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1 UNITED STATES OF AMERICA

2 NUCLEAR REGULATORY COMMISSION

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4 ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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6 OPEN MEETING

7 + + + + +

8 WEDNESDAY,

9 October 20, 2010

10 + + + + +

11 The meeting was convened in room T-02B3 of
12 Two White Flint North, 11545 Rockville Pike,
13 Rockville, Maryland, at 1:15 p.m., Bruce Thomadsen,
14 Ph.D., ACMUI Acting Chairman, presiding.

15 MEMBERS PRESENT:

16 BRUCE THOMADSEN, Ph.D, Acting Chairman

17 DARRELL FISHER, Ph.D, Patient's Rights Advocate

18 DEBBIE GILLEY, State Government Representative

19 MILTON GUIBERTEAU, M.D., Diagnostic Radiologist

20 SUE LANGHORST, Ph.D, Radiation Safety Officer

21 STEVE MATTMULLER, Nuclear Pharmacist

22 CHRISTOPHER PALESTRO, M.D., Nuclear Medicine

23 Physician

24 JOHN SUH, M.D., Radiation Oncologist

25 ORHAN SULEIMAN, Ph.D., FDA Representative

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MEMBERS PRESENT: (CONT.)

WILLIAM VAN DECKER, M.D., Nuclear Cardiologist
JAMES WELSH, M.D., Radiation Oncologist
PAT ZANZONICO, Ph.D, Nuclear Medicine Physicist

NRC STAFF PRESENT:

ROB LEWIS, Director, Division of Materials
Safety and State Agreements

CHRIS EINBERG, Designated Federal Official
MICHAEL FULLER, Alternate Designated Federal
Official

ASHLEY COCKERHAM, FSME/DMSSA/LISD/RMSB

MARC FERDAS, R-I/DNMS/MB

SOPHIE HOLIDAY, FSME/DMSSA/LISD/RMSB

DONNA-BETH HOWE, Ph.D, FSME/DMSSA/LISD/RMSB

VARUGHESE KURIAN, FSME/DWMEP/DURLD

ED LOHR, FSME/DIILR/RB-B

PATRICIA PELKE, R-III/DNMS/MLB

RON ZELAC, Ph.D, FSME/DMSSA/LISD/RMSB

ALSO PRESENT:

DAVE ADLER, ASTRO

CURTIS M. ANDERSON, Mele Associates, Inc.

PETER CRANE, UNKNOWN AFFILIATION

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1 ALSO PRESENT: (CONT.)

2 JAMES A. DEYE, NIH

3 JENNIFER ELEE, CRCPD

4 JESSICA LLOYD, SNM

5 DAVID WALTER, OAS

6 MICHAEL HAGAN, DVA

7 JESSICA LLOYD, SNM

8 GLORIA ROMANELLI, ACR

9 ERIC SOLTYCKI, AEHN

10 BHADRASAIN VIKRAM, NIH

11 ANN WARBICK-CERONE, MDS NORDION

12 JENNA WILKES, ASNC

13 GARY E. WILLIAMS, VA NHPP

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P R O C E E D I N G S

(1:22:36 p.m.)

1
2
3 ACTING CHAIR THOMADSEN: I would like to
4 call the meeting to order right now. Welcome to this
5 meeting of the ACMUI. And to start, we'll turn to Mr.
6 Lewis -- oh, I'm sorry, Mr. Einberg from the NRC for
7 some opening comments.

8 MR. EINBERG: Thank you, Dr. Thomadsen. As
9 the Designated Federal Officer for this meeting, I'm
10 pleased to welcome you to this open meeting of the
11 Advisory Committee on the Medical uses of Isotopes.
12 My name is Chris Einberg. I am the Chief of the
13 Radioactive Materials Safety Branch, and I have been
14 designated as the Federal Officer for this Advisory
15 Committee in accordance with 10 CFR Part 7.11. Present
16 today is the alternate named Designated Federal
17 Officer, Mike Fuller, who is the Team Leader for the
18 Medicine Radiation Safety Team. And, Mike, can you
19 raise your hand there.

20 This is an announced meeting of the
21 Committee. It is being held in accordance with the
22 rules and regulations of the Federal Advisory
23 Committee Act in the Nuclear Regulatory Commission.
24 The meeting was announced in the October 6, 2010
25 edition of the Federal Register, Volume 75, page

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2 The function of the Committee is to advise
3 the Staff on issues and questions that arise on the
4 Medical Use Byproduct Material. The Committee
5 provides counsel to the Staff, it does not determine
6 or direct the actual decisions of the Staff or the
7 Commission. The NRC solicits the views of the
8 Committee, and values their opinions.

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

15 At this point, I would like to perform a
16 roll call of the ACMUI members participating today.
17 The first person on the list here is Dr. Malmud, and
18 Dr. Malmud is ill today, so Dr. Thomadsen, as the Vice
19 Chairman of the Committee, will be presiding. Next,
20 of course, is Dr. Thomadsen, he is present. Darrell
21 Fisher.

22 MEMBER FISHER: Present.

23 MR. EINBERG: Ms. Debbie Gilley.

24 MEMBER GILLEY: Present.

25 MR. EINBERG: Dr. Guiberteau.

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1 MEMBER GUIBERTEAU: Present.

2 MR. EINBERG: Dr. Sue Langhorst.

3 MEMBER LANGHORST: Present.

4 MR. EINBERG: Mr. Steve Mattmuller.

5 MEMBER MATTMULLER: Present.

6 MR. EINBERG: Dr. Christopher Palestro.

7 MEMBER PALESTRO: Present.

8 MR. EINBERG: Welcome. And Dr. John Suh.

9 MEMBER SUH: Present.

10 MR. EINBERG: And welcome, as well. Dr.

11 Orhan Suleiman.

12 MEMBER SULEIMAN: Present.

13 MR. EINBERG: Dr. William Van Decker.

14 MEMBER VAN DECKER: Present.

15 MR. EINBERG: Dr. James Welsh.

16 MEMBER WELSH: Present.

17 MR. EINBERG: Dr. Pat Zanzonico.

18 MEMBER ZANZONICO: Present.

19 MR. EINBERG: I would note that Dr.

20 Guiberteau and Dr. Palestro do not have voting

21 privileges at this time, but they will speak on behalf

22 of the diagnostic radiologists and nuclear medicine

23 physicians, respectively.

24 I now ask the NRC Staff members who are

25 present to identify themselves. I'll start with the

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1 individuals in the room here, and next we will
2 identify members of the public who are participating
3 on the phone. So, with this, I would go to NRC Staff
4 members.

5 DR. HOWE: Dr. Donna-Beth Howe in the
6 Medical Team.

7 MR. FULLER: Mike Fuller, Team Leader,
8 Medical Radiation Safety Team.

9 DR. ZELAC: Ron Zelac, Senior Member of
10 Medical Radiation Safety Team.

11 MR. EINBERG: Ashley.

12 MS. COCKERHAM: Ashley Cockerham.

13 MS. HOLIDAY: Sophie Holiday.

14 MR. EINBERG: Thank you.

15 MR. LOHR: Ed Lohr, Rulemaking.

16 MR. EINBERG: Thank you. Okay. Is there
17 anybody on the phone from the NRC Regions that are
18 participating, as well?

19 MR. EINBERG: Okay. Next we will identify
20 members of the public who are participating on the
21 phone.

22 MS. COCKERHAM: There's nobody.

23 MR. EINBERG: There's nobody. Okay. I
24 would also like to add that this meeting is being
25 webcast, so other individuals may be watching on line.

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1 Following a discussion of each agenda item, the ACMUI
2 Chairperson or Vice Chair in this case, Dr. Thomadsen,
3 at his option, may entertain comments or questions
4 from members of the public who are participating with
5 us today.

6 At this point, I would like to turn the
7 meeting over to Dr. Thomadsen.

8 ACTING CHAIR THOMADSEN: Thank you much. I
9 will just interject that as noted, the Chair of the
10 Committee, Dr. Malmud, took sick just yesterday with
11 something like the flu and is not feeling well at all.
12 And we would like to send our well wishes to him for a
13 speedy recovery.

14 With that, I would recognize Mr. Lewis
15 from the NRC.

16 MR. LEWIS: Thank you, Dr. Thomadsen. I
17 would add our well wishes to Dr. Malmud, as well. We
18 just had a group photo, so it was the first time since
19 I've been involved that we've had a fully staffed
20 committee, and maybe we can have a Photo Shop contest,
21 do it next time.

22 From the NRC Staff, also, I would just
23 like to welcome our two new members, Dr. Christopher
24 Palestro, and Dr. John Suh. Welcome to the group, and
25 we look forward to your participation.

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1 Chris went through a lot of the
2 formalities, but I would just add, I think we have a
3 very healthy agenda today, and thank you for all of
4 those who have offered agenda topics. And, also,
5 thank you all for this morning. I know it was a lot
6 of effort to prepare for and deliver the remarks to
7 the Commission. And I have already received feedback
8 all the way up the chain that at least within the NRC
9 management, they're very happy with the results of the
10 meeting. I think all the issues were laid out very
11 clearly. There was good discussion by the Commission,
12 and a lot of information from which to proceed on
13 these issues. And we'll continue the discussion on
14 these issues the rest of this afternoon and tomorrow,
15 as I think most of the people here were there this
16 morning, and heard how they were started off.

