and I looked at that, that a lot of
3 those are no longer a medical event. So that's why you
4 see this huge number. It's not like somebody does not
5 know what they're doing.

6 DR. HOWE: But I think you'll see that
7 there's a decrease in the number of medical events we've
8 seen under 400, because of our enforcement discretion
9 policy that's being used. So, many of those medical
10 events that would have been identified purely on D90s
11 are not being identified now.

12 DR. OUHIB: Right, and if they use the
13 interim rule, basically, most likely there will not be
14 a medical event also.

15 DR. HOWE: Well, I just want to clarify.
16 There is no interim rule. There is only the current
17 rule, and then we have issued enforcement discretion,
18 because we've kind of interpreted that you could use,
19 activity could be a substitute for dose. But we don't
20 have an interim rule right now, okay. Just to make that
21 clear.

22 CHAIRMAN ALDERSON: Mr. Bollock.

23 MR. BOLLOCK: And I can expand Ms. Weil's
24 comments and Dr. Langhorst, with the reporting and how

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1 do we go back. And then also -- but first I'll, just
2 to add to what Dr. Howe responded to Dr. Dilsizian, with,
3 you know, what are, she covered a lot of the common
4 corrective actions that we see.

5 But it really just depended upon each
6 licensee, what the event was, what they determine the
7 cause to be. But those are the requirements, if there
8 is a violation, they have to take action to correct that
9 violation. So, it is dependent, but Dr. Howe covered
10 some of the common things that we do see.

11 Now, for the reporting and the follow-up
12 and getting that follow-up information, so all those
13 reports go into NMED. So that we have multiple levels
14 to reach back out and get the updates.

15 So NMED contractors, they actually go
16 through and periodically look for that, you know, the
17 more information in the record that doesn't have the,
18 you know, the required, you know, what were the actions,
19 if any planned, you know, to prevent and those type
20 things under our regulations.

21 They will reach out sometimes to the state
22 that it's in to then reach out to the licensee, or
23 they'll contact the NRC regional, the regions, to find
24 out if we've gotten any of that information. Because

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1 it sometimes does take time, especially from those
2 corrective actions, based upon what they found the cause
3 to be.

4 So event happens, we expect the licensees
5 to do some sort of evaluation to, you know, they want
6 to know what caused it. And that can take some time,
7 and then what actions will correct that cause and those
8 causes.

9 So there is some time. But we do, my staff,
10 as events come in, if it's something that we think is,
11 you know, we want to know what's going on now because
12 it's a higher priority or we're seeing trends in it, we
13 will reach out to either our regions or our states or
14 our regional state agreement officers to make sure that
15 we're getting that information.

16 So that, and then when it's in NMED, like
17 I said, NMED contractors, they do go back and check that
18 as well. So there is, you know, there is some looping
19 back to try to get as much information as we can to keep
20 it as consistent as possible.

21 And we do see, as you pointed out, it isn't
22 always the same. And any time we see that or lack of
23 information, we do try to get as much as we can.

24 MS. WEIL: But then is that information

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1 about the consequences of the event and the corrective
2 actions that are taken, is that information available
3 so that this whole process can be proactive in promoting
4 safety? Or is it simply retrospective information?

5 MR. BOLLOCK: So you mean proactive to get
6 it out to other licensees, or more retrospective?
7 Again, there is always some delay in getting that. And
8 actually, Dr. Howe's presentation, getting as much
9 information including those causes and actions that we
10 have now is information from last year.

11 This is our being proactive. You know, we
12 did hear, we had an audit from our Offices of Inspector
13 General on medical program, and that was one of the
14 recommendations, to be more proactive, get this
15 information out here. So Dr. Howe, yeah, getting this
16 out there.

17 You know, these slides they go on our public
18 website. Just, I mean, all of these slides, along with
19 everything in this meeting, are going to be on the public
20 website for the meeting.

21 But we will take this section out, we have
22 done this for the past year and a half, we'll put it also
23 on our website for the public or any other licensees to
24 be able to get this information, and gather, you know,

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1 as much as we have. But unfortunately, there is, you
2 know, we don't always have it in a timely manner. But
3 we are proactive in trying to get it as much as we can.

4 But, you know, it really does come down to
5 what the licensee shares with, either their respective
6 regulator, whether it's us or the state, and you know,
7 at one point in their investigation, what actions
8 they've been taking.

9 DR. HOWE: And as far as the public
10 website, they're currently on our Medical Toolkit,
11 which is, we hope, the place that most medical use
12 licensees go to for information.

13 CHAIRMAN ALDERSON: So I would have what I
14 would call an editorial question. And my question only
15 relates to how information is presented to this
16 committee. Nothing about NMED, nothing about how
17 reports go out. Just how it comes to this committee.

18 And I was struck this year, as I think I
19 haven't before, by the similarity between TheraSpheres
20 and SIR-Spheres. When you look at, almost there was
21 only one category that was different in the two, the
22 exact same number of events, a very low number of events.

23 Should there be a consideration to
24 potentially combine these? They have one table with

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1 both things right there so you can look at that. And
2 then go through the information, not with respect to SIR
3 versus Thera, but really the kind of issue that resulted
4 in a medical event.

5 DR. HOWE: I've tended to keep them
6 separate because the microspheres work slightly
7 differently. One's a much smaller microsphere,
8 generally has no stasis issues with it.

9 The other one's a larger microsphere that
10 has stasis issues. And I just kind of kept them
11 separate so that people could understand. There's
12 nothing that keeps somebody from just putting them all
13 together and saying, this is yttrium-90.

14 CHAIRMAN ALDERSON: That's fine, thank
15 you.

16 MR. BOLLOCK: Dr. Tapp may have something
17 to add.

18 DR. TAPP: If I may. I'd like to add to
19 Doug's comment on how we proactively get this
20 information out. And it doesn't go directly to the
21 public, but another thing we do is when we see some
22 medical events that maybe you or maybe your inspectors
23 are unaware of, we do webinar trainings periodically as
24 a medical team.

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1 And we give trainings to agreement state
2 and regional inspectors, who then, as they're going to
3 the fields, they're asking the questions, Have you
4 looked for this type of event, or How are you watching
5 for these type of events that we may have seen in the
6 past.

7 So it isn't publically available, but this
8 is a training for the inspectors who then are going out
9 to the field, as well as we do this with webinars. And
10 every month, we have calls with our regional inspectors
11 as well.

12 MR. BOLLOCK: Yeah, and if I could add.
13 Yeah, our inspectors are trained to ask for, you know,
14 to ask to look at the corrective actions, but they are
15 trained to look for, as Dr. Howe said, the extent of
16 condition and the extent of cause.

17 So, they are, you know, they're the eyes and
18 ears for not just us, but the agreement states have
19 inspectors as well. And they're the eyes and ears for
20 us to get that, you know, get these questions asked and
21 kind of start that ball rolling to get the information
22 back to us.

23 CHAIRMAN ALDERSON: Yes.

24 DR. DILSIZIAN: Just coming back to that

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1 index case of the prostate, it strikes me that
2 retrospectively, there were six-fold higher incidence
3 of events than they detected prospectively. So should
4 I take that index case and say that what we're presenting
5 here is probably six-fold less than what actually
6 happens in most centers?

7 DR. HOWE: I don't know if I would come to
8 that conclusion. But I would come to the conclusion
9 that, and it also was kind of a factor in the VA, is that
10 for prostate brachytherapy, many facilities were
11 confused as to what was a medical event. And so they
12 may not have recognized medical events, or they may not
13 have been proactively looking back to see.

14 And one of the things that we're fixing in
15 this rule, and hopefully it will go through, is that
16 we're saying under 35.40, which is your program to
17 provide high confidence that the administration is in
18 accord with what was asked for by the AU, that people
19 check against medical event to determine if they have
20 a medical event.

21 So we think that will add more focus on
22 people understanding what a medical event is for a
23 particular modality.

24 CHAIRMAN ALDERSON: Fine. Any other

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1 questions on this part of the report? Yes?

2 DR. SUH: Just a question, so you
3 mentioned, you know, one of the common things you see
4 kind of yearly, is just, in terms of medical event
5 reporting, is that same type of medical event occurs.

6 DR. HOWE: Yes.

7 DR. SUH: Universal time-out isn't done,
8 patient's name, birth date, correct site. And so if you
9 look at the Perfexion Gamma Knife case, they treated,
10 I'm assuming with the dose that they gave, a trigeminal
11 neuralgia case, which is a benign condition for facial
12 pain. And they treated, they mistreated the wrong
13 side.

14 And you mentioned that there was
15 dissemination of this information as a public website.
16 Do you have sense of what percent of licensees actually
17 go to that public website to actually learn about this
18 information?

19 Because one of the concerns I have is, in
20 terms of the education of what types of medical events
21 occur each year, I would assume that there are a number
22 of licensees that are not familiar with the website.

23 And furthermore, if this information was
24 more readily available and they read this, I can tell

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1 you as a radiation oncologist, I read that, wow, there
2 was a center that treated the wrong side of the brain.
3 I'd better be extra careful next time and make sure that
4 my procedures and policies of how I do a time-out is
5 universal.

6 And to give you an idea, where I practice,
7 I mark the ear, I ask the patient which side of the head
8 are we treating today? This side. And so there's a lot
9 of time-outs that we do, and maybe we're, say we're more
10 excessive than some.

11 But I think sharing this information and
12 perhaps sharing of best practices would help to promote
13 this culture of safety and also promote best practice,
14 which is that educational part which, I know it's the
15 practice of medicine, but I think it would serve the
16 public very well in terms of minimizing.

17 DR. HOWE: And we do have problems getting
18 information out to licensees. We've tended, the NRC
19 website is quite large, and we've tended to put this in
20 the Medical Toolkit. And every time we talk to someone
21 from a licensee, we'll walk them through the Medical
22 Toolkit and show them where they can find the
23 information they're looking for.

24 And at the same time, explain to them that

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1 we cover a lot of things in this toolkit, this is meant
2 to help you understand your requirements, your
3 responsibilities, and also the information that we're
4 providing. So every time we get a chance, we try to
5 promote the Medical Toolkit, because it is the central
6 location to find information for all the medical
7 modalities.

8 It gives you inspection information,
9 licensing information, experience information, and
10 regulatory information. And the latest announcements,
11 like our gallium/germanium, like the moly shortages.
12 We put that there.

13 And it's, you know, and every time we get
14 a chance to talk to somebody, we bring it up and we try
15 to advocate for it. Because otherwise, it could be
16 hidden on the medical -- on NRC's website, and no one
17 would ever find it.

18 DR. SUH: Sure. And even just from a
19 trainee standpoint, if you want to think about training
20 the next generation, how do you minimize the risk of a
21 medical event occurring, how do you improve quality and
22 safety. Having this type of information would be very
23 important, because, again, I think it's very impactful.

24 Like for me, one of things that happens

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1 every time I leave an ACMUI meeting is my awareness of
2 quality safety heightens even further, because I read
3 this, and like, well, this could be the institution I
4 practice in and these things could happen.

5 DR. HOWE: And we're kind of hoping that
6 you as ACMUI members will also take this back to your
7 locations and your professional organizations and talk
8 up the Medical Toolkit and what it provides, so that more
9 people are aware of it.

10 We certainly put that information out to
11 our license reviewers, inspectors in the agreement
12 states. But if you guys can also disseminate it, I
13 think you'll find this a very helpful place.

14 CHAIRMAN ALDERSON: So I would suggest to
15 everyone as they begin to further explore this that we
16 are behind time again, so again, if you have questions,
17 let's get them out there. Who was -- we'll let Dr.
18 Langhorst go, she's part of the committee.

19 DR. LANGHORST: I just wanted to say that
20 RSOs probably delve into the Medical Toolkit much more
21 than anybody else in a licensee location. So I would
22 encourage RSOs, I know I try to send this type of
23 information out to the people who it impacts to help
24 share that information and do just exactly what Dr. Suh

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1 is suggesting, is getting that information to the right
2 people.

3 And even the Medical Toolkit can be very
4 daunting in trying to find what you're looking for. But
5 I would encourage all the RSOs listening and everyone
6 who then talks to another RSO to please, hey, keep an
7 eye out for these things and share it with the right
8 folks under your license.

