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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

(ACMUI)

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MEETING

+ + + + +

OPEN SESSION

+ + + + +

MONDAY

OCTOBER 19, 2009

+ + + + +

ROCKVILLE, MARYLAND

+ + + + +

The Committee convened in Room EBB01-B13/15 at the Executive Boulevard Building, 6003 Executive Boulevard, Rockville, Maryland, at 10:30 a.m., Leon Malmud, Chairman, presiding.

COMMITTEE MEMBERS:

LEON MALMUD, M.D., Chairman

BRUCE THOMADSEN, Ph.D., Vice Chairman

DOUGLAS EGGLI, M.D.

DARRELL FISHER, Ph.D.

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1 COMMITTEE MEMBERS: (cont'd)

2 DEBBIE GILLEY

3 SUE LANGHORST, Ph.D

4 STEVE MATTMULLER, MS, Rph, BCNP

5 ORHAN SULEIMAN, Ph.D.

6 WILLIAM VAN DECKER, M.D.

7 JAMES WELSH, M.D.

8
9 CONSULTANT TO THE COMMITTEE:

10 MILTON GUIBERTEAU, M.D.

11
12 NRC STAFF:

13 ROB LEWIS

14 JIM LUEHMAN

15 CHRIS EINBERG, Designated Federal Official

16 CINDY FLANNERY, Alt. Designated Federal Official

17 ASHLEY COCKERHAM

18 NEELAM BHALLA

19 ANDREW BRAMNIK

20 OSSY FONT

21 CASSANDRA FRAZIER

22 SANDRA GABRIEL

23 DONNA-BETH HOWE, PH.D.

24 GRETCHEN RIVERA-CAPELLA

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2 GLENDA VILLAMAR

3 DARREL WIEDEMAN

4 MICHAEL ZEITLER

5
6 MEMBERS OF THE PUBLIC:

7 MELISSA ALLEN (via telephone)

8 CINDY TOMLINSON

9 DAVID BURTON

10 DAVID DODOO-AMOO

11 EIPING QUANG

12 GEORGE WESLEY

13 GLORIA ROMANELLI

14 JAMES ROSS (via telephone)

15 JOSEPH GOLDSTEIN

16 JOSH GOLDSTEIN

17 KAREN LANGLEY (via telephone)

18 LIN CLEGG

19 LYNNE FAIROBENT

20 MARY MOORE

21 MELISSA MARTIN

22 P. YORKO

23 PARKER MOORE

24 RANDALL SNOW

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MEMBERS OF THE PUBLIC: (cont'd)

VIRGIL DICKSON

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Adjourn

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

(10:30 a.m.)

CHAIRMAN MALMUD: Good morning, everyone.

It being 10:30, we can start the open session. I invite you all to join us at the table.

Chris Einberg will -- has the first item on the agenda, which is of course the opening statements. Chris?

MR. EINBERG: Okay. Thank you, Dr. Malmud.

As the Designated Federal Officer for this meeting, I am pleased to welcome you to this teleconference public meeting of the ACMUI.

My name is Chris Einberg. I am the Chief of the Radioactive Materials Safety Branch, and I have been designated as the Federal Officer for this Advisory Committee in accordance with 10 CFR Part 7.11.

Present today as the Alternate Designated Federal Officer is Cindy Flannery, who is the team leader of the Medical Radiation Safety Team.

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

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1 The meeting was announced in the September 21, 2009,
2 edition of the Federal Register, Volume 74,
3 page 48104.

4 The function of the Committee is to advise
5 the staff on issues and questions that arise on the
6 medical use of byproduct material. The Committee
7 provides counsel to the staff, but does not determine
8 or direct the actual decisions of the staff or the
9 Commission. The NRC solicits the views of the
10 Committee and values their opinions.

11 I request that, whenever possible, we try
12 to reach a consensus on the procedural issues that we
13 discuss today. But I also recognize there may be a
14 minority or dissenting opinions. If you have such
15 opinions, please allow them to be read into the
16 record.

17 At this point, I would like to perform a
18 roll call of the ACMUI members that may be
19 participating today. Dr. Leon Malmud, Chairman?

20 CHAIRMAN MALMUD: Here.

21 MR. EINBERG: Dr. Bruce Thomadsen, Vice
22 Chairman?

23 VICE CHAIRMAN THOMADSEN: Here.

24 MR. EINBERG: Dr. Douglas Eggli, Nuclear
25 Medicine Physician?

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1 MEMBER EGGLI: Here.

2 MR. EINBERG: Dr. Darrell Fisher, Patients
3 Rights Advocate?

4 MEMBER FISHER: Here.

5 MR. EINBERG: Ms. Debbie Gilley, State
6 Government Representative?

7 MEMBER GILLEY: Here.

8 MR. EINBERG: Dr. Sue Langhorst, Radiation
9 Safety Officer? She is present, but must have stepped
10 out. Oh, she is at her security briefing.

11 Mr. Steve Mattmuller, Nuclear Pharmacist?

12 MEMBER MATTMULLER: Here.

13 MR. EINBERG: Dr. Orhan Suleiman, Food and
14 Drug Administration Representative?

15 MEMBER SULEIMAN: Here.

16 MR. EINBERG: Dr. William Van Decker,
17 Nuclear Cardiologist?

18 MEMBER VAN DECKER: Here.

19 MR. EINBERG: Dr. James Welsh, Radiation
20 Oncologist?

21 MEMBER WELSH: Here.

22 MR. EINBERG: We have a quorum here. We
23 have at least seven members participating.

24 Dr. Guiberteau is representing the
25 diagnostic radiologists today. Dr. Guiberteau does

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1 not have voting privileges, but he will listen and
2 speak on behalf of the diagnostic radiologists.

3 I would like to thank Dr. Guiberteau for
4 acting in this capacity. Thank you.

5 I now ask that NRC staff members who are
6 present to identify themselves. We'll start with the
7 individuals in the room here, and then I will turn it
8 over to the NRC staff members on the phone.

9 MS. COCKERHAM: This is Ashley. Just as a
10 quick reminder, if anyone is speaking, could you
11 please make sure not only that you are speaking into
12 the mic, but straight on into it, so that the Court
13 Reporter can accurately record everything. These are
14 very directional mics. They don't pick up much from
15 the sides.

16 MR. EINBERG: Your name?

17 MS. COCKERHAM: Oh, my name. Sorry.
18 Ashley Cockerham. Sorry, I wasn't listening.

19 MS. FLANNERY: Cindy Flannery.

20 DR. HOWE: Donna-Beth Howe.

21 MR. EINBERG: And we have Gretchen Rivera-
22 Capella.

23 MS. RIVERA-CAPELLA: Yes. I don't have a
24 microphone.

25 MR. EINBERG: Okay. Are there any NRC

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1 staff members on the phone right now calling in from
2 the regions?

3 (No response.)

4 Hearing none, okay.

5 Next, we will identify members of the
6 public who are participating on the phone. Ashley, do
7 you have a roll call to go through?

8 Could people on the phone please identify
9 who is listening?

10 MS. LANGLEY: Karen Langley, University of
11 Utah.

12 MR. EINBERG: Is there anybody else?

13 (No response.)

14 Okay. Hearing none.

15 Dr. Leon Malmud, the ACMUI Chairperson,
16 will conduct today's meeting. Following a discussion
17 of each agenda item, the chair, at his option, may
18 entertain comments or questions from members of the
19 public who are participating with us today.

20 At this point, I would like to turn the
21 meeting over to Dr. Malmud.

22 CHAIRMAN MALMUD: Thank you, Chris.

23 The next item on the agenda is Ashley
24 Cockerham, who will discuss the topic of Old Business,
25 which is Item Number 7.

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1 MS. COCKERHAM: Okay. So if you will turn
2 to Tab 7 in your binders, everyone should have color
3 copies, so you can see the items that are in red.
4 Instead of going through every open recommendation
5 since 2007, I am just going to go over the items that
6 have changed or been updated. But anything that is
7 still open or pending is listed on these sheets.

8 So the first one is Item Number 3 from the
9 2009 recommendations. And it says, "NRC staff should
10 revise 10 CFR 35.490 and .690, as proposed, with one
11 exception." This has to do with deleting the word
12 "private practice" and using the word "clinic"
13 instead. And this item is pending. We have actually
14 changed the status. Donna-Beth is going to be
15 discussing this item tomorrow to get additional ACMUI
16 input.

17 Any questions on that one?

18 (No response.)

19 Okay. Item 6, ACMUI came to a consensus
20 on NCRP Report 160, which is deemed to be
21 scientifically sound and well written. ACMUI believes
22 NRC and agreement states should collect and maintain
23 dose records and keep ACMUI aware of the issues, but
24 should continue a policy of not intervening with
25 medical practice.

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1 ACMUI supports the medical principle of
2 "first, do no harm" and expressed continued concern
3 about exposure to children. And ACMUI's current
4 belief is that the benefit of medical procedures
5 involving radiation outweighs the risk. And this item
6 was presented at the June 25th Commission briefing, a
7 little earlier this year. And there was no action
8 that came out of that Commission briefing. So this
9 item is now closed.

10 For Item Number 8, NRC staff should not
11 require licensees to report therapeutic infiltrations
12 as medical events. The status on this item has
13 changed from "pending" to "not accepted." OGC
14 determined that therapeutic infiltrations should be
15 reportable as medical events, if the event meets the
16 criteria in 10 CFR 35.3045.

17 NRC staff will issue a regulatory issue
18 summary, or RIS, to communicate how the regulation is
19 to be interpreted and implemented.

20 Are there any questions or comments on
21 this one?

22 MEMBER GILLEY: Debbie Gilley. Is that a
23 compatibility B, this recommendation?

24 MS. COCKERHAM: I don't know what the
25 compatibility --

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1 MS. FLANNERY: I'm not certain we can --
2 this is Cindy. I'm not certain that we could answer
3 that right off hand. We would have to look that up.
4 Can I get back to you?

5 MEMBER GILLEY: Thank you.

6 DR. HOWE: This is Donna-Beth Howe. Also,
7 it doesn't involve any new rulemaking. It is an
8 interpretation of the current existing NRC regulation,
9 so whatever the level of compatibility is it is the
10 level of compatibility for the reporting requirements.

11 MS. COCKERHAM: This is Ashley. I have SA
12 -- is it 200? 300? SA-200 on my computer. So when I
13 get done with this I'll look and see what SA-200 says
14 for that regulation.

15 CHAIRMAN MALMUD: Ashley, could a member
16 of NRC staff give us two or three examples of what
17 infiltrations are? Examples. Therapeutic
18 infiltrations.

19 DR. HOWE: I will be -- this is Donna-Beth
20 Howe again. I have one that I will be talking about
21 later today that is a medical event. It was an I-125
22 therapeutic administration in which the person giving
23 the administration didn't find the port, and, for a
24 number of other errors, ended up delivering the I-125
25 monoclonal antibody subcutaneously to the individual.

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1 CHAIRMAN MALMUD: And then, may I ask a
2 question related to that? In the new therapeutics,
3 which are delivered directly into the hepatic system,
4 if the -- a portion of the dose travels elsewhere,
5 other than that which was intended, is that considered
6 an "infiltration"?

7 DR. HOWE: This is Dr. Howe. I think you
8 are referring to the Yttrium-90 microspheres?

9 CHAIRMAN MALMUD: Yes.

10 DR. HOWE: And the Yttrium-90
11 microspheres, we -- when we were developing the
12 guidance, we recognized that the microspheres may not
13 go exclusively to the liver, and so authorized users
14 were given an option in the written directive to
15 indicate the maximum dose to any other site as a
16 method of kind of a preemptive move to decide that, if
17 it went to the lung and the physician decided to give
18 it because of shunting, that was acceptable, not a
19 medical event. So we did address that to some extent.

20 CHAIRMAN MALMUD: Thank you for that
21 clarification.

22 MS. FLANNERY: This is Cindy. If I could
23 just add one thing. As far as the licensing guidance
24 for the Yttrium-90 microspheres, it does have some
25 real specific criteria of what qualifies as a medical

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1 event that is separate than what is addressed in the
2 regs, say infiltration of a material that would be
3 covered under 390.

4 CHAIRMAN MALMUD: Thank you. So that the
5 Yttrium microspheres are not referenced in this
6 particular therapeutic infiltration comment, is that
7 correct?

8 MS. FLANNERY: That is correct.

9 CHAIRMAN MALMUD: Thank you.

10 MS. COCKERHAM: Any other questions or
11 comments on Item Number 8?

12 (No response.)

13 Okay. We will turn the page to the 2008
14 recommendations. Item Number 21, "The ACMUI formed a
15 subcommittee to draft a set of proposed qualifications
16 that interventional radiologists must satisfy to
17 become authorized users for Yttrium-90 microspheres."

18 And that subcommittee reported to the full Committee
19 last meeting, so that item is now closed.

20 Item Number 24, "ACMUI formed a
21 subcommittee to develop a solution that satisfies both
22 the training needs of the residency program and the
23 NRC requirements for achieving authorized user status
24 using the Board certification pathway. The
25 Subcommittee should create a recommendation to be

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1 discussed at a future teleconference prior to the
2 spring 2008 meeting."

3 And the Subcommittee did create a report,
4 and they reported to the full Committee in May. So
5 that item is now closed as well.

6 For Item Number 28, "NRC staff should
7 revise 10 CFR 35.65 to clarify it does not apply to
8 sources used for medical use. However, NRC staff
9 should not require licensees to list the transmission
10 sources as a line item on the license. NRC staff
11 should also revise 10 CFR 35.590 to promote the use of
12 transmission sources under 10 CFR 35.500 by authorized
13 users meeting the training and experience requirements
14 of 10 CFR 35.590 or 35.290."

15 And this item was changed to "pending,"
16 because NRC staff is still considering whether there
17 is a basis to support spending the resources for a
18 rule change.

19 Are you going to address this one at all,
20 Donna-Beth?

21 DR. HOWE: Not today.

22 MS. COCKERHAM: Not today. Okay. So this
23 one is pending. But it has changed from "accepted" to
24 "pending" based on resources and the necessity of
25 making a rule change.

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1 CHAIRMAN MALMUD: Thank you.

2 MS. COCKERHAM: Okay. Continuing on for
3 the 2008 recommendations, Item 31, "NRC staff should
4 pursue a change to allow grandfathered authorized
5 users to be supervisors and preceptors." This item is
6 accepted and is now closed, and the direct final rule
7 was published on September 28th of this year. So
8 that's why this one is closed.

9 CHAIRMAN MALMUD: Thank you.

10 MS. COCKERHAM: Any questions?

11 (No response.)

12 If not, we will go to the 2007
13 recommendations. For Item Number 1, "NRC staff should
14 issue an information notice which describes the errors
15 previously made and provides examples of best
16 practices with regard to the units of air kerma
17 strength versus apparent activity in millicuries for
18 brachytherapy sources."

19 The information notice should be done in
20 collaboration with the American Association of
21 Physicists in Medicine, and coordinated with the
22 agreement states.

23 This item is closed. And the information
24 notice is dated August 28, 2009, and it was e-mailed
25 to ACMUI via the medical list server on September 9th.

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1 So everyone should have a copy of that. And the item
2 is now closed.

3 CHAIRMAN MALMUD: Thank you.

4 MS. COCKERHAM: Those are the only updates
5 I have. Does anyone else have a question on an item
6 that wasn't necessarily updated?

7 CHAIRMAN MALMUD: Are there any questions
8 for Ashley? Dr. Welsh?

9 MEMBER WELSH: Ashley, I have a question
10 about Item 30 in 2007 regarding the elected gamma
11 knife perfection. In 2007, we recommended that the
12 perfection be regulated under 1000 until 600 is
13 modified. Is there any update on where we might be in
14 this regard?

15 MS. COCKERHAM: I will have to ask Donna-
16 Beth. Actually --

17 DR. HOWE: Based on the recommendation
18 from the ACMUI, we added the request to move the
19 perfection into 35.600 in our user need memo for
20 rulemaking. Rulemaking has not indicated to us which
21 of those proposed rulemaking changes -- potential
22 rulemaking changes they are going to follow up on. So
23 it is in the process.

24 CHAIRMAN MALMUD: Question?

25 MS. COCKERHAM: This is Ashley. For

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1 anyone that is on the phone, could you press star 6 to
2 mute your line. And if you need to speak, you can
3 push star 6 again to unmute.

4 CHAIRMAN MALMUD: Did someone have a
5 question?

6 DR. GUIBERTEAU: Yes. I have a question
7 on Number 22.

8 MS. COCKERHAM: Which year?

9 DR. GUIBERTEAU: 2008.

10 MS. COCKERHAM: Okay.

11 DR. GUIBERTEAU: On the Y-90 microspheres,
12 in terms of moving that item from 10 CFR 35.1000 to
13 another section of the regulation, it says "partially
14 accepted." Could you --

15 MS. COCKERHAM: That means --

16 DR. GUIBERTEAU: -- that?

17 MS. COCKERHAM: -- we agree about the
18 concept of moving it, just like we are for the gamma
19 knife for the perfection, moving it from 1000 to the
20 appropriate section where it goes.

21 At this time, the microspheres guidance is
22 still changing. It is actually due for a revision
23 right now to add the interventional radiologist. As
24 long as the guidance is changing, we can't justify
25 putting it into regulation, because then we would be

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1 constantly revising the regulations every time we are
2 trying to -- like when we are in guidance space, we
3 have made, what, almost four changes in the past two
4 years? And we can't do that in rulemaking.

5 So for now microspheres remains in
6 guidance space until it is kind of steady, and we
7 have, you know, a basis. I know like the gamma knife
8 perfection, how long has it stayed the same, several
9 years?

10 DR. HOWE: Yes. And the gamma knife
11 perfection really had some changes that were going to
12 be stable that we could move in.

13 DR. GUIBERTEAU: So the difference between
14 "partially accepted" and "pending but open" are
15 "accepted" and "open"? I mean, I think this was the
16 only one that says "partially accepted."

17 DR. HOWE: If I say it's --

18 DR. GUIBERTEAU: I'm not clear on what
19 that means.

20 MS. COCKERHAM: Yes. It says "partially,"
21 because if I say "accepted," it means we are actively
22 writing a technical basis for it and sending it to the
23 rulemaking group and saying, "Please put this into
24 rulemaking," that we are doing something on it. It is
25 not pending, because we do accept it. And we will

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1 change it at some point. It's just not right now.

2 DR. GUIBERTEAU: But the concept has been
3 accepted.

4 MS. COCKERHAM: The concept is accepted.
5 And it's misleading if I put "pending," because then
6 you're like, "Well, are you going to not accept it?"

7 DR. GUIBERTEAU: Thank you. That helps.

8 MS. COCKERHAM: Okay.

9 MR. EINBERG: If I may add, Rob Lewis this
10 morning talked about in the closed session that we
11 have several -- or we have one rulemaking on Part 35
12 that is about to get started. And that is going to
13 encompass a lot of these changes that we are
14 discussing right now. We have put those into the user
15 need memo to our Division of Rulemaking, and they are
16 going to be addressing those.

17 But there is approximately anywhere
18 between 15 to 30 items that will be addressed in this
19 Part 35 rulemaking. And so these items will be
20 addressed, and if there is an adequate technical basis
21 developed, then they will be accepted.

22 MS. COCKERHAM: I think the idea with this
23 one is the rulemaking that Chris is talking about
24 right now, this is not included in that current
25 rulemaking. So it's not in that 15 or 30 items. But

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1 once those 15 or 30 items, like Rob said -- well, you
2 weren't here during the closed session -- we can only
3 have one Part 35 rule before the Commission at a time.

4 So once this group of 15 to 30 items goes through, it
5 is going to take several years.

6 We are assuming once those several years
7 are over that we could put this -- the microspheres
8 into rulemaking. So it could be -- what did I tell
9 you last, 2011? Something like that. A couple of
10 years from now. So we will look at this again, but it
11 would remain on our radar.

12 DR. GUIBERTEAU: Thank you.

13 CHAIRMAN MALMUD: Thank you.

14 MS. COCKERHAM: Any other questions?

15 (No response.)

16 That's all I have.

17 CHAIRMAN MALMUD: Thank you very much.

18 The next item on the agenda will be taken
19 out of order.

20 MS. COCKERHAM: No, we -- Jim, are you
21 going to take it? Okay. Actually, Jim is going to
22 fill in for Sue Woods.

23 CHAIRMAN MALMUD: Oh, okay. Thank you,
24 Jim.

25 MR. LUEHMAN: Yes. My name is Jim

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1 Luehman. I am actually one of Rob's deputies. I was
2 the former Deputy Director of the Office of
3 Enforcement. And, unfortunately, Sue Woods, the
4 Senior Enforcement Specialist who was going to do this
5 presentation, has -- she is out sick. Her kids I
6 think actually might have the flu. I don't know what
7 variety, but obviously that is of concern to all of us
8 as the numbers continue to go up.

9 So the better course of action for her is
10 to stay home, and so I am going to fill in for her
11 here.

12 Okay. So I apologize if this gets off to
13 a little bit of a rough start. Basically, the
14 presentation I am going to go through is an overall
15 overview of the enforcement process. From time to
16 time, we talk about the enforcement process here in
17 the -- with the Committee, and we just want to sort of
18 hopefully demystify a little bit some of our
19 terminology.

20 I will start out with some very general
21 concepts and slides, hopefully go through those really
22 quickly. At the end, get to some slides specifically
23 related to medical licensees, and then I will be open
24 for some questions.

25 So I am -- as it says on here, I am not

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1 Sue Woods. I am Jim Luehman. But from that, we can
2 progress.

3 Let's see. Basically, the enforcement
4 process, really what we want is we want good
5 communications with the licensee, because ultimately
6 we want them to identify their own problems and
7 whether or not they identify their own problems, which
8 is desirable, that they have a robust program that
9 does.

10 But even if they don't, in the cases where
11 it is done by inspection or other methods, the
12 problems are identified, that they take effective
13 corrective action. I mean, ultimately our enforcement
14 policy is predicated on licensees finding their own
15 problems and then taking good corrective actions to
16 fix their problems, because, as all of you know, our
17 regulations are pretty complex.

18 And there is not going to be any licensee
19 that all the time is in compliance with all --
20 everything. And we strive to get them there, and they
21 strive to be there. And so having a good set of
22 corrective actions is really what it is all about.

23 These are just some of the ways that we --
24 you know, we identify violations or potential
25 violations. The inspection process is different from

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1 the investigation process. In NRC vernacular,
2 "investigation" has a particular meaning, and that is
3 an investigation of potential wrongdoing or criminal
4 activity.

5 So that would be -- when you see the word
6 "investigation" used in NRC documents as opposed to
7 "inspection," inspection is done by our inspectors,
8 investigation is done by our Office of Investigation,
9 looking at potential, like I said, criminal activity,
10 willful -- you know, willful non-compliance with
11 regulations.

12 What we do is we exit with the licensee at
13 the end of an inspection. We let them know -- the
14 inspectors let them know preliminarily what the
15 violations might be, get the licensee's feedback on
16 that. Then, there is an inspection report. After
17 there is management review, there is an inspection
18 report that characterizes these violations as apparent
19 violations.

20 Then, the apparent violations are
21 considered internally at an enforcement panel to
22 determine whether they are of, you know, routine
23 significance or potentially escalated significance.
24 If they are escalated, potentially escalated
25 significance, we will have a pre-decisional

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1 enforcement conference with the licensee.

2 And we will review all of the information
3 we get at that conference, and then there will be a
4 final agency decision on what enforcement action, if
5 any, should be taken.

6 Like I said, I talked a little bit -- I
7 mentioned briefly enforcement panel. That is an
8 internal panel that has enforcement people, people
9 from the regional office or the inspection office,
10 whatever inspection office may have done it, as well
11 as people from the program office. In the case of
12 medical licensees, typically that would be -- that
13 would be one or more people from our staff in FSME in
14 on that as well.

15 When we -- you know, when we get the --
16 when we get a licensee at an exit meeting, we ask them
17 -- they will typically provide us their perspective on
18 some of these things, as well as whether they agree
19 that there is a violation.

20 Let's see. And, obviously, we review all
21 of the information, and then the decisions we have got
22 to make is: did a violation occur? What was the
23 significance? Is enforcement action warranted, and of
24 what type? And should that include a civil penalty?
25 And if so, what amount?

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1 Obviously, the actions we could take -- no
2 action, notice of violation, which is -- which doesn't
3 include a civil penalty, but it does -- it is a formal
4 document that requires the licensee to provide us on
5 the record their corrective actions, either the
6 corrective actions they have taken or intend to take.

7 And then, obviously, for the even more significant
8 ones, you can have a notice of violation with a civil
9 penalty.

10 Obviously, we have an order that can
11 either require -- amend the licensee's license,
12 including removing individuals or stopping certain
13 practices. And as I talked about in one of the first
14 slides, there is also a parallel. There is potential
15 criminal penalties for willful violations.

16 I've got to say, though, that
17 historically, while the Office of Investigation refers
18 any willful violations to the Department of Justice,
19 the Department of Justice takes very few of our
20 enforcement actions.

21 They typically leave it up to the
22 administrative processes of the agency to deal with
23 them, though we are required -- the Office of
24 Investigation is required by statute to refer all
25 potential willful or criminal violations to the

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1 Department of Justice for their review. And they do
2 that, but, like I said, very few of them.

3 Actually, DOJ usually refers them back to
4 the agency for administrative remedy. A lot of those
5 -- you know, I don't want to make that sound more
6 onerous than it is. A lot of the violations we are
7 talking about are individual -- potentially individual
8 employees who decide to take it on themselves not to
9 follow a procedure.

10 You know, in the settings that we are
11 talking about, in hospitals typically, you may have an
12 RP tech or a nuke medicine tech who is required to,
13 you know, do surveys at the end of the day, falsifies
14 the records because they want to go home, or because
15 their kid is sick or whatever their reasons are, they
16 are mad at their boss. And because they did that, you
17 know, deliberately, that would be, under our
18 regulations, the way that the regulations are
19 promulgated from the Atomic Energy Act, something like
20 that would be considered a potential criminal
21 violation.