17 There were a couple of things that have
18 happened since we last met. We had received -- we
19 delivered to the Commission a Medical Events
20 Rulemaking for Prostate Implant Brachytherapy. We did
21 receive the Commission's direction, which, in essence,
22 was to go back and get further stakeholder input and
23 bring them another rulemaking. And we will be
24 proceeding with that. As part of that, this is the
25 first step in that. We will talk about the progress

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1 today of the Medical Implant Brachytherapy
2 Subcommittee of this Committee. And I've asked the
3 Subcommittee, with informing the Chairman, to just
4 kind of freeze their work, because I think it will be
5 advantageous for them to benefit from the stakeholder
6 interaction, as well. Just freeze what they have
7 today, and deliver it, so that we can have it as a
8 data point from which to move forward. Because the
9 previous Commission meeting on the topic, I think
10 there were very good ideas that were somewhat new to
11 the NRC in terms of this rulemaking, and we want to
12 work from those.

13 Also, we received a SRM for that very
14 meeting that I mentioned, which directed several
15 things. It directed the NRC Staff to develop a pros
16 and cons paper for the Commission's consideration
17 about to whom the ACMUI should report, whether we
18 should continue to report as you do now through the
19 Office of Federal and State Materials programs, or
20 whether it should report to the Commission directly.
21 That issue has a long history. In fact, I think there
22 was a paper written in maybe 1997 on that very topic,
23 so we're going to dust off that paper and refresh the
24 issues to see if they haven't changed.

25 We also will be doing as part of the SRM

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1 response from that meeting a lot more outreach to
2 stakeholders as part of our rulemaking process. In
3 particular, we were asked to develop something that
4 I've been asking for, for quite some time, is a plan
5 to better integrate the feedback loops between the
6 Staff and the Committee. And, of course, and I
7 appreciate the comments this morning from Dr.
8 Thomadsen that the Committee delivers their views, and
9 the Committee feels comfortable that the NRC
10 understands their views, and we don't, necessarily,
11 always have to agree. However, I do think there's
12 some room for improvement in the feedback loop of how
13 we took your views, and what we did with them. And
14 the Commission has directed us to do just that, so
15 we'll hear about that, our initial thoughts on that,
16 at least, during the closed session tomorrow.

17 And, finally, a major accomplishment for
18 the Agency. The Chairman issued to the President and
19 to the Congress in mid-August a report on Source
20 Protection and Security. This is a four-year report
21 that the federal -- a task group of 13 different
22 federal agencies and two state organizations has to
23 deliver to Congress and to the President every four
24 years about the state of radioactive source security
25 in the United States, and what things are being done

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1 across the federal government in an integrated manner.
2 So, this is the second report. It was issued, as I
3 said, on August 15th, and I think copies have been
4 distributed to all the Committee members.

5 As far as medical goes, it doesn't impact
6 on many medical activities; however, it does address
7 blood irradiators, so some aspects of hospital and
8 blood bank uses are in the report. The majority of it
9 is dealing with the issues that you've seen in Part 37
10 rulemaking. And some of the efforts across the
11 government related to low-level waste disposal, also
12 be very interested -- you may be very interested in
13 that.

14 And, finally, I would mention we do have
15 the Part 37 Proposed Rule, as you all heard this
16 morning, out for public comment at this time. I would
17 encourage the Committee to make a public comment on
18 the record for that rulemaking, and also the guidance
19 that's associated with that rulemaking, which you'll
20 implement.

21 I would also encourage the Committee --
22 I'm sorry, I would encourage any individuals to spread
23 the word amongst licensees. That is the first of a
24 kind rule, and when we did the increased controls, we
25 did not have any opportunity for public interface on

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1 those, so we're making sure we do everything we can to
2 get very extensive stakeholder and public comment on
3 the rulemaking and the guidance before they become
4 enshrined in the CFR.

5 So, with that, I think I will turn it over
6 to Ashley, with the Chair's permission.

7 ACTING CHAIR THOMADSEN: You may.

8 MR. LEWIS: If she's ready, or else I can
9 keep talking.

10 ACTING CHAIR THOMADSEN: While she's
11 getting up to the front, on behalf of the Committee, I
12 would like to thank the NRC Staff for all of the
13 tireless work that they put into facilitating this
14 Committee's work. We appreciate that. Ms. Cockerham.

15 MS. COCKERHAM: Okay. We'll start with the
16 2007 ACMUI recommendations. You've had a look -- I
17 tried to print everything in color so you can see
18 highlights of what changed from last meeting to this
19 meeting. So, for Item 3, NRC Staff should revise the
20 regulations so that board certified individuals who
21 were certified prior to the effective date of
22 recognition, or were certified by previously
23 recognized boards listed in Subpart J of the previous
24 editions of Part 35 are grandfathered. And the update
25 is that the last meeting this was pending. This is

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1 now accepted. We confirmed acceptance in a memo from
2 July that our rulemaking group did accept this change,
3 and it's in the current rulemaking, the expanded
4 rulemaking that we talked about this morning. It's
5 included in that.

6 We'll jump down to Item 10, NRC Staff
7 should allow more than one RSO on a license. Same
8 thing here. This is in the expanded rulemaking, which
9 started this summer. And then for the second part of
10 that, where it says, "NRC should create a regulatory
11 issue summary," NRC did create that regulatory issue
12 summary. It's RIS-2010-09. It was published on
13 September 9th of this year to clarify the NRC
14 regulations as currently written do not allow for
15 multiple RSOs to be named on a medical use license.

16 We'll jump to Item 30, the Elekta
17 Perfexion should be regulated under 10 CFR 35.1000
18 until 10 CFR 35.600 is modified to be performance-
19 based. That has been accepted, but I noted here that
20 it's been delayed. As a part of that memo from July,
21 the rulemaking group accepted certain -- the 28 items
22 for the expanded rulemaking, this item was not
23 accepted into that memo, so it will be pushed out to a
24 future rulemaking. So, the use of the Perfexion will
25 continue to be regulated under 10 CFR 1000 until

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1 Subpart H is revised.

2 The same thing holds true for the next two
3 items. These are intraocular devices, so revisions to
4 Subpart F for the use of intraocular devices are not
5 included in the current rulemaking, the expanded
6 rulemaking due to prioritization. The use of the
7 Neovista device will continue to be regulated under
8 Part 1000 until Subpart F is revised. And then the
9 same thing holds true for Item 35, which is, I have
10 Perfexion here, but that doesn't read right. It's also
11 the intraocular device. Any questions from 2007
12 recommendations?

13 Okay. We'll jump to 2008. And NRC Staff
14 should revise the AO criteria. The update on this,
15 last time we heard, research was going to undertake
16 revising the abnormal occurrence criteria next month.
17 That has been pushed to next year, so they are doing
18 other things with, I know, the abnormal occurrence,
19 and their impacts from the reactor side of things that
20 have delayed this to next year.

21 For Item 19, NRC Staff should accept the
22 six recommendations of the Permanent Implant
23 Brachytherapy Subcommittee. This Medical Event Rule,
24 I think as we're all aware, is on hold, and we will
25 have an implementation plan that Mike will discuss

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1 later. The same holds true for Items 26 and 27.
2 These are all Medical Event rule-related
3 recommendations, and they'll be addressed in the
4 Medical Event Rule. Any questions on 2008?

5 There are no changes or updates for 2009.
6 And if we go to 2010, Item 3, NRC Staff should provide
7 information that describes safety culture problems as
8 contributing factors to violations. We did send you a
9 summary on September 29th of examples of violations
10 that were as a result of safety culture issues.

11 For Item 6, NRC Staff should consider the
12 necessity and evaluate options to collect or obtain
13 data for the denominator for medical events to improve
14 the overall value of the Medical Event Subcommittee
15 report. I believe this was discussed in-depth this
16 morning, and we did purchase those IMV reports. I
17 have one of them for the nuclear medicine procedures,
18 and then we're waiting for the radiation oncology
19 report, which they have a new one coming out, so
20 instead of buying the old data, we purchased the new
21 data. And that will be available later this month.
22 So, when the Subcommittee starts its work evaluating
23 all the NMED reports for fiscal year 2010, which is
24 the year that just ended, you will have the
25 information you need to get a denominator. And that's

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1 all I have.

2 ACTING CHAIR THOMADSEN: Thank you very
3 much. Any comments, questions from the Committee?
4 With that, thank you very much, and we'll move on to
5 Mr. Fuller discussing Medical Event Reporting Rule and
6 Implementation. I'm sorry, I missed a whole --

7 MS. ELEE: I answer to lots of names.

8 ACTING CHAIR THOMADSEN: But not Mr.
9 Fuller.

10 MS. ELEE: Not that one, no.

11 ACTING CHAIR THOMADSEN: And now -- I'm
12 sorry.

13 MS. ELEE: That's okay.

14 ACTING CHAIR THOMADSEN: Ms. Elee from the
15 CRCPD discussing the Committee on Radiation Medical
16 Events.

17 MS. ELEE: I apologize in advance for those
18 of you who were downstairs this morning. Some of the
19 slides you'll see are repeats, but there's some new
20 slides, so I tried to give you a little more
21 information since we have 30 minutes instead of five.