9 CHAIRMAN ALDERSON: Thank you. Dr. Ouhib
10 and Mr. Bollock.

11 DR. OUHIB: Yeah, I think I share what Dr.
12 Suh just said there, and perhaps the manufacturer can
13 also help. In looking at the TheraSpheres and
14 SIR-Spheres, there were quite a few that appears to be,
15 I'm not going to say they are, appears to be
16 manufacturing issues perhaps. Or training, so that
17 ties the manufacturer there.

18 And therefore, perhaps they could be
19 instrumental in sending that information, because they
20 have access to all their users. And said, be aware of
21 here's what's been reported, and then provide
22 corrective actions or, you know, additional training.

23 CHAIRMAN ALDERSON: Mr. Bollock?

24 MR. BOLLOCK: I mean, we know a lot of

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1 manufacturers do exactly that. And we encourage all
2 licensees to have this information passed along to
3 everybody have, I mean, the bottom line, and we try to
4 share this at society meetings, anywhere we go.

5 The bottom line is, licensees are
6 ultimately responsible for their use of byproduct
7 material. And we do as much as we can, and we highly
8 encourage everyone to use it. But, and we understand,
9 we cannot go and talk to 100% of everyone who uses it,
10 because we don't -- but we do everything we can to get
11 it out there. We make it available.

12 So again, just we encourage you all to take
13 it back. And you know, we did listen to a number of
14 things, and clarifying what a medical event is, gave
15 that information out publicly. Passed that
16 information to the agreement states. Same with this
17 information now. So, there are limits to what we can
18 do.

19 CHAIRMAN ALDERSON: All right, so let's
20 move on to other medical byproduct material events.
21 And Dr. Langhorst at this time.

22 DR. LANGHORST: Thank you very much.
23 We're doing this a little differently but not really,
24 because this is the model that my esteemed colleague

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1 Ralph Lieto established years ago with Dr. Howe. And
2 I would hope someone will step into my responsibility
3 for a future time.

4 So just to remind you, these are NMED events
5 that involve a medical licensee or an associated
6 licensee. I learned this year that it should also
7 include the 35.3047 events, which is dose to embryo
8 fetus or nursing child. And it does not include medical
9 events.

10 And so I'm going to go real quick because
11 I know we're fighting time. So what I've given here
12 were the numbers that were for FY16, and then for a
13 perspective, FY15 that we discussed last fall. I have
14 these categories, and they're not the best, because
15 miscellaneous has a lot of interesting data: leaking
16 sources, loss of materials, shipping issues, and
17 landfill alarms.

18 So let me go through these. This slide
19 will take just a little bit. But there were four
20 identified, potential occupational overexposures that,
21 none ended up being an overexposure. One was a high
22 dosimeter reading that they later attributed to a
23 potentially contaminated dosimeter. But they couldn't
24 prove that because it was a very short-lived PET

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1 isotope.

2 Another was extremity contamination.
3 This happened with QuadraMed administration that there
4 was a bit of a blowback during injection. And there was
5 contamination that they estimated was about one to two
6 millicuries. The radiation safety officer was not
7 contacted, even though there was personnel
8 contamination, occupational personnel contamination.

9 And did not appear that there was cleanup,
10 adequate cleanup afterwards. And so the RSO was
11 contacted the next day. It did not look like people
12 were going to get a high extremity dose, or over the dose
13 limit, but they did not follow their procedure. So
14 please, work with your RSO and have them involved.

15 Another one was a courier that came to pick
16 up PET, that's hard to say, PET isotope containers to
17 take back to the pharmacy. He accidentally picked up
18 a lead pig that contained two germanium calibration
19 sources. When loading it into his vehicle, the lid
20 slipped off, the sources came out.

21 He picked them up, just put them on top of
22 the stuff, and he took them back to the pharmacy. They
23 were concerned he might have gotten an overexposure, but
24 it turned out did not.

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1 The fourth one was a group of nuclear
2 medicine staff that had high dosimeter readings, and did
3 not make sense, because one of the higher dosimeter
4 readings was the director, who had not even worked with
5 radioactive material during that time. And the
6 licensee was investigating it as someone interfering
7 with those dosimeters and exposing them to radiation.

8 Two declared pregnant workers. One had
9 three months of higher readings. Again, that licensee
10 felt that there could have potentially been dosimeters
11 that were intentionally exposed by another person.

12 The second one was at nine months. The nuc
13 med tech had received just a little bit more than 535
14 millirem on their dosimeter. And so they were
15 enhancing their ALARA program to look to see that they
16 might change job duties as people got to certain
17 categories, or certain percentages of the dose limit.

18 Let's see. There was one 35.3047
19 exposure. The patient was nine days post-conception.
20 The pregnancy test did not identify it, and they said
21 the cause was that the patient did not follow
22 instructions to abstain from sex prior to the therapy.
23 And so that one you will see in the abnormal occurrence
24 report.

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1 There were two suspected public
2 overexposures. One was a patient being treated with
3 low dose rate therapy, cesium-137, and a person staying
4 the night with them, stayed the night with them, laying
5 in bed with them. And so procedures were not followed
6 to make sure visitors were not allowed to do that.

7 And another person was exposed to 200
8 millirem who had volunteered to test a cardiac PET scan
9 so that they could gain operational experience. That's
10 not quite allowed. There was equipment failure on an
11 HDR, this is during source exchange, and the service
12 engineer was there and aware. And so that was
13 equipment failure, but in a very controlled manner.

14 And contamination. One I-131 patient
15 returned to the ER an hour after administration and
16 didn't tell the ER about that. The ER personnel they
17 were estimating maybe got three millirem. So just a
18 reminder that patients, even if you give them a card they
19 can hand somebody.

20 And then one was an I-131 patient who had
21 trouble swallowing the capsule, and so instead tried
22 chewing it, and later expelled that. So they estimated
23 there was about 3.7 millicuries of I-131 contamination
24 on that one. And then there was no recordkeeping for

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1 this time.

2 Leaking sources. Most of the leaking
3 sources were identified by the normal sealed source leak
4 test. And so when you exceed a certain contamination
5 level, you have to report that.

6 There were a couple germanium-68 sealed
7 sources that, one they identified was maybe damaged
8 during maintenance. Another one they were not sure,
9 but these were on PET scanners. And so that they
10 identified that.

11 And one was an I-125 localization seed that
12 they felt potentially was damaged during a pathology
13 evaluation of the tissue following that procedure.

14 There were eight lost seeds from this I-125
15 localization procedures. Lost in various positions
16 along that process. I think that all were identified
17 as being found at the time they were removed from the
18 patient, but were lost either by the time they got to
19 pathology, or some time during pathology, so.

20 There were two stolen calibration sources.
21 One patient that was released pulled out 11 seeds from
22 a therapy and threw them in his home trash, so that was
23 another one.

24 And there was one where a licensee could not

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1 account for the generally licensed source that was in
2 a piece of equipment that had not been used for years.
3 They felt that they may have gotten rid of that generally
4 licensed source in the 1980s, but they didn't have any
5 documentation of that disposal, so that was a lost
6 source.

7 Shipping issues. There was issues with
8 delivery sources. Two carriers mistakenly
9 transferred, or a carrier mistakenly transferred
10 sources to the United Postal Service. And by the time
11 it ended up at the licensees, it wasn't, the sources were
12 for implants, they weren't hot enough to be used.

13 There was an accident where the vehicle was
14 taken to a tow yard but there was two radioactive
15 packages in there. And so those were found after the
16 vehicle got towed there.

17 Several shipping package issues with
18 contamination on the outside. So it's very good to make
19 sure you're checking for that. And sometimes the
20 activity, the isotope outside the package was not what
21 was inside. And a couple of them were where the label
22 was stuck on, that maybe contamination when they put
23 that final label on the package. So you'd have to be
24 careful on that.

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1 There was one where the location did not
2 have a license to receive. And this was for a Xofigo
3 shipment. The clinic had had a license and could
4 receive it. They merged with another entity, went
5 under that other entity's license, that other entity
6 didn't have license for that. And so that was
7 understandable. So be careful as you merge and change
8 licenses.

9 There was an HDR source that was sent the
10 delivery, and I meant to say this at the beginning, at
11 the first one, the delivery was tried after hours. And
12 there was lots of confusion of where the HDR source --
13 there wasn't confusion where the HDR source was, but it
14 was confusion about how, when they couldn't deliver it
15 after hours, how it was supposed to get there. And
16 there was a lot of sorting out of that.

17 There was two sources lost during shipment
18 -- excuse me, one lost during shipment. And then
19 another HDR source that wasn't the right source, the
20 vendor had sent the wrong source. And so it was
21 reported as lost, but it was found, and it was the wrong
22 source going to that licensee.

23 And then, here's my table for the landfill
24 alarms, and tried only to list those that could

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1 potentially be medical. Although I will mention that
2 the I-131s found in landfills could be from veterinary
3 procedures. And so here's the information on that.
4 Again, California has a robust program in this regard.

5 And that's the end of my presentation.

6 CHAIRMAN ALDERSON: Do we have questions
7 or comments on this medical event report?

8 DR. DILSIZIAN: Just one.

9 CHAIRMAN ALDERSON: Dr. Dilsizian.

10 DR. DILSIZIAN: Just a curiosity question.
11 The I-131 patient went to the ER. You said the
12 exposure, was that a therapeutic dose, a high dose?

13 DR. LANGHORST: Yes, yes.

14 DR. DILSIZIAN: So, as you know, the
15 patient should still have the name label on the wrist
16 and should have radioactive labeled on it, saying that
17 for three days, right, they're supposed to wear the
18 bracelet arm. That's usually the rule, so I was
19 wondering --

20 DR. LANGHORST: No, there's no rule.
21 There's no rule for that. That may be your process, but
22 no, there is no rule for that.

23 DR. DILSIZIAN: It's part of our directive
24 to, you know, you're supposed to wear that for three days

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1 just in case EMT or ER.

2 DR. LANGHORST: No.

3 DR. DILSIZIAN: That's the purpose. Oh, I
4 didn't know that was --

5 DR. LANGHORST: That's your local
6 facility.

7 DR. DILSIZIAN: So we have a good system.

8 PARTICIPANT: Maybe we should make that
9 part of the rulemaking.

10 CHAIRMAN ALDERSON: All right, so. Oh,
11 yes, Dr. Palestro.

12 DR. PALESTRO: Sue, very interesting
13 presentation. One particular case intrigued me was the
14 incident of the I-131 administration to a woman who was
15 pregnant, and it was attributed to the fact that she
16 didn't adhere to the admonitions to refrain from sexual
17 relations.

18 It's interesting to me because we do
19 several hundred I-131 therapies a year, and that's
20 always a concern. But I wonder how they arrived at that
21 conclusion. And the information isn't there. What
22 was the time interval between the pregnancy test and
23 treatment?

24 Did they have a document in front of them,

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1 a lab report, saying that the patient was not pregnant?
2 Was this an oral report over the phone, or something
3 faxed to them by another office? Was it a urine
4 pregnancy test, was it a blood pregnancy test?

5 All sorts of other questions that come up
6 that I think set the stage potentially for failure in
7 these circumstances. And then I think that sort of
8 incident would be an excellent educational tool. And
9 that's it.

10 DR. LANGHORST: And again, NMED doesn't
11 have all that information. So yes, I understand.

12 CHAIRMAN ALDERSON: Dr. Ennis.

13 DR. ENNIS: Just kind of thinking about
14 educational tool and what Donna-Beth said before. And
15 I know she's made a lot of effort and great to do outreach
16 now to the societies like ASTRO and all that. I would
17 suggest a particular focus on residency societies would
18 be really good, like in radiation oncology, there's a
19 society called ARO.

20 I'm sure in nuclear medicine, there are
21 similar societies. And I think those particular
22 audience where you have your greatest impact, people
23 thinking about getting out. And everyone gets a little
24 bit of exposure from their own practice, but they have

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1 no world view.

2 And they have no idea of what else is going
3 on outside of generally high quality programs, and where
4 are they going to end up, in a small practice. And all
5 of a sudden they have all this responsibility. And I
6 think bringing some case studies, for example, you were
7 kind of alluding to this could be a great case study,
8 I think you could have a lot of impact for the amount
9 of time.

10 CHAIRMAN ALDERSON: Do we -- we haven't
11 asked, I haven't asked this morning, but I will ask now.
12 Has there been any member of the public who's been on
13 the listening situation who would like to raise a
14 question in any way, or would like to ask us about some
15 of the events of this morning before we break for the
16 lunch hour?