22 Obviously, something of that significance,
23 the Department of Justice is not likely to take it.
24 Obviously, if we had more significant criminal
25 violations or deliberate violations, the Department of

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1 Justice may want to take it. But, like I said, the
2 occurrences where that actually -- the times that that
3 actually occurs are fairly rare.

4 As I mentioned, one of the determinations
5 we have to make is severity level. Severity Level I
6 is the most significant. Severity Level IV is the
7 least significant. To put it in perspective, Severity
8 Level I, in the medical context, would be something
9 where a patient actually died because of a violation,
10 or that there was severe harm to the -- physical harm
11 to the patient because of some violation of the
12 regulations.

13 Severity Level IV would be -- on the other
14 end of the spectrum, Severity Level IV would be, you
15 know, something where there -- where a procedure
16 wasn't followed, procedures weren't followed, but
17 there were no consequences of any type.

18 And then, obviously, Severity Level IIs
19 and IIIs are potentially -- because you see the line
20 -- potentially significant violations. But less than
21 Severity Level I typically, you know, a Severity Level
22 III might be something like a significant breakdown in
23 the program where there was no actual consequences,
24 but a significant procedure wasn't being followed,
25 something like that, not just in one instance but in a

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1 systemic or programmatic matter.

2 The enforcement policy -- the enforcement
3 decisionmaking is -- we use what we call in -- because
4 it was developed in the Washington area, the metro
5 map. And, you know, it is a fairly -- it is a fairly
6 simple diagram that tries to break it down. Once you
7 determine that something is potentially an escalated
8 enforcement action, what this chart does, if you
9 follow it through, is the entry-level question is: is
10 it a Severity Level I, II -- Severity Level I, II, or
11 III violation? Is the entry condition, the red -- the
12 colors red, yellow, those are -- that is a reactor
13 process that inputs this. So it is not really
14 applicable to this discussion.

15 And then, the key is, if you have a
16 Severity Level I, II, or III, you enter the decision
17 block. And then, the first block is: is this the
18 first non-willful violation? And, again, if you
19 follow the logic through, not -- willful violations
20 are considered obviously more significant than non-
21 willful, and that is why it asks that question.

22 If it's non-willful, and it is the first
23 one in the last two years, then you use the green
24 path. And if it's either -- if it is either willful
25 or it's not the first severity level escalated action

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1 in the last two years, then you enter the lower path,
2 and potentially you can get even larger civil
3 penalties.

4 What you need to learn from -- what you
5 need to take away from this diagram is not being --
6 obviously, not to be an expert, but is this thing
7 tells you that we give licensees -- as I said earlier,
8 we put a premium on licensees identifying their own
9 violations, preventing violations, so that if it's the
10 first one in the last two years, and if it -- or if
11 it's not -- and it's non-willful, then you are on the
12 upper path, which is going to give you the least
13 severe sanctions. Again, premium on good past
14 performance and a premium on correcting your own
15 mistakes.

16 If it's willful, we take a serious -- we
17 take more serious when people are acting willfully,
18 not following the regulations and -- or if it's -- if
19 they have a prior history. And then, you potentially
20 head to the red line at the bottom where you could
21 get up to two times the civil penalty.

22 So what you need to take away from that is
23 we take a dim view of willful violations, we try to
24 give licensees credit even if they have a significant
25 violation, if they take good corrective action, and if

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1 they have had a relatively good enforcement history,
2 which is the last two years or two inspections.

3 We also have -- under the enforcement
4 policy we have discretion to escalate and mitigate on
5 civil penalties, even if our road map would come out
6 that you would -- you should get a penalty or should
7 not get a penalty. The staff can exercise discretion,
8 and either include a penalty when one -- when the path
9 would not normally include one, or mitigate a penalty
10 or eliminate a penalty where it would say we should
11 have one.

12 The staff has limited discretion in this
13 area. If we want to escalate or mitigate above a
14 certain amount, then we have to get -- we have to take
15 that to the Commission and get their approval.

16 Enforcement actions become public
17 documents. Civil penalty -- actions that include
18 civil penalties or include orders, they have hearing
19 rights. The licensee and/or individuals have hearing
20 rights, if they are given a civil penalty or issued an
21 order. And all of this is discussed in the
22 enforcement policy.

23 Willful violations -- like I said, I think
24 that these -- we consider these much more significant.

25 There is typically an investigation by the Office of

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1 Investigation. There is a similar process that is
2 gone through before we issue an action to an
3 individual or to a company, if there is willful
4 violations.

5 The one difference when you have willful
6 violations -- and that is on the next page -- besides
7 they might be subject to criminal sanctions is we have
8 the Alternative Dispute Resolution process. In
9 accordance with the ADR Act of 1996, the NRC has
10 developed an Alternative Dispute Resolution process,
11 and we in enforcement specifically use it when it
12 comes to willful violations.

13 Why there? Well, typically, licensees
14 will agree with the NRC when a violation occurs. But
15 they usually take strong exception if the NRC -- if
16 the NRC concludes that one of their -- one or more of
17 their employees or people that work for them did it
18 deliberately or willfully.

19 And, really, rather than waste a lot of
20 time, you know, debating that point, we want to get
21 corrective action for the violation, ensure that they
22 move on. We have offered alternative dispute
23 resolution to try to offer another pathway to resolve
24 the differences with licensees and the NRC when it
25 comes to willful violations.

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1 What we found is that licensees typically
2 challenged these when we made -- when we issued
3 notices of violation. It took a long time to resolve
4 the disputes between the agency and the licensees, and
5 so we have offered alternative dispute resolution.
6 It's not necessarily going to give them a -- you know,
7 a more lenient sanction. It will just offer some ways
8 to give some -- to reach some resolution that is, you
9 know, outside the tight confines of our enforcement
10 policy.

11 I think the general consensus in the
12 agency is that alternative dispute resolutions worked
13 really well. I think licensees would -- have given
14 the same feedback, that it brings resolution much more
15 timely to these issues that are very contentious.
16 Like I said, nobody wants -- somebody might -- a lot
17 of licensees will admit when they have violations, but
18 they take strong exception when we say that one or
19 more of their employees potentially did it willfully.

20 Enforcement statistics -- I am not going
21 to bore you with a bunch of statistics. I am just
22 going to say that in the medical area, over the last
23 couple of years, the one area -- and this really goes
24 to the institution more than any kind of -- any of the
25 practitioners.

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1 The one area that we really -- that we
2 have had increased enforcement activity in the medical
3 area is the implementations of the increased controls.

4 And that is getting all of the various points of the
5 increased controls in place -- you know, agreements
6 with local law enforcement, setting up the proper
7 boundaries and barriers to protect particularly
8 significant quantities of material.

9 Our experience with the medical licensees
10 is no different than our experience with all of our
11 other materials users. There was a learning curve in
12 getting up to speed on these regulations, and we
13 pretty -- we used pretty liberal discretion, what we
14 called "good faith effort," because we were
15 promulgating a new regulation here. That if a
16 licensee really tried to -- you know, made a best
17 effort to implement the regulations as best they
18 understood it, we typically didn't take any
19 enforcement action, even though there may have been
20 violations of the requirements.

21 In the last couple of years, this has been
22 the major escalated enforcement area for not only
23 materials -- I mean, medical licensees, but materials
24 licensees that have quantities of concern in general.

25 We think that now we are over the hump as

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1 far as our understanding of what licensees are doing,
2 their understanding of the regulations or the orders
3 that implemented these increased controls. And we
4 think that, you know, with a few exceptions we are
5 probably pretty good steady-state now with licensees
6 implementing these, and we really haven't seen any
7 additional problems. But it was a learning curve, and
8 we did take that into account by using our discretion
9 not to cite violations in other areas.

10 The other area that -- where we have had,
11 specifically in the medical, that we -- that are not
12 unusual, not surprising, that the other two areas that
13 we have some violations in that reach potentially
14 escalated enforcement are under 35.41(a), and then --
15 which is implementing -- you know, implementing
16 directives to get -- to implement administrations to
17 patients, and following written directives, either
18 having a written directive or following a written
19 directive, which results in -- you know, which has
20 resulted in delivery of the wrong dosage or the wrong
21 sites. And so we have had a few violations in that
22 area.

23 And then, obviously, the other area that
24 we have had a number of violations in that have
25 reached escalated enforcement are under the medical

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1 reporting criteria. That -- those -- some violations
2 are escalated violations over a two-year period in
3 that -- in those areas are not unusual in any two-year
4 period.

5 And I think I have already covered that.

6 And with that, I really -- I don't know --
7 I am really finished really quickly with the
8 presentation. I don't know if there is any questions
9 that anybody has in the enforcement area. Yes, sir.

10 CHAIRMAN MALMUD: Thank you. Are there
11 any questions?

12 MR. LUEHMAN: Okay. Debbie?

13 CHAIRMAN MALMUD: Yes, Debbie?

14 MEMBER GILLEY: Describe to me the
15 enforcement procedures for identifying a facility is
16 not in compliance with the safety culture, and how you
17 are handling that.

18 MR. LUEHMAN: Okay. Safety culture is not
19 a regulation. There is a -- it's a policy statement.

20 In fact, the Commission has recently weighed in, been
21 provided a paper and weighed in on safety culture.

22 Safety culture really got -- as
23 background, safety cultures really started getting a
24 lot of attention on the reactor side after the Davis-
25 Besse event, an event where there was obvious problems

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1 at the reactor, but for various reasons people either
2 accepted the status quo of non-optimum conditions at
3 the plant, or people at the plant were afraid to raise
4 the concerns, because they felt they would retaliated
5 by their management, or they felt, "Well, I could
6 raise that concern, but management is not going to do
7 anything about it."

8 And so after the Davis-Besse event, which
9 was very significant on the reactor side, there was a
10 lot of -- there was a lot of development, interaction
11 with the industry, to come up with a safety culture
12 policy statement. And it was primarily directed at
13 large facilities, you know, a homogeneous group of
14 licensees of the reactors.

15 Subsequently, a policy statement went up
16 to the Commission, and the Commission has directed the
17 staff to now work with the materials -- on the
18 materials side to try to come up with a corollary or a
19 similar program for, you know, getting the
20 Commission's expectations on safety culture out to the
21 materials licensees.

22 Obviously, that is a big challenge,
23 because the materials licensees run the gamut from
24 very large institutions like fuel facilities and
25 hospitals all the way down to individual users of

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1 material.

2 And exactly -- we are engaged right now --
3 our office is engaged in a task force working with
4 NMSS and the other offices that have oversight -- NSIR
5 -- that have oversight on materials licensees to come
6 up with a policy that makes sense. How are we going
7 to get this information out? What information -- is
8 it reasonably -- is it reasonably -- can we reasonably
9 expect certain size and types of licensees to have?
10 What kind of -- what should a safety culture look like
11 at a small institution?

12 Obviously, the larger institutions, the
13 same kinds of things that we expect from a reactor
14 licensee is about as far as having procedures and, you
15 know, a program where people can raise their concerns,
16 and people in that program that can answer those
17 concerns. Those can be -- you know, those can be done
18 very well at a big facility. And, in fact, many
19 facilities have those in place in other areas already.

20 The real question is going to be -- to get
21 down is: how low do you take it into the materials
22 licensees? And how much do you take down to those low
23 levels? What can be reasonably expected at those
24 levels?

25 So, really, it is more of -- it is a

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1 policy statement. It is more of a good practices kind
2 of thing that the Commission wants to get out. But,
3 like I said, the materials licensees are very diverse,
4 and it is a challenge to come up with a policy that is
5 tailored to meet needs at various levels.

6 CHAIRMAN MALMUD: Thank you.

7 Dr. Van Decker?

8 MEMBER VAN DECKER: In regards increased
9 controls, do you believe right now that the NRC has
10 done a reasonable job identifying model program type
11 setups for different sizes and shapes of all the
12 different providers out there in communicating, you
13 know, possibilities to them? A.

14 And, B, in this enforcement process of
15 coming across these, have you run into sites that have
16 problems with the cost issue in putting increased
17 controls into place and what we do about those types
18 of situations?

19 MR. LUEHMAN: Well, I think that -- I
20 think that, you know, that the -- to answer your first
21 question, I think there was a learning process on both
22 sides as we went through the first round of
23 inspections, and that is why we learned -- we used a
24 lot of what we called -- well, it was really
25 enforcement discretion, but we used the term "good

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1 faith effort," where licensees attempted to do
2 something.

3 And I think that we did have to make some
4 adjustments, and we have, for those licensees. We
5 have what we call the IC Toolbox, which is available
6 to those licensees, where we have questions and
7 answers that try to get to providing more uniformity.

8 And I think that over a couple of rounds of
9 inspections now in those areas we have reached some
10 uniformity on our expectations.

11 One of the things that was always in the
12 rule and in the requirements is we didn't expect
13 licensees to make, you know, physical modifications to
14 facilities. I mean, there were -- you know, a lot of
15 the things that are in the ICs -- and I want to be
16 careful I don't go too much into the ICs here -- but a
17 lot of the ICs, you know, there were a lot of
18 questions, and they are answered in the Toolbox, of
19 what NRC expectation is.

20 So I think that we do have -- we have
21 reached -- we tried to set it out initially, but I
22 think that obviously, even before the inspections,
23 what our expectations were. But it did take some --
24 it was an iterative process.

25 We had to go out there and look at what

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1 the licensees had done, because, obviously, as you
2 implied, Dr. Van Decker, not -- one size doesn't fit
3 all. And we did -- and I think the IC Toolbox does
4 address those kinds of questions that came up.

5 As far as the rest of your -- you know,
6 the rest of the question, I think that -- I don't know
7 how -- what the best way to answer. I think that we
8 have -- no, I don't know. Can I get some help here?
9 Chris, I --

10 MR. EINBERG: As I recall, your question
11 was: have we communicated?

12 MEMBER VAN DECKER: No, I think that the
13 first -- the explanation for Part A was reasonable for
14 what I was trying to get to. Part B was just cost,
15 did you find problems with some of this issue as a
16 cost issue? And --

17 MR. EINBERG: Okay. Sorry.

18 MEMBER VAN DECKER: -- I would go from
19 there.

20 MR. LUEHMAN: I think that -- again, I
21 think because we didn't require, you know, facilities
22 to make modifications, I don't think that the cost --
23 I don't think that the cost issue has proven to be an
24 issue that many licensees have raised, specifically,
25 on the modifications.

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1 The one place we have heard the cost issue
2 has been in the area of doing the trustworthy-and-
3 reliable checks on individuals -- you know, having a
4 trustworthy and reliable -- somebody that makes those
5 types of determinations and then running through the
6 -- all of the staff that need to have that.

7 I think, though, that now that we are sort
8 of over the hump that there was a big -- there was a
9 big number -- a huge number of people that had to be
10 run through that process. But now that we are much
11 more in a steady state, you know, a person leaves here
12 or there, another person comes on, I don't think that
13 there is -- that we have -- we continue to get a lot
14 of concerns from licensees that there was -- that
15 there is a big cost issue.

16 But that is the one area where we did hear
17 some feedback from licensees, especially smaller
18 licensees, that the cost of creating a trustworthy and
19 reliable official, and running all of their people
20 through the background program and getting them
21 approved through fingerprinting, was a sizeable cost,
22 especially at smaller facilities.

23 CHAIRMAN MALMUD: Thank you. Are there
24 other questions?

25 DR. GUIBERTEAU: Just to follow up on

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1 Bill's question. I think that is a very admirable
2 attack to take with many of the smaller --
3 particularly the rural facilities in many parts of the
4 country. But I am curious to know, in the terms of
5 the proposed rulemaking for physical protection of
6 byproduct material, there are two items in there that
7 seemed of interest to me, and one was the access
8 authorization program with background investigations
9 for Categories 1 and 2 material quantities.

10 And under security plans, the term
11 "security zones," are these going to be things that
12 might impact, as Bill was suggesting, the cost of
13 these, you know, of these sorts of things, in terms of
14 control?

15 MR. EINBERG: Jim, I think we have to be a
16 little careful. That's a proposed rule that was put
17 out, or was provided to the ACMUI members for review
18 and comment. I don't believe that has been -- I don't
19 believe that is publicly available right now, so we
20 can't really discuss what is in the proposed rule.

21 CHAIRMAN MALMUD: Thank you.

22 MR. LUEHMAN: The one thing I would just
23 add to that, though, is that I think the intent of the
24 rule as it moves forward is that, by and large, it is
25 not going to expand greatly on -- I mean, it is there

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1 to a great extent to codify what already is required
2 under the orders. And so I don't -- I don't imagine
3 -- and, again, with Chris', you know, caution there
4 that this is all that is preliminary.

5 But I don't imagine that the final rule is
6 going to greatly expand the amount of -- the amount of
7 cost or work that the licensee has to do, that they
8 don't presently do under the orders. Having said
9 that, is there some new terminology? And is there
10 some added -- will there likely be some added -- a few
11 added requirements in areas like recordkeeping? The
12 answer is probably yes.

13 I think that that -- when you go to a
14 rule, you get those -- a little bit more formal than
15 the -- and more specific than the order. But by and
16 large, I think that they are just going to codify what
17 is already in the ICs.

18 CHAIRMAN MALMUD: Thank you. Are there
19 any other questions? Comments?

20 (No response.)

21 If not, that completes your presentation.
22 Thank you.

23 MR. LUEHMAN: Thank you.

24 CHAIRMAN MALMUD: We now have a break, do
25 we not? Lunch?

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1 MR. EINBERG: We have lunch.

2 CHAIRMAN MALMUD: When shall we return?

3 MS. COCKERHAM: I suggest coming back at
4 1:00, mainly because I think people are planning to
5 attend Steve Mattmuller's presentation on medical
6 isotopes. And if we start early, I'm afraid people
7 won't be here.

8 CHAIRMAN MALMUD: So we will start
9 promptly at 1:00 in order to maintain the schedule for
10 those members of the public who wish to attend.

11 MS. COCKERHAM: Yes.

12 CHAIRMAN MALMUD: Thank you. We will
13 reconvene at 1:00.

14 (Whereupon, at 11:21 a.m., the proceedings in the
15 foregoing matter recessed for lunch.)
16

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

(1:00 p.m.)

CHAIRMAN MALMUD: Welcome, everyone, to the afternoon session. It being 1:00, we will start promptly with the first item on the agenda, which is the update on medical isotope shortage. Steve Mattmuller will do the presentation, and it is Tab Number 9 in your books.

MR. EINBERG: Excuse me, Dr. Mattmuller. Ashley is telling me we should do a roll call on who is on the phone, if we could --

CHAIRMAN MALMUD: Thank you.

MR. EINBERG: -- take a moment.

CHAIRMAN MALMUD: If we may, we will begin with the roll call of those who are joining us by telephone. Ashley, do you want to --

MS. COCKERHAM: They should be on here. I don't have a call sheet. They just need to identify themselves. Can you guys hear us on the phone?

MS. ALLEN: Yes.

MS. COCKERHAM: Can everyone please identify themselves?

CHAIRMAN MALMUD: Will the person who said "yes" begin? I'm sorry? I couldn't hear you.

MR. DAVIDSON: Will Davidson from the

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1 University of Pennsylvania.

2 CHAIRMAN MALMUD: Davidson from Penn.

3 Next?

4 MR. ROGERS: Joe Rogers, Therogenics
5 Corporation.

6 CHAIRMAN MALMUD: Rogers, Therogenics
7 Corporation.

8 Next?

9 MS. BOWIE: Jennifer Bowie, GE.

10 CHAIRMAN MALMUD: General Electric. I'm
11 sorry, Jennifer. I apologize for addressing you by
12 your first name, but I didn't hear your last name.

13 MS. BOWIE: Bowie.

14 CHAIRMAN MALMUD: Would you spell it,
15 please?

16 MS. BOWIE: B as in bravo, O-W-I-E.

17 CHAIRMAN MALMUD: Thank you.

18 Is there someone else who just joined us?
19 Could you speak up, please?

20 MS. ALLEN: Melissa Allen, GE.

21 CHAIRMAN MALMUD: Melissa Allen, GE.
22 Thank you.

23 Anyone else?

24 (No response.)

25 Thank you. Thank you for identifying

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1 yourselves, and welcome to the afternoon session.

2 Steve Mattmuller will begin with the
3 update on medical isotope shortage. Steve?

4 MEMBER MATTMULLER: Good afternoon. I'm
5 Steve Mattmuller, and I will be discussing our current
6 shortage of molybdenum-99, or moly as I will refer to
7 it.

8 Moly is important, because it is the
9 parent isotope to technetium-99M or technetium, and it
10 is used in more than 16 million nuclear medicine
11 procedures each year in the United States. These
12 procedures are unique as they produce images based on
13 physiology on a molecular level versus anatomy as in
14 CT or MRI.

15 Nuclear medicine procedures are some of
16 the most accurate methods and essential tools used by
17 physicians to provide optimal patient care to their
18 patients. Our technetium radiopharmaceuticals have
19 two components -- the technetium isotope and a
20 chemical component. And the chemical component, based
21 on its structure, determines where the isotope goes in
22 the body.

23 For example, on this slide on the left is
24 a study done to diagnose coronary artery disease.
25 Technetium sestamibi -- and sestamibi is the chemical

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1 component in this slide -- is used here to look for
2 areas of poor perfusion in the left ventricle as
3 pointed out by these yellow arrows on the slide. You
4 would like to see constant steady update in the
5 ventricle indicating good perfusion, and here we have
6 a defect indicating atherosclerosis or an infarcted
7 area.

8 On the right is an example of a bone scan
9 using technetium MDP. Again, MDP is the component,
10 and it is a skeletal avid agent. And the bone scan is
11 used in this case to find sites of metastatic bone
12 disease, which show up in the skeleton as, sadly for
13 this patient, numerous dark spots.

14 For our supply chain of moly, we need
15 nuclear reactors. We need the reactors for neutrons.

16 We need the neutrons to irradiate uranium targets to
17 produce moly. Once irradiated, the second step is for
18 a processor to prepare purified moly from the target.

19 Once it is purified, it is moved on to the generator
20 manufacturer, and the generator is our source of
21 technetium used in nuclear medicine.

22 Buying a moly generator is a lot like
23 buying ice on a warm, sunny day, because, as it decays
24 or ages, it produces less and less technetium each
25 day. Hence, we need new moly to be produced each

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1 week. On this graphic, you can see we have six -- in
2 yellow -- are the reactors around the world that we
3 depend on for our moly.

4 It is -- the first one, top left, is AECL.

5 That's the NRU reactor in Canada, and the HFR in The
6 Netherlands. I'm sorry, I can't read this, but I
7 think it's Osiris in France, and the BR2 in Belgium,
8 and Safari is down in South Africa. And this graphic
9 also has added OPAL, but they have not entered the
10 market yet.

11 In gray are the processors. They take
12 their irradiated targets and purify -- separate out
13 the moly and purify the moly. In Canada we have
14 Nordion, in Europe we have Covidien and IRE, NTP down
15 here in South Africa, and ANSTO in Australia.

16 Generator manufacturers are in purple. We
17 have two in the U.S. -- Lantheus and Covidien.

18 Of course, due to its 66-hour half-life,
19 the greater the distance between the reactor and the
20 generator manufacturer, the more moly you lose due to
21 decay during the shipping. As you can see from this,
22 we have two generator manufacturers in the U.S., but
23 we don't have a reactor.

24 Typically, for the U.S. market, 60 percent
25 of our moly comes from the NRU reactor, or that is

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1 operated by AECL. And typically most of their output
2 goes to Lantheus for the production of their
3 generators, and they usually command about 60 percent
4 of the U.S. market. The rest is covered by Covidien,
5 and they get their moly from the HFR reactor in The
6 Netherlands. And their processing facility is right
7 next door to it, and from there it is shipped overseas
8 to St. Louis.

9 This graph shows the typical contributions
10 of reactors around the world for moly production. And
11 maybe I shouldn't say "typical," because with six
12 periods of supply interruption since January of 2007
13 -- yes, six periods of supply interruption since
14 January 2007 -- a typical moly-99 supply may not exist
15 anymore. The U.S. gets 40 percent of our moly from
16 the HRF -- excuse me, HFR reactor, but it is 47 years
17 old. And it was responsible for the shortage that
18 started in August of 2008 that ended early in 2009.

19 And its shutdown was due to corrosion
20 issues in the cooling system. They didn't repair it
21 at that point in time, but they do plan, in March of
22 2010, to repair the cooling system, and they think it
23 will take six months. It does have some additional
24 capacity to fill in where it can, and it can handle
25 about 50 percent of the U.S. needs.

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1 The NRU reactor in Canada, which is now
2 down, and typically supplies 60 percent of our needs,
3 is 51 years old. And its shutdown is due to a leak in
4 the reactor vessel, and it is estimated to return to
5 service in the first quarter of 2010. It is, as we
6 say, the "grandam" of moly production, as it has
7 additional capacity to where it can produce about 100
8 percent of the U.S. needs.

9 From this graphic, you also see the
10 contributions of the other three reactors. For two of
11 them, one reason they produce such a small amount of
12 moly is their short duty cycle. The French reactor,
13 the Osiris reactor, operates for 220 days a year, and
14 the BR2 operates for 115 days a year.

15 The duty cycle can be limited by reactor
16 design, refueling process, licensing requirements, or
17 the primary objective of the reactor. One has to
18 remember that none of these reactors were built just
19 to produce medical isotopes. In most of them, it was
20 a capability added later.

21 Also, with all of these reactors, they all
22 use HEU targets for moly production. So now we have
23 Global Threat Reduction Initiative implications.

24 Conversion to LEU targets, while
25 technically feasible, will take time and money. But a

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1 big question is: will all of these reactors spend the
2 time and money on conversion as they are all nearing
3 the end of their life cycle?