22 ACTING CHAIR THOMADSEN: Yes.

23 MS. ELEE: We can go a little more in-
24 depth. And I am Chair of the CRCPD Committee on
25 Radiation Medical Events, and I'm just going to kind

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1 of give you a little background on how we got started,
2 and where we're going, where we are, that kind of
3 thing.

4 CRCPD first broached this subject of
5 having a Committee and looking at doing a database on
6 Non-Material-based events, because there was not a
7 database for that. We were initially looking at
8 therapy. We looked at this, we began looking at this
9 in May of '08, I believe was the meeting that we
10 agreed to create this Committee. It may have been
11 '09. It's been a couple of -- it was prior to all of
12 the publicity and all that we've seen in the
13 newspapers that we looked into this. And we created
14 the Committee, and that's where we've been, and we've
15 kind of evolved as things have ramped up, and we've
16 seen a lot more information.

17 Why were we interested in events? We feel
18 like we are uniquely situated that we have interaction
19 with all of the state programs, many of the federal
20 agencies, and a lot of the associations that are out
21 there, as well. We know that the state programs
22 already receive and evaluate reports of medical
23 events. And not only just material events, but
24 machine-based, as well, and have been doing that for a
25 number of years.

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1 Many of the states, as we said, approve
2 and license physicists, therapists, and physicians,
3 it's not always in the same house at the state, but a
4 lot of the States -- most of the States do have some
5 purpose for that. And they do track compliance. We
6 usually look at your QA program as part of the
7 regulatory inspection process.

8 Our Committee charges, and this is a new
9 slide for you, and we have revamped them as things
10 have changed, and they're there. Oversee the
11 development and maintenance of a national database of
12 radiation medical events, develop a definition of a
13 reportable radiation medical event from a radiation-
14 producing machine. As I said this morning, we really
15 did not have anything to go by, especially in terms of
16 diagnostic machine-based events, so we felt like that
17 was a good place to start. Develop and format
18 mechanism for reporting radiation medical events. And
19 once we do that, and we get started, we would have to
20 find a way to review those reports to make sure
21 they're complete and accurate, and have all the
22 correct information on there.

23 We want to prepare an annual summary and
24 an article for the CRCPD News Brief, and a mechanism
25 for referring our information to our subject matter

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1 committees. We have one experience with this that
2 works very well, and that was with the CT Brain
3 Perfusion. And when that came in, we actually went to
4 our CT Committee, and I don't know if any of you all
5 received a notice that was put together. It was a
6 very good notice. It was put together in about, I
7 don't know, 10 days time, and went out to all the
8 state programs, and actually all CRCPD members in
9 terms of this is what's happened, and this is what we
10 suggest, you look at your facility and see are you
11 doing this exam, what protocols are you using, et
12 cetera. And we would provide a verbal report at the
13 CRCPD annual meeting.

14 These are our Committees and advisors, and
15 I didn't include the advisors. I should have taken
16 that off the list. There's too many for me to fit on
17 one slide now, but our Committee members are state --
18 work for state radiation control programs, and our
19 resource individuals, as you can see, represent a wide
20 variety of associations and federal agencies.

21 So, what have we done? CRCPD does have
22 suggested state regulations, which include medical
23 event reporting for therapy in Part X. We have
24 created and staffed the Committee, and we have
25 conducted two separate surveys of state programs. And

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1 I'm going to go into those a little bit now.

2 We had a special interest meeting in Rhode
3 Island, several of you were there, and it was a very
4 good meeting. We had a lot of talk, and a lot of
5 ideas, and realized there are a lot of things that
6 would go into this that make it quite an undertaking.
7 We've also participated in the workshops on
8 Fluoroscopy and Therapy, and the AAPM workshops on CT,
9 and Safety and Therapy, and in the roundtables that
10 were held this week sponsored by FDA, actually the
11 foundation for NIH.

12 All right. Our initial survey results, we
13 had 29 and 48 responses. As I said, we have two
14 states without directors, so that's why it's 48, not
15 50. Seventy-nine percent had suggested State
16 regulations for accelerators, and 70 for medical
17 therapy. And this is just a little more detail and
18 information on the reporting. But, interestingly, all
19 those that did not have regulations for reporting in
20 therapy, stated that they were in the process of
21 promulgating some type of regulation for that.

22 All right. Our special interest meeting
23 was, like I said, very well attended. We had a very
24 interesting discussion of what States and/or
25 facilities would be willing to report into a system,

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1 and how feasible is it to have both states and
2 facilities report into a system. Discussion of how a
3 non-material event database, basically, from machines
4 could coincide with NMED for material issues, and
5 within FDA database for manufacture issues, and is it
6 possible to have a single aggregate database for all
7 of these issues. And one of the things that was
8 brought up earlier in the week at some of those
9 meetings was that it -- the foundation has had several
10 projects that had great success in pulling from
11 separate databases with point items into one database
12 to look at the information in aggregate, so I think it
13 is doable for -- not to everybody trash their own
14 database, but in some ways bring that information
15 together.

16 We looked at some databases that are
17 there, New York and Florida, they have excellent
18 requirements and keep excellent track of their stuff.
19 European, we looked at ROSIS, which is a little more
20 difficult to weed through, but it's there. And the
21 question comes up is, are we collecting for regulatory
22 or best practice purposes, or both? Do we have to
23 collect for one or the other, or can we collect for
24 both? And then, of course, how do we have one that
25 includes everything. And liability becomes an issue

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1 there, and how do we make sure that not only the
2 patients and facilities are protected, but the states,
3 the agencies that would enter information protected,
4 as well.

5 So, with all of that information, in a
6 couple of meetings we realized we had to get a better
7 handle, and we did another survey. And we were very
8 fortunate, I think since I did this slide, we had one
9 more response. We had 37 responses, and when you add
10 in the two states that we did not expect to hear from,
11 that's 39, which is really a great feedback in terms
12 of -- for those of you who have done surveys before,
13 begged and pleaded for people to respond, we were very
14 pleased with that.

15 The basic initial question was, does your
16 state have reporting requirements, period. We didn't
17 differentiate between RAM or Machine-based events.
18 And 97 percent of those that responded said yes, they
19 did. Interestingly enough, as we got a little more
20 detailed in the survey, as I said this morning, for
21 therapy 92 percent had pretty clear requirements for
22 RAM-based reporting, and 81 for diagnostic RAM-based
23 reporting. And we certainly attribute most of that to
24 NRC and the Agreement States and the regulations that
25 are in place that a lot of the Agreement States

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1 already have there.

2 When we looked at the Machine-based, it
3 got a little more tricky. And for Machine-based
4 therapy, 83 percent had reporting, and approximately
5 130 events. We used January of 2009, just that seemed
6 we would get a full year's worth of data, plus some,
7 by doing it that way. And 130 events were reported
8 from January of 2009 through about June of 2010, was
9 the frame we were looking at to the state and/or local
10 programs. We didn't ask them to give us the events.
11 We just were getting a number at the time, so this is
12 just a total number of events that were reported. I
13 can't tell you if they were patient-related, or non-
14 patient-related, but that's what we had.

15 For diagnostic machine-based, it really
16 drops off heavily, 43 percent had reporting for that.
17 And since January of 2009, about 53 events have been
18 reporting to the state and local programs. This is
19 very concerning, especially in that when we look at
20 the number of machines out there diagnostic, in the
21 survey we ask how many registrants do -- or how many
22 machines do you register in your state for diagnostic
23 and for therapy. For diagnostic it was about 275,000,
24 and for therapy about 2,800. So, when you look at
25 those numbers and the number of events reported, it's

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1 very few in terms of that.

2 Of the states responding, 30 percent make
3 the events very easily available to the public. You
4 can go to the state website, you can see a summary of
5 all the events in that state, I mean, all the facility
6 names, and patient names have been cleansed, but as
7 far as finding out what the events was, it's very easy
8 to pull up and look at. Some have an annual summary
9 report that they put out, and that's easily gotten,
10 too.

11 Most of the other states, and all that I'm
12 aware of do you have methods in place for you to get
13 the records of the events. It may not all be in one
14 place like it is in some. You may have to do a FOIA
15 request to get the information, but it is there, and
16 it is available for you to get the information you
17 want.

18 So, where are we? We have developed a
19 definition for machine-based radiation, which includes
20 therapy and diagnostic. I didn't include that in the
21 slides. I can read it to you, if you'd like, or I can
22 forward you a copy. It's certainly a work in
23 progress. We would love to have feedback on what you
24 like or don't like, but we've definitely looked at
25 dose as part of when an event should be reported.

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1 We've held several calls, like
2 participated in many meetings, and where are we going?
3 Right now, our next meeting is the 3rd, I believe, of
4 November, a conference call, and we have gathered all
5 of the reporting forms, and I use forms as a very
6 loose term, but that are available through NMED, and
7 the MAUD system with FDA, ROSIS, some of the state
8 forms, so that we can take a look at them, and say
9 this is a good idea, we really like this. I'm not too
10 sure if this would be that important, and come up with
11 a form that we could use for reporting.

12 We have discussed, and really would like
13 to look into expanding the definition that we have
14 come up with to include radioactive materials in our
15 definition. Several of the resource people on our
16 Committee feel it's very important, especially in the
17 diagnostic area where maybe it's not as clear as in
18 the therapy area, that we look to do that. And our
19 definition is not meant to be a regulatory definition.
20 It is a definition to work with the information that
21 we want to collect for the database.