17 There's no one on the phone. They're all
18 at lunch. That answers that question. All right, are
19 there any other issues that people wish to bring before
20 us before we break?

21 DR. OUHIB: Yeah, let's just comment.
22 There has been an effort, I know the ABS just recently,
23 like the last week, I was actually chairing the medical
24 event session, and that was oriented toward residents.

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1 We are doing something similar at the AAPM,
2 the medical event section. And that's oriented toward
3 new graduate or graduate students, or new medical
4 physicists, to actually educate them about that whole
5 process. So there's a lot of effort there to actually
6 educate people.

7 And the ABS, we talked about it, and having
8 another one which will be more like a few hours session
9 for residents going through eight different places how
10 you prevent it, what actually could happen, and so on
11 and so forth. So there's a lot of work involved.

12 CHAIRMAN ALDERSON: Good. Given that we
13 just have a moment here, I'd like to go ahead and do a
14 bit of business, which is to talk about the subcommittee
15 that we're establishing to review the Icon Gamma Knife
16 details.

17 And of course, this is a therapy issue, and
18 I know that John, Dr. Suh is an expert, certainly not
19 experienced necessarily with Icon, but with the Gamma
20 Knife.

21 DR. SUH: I actually have that experience
22 now.

23 CHAIRMAN ALDERSON: Good, well, I'd like
24 to suggest that perhaps you would be the chair of this

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1 committee. That Ron, as another radiation oncologist,
2 not with experience, but that you be a member of this
3 committee. I think Dr. Ouhib would be good. He can
4 only be a consultant now, I believe, because he is not
5 fully approved. Yes --

6 MR. BOLLOCK: Yeah, he can only do it on a
7 voluntary basis.

8 CHAIRMAN ALDERSON: He would like to
9 volunteer.

10 DR. OUHIB: I'd be happy to.

11 CHAIRMAN ALDERSON: Yeah, he's a voluntary
12 consultant.

13 MR. BOLLOCK: Yeah, unfortunately we
14 cannot ask, and thus you cannot ask him to be an official
15 member to actually do official work.

16 CHAIRMAN ALDERSON: Well, then if you
17 would like to approach Dr. Suh, you know. Free advice.

18 MS. SMETHERS: Dr. Alderson, could I just
19 say, so now that we have ten voting members, we can only
20 have up to four on a subcommittee. I thought it was five,
21 it's four.

22 CHAIRMAN ALDERSON: Yeah.

23 MS. SMETHERS: The past is okay.

24 DR. ENNIS: Including consultants?

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1 MS. SMETHERS: Good question. He's not a
2 member, so, yeah.

3 CHAIRMAN ALDERSON: So we could have up to
4 four. So there was one more member I was going to ask
5 to consider this. And that's Laura Weil, because it is
6 basically a safety, ultimately that's what your
7 questions were earlier, and it is a patient safety
8 issue. So would you be willing to be on this group?

9 MS. WEIL: Sure.

10 CHAIRMAN ALDERSON: Okay. All right, so
11 we know that we have Dr. Suh, Dr. Ennis, and Ms. Weil.
12 And other people might want to volunteer to join them,
13 but we will say nothing official about that particular
14 issue. Are there any other comments before we break for
15 lunch? Hearing none, I think we're adjourned until one
16 p.m.

17 (Whereupon, the above-entitled matter went
18 off the record at 11:54 a.m. and resumed at 1:03 p.m.)

19 CHAIRMAN ALDERSON: All right, we've
20 reconvened, so if no objections, we'll get the afternoon
21 session underway.

22 And, then up will be Dr. Palestro and his
23 group on the training and experience for all
24 modalities.

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1 DR. PALESTRO: Thank you, Dr. Alderson.

2 First, I'd like to acknowledge the efforts
3 and contributions of the Subcommittee Members, Sue
4 Langhorst, Darlene Miller, John Suh and Laura Weil,
5 thank you.

6 So, the ACMUI Standing Subcommittee on
7 Training and Experience was established about a year ago
8 with the specific charge to periodically review
9 training and experience requirements currently in
10 effect for all modalities and to make recommendations
11 for changes as needed.

12 We were charged with the review of the
13 training and experience requirements for the uses of
14 unsealed byproduct materials including 10 CFR 35.100,
15 200, 300 and 1000 as well as for sealed byproduct
16 materials, 35.400, 500, 600 and 1000.

17 The guiding principle under which we
18 function is that our recommendations regarding training
19 and experience should ensure that, number one, the
20 requirements and provisions in Part 35 which provide for
21 the radiation safety workers, the general public,
22 patients and human research subjects are satisfied.

23 And, number two, that patient access to
24 these procedures is not unnecessarily compromised.

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1 In other words, we really have a balancing
2 act between maximizing safety and maximizing patient
3 access.

4 The issues that need to be addressed and are
5 being addressed by the Subcommittee include the
6 periodic review of these training and experience
7 requirements, addressing competency and addressing
8 patient access. And, these really are all very much
9 interrelated.

10 In terms of what constitutes a reasonable
11 review interval, while it's been about 15 years since
12 the training and experience requirements were reviewed
13 and revised and 15 years, I think is too long, much too
14 long particularly considering the accelerating pace of
15 new developments over time.

16 At the other extreme, a one year interval
17 is simply impractical. And, the Subcommittee has
18 settle on at least for the moment, what we think is a
19 reasonable, practical and attainable interval of five
20 years.

21 However, that five year interval does not
22 preclude an accelerated review if circumstances
23 warrant. And, what sort of circumstances might warrant
24 an accelerated review?

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1 The introduction of a new procedure
2 potentially, an increase in the number of medical events
3 or radiation safety events and perhaps other situations
4 that aren't enumerated here.

5 One of the things that we have or one of the
6 issues that we have encountered is, in going back
7 through the old records and the information available,
8 it's not entirely clear as to how the training and
9 experience requirements were established and what the
10 thought processes were behind them.

11 And, it's not to suggest that they are wrong
12 or they are incorrect, but it would have been extremely
13 useful, extremely helpful to us, if we understood the
14 rationale for their implementation and for their
15 design.

16 And so, we've decided that we really need
17 to try to develop a review template to standardize our
18 approach to the review of each of these various
19 categories.

20 And so, this is a template, a draft
21 template, if you will, that we have developed for
22 training and experience requirements for 35-whatever
23 and classification of the training and experience
24 requirements could be into broad categories such as

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1 appropriate, inappropriate, obsolete even.

2 But, if we're going to classify them, how
3 are we going to evaluate them? There has to be some sort
4 of rationale behind that classification.

5 So, we would propose to look at medical
6 events, radiation safety events and issues regarding
7 patient access.

8 In terms of classifying the training and
9 experience requirements, first, we have appropriate,
10 inappropriate, obsolete even. But, if we're going to
11 classify them, how are we going to evaluate them? There
12 has to be some sort of rationale behind that
13 classification.

14 So, we would propose to look at medical
15 events, radiation safety events and issues regarding
16 patient access.

17 In terms of classifying the training and
18 experience requirements, first, we have appropriate.
19 Inappropriate we can further subdivide into
20 insufficient requirements, and, at the other extreme,
21 excessive requirements and then, finally, requiring
22 training and experience requirements and perhaps for
23 obsolete.

24 So, what would be the definition of

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1 appropriate training and experience requirements?

2 Well, in evaluating medical events and
3 radiation safety events, few or none. And, how one
4 defines few, I think, is really, at this point, a matter
5 of conjecture. It might be a certain percentage
6 threshold which could be defined as few.

7 Constant or trending downward number of
8 these events over time and finally, adequate patient
9 access.

10 What about inappropriate training and
11 experience requirements?

12 Well, let's take a look at the insufficient
13 category. If there are frequent or many medical events
14 or radiation safety events, again, with those numbers
15 thresholds to be defined or there is an upward trending
16 of the -- in terms of numbers of these medical events
17 or radiation safety events.

18 At the other extreme or inappropriate are
19 the excessive requirements, few or no medical events,
20 radiation safety events, no upward trending of these
21 events.

22 But, then, there's inadequate patient
23 access, it's time to reevaluate those requirements to
24 see what can be done to improve patient access without

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1 compromising safety.

2 Then finally, there's a potential
3 category, obsolete. And, those training and
4 experience requirements would be classified as
5 obsolete, for example, for procedures that are no longer
6 performed or perhaps there are no authorized users.

7 So, the classification of the training and
8 experience requirements should be based, at a minimum,
9 on an evaluation of medical events, radiation safety
10 events and patient access.

11 In evaluating and looking at medical
12 events, it's not simply enough to look at the number and
13 the trends, but we really need to try to analyze why
14 these medical events are either increasing in number or
15 trending upward or they are occurring frequently.

16 And, the analysis could look at, is it a
17 procedural issue? For example, is this a new procedure
18 that's been recently introduced? Is there a problem
19 with the procedure?

20 It could be a procedure that's already in
21 place where something in that procedure has changed that
22 may account for an increasing number of medical events.

23 Is it a competence issue? Or, is it
24 equally possible, a combination of both procedure and

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1 competence?

2 The same is true for radiation safety
3 events, and these are some examples, high occupational
4 doses, lost sources, improper record keeping, lack of
5 instrument checks or calibrations.

6 Evaluate the number and trending, look at
7 the number of enforcement actions, the type of
8 enforcement actions, and again, with those data in hand,
9 analyze the explanation, the causes.

10 Once again, is it a procedural issue? Is
11 it a competence issue? Or, in fact, is it a combination
12 of the two?

13 What about patient access? Do current or
14 proposed regulations limit patient access to
15 procedures? Do current or proposed regulations
16 provide adequate protection from unintended radiation
17 exposure and, in fact, are the pathways accessible and
18 reasonable for individuals seeking to obtain authorized
19 user status?

20 Competency is an issue that the
21 Subcommittee continues to grapple with. General
22 definition of competence or competency is the ability
23 of an individual to do something, to perform a task,
24 especially when measured against the standard?

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1 The medical definition of competency is
2 that it is a principle of professional practice that
3 identifies the ability of a provider to consistently
4 administer safe and reliable care.

5 How does one determine or how do we
6 determine competence or competency?

7 Well, the vast majority of authorized
8 users, obtain authorized user status by passing a
9 certification board -- certification examination given
10 by one or more Boards, such as the American Board of
11 Nuclear Medicine, the American Board of Radiology, that
12 have achieved or have been designated deemed status by
13 the Nuclear Regulatory Commission.

14 And, that's the simple part.

15 But, what about the potential alternative
16 pathway for individuals who are not certified by these
17 Boards?

18 One question that certainly arises is,
19 should there be an alternative pathway? And, that's a
20 question that needs to be addressed.

21 Assuming that the answer is yes, there is
22 at least being considered, what's the best structure for
23 that alternative pathway?

24 One is didactics and some practicums with

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1 examinations and so-called hands-on experience with
2 preceptor certification.

3 Another interesting alternative that was
4 recently brought up, and I suspect that some people --
5 some organizations will view this as heresy, it is
6 simply a practical examination. That is, there is a
7 course, if you will, for lack of a better term, course
8 outline indicating what the necessary knowledge is for
9 an authorized user.

10 And, rather than establishing numbers of
11 hours, laboratory, clinical experience, so forth and so
12 on, simply devise an in depth practical examination that
13 would be carried out by an independent examining
14 committee.

15 And, by that I mean, a situation or
16 examination in which various simulations can be carried
17 out and simulations have become an integral and
18 important part of medical education where you can have
19 simulated medical events, simulated radiation safety
20 events and so forth.

21 So, under this concept, or under this
22 possibility, there would be no number of hours. There
23 would undoubtedly be a certain number of cases, minimum
24 number of cases in which an individual would have to

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1 participate.

2 But, the determination of competency and
3 authorized user status would be based on satisfactory
4 passing or completion of this so-called practical
5 examination.

6 So, this is the review template example. I
7 know that there is a lot of interest and enthusiasm and
8 angst, if you will, about 35.300, but it was clear to
9 the Subcommittee that, at this point, we simply were not
10 ready to try to make recommendations about 35.300 and
11 we chose a much narrower, less complex category, 35.190,
12 which is training for uptake, dilution and excretion
13 studies.

14 So, when we evaluate 35.190, we found that
15 there were no medical events reported over the past ten
16 years.

17 Unfortunately, data on radiation safety
18 events are not available and Dr. Howe, please correct
19 me if I misstate what I'm going to state now.