4 To measure the impact of the shortage, I
5 would like now to discuss some survey data collected
6 by the Society of Nuclear Medicine, or the SNM. The
7 SNM conducted this survey in August to collect
8 information relating to the current shortage of moly
9 caused by the shutdown of the NRU reactor, and also
10 the shutdown of the HFR reactor.

11 The SNM had a total of 710 departments
12 responding, and it was a quick survey. The intent was
13 really just to provide a quick snapshot of the
14 shortage to gauge its impact.

15 On this slide you can see where 94 percent
16 of the departments were impacted, which actually I am
17 very surprised that any could answer no. Possibly,
18 they are very small departments whose needs are very
19 minimal and only need a few doses a week, or perhaps
20 they belong in the NA group, which is composed of PET-
21 only imaging departments that use FDG and, hence,
22 don't rely on moly for their imaging needs.

23 This is question 4, which builds on the
24 previous question 3, which asks, how many of the
25 departments had an alternate source of technetium

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1 during the shortage? And that answer for Q3 was 30
2 percent. So this is -- describes where those sources
3 are. And given that the vast majority of departments
4 use unit dose service from a pharmacy, it is not
5 surprising that another pharmacy would be their top
6 choice.

7 At the top, another hospital as an
8 alternate, this really shows some creativity by
9 hospitals, as hospitals are sharing a generator. And
10 I am aware of this occurring in the rural areas of the
11 upper peninsula of Michigan where a small hospital
12 would use a generator for a few days, box it up, ship
13 it to another hospital, and they would use it there.

14 Another manufacturer -- Lantheus -- has
15 been the most severely affected during this current
16 shortage. And on some weeks Covidien has been able to
17 provide some generators to their customers. But this
18 survey question is really a question of access, and it
19 does not in any way suggest that these alternate
20 sources could meet 100 percent of their needs.

21 If you remember question 2, it was trying
22 to measure how many departments were affected. That
23 is, 94 percent were affected. This question is trying
24 to measure how much they were affected. If you add up
25 the first three ranges, 62 percent of the departments

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1 are, or have been, at less than 75 percent of their
2 normal full capacity.

3 This slide shows how the departments are
4 adapting to the shortages. Eighty percent of the
5 departments had to postpone patients. The most
6 discouraging change is that 47 percent of the
7 departments had to cancel patients.

8 Transfer of patients -- I am hoping these
9 were all outpatients where it may have been much
10 easier to have a patient drive elsewhere versus
11 shipping material between departments. I hope they
12 are not in-patients, because in-patients are much more
13 difficult and complex to transfer. If these are in-
14 patients, perhaps we need to do a better job of
15 educating departments of the NRC exemptions that make
16 it easier to transfer material between licensees.

17 For our hospital department whose primary
18 mission is patient care, this is very discouraging
19 data.

20 MEMBER SULEIMAN: Can we ask questions
21 here, or wait until the end? Why don't those add up
22 to 100? I understand some of the --

23 MEMBER MATTMULLER: Right.

24 MEMBER SULEIMAN: Eighty-one percent said
25 they postpone and --

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1 MEMBER MATTMULLER: Right. The question
2 is: why don't these percentages add up to 100?
3 Because this is -- or let me explain it this way.
4 Eighty percent of the respondent -- and not all of the
5 respondents in the survey answered each question. But
6 also, for this question, 80 percent had to postpone a
7 patient and/or 40 percent -- 47 percent -- I mean,
8 they could be doing multiple -- this isn't either/or.
9 They could be doing all of these.

10 MEMBER EGGLI: As an answerer to this
11 survey, I can tell you this was a multiple choice
12 question. We have postponed procedures, we have
13 canceled procedures, we have changed procedures, we
14 have changed the isotope use. They were independent
15 answers to each of these questions.

16 CHAIRMAN MALMUD: Thank you. Yes?

17 MS. FLANNERY: I just wanted to point out
18 Cindy back here wants to make a comment.

19 CHAIRMAN MALMUD: A member of the public?

20 MS. TOMLINSON: Cindy Tomlinson. I'm from
21 SNM, and I just wanted to give a quick clarification
22 on the survey. Our survey system is not very good.
23 That is the first problem, just the technical part of
24 it.

25 The other thing, too, is that a lot of

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1 people -- not everybody answered every question. So a
2 lot of people skipped around on some of the questions,
3 and that's why it doesn't -- they don't always add up
4 to 100, because what it does is it totals the number
5 of people who clicked to the survey, not necessarily
6 the number of people who answered every question.

7 So that's why the numbers are a little
8 fuzzy. So I just wanted to clarify that for you all.

9 CHAIRMAN MALMUD: Thank you.

10 MEMBER MATTMULLER: Question 7 is
11 comparison to past shortages. Okay. Comparison to
12 past shortages, okay. This is actually a compilation
13 of three SNM surveys in 2008, June '09, and August
14 '09, showing the increasing severity of the three
15 shortages or, with apologies to Clint Eastwood, as I
16 would call them, the good, the bad, and the ugly.

17 The 2008 shortage -- if a shortage can be
18 good, this was a -- it was bad at first when the HFR
19 reactor was first down, but then it became less severe
20 as the NRU, with its excess capacity, was able to ramp
21 up production to compensate and minimize the effects
22 of this shortage. It was able to, in essence, fill
23 the gap.

24 June 2009, this was a bad shortage. It
25 started in May when the NRU reactor went down. Other

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1 reactors have limited capacity to ramp up production,
2 but they have not been able to fill the gap.

3 The August 2009 are the worst numbers.
4 This is an ugly shortage. Both reactors -- the NRU
5 and the HFR reactor -- were both down for about a
6 month. The gap is now more of a black hole. Right
7 now, with the HFR back operating and producing moly, I
8 would say departments are back in the bad area, the
9 June '09 data.

10 However, we could return to the August '09
11 data in 2010 when -- if AECL encounters additional
12 problems that lead to a delay in the NRU's return,
13 past its scheduled restart date, the first quarter of
14 2010. If its delay goes into March when the HFR will
15 shut down for repairs for six months, then we will be
16 back into the ugly zone, with both of our major
17 reactors shut down again.

18 Question 8 is building -- again, it is
19 trying to get more detail from a previous question,
20 in 7. As far as if you had to postpone, how long did
21 the postponement in scheduling occur? And if you add
22 the totals from the four time ranges of the longest
23 delays, the four bottom ranges, over 65 percent of the
24 postponements are for a week or more.

25 Again, trying to get more information as

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1 far as how departments are adapting to the shortages
2 -- wrong button, sorry -- 53 percent responded that
3 they are substituting thallium-201 for technetium. On
4 a smaller scale, departments are substituting the PET
5 agent F-18 sodium fluoride for a bone scan, or, from a
6 cardiology aspect, they are substituting the PET agent
7 rubidium-82 for a technetium heart agent. Both of
8 those are small percentages.

9 Other non-nuclear procedures -- 26 percent
10 of the time. And I would say these are the most
11 troublesome for patient care, as these tests provide
12 different information, anatomical versus
13 physiological.

14 Years ago, myocardial perfusion imaging
15 first gained widespread acceptance with thallium, but
16 its use was replaced by the superior technetium agents.

17 Now, as some would say, we are taking a step back in
18 myocardial perfusion imaging.

19 The thallium isotope has a 74 keV X-ray
20 versus the 140 keV gamma ray of technetium, just over
21 half of the energy. So with this lower energy there
22 is far more patient continuation and degradation of
23 image quality. It has been estimated that 50 to 60
24 percent of cardiac patients are not good candidates
25 for thallium, because of large body mass and/or large

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1 breast size.

2 An important component of myocardial
3 perfusion imaging with technetium agents is that we
4 can perform gating while we synchronize the heartbeat
5 with an EKG. We can see the left ventricle wall move
6 at max diastole or rest, its maximum size, through
7 maximum systole or contraction. And the physician can
8 watch the wall motion, see if it is even and
9 consistent.

10 The physician can also calculate the
11 ejection fraction of the ventricle to see how
12 efficiently the left ventricle is pumping. This part
13 of the test is much more difficult to do with
14 thallium.

15 Bone scans perhaps are the most
16 challenging aspect of this shortage, as bone scans
17 account for about a third of our total studies and
18 there is no other imaging procedure that comes close
19 as a substitute. The PET agent, sodium fluoride, is
20 on the horizon as the substitute, if not an actual
21 improvement, but the Center for Medicare Services, or
22 CMS, has not approved payment for a sodium fluoride
23 study. So it is very difficult for it to gain
24 acceptance without reimbursement.

25 Substituting a PET study, such as sodium

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1 fluoride, is not a universal solution, as it is
2 limited to those departments that have a PET scanner
3 and also access to sodium fluoride. Rubidium is even
4 more challenging, as it needs a generator onsite
5 because of its short 75-second half-life. And even if
6 a department has a PET scanner, it can still easily
7 take three to four months for a department to be ready
8 to use rubidium.

9 This question addresses the size of the
10 departments, in essence before and during the
11 shortage. The department size is based on numbers of
12 patients per week, are in decreasing order, largest on
13 the left, smallest on the right. From the data of --
14 comparing prior to now, you can see that the majority
15 of patients -- excuse me, departments -- are small.
16 Most are in the zero to 100 to 100 to 200 procedures
17 per week.

18 And as you compare the percentages of now
19 versus prior, there is a definite trend of departments
20 being bumped down to the next smaller size, until they
21 get to the smallest size where there is a large
22 increase.

23 Now I am going to discuss a couple slides
24 of surveys that went out to nuclear pharmacies. And
25 with the help of National Association of Nuclear

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1 Pharmacies, or the NANP, SNM conducted this survey
2 with the intent of collecting information from the
3 pharmacies relating to the shortage of moly caused by
4 the shutdown of both reactors, the NRU and the HFR, in
5 August.

6 Total respondents for this survey -- 97.
7 Far fewer than the 710 in the previous survey. But
8 the pharmacies are positioned in the supply chain
9 between the generator manufacturers and the
10 departments. So they are dealing with a far larger
11 number of doses, as one pharmacy can supply numerous
12 departments, oftentimes thousands of doses per week
13 versus the hundreds of procedures per week by a
14 department.

15 Actually, their survey was just as long as
16 the departmental survey, and I will just discuss a few
17 of the results as, not surprisingly, they show
18 parallel effects from the shortage. Perhaps what is
19 most interesting is the number of different changes
20 being employed at the pharmacies to minimize the
21 effect of the shortages. However, most of these
22 changes, though, have costs associated with them.

23 At the top, trying to reschedule patients
24 to another day or time. Before the shortage more
25 departments were open Monday through Friday, but

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1 technetium, with the generators available Monday
2 through Sunday. So they are trying to move some
3 patients to Saturdays when a department in the past
4 had been closed.

5 But a department that was fairly busy
6 Monday through Friday, their staff is not as busy if
7 they imaging the same number of patients Monday
8 through Saturday. So they lose efficiency and staff
9 utilization.

10 Decrease in dosage -- they are decreasing
11 in millicuries the size of the doses that they are
12 sending out to the departments. And the down side is
13 that I can now take longer to image the patients to
14 get the same number of counts for a good image. The
15 longer imaging time can lead to increased discomfort
16 of a patient.

17 Hence, with more patient movement, there
18 is an increased chance of image degradation,
19 especially for bone patients who are being imaged for
20 metastatic sites, which often the metastases can be
21 very painful. So it's difficult for these patients to
22 lie still for a long period of time.

23 Myocardial perfusion of patients often are
24 imaged with their arms up above their heads, and so it
25 can be difficult for patients to hold their arms over

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1 their heads for a long period of time.

2 Elimination of bulk orders -- this is for
3 technetium protectant tape, which is intended to be a
4 small inventory of technetium in the department to be
5 used for a stat procedure in the afternoon or that
6 evening.

7 So without a supply at the department,
8 when there is a stat procedure, additional time is
9 needed to get the dose. You need to get hold of the
10 on-call pharmacist. He has to get -- or she has to
11 get to the pharmacy, prepare the dose, package it up,
12 ship it to the department. All of these are delays in
13 delivering the procedure to the patient.

14 This is the same question as the previous
15 slide, just additional answers in how they are trying
16 to cope with this. Oh, excuse me. In regards to the
17 bulk being eliminated, what can be an additional cost
18 is -- comes about in additional shipping charges.

19 Examples of typical delivery charges, from
20 a contract that I happened to see from a local Midwest
21 hospital, Saturday and Sunday it is \$15 for the first
22 delivery, but then \$175 for additional. Business
23 hours, if the pharmacy happens to be open, if they
24 need a stat delivery, it's \$75, or, if after the
25 pharmacy is closed and you need a stat delivery, the

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1 delivery charge is \$175. So, as you can see, the
2 additional delivery charges can be quite substantial.

3 To follow up on this slide, rather than
4 ship a pre-calibrated afternoon dose, which it would
5 then be pre-calibrated by four to six hours in a
6 morning shipment, the activity is now used for
7 additional morning doses. And this forces the
8 pharmacy to loop their generator again, more often,
9 and prepare additional technetium kits, where now,
10 instead of preparing one large kit in the morning,
11 they are probably preparing two or three smaller kits
12 throughout the day, and then some afternoon doses in
13 the afternoon.

14 And so they have to ship more frequently,
15 more, as they say, just-in-time deliveries. And some
16 of these just-in-time deliveries can also add to
17 additional shipping charges.

18 All of these results show how we are
19 trying to minimize the effects of the shortage, but we
20 are just minimizing them. We are not avoiding all of
21 them. Like us, physicians are concerned about patient
22 care, and they are trying to take care of their
23 patients.

24 Nuclear medicine tests are unique, because
25 the images are based on physiology. Every other test

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1 is based on anatomy. Hence, there is no easy
2 substitute, especially in the case of a bone scan. As
3 mentioned before, there is no current approved
4 substitute for a technetium bone study. And this
5 study accounts for a third of our studies.

6 Myocardial perfusion studies often serve
7 as a gatekeeper to cardiac catheterization. That is,
8 of studies found to be normal, it rules out the need
9 for cardiac cath. But now some physicians may go
10 straight to cardiac catheterization, which is far more
11 expensive and has a higher radiation dose to the
12 patient.

13 Up to now I have been talking about
14 departments and pharmacies and how they are trying to
15 adapt to the shortage. Now I will take a few minutes
16 to talk about the manufacturer's response.

17 In this slide we have -- we start with our
18 supply chain of the five major nuclear reactors. In
19 the middle are the gray processors, purifying the
20 moly, and if we had a little bit darker room these
21 would be orange generator manufacturers on the right,
22 Covidien and Lantheus here in the U.S.

23 The solid arrows represent major supply
24 lines or major quantities produced by the reactors
25 that go to these processors. And the dotted lines --

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1 dotted arrows are minor. And on the left is how we
2 would like to be, and on the right is how it currently
3 is now. And you can see where the NRU is down and it
4 is -- Nordion is not doing much either, and Lantheus
5 only is able to get minor supplies from the other
6 processors, NTP and IRE, NTP being in South Africa and
7 IRE being in Europe.

8 From one of the earlier slides, there was
9 an OPAL reactor listed in Australian. But moly from
10 it has not yet reached the U.S. market. And we hope
11 that will happen -- or occur in a few months. But
12 when it does, it will be a minor supplier. It will be
13 welcome, but it will be a minor supplier.

14 The OPAL's original plan was to supply
15 just Australia and the South Pacific market. So if
16 they were to enter the world market in a significant
17 amount, they would need to build a larger processing
18 center, as their reactor can produce more moly, but
19 there are limitations on the size of their processing
20 facility.

21 This is an example of a Covidien supply
22 estimate. Periodically now Covidien has been
23 publishing letters as to what they think is going to
24 be the supply of moly, and, hence, technetium through
25 the industry. Between the two generator

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1 manufacturers, they of course are in better shape for
2 the moment. And this is what they expect to happen.

3 Green is -- boy, it has gotten faded here
4 -- green or gray at the top, they expect their usual
5 generators' orders to be met, but there will be
6 minimal effects on the unit dose. Wow, I was -- the
7 second color was yellow on a bright screen, more of a
8 pea green here. And that is where, again, they think
9 their standing orders for generators will be met, but
10 there won't be any extra technetium, and there will be
11 some unit dose reductions.

12 This was orange. It is now more of a
13 brown. There will be shortages, even with their
14 standing orders and unit dose impact. There will be a
15 significant technetium shortage and unit dose impact.

16 As you can see at the bottom, they have a
17 disclaimer that information is on -- current
18 information is subject to change. And I am here to
19 tell you -- and it is no fault of theirs -- but, yes,
20 they do change. We still -- even with their best
21 estimates, we still get many nasty surprises, despite
22 their best efforts.

23 Another way of looking at this calendar is
24 that green is good, yellow is bad, and orange or brown
25 is ugly. At the end of July into August, from here

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1 into August, this is when both reactors were down --
2 the NRU and the HFR. So at this point in time, we
3 were missing about 64 percent of the world's supply
4 for moly.

5 You also see a lot of Sundays involved, as
6 this is the biggest day volume-wise to produce
7 technetium generators, as on Mondays these generators
8 will then be able to produce their greatest amount of
9 technetium and allow a department or a pharmacy to use
10 the generator in the most cost effective manner.

11 This was their letter they sent out. This
12 is the second one. I'll show you -- they probably
13 have had a dozen already. But this was dated 9/22.
14 But this has changed already.

15 If you can see this -- I'm sorry, someone
16 wouldn't let me update my slides --

17 (Laughter.)

18 But compared to what is on the screen now,
19 where you see green, all the green is now gone. It is
20 just yellow. So we have no good days ahead of us. We
21 just have bad and ugly days going from October,
22 November, and December.

23 I have talked about departments,
24 pharmacies, and now on the horizon some new moly
25 producers. This is the OPAL reactor. It is a brand-

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1 new reactor commissioned in 2007 fueled with LEU, and,
2 most importantly, produces moly with LEU. Hence,
3 minimal Global Threat Reduction Initiative concerns.
4 Its LEU-produce moly has also already been approved by
5 our own Food and Drug Administration for use by
6 Lantheus in their generators.

7 They have not started supplying Lantheus
8 yet, but they do start hopefully in the next few
9 months. It is one of the few good bits of news we
10 have. Even though they are limited in supply, it is a
11 new supplier from a new reactor and from LEU, and it
12 operates 340 days a year. Its only real down side is
13 it is halfway around the world. Current estimates are
14 that it will take 40 hours for the flight, and the
15 time needed to clear Customs, just to get to Boston.

16 Forty hours is a long time for a product
17 with a 66-hour half-life. It will lose 35 percent of
18 its activity in that time to decay.

19 It is a start. A lot can happen in that
20 40 hours. But we are still in need of a robust moly
21 supply here in the U.S.

22 Here is the first of two projects with
23 great potential in the U.S. -- Missouri University
24 research reactor in Columbia, Missouri. Over the
25 years they have built an exemplary safety record, and

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1 they have gained extensive experience as a producer of
2 medical isotopes.

3 They do use HEU for fuel, but an LEU fuel
4 conversion project is underway. And, once completed,
5 they will need a new license as they will need to
6 operate at 12 megawatts for good moly production. But
7 current licenses for research reactors stop at 10
8 megawatts, so it needs some NRC regulatory relief.
9 Otherwise, it will need to be classified as a test
10 reactor, but these licenses are much more complex and
11 burdensome.

12 They also are going to need help with
13 radioactive waste. A new bill in Congress that has
14 been recently introduced -- the Markey bill -- has a
15 provision in it that will help deal with that. And I
16 failed to mention that earlier, that right now there
17 is no facility in the U.S. that will take LEU waste
18 from a non-DOE facility. So the Markey bill has this
19 provision, and so its passage is critical to address
20 the radioactive waste issues for the Missouri reactor.

21 They also need help with funding, which,
22 as a public institution, is a bit more difficult to
23 obtain than a private corporation. And, again, the
24 Markey bill here is very important, as it provides
25 funding provisions that would be very, very useful to

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1 Missouri.

2 And did I mention it's in the U.S.? If
3 you Google it on the internet, Columbia is 110 miles
4 to St. Louis where Covidien is at, or 1,300 miles to
5 Boston where Lantheus is at, as opposed to the
6 distance between Sydney and Boston -- I'll caution
7 here, if you use Google to calculate distances, it
8 only does it by car. So in this case it is 26,000
9 miles, and, of course, you would have to build a few
10 Trans-Pacific bridges -- a fact that didn't seem to
11 bother Google.

12 (Laughter.)

13 But by air, as mentioned before, 40 hours
14 for the 10,000 miles.

15 Here is the other good potential U.S.
16 solution -- Babcock and Wilcox has partnered with
17 Covidien for moly production using LEU. And they are
18 using not a new -- well, new for isotope production --
19 a reactor called an AHR, or aqueous homogeneous
20 reactor, where it has liquid fuel and target material.
21 It is all one in the same.

22 And they are calling those a MIPS, a
23 multiple isotope production system, whereas this
24 reactor from here to here is about the size of a large
25 oil drum. It is about four feet tall. And it would

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1 -- and 200 kilowatts is its energy rating. So very
2 small compared to even today's research reactors.

3 They would operate it to produce the moly,
4 and shut down the reactor, remove the fuel, separate
5 out the moly, purify the moly, and then return the
6 fuel back to the reactor to produce additional moly
7 within each unit. And they have a series of them, so
8 as one is down for removing the fuel, or going through
9 the purification process, the other three can continue
10 producing moly. That is, as they call it, the MIPS.

11 This type of reactor is very safe. It has
12 a large negative coefficient of reactivity, which if
13 you read about the Maple reactors in Canada you are
14 forced to learn about coefficient of reactivities.
15 Its waste stream is also greatly reduced versus a
16 typical solid LEU target or HEU target, and it will be
17 in the U.S.

18 Their potential down side, which will be
19 measured in time, as in a delay to entering the supply
20 chain, is that they still have to perfect the
21 extraction and purification process of the moly from
22 the liquid fuel mixture. But through personal
23 communications with company officials, they claim
24 their R&D optimization efforts are going very, very
25 well. They are not concerned about that.

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1 Their biggest challenge -- their biggest
2 challenge is with, as I would say, they are in
3 regulatory purgatory. There isn't a reactor license
4 that fits their AHR reactor very well. It could be a
5 research reactor, but a research reactor has limits of
6 not more than 50 percent of its activities can be for
7 commercial activities. And this will be 100 percent.

8 They are too small to be a power reactor,
9 and they don't fit well as a test reactor. So there
10 really isn't a license category for this type just
11 yet.

12 The other issue is that if you remember
13 the earlier graphics where the reactors were either
14 yellow or green, or they were on the left, since our
15 colors are off right now, and in the middle were the
16 gray moly producers, Babcock and Wilcox, in essence
17 they will be both. They will be the processor and the
18 reactor all in one building. So that is yet another
19 licensing issue.

20 Their MIPS system combines two of these
21 functions -- the reactor and the processor. So
22 instead of two separate facilities with two separate
23 licenses, they would like to have one license for
24 their MIPS unit.

25 This is the bill that has recently been

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1 introduced in Congress that I mentioned earlier. This
2 is -- officially, it's the American Medical Isotopes
3 Production Action of 2009, or as I have been calling
4 it, the Markey bill, since Congressman Markey of
5 Massachusetts introduced it.

6 This has several important provisions for
7 our moly supply. The first is authorization of
8 appropriations. They are authorized -- they will
9 authorize the Secretary of Energy to provide
10 \$163 million to potential U.S. producers of moly in
11 the U.S. in regards to waste. They have a provision
12 for uranium lease and take-back.

13 "The Secretary of Energy shall establish a
14 program to make low enriched uranium available through
15 lease contracts or irradiation for the production of
16 moly for medical use. These contracts will provide
17 the Secretary of the DOE to retain responsibility for
18 the final disposition of the radioactive waste created
19 by the irradiation processing or purification of the
20 leased uranium."

21 So this is a very, very important aspect
22 of the bill for not just Missouri but also for Babcock
23 and Wilcox.

24 On 10/14, last Wednesday, this bill moved,
25 with minor amendments, out of the House Energy and

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1 Environmental Subcommittee of the House Energy and
2 Commerce Committee. So while this is an important
3 first step for its passage, it is essential that it
4 does pass, so we have U.S. suppliers of moly.

5 If you noticed in my title slide, I had a
6 little asterisk by "moly," and that is because we have
7 now experienced shortage with other medical isotopes,
8 most notably iodine-131. Iodine is supplied in two
9 pharmaceutical forms -- solution and capsules,
10 capsules of different strengths. And Covidien has
11 been out of iodine completely, or out of iodine
12 solution from August 21st to August 2nd, and they have
13 had a very uneven supply of their capsule sizes.

14 And this is primarily due -- not
15 necessarily due to the reactor issue, but how the
16 iodine is produced. For iodine in the U.S. -- and
17 Nordion is the primary processor -- it needs to be
18 produced through the N gamma reaction of
19 tellurium-130. And so here we will be using the
20 reactor as a neutron source, but they have a separate,
21 distinct target of tellurium-130 to be bombarded by
22 the neutrons to produce the I-131.

23 It is possible through -- when the uranium
24 targets are irradiated to produce moly. They can also
25 -- they also produce iodine-131, and that is referred

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1 to as n. fission I-131. But iodine of this source is
2 not allowed to be used in the U.S. at this point in
3 time by the FDA.

4 The disruptions in the supply have caused
5 postponements for some of our iodine-131 patients.
6 And this has been a bigger problem for the larger
7 doses that are used for therapy, where the patient's
8 post-treatment precautions can be complicated.

9 For example, especially for those who are
10 parents with young children, they may have to make
11 arrangements to have someone else care for their
12 children for the first few days after their --
13 immediately after their administration. So even a
14 delay of one day can be a very big deal for these
15 patients.

16 The lack of solution is also an issue,
17 especially for the larger doses, as some physicians
18 prefer solution for their patients, as patients have
19 -- may have a higher incidence of gastritis with
20 capsules, since sometimes a capsule may not dissolve
21 right away in the stomach, or it may actually get
22 accidentally lodged in the esophagus.