22 And, of course, the biggest call, we're
23 looking into cause, looking at what type of personnel
24 commitment are we looking at to run a database, to
25 gather that data. Are we talking, you know, somebody

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1 a week, quarter, every day, what's the commitment that
2 it's going to take to do this? So, we're trying to
3 get some handle on a lot of that. And it's, actually
4 — it sounds really easy, but when you really get to
5 looking at the nuts and bolts, it's not nearly as easy
6 as it sounds.

7 What would we do with what we collect?
8 And what we would like to be able to do, and I think I
9 heard several of you make these comments this morning,
10 too, is look at causes and contributing factors. What
11 are the types of errors made? Provide some summary
12 reports, and, if necessary, provide a timely notice.
13 If it's something that we think needs to be dealt with
14 immediately, or you need to be aware of immediately,
15 we could put that out in a notice. We think that's
16 really a valuable part that we could provide in the
17 database.

18 And the other thing we feel that bringing
19 this information together, each state -- obviously,
20 we're not talking about a lot of events, total. And
21 when you break that down per state, it's even fewer.
22 So, if we can look at it all together, Debbie is in
23 Florida, I'm in Louisiana, somebody in Alabama may all
24 have the same problem, and maybe we could attribute
25 that back to training. Maybe even though they're in

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1 different states, they were all trained by the same
2 person. I don't know that a single state could
3 ascertain that on their own. So, that's kind of an
4 example of some of the things we'd like to see if we
5 could pull out of this.

6 And, like I said, in summary, we feel like
7 a lot of the states have experience tracking data. A
8 lot of the state programs look at radioactive
9 materials, they look at x-ray, they look at all of
10 these things when they go in to inspect. We know a
11 lot of your facilities, you deal with everything. You
12 don't just deal with material, you deal with machine-
13 based therapy, or diagnostic work. So, it makes sense
14 to us to pull all of this medical stuff, for lack of a
15 better word, together and see. It would be easier for
16 the facilities, it would be easier for the states,
17 rather than is this something I need to send to FDA,
18 is this something that needs to go here, and see if we
19 can get that all together. Because, like they said
20 this morning, and FDA said yesterday, both of their
21 databases collect a lot more than medical information,
22 so for the medical community, there's a lot of
23 information in those databases that really isn't
24 relevant. You're only looking for your part of that
25 pie, and we're looking at doing a database on medical

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1 events.

2 We would like to -- we plan to establish
3 the database. We want to do evaluation of the data,
4 and we want to inform the interested parties. These
5 are all great things that we'd like to do. Of course,
6 as I said this morning, it takes time and it takes
7 resources.

8 We have a pretty good handle on what we
9 can get from the states, and what we can put into a
10 database from the states. From what I'm hearing from
11 a lot of people in the field is they would like more
12 than that. And to do more than that, of course,
13 becomes a more robust database, and a lot more
14 information. So, I'd love to have your feedback on
15 what you feel like -- would you be receptive to
16 including some material information in such a way. Do
17 you think it makes sense to have the two, the machine
18 and the radioactive material together when we're
19 talking about medical in terms of a database? So, I'd
20 love to hear what you have to say, or ask if you have
21 any comments or questions for me?

22 ACTING CHAIR THOMADSEN: Thank you very
23 much. And for the Committee, comments? Mr.
24 Mattmuller. I'm sorry.

25 MEMBER VAN DECKER: We look alike after a

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1 while.

2 (Laughter.)

3 ACTING CHAIR THOMADSEN: Dr. Van Decker.

4 MEMBER VAN DECKER: Thank you, Dr. Malmud.

5 (Laughter.)

6 MEMBER VAN DECKER: Dr. Thomadsen, I'm
7 sorry.

8 ACTING CHAIR THOMADSEN: We start looking
9 alike after a while, too.

10 MEMBER VAN DECKER: I have a comment, and
11 then I have, actually, a large handful of questions.
12 I'm trying to see where we're trying to go with this.
13 I guess my comment is, looking at your -- this looks
14 like it's gone a good ways, with a lot of people
15 thinking about it. When you look down your resource
16 individuals, and your acronyms, I would put out to you
17 I don't see anything where it says ACC. And,
18 obviously, cardiology between fluoro and nuclear, and
19 some CT here is a player in all this, and we have --
20 want to be citizens in this, and we want to know
21 what's going on, dah, dah, dah, dah, dah, dah, all
22 that type of stuff. Okay. That aside.

23 So, here --

24 MS. ELEE: Are you volunteering?

25 MEMBER VAN DECKER: Most people would tell

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1 you that Van Decker is the perpetual volunteer. We
2 can talk about that offline.

3 I guess my questions are the following.
4 You know, there has always been this concept of where
5 does reporting go for machine-based, and is it each
6 little individual state, or is there a national thing?
7 And then there's the NRC with the materials, and so
8 how do you see yourself fitting in between NRC and
9 FDA? Do you look at this as a overreaching program
10 you're trying to present where the states become
11 coordinated among 50 states, use standard definitions
12 that they all agree on, Level B compatibility, and
13 there's absolutely no doubt what that is, and you guys
14 become a repository for all reported events that reach
15 a regulatory reporting requirement, because some red
16 flag has shown up, rather than just data gathering for
17 practice improvement? And then that database would
18 then report on a national level between FDA and NRC,
19 depending on where that data really fits to in the
20 national regulatory realm. Where do you really see
21 this program fitting in, and what are we really trying
22 to accomplish?

23 MS. ELEE: CRCPD, itself, is not a
24 regulatory agency. We have had much discussion with
25 the states. If it's reportable to the state, it's

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1 still reportable to the state, and you could not
2 bypass that reporting requirement by reporting into a
3 non-PD database. I mean, that, of course, has come
4 up.

5 MEMBER VAN DECKER: So, there are three
6 databases then. Three times 50, that's 150.

7 MS. ELEE: Yes.

8 MEMBER VAN DECKER: And there's one, and
9 two.

10 MS. ELEE: Actually, our thought is to
11 gather that information from the States, who seem
12 willing to work with us on that to get it all
13 together, because they also see the need. There are
14 few events when you look at it on a more national
15 level, and there are many events, it gives you a lot
16 more information.

17 We're still in the planning stages. One
18 of the things that came up at the meeting earlier in
19 the week, which was very interesting, and not
20 something I had thought of, but I think it's very
21 worthwhile to look into, was with a lot of the drug
22 trials. They pull from separate databases into a
23 single database to look at certain information. And
24 it may be that we could set something up that way,
25 where we could get information from NMED and from FDA,

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1 but there's still a gap of information that's not
2 going to be collected by either one of those, where we
3 would like to fill that gap, and then pull the other
4 information into our database. And that's very -- I'm
5 talking off-the-cuff here, because I haven't even --
6 we haven't even gone into that in Committee, because
7 that was something that just was brought up yesterday,
8 but it's a thought of, if it's worked well for them,
9 maybe it is plausible to do that, so that you're not --
10 - we don't want facilities multiple reporting, and to
11 have to report to 18 facilities, 18 different groups.
12 That is, certainly, not our plan. Our plan is --

13 MEMBER VAN DECKER: Eighteen different
14 definitions for each of those groups --

15 MS. ELEE: Right. Our plan is, actually, to
16 try to fill in where there is no -- where things don't
17 fit, and we could gather that information, in addition
18 to the information that's out there, and try to pull
19 it all together. I don't know if I answered your
20 question.

21 MEMBER VAN DECKER: You danced around a
22 little, so --

23 ACTING CHAIR THOMADSEN: Dr. Suleiman.

24 MEMBER SULEIMAN: Let me clarify a little
25 bit of how FDA does it.

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1 MS. ELEE: Yes.

2 MEMBER SULEIMAN: FDA has a comprehensive
3 program called MedWatch, and I remember when the
4 Commissioner at the time, they wanted drug reporting,
5 they wanted medical device reporting, so that -- now
6 the companies, industry must report to us when
7 something goes wrong. Of course, they'll say it's a
8 user issue, so sometimes they'll wonder whether it's
9 reportable. There's also a voluntary component that
10 allows consumers to report, but that's voluntary. And
11 often, both communities will point at each other, so
12 that's always clearly the issue, is it a technology
13 problem, or is it the way it's being used?

14 We require reporting of adverse events and
15 severe adverse events, which are life threatening.
16 It's a terrible system. It's probably better than
17 anything else out there. This post-market monitoring
18 is terrible, because it's extremely difficult. These
19 are not prospective clinical trials where you control
20 everything. These are retrospective trying to figure
21 out what went wrong, if, in fact, you even realize
22 something went wrong.

23 I think with the broader health
24 initiative, the Medical Record issue that pops up,
25 which is much larger than just this, there's been talk

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1 about gee, here's an opportunity to standardize on
2 this template. In some ways, it's good that there's a
3 lot of discussion going on. I think maybe a lot of
4 these ideas are way ahead of executing them.

5 I, personally, think there's got to be
6 some sort of legislation that would allow -- you've
7 got multiple jurisdictions, you've got who would
8 collect this information, confidentiality, so I think
9 to think that this is going to get consummated in the
10 next year or two is not realistic.