20 And, the reason why those data are not
21 available is because, apparently, there are no
22 individuals who are authorized users only for 35.190,
23 at least no data available on them. And, hence, these
24 radiation safety events are grouped in with 35.200.

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1 Is that correct, Dr. Howe?

2 DR. HOWE: We may have one or two somewhere
3 in the country, but not much more than that.

4 DR. PALESTRO: So, based on the data that
5 we have available to us, we would classify this 35.190
6 training and experience as appropriate.

7 Though the Subcommittee acknowledges and
8 appreciates the NRC staff input, particularly with
9 reference to radiation safety events, especially the
10 efforts of Ms. Maryann Ayoade. And, we strongly
11 encourage continued input from not only the NRC staff
12 and the remainder of the ACMUI, but stakeholders as
13 well.

14 In terms of stakeholder input, we can talk
15 about informal and formal.

16 Informal stakeholder input is when
17 stakeholders, interested individuals, interested
18 organizations contact myself or members of the
19 Subcommittee or when I or members of the Subcommittee
20 reach out to various individuals and organization and
21 ask for your input.

22 This is a lot faster than going through the
23 formal review, formal request for stakeholder input.

24 The downside of this is that it offers

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1 a potential for bias. And, why do I say that? Because,
2 in all likelihood, I'm going to approach individuals who
3 I know, with whom I work, organizations with which I am
4 familiar and probably to a very great extent have the
5 same mind set, the same thoughts as I do.

6 So, again, there's that potential for bias.

7 On the other hand, it certainly is a good
8 way to start.

9 At some point, if and when we advocate for
10 rule changes, then we'll have to go through the formal
11 stakeholder input which will be slower but will have the
12 advantage of incorporating a broader respondent base.

13 Thank you.

14 CHAIRMAN ALDERSON: Dr. Palestro, I'd like
15 to compliment you on really outlining an excellent
16 process, you and the Committee. I think this is a
17 process that can be sustainable as you go forward.

18 But, the question I would start this
19 session of questions with is, so what's the next steps?

20 So, now that you've got the paradigm and
21 you've looked at one limited category, what's the
22 Committee's view about what will happen next?

23 DR. PALESTRO: I think I speak on behalf of
24 the Subcommittee that the next step would be to go

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1 through each of the subcategories of 35.

2 And again, I know that 300 is a, quote,
3 unquote, hot topic but I kind of think that the next one
4 that we would be doing or should be doing is 200.

5 It's larger than 100, it will give us a
6 chance to flesh out the template, the review template,
7 and perhaps identify deficiencies, if you will, in the
8 template as it currently is.

9 And, we'll also allow time for input from
10 various individuals, stakeholders and so forth, that
11 will allow us to tackle 35.300, which I think is going
12 to be far and away more complicated.

13 CHAIRMAN ALDERSON: Yes, but for me,
14 that's a good answer. I think that's a good approach.

15 Comments from the ACMUI or questions?

16 Pat? Zanzonico? Dr. Zanzonico?

17 DR. ZANZONICO: Yes, I think it was an
18 excellent start to what seems like an intractable
19 problem at times. I mean, really well done.

20 The emphasis, I think, appropriately is on
21 radiation safety. You know, another aspect of this
22 obviously is clinical competency. And, that may be
23 beyond the scope of regulation and so forth.

24 So, is that implicit in your approach or --

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1 well, that's the question. Is that implicit in the
2 approach that clinical competency is left to the
3 certifying Boards, professional societies, so forth and
4 so on, independent of AU status?

5 DR. PALESTRO: Yes.

6 DR. ZANZONICO: Okay.

7 DR. PALESTRO: Yes, I don't think that
8 we're in a position to judge clinical competency, nor
9 should we attempt to.

10 DR. ZANZONICO: No, I agree, I think that
11 should be a sub-policing sort of component of all this.
12 But, yes, I think it's a great start and very systematic
13 approach.

14 DR. PALESTRO: Thank you.

15 CHAIR ALDERSON: Yes? Dr. Dilsizian?

16 DR. DILSIZIAN: Again, great
17 presentation, challenging.

18 And, I understand why the Committee had
19 difficulty with the competency issue.

20 So, a couple of comments, when you said the
21 primary competency is based on certification, I think
22 where there needs to be clarification is that that's
23 just not just certification, you need to have a
24 predetermined years of training that follows to a

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1 certification.

2 No one can sit on an internal medicine board
3 unless you've done three years of internal medicine
4 residency.

5 So, I think that I would just expand on
6 that. It's not just a certification, it's having
7 proper training as defined for that subspecialty which
8 follows by certification.

9 You want to answer?

10 DR. PALESTRO: Yes, you know, I understand
11 what you're saying.

12 DR. ZANZONICO: No one sits on a Board
13 without having proper years of training, no one. That
14 is a requirement.

15 DR. PALESTRO: You're absolutely correct,
16 but I'm not sure that that's germane to this because
17 ultimately, the determination of whether or not the
18 individual attains authorized user status is whether or
19 not they pass the certification examination.

20 And, in addition to that, there are some of
21 the Boards that give credit for all sort of different
22 things that an individual has done.

23 So, that individual may or may not have
24 spent the quote, unquote requisite three or four years

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1 in the training program.

2 DR. ZANZONICO: And, that's good.

3 And, then the reason I say that is because,
4 part two, which is your alternative pathway which is a
5 slippery slope.

6 Because, if you make it so that the
7 alternative pathway, you know, you can just do a weekend
8 course and have some questions answered, why would
9 anybody go through regular three years of training plus
10 a Board certification if I can go through the alternate
11 pathway that happens to be much easier?

12 So, I mean, just as a thought, I think that
13 there should be equally competent competency. It
14 should be regimented so that there's not an easier
15 pathway that, therefore, the regular pathway which is
16 well-defined becomes minimized.

17 DR. PALESTRO: Yes, I understand and I and
18 the Subcommittee agree with you that, whatever criteria
19 are established for an alternative pathway, assuming
20 there is one, have to be equally stringent.

21 But, that doesn't mean that someone
22 necessarily had to spend four years in a program to meet
23 equally stringent requirements.

24 For example, and again, I say I'm sure that

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1 there are a lot of folks consider it heresy if we say,
2 there are no requirements other than X number of cases
3 but you have to come and complete a very rigorous on site
4 personal examination. That, too, might suffice.

5 And, I'm not saying that it does, we're just
6 simply putting it out there as an alternative and
7 looking to gain feedback such as from yourself to help
8 guide us as to what the best approach is. And, I'm not
9 sure that we've fully resolved that yet, to be honest
10 with you.

11 CHAIR ALDERSON: Other questions? Yes,
12 comments?

13 Mr. Green?

14 MR. GREEN: I think it's a great template.
15 It's a big issue to tackle and it was an issue that came
16 up at the fall meeting.

17 I've seen RAM licenses where, for some
18 reason, the licensing agency felt that this authorized
19 user position should be restricted to unit doses only
20 versus someone who has the training experience to -- or
21 the facilities, I'm not sure why, but to have a generator
22 of made kits and a usable bulk tech.

23 And, I've seen RAM licenses that say, you
24 can use capsule iodine only or you can use liquid iodine.

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1 And, we're looking at the 100 to 200 to 300
2 and the various other categories in 35 CFR, but I wonder
3 if there's a possibility to take that kind of a spin on
4 limited access? Whether a unit dose user only of
5 certain types of products, if that would allow a
6 different educational path?

7 You know, a full authorized user position
8 has to know imaging, gamma cameras, quality control, all
9 of that. But, in the beginning of the 300s, you don't
10 have that, the camera, all the imaging aspects of the
11 authorized users dealing with the medicine today.

12 DR. PALESTRO: That's one of the issues
13 that the Subcommittee and, obviously, the ACMUI will
14 have to deal with when we get into the 300 category which
15 is why I want to proceed slowly and start with 200
16 because some of the issues you mentioned actually may
17 come up in the 200 series even for diagnostic.

18 CHAIRMAN ALDERSON: Dr. Zanzonico has a
19 comment.

20 DR. ZANZONICO: Yes, what I like about this
21 approach is that it implicitly or it may be explicitly,
22 it separates the issues of clinical competency which is
23 a nonregulatory issue from radiation safety competency
24 which is a regulatory issue.

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1 And, whatever the ultimate form of the
2 radiation safety competency is, that shouldn't replace
3 at all or detract from clinical competency and,
4 therefore, from clinical training.

5 So, I don't think the alternative pathway
6 is, in a sense, a threat to physicians, specialists, who
7 go through that pathway.

8 It's like it's a different skill set and I
9 think part of the complexity of what we're trying to deal
10 with is that, they've been mixed together.

11 And so, it's hard to address either one
12 rationally in a sense. But, in terms of what the
13 approach you've proposed, effectively separates out the
14 radiation safety competency and I think it makes it a
15 lot more tractable and so forth.

16 But, the point I want to make is, I don't
17 think it at all limits or provides any sort of shortcut
18 to specialist in terms of clinical competency. I mean,
19 I think they still would be required to go through a
20 lengthy residency and fellowship program where they
21 learn that clinical specialty.

22 The question is, how can they meet the
23 requirements for radiation safety competency in a
24 reasonable way? And, I think that's an excellent

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1 approach that you've provided.

2 CHAIRMAN ALDERSON: Thank you for that
3 comment.

4 Other comments?

5 Yes, Dr. Langhorst?

6 DR. LANGHORST: I think one of the
7 difficulties on the alternate pathway has always been
8 how you judge the clinical competency. And, I think
9 it's always been an uneasiness for the preceptor to sign
10 off on it.

11 And, we've suggested several statements of
12 really what they're saying and it really comes down to
13 the radiation safety, the regulated piece of what
14 they're doing.

15 But, it doesn't come down to the clinical
16 competency.

17 The Boards help support the documentation
18 that someone has had the radiation safety regulatory
19 training. They also address the clinical competency.

20 So, there's always been that uneasiness
21 with the alternate pathway. The alternate pathway also
22 is hard to judge when you have someone who is practicing,
23 has gone through their clinical training.

24 But, how do they now step into a new role?

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1 And, what is exactly the competency and the radiation
2 safety aspect of what they need to do?

3 And so, do they have to go through a
4 residency again? Well, that's crazy. In fact, some
5 people think they don't need to go through all the
6 training that's listed in the alternative pathway.

7 But, I think the alternative pathway, the
8 emphasis then really has to be on how you meet the
9 regulatory requirements for safety and safe radioactive
10 materials.

11 Thank you.

12 CHAIR ALDERSON: I don't see any other
13 hands here at the moment. I'm going to ask if there are
14 people -- there is a hand.

15 Mr. Fuller?

16 MR. FULLER: Yes, I would just like to ask,
17 because, up until this discussion today, we've kind of
18 discussed this and with slightly terminology. So, I
19 just want to make sure that I understand and the medical
20 team understand what everyone means.

21 Because, obviously, we're not clinically
22 trained and so, we need to make sure that we understand
23 what you mean by clinical competency.

24 So, to put it in different terms, what we've

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1 talked about in the past and what we rely upon the ACMUI
2 for is the patient safety aspect.

3 So, when it comes to occupational safety
4 with the use of these materials, we understand that and
5 we have that. We have those skills, we have that
6 knowledge, we have that expertise.

7 When it comes to public health and safety,
8 we've got that.

9 When it comes to patient safety, that's
10 where we rely upon this body, to help us understand what
11 the regulatory requirements should be in order to ensure
12 that the patients are safely administered the
13 radioactive material.

14 So, what I'm hearing today is maybe a little
15 bit of a different twist on that in that you're talking
16 about the radiation safety aspects versus the clinical
17 aspects.

18 And so, it would be nice, I think, for the
19 staff to hear a little bit more about how these slightly
20 differing approaches to this problem either overlap or
21 where the nexus is.

22 Because our Commission in the past, when
23 we've gone through rulemaking for this sort of this has
24 made it clear that patient safety is also very, very

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1 important and has to be addressed in our regulations.

2 So, if somebody could help me with that?

3 CHAIR ALDERSON: That's an excellent
4 comment. I'm going to turn it to Dr. Palestro, because
5 I believe that in listening to the paradigm that you've
6 developed this template that you must have considered
7 that really very difficult question in doing what you
8 did. So, please, Dr. Palestro?