23 And there is an updated handout to this,
24 but it, too, is incomplete. And I tried to use my
25 extensive creative abilities to adapt this in the moly

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1 supply chain, so everything looks the same except now
2 we are talking about iodine versus moly. And this
3 slide and what is in your book has an errant arrow.
4 I'm not sure where that one is going.

5 This was rather frustrating, trying to put
6 this information together, because one would think
7 that if the -- if you call up a company and ask for
8 this information and mention that it is for the U.S.
9 NRC that they would respond. That has not been my
10 experience.

11 In relative terms compared to what we need
12 for moly, our needs for iodine are much smaller. But
13 we are experiencing some shortages, and it is not
14 necessarily because of the lack of reactors, it is the
15 source or type of target for the iodine that is being
16 used.

17 So right now, normally, the South African
18 reactor can process it -- the materials processed by
19 NTP and can go to Draxis, which is a Canadian firm.
20 And also they -- and also, that same iodine gets to
21 Covidien, but first it goes to Nordion in Canada. And
22 they supply it to Canada.

23 So to be more -- what I have now, it is
24 the most up to date -- is that there should be a
25 dotted arrow going up to Covidien, from the Nordion

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1 processor in Canada up to the Covidien manufacturer in
2 St. Louis, while the NRU is still down.

3 So we are still in a very tight spot. If
4 the NRU comes back online in the first quarter of
5 2010, our situation will definitely improve. But the
6 NRU is in the midst of a very technically-demanding
7 repair process that could have delays.

8 And this is how dire our situation is.
9 Now our best hope lies in the fate of a 52-year old
10 reactor. And, of course, we are all hoping for its
11 return on schedule, but we will still have a 52-year
12 old reactor that uses HEU for moly production. And in
13 addition to the repair expenses, it is estimated AECL
14 will have to spend \$200- to \$300 million to extend its
15 operating license that expires in 2011.

16 Add in the uncertainty of which of the
17 other reactors will take the plunge to convert to LEU
18 from moly production and it gets more interesting. It
19 is critical the U.S. has its own producers. Missouri,
20 Babcock and Wilcox, are making progress, but they need
21 help and are several years away.

22 We may be in this tight spot for several
23 more years, complicating our efforts to take the best
24 care of our patients, the 16 million patients a year
25 we try to take care of.

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1 Thank you.

2 CHAIR MALMUD: Thank you, Mr. Mattmuller.

3 Very thorough presentation. We have a couple of
4 questions, if I may, to summarize what you have said,
5 and then questions or questions first? Dr. Van
6 Decker?

7 MEMBER VAN DECKER: Whichever you prefer,
8 Mr. Chairman.

9 CHAIR MALMUD: The Chair always bows to
10 the members of the Committee. Dr. Van Decker?

11 MEMBER VAN DECKER: Steve, I wanted to
12 thank you for a great presentation on something that
13 clearly is affecting patient care throughout this
14 nation. I mean, we're really having problems in a lot
15 of places getting access to isotopes. And things are
16 being shifted in paradigms of patient management,
17 which is not necessarily a good thing when it's not
18 being done due to new scientific paradigms. But it's
19 just being done for pragmatic purposes.

20 I have three questions as I try to think
21 my way through this. And maybe you can help me with
22 this, and maybe the NRC can. Number one, I guess we
23 want to thank the FDA for its review of the Australian
24 product. That is hopefully going to be helpful to us.

25 Do you know of any NRC or state

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1 regulations that would slow that process for becoming
2 available at least, despite the plane trip and
3 everything else?

4 MEMBER MATTMULLER: No, I don't believe
5 so. I think once the Australians are up and able to
6 get it here, we'll be able to use it.

7 MEMBER VAN DECKER: Well, that is good
8 news.

9 I guess my second question, which I know I
10 really need some help with, is this concept of what is
11 going on with new science for reactor science and
12 processing science here, especially since it looks
13 like there will be multiple areas of industry trying
14 to do this different ways to fill in the hole.

15 Can you give me some sense for what is the
16 scientific vetting process for all of these different
17 alternate possibilities coming to the forefront? How
18 will that vetting process slow or speed where we're
19 trying to get to? And do you see issues in the
20 regulatory realm, as opposed to even just the FDA
21 approval realm of some of those different processes
22 for moving forward?

23 And do you see the Markey bill as being
24 really an appropriate funding mechanism for moving
25 some of that forward? Is this getting us where we

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1 need to be? And where are we with that? Where do the
2 FDA and the NRC come into play with all that piece of
3 it?

4 MR. LEWIS: I am not sure the NRC would be
5 the right person to speak to the state of the science
6 of the potential applicants, the two that were
7 mentioned. But I will say that they do need to design
8 their system and make an application to NRC. Neither
9 has done that. They have come in for some
10 pre-licensing meetings, but that is it at this point.

11 It will need to be reviewed by NRC in
12 terms of reactor safety and environmental impact.
13 Those processes are long, necessarily long, because we
14 want to make sure they're safe. And in terms of one
15 of the reactors, it is a very unique design. There
16 has never been an aqueous reactor licensed in the U.S.
17 before. Unique designs usually mean longer regulatory
18 review processes.

19 Chris, do you want to add anything to
20 that? The people that are from the Office of Nuclear
21 Reactor Regulation have the lead in that. I don't see
22 them in the room here.

23 MR. EINBERG: The only thing that I would
24 add is that the NRC has found this estuary close and
25 has them put together a working group to expedite any

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1 applications that do come in.

2 So in tracking any issues with the
3 University of Missouri or Babcock and Wilcox. And
4 it's an interagency, but it has broad representation
5 from the agency, from the different offices. And we
6 have Donna-Beth is our lead for that working group as
7 well. So it does have high attention here at the NRC.

8 MR. LEWIS: And let me just add that from
9 outside the reactor licensing process, which is
10 something in and of itself, we are always looking for
11 this Committee and for the users to identify any
12 regulatory obstacles, such as we have recently issued
13 exemptions to facilitate the use of any excess
14 technetium.

15 And if there is anything that we can do
16 along those lines, we need to hear about them because
17 we can take action. I'm not saying we would do them,
18 but we can look at the pros and cons of doing such
19 things.

20 MEMBER VAN DECKER: We have greatly
21 appreciated that in the provider community. Before I
22 seg to Dr S., who is going to pick up the FDA piece of
23 this with the newer options, I guess I would ask Steve
24 if he knows the answer to the rumor circulating in the
25 community that the Canadian government has essentially

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1 decided it is out of the production of medical
2 isotopes in the future and that the situation up in
3 western Canada may not be long-term solvable, which
4 will really leave us in the bind that is coming up
5 with two reactors down very shortly.

6 Is that from your understanding or if you
7 have any knowledge of that a political decision? Is
8 that a regulatory exchange decision? Do you have any
9 sense for any of that or whether that is true or not?

10 MEMBER MATTMULLER: The Canadians have
11 politics going on, as we do down here. And if you pay
12 too much attention and try to read everything, as some
13 people do, it gets to be confusing at times as to what
14 group of Canadian government is addressing this and
15 what group is trying to solve it and what group is
16 trying to walk away from it.

17 Then it's all complicated. And I am not
18 even sure that you have -- Nordion is a former Crown
19 company. AECL is a Crown company. And it is in the
20 midst of being reorganized. They would like to keep
21 -- and there are issues going on that fall over into
22 the power reactor and issues as far as Canada wants to
23 build a couple of new power reactors and how critical.
24 And that is very critical for AECL's future to have
25 positive outcomes there also.

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1 There have been statements in the press
2 from -- I forget which minister it was who said they
3 wanted to get out of the business, but most of the
4 people I have talked to don't put a lot of stock in
5 that.

6 As they say, he was at a public function
7 for a total -- I think as the Argentinean ambassador
8 was in town and they were discussing completely
9 different topics. And he was bombarded with that and
10 so didn't perhaps speak as accurately as he would have
11 liked to.

12 Then if you look at the extensive efforts
13 the Canadians are putting into repairing, I would have
14 to say they are serious about bringing it back on. If
15 you check on the Web, they do have a very extensive
16 website listing their progress.

17 They even have videos on YouTube available
18 of the steps they are taking to analyze the inside of
19 the reactor vessel, how they plan to repair it with
20 built-up welding techniques and design the special
21 tools that they have to use to go through a 4-inch
22 hole down 30 feet, make a right-hand turn, and then
23 work on the inside of the vessel. It is all very
24 technically demanding.

25 Since that one statement of them saying

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1 they want to get out, I have not seen anything else
2 that would support that statement. So for the time
3 being, I would say they are in it. And they are in it
4 for another five more years once they get it fixed.
5 But it is still an old reactor.

6 Also on some of your earlier questions,
7 waste disposal is a critical issue in the U.S., to
8 reemphasize that. If there were a moly producer right
9 now in the U.S., there is no place for them to send
10 their waste.

11 And so that is a critical provision of the
12 Markey bill addressing that, that the DOE will release
13 uranium to these sites. They can use it, irradiate
14 it, extract the moly from it, and then send the used
15 uranium back to the DOE so the DOE can dispose of it.

16 MEMBER SULEIMAN: They can figure out what
17 to do with it.

18 MEMBER MATTMULLER: Right. Well, they are
19 doing it now. And, actually, I think at one of the
20 national labs, I believe in New Mexico, they do have
21 an AHR or they used to have an operating AHR reactor.

22 So these would not be the first to be built in the
23 U.S. But I don't think it is operating at the moment.

24 MR. LEWIS: Yes. There was a solution
25 reactor in the past in Los Alamos, I believe, but it

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1 wasn't licensed by the NRC. It's not a commercial --

2 CHAIR MALMUD: Dr. Suleiman?

3 MEMBER SULEIMAN: Before I try to ask some
4 factual or objective questions, I think we are
5 subjected to the winds of a lot of politics in both
6 countries. I think there is no coherent policy on a
7 number of issues, in some cases conflicting.

8 I agree with Steve. I think the Canadians
9 from my observations are intensely working on
10 reactivating the NRU with all its problems. And
11 clearly this has had a major impact on nuclear
12 medicine procedures. How this is all going to play
13 out I don't know.

14 Just an element of caution, I mean, I have
15 asked this question over the last 10-20 years. I say,
16 "What is the gold standard for cardiac imaging?" And
17 I, frankly, get different answers from different
18 specialists about which is the superior.

19 So, even though I think this is a great
20 problem for the nuclear medicine community, I think
21 that I wouldn't want to see it get into a turf war
22 over different images and more valleys being superior
23 or inferior.

24 I think that the loss of the nuclear
25 medicine community is real. And I think that we need

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1 to do everything to address that but implying that all
2 of these nuclear medicine procedures may be superior
3 to all of the alternatives I don't think is
4 necessarily true.

5 I have some questions that I have asked
6 that I still don't have an answer to. I have asked
7 colleagues. They are pretty simple questions. One
8 is, if you were to take a reactor and make the
9 conversion to LEU from HEU, what would the yield be?
10 Would it be the same or would the inherent yield of
11 such a reactor be less? So this has implications in
12 terms of let's say today right now you can convert all
13 of the operational reactors to LEU. Would that drop
14 in terms of total yield?

15 Some money questions. I heard the number
16 163 million. This is from a conversation I had with
17 the National Academy committee. I have never
18 validated these numbers.

19 I was told that the Canadians were given a
20 solution for their NRU. It was basically to scrap the
21 current reactor design and replace it completely with
22 two LEU reactor vessels with known technology, which
23 would run about 40 to 60 million dollars. I don't
24 know how true that is.

25 And the answer was "No, we're not going to

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1 do that," whether it was politically driven or
2 whatever. So if that is a real solution, if they took
3 the Maple reactors and scrapped the reactor vessels
4 themselves and replaced them with LEU-based known
5 technology, like the Argentinean or the Opal, that
6 solve the problem.

7 It wouldn't be a short-term solution. It
8 would take a couple of years to undertake that. But
9 that to me, at least to me, seems like it would be a
10 long-term solution to the problem if we're looking to
11 Canada as in this together with us.

12 Those two questions are ones that go
13 through my mind: the security policy, the long-term
14 storage. Some of these are regulatory, and some of
15 these are clearly issues we don't have any control of.

16 And also the Society of Nuclear Medicine
17 deserves a lot of credit. The survey may not be
18 perfect, but it's the best that there is. And I
19 haven't seen anything that comes close to it in terms
20 of giving us a sort of sense of what is going on out
21 there.

22 CHAIR MALMUD: Thank you, Dr. Suleiman.

23 Dr. Eggli?

24 MEMBER EGGLI: Doug Eggli. As bleak as
25 the numbers are that Steve presents, it doesn't really

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1 say much about what is happening in clinical practice
2 because they are simply numbers.

3 The impact on us is asymmetric. And you
4 don't want to be a patient who needs a nuclear
5 medicine imaging study between 8:00 p.m. and 8:00 a.m.
6 because there aren't no technetium to be had anywhere
7 for those studies.

8 There are a number of studies where we
9 don't have to debate whether a nuclear heart perfusion
10 test is better than an MRI, better than a coronary CTA
11 because in some of the tests, there aren't a lot of
12 substitutes.

13 In a gastrointestinal bleeder, the nuclear
14 medicine study is ten times more sensitive than the
15 arteriographic study. And often an arteriographic
16 study follows a positive nuclear medicine study, but
17 in the situation where there is no nuclear medicine
18 study first, catheter time is two or three-fold
19 longer.

20 Complications from an inter-arterial
21 procedure rise exponentially with catheter time. The
22 contrast loads that have to be used in a catheter
23 study when there is no nuclear medicine study to guide
24 the way are much larger and, therefore, much more
25 toxic potentially to the patient. And these are

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1 patients who often have compromised renal function
2 where contrast is very toxic.

3 If you want to take examples of lung
4 scanning, it's largely been replaced by CT, but in the
5 patients who are allergic to the iodinated contrast
6 material, there just plain is no substitute for the
7 nuclear medicine lung scan.

8 For those of us who use technetium aerosol
9 for our ventilation agent, it takes about 50 to 100
10 millicuries to inoculate the nebulizer to get one
11 millicurie into the patient. Even when I have bulk
12 tech these days, I don't have 100 millicuries. So for
13 a critical subset of patients, there is just no
14 alternative.

15 In the last six weeks, I think we have
16 managed to get a generator once. In the last six
17 weeks, I think we have managed to get some bulk tech
18 for after-hours use once. We literally are shut down
19 between 8:00 p.m. and 8:00 a.m. and can offer no
20 emergency services.

21 So the impact is asymmetric. It affects
22 the sickest patients in the middle of the night.

23 CHAIR MALMUD: Thank you, Dr. Eggli.

24 Was there another comment?

25 MEMBER FISHER: May I?

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1 CHAIR MALMUD: Please?

2 MEMBER FISHER: Darrell Fisher. Two quick
3 comments. I noted, Steve, that 10 of your 28 slides
4 dealt with diminished standard of patient care and
5 lower quality of service at higher cost to patients.
6 This is a patient concern issue. And I want to
7 emphasize the importance that we help this agency and
8 others look for solutions because it is a major
9 patient concern issue.

10 Secondly, I thought that Bill Van Decker's
11 comment was very appropriate. The two technologies
12 you presented are too among many. And our solutions
13 in the United States are by no means limited to the
14 two you presented.

15 I have looked recently at another concept
16 involving photon irradiation of, I think it is,
17 deuterium oxide that produces neutrons that irradiate
18 a uranium, low-enriched uranium, solution that looks
19 very promising and cost-effective.

20 I have also reviewed another patent that
21 was recently granted involving the placement of
22 targets in commercial nuclear power plants for easy
23 insertion and rapid removal that could help solve this
24 problem.

25 So I think Dr. Van Decker was right on

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1 when he said that the ultimate solution for this
2 country involves looking at a broad spectrum of
3 different technologies. Some are going to be more
4 promising than others.

5 Thank you.

6 CHAIR MALMUD: Thank you.

7 Dr. Welsh?

8 MEMBER WELSH: Jim Welsh. Two simple
9 questions regarding the shortage of iodine-131. You
10 mentioned that the IRE in Belgium uses the (n,
11 fission) approach and it was not FDA-approved. So,
12 number one, do you anticipate approval? And is that
13 going to be a difficult process?

14 And, number two, if it does get approval,
15 is it going to solve the shortage problem to any
16 significant extent?

17 MEMBER MATTMULLER: I would suggest the
18 gentleman next to you could answer that best.

19 MEMBER SULEIMAN: Well, there is no
20 perfect answer. I think we would take applications on
21 a case-by-case basis. I want to thank being
22 complimented before it takes place whenever it gets
23 it, but I think also we deserve criticism sometimes.
24 But I think a lot of the controversy over approval of
25 the LEU was in my opinion and my colleagues' at the

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1 agency way overblown.

2 We never anticipated it was a problem. We
3 never stated we thought it was a problem. And the
4 approval indicated that. I think it was approved in
5 about six days. LEU, the uranium, the target
6 material, is just way, way upstream from us.

7 However, when you get to the medical
8 product in the eye and the illusion, our chemists look
9 at this very, very closely. And whether it gets
10 approved or not, frankly, depends upon the quality of
11 the submission. And if it's put together right, the
12 agency is extremely sensitive to the issue.

13 We have our people on it. And it will get
14 high priority. I think, again, the LEU approval is
15 just one example of that. But sometimes if these
16 approvals are difficult, don't look at the FDA. I
17 think you have to look at the quality of the
18 submission. And there are other issues which we just
19 are not able to make public.

20 So I think if it is properly prepared, I
21 don't think it will be a bottleneck.

22 CHAIR MALMUD: Thank you, Dr. Suleiman.

23 Another comment?

24 MEMBER MATTMULLER: Well, I just wanted to
25 add that if the manufacturers have approved the FDA

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1 about getting the other source of iodine approved.
2 And I doubt that they would answer me if I did ask.
3 So at this point I don't know where we stand with
4 that.

5 CHAIR MALMUD: Another comment?

6 MR. LEWIS: Well, the quality and
7 completeness of the application is our key variable as
8 well, but that wasn't my comment.

9 I guess maybe a naive comment, but at
10 least for the cardiac uses of technetium, is there a
11 seasonal demand variance? I mean, most people think
12 that heart attacks happen more often in the winter or
13 -- I mean, I thought that, but --

14 CHAIR MALMUD: From my understanding, the
15 answer is no. It's not seasonal. It does vary from
16 time of day but not from season to season.

17 Dr. Van Decker, this is your area of
18 expertise. Would you care to comment?

19 MEMBER VAN DECKER: I was going to say
20 most people ignore their symptoms while they are on
21 vacation.

22 (Laughter.)

23 MEMBER VAN DECKER: But the type of
24 physiology of the process is no different.

25 CHAIR MALMUD: If I may, I will try as

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1 Chair to summarize that which has been so
2 well-discussed over the last 70 minutes or so. First
3 of all, medical techniques are somewhat similar to
4 defense techniques and armaments. We recognize that
5 that which we do today may be outdated in the next
6 decade or so.

7 Nevertheless, we have to address the
8 threat that is present today and the threat that is
9 present today we see in the statistics for morbidity
10 and mortality in the United States.

11 The two leading killers in the United
12 States are cardiovascular disease, number one; and
13 cancer, number two. The isotopes that we are talking
14 about, specifically the technetium isotope with its
15 partnership with various chemicals, are used to
16 diagnose, to stage, and restage cancer and to diagnose
17 cardiovascular disease in a relatively non-invasive
18 way.

19 If we look at cardiovascular disease
20 first, this is an injection into a vein in the arm
21 usually. It's less invasive than angiography. It's
22 used as a screen for angiography. It's also less
23 expensive than angiography and offers a radiation
24 burden less than that of angiography. Therefore, it
25 is at the current time an ideal screen. Those

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1 patients who do not need angiography are spared it.
2 Those who require it get it.

3 The absence of the technetium isotope in
4 the diagnosis and treatment of patients with heart
5 disease is already being felt throughout the United
6 States in its lack of uniform availability, which
7 results in patients either going directly to
8 angiography when some could be spared -- some cannot
9 -- or in delay of diagnosis, which can lead to
10 increased morbidity and perhaps in some cases, though
11 there are no statistics, increased mortality.

12 Since our number one concern is the
13 quality of patient care and the health and welfare of
14 the population, it is an important issue. And
15 assuming that new technologies will come along to
16 replace these is a valid assumption but not relevant
17 to the problem of today.

18 With respect to bone scintigraphy, we're
19 really talking about cancer screening, although bone
20 scintigraphy is very useful in other situations, such
21 as in sports injuries and in occult fractures and in
22 infection of the bone. But the primary use is in
23 bone.

24 How do we use it? We use it for
25 diagnosing two of the most prevalent cancers in

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1 humans: breast cancer in women because breast
2 metastasizes to bone, and prostate cancer in men
3 because prostate metastasizes to bone, and lung cancer
4 in both men and women because lung can metastasize to
5 bone as can other tumors, such as kidney. So this is
6 a very relevant issue.

7 The absence of bone scintigraphy means
8 that the patient cannot be staged as accurately as
9 necessary for treatment planning. Treatment planning
10 at the time of diagnosis of a tumor depends upon the
11 tumor itself and the extent of the tumor as measured
12 by its spread to lymph nodes and distant areas. That
13 is the way tumors are staged. And it is based upon
14 the staging that the treatment goes forward.

15 This is an integral part of that process
16 today. Theoretically it may be replaced in the future
17 but not currently. Therefore, we need these studies
18 today.

19 The problem, as presented very well by Mr.
20 Mattmuller, indicates that there is currently no
21 production of these isotopes in the United States.
22 That we have gotten to this point is a national
23 embarrassment, but here we are. We have depended on
24 overseas production of these isotopes, which we then
25 bring into the United States and package in forms that

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1 are useful for administration to patients.

2 There are two potential sources currently
3 available in the United States. One is the reactor in
4 Columbia, Missouri. And the other is the Babcock and
5 Wilcox reactor. Neither of those two parties has yet
6 appealed, as far as we know, to either the FDA or the
7 NRC for approval.

8 We have two federal agencies that are
9 interested in dealing with this and that will respond
10 to appropriate applications. So the question is, what
11 has happened in the past? And what is happening now
12 that has prevented these two agencies, the FDA and the
13 NRC, from entertaining these opportunities?

14 And the answer is apparently that neither
15 party, neither Columbia, University of Missouri at
16 Columbia, nor Babcock and Wilcox, has invested the
17 funds, which they do not have apparently, to move this
18 forward.

19 So we are really asking to inform Congress
20 once again and to hopefully increase their awareness
21 of the importance of these techniques so that they may
22 fund some of the R&D necessary to move these
23 applications forward if Babcock and Wilcox and the
24 University of Missouri at Columbia are still
25 interested in doing this.

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1 Is that a good summary of where we stand?
2 If so, Dr. Suleiman?

3 MEMBER SULEIMAN: I would add that the
4 total product life cycle, the waste storage component,
5 shouldn't be ignored either. I don't know whether you
6 --

7 CHAIR MALMUD: The waste storage?

8 MEMBER SULEIMAN: Right, which has
9 implications, obviously, for --

10 CHAIR MALMUD: It has implications, but in
11 the past, we have produced the material. And we are
12 still using radioactive material for other reasons,
13 including power generation.

14 And we as a nation are also way behind.
15 The French I think are producing 90 percent of the
16 electricity from nuclear power. And we produce, what,
17 20 percent, something like 20 percent. So we have a
18 long way to go.

19 We were frightened by TMI. The icing on
20 the cake was the China Syndrome, which came out about
21 the same time as TMI. And then perhaps the final
22 shovel of earth was thrown on it by what occurred in
23 the Soviet Union.

24 But we are not the Soviet Union. We don't
25 have their safety record, thank God. They don't have

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1 the NRC to watch over them. And there is no reason
2 why we can't mimic the French in their success except
3 that there is the public ignorance of the value of
4 nuclear power and of radioactivity in general. More
5 people die digging up coal each day than have died
6 from all of the nuclear power accidents in the Western
7 Hemisphere and all of history.

8 I didn't mean to editorialize. I just
9 meant to summarize. Sorry.

10 (Laughter.)

11 CHAIR MALMUD: So, Steve, did we
12 adequately cover the points that you wanted to make so
13 well?

14 MEMBER MATTMULLER: Yes, with one minor
15 clarification on your remarks in that Babcock and
16 Wilcox has contacted the NRC about how they believe
17 their facility should be licensed.

18 And part of that is because they don't fit
19 in any -- I mean, it's like the old adage of pounding
20 a round peg into a square hole. They don't fit neat
21 into anything.

22 CHAIR MALMUD: So it may require some
23 legislation?

24 MEMBER MATTMULLER: Well, I don't know if
25 legislation. I think regulatory guidance by the NRC

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1 from, of course, not this group but other parts of the
2 NRC. That reactor group, that needs to respond,
3 hopefully on a more timely basis, to them. But they
4 have asked.

5 CHAIR MALMUD: Good. That is one step
6 forward.

7 Did you want to have a comment?

8 MR. LEWIS: If I wasn't clear before, both
9 groups have had pre-licensing interactions with the
10 NRC.

11 CHAIR MALMUD: Good. So they are moving.

12 MR. LEWIS: They are moving.

13 CHAIR MALMUD: What can we do to help
14 them? Is it a matter of informing any parties? Can
15 we be of service in that capacity? I mean, we have
16 discussed this amongst ourselves. Now, what can we do
17 as a next step?

18 MR. LEWIS: I think what the committee is
19 doing now is appropriate, is just keeping abreast of
20 the issues. As you said in your comment, the burden
21 is really on the applicants at this point and in some
22 measure on the Department of Energy of the legislation
23 were to pass, for example.

24 So if this Committee could just keep aware
25 of the issues, keep raising the issues, any form that

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1 you may have about the importance of the medical
2 isotope supply, that goes the furthest.

3 CHAIR MALMUD: The government seems in a
4 generous mood at the current time. Perhaps they can
5 do for the nuclear power industry and for
6 radioisotopes in general that which they have done for
7 General Motors and Wall Street.