11 What I would suggest in terms of being
12 constructive, I learned this as a graduate student. I
13 think you may have to have criteria that's either
14 modality-specific, just like with drugs. They don't
15 start looking at events across the board; they say
16 this is the drug. They've been fortunate because we
17 have large insurance companies. They collect this
18 information, so they look at all the cardio, all the
19 patients that they consider cardiovascular risk, and
20 they see gee, they're all taking Drug A. And then
21 they can see, looking at a big spreadsheet that the
22 numbers are changing. But those are actually a little
23 bit more credible data, so you almost have to go by
24 exam. Even if you've got the same piece of equipment,
25 you may have several different exams.

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1 MS. ELEE: I don't know if this helps you
2 any. What we came up with, and like I said, this was
3 for machines, not for radioactive material. But for
4 therapy, other than an event that results from an
5 intervention by a patient or human research subject, a
6 registrant shall report, and where is still, that's
7 what we're working on, any event in which the
8 administration of a therapeutic radiation machine
9 therapy dose, and we have several -- and a lot of them
10 are going to sound very familiar, involves the wrong
11 patient, or wrong treatment modality, or wrong site,
12 for which they calculated weekly administered dose
13 differs from the weekly prescribed dose by more than
14 30 percent, which the calculated administered dose
15 differs from total prescribed dose by 20 percent for
16 the total prescribed dose, and for the total
17 treatment, and for which the dose differs by 50
18 percent or greater for any single fraction of a multi-
19 fraction treatment.

20 And then we have the one that we're really
21 not sure where to go with, but it's one that a lot of
22 the associations won't see, and that's the kind of how
23 do you catch a near miss, which is something that they
24 feel is very important to have in the database. So,
25 the way it's worded now, and it needs word smithing,

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1 is any equipment failure, personnel error, accidental
2 mishap, or other unusual occurrence that causes, or is
3 likely to cause significant physical, and the word
4 that's in there now is harm, which is not a good word.
5 I know that word needs to be changed, but I don't know
6 if it would be significant exposure, or additional
7 exposure to the patient. So, that's kind of where we
8 are with the therapy.

9 For diagnostic, which is a lot more
10 difficult, because we had really very little to go by,
11 what we came up with was the same intro, no patient
12 intervention, or whatever. And results in an
13 unintended dose to the skin greater than 2 greater
14 than 2 Gray or 200 rads to the same area for a
15 procedure or series, results in a dose that is five
16 times the facility's established protocol for a
17 procedure or series, involves the wrong patient, or
18 wrong site for the entire diagnostic exam, and results
19 in a total effective dose of greater than 5 rads for
20 the procedure or series. And we have a caveat with
21 that that says any wrong patient or wrong site,
22 regardless of dose, should be reported, documented,
23 and addressed internally within the facility, itself.
24 However, if we're looking at a database, we don't want
25 to cloud that up with every very insignificant, or

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1 dose-wise exam that is the wrong hand done, and we put
2 that in our -- even more extreme if we're looking in
3 the big picture, every dentist that does the wrong
4 tooth. You know, that gets pretty cumbersome. And
5 then, again, the near miss category, which would be
6 any equipment failure, personnel error, accident, or
7 mishap, or unusual occurrence involving the
8 administration of radiation.

9 So, we have looked -- when we were looking
10 at machines, we split it out into the therapy or
11 diagnostic. You could look at going even more
12 modality-specific, you know, CT, fluoroscopy, but
13 that's very cumbersome. Of course, we haven't gotten
14 there yet.

15 MEMBER SULEIMAN: The advantage that if you
16 start out with some that are clearly defined, that
17 you've got good consensus agreement, and then you sort
18 of build on that. Trying to attack everything right
19 from the beginning, I think you're going to have
20 implementation problems.

21 MS. ELEE: Well, and a thought is, and
22 something that is feasible for us to do, because we're
23 only looking at about 200 events total, is to back-
24 populate, to look at the events that are out there
25 from the states, and maybe back-populate a database

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1 and see what we can extract from that before we move
2 forward. I don't know. Like I said, we're very
3 early. We want to do it, and we know it can be done,
4 but we know it's a big undertaking.

5 ACTING CHAIR THOMADSEN: Okay. Dr.
6 Guiberteau.

7 MEMBER GUIBERTEAU: First of all, since you
8 brought it up, I want to compliment the CRCPD for its
9 timely work on the CT Brain Perfusion issue. I know
10 the Texas Department of State Health Services made
11 very good use of that with its facilities.

12 I do have a concern with the idea of
13 developing a database on any of these events, not from
14 the point of view of the good intentions, but it seems
15 to me that the development of databases and registries
16 seems to be a very popular thing these days. And the
17 fragmentation of this data is a very important issue.
18 In fact, several organizations, both governmental and
19 private, have written on this. And I think the CRCPD
20 needs to be very careful of this. And when you talk
21 about merging databases for de-identified data, this
22 can be a very huge issue in the sense of over-
23 representing certain data points; that is, duplication
24 of things.

25 MS. ELEE: Right.

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1 MEMBER GUIBERTEAU: But I know the ACR is
2 working on a CT dose index on the machine side. And
3 when you collect data from every CT scan from certain
4 facilities, you don't, necessarily, report events, but
5 you know per exam what the dose is, at least the dose
6 indexes are, indices are, and the DLPs are. So, I see
7 a lot of duplication here. I also see a lot of work
8 for those being regulated. I see fragmentation of the
9 data, and I think before you get too seriously into
10 this, that somebody -- I think we need a registry and
11 a database czar here to coordinate this, because I
12 think you could be duplicating effort not only
13 unnecessarily, but also, perhaps, in terms of
14 misrepresenting the data.

15 ACTING CHAIR THOMADSEN: Thank you for the
16 comment. Dr. Howe.

17 DR. HOWE: In your initial definitions,
18 you're excluding patient intervention. And I would
19 caution you on that. When NRC looked at its Medical
20 Event Reporting requirements, it doesn't exclude all
21 patient intervention. In some cases, the patient has
22 to intervene because the treatment is not right, and
23 they have to take action. So, we included a second
24 set where you do report it, if there is a permanent
25 injury to the patient. So, you might want to put a

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1 caveat on your patient intervention to make sure you
2 capture those things where the patient has to
3 intervene, because of errors in the procedure.

4 MS. ELEE: Well, I'll put the word in, yes.
5 We discussed that a lot. And, like I said, it seemed
6 to be a sticking point for some of the associations.
7 This is not a regulatory -- is not meant to be a
8 regulatory -- and if a patient gets up and leaves the
9 table of their own accord because they want to,
10 there's not much the tech can do about that. So, that
11 was the kind of thing that they didn't want to be
12 included.

13 ACTING CHAIR THOMADSEN: Dr. Langhorst.

14 MEMBER LANGHORST: Thank you very much for
15 the additional slides for our presentation this
16 afternoon. I just had a curiosity question on your
17 survey results. You said, especially on the follow-up
18 survey that you had 36 states respond. And I wondered
19 -- I was curious whether there was some correlation
20 with were those majority of Agreement States, or --

21 MS. ELEE: No. Believe it or not, it was a
22 pretty good representation of both. And we wanted to
23 make sure that we had at least some of the larger
24 states, and we did. In fact, we had Florida, we had
25 Texas, we had Massachusetts, we have Pennsylvania, New

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1 York, we had a lot of those big states. California is
2 probably -- Texas was in there. California is
3 probably the only big state that did not respond.
4 They had legislation pending at the time, and maybe
5 didn't feel like it was good to jump in, you know.
6 But, yes, it was quite an assortment, and I was very
7 surprised at that, too, because when the 36 came up,
8 your initial thought would be these are all Agreement
9 States. But, actually, no, it was quite a mix.

10 MEMBER LANGHORST: Did you look at any of
11 your results from your machine-based survey results
12 and whether those programs were more robust in an
13 Agreement State, or less robust?

14 MS. ELEE: We have not yet. I mean,
15 there's a lot that we can do with this information
16 that we would like to do. But, yes, this -- we
17 haven't done that yet, but that's a very good thing to
18 see.

19 MEMBER LANGHORST: I was just curious, yes.

20 MS. ELEE: Yes.

21 MEMBER LANGHORST: Okay. Thank you.

22 ACTING CHAIR THOMADSEN: Any other
23 comments? Dr. Zelac.

24 DR. ZELAC: If you could, I'd like you to
25 expand a little bit on one of the things you said in

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1 the presentation, and that had to do with those states
2 that have gathered data on events, and make it
3 available to the public. You indicated that the
4 information that is made available, of course, doesn't
5 have the patient's name, but you also said it does not
6 have the facility's name. Do you have any idea why
7 that is, and what's your opinion on that being
8 withheld?

9 MS. ELEE: I don't know why, but they don't
10 -- the ones that are there don't. My guess -- I would
11 say you would have to cleanse the facility name. If
12 you're going to put it out there on the web, which
13 these are, they're on the web, and you can pull it up
14 and read it, my guess would be liability would be --
15 but I don't know that. I know that, initially,
16 Richard Martin with ASTRO was looking into the whole
17 liability side of it, which is quite complex in terms
18 of the information that you release publically.

19 DR. ZELAC: Clearly, our position at NRC
20 has been that if there is a problem at a facility, the
21 public has a right to know. They can make their own
22 informed decisions as to what they want to do, or not
23 do.