9 DR. PALESTRO: The answer is, radiation
10 safety events, radiation safety section was
11 incorporated at the recommendation of staff.

12 And, our concept is that, in order to carry
13 out, if you will, the mandates of maintaining patient
14 safety, public safety and so forth, that an individual
15 has to be quote, unquote, competent, not only in medical
16 or clinical safety, if you want to call it that, but
17 radiation safety as well.

18 It's not enough to understand how to
19 prevent or how to manage a medical event when you don't
20 know how to deal with a radiation safety event.

21 Some of the examples that we gave, the lost
22 sources and so forth and so on.

23 So, I think it's a broader scope than what
24 we originally focused on because I certainly, as the

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1 Chair of the Subcommittee, wasn't thinking about
2 radiation safety events. I was thinking about medical
3 events because I deal with the patient on a daily basis.

4 And quite frankly, our RSO deals with the
5 radiation safety events.

6 But, I think if want to approach it from a
7 more complete aspect and remember that, in the majority
8 of institutions in this country, often times the AU is
9 also the RSO. That individual has to be cognizant not
10 only of medical events, be aware of capable of clinical
11 competency, but also has to be aware and capable of
12 managing radiation safety.

13 I don't know if that answers your question.

14 MR. FULLER: That helps, thank you.

15 CHAIR ALDERSON: Yes, Dr. Ennis?

16 DR. ENNIS: I haven't had a lot -- I
17 obviously haven't really had time to think about this,
18 but that much, but Mike's question, I think is really
19 actually very insightful.

20 And, it makes me feel like I don't really
21 agree with the dichotomy that you, Pat, suggest. I'm
22 feeling like they're completely intertwined, they are
23 not separate.

24 How can I be trained in the regulatory

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1 aspects of I-125 brachytherapy, for example, without
2 understanding the clinical aspects of how that
3 radiation interacts with the patient?

4 And, the -- by authorization to use I-125
5 isn't just because I know how to use a survey meter or
6 do a dose calculation or have memorized the half-life
7 or --

8 But, it's how it interacts with the patient
9 which is in part clinical. And, this is probably why
10 this committee is always struggling with what's
11 regulatory versus clinical.

12 But, the formulation I think I heard, it
13 didn't really dawn on me until Mike articulated it, but
14 feels very much like a Radiation Safety Officer job as
15 opposed to a nuclear medicine physician or a radiation
16 oncology physician.

17 And, which I think NRC has turned to the
18 Boards to kind of give the authorization because they
19 are the ones who can kind of do both pieces of that as
20 an integrated unit.

21 And, it feels to me like that's what needs
22 to be. And, we cannot separate radiation safety
23 aspects of a medical physician's practice using
24 radioactive materials from the clinical aspects, unless

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1 the clinician is doing non-radioactive treatments like
2 I do treat patients without radiation sometimes.

3 Follow ups, I do check ups, I do hormone
4 therapies. So, that is obviously medical, but not
5 radioactive.

6 So, I don't see that dichotomy working
7 which obviously makes it very problematic for this
8 alternative pathway.

9 Because, with what I'm articulating, then
10 how do you come up with an alternative pathway outside
11 of a Board? And, I don't know, maybe the answer to that
12 is you cannot or the Boards need to come up with an
13 alternative pathway that we can then use.

14 But, anyway, those are my thoughts.

15 CHAIR ALDERSON: Well, since I don't see
16 another hand, do you want to comment on that? I'll be
17 glad to comment on that also.

18 DR. PALESTRO: Yes, I understand what
19 you're saying, but I think determining whether or not
20 an individual is quote, unquote clinically competent to
21 manage a patient is way beyond the scope of what the NRC
22 responsibilities are.

23 And, our paradigm, our template looks at
24 what looks at the NRC requirements and they have nothing

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1 to do with managing the patient clinically.

2 And, I have to tell you, to use myself as
3 an example, when I administer I-131 for thyroid cancer
4 or for hyperthyroidism, I don't manage that patient.
5 That patient is turned back to the endocrinologist for
6 subsequent follow up and managing.

7 I understand administering activity. I
8 understand what the consequences of the activities.
9 But, I do not turn that -- I do not manage those patients.

10 You know, there's lutetium-177 DOTATATE I
11 think that will undoubtedly be available in the not too
12 distant future for treatment of neuroendocrine tumors
13 and I look forward to my division being actively
14 involved in the administration of the treatment -- of
15 that treatment to those patients.

16 But, there is no one in my division, and I
17 think for most nuclear physicians in general, who are
18 in a position to manage those patients after the
19 treatment.

20 CHAIR ALDERSON: So, I think that's a very
21 fair answer.

22 I think it's sort of an issue of semantics,
23 but obviously, eventually, you have to have the whole
24 package in order for the patient to be safe.

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1 But, quite right, the NRC is not in the
2 business of regulating the practice of medicine.

3 So, in the alternate pathway, I'll just
4 move right to that alternate pathway, the Committee may
5 come back with a recommendation that there has to be in
6 the alternate pathway, another standard.

7 And, if one has the Boards or something like
8 that, well, that's easy, that's the easy part of that.
9 That's fine, that works.

10 If they don't, then conceivably, for
11 example, the NRC could say, just like people issue RFPs,
12 they could say, well, we're prepared to go forward in
13 this, but for certain groups, we don't have an effective
14 alternate standard and we invite the comments of people
15 from the public or other places to recommend a standard
16 that at least the NRC could find acceptable without
17 itself actually managing that medical side of this
18 question. That would be one way to approach it.

19 I think the fact that they've somewhat
20 separated the safety from the clinical competence is
21 actually a good way to get started down the road, which
22 didn't quite exist before.

23 Now I see several hands up. Ms. Tapp, Dr.
24 Tapp hasn't commented yet, so Katie Tapp?

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1 DR. TAPP: I actually had a question to
2 follow on what Dr. Palestro just said.

3 You said that you don't manage patients
4 following administration in internal nuclear medicine.
5 But say a medical event were to occur, I would say
6 nuclear physicians would usually be the ones trained to
7 know if a medical event occurred and then what to do,
8 not the endocrinologist, but maybe the nuclear medicine
9 physician what to do if the medical event occurs, how
10 you would --

11 DR. PALESTRO: I guess the question is when
12 did the event occur?

13 DR. TAPP: If it occurred during your
14 treatment?

15 DR. PALESTRO: That's a different story.

16 DR. TAPP: And, that is part of the
17 training you need, what to do and --

18 DR. PALESTRO: I would know what to do and
19 I would certainly know what step to take next.

20 For example, if the patient went into
21 cardiac arrest, the first thing we'd do obviously is
22 call a code, right, and take whatever other measures we
23 needed until the individual, the appropriately trained
24 individuals came to nuclear medicine and took over.

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1 So, yes, that's the sort of thing that we
2 can manage. I'm not referring to that, I'm referring
3 to the ongoing care of the patient after the fact.

4 DR. TAPP: Radiation NRC medical event.

5 DR. PALESTRO: I'm sorry, I misunderstood
6 you, yes. Yes.

7 CHAIR ALDERSON: Dr. Dilsizian had his
8 hand up.

9 DR. DILSIZIAN: I -- maybe I don't have to
10 persist on this, but the alternative pathway, it
11 actually exists for certain occasions. As you know, it
12 can be really a nuclear medicine physician like me being
13 a cardiologist and doing one year of nuclear medicine
14 training and be Board certified to do radiology,
15 radiation oncology. But they're different pathways
16 that's already there.

17 The ultimate test of competency has become
18 the certification Boards. So, whatever training
19 pathway you're going to come up with, ultimately, I
20 think there's got to be some certification that says
21 this person passed this test and therefore is competent.
22 That's how we judge ourselves right now.

23 So, whatever you design with this alternate
24 pathway, I think ultimately it has to have some type of

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1 objective testing just like we've all gone through that
2 says you're competent.

3 So, right now, it's done through the
4 clinical pathway and ends up with Boards. I'm not sure
5 what you're going to come up with that's not going to
6 end up in some type of Board certification.

7 DR. PALESTRO: The answer is, if you go
8 back and look at the slide on the alternative pathway,
9 it says with satisfactory or with satisfactory
10 completion of an examination of one sort or another. It
11 doesn't necessarily have to be sponsored by a particular
12 Board. It could be an independent committee of quote,
13 unquote qualified individuals who conduct the
14 examination.

15 But, we didn't say there should be no
16 examination and that anyone under the sun can become an
17 authorized user. What we're looking at and just sort
18 of suggesting were different ways of attaining AU status
19 alternative pathways.

20 And the two that we mentioned both included
21 one sort of examination or another. So, yes, that is
22 there.

23 CHAIR ALDERSON: And, Laura Weil?

24 MS. WEIL: We should recognize that there

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1 is an existing example of this alternative pathway with
2 endocrinologists being certified as authorize user for
3 iodine-131.

4 And, that's with only 80 hours of training
5 and experience in addition to their clinical degree.

6 We could assess whether that works or
7 whether it doesn't work and use it as a cautionary model
8 for going forward.

9 DR. PALESTRO: There is -- you're correct.
10 There is a -- they call themselves the American Board
11 -- there is a Board, an endocrinology Board, and I
12 apologize, I don't recall --

13 CHAIR ALDERSON: Dr. Howe may know.

14 DR. PALESTRO: Dr. Howe may know the name
15 for endocrinologists who undergo certification and that
16 particular Board has deemed status with the NRC. So,
17 that's how they attain it, yes.

18 DR. HOWE: Yes, that particular Board came
19 in and asked for us to recognize them and they had to
20 demonstrate that they met the criteria for a Board under
21 35.392 and 396. There are criteria there.

22 They happened to be essentially the same
23 criteria as the alternate pathway. And then, we
24 recognized them.

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1 CHAIR ALDERSON: Yes, Dr. Ennis?

2 DR. ENNIS: Just a follow up on the
3 conversation.

4 So, if there's an isotope that a patient is
5 referred for, but they shouldn't get it because of some
6 medical condition they have, that is something that
7 would be under the purview of the nuclear medicine
8 physician?

9 DR. PALESTRO: It would be under the
10 purview of the authorized user, whoever that is, that's
11 correct.

12 DR. ENNIS: Right, okay. So, that is a
13 clinical decision, not a radiation safety decision, to
14 make my point.

15 And, that shows to me how they're so
16 intertwined and to separate them out and to make it only
17 about radiation safety, I think misses the point of what
18 we're doing.

19 CHAIR ALDERSON: Yes, Dr. Ouhib?

20 DR. OUHIB: Yes, you know, we have proven
21 Boards with records and all that, it just makes me
22 nervous that we're looking at an alternative pathway and
23 looking at these group of people that decide that they
24 can examine an individual and handle this delicate --

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1 you are good to go. It just makes me nervous.

2 Like somebody said, you know, this is a
3 slippery area. I will echo that same sentiment that
4 this could be -- that could come back and bite us
5 actually.

6 CHAIR ALDERSON: Yes, Mr. Bollock?

7 MR. BOLLOCK: I just wanted -- you know, we
8 are at a hard position here because we don't want to
9 interfere with the practice of medicine, but as Mike
10 pointed out, we are -- we still regulate the safety of
11 the patient as well.

12 So, something Dr. Palestro pointed out to
13 kind of like where we get to that grey area is
14 understanding the consequences of administration of the
15 radiation to the patient. That is patient safety under
16 our purview.

17 So, that is important and it -- so there is
18 a clinical tie. It's like anything -- even the other
19 things that we regulate or anybody regulates. There's
20 always like this on the job training of some sort and,
21 you know, there's some expectation for different
22 certifications and like I said, any other --

23 And it's not just us, it's across the board
24 in other practices, professional -- any professional

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1 society or professional groups.

2 So, there is a tie because that clinical --
3 a certain level of clinical that's in the medical
4 decision and some of it is that helps the protecting the
5 patient on the radiation side as well. I mean there is
6 a tie.

7 And, as Mike said, that's why we rely upon
8 the advice of you all in making sure that we're not
9 overstepping our bounds, but still meeting that, you
10 know, the safety requirements for the patient in that
11 administration.

12 CHAIR ALDERSON: And, there would have to
13 be not only a way to initially determine that a
14 particular external organization fit the criteria for
15 a Board, for whatever.