8 The next item on the agenda, "Medical
9 Related Events," that would be Dr. Howe. And I
10 noticed a typographical error, which I wanted to
11 correct for the minutes. And that is that Dr.
12 Guiberteau is listed as Mr. Guiberteau. He has been
13 an M.D. as long as I have known him. And we hope that
14 that correction will reflect in the summary of those
15 attending the meeting.

16 DR. HOWE: Dr. Malmud, if the Committee is
17 ready?

18 CHAIR MALMUD: Yes. Thank you. Yes, Dr.
19 Howe?

20 10. MEDICAL RELATED EVENTS

21 DR. HOWE: My talk today is one of a
22 continuing series. It is the status of medical events
23 and other reported events that are associated with
24 medical use of isotopes.

25 I would like to point out that each year I

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1 query the INMED system. And I query it for those
2 medical events or events involving patients that were
3 reported in the last year. And I use the fact that
4 they are reported in the last year because in many
5 cases, we have events that were discovered years after
6 they occurred.

7 And if you were to give a presentation on
8 those events that happened during the year, then you
9 would lose a lot of events that were discovered years
10 after they occurred. So I just wanted to make that
11 clear. That way we guarantee that we catch all of the
12 events as they are happening and present them to the
13 ACMUI.

14 I would also like to say that what I am
15 doing is I have done some of the groundwork. I have
16 done the NMED search. I have grouped cases by
17 modality. I am giving you a very brief overview of
18 the types of medical events that were reported in the
19 last fiscal year.

20 I understand there is a subcommittee that
21 will look at this data. And I am hoping that what
22 will happen is that the subcommittee will see
23 something of interest to go into in more depth, not
24 necessarily repeat what I have done but really go into
25 more depth if they see a trend or an issue that they

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1 find is especially interesting.

2 One of the things that I normally do each
3 year is I will give a -- the first slide will be kind
4 of a summary of what happened the year before. And
5 the idea is to put the past fiscal year into context
6 with the year before.

7 This year I have gone back two years just
8 to give you kind of a flavor for a slightly longer
9 period of time. The subcommittee may want to go back
10 over many years to pick a trend because we only get
11 about 40 medical events per year. And that is not a
12 large enough number to have any statistical
13 significance. So you may want to go back over a
14 longer period of time.

15 Also, in the NMED reports that we have
16 printed out for you, you have a paragraph that pretty
17 much describes the event. AT the bottom of that page,
18 you also see references. And if it is an ongoing
19 event where we are getting additional information,
20 when the subcommittee gets ready to do whatever it
21 wants to do, it should really consider going back and
22 pulling out some of that reference material so that
23 you can get more information about the event and then
24 maybe more current information later when they do
25 that. So those are just a few remarks I wanted to

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1 make just to kind of set up for the presentation.

2 In my first slide, you will see that I
3 have gone back over the previous two years, F.Y. 2007
4 and 2008, to show you how many medical events we had
5 by the different modalities.

6 For those of you who are not familiar,
7 35.200 is imaging and localization. Those are things
8 that don't require written directive. 35.300 is
9 generally your therapeutic, but we don't call it
10 therapeutic. We call it those areas of nuclear
11 medicine that require written directives. It also
12 includes anything in excess of 30 microcuries of
13 I-131, sodium I-131. And 35.400 is the manual
14 brachytherapy modalities. 35.600 you'll see a
15 breakdown below because 35.600 comprises high dose
16 rate remote afterloader events or other afterloader
17 events, also gamma knife events, also teletherapy
18 events. And 35.1000 is your emerging technologies.

19 So what you will see is that we had 40
20 cases in 2007, 31 in 2008. If you looked at the
21 35.400 reports in 2008, many of those reports, a
22 number of those reports, came from the Department of
23 Veterans Affairs. And you will see that in F.Y. 2009,
24 that we also have additional reports from the
25 Department of Veterans Affairs that came out of their

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1 going back and looking at all of their prostate
2 procedures.

3 You will see that very rarely do we have
4 one, but we did have a teletherapy event in 2008. We
5 didn't have any this year. Most of our 35,1000
6 emerging technologies issues are associate with
7 microspheres, both the TheraSpheres and also the
8 SirSpheres microspheres.

9 And in some cases, we are able to tell you
10 which manufacturer was involved. In other cases, the
11 information coming into NMED was not specific enough
12 to make that identification. Okay?

13 So in the next slide, I am moving on to
14 F.Y. 2009. You can see we had a bumper year for
15 medical events. We had 46 medical events this year.

16 We range between the high 30s and mid 40s.

17 I presented those medical events. And I have given
18 you a change from those that occurred the year earlier
19 so you can see where we have gotten more events in one
20 category, less events in another category.

21 We had essentially a bumper year in the
22 manual brachytherapy. We had an eye applicator event.

23 We don't normally have eye applicator events. Most
24 of the 35,400 were in prostate brachytherapy.

25 In 35,600, we also had more than we had

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1 the previous year. And you will see that most of
2 those were an increase in the gamma knife events. We
3 didn't have very many gamma knife events last year.

4 Yes?

5 MEMBER GILLEY: Are there new slides?

6 DR. HOWE: These I think are the slides
7 that are in your booklet.

8 MEMBER EGGLI: There is a change in
9 35.300.

10 DR. HOWE: Now, I have a few typos also
11 because I did these runs before I went off for
12 vacation. I came back, and we ran them. And I
13 updated some numbers but may not have gotten all of
14 the numbers in. So does everybody have the new
15 slides?

16 MS. COCKERHAM: You can just take out what
17 is in your binder and replace it.

18 DR. HOWE: That should make life a little
19 easier.

20 MEMBER GILLEY: Thank you.

21 DR. HOWE: Now, one of the other things I
22 do is I go over the specific modality medical events
23 for the year and just give you a flavor for what
24 happened with them.

25 The first group would be modality 35.200.

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1 These are your imaging and localization. In this
2 case, the physician intended an iodine-123 procedure,
3 which would not require a written directive, but,
4 instead, an I-131 was given, which did require a
5 written directive.

6 There were all kinds of errors that
7 happened here, many of them with communication. And
8 you will see that later on I had another case that is
9 in the very back of your slides that didn't turn out
10 being a medical event that had many of the similar
11 situations here.

12 The referring physician gave a verbal
13 order for I-123. The secretary scheduled an I-131. A
14 technologist took a history. The patient had a
15 thyroid. There should have been flags put up at many
16 different points along the way. All of these flags
17 were missed.

18 The patient was given an I-131 millicurie
19 study when, in fact, they had a thyroid. And that
20 would have been a therapeutic. It would not have been
21 a whole body study for them. So there were many, many
22 flags that could have been seen, understood, and
23 prevented the medical event, but that didn't happen.

24 Let's move on to 35.300. This is where
25 you have written directives required. We ended up

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1 having five of these. So the slide is a little bit
2 out of date. We had one monoclonal antibody. And
3 this is the one that they were injecting into a port.

4 They did not visualize the port. They did not
5 palpate the port. And when they injected the
6 monoclonal antibodies, they did not get them into the
7 port. So they went into subcutaneous.

8 Most of the 35.300 medical events were
9 sodium I-131. We have two cases of delivery issues.
10 In one case, the capsule got lodged in the esophagus
11 because it was an obstruction. And it took hours for
12 them to get the iodine capsule dislodged. In the
13 meantime, it started to dissolve. The esophagus got
14 an additional 790 rads in addition to what it would
15 have gotten if the I-131 capsule had been swallowed
16 correctly and the dose had been given to the thyroid.

17 In the second case, a patient had a
18 feeding tube. And they gave the I-131 through the
19 feeding tube. It wasn't until a few days later, when
20 they realized that the radiation measurements for the
21 patient were consistent with decay and not with
22 biological elimination, that they realized they had a
23 problem. They took out the feeding tube. And it
24 appeared that at least 50 percent of the I-131 had
25 adhered to the feeding tube and was not delivered as

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1 intended.

2 Now, we had a case where they requested
3 the wrong activity. And they delivered a 29 percent
4 overdose. We had a case where they prescribed four
5 millicuries, but someone gave them 100 millicuries
6 because they marked therapeutic, instead of
7 diagnostic. And I think one thing you will always see
8 is we have many, many simple human errors that could
9 have been caught if people were cognizant of what they
10 were seeing and asked questions. So those are our
11 I-131 events.

12 35.400, we had an eye applicator event.
13 In this case, they didn't realize that the filter and
14 the cap were still sitting on the eye applicator, and
15 they gave the eye applicator procedure with the right
16 time. And then later they realized the filter and the
17 cap were there. And so only a very, very small
18 fraction of the dose was delivered to the eye.

19 Okay. Most of our cases were prostate.
20 We had five cases from the Department of Veterans
21 Affairs. Many of these were as a result of the
22 Department of Veterans Affairs going back and looking
23 at their manual brachytherapy program in a much closer
24 manner. One of them was six new cases from one
25 hospital. The same hospital reported an incident the

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1 year before.

2 Okay. We ended up with two overdoses.
3 One was a human error. They didn't use a correction
4 factor. It was supposed to be a boost. So it was
5 supposed to only get 67 percent of the amount normally
6 given. The dosimetrist wrote the 67 percent down but
7 when they did the calculations didn't factor in the 67
8 percent. So they got an overexposure in that case.

9 Another one was a human error that they
10 really didn't explain what the cause, the basic cause,
11 was. They just associated with human error.

12 We had four cases of improper positioning.
13 We had at least one case where none of them were in
14 the prostate. We had several cases where most of them
15 were outside the prostate. And then we had one case
16 where a third of them were in the bladder.

17 Let me see where my line goes on that one.

18 We had another case where all of the seeds were put
19 into the prostate, but they were clumped. And,
20 therefore, the patient got 37 percent of the D-90. I
21 think that shows that the geometry of the positioning
22 of the manual brachytherapy sources is really critical
23 to delivering the dose that is prescribed for the
24 patient. And just getting the seeds into the prostate
25 is not sufficient to determine whether the patient has

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1 been adequately treated.

2 In this particular case, we also had an
3 interesting situation where the authorized user in the
4 written directive gave a range. The D-90 was supposed
5 to be between 90 percent and 135 percent. Now, they
6 missed it because they only gave 37 percent to the
7 prostate, but that is an issue that we may want to
8 look at also.

9 We had three underdoses where no reason
10 was given. Two of them were from the same licensee.
11 They discovered them later. We had one of our typical
12 medical event criteria issues. And that is the air
13 kerma and the millicurie confusion.

14 Now, one of the things I also looked at at
15 the prostate cancer medical events was, how quickly
16 were people identifying medical events? And of the
17 16, 7 of them were identified within the first day or
18 two, which meant the licensees were doing follow-up
19 CTs, either that day or within 24 hours.

20 We had five that were identified within a
21 month, which meant those licensees were doing the
22 follow-up dosimetry CTs within the month. We had one
23 that was years later. And they went back and did a
24 quality control test. We had three of them that were
25 three to four months after the fact, which meant those

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1 licensees were waiting three to four months before
2 they did the dosimetry test.

3 Moving on to 35.600, in this case, the 6
4 at the top of the slide should be a 7. We had five
5 cases in which the medical event was caused by the
6 wrong site. And the wrong site was due to they had
7 programmed the distance incorrectly. And so the
8 source stopped ten centimeters short of the treatment
9 site in one case.

10 In one case, the tandem was not fully
11 inserted into the cylinder. So the dose was not
12 delivered to the right treatment site. I think it was
13 delivered -- I'm not sure where that one was.

14 We had one where a CT interpretation error
15 gave the wrong distance. And in that case, the dose
16 was delivered outside to the skin. And that
17 individual received 800 rads to the skin.

18 We had one where the catheter was too
19 long. That was an endobronchial case. Where it
20 should have been 21-23 centimeters long, they used a
21 31-centimeter-long tube.

22 We had one where the source tube movement
23 gave a positioning error that ended up causing 700
24 rads to the wrong treatment site. So those are the
25 kinds of root causes that we found in the first five

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1 HDRs.

2 Now, I have over a number of years
3 separated out the MammoSites and delivered them as a
4 separate category. You may consider them to be part
5 of the HDRs. You may consider them to be something
6 different.

7 In the MammoSites, we had two medical
8 events. We had source positioning error. The source
9 hadn't moved completely into the balloon. It was
10 three centimeters from the intended site.

11 And in one, which we are still looking at
12 because we are not sure whether it will remain a
13 medical event, the source failed to retract. So we
14 are still trying to get information from the licensee
15 as to what the dose was to the treatment site. And it
16 was a boost dose. And it will all depend on the
17 timing and the percent dose delivered relative to the
18 boost.

19 The information we have in NMED is a
20 little unclear as to whether the licensee was
21 considering the percent difference to be the total
22 dose that they were going to deliver to the whole
23 site, including the boost or just the boost. So we're
24 waiting to get additional information on that one.

25 This year we also had a bumper crop for

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1 gamma knife. I don't know whether it is because we
2 have more gamma knives, more people are using them, or
3 exactly why.

4 We had two that were the wrong site. In
5 this case, they marked the sheet wrong. In the other
6 case of wrong site, they didn't give us a reason. We
7 had on case of wrong site because they were supposed
8 to send it out for the fifth cranial nerve, and they
9 gave it to the seventh cranial nerve, intracranial
10 nerve.

11 We had equipment malfunctions. There was
12 a fiduciary marker box used to register the CT images,
13 and it was misaligned. So they didn't get the right
14 reading. We had an automatic positioning system that
15 was off on one axis. So that gave errors.

16 We had an authorized user that wrote a
17 written directive for one site, had discussed two
18 sties. They gave treatment to two sites, but they
19 didn't have a written directive for the second site.

20 We also had a licensee that was supposed
21 to be giving a gamma knife procedure with an
22 8-millimeter collimator, and they gave it with an
23 18-millimeter collimator.

24 Okay. So that completes our 35.600
25 medical events. In 35.1000, we haven't seen this one

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1 for a long time because there haven't been that many
2 out in use. But we once again had an intravascular
3 brachytherapy.

4 In this case, the licensee thought,
5 couldn't determine whether the sources went to the
6 intended site, tried again, couldn't see the sources
7 at the intended site, tried to retract the sources,
8 had difficulty retracting the sources, finally pulled
9 the catheter and everything out of the patient. So we
10 had an intravascular brachytherapy medical event.

11 We had a bumper year for yttrium-90
12 microspheres. I have broken them down by manufacturer
13 because sometimes we have some common issues within a
14 given manufacturer, but I also had one that I couldn't
15 tell what manufacturer it was. And the 8 up at the
16 top of this slide should be a 9.

17 In the next to the last line at the
18 bottom, "not identified" should be marked out because
19 that was actually the one that was prescribed, 24
20 millicuries, and they administered 46 millicuries.
21 And they did not explain why they ended up delivering
22 the activity they did when they had prescribed for the
23 lower.

24 In SirSpheres, we had a number of problems
25 with equipment, one overpressurized. Note, the

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1 three-way valve gave out, and the sources didn't go to
2 the patient. In one case, the treatment catheter
3 became occluded. And, therefore, the patient didn't
4 receive the treatment they were supposed to. In the
5 third case, no cause was given.

6 For the TheraSpheres, we ended up with
7 fluid leakage from the outflow valve and needle
8 insertion. So the final activity delivered wasn't as
9 intended. We ended up with 3 cases which over 20
10 percent of the dose adhered to the dose vile septum.

11 In this case, the manufacturer put out the
12 word that you should not invert the vile because when
13 you invert the vile, the microspheres can adhere to
14 the septum. And when they adhere to the septum,
15 you're not going to deliver the dose that you
16 intended. So we had a common thread in those. And
17 then we also had a leaking septum v-vile. Okay?

18 And that concludes the medical events.
19 Now, we did have three interesting cases that were not
20 medical events. They originally reported, but then
21 they were either retracted or determined they weren't.

22 And if you remember the very first medical
23 event in 35.200, where there were all kinds of
24 communication errors, well, the very first one here is
25 very similar to that. Three and a half millicuries of

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1 I-131 were what was in the written directive. But
2 that wasn't what the doctor wanted to give. He wanted
3 to give technetium-99 in whole body scan.

4 There were many, many opportunities to
5 determine this was the wrong procedure. No one
6 questioned it. There were many, many cases in which
7 the communications were really bad and one error just
8 built upon another error until they ended up with
9 this.

10 It was not a medical event because the
11 written directive asked for three and a half
12 millicuries. And our criteria for medical event is
13 that you give what is in the written directive, not
14 what the doctor intended if he wrote the wrong thing
15 but what was in the written directive. Okay?

16 We had one manual brachytherapy case in
17 which only 6 of 88 seeds were delivered. In that
18 case, the physician revised the written directive and
19 said six was all he was going to give. We are going
20 back to find out additional information on this to
21 make sure that the six that he did give at least went
22 into the prostate.

23 It is not a medical event for us because
24 right now the written directive has two components to
25 it in a manual brachytherapy. So we don't want to use

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1 the word "revise," but the second part of the written
2 directive could indicate the six was what he wanted to
3 give. But we also have a question based on the VA
4 cases, did the six even go to the prostate? So we
5 will be asking that question.

6 We also had an HDR issue with an
7 endobronchial treatment. In this case, we had a
8 technician that believed that the catheter was not
9 where it started out being when it was set up, but we
10 also had either a medical physicist or an authorized
11 user that said, "No. The technologist moved it and
12 then said it was in the wrong place." It was really
13 in the right place, and they did some medical
14 evaluation to determine if they had any additional
15 radiation damage to the esophagus and they didn't see
16 it.

17 And so it was not called a medical event
18 because we did have conflicting observations and the
19 authorized user medical physicist indicated that they
20 believed it was given correctly and had not seen the
21 endobronchial tube displaced. And they were there at
22 the same time the technician was. So it's a question
23 of which one is right. We decided to go with the AU
24 in that case.

25 So that completes just my overview of the

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1 medical events and some of the cases that weren't
2 medical events that were reported to us in F.Y. 2009.

3 Are there any questions or comments?

4 CHAIR MALMUD: Thank you, Dr. Howe. There
5 is a question from Dr. Welsh.

6 MEMBER WELSH: Jim Welsh. On this
7 particular slide, the second bullet item, six seeds
8 were implanted into the prostate or we hope wound up
9 in the prostate. What happened to the other 82 seeds?
10 Do we know?

11 DR. HOWE: Most of them he did not give,
12 though I believe this was a case where the patient was
13 in such distress they stopped giving, implanting,
14 other seeds. But we weren't sure where the first six
15 seeds went.

16 If you will look in your book, you will
17 see at least a description of it very close to the end
18 of this tab 10, probably the second page from the end.

19 CHAIR MALMUD: Dr. Howe, if the patient
20 asked to stop the procedure and the 6 seeds went where
21 they were supposed to but the other 82 were not
22 delivered, that wouldn't be a medical event. Am I
23 correct, patient --

24 DR. HOWE: Well, it is not patient
25 interference, but if the patient asked for it, if it

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1 was so painful for the patient because they were in
2 the wrong place, then it could be a medical event.

3 If the six seeds went into the prostate
4 and the physician decided to change and changed the
5 second part of the written directive, then it wouldn't
6 be a medical event.

7 CHAIR MALMUD: I guess I didn't express
8 myself well. If the six seeds had gone into the
9 prostate, you don't know whether they did or they
10 didn't, but if they had, and the patient said, "I
11 don't want this procedure to continue. I am
12 uncomfortable. Stop," that is not a medical event.
13 That is the patient saying, "Terminate the procedure."

14 Am I correct under the circumstances in
15 which the six seeds have gone where they are supposed
16 to --

17 DR. HOWE: I think if the six seeds --

18 CHAIR MALMUD: -- and the patient said,
19 "Stop"?

20 DR. HOWE: I think if the six seeds went
21 where they were supposed to, yes, we wouldn't call it
22 a medical event.

23 CHAIR MALMUD: Not a medical event. The
24 only question here is, where did the six seeds go?

25 DR. HOWE: Yes.

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1 CHAIR MALMUD: What was the fate of the
2 other two? They were returned or --

3 DR. HOWE: They weren't used.

4 CHAIR MALMUD: Okay.

5 MR. LEWIS: I think you said, Donna-Beth,
6 this, in fact, was not reported as a medical event.
7 It was just reported.

8 DR. HOWE: We are still following up on it
9 to make sure where the six went, but --

10 CHAIR MALMUD: But if I understood your
11 comment correctly, if the six seeds did not go where
12 they were supposed to, then it would have been a
13 medical event.

14 DR. HOWE: Yes.

15 CHAIR MALMUD: Thank you.

16 Dr. Welsh?

17 MEMBER WELSH: Just one comment regarding
18 item 080896. There is a typo in the description
19 listed here. A site inspection was performed on
20 12-18-09. So that should be '08.

21 DR. HOWE: Okay. Which number are you
22 working on?

23 MEMBER WELSH: 080896, the gamma knife.

24 DR. HOWE: The gamma knife?

25 MEMBER WELSH: Gamma knife event.

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1 DR. HOWE: Yes.

2 MR. LEWIS: So we could check to make sure
3 it's accurate, NMED.

4 DR. HOWE: I think I will probably have to
5 ask you for the number one more time because I don't
6 have the pages numbered. So it's 08?

7 MEMBER WELSH: 080896.

8 DR. HOWE: 896. Okay.

9 CHAIR MALMUD: Can I ask a question of the
10 radiotherapists here? In a surgical procedure, they
11 now have something called time-out, where right before
12 the surgery is to be done, they check to make sure,
13 number one, it is the right patient; number two, it is
14 the right limb if it is one limb or another; et
15 cetera, et cetera.

16 Is there a time-out in radiotherapy as
17 well? Has that concept been introduced yet into
18 radiation therapy?

19 VICE CHAIRMAN THOMADSEN: Yes, it is to
20 some extent. For procedures, it is basically
21 required. The Joint Commission has decided
22 procedures, such as an implant or like surgical
23 procedures. So they needed time-out.

24 It is ambiguous if something like a linear
25 accelerator treatment is considered a procedure where

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1 a time-out is required. And the Joint Commission at
2 first said, "Yes, it definitely is." And then they
3 backed off and said, "We don't know."

4 CHAIR MALMUD: Thank you.

5 Dr. Welsh?

6 MEMBER WELSH: I can just comment that in
7 my own practice, we do have a time-out for everything
8 that goes on, brachytherapy or linear accelerator
9 treatment, prior to each and every treatment
10 delivered.

11 But I don't think that it's mandatory. I
12 think it is at the discretion of the medical director
13 or attending physician.

14 CHAIR MALMUD: Thank you.

15 DR. HOWE: And I think in one of the
16 corrective actions taken -- I am not sure which
17 medical event it was; so I don't know if it was
18 appropriate -- they had instituted a time-out. So
19 that was one of the corrective actions for one of
20 these.

21 MR. LUEHMAN: That issue will probably
22 come back before the Committee in the future because
23 one of the big projects at NRC I think you heard about
24 at the last ACMUI meeting and I think Jim mentioned
25 this morning is safety culture and how to regulate a

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1 good safety culture. That would be maybe an example
2 of a good safety culture.

3 CHAIR MALMUD: Thank you.

4 MEMBER GILLEY: Debbie Gilley. One of the
5 things that we have seen as a trend, though there is
6 not a lot of numbers, is some issues with high-dose
7 remote afterloaders and the availability of different
8 routes: transfer tubes and catheters.

9 And I wondered what the other members of
10 the Committee might be interested as a solution that
11 might be proprietary connectors or color-coding of
12 these devices to maybe eliminate that as our problem.

13 We are still seeing HDR misadministrations with wrong
14 catheters and transfer tubes in those combinations.

15 DR. HOWE: Debbie, just to kind of give
16 anecdotal data on that one, we had a case a number of
17 years ago with a MammoSite. And it was because they
18 used the wrong connector for it.

19 We went back to the MammoSite manufacturer
20 and said, "Well, don't you think you should be the
21 ones telling the HDR unit what catheters are
22 compatible with your unit?"

23 And they were going to put all of the
24 responsibility on the HDR manufacturer, who may have
25 manufactured the HDR unit years before they ever came

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1 out with their product. And I think we made some
2 inroads with them.

3 CHAIR MALMUD: Debbie?

4 MEMBER GILLEY: However, you as NRC or the
5 agreement states do the sealed source and device
6 registry for these activities. And I would think that
7 this would be a component of safety of those devices
8 in that review.

9 DR. HOWE: But what we will do in the
10 sealed source and safety device review is the HDR unit
11 and its ability to bring the source back safely. We
12 don't look at all of the catheters that are associated
13 with it.

14 And a lot of them are after-market
15 catheters. So that is not a part of the sealed source
16 and device safety review right now.

17 CHAIR MALMUD: Does that answer your
18 question, Debbie?

19 MEMBER GILLEY: It just seems to me we
20 could eliminate these types of misadministrations or
21 medical events if we just did a little bit more
22 insistence on the manufacturers to either put the
23 proprietary catheters or color-code these devices so
24 these events would not happen.

25 CHAIR MALMUD: Dr. Thomadsen?

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1 VICE CHAIRMAN THOMADSEN: The different
2 catheters are already color-coded. They are white and
3 yellow. So they're pretty close, but they are
4 color-coded. So that is not stopping them.

5 MEMBER GILLEY: Are the transfer tubes
6 also?

7 VICE CHAIRMAN THOMADSEN: That's what I
8 mean. The transfer tubes are, yes.

9 MEMBER GILLEY: But the catheters are
10 different also, not just the transfer tubes.

11 VICE CHAIRMAN THOMADSEN: Which catheters
12 are you talking about is the question? If you're
13 talking like the MammoSites, those are cut and have to
14 be measured so that each one is its own.

15 As a matter of fact, all of the breast
16 applicators like that, you have to measure the length
17 of the catheter part that goes to the transfer tube.
18 And there have been at least two misadministrations
19 where that measurement has been incorrect for various
20 reasons.