24 MS. ELEE: Debbie, with you all --

25 MEMBER GILLEY: We don't put ours on the

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1 website, but we do, if you request a public records
2 request, we give you everything that we have. Now, we
3 do not allow the licensee or the registrant to send in
4 patient identification information at all, so we don't
5 have to worry about redacting or anything slipping
6 through. We just tell them they can't send that in.
7 They can assign some nebulous number for their
8 tracking, but we don't want to know that. And we do
9 medical errors presentation to our medical profession,
10 medical physicists, and radiation therapists every
11 year. And we don't give the patient's name. That's
12 not the purpose, the purpose is education to help
13 share the word about preventing future errors that are
14 similar to these.

15 MS. ELEE: Do you give the facility names?

16 MEMBER GILLEY: We don't give the
17 facility's names. We refer to them as a facility in
18 Florida. I mean, that's -- the specific location of
19 where these things happen, most of the time they're
20 known, anyway, because the medical community
21 communicates well with each other, but it's not any
22 reason for me as a regulatory, that's not the purposes
23 for me to point a finger at one facility or another.
24 The purpose is to tell what happened, what the
25 corrective action was, so that we can prevent it from

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1 happening at another facility.

2 MS. ELEE: And, as was mentioned, if they
3 reported it, they complied. They reported it so that
4 the state knows about it. They met that part of the
5 requirement. And I would venture a guess, and the one
6 that comes to mind that I've looked at, that really
7 has a lot on the web is the State of Michigan. And I
8 would venture a guess that if you wanted to do a FOIA
9 request, you could get additional information from
10 what is on the website. But if you're just interested
11 to know what events happened, you can go to the
12 website and see them.

13 MEMBER GILLEY: The other thing is that 99
14 percent of these medical events are self-reporting, so
15 in my state, we want to encourage self-reporting, so
16 that's another reason. We want them to share with us
17 these things, because we want to prevent them from
18 happening at another facility, or repeat violation, or
19 repeat incident that might have impact.

20 ACTING CHAIR THOMADSEN: Thank you. Any
21 further comments or questions? Thank you very much
22 for coming and discussing this.

23 MS. ELEE: I've written all your names
24 down, and I'm going to be -- no, like you don't have
25 enough to do. Thanks.

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1 ACTING CHAIR THOMADSEN: And now I think
2 Mr. Fuller, discussing 10 CFR Part 35 Medical Event
3 Reporting Rule and Implementation Plan.

4 MR. FULLER: Good afternoon, everyone. I'm
5 Mike Fuller. I'm the Team Leader of the Medical
6 Radiation Safety Team here at NRC. I think I know
7 most of you, but some of you I haven't met yet, so
8 it's my pleasure to be here to discuss the status of
9 NRC's Medical Event Reporting Rule with a focus on our
10 plans for moving forward on this issue.

11 I want to take a moment to clarify what we
12 mean when we refer to the Medical Event Rule, and this
13 was clarified, thankfully, this morning some in the
14 Commission meeting. So, when we speak about proposed
15 changes to the Medical Event Reporting requirements,
16 when we say these things, we're only talking about the
17 proposed changes as they relate to Permanent Implant
18 Brachytherapy. When it comes to Gamma Knife, or other
19 types of modalities, as was indicated this morning, I
20 think folks, for the most part, are pretty happy with
21 the reporting criteria for medical events. So, we're
22 really talking about Permanent Implant Brachytherapy
23 here.

24 I plan to move through this presentation
25 fairly quickly, and we have 30 minutes on the

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1 schedule, so my hope is that when we get to the
2 questions on the question slide, I can answer some
3 questions, but I also would like to hear from you, and
4 have a fairly fruitful discussion, if we may.

5 I know that most of you are familiar with
6 the history associated with this issue, but for some
7 of you, a brief history may be helpful. And for all
8 of us, I think a bit of background should add some
9 context.

10 On July 25th, 2008, in a Staff
11 Requirements Memorandum, the Commission approved
12 recommendations by the Staff to make amendments to
13 CFR Part 35 for changes in the reporting requirements
14 related to Medical Event Reporting for Permanent
15 Implant Brachytherapy, and to make specific changes to
16 the reporting criteria based upon activity only.

17 Now, I'm going to skip over some key
18 events, and reworking of some of the proposed rule,
19 but on May 18th, skipping ahead to May 18th, 2010, the
20 Staff recommended to repropose this rule change that
21 would add some activity-based criteria, but retain the
22 dose-based criteria. On July 8th, 2010, Staff, along
23 with Dr. Welsh and Dr. Thomadsen, and some other key
24 stakeholders met with the Commission to discuss the
25 repropose rule. And then finally on August 10th,

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1 2010, Staff received another Staff Requirements
2 Memorandum that disapproved the Staff's
3 recommendations for the repropoed rule, and provided
4 further direction.

5 Next slide, please. Okay. In the August
6 10th SRM, the Commission provided staff with some
7 specific directions. The Commission directed staff to
8 work closely with this Committee and the broader
9 medical and stakeholder community to develop new
10 medical event definitions.

11 The Commission also directed staff to hold
12 a series of workshops to discuss these issues. And
13 the Commission directed staff to develop an integrated
14 plan for completing this rulemaking incorporating
15 ACMUI and agreement stat input.

16 We are in the early stages of developing
17 this integrated plan. And I want to share what we
18 know and what we have done so far with you now. The
19 integrated plan is due to the Commission in the spring
20 and specifically in March of 2011.

21 Next slide. The way the staff sees things
22 currently we think we have basically three options for
23 rulemaking. The first option is to continue with 10
24 CFR part 35 expanded rulemaking, the rulemaking that
25 is currently underway and has just begun getting

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1 started, then to begin a new permanent implant
2 brachytherapy medical event rulemaking after that
3 rulemaking is complete.

4 Another option would be to begin a new
5 permanent implant brachytherapy medical event
6 rulemaking now and put off the expanded 10 CFR part 35
7 rulemaking that is already underway,

8 And then the third option is to combine
9 the 10 CFR expanded rulemaking with a new permanent
10 implant brachytherapy medical event rulemaking. So
11 that's the way we see it in a fairly simplified way.

12 Next slide, please. One thing to keep in
13 mind -- and this is very important -- is that,
14 regardless of what we do, the current rules for
15 permanent implant brachytherapy and the associated
16 medical event reporting requirements will be in effect
17 for at least three more years. So what do we do in
18 the interim?

19 Currently we are drafting enhanced
20 permanent implant brachytherapy and medical event
21 reporting inspection and licensing guidance for the
22 current rules. We will soon be sharing our enhanced
23 guidance with this Committee and the Organization for
24 Agreement States for a fairly high-level feasibility
25 review. We plan to use this draft guidance as a

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1 starting point for a series of public workshops.

2 And one of the things that we think that
3 is at least plausible, although we don't yet, is that
4 if the enhanced guidance is found to be effective; in
5 other words, if we can clarify for the regulators and
6 the license community the current rule well enough
7 that a combined rulemaking may be feasible as long as
8 the changes associated with this particular rulemaking
9 are somewhat limited.

10 Let's talk a little bit about the
11 schedule. This winter and into the Spring of 2011, we
12 will be developing the enhanced guidance that I've
13 just referred to along with agreement state
14 participation. In fact, we are discussing perhaps
15 devoting the entire May 2011 ACMUI meeting to 10 CFR
16 Part 35 rulemaking issues.

17 In the Spring and Summer of 2011, we will
18 be holding two or three public workshops. And the
19 scope of these workshops may be expanded to include
20 discussion of all of the more controversial 10 CFR
21 part 35 rulemaking topics if a combined rule is
22 undertaken.

23 Next slide. The current schedule for 10
24 CFR part 35 rulemaking is to have a proposed rule in
25 March of 2012 and a final rule up in September of

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1 2013. If the rulemaking is expanded to include the
2 medical event reporting and permanent implant
3 brachytherapy changes, it will be held in the
4 workshops or we estimate -- these are all estimates --
5 we would anticipate holding the workshops again in
6 Spring, Summer 2011, consolidate and, in other words,
7 receive comments on the consolidated rule through the
8 Summer of 2011. I'm sorry. I misspoke. We would be
9 consolidating the comments that we receive during the
10 workshops during the Summer of 2011 and then start the
11 proposed rule in Fall of 2011.

12 Next slide. Complete the proposed rule in
13 the Winter of 2012-2013, publish the proposed rule in
14 the Spring of 2013, then conduct three public meetings
15 for comment on the proposed rule in the Spring of 2013
16 with a final rule to the Commission in the Fall of
17 2014.

18 So, essentially, in comparison to what we
19 heard this morning with the expanded Part 35 rule, it
20 would kick it out, it looks like, about a year or so.

21 Okay. So that's what I had to present.
22 As I said, it would be short and sweet. So I am
23 prepared to answer questions. And I am also very
24 interested in hearing any feedback that might come
25 from this Committee.

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1 ACTING CHAIRMAN THOMADSEN: Comments from
2 the Committee, please? Dr. Suleiman?

3 MEMBER SULEIMAN: The only point I want to
4 make because I think it is relevant to the previous
5 speaker as well is how much effort is going into this
6 very specific treatment in terms of how you define
7 things.