16 But, there has to be a way, I think, to
17 continue the maintenance and certification idea to
18 determine, over a period of time, that whatever
19 physicians were eligible are eligible to be the AU or
20 whatever persons, those people have to maintain that
21 same level of competence, I'll use that word, in the
22 future just as all the Boards say physicians have to now.

23 And, that's another aspect to this. So, I
24 don't think these problems are necessarily going to be

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1 resolved, you know, extremely quickly and that's why we
2 have a standing committee and they're looking at these
3 issues in a stepwise fashion. And, you may be able to
4 develop these templates as you go forward and, you know,
5 solve the harder problems after you've had a little
6 experience.

7 But, all these issues have to be included.

8 Dr. Langhorst?

9 DR. LANGHORST: Thank you.

10 I don't remember what the NUREG is, but the
11 NRC has a NUREG document on medical licenses and what
12 they consider the basis for these licenses.

13 And, it's a three-prong basis for a
14 licensee who has a medical license. It's executive
15 management. It's the Radiation Safety Officer. And,
16 it's the authorized user.

17 And, the three of them have to understand
18 the license requirements, commitments and have to be
19 part of that.

20 That's why it's so important to make sure
21 the training of the authorized user is appropriate, is
22 adequate to help support that triad.

23 That's why, if you have a physician who
24 works in a different area and now there's a radiation

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1 radioactive drug, let's say, that treats something in
2 their purview, well, they just want to be able to use
3 it and administer but they can't because they need to
4 have that broader, and if you want to say radiation
5 safety, I mean, it's operative to say that it's a cut
6 and dry thing, they have to have that whole
7 understanding of the regulatory environment and their
8 commitments to it.

9 That's why, I mean, When we talk about
10 alternative pathways, we have alternative pathways
11 already. So, we're not talking anything new, it's just
12 the way of how do you judge a person meets both the
13 clinical and the regulatory, let's say, radiation
14 safety, whatever you want to call it, aspect of using
15 these radiation sources or radioactive drugs.

16 And, it's not so easy, but I think it's very
17 easy to explain it to outside physicians that think they
18 can just, oh, I want to add this drug to my use now. You
19 can't do it because you have to have a whole different
20 license to be able to do that kind of work.

21 That's the difficulty in trying to figure
22 out how you bring people who are already practicing
23 medicine into the fold or you don't bring them into the
24 fold or what are the competencies they have to have to

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1 meet in order to work with that.

2 CHAIR ALDERSON: Absolutely. That's why
3 we asked Dr. Palestro to lead this committee.

4 (Laughter.)

5 CHAIR ALDERSON: He has a comment today.

6 DR. PALESTRO: Yes, I'd just -- I wanted to
7 respond to Zoubir's comments in particular.

8 The Subcommittee is not necessarily
9 advocating for or against alternative pathways. We've
10 simply indicated a couple of potential alternative
11 pathways.

12 I think to unilaterally and perhaps
13 arbitrarily say, that alternative pathways or there
14 should not be any alternative pathways, is to turn the
15 blind eye to what is going on and what will continue to
16 go on around us.

17 If, in fact, we feel that alternative
18 pathways are harmful or shouldn't exist, we should in
19 some way be able to back that up with facts and not just
20 say, well, we think that it doesn't belong. Because,
21 after all, we need X amount of training and so forth.

22 So, I think it needs to be investigated. I
23 don't have any preconceived, at least I'm trying to
24 avoid, preconceived notions about whether or not they

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1 exist, but I don't think the issue can be ignored.

2 Because, quite frankly, it's not going to
3 go away.

4 CHAIR ALDERSON: Right, absolutely.

5 I'd like ask, are there any people on the
6 phone? Do any of you know if there a person on the
7 phone?

8 He's checking.

9 PARTICIPANT: Yes.

10 CHAIR ALDERSON: We'll move along with our
11 discussion then, but I would like to make sure that
12 during this segment, particularly, that we are sure that
13 if anyone's out there that they get to make comments.

14 MS. SMETHERS: Are the lines open?

15 CHAIR ALDERSON: Well, while we're waiting
16 for the answer to that --

17 MR. BROWN: The line's open.

18 CHAIR ALDERSON: The line is open. So, we
19 must ascertain then that there is no one there who wishes
20 to comment or ask a question about this issue, is that
21 correct?

22 People seem to think that is correct.

23 Is there anyone in the room want to make a
24 comment? No one, okay, so it's fine, it's back to us.

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1 We've tried.

2 Yes, Sophie?

3 MS. HOLIDAY: If you're on the bridge line
4 and you wanted to ask a question or make a comment, you
5 may have to dial star six if that's what you used to mute
6 your phone so that you can unmute it.

7 CHAIR ALDERSON: All right, we'll sit just
8 a moment and see if anyone happens to dial star six and
9 speak up. But after we've waited just a brief few
10 seconds, because they can do that right now if they're
11 listening in, then we'll go back to our own discussion
12 and I will feel like we have done the appropriate thing
13 to be sure that the general public has as opportunity
14 to discuss this particular issue.

15 Is anyone there?

16 (No response.)

17 CHAIR ALDERSON: Hearing none, Dr.
18 Zanzonico would like to speak.

19 DR. ZANZONICO: I think it's important to
20 bear in mind what generated this latest incarnation of
21 characterizing training and experience. It was the
22 Bexar issue.

23 And, I think the specific issue there was
24 the necessary training in the number of hours of

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1 training, specifically in nonclinical areas, in
2 radiation physics and radiation safety and so forth.

3 And, I thought that was the scope primarily
4 of this Subcommittee. I think it's beyond the scope of
5 the Subcommittee to address overall competency and, you
6 know, that's left to the certifying Boards,
7 professional societies, et cetera, et cetera.

8 And so, my earlier comment, in terms of the
9 approach of the Subcommittee was in relationship to
10 defining some reasonable number of hours of training in
11 the technical aspects that authorized users need to be
12 competent in.

13 So, I think we've got it -- we've expanded
14 the scope in terms of trying to define clinical
15 competency and overall competency rather than just
16 trying to define some numbers of hours.

17 And, I think the approach the Subcommittee
18 used in addressing that specific question is very
19 reasonable.

20 I think the broader question of clinical
21 competency, alternate pathways, et cetera, et cetera,
22 may be beyond the scope of what was originally intended
23 and complicates things maybe intractably in the short
24 term.

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1 CHAIR ALDERSON: Dr. Palestro?

2 DR. PALESTRO: Yes, going back to the -- it
3 was actually the Zevalin.

4 DR. ZANZONICO: Zevalin, I'm sorry.

5 DR. PALESTRO: That was a separate
6 Subcommittee that was formed to look at that and to try
7 to make a determination of whether or not the decrease
8 in use of that radiopharmaceutical is related to a lack
9 of patient access.

10 That Subcommittee concluded the ACMUI
11 agreed that there was evidence to support that.

12 Subsequent to that, it was decided that a
13 new Subcommittee should be formed, a Standing
14 Subcommittee, to look at the training and experience
15 requirements for all modalities.

16 There was nothing in that that focused
17 specifically on a number of hours of training. And, in
18 fact, that was one of the major issues that came up is
19 hours in and of itself, a good way to approach education.

20 And, in the current milieu, the educational
21 paradigms don't focus on hours of training.

22 So, yes, the charge committee -- the charge
23 to the Subcommittee has been greatly expanded or is
24 very, very comprehensive. And, it's not easy.

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1 The members of the Subcommittee will tell
2 you, but that's sort of what we're left with.

3 CHAIR ALDERSON: Dr. Howe and then Dr.
4 Dilsizian.

5 DR. HOWE: Just from a historical
6 perspective, you're talking now about the Boards and
7 saying that you may just go exclusively to Boards. That
8 would be a tremendous shift in where NRC has been
9 historically.

10 Because the Boards are the second group
11 that came in to be recognized. The first group were the
12 alternate pathways now. They were the only pathway
13 when we started regulating medical use of isotopes.

14 And, in 2002, one of the issues that we had
15 to deal with was, are the Boards focusing on radiation
16 safety? Or, are they focusing on other issues that are
17 important for medical care, but not radiation safety?

18 And so, in 2002, the Commission decided
19 that, if you were a previously recognized Board in
20 Subpart J, you were not going to be recognized when the
21 2002 rule went into effect because you may not have been
22 asking questions on your Board that pertain to radiation
23 safety and the radiation protection of patients and
24 workers, et cetera.

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1 And so, there was a shift at that time to
2 make sure that the Boards were asking questions that we
3 were concerned about.

4 And so, I think as you go forward, you have
5 to keep that in mind that, if you just go to the Boards
6 and you don't have criteria to keep us as part of that
7 examination process, you may have lost what we gained
8 in 2000.

9 CHAIR ALDERSON: Yes, and I would -- I just
10 I agree with what you said, Dr. Howe. And, but I do want
11 to make a comment on one aspect of it.

12 I don't want anybody to get the impression
13 that right now, at least as I am hearing this, that the
14 Committee is suggesting that Boards will be the only way
15 to get this resolved. That was not said.

16 There is a huge spectrum of approaches that
17 will have to be worked out over the months or perhaps
18 years to come with this Committee, but that is not the
19 conclusion that has been drawn at all at this time.

20 And now, there was another hand over here.
21 It's Mr. Green and then Dr. Palestro.

22 MR. GREEN: I'd like to follow upon Dr.
23 Howe's comments.

24 It's very astute that the alternate pathway

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1 for a nuclear pharmacist is the primary pathway. You
2 -- there are only five legacy schools today that have
3 collegiate training in nuclear pharmacy.

4 Unless you go to one of those schools, you
5 have to take a post-graduate program, a one offered
6 after you get your pharmacy license.

7 And so, you become an authorized nuclear
8 pharmacist and then you're required to work 2000 hours
9 and then be eligible to sit for a Board certification
10 of the pharmacy.

11 There's, the number's kind of fuzzy, one
12 and a half, 2000 nuclear pharmacists in the United
13 States today. There are 431 Board certified nuclear
14 pharmacists.

15 I am the Chair of the BPS Nuclear Pharmacist
16 Specialty Counsel for the next two years. I'm very aware
17 of how many there are. It's a very small number.

18 But, in, at least with nuclear pharmacy,
19 it's the alternate pathway that leads and then the
20 certification follows.

21 CHAIR ALDERSON: Dr. Palestro?

22 DR. PALESTRO: Yes, I just want to
23 emphasize to Dr. Howe and to everyone that the
24 Subcommittee is not recommending against the

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1 alternative pathway. We're trying to remain as
2 impartial as we can without any preconceived notions of
3 whether or not an alternative pathway or pathways are
4 good or bad, but they need to be looked at and eventually
5 when we're able to assemble the data based on input from
6 all the various stakeholders, we can come to a
7 conclusion.

8 But, the Subcommittee under no
9 circumstances has taken or is taking a position that the
10 alternative pathway should be done away with.

11 CHAIR ALDERSON: Are there any other
12 comments or questions?

13 Let's have one final comment and we'll wrap
14 up this discussion.

15 DR. DILSIZIAN: So, I know that this has
16 been said many times, and I'm sure you don't mean that
17 when you say hours are no longer the way to deal with
18 competency. I don't think you mean -- I know you don't
19 mean that.

20 Because GME wants hours followed by
21 competency. So, whatever we do, it's number of years
22 or 200 hours, 80 hours or, you know, of classroom work
23 and then competency.

24 So, it's not GME is not saying just

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1 competency, it's training followed by competency that
2 whatever you did during your training period actually
3 translates to knowledge.

4 So, I just want to clarify, you keep saying
5 hours is no longer, I don't think that's true.

6 DR. PALESTRO: I'm not sure I understand
7 you when you say GME. What do you mean GME?

8 DR. DILSIZIAN: I'm just saying Graduate
9 Medical Education, all those rules, isn't just on
10 competency. They want you to, when we evaluate
11 students, it isn't just on competency, it's that they
12 spend a certain number of hours in our rotation and then
13 you say, are they competent based on that four weeks or
14 four months.

15 It isn't that --

16 DR. PALESTRO: But the hours -- when you're
17 talking about -- if you're talking about in order to
18 obtain authorized user status?

19 DR. DILSIZIAN: No, anything, any
20 education requires a certain number of classroom hours,
21 education, training and then you -- just like surgeons,
22 you can't operate unless you a certain number of cases.
23 And then you say, are you competent to do the operation?