21 CHAIR MALMUD: Dr. Van Decker?

22 MEMBER VAN DECKER: Just a simple question
23 from a guy who was doing some pre-calculus homework
24 with his kids this weekend. You know, if you go from
25 31 medical events to 46, somebody is going to do the

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1 math and say that was a 50 percent increase in one
2 year.

3 Do you have any sense for the denominator
4 by CPT coding for some of these? Some of these
5 procedures are obviously on rapid rise growth, being
6 new technology. And obviously it may not as a
7 percentage be what it kind of purports itself as as
8 you see it.

9 DR. HOWE: You could say it's a 50 percent
10 increase, but the numbers are so low and the
11 denominator is so big that it really isn't a
12 statistically significant jump. We have routinely
13 seen -- I would say that the 31 events in 2008 were an
14 anomaly. We are normally up around 40, plus or minus,
15 40 to 45 for medical events. So I wouldn't put any
16 statistical significance to it.

17 CHAIR MALMUD: Member of the public, would
18 you come to the microphone, please, and identify
19 yourself right over here? Thank you.

20 DR. WESLEY: Hi. My name is George
21 Wesley. I am the Director of Medical Consultation for
22 the VA Inspector General's Office.

23 I was wondering, Dr. Howe, if you could
24 clear up some confusion I have on the numbers.
25 Apparently at the last meeting of this Committee, I

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1 was under the impression the VA reported 92 medical
2 events. Then there were an additional 6 in August, to
3 make 98.

4 But on the slide that we just saw, it
5 looked like there were about 32 in F.Y. '07, 40 in
6 F.Y. '08, in that order of magnitude. I am very
7 confused about the numbers.

8 DR. HOWE: It is how we count things. We
9 count medical events if they come from one facility
10 and we know they are associated as one medical event.

11 But it may affect many patients. So for the VA
12 Philadelphia case, we had one NMED number, but that
13 NMED number has many, many entries in it until you get
14 up to the 98 patients.

15 DR. WESLEY: I know that is actually the
16 topic of the next talk anyway, but --

17 DR. HOWE: Yes. But I also have two
18 medical events in here that were reported by the same
19 facility. I think they were gamma knives or they may
20 have been microspheres where they reported them on
21 different days and they didn't really acknowledge that
22 they may have been related.

23 So they came in as two separate events.
24 So it depends on how they are reported for the
25 Philadelphia. I mean, we could have had open wound for

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1 every single patient. We would have had tons of
2 NMEDs. And we wouldn't have been able to relate them
3 as a group in the end. So you do get multiple
4 patients in some of these.

5 CHAIR MALMUD: Other questions or
6 comments? Dr. Thomadsen?

7 VICE CHAIRMAN THOMADSEN: I applaud the
8 work. It is very interesting, thorough, and I think
9 your analysis has been very good. And obviously the
10 discussion has been vigorous and interesting.

11 I am not sure why we are doing this twice
12 a year. I thought that we were going to be doing this
13 once a year. And it would make sense to do this once
14 a year because when we do it in October, we will be
15 repeating probably a lot of the stuff that you have
16 just done.

17 I mean, we could do it in the spring and
18 have you go through it, although that misses if you're
19 doing it by calendar year. That, of course, would
20 miss things, although it's not clear when we do it in
21 the fall that we haven't missed some things towards
22 the end of the calendar year that haven't gotten into
23 the database.

24 As I said, I am not sure why we are doing
25 this twice a year.

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1 DR. HOWE: I think from my perspective,
2 the way this was initially set up is I would present
3 in October to give you and to give the NRC a chance to
4 really get a look at what happened in the past fiscal
5 year and that your group would then take this
6 preliminary. And you would say, "Well, gee, I really
7 think we should focus on prostate brachytherapy
8 medical events" or "Gee, I think we really ought to
9 look at the gamma knives."

10 And you would come up with something that
11 you thought ought to be delved into in more depth. I
12 don't think when we started we expected you to repeat
13 what I did but just this gives you the information
14 sorted and organized so that maybe you could see more
15 trends, you could see something we didn't see. And
16 you would delve into something you thought would be
17 more interesting.

18 And then we also provide each NMED report,
19 at least in a short frame, that gives you references
20 so that if you did want to delve into something, you
21 had a starting place.

22 So the original scope was not to have you
23 repeat what I do but have mine just be an introduction
24 to it and then wherever the ACMUI wanted to take it
25 from there.

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1 VICE CHAIRMAN THOMADSEN: Well, I think
2 that if we were going to do that, which that is not a
3 bad idea, then it would make more sense for you to
4 give your presentation in the fall, after the close of
5 or in the spring, after the close of the fiscal year,
6 so that you would have all of the events for that
7 calendar year if that is what we are going under if we
8 want to look at numbers.

9 DR. HOWE: And that is what I have done.
10 These are all of the medical events reported in F.Y.
11 2009. It is a complete set.

12 VICE CHAIRMAN THOMADSEN: Okay. So they
13 all have gotten into the database and everything?

14 DR. HOWE: Yes.

15 VICE CHAIRMAN THOMADSEN: Okay.

16 DR. HOWE: And I use it based on
17 reporting. And so it is up to September 30th. And
18 that is one reason I just did a run last week, to make
19 sure that I had captured everything and reported in
20 F.Y. 2009. So I ran it earlier in September.

21 And so this is a complete data set for you
22 to start off with.

23 VICE CHAIRMAN THOMADSEN: Okay. When we
24 have done ours, I know that we have gone into the
25 database and combed. And it seemed that there seemed

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1 to be some differences. I am not sure why that would
2 be, then.

3 DR. HOWE: There is a difference between
4 reported and occurring.

5 VICE CHAIRMAN THOMADSEN: We always used
6 the reported, same as you.

7 DR. HOWE: And there are a few in here
8 that may fall out of medical events based on
9 additional information coming in, especially those
10 that are in the NMED system near the end of the year.

11 I think I mentioned one of them that came
12 in about the 21st of September. And there is a
13 question of whether it is going to be a medical event
14 based on the boost rate, wrong treatment site, time or
15 not. And so that one will kind of follow. And it may
16 fall back out again. But you shouldn't see any new
17 ones coming in because these are all of those that
18 have been reported.

19 And the meeting in October is generally
20 far enough away from the September 30th date that we
21 do have them in for NMED and we do have the event
22 reports so that we do a background check to make sure
23 we are catching all of those events that were
24 reported. Okay?

25 CHAIR MALMUD: I would just comment that I

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1 know from discussion with the commissioners that they
2 are very concerned about the number of events and
3 their frequency. So that may be the reason that we
4 would want to review them twice a year anyway because
5 of the commissioners' concern.

6 MR. LEWIS: We are very interested in
7 improvements in the process. I mean, our only goal in
8 doing this is to get your subcommittee up and running
9 in the most efficient way possible. And if there is a
10 better way, let us know.

11 VICE CHAIRMAN THOMADSEN: Well, I think
12 that we do find -- and this was every year when we
13 were going through this -- that the reports in NMED
14 are not very complete, shall we say. And it could be
15 that having a different format for entering the data
16 that might guide the inspector's entry might be useful
17 as a study database, such as Roesis, has been working
18 on trying to establish what the set of information for
19 events that would be most useful for sorting and
20 analysis would be. And it could be that working in
21 conjunction with some of the other databases that are
22 gathered on such events might be useful.

23 CHAIR MALMUD: Thank you, Dr. Thomadsen.

24 I think we have another question.

25 MEMBER LANGHORST: Yes. Sue Langhorst. I

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1 think in that respect and responding to commissioners'
2 interest, it is very important to have that
3 denominator number so that you can see if that overall
4 procedure is growing, as I know SirSpheres and
5 TheraSpheres are.

6 CHAIR MALMUD: Yes. I think we recognize
7 that these are new techniques. And, therefore, that
8 number will grow with the improvement in efficacy of
9 the technique, as it has been growing. So for
10 something as limited as the SirSpheres or so, it might
11 be possible to get the denominator.

12 I think in terms of radiation therapy
13 treatments per se, that is a more difficult number to
14 gather, I would assume. But I would ask one of the
15 radiation oncologists from the ACOG group.

16 VICE CHAIRMAN THOMADSEN: I don't know
17 about from the ACOG group, but from the NCRP report
18 160, we did develop techniques for getting that
19 information. We could get that information again as a
20 second snapshot because the information we had was for
21 2004 or 2005, and it was extrapolated to 2006. We
22 could do that again for 2009 next year.

23 It would cost the NRC some money because
24 the most useful information was through a survey
25 company, which does survey of radiological facilities

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1 of different, for different types of uses with an
2 incredibly high results; that is, response rate.

3 And the surveys aren't cheap, but they
4 aren't expensive in the overall view of things. And
5 if we are really serious about wanting to know how the
6 numbers have changed since 2004, this would help, that
7 along with Medicare data, which was used in that
8 report, and VA.

9 CHAIR MALMUD: Thank you.

10 Dr. Howe?

11 DR. HOWE: I just wanted to make a quick
12 comment. Especially with the yttrium-90 microspheres,
13 we discovered really early on that delivery is
14 probably one of the most important parts. And because
15 we have been picking up the medical events and picking
16 up the root causes, the manufacturers have made great
17 strides in engineering better delivery systems.

18 So while we may not have statistically
19 significant numbers, we are seeing engineering trends
20 that are responding to difficulties people are having.

21 And I think the NMED reports and the medical event
22 reports are very important in the new technologies.

23 We had the same thing with the
24 intervascular brachytherapy and the new engineering
25 changes that happened with that.

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1 CHAIR MALMUD: I would also just remind
2 the Committee that the last time we discussed this,
3 which was, again, with interest in the denominator,
4 the feeling was that what we should be striving for is
5 the same low number of incidents that occurs in the
6 airline industry in a good year. And that is
7 independent of a denominator, though the denominator
8 has great relevance to that which we are trying to
9 achieve.

10 We agree with Dr. Thomadsen's point.
11 However, we still are striving for perfection, which
12 we will never achieve but we keep striving for.

13 May we move on to the next item on the
14 agenda, which I believe is a break? Am I correct?

15 MS. COCKERHAM: Dr. Malmud, before you
16 conclude this topic, Mr. Lieto was chair of the
17 committee, the subcommittee that did the work, the
18 analysis on these medical events.

19 CHAIR MALMUD: Yes.

20 MS. COCKERHAM: And Dr. Nag, I believe,
21 was also on that subcommittee.

22 CHAIR MALMUD: Yes.

23 MS. COCKERHAM: So that leaves you two
24 subcommittee members short and minus a chair. So if
25 the subcommittee wishes to continue, we need to name

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1 some new members or, at a minimum, a chair so that
2 they can continue their work.

3 CHAIR MALMUD: Thank you.

4 We will seek volunteers first. Mr. Lieto
5 is a physicist. And Dr. Nag is a radiotherapist.

6 MS. COCKERHAM: Debbie, am I correct that
7 they were both on the committee?

8 DR. HOWE: I think that --

9 CHAIR MALMUD: Yes.

10 MS. COCKERHAM: Okay. You were on there
11 and --

12 DR. HOWE: Orhan and myself.

13 MS. COCKERHAM: Okay. So there are two
14 members currently on the subcommittee.

15 DR. HOWE: Yes, right. We divided up by
16 --

17 CHAIR MALMUD: Excuse me. I wasn't
18 suggesting no one else was on the committee. What I
19 was indicating was that these are the two vacancies we
20 would like to fill.

21 MEMBER GILLEY: There were five of us.

22 CHAIR MALMUD: We have --

23 MEMBER LANGHORST: I would certainly like
24 to be on the committee. I am not sure I am ready to
25 chair.

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1 CHAIR MALMUD: All right. By all means.
2 And Steve agrees with you.

3 (Laughter.)

4 MEMBER MATTMULLER: I agree. I am willing
5 to do the same, serve on the committee but not as the
6 chair.

7 CHAIR MALMUD: Yes? Do you have a
8 comment?

9 MR. LEWIS: Well, I thank them for
10 volunteering. I would suggest maybe that that we
11 revisit this a swell in the future when we get the new
12 oncologist on the committee as well.

13 CHAIR MALMUD: We need those skills
14 represented. We're not denigrating the skills that
15 you would bring, but we do need those skills. That's
16 why I mentioned their particular specialties when I
17 mentioned the vacancies.

18 And we can flush out the committee now.
19 And then can we have temporary appointments to the
20 committee? Is that acceptable? What is tradition?

21 MS. COCKERHAM: Subcommittees are solely
22 at your discretion.

23 CHAIR MALMUD: Ah, okay. I would suggest
24 that we add two temporary members to the committee
25 awaiting the appointment of those to fill the

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1 vacancies. And at that time, we can make a decision
2 about the size of the committee and the membership of
3 the committee permanently.

4 Is that acceptable to the members of the
5 whole Committee? I don't want to make a unilateral
6 decision without your participation. Dr. Welsh?

7 MEMBER WELSH: If Dr. Nag is no longer on
8 this committee and you need a radiation oncologist, I
9 would be willing to participate as well.

10 CHAIR MALMUD: Thank you. I was hinting
11 at that when I first asked the question. So we now
12 have a radiation oncologist as well. So we have lost
13 two and gained three? Thank you. So that is Dr.
14 Welsh, Mr. Mattmuller, and our newest member.

15 Now we need a chairman of the committee,
16 at least an acting chairman of this committee. And
17 the one with the most seniority in this area would be
18 Dr. Welsh.

19 (Laughter.)

20 MEMBER MATTMULLER: I second the motion.

21 (Laughter.)

22 MEMBER WELSH: I guess I am glad I am on
23 the committee now.

24 (Laughter.)

25 CHAIR MALMUD: Thank you for having

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1 volunteered, Dr. Welsh. Have we resolved that issue
2 for the moment?

3 MEMBER SULEIMAN: With Dr. Welsh as chair?

4 CHAIR MALMUD: Yes. Everyone seems to be
5 in agreement. At least no one is willing to speak in
6 opposition. You have always offered to help out when
7 we really needed you. I very much appreciate that,
8 Dr. Welsh.

9 MEMBER WELSH: Thank you.

10 CHAIR MALMUD: The next item on the
11 agenda, break. And we'll resume at 15 minutes. Is
12 that fine, 15 minutes? All right. Thank you.

13 (Whereupon, the foregoing matter went off
14 the record at 3:12 p.m. and went back on the record at
15 3:34 p.m.)

16 CHAIR MALMUD: Welcome back to the second
17 part of the afternoon session. The next topic on the
18 agenda will be the update on permanent prostate
19 brachytherapy medical events. And we're looking
20 forward to hearing this presentation. It will be by
21 D. Wiedeman and C. Frazier, both of the NRC. And this
22 will focus on the medical events that have occurred at
23 the Veteran's Affairs medical centers.

24 Who will lead off? Thank you.

25 11. UPDATE ON PERMANENT PROSTATE

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BRACHYTHERAPY MEDICAL EVENTS

MS. FRAZIER: I am ready to start. Good afternoon. My name is Sandy Frazier. I am the project manager for the Veteran's Affairs master materials license.

I will apologize up front. I have kind of a cold. And I am very stopped up, and my ears are totally plugged from my flight this morning.

Today we will be presenting an update on the medical events involving the prostate brachytherapy treatments at V Philadelphia. In today's presentation, we will include updated background information on the medical events. We will look at the current status of the VA Philadelphia program. We will also review CT images of the prostate brachytherapy treatments resulting in the medical events. And, lastly, we will do a brief overview of some of the causes of the medical events as well as the corrective actions taken by VA Philadelphia.

Background information. At the last ACMUI meeting, Department of Veteran Affairs had reported 92 medical events. And I think, as Donna-Beth said earlier, in August of 2009, they reported an additional 6 medical events. To date, the Department

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1 of Veteran Affairs has reported a total of 98 medical
2 events.

3 Of the 98 medical events, 63 medical
4 events were due to doses less than 80 percent of the
5 prescribed dose, which we refer to as an underdose,
6 and 35 medical events were due to the dose to the skin
7 or an organ or tissue other than the treatment site
8 that exceeded 50 rem. Those are overdoses to the
9 rectum, bladder wall, or surrounding tissues.

10 On March 30th, 2009, NRC, we issued a
11 special inspection report. That inspection report was
12 based on inspections conducted by special inspection
13 teams in July of 2008 as well as September of 2008.
14 Six apparent violations of NRC regulations were
15 identified by the inspectors. And I am going to give
16 you a brief overview of the violations just to give
17 you a perspective of the issues that were identified
18 during our inspection.

19 The violations involved the failure of the
20 VA to develop adequate written procedures to provide
21 high confidence that each of the prostate seed
22 implants was administered in accordance with the
23 written directive as well as procedures that addressed
24 methods for verifying that the dose administered was
25 in accordance with the treatment plan and the written

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1 directive.

2 These apparent violations pertain to have
3 the adequate procedures to ensure that what the
4 physician prescribed was actually administered to the
5 patient.

6 The other apparent violations had to do
7 with the failure to train the supervised individuals,
8 the medical physicists, as well as the physicians.
9 Also, there was a violation on reporting required
10 information on the written directive. And, lastly,
11 there was a violation pertaining to providing
12 insufficient information in the 15-day reports.

13 Also, based on additional inspection
14 efforts, we had an apparent violation on notifying NRC
15 within the next calendar date after a medical event
16 was discovered.

17 There were also several areas of the
18 concerns that were identified. They involved
19 inadequate management oversight as well as a lack of
20 safety culture.

21 May 26th, 2009, NRC issued a demand for
22 information to Dr. Kao to obtain specific information
23 regarding his current and future uses of byproduct
24 material. Based on information received in response
25 to that demand for information, Dr. Kao did indicate

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1 that he is not currently or planning to participate in
2 activities that involve byproduct material as well as
3 committing to informing NRC within 72 hours prior to
4 using byproduct material.

5 NRC conducted additional on-site
6 inspection activities. In June of 2009 and August of
7 2009 and also most recently last week, October 2009,
8 we performed inspections at VA Philadelphia. These
9 inspections were to evaluate the dose information
10 generated for all 114 patients.

11 The reason that we did three separate
12 inspections was due to the inconsistencies in the
13 information that was provided to NRC regarding the
14 dose information by VA Philadelphia.

15 Currently NRC, we are evaluating the
16 medical events against the abnormal occurrence
17 criteria. We also looked at this information during
18 the June inspection. We had a highly effective
19 inspection team that involved the region 3 office as
20 well as the headquarters office.

21 MR. WIEDEMAN: The VA had eight patients
22 that were sent back to Seattle VA and reimplanted.
23 They had a total of 18 patients. Ten of them declined
24 for a reimplant. So they are being treated either by
25 hormone therapy or cryotherapy.

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1 Now, the reason I put that third line in
2 there, the seed patterns were inferior to prostate
3 during our interview of the physician, oncologist. He
4 indicated that because he had had a problem in 2003
5 and 2005, when he did an implant and he ended up
6 putting pretty close to 50 percent of the seeds in the
7 bladder, he said that he would intentionally back off
8 a little so he wouldn't get them in the bladder. And,
9 as you will see later on, -- I'll show you -- he went
10 a little too far. And sometimes he even missed the
11 prostate altogether.

12 The NRC had an NRC medical consultant
13 review a total of 39 cases. At this time, his report
14 is pending. And that will be included in our
15 inspection report as an addendum. We will be issuing
16 an inspection report regarding the results of our
17 June; August; and we just finished doing another part
18 of the inspection, October, in the near future. We
19 hope within the next two or three weeks. And we are
20 going to schedule a predecisional enforcement
21 conference with the licensee.

22 Currently the program remains suspended.
23 And the VA is reevaluating all of their implant cases
24 to determine the exact dose to the treatment sites and
25 the adjacent organs. They have retained the services

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1 of an outside medical physicist to review all of the
2 pre and post-treatment plans. And they have hired a
3 specialist in doing contouring of the prostates.

4 Now, for those of you who are not familiar
5 with this particular slide, this is from the VeriSeed
6 program. And what we have here is a sagittal view.
7 It's like cutting me right down the center. And we
8 have the bladder; the prostate; and then, of course,
9 the rectum. In this particular case, you can see that
10 there are about eight seeds that are outside of the
11 prostate.

12 When our medical consultant looked at
13 this, he made a comment. He says, "You know, you
14 really don't even have to be a medical physicist to
15 realize that this is a dose to an unintended area."
16 It wasn't in the preplan. So he certainly didn't plan
17 this ahead of time. And he says, "I just often wonder
18 if it wasn't a resident or an intern that was
19 practicing during surgery because those things are way
20 off." Initially they had prescribed 160 gray to the
21 prostate. The actual dose is about 143. Other than
22 the dose to the unintended area, it would have been a
23 pretty good implant.

24 This was an anterior view of the VeriSeed.
25 We have once again the bladder and then the prostate.

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1 And, as you can see, there is a line of seeds down in
2 here. And there are some seeds on the outside.

3 Here is a case where 160 gray was
4 prescribed. Actual dose administered was 120 gray.
5 The periprostatic tissues, the areas out here, were
6 calculated out to about 200 gray. And, as you can
7 see, there are about eight seeds that are outside the
8 prostate. So that was definitely a dose to an
9 unintended area.

10 This is the anterior view. Once again,
11 you can see the seeds down a good probably two inches
12 away from the prostate. Here is the prostate here.
13 And in this case, 160 gray was prescribed. The actual
14 dose was 42. So, remember, earlier I said that he was
15 always concerned about putting seeds in the bladder.
16 So he said he would intentionally back off a little.
17 There was a case where he backed off and almost missed
18 the prostate completely.

19 The dose to the unintended area of the
20 periprostatic tissues was calculated out to about 350
21 gray. So this one we have an abnormal occurrence. In
22 this particular case, 160 gray was prescribed. We
23 actually gave 28 gray. And the dose to the
24 periprostatic issues worked of to about 600 gray. So
25 this is an abnormal occurrence.

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1 These are some of the worst. And then a
2 last one, this is an oblique view just to show you how
3 we have got so many seeds outside the prostate.

4 Now, you say, well, how did all of this
5 happen? Well, for one, the big problem was incorrect
6 placement of the seeds. There the procedures were
7 inadequate. They had inadequate training and limited
8 experience.

9 This doctor, he had like a week of
10 experience out in Seattle of doing implants and
11 watching a few cases. He had poor management
12 oversight or no oversight at all, no peer review. And
13 there was definitely a lack of safety culture.

14 They were sort of working on their own,
15 the VA. They felt that they had hired the experts of
16 the field. They knew a little about brachytherapy,
17 but they wanted to hire the best. And so they went to
18 University of Pennsylvania to hire them to do all of
19 their brachytherapy treatments. And so they assumed
20 that they were getting the best possible care.

21 They perform the verification CTs on all
22 of their patients that receive prostate implants,
23 starting back at 2003 and going forward. And, as I
24 said earlier, the oncologist and the hired consultant
25 physicist have not reevaluated the doses that were

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1 delivered to the treatment areas.

2 They are still in the process of doing
3 that. They had reimplanted brachytherapy seeds at a
4 different VA facility just in case it was Seattle, to
5 aid individuals. And, of course, they removed that
6 one individual from performing brachytherapy from the
7 VA. He has lost his staff privileges.

8 Any questions? Yes, sir?

9 CHAIR MALMUD: Was the individual named
10 here the only individual to perform brachytherapy at
11 the VA?

12 MR. WIEDEMAN: There were two physicians.
13 One of them did I think a total of three cases. The
14 other 112 cases were done by Dr. Kao. I think it is
15 fair to say his name is all over the New York Times
16 and the Philadelphia Inquirer. It is not a secret.

17 CHAIR MALMUD: But the VA contracted with
18 University of Pennsylvania?

19 MR. WIEDEMAN: That is correct.

20 CHAIR MALMUD: So their assumption was
21 that the University of Pennsylvania would send them an
22 experienced therapy?

23 MR. WIEDEMAN: That is correct.

24 CHAIR MALMUD: Thank you.

25 Other questions?

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1 MR. LEWIS: Just I would add that we have
2 done since also an inspection of the University of
3 Pennsylvania. It is now the State of Pennsylvania is
4 an agreement state. They went with our Region I
5 office to do an inspection of the University of
6 Pennsylvania's brachytherapy program. And the
7 inspection report for that has not been issued yet.

8 CHAIR MALMUD: Dr. Welsh?

9 MEMBER WELSH: Would you be able to please
10 go back to any one of the slides that has the diagrams
11 with the locations of the seeds? For example, in that
12 one you have there, the question that always comes up
13 -- and I think I have raised it before -- is, who drew
14 those contours?

15 And how do we know that the structures you
16 have in red, green, and blue are truly the bladder,
17 prostate, had rectum and it's really as bad as it
18 looks in this diagram without the CT or the ultrasound
19 in the background there, it is impossible for any of
20 us to say whether that is a depiction of reality or
21 not?

22 MR. WIEDEMAN: Oh, yes. There is no doubt
23 about that. This is just the computer rendition. It
24 was made up from the contouring of the ultrasound and
25 from the CT.

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1 Dr. Kao did the original contouring of the
2 prostate. And then the consultant oncologist that
3 they hired -- I believe he is an oncologist; he may be
4 a urologist -- has gone back and looked into all of
5 these cases. He has rechecked the contouring of the
6 prostate. And then they rerun the VeriSeed program
7 based on the current contouring of the prostate.

8 MEMBER WELSH: But that is the crux of my
9 point. One doctor probably thinks that he hit the
10 target. The other physician is contouring things that
11 makes it look like it's so far off target. If only
12 two physicians are involved, which one is right or are
13 there multiple reviewers who have seen this?

14 DR. HOWE: I have a question.

15 CHAIR MALMUD: Dr. Howe?

16 DR. HOWE: Dr. Welsh, I was part of the
17 June inspection. And when we looked at the data, in
18 many cases, not all cases because sometimes the CT
19 scans were corrupted, we looked at the VeriSeed coming
20 from the contour lines that Dr. Kao drew on the day
21 after. So there are only a few of these that are
22 based on the second physician drawing things. In many
23 cases, the VA has the data for the original Dr. Kao
24 drawing where he thought the bladder, the prostate,
25 and the rectum were.