8 So the flip side of that is you can't have
9 a set of definitions that apply across the board
10 because this treatment modality has had its own unique
11 issues in terms of how you define dose, how you define
12 volume, how you define a whole bunch of things.

13 MR. FULLER: I agree. And I think that's
14 kind of what I was alluded to earlier. And what I
15 want to make sure that we're always keeping in mind
16 when we say -- and in the SRM, it is very generic in
17 that regard. So we have had to go back and get
18 clarification, which I am glad we got today a little
19 bit more.

20 We are only talking about permanent
21 implant brachytherapy when we're talking about making
22 changes to the medical event definitions because the
23 definitions seem to be working quite well for the
24 other modalities. So you're right. And we're very,
25 very sensitive to that.

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1 ACTING CHAIRMAN THOMADSEN: Ms. Gilley?

2 MEMBER GILLEY: Yes. You realize that
3 moving it out for a year puts another three years
4 before this rule change would be to the agreement
5 states, which have 85 percent of the licenses that are
6 doing these activities. You have three years to adopt
7 it after NRC adopts it. So you're really looking at
8 an implementation date somewhere between 2014 and 2017
9 to fix a bad rule.

10 MR. FULLER: We are. Yes, we are very
11 well aware of that. And that's why I laid out our
12 options the way I did, you know. And we're not
13 necessarily wed to any of those.

14 We have already begun the expanded 10 CFR
15 part 35 rulemaking, the 28 issues that were discussed
16 this morning. That is underway. One option is to --
17 see, we can't have two different rulemakings. My
18 understanding is we cannot have two different
19 rulemakings for one rule ongoing at the same time. So
20 we would have to do one or the other in series or
21 combine the two. That's why I believe that it is
22 very, very important that we do a good job early in
23 the developing guidance and see if we can at least
24 make some improvements in that way in how things are
25 done.

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1 ACTING CHAIRMAN THOMADSEN: Dr. Welsh?

2 MEMBER WELSH: On your slide number 4, you
3 talk about an integrated plan and three options. Of
4 the three options, which would be the most efficient
5 in your opinion to get the important task of the
6 permanent implant brachytherapy rulemaking addressed?

7 MR. FULLER: Well, if we are going to
8 limit the scope of this discussion to what is the most
9 efficient for permanent implant brachytherapy
10 rulemaking and the associated medical event reporting
11 criteria, then the fastest way would be to start with
12 that one and put off the one that is underway right
13 now. But I am not sure that that will be something
14 that needs to be considered.

15 MEMBER WELSH: So, as a follow-up point, I
16 would say that with the tradition of the squeaky wheel
17 getting the oil, right now to me it seems that the
18 issues surrounding permanent implant brachytherapy is
19 the squeaky wheel. And that's why I asked this
20 particular question.

21 MR. FULLER: I'll let somebody else reply.
22 We've got a lot of squeaky wheels.

23 MEMBER GILLEY: I would suggest the issues
24 with training and experience and radiation safety
25 officers and authorized medical physicists are

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1 probably a higher priority if there were some way you
2 could write procedurally or a guidance document for
3 inspection in licensees to handle the definition of
4 written directive for permanent implants.

5 MR. FULLER: That's what we're really
6 working hard on right now, is trying to figure out if
7 that is not feasible. It's early. And, Rob, please
8 speak up.

9 MR. LEWIS: No. Just on that point. And
10 all of these discussions need to happen and will
11 happen with the Committee about this integrated plan.
12 Like Mike said, we're in our infancy on it.

13 But if the training and experience --
14 right now our petition issues are such a major impact,
15 as we have heard this morning. One thing that didn't
16 come out this morning and I've always wanted to ask
17 but triggered my mind again this morning, why aren't
18 we seeing a bunch of exemption requests or individual
19 users riding us? You know, I don't see -- the stated
20 impact isn't aligning in my mind with the user need of
21 individual entities.

22 You know, we can do exemptions. And so
23 can most of the agreement states, I would assume. And
24 I don't know of a single exemption that has been
25 requested for that.

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1 ACTING CHAIRMAN THOMADSEN: Dr. Zelac?

2 DR. ZELAC: The response to Dr. Welsh's
3 question has already been offered by several people.
4 I will add a couple of more elements to it, things
5 that are considered to be important and meeting timely
6 correction, the first of which is the molybdenum
7 breakthrough. You may not think it is an issue, but
8 it is. And it wasn't fully explained at the meeting
9 this morning, but it has great ramifications.

10 The second, of course, is the question
11 relating to training, experience, and attestation and
12 the requirements that are existing now that view, in
13 fact, be highly recommended be changed asap.

14 So what I am basically saying is that
15 there were several of the items that are in the
16 expanded rule that also do need attention rather
17 promptly. And if that rulemaking were to be put off
18 until the one that you think or have expressed an
19 opinion is a high priority one, which it is, then they
20 will have to wait in abeyance. And that is not
21 desirable.

22 ACTING CHAIRMAN THOMADSEN: Dr. Langhorst?

23 MEMBER LANGHORST: I have a kind of a
24 process question, I guess. And if you combine this
25 effort with the current rulemaking, can't you be doing

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1 some of this all in parallel? And is it a matter of
2 resources, then?

3 It seems like a lot of these issues are
4 very important. And why does one get put off until
5 next rulemaking cycle? I don't understand the --

6 MR. FULLER: I think I can speak to some
7 of that. And I'll let Rob speak to more of the
8 resource issues, but that is kind of why we -- and you
9 are exactly right. A lot of these things we believe,
10 at least the way we have envisioned it, we believe can
11 be done in parallel, if they were combined, obviously.
12 We could use the workshops and the public meetings
13 after the proposed rule is out for everything so we
14 wouldn't have to do those things in series.

15 But because of the complexity and the
16 amount of time that it would take to add this in,
17 we're -- in other words, instead of being three years
18 and then three more years for the next one if you do
19 them in series, we think that by combining them --
20 and, again, this is based upon some really preliminary
21 estimates and brainstorming, if you will, kind of
22 laying things out. But we think we could do
23 everything that would only delay one year, instead of
24 three years.

25 Now, I realize that one more year is for

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1 some folks' minds unacceptable. So, again, I think
2 the key is that we'll see how successful we are in
3 developing guidance and see how many of the problems
4 we might be able to address effectively and then
5 successfully in that space. And then by expanding the
6 current rulemaking to include some limited changes to
7 the rule associated with this issue might be something
8 that folks would find acceptable.

9 Again, we're going to be readying this out
10 with a lot more detail and be providing this to this
11 Committee. And we will definitely, you know, before
12 we make any major steps, we will, be sharing things
13 with you and the Organization of Agreement States in
14 draft form and to get comments and so forth. So it's
15 pretty much in its infancy right now as far as the
16 formulation of this plan.

17 ACTING CHAIRMAN THOMADSEN: Mr. Einberg?

18 MR. EINBERG: I would also add that the 28
19 rulemaking items that you heard about this morning,
20 those are already underway. There is a rulemaking
21 working group that is already drafting the proposed
22 rule.

23 We'll work on the regulatory basis. So
24 there are efforts out there already underway. And if
25 we were to have an even more expanded rulemaking, this

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1 one that has the permanent implant brachytherapy
2 medical event reporting requirements in there also,
3 this could feed right into that.

4 So work is underway right now. And so
5 we're taking that into account as well.

6 ACTING CHAIRMAN THOMADSEN: Go ahead.

7 MEMBER LANGHORST: Sorry. I would also
8 like to say I know that your resources are limited.
9 Our resources are limited, too, in trying to keep up
10 with these types of changes and give you meaningful
11 comments back.

12 And I speak as an RSO in that regard who
13 really has to have her fingers in everything that is
14 happening. And it's tough to do when you're drinking
15 out of a fire hose. So I'm there with you, too, but I
16 --

17 MR. FULLER: Welcome to our fire hose.

18 MEMBER LANGHORST: Right, right.

19 ACTING CHAIRMAN THOMADSEN: Dr.
20 Guiberteau?

21 MR. FULLER: I'm also sensitive, just to
22 follow up with you, Dr. Langhorst. We are very
23 sensitive. As members of the ACMUI, various
24 subcommittees, I know we send a lot of stuff out. And
25 it actually helps us with that getting information.

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1 And we say, you know, "Here's something.
2 We're really interested in your comments. It seems
3 like we always have fairly quick turnarounds because a
4 lot of times we're reacting to something."

5 But yes, the resources are something that
6 we are sensitive to as well.

7 ACTING CHAIRMAN THOMADSEN: Dr.
8 Guiberteau?

9 MEMBER GUIBERTEAU: I think that anything
10 that delays the current rulemaking the NRC would do at
11 its peril in terms of delaying the impact of the
12 changes of petitioners and stakeholders and
13 practitioners and patients who have been waiting for
14 changes in the rule that may not be implemented in
15 certain states until ten years after they were
16 initiated.

17 I think the perception that the NRC is
18 insensitive to some of these concerns would only be
19 perpetuated. I think that would be a bad thing for
20 us.

21 And, you know, not to say that this issue
22 is not important, but I think, as was stated this
23 morning, in terms of a small number of patients being
24 impacted, as opposed to a large majority of patients
25 who are treated with and who are diagnosed using a

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1 byproduct material, I think it is imperative that we
2 continue with the current rulemaking process.