24 DR. PALESTRO: You know what? I've been

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1 off the review committee for nuclear medicine for a
2 couple of years. But, it is my recollection that the
3 last time we did the program requirements, that while
4 we listed topics that needed to be covered, that there
5 was no specified number of hours, didactic hours that
6 had to be included, that we listed specified topics.

7 You can check and see, I don't think I'm
8 mistaken because I had the misfortune of being in charge
9 of rewriting those requirements.

10 So, if I said doing away with perhaps, I
11 misspoke. I think a more appropriate term would be
12 de-emphasizing hours, all right, that there are, and I'm
13 sure we could probably all sit down and agree, a majority
14 of us, agree on the topics that should be covered very
15 easily.

16 Arguing whether they should be covered in
17 10 hours or a 100 hours, then becomes the debate.

18 And, what I am suggesting, and I think what
19 the Subcommittee is suggesting is that maybe it's time
20 to de-emphasize hours, focus on topics with the ultimate
21 criterion for competency being the examination.
22 That's really what I mean.

23 CHAIR ALDERSON: Well, thank you, Chris, I
24 think that's a great overview statement on which to end

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1 this discussion.

2 So, I want to thank the Committee and Dr.
3 Palestro again for their excellent work.

4 And, I think as the meetings go on of the
5 ACMUI that we'll expect at least for there to be a brief
6 report each time about what the Committee's been doing,
7 where it currently is and its progression through the
8 paradigm that it provided to us and we'll continue to
9 discuss these interesting issue.

10 So, thank you, again, for an excellent job.

11 All right, that brings to the next topic
12 which is Patient Release Project Update and Dr. Howe is
13 going to help us with that.

14 DR. HOWE: Thank you, Dr. Alderson.

15 The Patient Release Project has been a many
16 year and multiple project endeavor.

17 The one I'm going to be talking about
18 started with a Staff Requirements Memorandum in April
19 28, 2014 and the topic was the background and proposed
20 direction to NRC staff to verify assumptions made
21 concerning patient release guidance.

22 The Commission wanted input from a wide
23 spectrum of stakeholders, public, patient, patient
24 groups, physicians, professional societies, the ACMUI

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1 and Agreement States.

2 And, in order to get the public input, we
3 had to, in some cases, go through the Office of Budget
4 and Management Clearance to get it on the clearance to
5 be able to ask the public questions.

6 We had to publish in the Federal Register
7 to let people know that we were looking for information.
8 And, we had public meetings.

9 We've had two parts to this. The first
10 part was to collect information and the reason we split
11 it into two parts, because the second part had more to
12 do with the possibility of looking at -- to see if we
13 were going to do any regulatory changes.

14 And, we felt that, if we put the possibility
15 of doing any regulatory changes in the first set of
16 public participation things, we would never find any
17 information that we were looking for the patient side
18 of things.

19 So, our focus on -- so, that's why we split
20 it into two parts.

21 And, the first part was information that
22 patients believe would help them understand their I-131
23 treatment and the SRM was primarily focused on I-131,
24 and at the later part, to the SRM it says, well, we'd

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1 like to have you modify guidance on all isotopes, not
2 just I-131. But, that was the major focus.

3 And, they wanted information on physicians
4 and licensees best practices when making an informed
5 decisions on releasing I-131 patients.

6 So, we had four basic questions. The next
7 one was information provided to patients on how to
8 reduce radiation dose to others. And, if a patient
9 advocacy group or medical professional organization,
10 licensees or other individuals had brochures, that
11 would address much of this information in an already
12 published form.

13 So, we got out OMB clearance and we
14 published in the Federal Register November 16th, 2015
15 with a 60-day comment period. And, we held two public
16 meetings December 2015 and January 2016.

17 And we got a number of comments and we've
18 been working through those comments and we're getting
19 ready to publish an Information Notice for one set of
20 comments on best practices.

21 Who did we get comments from? We got them
22 from everybody. We got it from individual physicians,
23 we got it from clinics, hospitals, professional
24 societies, patient advocacy groups and individual

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1 patients. So we really got a good, broad spectrum.

2 And, the best practices that we're going to
3 be using are in a generic communication which is the
4 Information Notice that should be coming out in the
5 summer of 2017.

6 And, as part of this information
7 collection, we identified two items that we thought
8 should be included in part two of the Commission
9 Directive.

10 And, part two was we were asked to evaluate
11 whether significant regulatory changes to the patient
12 release program are warranted.

13 We were not told to make changes, we were
14 asked to evaluate whether changes were warranted. So,
15 we are really in early stages here.

16 And we were to explore with the public,
17 licensees and stake partners whether we should change
18 10 CFR Part 35 for specific reasons.

19 And, these are the things that we were asked
20 to look at, should -- and we've published a Federal
21 Register Notice April 11th, 2017 on this.

22 And, they are -- and we have six questions
23 we are asking for public input on.

24 The first one is, should the Agency change

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1 35.75 to require an activity-based patient release
2 threshold under which patients would be required to
3 maintain -- be maintained in a clinically sponsored
4 facility, that would be a medical facility or facility
5 under the licensees control, until the standard for
6 release is met?

7 The second question we have is, should we
8 clarify the time frame for the current dose limit in 10
9 CFR 35.75(a) for releasing patients?

10 The 500 millirem dose limit is just stated
11 as 500 millirem. It does not say it's per
12 administration or per year or per other time.

13 Third one was, should the NRC continue to
14 apply the same dose criteria of 5 millisieverts, .5 rem
15 to all members of the general public including family
16 members, young children, pregnant women, caregivers,
17 hotel workers and other members of the public when
18 considering the release of patients?

19 So, should we have the 500 or should there
20 be a differentiation between different groups? And, it
21 could go up or it could go down.

22 And, question number four was, to have a new
23 requirement for the release of a patient who is likely
24 to expose young children or pregnant women to doses

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1 above the 10 CFR Part 20 public dose limit?

2 Right now, we have the 500 millirem limit.
3 And then, if you're going to expose somebody in excess
4 of a 100 millirem, you have to provide instructions,
5 including written instructions to keep doses as ALARA.

6 And, the two that we have added based on the
7 information received from the part one public comment
8 period and information collection was, should we have
9 a specific requirement for licensees to have a patient
10 isolation discussion with the patients in sufficient
11 time prior to administration to provide the patient time
12 to make an isolation arrangements or for the licensee
13 to make plans to hold the patient if the patient can't
14 be immediately released?

15 And, during the public comment period for
16 phase one, we had more than one patient that called in
17 and said that they were going -- undergoing I-131
18 treatment in the next two weeks and no one had talked
19 to them at all about whether they had to be isolated.
20 And, they had small children.

21 And so, they didn't believe they were going
22 -- if they hadn't looked at a website, they wouldn't know
23 that they needed to make arrangements.

24 And, our last question is, should NRC

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1 explicitly include a time frame for providing
2 instructions in the regulations and somehow indicate
3 that the instructions should be provided prior to a
4 procedure?

5 Because we heard from a number of patients
6 that they received their instructions after they got the
7 I-131 treatment and it may have been in a packet of
8 release papers and there really had been no discussion
9 or pointing out that this was what they were needing to
10 follow or question whether they could follow it.

11 So, these were the six questions that we
12 have asked in the Federal Register. And, for -- we want
13 them to give -- we want people to give us open ended
14 responses.

15 But, we want to make sure that, if we've
16 asked for whether a change is needed or not, people
17 respond with no, you don't need to make a change and
18 explain why we don't need to make a change.

19 If they think we do need to make a change,
20 they should provide the criteria that NRC should use and
21 explain why we should make a change.

22 And, if there's specific groups involved,
23 we want them to specify the groups for each criteria.

24 And, in all cases, we're really looking at

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1 health and safety. So, we're asking people to provide
2 us with information on what they perceive as the health
3 and safety benefits or lack of benefits to individuals
4 being released, the licensee and to individuals members
5 of the public.

6 So, this is the kind of information that
7 we're asking.

8 And so, we've published our Federal
9 Register Notice. We asked these six items. We have
10 the three questions below.

11 We are in the middle of a 60-day public
12 comment period. We have gotten one request to extend
13 the public comment period. We are considering that.
14 We believe we will extend the public comment period for
15 15 days. And, if we do that, we will be publishing that
16 in the Federal Register to let everybody know.

17 We plan to have two public meetings. We
18 had one public meeting yesterday and we are going to have
19 the second public meeting May 23rd. And they're going
20 to be at NRC Headquarters.

21 We're going to be webcasting the public
22 meeting and we're also try to webinar so that we have
23 a backup system and then we'll have a telephone
24 conference line.

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1 And, if anybody checked in on our public
2 meeting yesterday, you would find out that NRC's webinar
3 has been down for over a week. And so, that backup
4 system wasn't working and halfway through the meeting,
5 our webcast system server crashed.

6 And so, we had no more visualization on it
7 and we were left with our telephone lines. But, we had
8 to go -- but at least we had our telephone lines open.

9 So, you know, you plan for these things, and
10 yesterday, it all hit.

11 And, what are we going to with the results
12 of this? Well, we're going to take the public comments
13 and we're going to be forming a SECY paper to the
14 Commission and we're going to give them our view of
15 whether we should pursue changes to 10 CFR 35.75.

16 If we decide we aren't going to -- we don't
17 believe we should be making changes and the Commission
18 agrees, that's the end.

19 If we decide we are going to make changes
20 and the Commission agrees, then we'll certainly go into
21 proposed rulemaking and the whole rulemaking process.
22 So, there'll be plenty of opportunity to comment
23 afterwards if that's the direction we take.

24 At this particular point, we're still

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1 collecting information and so, it's too early to say one
2 way or the other.

3 Are there any questions?

4 CHAIRMAN ALDERSON: Yes, thank you, Dr.
5 Howe.

6 Yes, Dr. Ennis?

7 DR. ENNIS: I'd suggest an additional
8 possibility to be considered is whether the training and
9 experience requirements for the authorized user should
10 be changed.

11 I must say that I'm struck by every time
12 we've had this conversation, it seems to me, the core
13 of the -- these are symptoms of a more core problem in
14 that the authorized user who is treating the patient is
15 not sufficiently sophisticated to convey to the patient
16 or understand what the issues are.

17 These -- I mean, I'm flabbergasted that
18 patients could be going around getting these treatments
19 and not being explained to them that they're radioactive
20 and all this.

21 So, to me, these are just symptoms and
22 putting out the little fires.

23 The core issue, seems to me, is likely in
24 many situations, it's just the training requirement of

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1 the authorized users is inadequate, that they don't
2 really quite understand what they're doing and what
3 they're using.

4 CHAIRMAN ALDERSON: Ms. Weil?

5 MS. WEIL: I'd certainly like to echo that
6 sentiment. But, can you just informally give us some
7 sense of what happened at yesterday's meeting?

8 DR. HOWE: Okay, we had a public meeting.
9 We elected to give an hour for each one of our questions.
10 And, we had an agenda and we stuck to the agenda.

11 We had a total of 37 people on the phone for
12 the morning session and we had 57 for the afternoon
13 session.

14 We had hoped we would get a lot of dialogue
15 and comments. Most people on the phone were silent.
16 We did get comments from Peter Crane and eventually,
17 other people would give their comments, too.

18 But, we had very long periods of where we
19 had to break because we just didn't have anybody
20 commenting.

21 So, we tried as best we could to get people
22 to talk. So, if we had a subject on for an hour and in
23 the first 15 minutes, we had no more people on the
24 telephone to ask us or to give a comment, then we took

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1 a break and then before the hour was over, we came back
2 to that question in case we had somebody join us later
3 and that helped. We got a little bit more discussion
4 going.

5 So, in the afternoon, we got some good
6 discussion going but we didn't have the participation
7 on the lines that we expected.

8 MS. WEIL: Was it primarily patients or
9 were there clinicians?

10 DR. HOWE: We had probably a mixture
11 because we did have patients that were talking to us and
12 making comments. And, we also had Radiation Safety
13 Officers from medical facilities that were talking to
14 us, too.

15 Now, yesterday's meeting was fairly close
16 to when we published the Federal Register Notice, so the
17 word really may not have gotten out as well and we'll
18 have to work on publicizing it a little better for the
19 next meeting.

20 And, based on our output for yesterday's
21 meeting, we may shorten the meeting.

22 CHAIRMAN ALDERSON: Dr. Langhorst?

23 DR. LANGHORST: I want to make mention,
24 again, on 35.75. While the dose does not have a time

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1 period in the final rule, it is stated explicitly that
2 it is a per release limit.