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1 And so that takes out the question of one
2 physician versus another physician. On many of the
3 cases, that data is available.

4 MEMBER WELSH: Could you clarify? Maybe I
5 misunderstood what you said. The day after? Do you
6 mean the day after the procedure?

7 MS. FRAZIER: The day after the procedure.
8 He, Dr. Kao, in almost all cases did a CT scan the
9 day after the procedure because, from what we heard,
10 he didn't believe the patients because they were from
11 out of state would be able to come back at 30 days.

12 MEMBER WELSH: That is a practical
13 problem. And sometimes that solution is implemented,
14 but it is well-known that the day after the procedure,
15 there is so much volumetric change that it is very
16 difficult to interpret things, which is why there are
17 recommendations for when the CT should be done for
18 adequate post-procedural dosimetry.

19 MS. FRAZIER: We understand that, but the
20 VA, they chose to do the CT the day after. As Dr.
21 Howe said, it's primarily due just to convenience of
22 having the patients there. So that was a decision
23 chosen by the --

24 MEMBER WELSH: Understood. But when you
25 are saying there are doses of 200 gray, 300 gray, 2

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1 areas that might not be targeted, it has to be
2 recognized that there are some serious challenges in
3 dealing with post-implant dosimetry when done at
4 nonstandard time points.

5 MR. WIEDEMAN: Another thing you have to
6 remember, their VeriSeed program and the computers
7 were not talking to each other for about a year. So
8 there was about a year they weren't even doing
9 post-plans. So some of these VeriSeed readouts that
10 you're looking at occurred about a year after the
11 patient was implanted. So the swelling had certainly
12 gone down by then.

13 CHAIR MALMUD: Excuse me. We have a
14 member of the public, but if you are a member of the
15 public and you wish to make a comment, come on up to
16 the microphone. No? You're invited to if you wish
17 to. Would you please introduce yourself first and
18 then your question or comment?

19 DR. DODOO-AMOO: My name is Dr. David
20 Dodoo-Amoo. I think I have a lot of questions on the
21 placement of the needles.

22 I don't know what type. There are two
23 methods of doing this implant, where we have the
24 real-time or the pre-plant, where the seeds are
25 loaded, preloaded in the needles and then you go. And

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1 then with the plant, you get that from the VeriSeed.
2 And then you put the needles in.

3 Now, the reason why this is occurring is
4 they are using one side of the ultrasound. The
5 ultrasound you have two views. You have the axial
6 view or the sagittal view.

7 Now, if you are looking at it from the
8 sagittal view, this problem will always occur because
9 you are advancing, you are moving the needle this way.

10 So you move it until you hit the point and say,
11 "Okay. This is the base." And then you adjust by
12 retracting the needle.

13 But if you look at this this way, you can
14 see where the base of the bladder, the prostate is,
15 and then you can adjust your needle. In that case,
16 you can drop the seed packet here.

17 I think that is the problem that is
18 happening here. If you are just going by the one
19 view, most of the time, 50 percent of the time, you
20 miss the target. So I see this as small, the seed
21 problem, than just the technique.

22 So I don't know how I can comment to help
23 because that is some of the work that we do a lot.
24 And we are having some of these problems. And we
25 adjust the technique. And we are getting about 90

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1 percent of the dose delivered to the prostate.

2 Thank you.

3 CHAIR MALMUD: May I ask you your
4 question?

5 DR. DODOO-AMOO: Yes, just a contribution.

6 It is not a question. Just because I deal with this
7 a lot, I know where the problems come up. So I am
8 trying to contribute to how they can solve this
9 problem.

10 CHAIR MALMUD: How they can solve the
11 problem.

12 DR. DODOO-AMOO: The problem, yes.

13 CHAIR MALMUD: Thank you. It wasn't clear
14 to me what point you were making. Thank you very
15 much.

16 Other comments or questions? Dr.
17 Guiberteau?

18 DR. GUIBERTEAU: I would just be curious
19 to know a little bit more about the credentialing
20 process at the VA, not having worked in one.
21 Generally for procedures that have a high potential of
22 harm to patients if they go awry, there are some
23 pretty stringent credentialing criteria in place,
24 usually by the medical staff or delegated to the
25 department.

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1 And I am just curious to know in this
2 instance, since there seemed to be an issue with
3 training and limited experience where the failure was.

4 First of all, were there criteria in place or were
5 they delegated to the entity to which the department
6 was outsourced?

7 MS. FRAZIER: They had a consulting
8 company. The consuler that they had, the physicians,
9 as well as the physicists, they were all consulted
10 from locations, hospital. So they pretty much would
11 do the procedures.

12 As we said, oversight was one of the
13 issues that we found in our inspection because they
14 felt that they had the expertise and they were
15 consultants. So they felt that they were able to do
16 the prostate brachytherapy procedures pretty much
17 unsupervised.

18 DR. GUIBERTEAU: But, in general, in order
19 to be on the staff -- and apparently he did have
20 privileges because he lost them -- there is a process
21 by which the institution makes a determination whether
22 those privileges will be granted.

23 MS. FRAZIER: And they have a radiation
24 safety committee. And that radiation -- I'm sorry.

25 DR. GUIBERTEAU: No. This is a committee

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1 of the medical staff that does this.

2 MS. FRAZIER: Oh, okay. Outside of the --

3 DR. GUIBERTEAU: In the institution.

4 MS. FRAZIER: Right.

5 DR. GUIBERTEAU: I mean, now, the VA may
6 work differently, but my understanding is that is the
7 way it works in any hospital. And I'm just curious if
8 this was another area of failure that needs to be
9 addressed.

10 MR. WIEDEMAN: This particular facility is
11 a broad-scope medical. The credentials went before
12 the radiation safety committee. They reviewed. And
13 they determined that he was qualified.

14 CHAIR MALMUD: If I may, I think I can
15 clarify. When we practice at a hospital, putting
16 aside the issue of radiation for the moment, when we
17 practice at a hospital, we are credentialed by our
18 department chairmen. For example, I am a nuclear
19 physician, not a radiologist.

20 So, although I am in the Department of
21 Radiology, I am not credentialed to do anything in
22 radiology except for nuclear medicine. And there are
23 internists who are credentialed to do endoscopies but
24 not to do other procedures not in their area.

25 So the question is, since this is standard

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1 procedure in almost every hospital that I am aware of
2 in the United States, they have a credentialing
3 committee of the medical staff. And the chairman of
4 the department must sign off on the credentials and
5 submit them.

6 In the case of radiation oncology at the
7 VA, was that an assumption of the VA or was that
8 delegated to the University of Pennsylvania to
9 credential the radiation oncologists at the VA? Is
10 that your question, Dr. Guiberteau?

11 DR. GUIBERTEAU: Yes, it is. Yes. Thank
12 you.

13 CHAIR MALMUD: That is Dr. Guiberteau's
14 question. Do you know?

15 MS. FRAZIER: What we know is that they
16 had a contract with consultants. The scope of the
17 contract is outside of what NRC would regulate. So we
18 don't know the specific answer to that particular
19 question.

20 CHAIR MALMUD: Thank you.

21 DR. GUIBERTEAU: I would think it would be
22 an important point.

23 MS. FRAZIER: I would think it would be
24 part of the contract when they contracted with the
25 consultants. But, like I said, we don't have that

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1 information.

2 MR. LEWIS: Right. Since it isn't a part
3 of the Part 35 regulations, then we wouldn't look at
4 that during an inspection.

5 CHAIR MALMUD: Yes. Each of your
6 statements is correct. Dr. Guiberteau's question
7 relates to how an individual can perform a procedure
8 for which he or she hasn't been credentialed.

9 And you are correct. It is not an NRC
10 issue in terms of performing the procedure. It's a
11 hospital credentialing issue, which is outside of the
12 scope of the NRC. Apparently, though, it is an
13 important point but not related to your investigation.

14 Dr. Eggli?

15 MEMBER EGGLI: Working in a department
16 that had a VA contract for several years, the VA has a
17 credentialing process similar to what you described.

18 CHAIR MALMUD: Thank you.

19 Dr. Welsh?

20 MEMBER WELSH: Jim Welsh. I am still
21 trying to get a better understanding about how all of
22 this could have possibly happened. And the points
23 just raised about the questions regarding
24 credentialing are important points that should be
25 answered. I don't know if anybody would have the

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1 answer to these questions, but I throw them out
2 anyway.

3 Do we know if these were done via a
4 pre-plan versus intraoperative planning? And if they
5 were done by pre-plan, which is what I assume, we know
6 that hormone therapy can cause a very drastic change.

7 And do we know what fraction of these patients might
8 have had hormonal therapy that could have led to a
9 very different size/shape prostate during the
10 procedure compared to when the pre-plan was done?

11 These are factors that come into play
12 whenever you're looking at an outcome in terms of
13 dosimetry that differs substantially from what was
14 initially anticipated. And so I am just trying to
15 figure out how this could have possibly happened if
16 there is anything other than incompetence that could
17 explain it, for example.

18 MR. WIEDEMAN: There was one case that I
19 was aware of that there was a patient that was on
20 hormone therapy, but that is only because it came up
21 about the size of his prostate, which was real large.

22 And they were trying to compensate for that.

23 MEMBER WELSH: But, as far as you know,
24 it's not like all of these patients had hormone
25 therapy because that could explain things.

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1 CHAIR MALMUD: Dr. Welsh, your point is
2 that the installation of the seeds itself will cause
3 the prostate to swell because of the penetration of
4 the prostate. And, therefore, 24 hours later is too
5 soon to determine the dosimetry. And at the same
6 time, hormonal therapy will shrink it and cause some
7 change in the geometry as well? Those are the two
8 points you were making before?

9 MEMBER WELSH: You are correct. The first
10 point is that poking any organ with a bunch of needles
11 and implanting foreign bodies is going to cause
12 significant swelling. And that edema can occur right
13 after the procedure, making post-implant dosimetry
14 right after the procedure especially challenging.

15 But my second question was regarding the
16 hormone therapy, which we know can cause a significant
17 reduction in prostate volume. We intentionally do
18 this on occasion. When the prostate is too large for
19 implantation, we want to shrink it down.

20 But if we do the pre-plan before the
21 prostate has stabilized in terms of its ultimate
22 shrunken-down volume, you can get a very misleading
23 pre-plan. And it could be that the prostate would be
24 one-half the volume when you do the procedure than
25 when you did the plan. And that can lead to

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1 significant difficulties intraoperatively.

2 CHAIR MALMUD: Thank you.

3 Are there other questions or comments?

4 Yes?

5 MR. LEWIS: Well, if I could just make an
6 observation that all of these insights are very
7 valuable? In terms of roles and responsibilities,
8 what the inspectors have presented here is largely the
9 VA's only analysis.

10 And our oversight of their analysis is
11 through our inspection process, in which we're looking
12 for safety issues, regulatory compliance in compliance
13 with any commitments they have made in a license
14 application.

15 We have our own independent medical
16 consultant to verify what the VA has analyzed, but our
17 role is that, is verification. And a lot of the
18 comments that have been made around the table might be
19 very valuable for VA to think about when they respond
20 to our inspection report, but in terms of roles and
21 responsibilities, it is not for NRC to decide -- well,
22 it is for NRC to decide if compliance existed. It is
23 for the licensee to provide for the safety of the
24 patients and the workers.

25 CHAIR MALMUD: Thank you.

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1 We have a question from a member of the
2 public. Would you please introduce yourself and then
3 your question or comment?

4 MS. FAIROBENT: Lynne Fairobent with AAPM.

5 I think this might be to Rob because I think you may
6 have answered Debbie Gilley's question earlier
7 regarding safety culture implications.

8 Since one of your findings is that you
9 determined lack of safety culture, I am curious since
10 we are awaiting further direction, discussion,
11 whatever, on safety culture and implications for our
12 materials users, in lieu of the fact that there hadn't
13 been a policy prior or during this period, how did you
14 make a determination? And what are you judging that
15 you found a lack of safety culture there? What are
16 you measuring it against to determine that finding?

17 CHAIR MALMUD: Your question is for whom?

18 MS. FAIROBENT: NRC. They're all nodding
19 to each other as to who might respond to that.

20 MS. FRAZIER: I will respond to that. The
21 lack of safety culture that we are speaking of has to
22 do with reporting radiation concerns to the
23 appropriate individuals. And I will give you an
24 example.

25 We interviewed two of the medical

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1 physicists that were involved in the treatments. And
2 one of the physicists indicated that he raised a
3 concern to the authorized user physician and no action
4 was taken by the physician. However, the physicist
5 did not raise the concern with the radiation safety
6 staff at the VA Philadelphia.

7 Another example is the other physicist
8 also had a concern. And the concern that they had was
9 that the physician that they worked with was
10 underdosing the patient. Now, they raised this
11 concern to the affiliated institution because they
12 were consultants, but they did not raise the concern
13 to the radiation safety staff at VA Philadelphia.

14 So there seemed to be no procedure in
15 place that would cause them to raise a concern that
16 was not taken care of by, say, the physician and raise
17 it higher to the RSO or the radiation safety staff or
18 the Committee or outside of the physician. So when we
19 say, "lack of safety culture," that is what we are
20 speaking of.

21 CHAIR MALMUD: Did that answer your
22 question?

23 MS. FAIROBENT: Not completely. If there
24 is noting to require that that may have existed, then
25 how can you find action against something that they

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1 did not do if they did not know to do it and there was
2 no requirement requiring them to do it?

3 MS. FRAZIER: Well, actually, when we
4 interviewed the radiation safety officer and the
5 staff, they did have procedures in place that if
6 something did not go right or if they had a problem,
7 they were told to raise it to the radiation safety
8 officer. But this did not take place.

9 CHAIR MALMUD: Thank you. Would you
10 please once again introduce yourself and then make
11 your comment or question?

12 DR. DODOO-AMOO: Again, my name is Dr.
13 David Dodoo-Amoo.

14 My question is of you during your
15 inspection because at least I saw that you were giving
16 these after, after you had done the procedure and you
17 are looking at files from scan. Did you take your
18 time to follow through from the initial stage to the
19 end, like the volume steady, all that it does from the
20 VeriSeed to the OR, even how they receive the seed,
21 all of those procedures? Did you follow through all
22 of them?

23 Because along that line, did you check
24 whether the equipment, the ultrasound, is even showing
25 because if there are a lot of problems with the

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1 ultrasound, you may not see the prostate? It is very
2 difficult with some of these ultrasounds to see that
3 prostate on the screen.

4 So did you take your time to follow
5 through every step to the end, even after the
6 pre/post-plan to submit all of them? Did you take
7 your time? Because all that you have here is on
8 paper. And that will help you to identify where the
9 actual things were. Did you do that?

10 MR. WIEDEMAN: That's one of the reasons
11 why this inspection has taken so long. We looked at
12 every one of the cases from the pre-plan. Everyone
13 had a pre-plan all the way through to the post-plan
14 and then for the re-evaluation done by the new
15 contracting physicist and oncologist.

16 But you have got to remember, some of
17 these occurred back in 2003-2004. So to follow all
18 the way through surgery, that would be totally
19 impossible because it is past tense.

20 And, plus, our medical consultant has
21 reviewed all of the medical records, the therapy
22 follow-up on the patient, looking at PSAs and Gleason
23 tests. So I think we have done a very thorough job in
24 evaluating each one of these cases.

25 DR. DODOO-AMOO: What I was trying to ask

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1 is you send some patient to other hospitals to
2 reimplant. I mean, from there, you are going to look
3 at the live procedure. What is it you are doing from
4 the onset to the end? Did you also look at that?
5 Because those were sent for reimplant. That is where
6 you can also look at that and then see what is going
7 on. Then you can see those.

8 I mean, you can go back to the same
9 hospital with the same doctor because that is a
10 problem that when you send a patient to another VA
11 hospital, did you follow through on those patients
12 from the beginning to the end?

13 MS. FRAZIER: As far as our inspection or
14 looking at it from the regulatory side, we did follow
15 the patients from the pre-treatment to the
16 post-treatment.

17 Now, as far as the patients being the
18 decision to have them re-treated, that is the clinical
19 aspects of it. And we don't follow through from the
20 clinical side just looking as far as our inspection
21 was involved.

22 We do get information on the number of
23 patients that were re-treated, but we have not gone
24 beyond that because, really, we just had that
25 information during our last inspection.

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1 But just keep in mind that we are looking
2 at the regulatory aspects of the medical events.

3 CHAIR MALMUD: Thank you.

4 We have another question from a member of
5 the public. Please reintroduce yourself.

6 DR. WESLEY: Yes. I am Dr. Wesley again
7 from the VA IG's office.

8 To the NRC team, do you have any
9 indication that the kind of problems you identified
10 extend to other VA facilities other than Philadelphia,
11 number one? And, number two, do you have any sense
12 that these kind of events happen in the private
13 sector?

14 MS. FRAZIER: We have had medical events
15 that have been -- at some of the other VA facilities,
16 they have 13 total facilities that do prostate
17 brachytherapy. And we have had medical events at the
18 other facilities.

19 We have not had the numbers that we have
20 at VA Philadelphia. So we don't believe that the VA
21 Philadelphia is at this point an isolated issue. We
22 are still looking into the other cases.

23 We have five facilities thus far that have
24 suspended their programs based on the medical events
25 that they have reported to NRC.

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1 DR. WESLEY: Second half of the question,
2 do you see these kinds of things in the private sector
3 or is this the VA reporting a lot?

4 MR. WIEDEMAN: Well, I can add to that.
5 Now, I have gone out, and I have looked at Jackson,
6 Mississippi; Minneapolis, Minnesota; Cincinnati VA;
7 the Seattle VA; the Reno VA. And there are other VA
8 facilities that have very similar problems, not to the
9 degree that Philadelphia has but very similar, similar
10 in the sense that they have medical events.

11 They had physicians that disagreed to how
12 an implant should be done. They were behind on
13 post-implants, doing post-implant treatment plans.
14 But they were all aware of the Philadelphia problems,
15 and they were trying to get these problems corrected.

16 DR. WESLEY: That wasn't going to the
17 question about the private sector. Do these things
18 happen in the private sector?

19 MS. FRAZIER: I think we have medical
20 events.

21 CHAIR MALMUD: Dr. Howe?

22 DR. HOWE: I've been looking at the
23 medical events now since probably 2003. We have
24 medical events in manual prostate brachytherapy in the
25 private sector. When we have medical events, we may

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1 have one or two cases at a given facility.

2 We have never had the level that we had at
3 VA Philadelphia, where you are talking 80-90 percent
4 of all the people treated for a medical event. So no,
5 we have not had anything similar to that.

6 We had in other cases had a high number of
7 medical events. And in this case, I am referring to
8 teletherapy medical events or eye applicator medical
9 events, where the high numbers have been as a result
10 of a mechanical type of interpretation at the
11 beginning of decay or generally decay. And that error
12 has followed through for a number of years until it
13 was identified but nothing like this in prostate.

14 CHAIR MALMUD: Other questions or
15 comments? Dr. Suleiman?

16 MEMBER SULEIMAN: This is one of my
17 conflicted areas where I see sometimes we'll from my
18 agency write a simple regulation, one sentence, and
19 defer it to the professional practice. And then
20 you've got different professionals with different
21 responsibilities, some ethical. And you have got a
22 fuzzy area where it is acceptable, where you have
23 professional disagreements. What happens when
24 something like this happens and you swing in the other
25 direction, you get more prescriptive, more control,

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1 more oversight?

2 But what bothers me -- and I'll air it
3 here -- is I see this all the time where we have
4 experts running all over the place and saying they're
5 not doing a good job, but how do you establish some
6 sort of infrastructure -- safety culture is what you
7 are mentioning -- where people go to the right people
8 and not get blown off because, oh, that's just the way
9 we do things.

10 And is it the physicist's responsibility?
11 Is it the institution's responsibility? Is it the
12 other physician's responsibility? How is this
13 described?

14 And in terms of the private sector, this
15 stuff is way, way under-reported. I mean, we know
16 that. Adverse events just capture the tip. These are
17 soft, soft numbers. But the point is it brings issues
18 to the surface. And it addresses issues that could be
19 resolved.

20 What are the lessons learned from this
21 exercise? Who is going to be responsible for not
22 over-regulating these specialists but at the same time
23 capturing something like this before it gets on a
24 scale that we have just observed?

25 MR. WIEDEMAN: That's an interesting

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1 question because Sandy and I both interviewed the
2 physicist and the physician. When you talk to the
3 physician, he would say that "I relied on the medical
4 physicist to tell me if I have a medical event."

5 And you go to the medical physicist. And
6 he says, "Well, I have relied on the physician. That
7 is a medical decision, not mine." And so we have got
8 them both pointing fingers at each other, but neither
9 one will assume the responsibility.

10 MS. FRAZIER: I just wanted to add I think
11 the VA Philadelphia, one of their corrective actions
12 that they have taken is to provide training to the
13 radiation oncology staff as well as to the physicist,
14 all new employees and trainees. What they're training
15 their staff is the NRC regulations, how to identify a
16 medical event, how to report and who to report the
17 medical event to.

18 And also included in their training, they
19 have an open-door policy that they have initiated.
20 And this is for reporting concerns and suspected
21 violations.

22 So I think one way that they are in a
23 process of resolving this is to do it by training your
24 staff.

25 MEMBER SULEIMAN: You see, what bothers me

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1 is that if you had a real professional relationship
2 among the different -- they would be communicating.
3 And when an issue was raised, somebody would say,
4 "Maybe they've got a point" and look into it. It
5 shouldn't have to get to the regulatory agencies to
6 spell something out. And I think that is the fault of
7 the professionals themselves. I think they've got to
8 regulate themselves in a more effective manner.

9 CHAIR MALMUD: Dr. Guiberteau?

10 DR. GUIBERTEAU: I just want to make a
11 philosophical comment based on a lot of reading in
12 safety cultures. I think what was just said about
13 pointing fingers, about professionals, it isn't just
14 the professionals. I mean, a safety culture should be
15 pervasive in an institution.

16 And one of the number one causes of a
17 failure of a safety culture, which is what the airline
18 industry has mastered, by the way, is that it turns
19 out to be a federation of safety subcultures, little
20 silos. And people don't know what the people are
21 doing.

22 I am just saying that is one thing that we
23 all ought to remember, that when these things fail, it
24 is not just because of the professionals. It is the
25 people who work under the professionals. It is the

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1 administrators. It is everybody. And too often we
2 forget that.

3 CHAIR MALMUD: Dr. Howe?

4 DR. HOWE: I would just like to make a
5 point, kind of as a tangent. This Committee has
6 discussed many, many times about training and
7 experience for authorized users. And they have
8 contrasted between the alternate pathway and the Board
9 certification pathway.

10 I think it is important for you to know
11 that the individual who made all of these medical
12 events was a Board-certified radiation oncologist and
13 was considered an authorized user under the Subpart J
14 criteria of Board certification. And I think that is
15 important to keep in mind.

16 CHAIR MALMUD: Thank you. I don't believe
17 anyone assumed otherwise, but thank you for the
18 clarification.

19 Dr. Welsh?

20 MEMBER WELSH: Jim Welsh. I am sorry to
21 belabor these minor details, but one final comment I
22 might have regarding reconstruction of dose. I
23 mentioned earlier that if you do the post-implant
24 dosimetry too soon, you can be misled because of the
25 edema that goes along with the procedure, but,

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1 similarly, you can be misled if you do the
2 post-implant dosimetry far too late. And, as you
3 mentioned, some of these scans were done a year or
4 longer afterwards.

5 And I just throw that out as a caveat in
6 that there can be some atrophy in areas that are dosed
7 and perhaps compensatory hypertrophy in areas that
8 were underdosed, leading to a prostate that, for
9 example, in the example you have on the slide, it
10 could lead to a pear-shaped prostate down the road.
11 And if you do the dosimetry at a later time point, you
12 could be misled.

13 I think that is understood, but I would
14 just bring it up since we are discussing this.

15 MS. FRAZIER: I think I just want to just
16 add that the dose assessments that we have received
17 from VA, VA Philadelphia, they had decided that they
18 were using the next-day CT. They did do CTs on all of
19 the patients in 2008. And then this year they were
20 looking at those CTs versus looking at the one-day CT.

21 And they're coming in with analysis. But they have
22 decided to do the one-day CT, as opposed to the 2008
23 CT.

24 CHAIR MALMUD: May I ask a question as a
25 non-radiation oncologist? What is the standard in the

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1 United States for doing the post-therapy CTs? What
2 number of days, weeks? Dr. Thomadsen?

3 VICE CHAIRMAN THOMADSEN: The
4 recommendation, both by the ABS and new AAPM task
5 group is for iodine at about 30 days, although there
6 are a number of places which do maintain that it is
7 good to do it the day of the implant, immediately
8 following, to make sure that you have covered things
9 and don't have major gaps or hot areas.

10 CHAIR MALMUD: So the standard, the
11 recommendation, of the ABR is the next day?

12 VICE CHAIRMAN THOMADSEN: No. Thirty
13 days.

14 CHAIR MALMUD: Thirty days.

15 VICE CHAIRMAN THOMADSEN: ABS. ABS, not
16 ABR.

17 CHAIR MALMUD: Okay. ABS is 30 days?

18 VICE CHAIRMAN THOMADSEN: The American
19 Brachytherapy Society.

20 CHAIR MALMUD: Thirty days?

21 VICE CHAIRMAN THOMADSEN: Thirty days.

22 CHAIR MALMUD: And how long has that
23 standard been in place?

24 VICE CHAIRMAN THOMADSEN: Several years.
25 I don't know exactly. I don't remember.

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1 CHAIR MALMUD: Only several years.

2 VICE CHAIRMAN THOMADSEN: Several could be
3 a decade.

4 CHAIR MALMUD: A decade.

5 VICE CHAIRMAN THOMADSEN: It could be
6 five. I don't remember what it was. We could look
7 that up, of course.

8 CHAIR MALMUD: Thank you.

9 Dr. Suleiman?

10 MEMBER SULEIMAN: Just a quick question.
11 Do they not do it immediately because there is
12 swelling in whatever? And other studies would show,
13 I'm sure, what is the difference between the images
14 taken immediately after, within 24 hours, and 30 days
15 later?