3 And so, I see there is no confusion over
4 what it is. The final rule stated it was a per release
5 limit.

6 I'll also remind the Committee that 35.75
7 patient release is not specific to I-131. It includes
8 all radioactive materials.

9 If the dose to any given group or dose to
10 over a time period is set, how do you administer that?
11 I mean, if someone is -- someone's had a lot of therapy
12 and they've had many nuclear medicine procedures, are
13 they almost the end of the year, you can't give them that
14 next diagnostic test because it might put their family
15 member over 500 millirem?

16 And, how do you know? That's only if
17 you're taking care of that one patient and you're the
18 only one taking care of them. I mean, I don't -- it's
19 impossible to do unless you just maintain it on a per
20 release basis.

21 Thank you.

22 CHAIRMAN ALDERSON: Dr. Ouhib?

23 DR. OUHIB: I'd just like to echo Dr. Ennis
24 -- sorry. I would just like to echo Dr. Ennis' comment

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1 that it almost sounds like this is, you know, based on
2 explicitly on the iodine-131.

3 This is more like a practice guideline
4 issue and maybe someone from nuclear medicine can tell
5 me if there is one or if there isn't, maybe it's time
6 for such a thing can have practice guidelines for
7 authorized users on how to actually administer, not
8 necessarily just iodine-131, but these types of
9 isotopes and what should be in place basically.

10 And, I think that might correct part of the
11 problems.

12 CHAIRMAN ALDERSON: We have someone at the
13 microphone?

14 MS. KUBLER: Hi, this is Caitlin Kubler
15 with the Society of Nuclear Medicine and Molecular
16 Imaging.

17 I just wanted to comment on Donna Beth's
18 mention about the webcast and we did have a few members
19 that participated. It was simply the timing that we
20 couldn't get together and formalize our comments in time
21 to share them yesterday.

22 But, we will be participating either in
23 person or on the webcast on the 23rd of May and we are
24 going to, you know, make our comments available.

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1 Thank you.

2 DR. HOWE: Thank you.

3 CHAIRMAN ALDERSON: Thank you.

4 Dr. Ennis?

5 DR. ENNIS: Just a brief follow up.

6 Again, I wish we could verify this, because
7 my suspicion is not about nuclear medicine, Board
8 certified nuclear medicine physicians. [INAUDIBLE]

9 I'm concerned about the alternative
10 pathway endocrinologists, specifically. And, I wish
11 we could actually verify that but this is what it smells
12 like to me and that would be very informative for us in
13 terms of our other committee conversations.

14 And, it would really be quite helpful.
15 But, that's what I was getting at.

16 DR. HOWE: In our public comment period, in
17 our public meetings last year, the two individuals were
18 going to very reputable hospitals.

19 CHAIRMAN ALDERSON: I'll ask a question
20 and make a comment and, it may be that this is no longer
21 the extant, but I have to ask it.

22 With respect to what's in the rule 35.75 or
23 whatever the appropriate rule is, if it is not
24 particularly definitive in terms of the issue at hand,

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1 particularly, I think I-131, that being the most common
2 one.

3 What I experienced a few years ago as these
4 things were changing and I was still involved in the
5 clinical side of the picture a bit more, was something
6 that you can't control and for which you're not
7 responsible. It was whether an insurer would pay for
8 the room in the hospital to keep the patient.

9 And so, as the rule became less definitive,
10 the insurers said, well, this doesn't say X. This
11 allows latitude, we've look at this and we're not paying
12 for this room anymore. And, out the patient would go.

13 So, if that is still a problem and having
14 experienced a number of insurers without being too
15 negative, I would say it probably is, I think that I
16 would just encourage you, the more definitive you can
17 be about the sort of thing that should require a patient
18 to stay in the room, the more likely there'll be someone
19 to pay for that room.

20 So, that is just an additional problem.

21 Yes, Dr. Langhorst?

22 DR. LANGHORST: We are working through
23 such an issue with high plaque patients. Okay? And,
24 it's not just the insurers, it's oh well, if you do it

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1 with this patient, then you should do it with this
2 patient, too. And, you shouldn't treat them
3 differently.

4 But, one of the things that you have to
5 assure is that you believe your patient can and will
6 follow the rules. Not that you guarantee it, but, if
7 you don't think a patient is capable of doing that, then
8 you need to keep them in the hospital no matter whether
9 it's high plaque or --

10 CHAIRMAN ALDERSON: Yes, I heard that.

11 DR. LANGHORST: So, it's not just -- I mean
12 the insurance is one thing, but you have to have a
13 patient who's cooperative and willing to do what you
14 hope understands.

15 And, that's why it is so unbelievable that
16 you don't have a discussion with your patients on what
17 this all means.

18 CHAIRMAN ALDERSON: Dr. Zanzonico?

19 DR. ZANZONICO: I think my feelings on this
20 topic are pretty well known. But, I find it -- I am
21 really very surprised that question one is still on the
22 table.

23 There's no question that an activity-based
24 release criteria is wrong science and for the

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1 radiation safety.

2 We know, for example, that individuals
3 around a hyperthyroid patient treated with 10
4 millicuries will get substantially higher doses than a
5 thyroid cancer patient treated and released with
6 several hundred millicuries. I mean, that's settled
7 science.

8 And so, I just don't understand the
9 rationale why this is still an issue and why opinion is
10 still being solicited on that point.

11 DR. HOWE: This was directed by the
12 Commission. It was a Commission Memo from then
13 Chairman MacFarlane and Commissioner Magwood.

14 And so, they -- these are specific
15 questions one through four that they wanted the staff
16 to look at. And, it can be that it came because we get
17 letters or we at least did get letters until this SRM
18 came out routinely about activity versus dose. So,
19 this may be a way to answer the question, answer the
20 mail, put a period.

21 DR. ZANZONICO: But, I mean, presumably,
22 the Commission must be aware that, I mean, there's no
23 scientific basis for an activity-based release criteria
24 being more protective of public safety than a dose-based

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1 release criteria.

2 DR. HOWE: We cannot answer for the
3 Commission.

4 MR. BOLLOCK: But, and not to answer for
5 the Commission, but to give a little bit -- as Donna Beth
6 -- as Dr. Howe just stated, prior to that time, they had
7 heard, you know, letters basically saying, go back to
8 the way it used to be.

9 We haven't received those since that time
10 frame.

11 But, and then, just another kind of
12 background information as to why they're asking or
13 possibly why their asking again, just something else we
14 didn't know is that internationally, the international
15 standards for patient release are not what the U.S.
16 standards are in a majority of the European countries.

17 DR. HOWE: They're still activity -based.

18 DR. BOLLOCK: They're still activity --
19 right. So, that's another -- so they had that
20 information. We've provided that information for them
21 about that time frame.

22 So, it -- they have information saying the
23 U.S. is different from a majority of the rest of the
24 developed world. You know, so why are we different?

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1 So, there is -- there are reasons why they
2 did it, you know, that are, I guess on a just
3 straightforward --

4 DR. ZANZONICO: Just not scientific
5 reasons.

6 MR. BOLLOCK: Logical apples to oranges,
7 you know, why are we -- so, there were things that went
8 into the, you know, the asking this. But, yes, no, we
9 have not, to my knowledge, we have not received any other
10 -- or the Commission hasn't received any other letters
11 advocating to change back in the sense that this has
12 gone.

13 DR. HOWE: Since this came down, so
14 everybody's kind of waiting for this SRM to be resolved.

15 CHAIRMAN ALDERSON: So, the next step will
16 be the second meeting and an additional attempt to get
17 public and other input on this question.

18 And then, after that, you'll I guess come
19 back to the ACMUI, among others, like perhaps at the next
20 meeting and say, here's where we are.

21 DR. HOWE: As we'll be developing a SECY
22 paper and as a part of our process, when the SECY paper
23 is going through concurrence, we will give the ACMUI a
24 chance to review it and comment on it.

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1 And, we are having the public meetings but
2 the actual official comments have to come in through the
3 -- electronically through regulations.gov or in writing
4 to our Office of Administration. And, that information
5 is in the Federal Register Notice.

6 So, we are having discussion in the public
7 meetings but those are not considered the final
8 comments. And so, if there is a group that hasn't
9 formalized its formal comments but they still want to
10 discuss and get questions answered, the public meeting
11 is the perfect place to do that.

12 CHAIRMAN ALDERSON: Well, I think that we
13 all would appreciate hearing how this area evolves and
14 where we come out perhaps at the fall meeting of this
15 Committee.

16 Are there any other comments people would
17 like to ask at this particular time?

18 Yes, Mr. Bollock?

19 MR. BOLLOCK: Just as Dr. Howe just said,
20 you will see this.

21 CHAIRMAN ALDERSON: We will see this?

22 MR. BOLLOCK: You will see it, yes, you
23 will get to see what we are going to tell the Commission
24 in the SECY paper. You will have a chance to review it

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1 and so, to give you a heads up, we likely, we will want
2 ACMUI's opinion, which could mean Subcommittee, you
3 know, as the middle of the process to get back. So then,
4 we would include that and your recommendation or your
5 thoughts on our SECY.

6 CHAIRMAN ALDERSON: Yes, well thank you.
7 We think that's appropriate.

8 DR. HOWE: And, we may be under a very tight
9 deadline.

10 CHAIRMAN ALDERSON: Time line.

11 DR. HOWE: So, we may want to think about
12 having a subcommittee that's ready.

13 CHAIRMAN ALDERSON: I see. Perhaps
14 appointing a committee now to be ready for when that
15 comes out? Okay, thanks very much for that.

16 Yes, Dr. Langhorst?

17 DR. LANGHORST: I have -- remind us when
18 are comments due?

19 DR. HOWE: I haven't looked at the calendar
20 yet, but the -- if you look at the Federal Register, add
21 15 days from then. I think they're due in May.

22 MR. BOLLOCK: No, mid-June, June 11th,
23 yes.

24 DR. LANGHORST: Okay, thank you.

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1 DR. HOWE: They're supposedly due right in
2 the middle of the Society of Nuclear Medicine meeting
3 and so we're going to extend it 15 days, then the 12th.

4 DR. LANGHORST: My question is kind of a
5 logistical question and probably for you, Doug. And,
6 you may not be able to answer it right now, but I'll pose
7 the question.

8 On the Category 3 source comments, it took
9 forever for those comments to be posted on
10 regulations.gov. Is -- and I was told it was because
11 NRC doesn't have the staff to put those comments up as
12 quickly. I just wondered will we have the comments
13 available for the public to review soon after they're
14 made?

15 MR. BOLLOCK: This is a --

16 DR. HOWE: All I can say is the experience
17 we had last year with the public comments and they went
18 up pretty fast. They would send them over to us to make
19 sure there was nothing that couldn't be put up, yet
20 everything was put up-able. So --

21 DR. LANGHORST: And, it might have been
22 because it was Category 3 sources that it took extra
23 time, but that was extremely frustrating to not be able
24 to see those comments as they were being made.

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1 MR. BOLLOCK: Yes, we -- I don't know if we
2 really control that. I mean, we can -- we checked on
3 it, we work with our other staff that works towards that.
4 And they, yes, we haven't had issues in the past, but
5 --

6 DR. HOWE: We have no knowledge.

7 MR. BOLLOCK: -- again, if there's -- we --

8 DR. LANGHORST: It took a long time.

9 DR. HOWE: And, I think in our last public
10 comment period, we had people that responded directly
11 to regulations.gov and those went up.

12 We had people that emailed us, those had to
13 come into whoever they were addressed to and then get
14 sent to ADAMS and then regulations.gov.

15 Sometimes, they came in to other people and
16 had to be recognized as a comment on it.

17 So, it depends on the pathway things come
18 in as to how fast they go up.

19 DR. LANGHORST: Okay, thank you.

20 CHAIRMAN ALDERSON: Are there any other
21 comments before we close the open session of the meeting
22 today? It's about time for us to do that.

23 Are there any people in the audience who
24 wish to comment? People on the phone line who wish to

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1 make a comment? Here at the table?

2 (No response.)

3 CHAIRMAN ALDERSON: Seeing or hearing none
4 from any of these sources, I think we will now go on to
5 break. This will end the open session and we will
6 reconvene at 3:00 p.m. for the closed session.

7 (Whereupon, the above-entitled matter went
8 off the record at 2:33 p.m.)

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