16 VICE CHAIRMAN THOMADSEN: Bruce Thomadsen.
17 The answer to your question have there been studies,
18 yes. People who have done that have shown that there
19 is not the maximal swelling immediately after that
20 comes about a day or so later. It goes up. But there
21 is swelling compared to a month later.

22 A month later you still have some
23 swelling, but the month has been picked with iodine as
24 a good time to do the dosimetry to represent over the
25 year of treatment what would probably be the dosimetry

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1 that the implant would get.

2 CHAIR MALMUD: Dr. Welsh?

3 MEMBER WELSH: If I might just add, things
4 get a little bit complicated when we use isotopes
5 other than iodine-125 with its 60-day half-life. For
6 example, if you're using palladium-103 or if you're
7 using cesium-131 with shorter half-lives, the impact
8 of the edema on the dosimetry can be relatively more
9 significant. And, thus, there is not a uniform time
10 point for which post-implant dosimetry was
11 recommended. It is isotope-dependent. And it is
12 still debated.

13 CHAIR MALMUD: So if I understand what you
14 are saying is that at this institution, they used
15 I-125 seeds. And there is no standard for I-125
16 seeds.

17 MEMBER WELSH: The ABS recommendation is
18 one month.

19 CHAIRMAN MALMUD: The ABS recommendation
20 is one month for I-125 seeds. And was that performed
21 at one month? No because I think you said the
22 patients were from out of town, and they didn't
23 schedule it. Thank you.

24 Any other questions regarding this issue?

25 (No response.)

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1 CHAIRMAN MALMUD: If not, we thank you for
2 bringing it before us. We have been concerned about
3 it and interested. And we appreciate the information.
4 Thank you.

5 MR. WIEDEMAN: Thank you.

6 MS. FRAZIER: Thank you.

7 CHAIRMAN MALMUD: Dr. Welsh, by what
8 percent does the volume of the prostate increase
9 maximally after the insertion of the seeds? I know
10 it's not uniform, but what is the most you have seen
11 it increase?

12 MEMBER WELSH: I have read in the
13 literature. I have experienced in my own practice a
14 factor of 1.4.

15 CHAIRMAN MALMUD: 1.4. Total volume?

16 MEMBER WELSH: Yes. So if you have a
17 volume on day zero of 50 cc, the day after the
18 implant, after maximum --

19 CHAIRMAN MALMUD: Only one conversation at
20 the table, please. Only one conversation at the
21 table.

22 MEMBER WELSH: Due to the trauma of the
23 needle insertions, due to the foreign bodies, due to
24 the radiation, it can be 40 percent larger.

25 CHAIRMAN MALMUD: And is the swelling

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1 sufficient to close off the urethra and require
2 catheterization?

3 MEMBER WELSH: Yes. In my practice and
4 many others, a Foley catheter is left in for at least
5 the first 24 hours, but it is not at all uncommon for
6 patients to require recatheterization after that Foley
7 catheter is removed because of this problem.

8 CHAIRMAN MALMUD: So in your practice, how
9 long do you have to keep track of those patients
10 following therapy in the event they need to be
11 catheterized?

12 MEMBER WELSH: Well, the catheter is
13 removed the next day. And they are instructed to
14 contact, go to an emergency room if necessary because
15 of inability to void. But they would be in regular
16 contact with the oncology team for the next several
17 days and come in for routine follow-up about two weeks
18 later.

19 CHAIRMAN MALMUD: Thank you very much.

20 We have another item on the agenda. And
21 we'll move forward to the International Commission on
22 Radiological Protection Publication 103 Subcommittee
23 report and discussion. Dr. Thomadsen?

24 VICE CHAIRMAN THOMADSEN: Thank you.

25 CHAIRMAN MALMUD: Microphone.

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1 VICE CHAIRMAN THOMADSEN: Thank you.

2 12. INTERNATIONAL COMMISSION ON
3 RADIOLOGICAL PROTECTION (ICRP) PUBLICATION

4 103 SUBCOMMITTEE REPORT AND DISCUSSION

5 VICE CHAIRMAN THOMADSEN: At the last
6 meeting, a subcommittee was set up with Ms. Gilley,
7 Dr. Van Decker, and myself to look at the
8 recommendations of the ICRP publication 103 and make a
9 recommendation to this Committee as far as what maybe
10 should be adopted from that.

11 Here is our charge, which if you just slip
12 down to number 3 on the slide to discuss the options,
13 consider the cost benefits, and fundamentally dues
14 associated with revising the radiation protection
15 framework, as presented by Dr. Cool, with regard to
16 effective dose terminology, numerical values,
17 occupational dose limits, dose limits for embryo and
18 fetus, and constraints, and to identify other code 10
19 CFR Part 20 issues, which might arise from adoption of
20 ICRP 103.

21 Terminology in radiation protection has
22 always been a bit confusing, particularly because the
23 actual terms used changed frequently but have little
24 changes. And the difference in the names between
25 quantities also does not help distinguish one quantity

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1 from another. And moving from effective dose, rather
2 than total effective dose, would simply both the name
3 and the quantity at the moment, at least, with
4 qualifications that we will be discussing through
5 here.

6 One of the recommendations of ICRP is to
7 use effective dose. And with the most to effective
8 dose, it would be expected that licensees could
9 calculate that. For the most part, they cannot. For
10 the most part, a licensee will have a badge reading.
11 And from that badge reading, if they were to calculate
12 effective dose, they would need to know the doses to
13 the various organs because for effective dose, you
14 have to convert the dose given to the dose to each
15 organ multiplied by that organ's weighing factor and
16 add that all up to get the effective dose.

17 You don't have enough information to do
18 that. Almost no licensee could do that. To
19 demonstrate compliance, then, we would have to have
20 something where the badge readings would stand in as a
21 surrogate for the effective dose with the assumption
22 that the radiation received by the badge wearer was to
23 the whole body.

24 To do this; that is, allow the badge
25 reading to be used in place of the effective dose

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1 would require recognition of methods to convert
2 readings to effective dose and some approximations,
3 such as the methods of the National Council of
4 Radiation Protection and Measurements in the report
5 122, which gives algorithms to try to approximate
6 effective dose given badge readings.

7 The weighing factors in ICRP 103 are
8 different from the previous, which would be ICRP 60,
9 but the changes in the weighing factors would have
10 very little effect in the medical community since
11 people couldn't really use those anyways except for
12 internal exposures.

13 The use of effective dose replaces the
14 organ-specific limits in ICRP. Whereas, right now in
15 the regulations, we have limits for organs, that goes
16 away with just looking at effective dose.

17 And for a single organ irradiation, most
18 often this would be an increase in allowed exposure,
19 but when you don't have irradiation of a single organ,
20 which is the most common situation here, it is
21 probably a decrease. But you would have to go on a
22 case-by-case basis. The subcommittee supports moving
23 the value through the weighing factors in both the
24 numerical values and for the items in the lists of
25 things which are given weighing factors.

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1 Just so that our regulations would be more
2 compliant with the rest of the world at the moment
3 and, as we said earlier, this is probably not going to
4 change anything for most medical uses of radiation.

5 Values for occupational limits are
6 different in ICRP 103. And if we adopted those, the
7 occupational limits would change from the 50
8 millisievert per year to 20 millisievert per year.
9 Actually, ICRP is more complicated than that.

10 And I put an asterisk there with a
11 footnote to show it is actually 20 millisievert per
12 year averaged over 5 years and less than 50
13 millisievert in a year and whether you would want to
14 have this more complicated rule or just have the 20
15 millisievert per year would be a decision that would
16 have to be made.

17 Lowering the limit for the most part would
18 not be a problem for the medical community given the
19 following. If badge readings were converted to
20 effective dose, as noted before, we could use a
21 method, such as the NCRP 122 algorithm or there are
22 several others in the literature. If that badge
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10 method, such as the NCRP 122 algorithm or there are
11 several others in the literature. If that badge
12 reading were allowed as a surrogate for effective
13 dose, then that would take care of one problem.

14 Another issue that could cause a problem
15 for the medical community is the ALARA levels. For
16 the most part, while the current regulations would
17 allow 50 millisievert per year, most people assume
18 that following ALARA, those limits should be held at
19 about a tenth of that to 5 millisievert per year.

20 If that level were kept the same and moved
21 down 2 millisieverts per has. Then that would not be
22 a problem for most medical facilities. If it would
23 have moved to two millisievert per year, that could be
24 a big problem from any medial facilities, particularly
25 for interventionalists, who frequently might be

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1 pushing that limit.

2 We also noted it is clear that the badge
3 change frequency depends on the expected reading and
4 should be allowed to vary with the expected readings.

5 And investigational levels should vary with the
6 application, rather than just have a blanket
7 investigation level for everybody in a facility.

8 Further conditions regarding occupational
9 limits, shielding should not have to be retrofitted to
10 meet the new limits. Grandfathering of installations
11 that are already built should be allowed. Otherwise
12 you would probably have a large, an extremely large,
13 cost to the culture, to meet the new limits with
14 probably very little benefit.

15 Actually, this likely will satisfy the new
16 limits only because people who do the shieldings
17 usually make various conservative assumptions and
18 probably had built in limits already. The rationale
19 to reduce limits is not strong enough, though, to
20 mandate additional costs for redoing the shielding.

21 Dose limits to the embryo and fetus would
22 have a major effect on the medical community in that
23 ICRP 103 recommends reducing the limit to one
24 millisievert per term, currently have a limit of five
25 millisievert per year per term.

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1 This would most likely require removing
2 staff from service at times, particularly if somebody
3 works in a fluoroscopy environment. This could
4 deprive patients of those expertise.

5 If this change occurred, it would have to
6 be clear that a badge worn under a lead apron would
7 apply and not a badge outside the apron that you would
8 accept that the lead apron does attenuate most of the
9 radiation that would go to the embryo or the fetus.

10 In the document that gave us our charge as
11 to what to consider as far as the changes with ICRP
12 103, there are three options that should be
13 considered. One is to change the limit to one
14 millisievert after the declaration. And that was sort
15 of discussed in the previous slide and the problems
16 with that.

17 Another is to limit to .25 millisievert
18 after the declaration, to keep the total below one
19 millisievert assuming that the person has worked with
20 radiation and has gotten some doses beforehand and
21 look at the note for the next option, which is to make
22 no changes in the rule.

23 And for both these last, we have, next
24 slide. When we considered the dose limits for the
25 embryo or the fetus, the limit of one millisievert per

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1 term comes out to .11 millisieverts per month, or 11
2 millirem per month in the older units. This is
3 usually right at the edge of badges', radiation
4 badges', ability to measure the radiation.

5 The one millisievert itself, the limit for
6 the term, is less than background in many places, not
7 counting inhaled radon. One millisievert is actually
8 less than the variation in background that we have.
9 And there is no evidence of detrimental effects at
10 that level or at the variations in background around
11 that level. And so it is not clear that making the
12 change really has any benefit to society.

13 Another aspect dealt with in ICRP 103 is
14 potential exposures. For those who may not be
15 familiar with this, a potential exposure is not one
16 that has happened but one that could happen. And it
17 is based on risk analysis where a facility goes
18 through risk analysis, decides that exposures somebody
19 might end up with due to accidents, what are the
20 probabilities, and assign some weighted probability
21 dose to these people already, and reduce that from
22 their allowed limit.

23 The recommendation of this subcommittee is
24 the NRC should not adopt the concept of potential
25 exposure. The benefit is not clear. The principle is

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1 not well-supported. Assigning variability and making
2 assumptions to guess at potential exposures will be
3 very difficult and very onerous for the licensee to
4 try to accomplish. The considerable cost would not be
5 offset by any benefits. And compliance would be hard
6 to impossible to assess.

7 On the other hand, emergency exposures are
8 dealt with, although likely, by the ICRP, which gives
9 very little guidance but some on emergency exposures.

10 But if the NRC is rewriting the NRC rules, it might
11 be a good time to consider this issue and provide some
12 guidance to users as far as what to consider in those
13 situations. Keeping the language to allow increased
14 exposure for caregivers and families of radioactive
15 patients would be essential without compromising
16 health care.

17 And just a couple of final points. Any
18 changes in the rules must not be onerous or compliance
19 will suffer. For example, if we make the doses too
20 low, people will find it useful to keep the dosimeter
21 in their desk, at least much of the time.

22 The ICRP recommendations are based on
23 studies that have been criticized, and highly
24 criticized, for ignoring oppositional data in studies.

25 For example, studies by Bernard Cohen are not even

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1 cited in the literature on which ICRP 103 based their
2 recommendations. That leaves a suggestion for lower
3 limits very poorly supported.

4 And, with that, I will close the
5 presentation on our study and open the floor for
6 discussion at the discretion of our Chair.

7 CHAIRMAN MALMUD: Dr. Van Decker?

8 MEMBER VAN DECKER: Thanks.

9 I would just like to amplify one of the
10 concepts here, feeling mildly on ease as the surrogate
11 clinical representative of probably the most regulated
12 group here, being the occupational clinical exposure
13 from sinifluoro, usually affecting mostly obviously
14 interventional cardiology and interventional
15 radiology, although I guess some high-volume PET
16 facilities could touch some of these over a year.

17 You know, there is always this give and
18 take of making sure that you keep productive workers
19 productive. You know, people who are radiation-savvy
20 have been trained to handle themselves in these
21 situations so that you don't get yourself in a
22 situation where you have to increase your output of
23 experienced workers in order to match your case volume
24 of needed procedures, especially in a field where we
25 haven't seen dramatic abnormalities occurring with our

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1 current limits. And I would point to the final two
2 points on Bruce's last slide in that regard.

3 I did appreciate interacting with my two
4 colleagues on the subcommittee. And after a lot of
5 thought here, I think there is a lot to be said for
6 the fact that the current fears of being close are
7 usually due to external badge readings and that the
8 use of effective dose as a more reasonable calculation
9 of internal exposure, which may in the end be much
10 more administratively simpler than what is going on
11 right now and from what we know about those
12 calculations, actually may make these calculations
13 well within reason for this lowered standard for our
14 annual allowed exposure I think makes sense.

15 And I am hopeful that those communities
16 will find it that way as well, but I am sure there
17 will be some discussion about it from the outside
18 stakeholders' discussions as well.

19 CHAIRMAN MALMUD: Thank you, Dr. Van
20 Decker.

21 Dr. Suleiman?

22 MEMBER SULEIMAN: I commend the committee
23 for the report. I agree with most of the comments
24 very strongly. I have a real problem with any
25 regulatory limits below background radiation. I am

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1 glad you addressed that.

2 I see that all the time from my colleagues
3 at FDA who don't have a radiation background. These
4 are our physicians. And when I explain what the
5 natural background levels are, they say, "Why would we
6 bother?" So I think that I am glad you addressed it
7 and didn't ignore it.

8 We have had some experience in terms of
9 monitoring organ doses and whole body doses. Our
10 experience with some of our research protocols is
11 that, yes, the organ doses are the constraining limit.

12 Rarely do people exceed the whole body or in this
13 case the effective dose limits.

14 That could result in higher doses. And it
15 is possible that you may want to consider specific
16 organ dose limits because it is possible that some
17 organs could receive a very high dose -- let's say all
18 the dose was in one organ -- and still be very, very
19 well below the effective dose limit.

20 So I wouldn't throw the organ
21 dose-specific constraints completely outside, but it
22 may need some attention. And I think the ICRP
23 addresses that like for the eye for cataract and some
24 other issues. Otherwise I think very nice, very nice
25 summary.

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1 CHAIRMAN MALMUD: Thank you.

2 Other comments? Rob?

3 MR. LEWIS: Well, I am going to have to
4 excuse myself in a few moments. A couple of thoughts.

5 I agree with Dr. Suleiman. I thank the group for
6 looking at this issue and the recommendations.

7 I am glad you mentioned cataracts because,
8 as I understand, ICRP does address. There is a lot of
9 anecdotal information at the current lens of the eye
10 limit in our regulations that is not protected. And
11 there is a lot of information that says it is
12 protected. I think that is a key policy issue that we
13 need to look at in terms of part 20.

14 Another thing, I'm surprised you mentioned
15 in passing is caregivers. Why the NRC or any
16 regulatory agency says a caregiver can only get 500
17 millirem is a question that I think we could look at
18 closer. I am surprised, frankly, that the
19 subcommittee didn't come out stronger on that point of
20 why shouldn't it be a higher amount.

21 CHAIRMAN MALMUD: Thank you for that
22 comment.

23 MR. LEWIS: Thank you.

24 I assume that these will be submitted as
25 an overall Committee letter to the NRC or something in

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1 the future?

2 CHAIRMAN MALMUD: Yes, it will.

3 MR. LEWIS: Okay.

4 CHAIRMAN MALMUD: Yes. Dr. Welsh?

5 MEMBER WELSH: I would like to just
6 reiterate what Dr. Suleiman said, commend the
7 subcommittee for the great job it has done and just
8 raise the question once again, the general question,
9 about what the purposes are of having these
10 limitations. They are supposed to be for public
11 safety.

12 The question that always rears its head
13 when we are dealing with this particular topic is,
14 what evidence is there that these low doses are really
15 detrimental? And should we be arguing about one
16 millisievert versus five millisievert when we know
17 that the populations and areas in India, Iran, China
18 have natural background radiations that are in some
19 cases an order of magnitude higher than what we are
20 talking about here? Yet, there is no evidence that
21 these people are really harmed.

22 So if we were to extend this concept to
23 its fullest extent, we would say that somebody who
24 lives in an area around the Gulf states in this
25 country might have to have a different annual limit

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1 than somebody who lives in the Rocky Mountain states
2 because of the natural background rivaling the numbers
3 that we're talking here.

4 Hopefully the argument will never be
5 carried to that ultimate foolishness, but I bring it
6 up because it is something that always has to be
7 thought of when we are talking about such low numbers.

8 CHAIRMAN MALMUD: Thank you.

9 Dr. Eggli?

10 MEMBER EGGLI: You actually don't have to
11 go as far as India. You get to central Pennsylvania,
12 and it's three times the limit proposed here.

13 The other thing is I think the
14 sensitivities to radiation are a public perception
15 issue. ICRP is dominated by in a large sense I think
16 a European perspective, where public sensitivities to
17 issues related to radiation are much greater than they
18 are in the United States.

19 So I think that, in fact, what we are
20 talking about is not necessarily always radiation
21 safety but the politics of perception. And to do
22 something that will cause more harm than good by
23 lowering levels to unreasonable limits does not really
24 accomplish the goal of protecting the public.

25 Certainly with occupational workers, it is

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1 clearly true that someone whose livelihood depends on
2 being a radiation worker is going to take off their
3 badge and put it away if they are approaching these
4 limits. There is just no question about that. It is
5 going to happen.

6 You know, if you are engaging in the
7 safest practice you can and your practice takes you
8 towards what is now an unreasonably low limit, you
9 will take off your badge and you will put it away.

10 So I think that we need to resist the
11 pressure to follow suit with the Europeans simply
12 because they face different political pressures than
13 we do in the United States.

14 CHAIRMAN MALMUD: Thank you, Dr. Eggli.

15 MEMBER FISHER: Yes. Thank you. The
16 subcommittee should be commended for doing a pretty
17 thorough job of analyzing the problem. One comment I
18 would like to add is that in many institutions, we
19 have institutional limits that are far lower than
20 those required under the current part 20, 10 CFR part
21 20, and sometimes a factor of ten lower.

22 So the impact of changing the basic
23 radiation protection limit for some institutions is
24 going to be to drive the regulations down below
25 background. I mean, it could have that effect.

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1 I also agree that the anti-nuclear
2 community will perceive these limits as being limits
3 at which radiation damage is dangerous or radiation
4 exposure is harmful. So we have to be somewhat
5 careful in the setting of radiation limits.

6 That said, I think the committee has made
7 some pretty good recommendations.

8 CHAIRMAN MALMUD: Thank you.

9 You have had three accolades thus far.
10 That is a record for the day, Dr. Thomadsen.

11 VICE CHAIRMAN THOMADSEN: Maybe I should
12 quit.

13 (Laughter.)

14 CHAIRMAN MALMUD: Dr. Eggli?

15 MEMBER EGGLI: Well, I didn't give the
16 committee an accolade in my first comment. I will.
17 But I would like to cycle back to what Rob said about
18 the caregiver limit. I think that would be the only
19 area of the subcommittee report where I would wonder
20 if sticking -- because we have had the conversation
21 before of the current limit not being adequate in many
22 situations for caregivers.

23 So do we want to maintain a limit that we
24 ourselves have said in many cases may be inadequate?

25 CHAIRMAN MALMUD: Dr. Thomadsen?

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1 VICE CHAIRMAN THOMADSEN: One reason we
2 didn't talk about the caregiver is that in ICRP 103,
3 that is not really different. That didn't change.
4 And so we didn't address that.

5 If we are bringing up caregivers quite
6 outside of the scope of ICRP 103, I have very definite
7 feelings. And I think there is a very definite need
8 to address that issue.

9 We are just starting MIVG I-131 treatments
10 where the parents take care of children who have 800
11 millicuries of I-131 on board. They need special
12 limits on them. And with the increase of these types
13 of therapies, this is something that is required for
14 patient care. That was not an issue as part of this
15 docket.

16 CHAIRMAN MALMUD: Dr. Suleiman?

17 MEMBER SULEIMAN: Yes. And I want a
18 clarifying point also. I think the caregivers are
19 neither occupational nor public. I think they warrant
20 a special category.

21 VICE CHAIRMAN THOMADSEN: Yes.

22 MEMBER SULEIMAN: But I thought we had
23 discussed this in the past.

24 CHAIRMAN MALMUD: Malmud. We did discuss
25 the issue of caregivers when there was a case that

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1 came to our attention of a daughter who was caring for
2 a terminally ill mother who had received a high dose
3 of I-131. And the daughter refused to separate
4 herself physically from her mother and, therefore,
5 received an estimated excess radiation burden.

6 We felt very empathetic with the daughter
7 in the care of her mother. The issue there, as I
8 recall, was not with the daughter's behavior, which
9 was unapproved of but, nevertheless, understandable,
10 but with the manner in which it was reported or not
11 reported in a delayed manner to the NRC regional
12 office. But our sympathy was with the institution.

13 So the issue comes back to us again with
14 respect to loosening the regulations for caregivers.
15 And that might be a subject to be handled separately.

16 Dr. Howe, you are looking at me. Did I
17 recall correctly the issue?

18 DR. HOWE: You recall that one correctly,
19 but we also had another case for the MIVG for the
20 infants. In that, I believe we set up a policy for
21 essentially granting exemptions quickly if that was
22 needed.

23 I do think that if the NRC is thinking
24 about revising part 20 and they're looking at this
25 NCRP, we have an issue with putting caregivers into

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1 part 20 that was going to be delayed based on using
2 the exemption.

3 So it would be a good time to talk about
4 it and try to get it into regulatory space.

5 CHAIRMAN MALMUD: Good. So something may
6 come out of that as well. Who is going to be handling
7 that?

8 DR. HOWE: It won't be the medical group
9 because it's part 20. It will be another group. I
10 think Dr. Cool will be a major player in it. And so
11 we just have to make sure he is plugged in.

12 CHAIRMAN MALMUD: Rob, thank you.

13 MR. LEWIS: Thank you.

14 CHAIRMAN MALMUD: Is there a motion for
15 adjournment? Dr. Suleiman, is there a motion for
16 adjournment?

17 MEMBER SULEIMAN: I so move.

18 CHAIRMAN MALMUD: Dr. Suleiman moves. I
19 see we have another hand raised.

20 MS. COCKERHAM: Can I make two quick
21 announcements? In your binders, look behind tab 18.
22 There is a calendar. Please check your calendars
23 tonight to determine your availability for the next
24 meeting. There are dates on that calendar that are
25 already circled that are available for you to meet.

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1 And then the second one is everyone please
2 take your name tags off and set them on the table so
3 you will have them tomorrow.

4 CHAIRMAN MALMUD: Ashley, we want to thank
5 you for a very well-organized first day of this
6 meeting. If tomorrow goes as well, it will be
7 perfect.

8 MS. COCKERHAM: Thank you. I will tell
9 Gretchen thank you, too. I think she already stepped
10 out.

11 CHAIRMAN MALMUD: Oh, we have one more
12 comments from Dr. Welsh.

13 MEMBER WELSH: Actually, tomorrow we are
14 scheduled to break relatively early for an ACMUI
15 meeting. But when will we know if we are really going
16 to be aiming to finish up at 11:30 or not for those of
17 us who might want to change our travel plans?

18 DR. HOWE: There is also the issue of drug
19 testing.

20 MEMBER WELSH: Yes.

21 MS. COCKERHAM: Well, one, the meeting may
22 or may not run late. You know how these meetings go.
23 And, two, we do have the issue of drug testing, which
24 is scheduled for 1:00 p.m. tomorrow for those who will
25 be subject to drug testing. We will have that either

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1 tomorrow morning or at lunch.

2 MR. EINBERG: I think we can probably work
3 with it and let you know in the morning.

4 CHAIRMAN MALMUD: Ashley, you don't mean
5 at lunch because the agenda says meeting is over at
6 11:30.

7 MS. COCKERHAM: Yes. You would know at
8 11:30 because that is more than an hour.

9 CHAIRMAN MALMUD: Okay.

10 MS. COCKERHAM: The form says an hour
11 before testing. But, like Chris said, I think we can
12 talk to admin. They have been very accommodating so
13 far with your drug testing. So we should be able to
14 tell you first thing in the morning.

15 CHAIRMAN MALMUD: Thank you. The meeting
16 is adjourned. Thank you.

17 (Whereupon, the foregoing matter was
18 recessed at 5:01 p.m., to be reconvened on Tuesday,
19 October 20, 2009, at 8:00 a.m.)
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