3 ACTING CHAIRMAN THOMADSEN: Thank you.

4 I have a question for Ms. Gilley. If the
5 NRC were to address permanent implant events with
6 guidance, as opposed to rulemaking, immediately and to
7 put off that until after the current work on Part 35
8 expansion, where it was finished, how could the State
9 Programs deal with that? Would that be adequate to
10 start their changes?

11 MEMBER GILLEY: If it was not a
12 compatibility issue. If it's a compatibility issue,
13 then, of course, we have to do what NRC has as
14 compatibility B or A. If it's got flexibility in it,
15 then, of course, the states can start rulemaking
16 process immediately to address all 28 issues if
17 there's not a compatibility issue. NRC takes the lead
18 on it because of compatibility.

19 ACTING CHAIRMAN THOMADSEN: In that case,
20 I would throw the question to the NRC staff.

21 MR. LEWIS: Well, I can offer a little
22 perspective. If we're trying to define what is a
23 medical event and a subset of those are AO anticipated
24 -- abnormal occurrences -- excuse me. It's been a
25 long day. Then we really have to look at a nationwide

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1 approach because the AOs get reported to Congress.

2 And we wouldn't want to report
3 inconsistently to Congress of what are the big issues.
4 And all the AOs nowadays happen to be medical, which
5 has a good explanation, but that is the fact.

6 So in terms of when we do guidance, we
7 look at compatibility from that perspective of whether
8 it should be a program element for a State. And in
9 certain guidance States, we would look through our
10 IMPEP process for States to do. And this would
11 probably be one of those that we would look for states
12 to do it consistently to NRC, although we try to be
13 flexible, even within that. But as much as we can, if
14 we're talking about what we want to report to
15 Congress, we have to get to that point of consistency.

16 And in the case of guidance, states do not
17 have three years. They have only six months to
18 conform. But that's something we would have to work
19 with through the states.

20 MR. FULLER: One thing I would add about
21 the state participation, so forth, when I referred to
22 enhanced guidance or improving our guidance and so
23 forth, we would follow the normal guidance development
24 process where we would develop a working group. We
25 would have agreement state representation and

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1 participation, hopefully. We would certainly invite
2 it and encourage it, but we would want agreement state
3 participation in the development of that guidance as
4 well. So it wouldn't just be something that NRC would
5 be doing only for the NRC regions and so forth.

6 ACTING CHAIRMAN THOMADSEN: Dr. Langhorst?

7 MEMBER LANGHORST: Also Dr. Guiberteau
8 reminded me of something that was said this morning in
9 the Commission briefing. I know the vast majority of
10 these brachytherapy procedures involve prostate
11 therapy. But those aren't the only ones. And what
12 works for prostate therapy may not work for other
13 therapies.

14 And so I would just remind all of us about
15 that aspect. And we're not just talking prostate
16 therapies.

17 MR. LEWIS: Yes, for permanent implant.

18 ACTING CHAIRMAN THOMADSEN: Dr. Fisher?

19 MEMBER FISHER: And also, to add to what
20 Sue just mentioned, state of art is advancing as well.
21 So this rulemaking cannot just be a snapshot of the
22 state of art for the last ten years, but it has to be
23 somewhat forward-looking into the new types of medical
24 devices that will be coming that are being developed
25 now and would be coming on line later, where some of

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1 the definitions fixed to date may not be fully
2 applicable.

3 I can give specific examples later, but I
4 think we have to anticipate the technology will
5 change.

6 ACTING CHAIRMAN THOMADSEN: I would like
7 to ask the Committee if we have -- well, I will ask
8 the Committee in one moment. Dr. Howe?

9 DR. HOWE: Just to digress for a minute,
10 it isn't clear to me whether Dr. Guiberteau was
11 talking about the 28 items that we are trying to get
12 to or the past rulemaking. So would you clarify when
13 you say "current rulemaking," which one you are
14 referring to?

15 MEMBER GUIBERTEAU: I was talking about
16 the 28 items.

17 DR. HOWE: Thank you.

18 ACTING CHAIRMAN THOMADSEN: And now I will
19 come to the Committee just to ask if we can give some
20 guidance to the NRC. Mr. Fuller has presented options
21 for them as far as addressing the needs for changes.

22 We have discussed this. Does anybody have
23 a motion they would like to make recommending one
24 direction or another? We may not have a direction
25 that we would make we would suggest at the moment, but

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1 if we do, we should let them know.

2 Does anybody wish to make a motion? Dr.
3 Guiberteau has almost made one.

4 MEMBER GUIBERTEAU: Well, I don't think I
5 have voting privileges. So I'm not sure I have
6 privileges to make a motion.

7 ACTING CHAIRMAN THOMADSEN: That's a very
8 good point.

9 MEMBER FISHER: But you could recommend.

10 ACTING CHAIRMAN THOMADSEN: Right.

11 MEMBER GUIBERTEAU: I think for a number
12 of reasons that continuing with the 28 items that
13 we're talking about on schedule would be my
14 preference. I do think that there are considerable
15 changes in terms of the focus of the brachytherapy
16 issue in terms of technology that might be better
17 served with more thought.

18 So my feeling is that if we continued with
19 the 28 items on schedule and then took up the issue of
20 to follow, brachytherapy would be my preference.

21 I think if you combined them and had just
22 one year, it might be okay, but I clearly think taking
23 up this issue first and shelving everything else is
24 not an acceptable alternative.

25 ACTING CHAIRMAN THOMADSEN: And, Dr.

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1 Welsh, since you almost spoke against that position,
2 how do you feel right now with the order of things?

3 MEMBER WELSH: Well, I speak as a
4 radiation oncologist. And from my perspective, I
5 acknowledge and accept that there are many squeaky
6 wheels that I was not paying as close attention to as
7 the loud and squeaky permanent implant brachytherapy
8 wheel is squeaking.

9 My personal feeling is that this issue has
10 been dragging along for quite some time. We have had
11 recommendations from the ACMUI dating back several
12 years. We have had reposed rules that have come
13 and gone and are being revised again.

14 And I believe the consensus of the
15 regulated community is that the present rules are less
16 than optimal. The reposed rules were even worse.
17 And, therefore, my personal feeling and recommendation
18 are in favor of moving forward with this as a high
19 priority.

20 I would probably favor on your integrated
21 plan on slide 4 maybe number 2, "Begin the new
22 permanent implant brachytherapy rulemaking and then
23 the expanded Part 35." That is my perspective as a
24 radiation oncologist.

25 ACTING CHAIRMAN THOMADSEN: Do we have

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1 somebody who would like to speak for one of the other
2 options? Dr. Van Decker?

3 MEMBER VAN DECKER: Sure. Get my name
4 right when I'm going to make an enemy. You know, with
5 all due respect to my colleague who just spoke, you
6 know, if you had to ask me looking at these three,
7 which one of the three I think is going to be
8 unacceptable to the community at large, it's
9 unfortunately probably going to be number 2.

10 I think most people are going to say we
11 have spent 4 years now arguing and building up a list
12 of 28. And to put it off for another three years and
13 three years more is going to cause great consternation
14 in the stakeholder community.

15 And so that's going to leave us actually
16 at that point with options 1 or 3. You know, I think
17 that, you know, 3 is obviously kind of the compromise
18 position trying to do everything at once except it
19 argues against everything we heard this morning about
20 doing things in parallel and cutting down on time,
21 rather than adding a year, year and a half to things.

22 I guess the question to be brought back to
23 the Commission in our new era of close communication
24 is why is there not a parallel path to do this that we
25 can't find. Because I suspect I know the one thing

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1 that we really can't tolerate is opening the workshops
2 to expand both these topics at the same time because,
3 as pressing as these topics are, the brachytherapy
4 topic is going to be a portion of the regulated
5 community that is going to have very intense needs to
6 get this sorted out.

7 The other issue in this list of 28 is
8 going to be a larger group of people from a wide
9 variety of backgrounds, all of whom want their voices
10 heard across a large number of different issues. And
11 you are going to get a lot of people showing up for
12 those issues, as opposed to this, which is going to be
13 a smaller, more intense issue. And you could even do
14 these in separate town meetings essentially.

15 I don't know how to answer this. How do
16 we get to number 3 without adding time, I guess is the
17 real question. And that is procedural stuff that you
18 guys, unfortunately, need to come up with.

19 Number 2, unfortunately, I don't think is
20 going to fly.

21 ACTING CHAIRMAN THOMADSEN: The question I
22 was trying to get at before I'm not entirely sure of
23 the answer. Could we run with number 1 but deal with
24 the permanent implants with guidance until such time
25 as the rulemaking could be finalized? Is that a

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1 practical approach?

2 MR. FULLER: I can only speak from based
3 upon, again, very early preliminary discussions that
4 we have had here amongst the staff that that might be
5 -- we believe that that is a feasible approach,
6 although it will be a while before we could get to
7 starting a new rulemaking for permanent implant
8 brachytherapy and the associated medical event
9 reporting requirements and changes thereto.

10 So it would be a delay, but we were at
11 least hopeful in thinking it might be feasible that we
12 could do enough guidance. We're going to have to do
13 -- let me put it this way. We're going to have to do
14 the workshops on this issue in parallel. And there's
15 nothing that would keep us from doing that. It
16 doesn't necessarily have to be rulemaking.

17 I mean, sorry. It's still in preparation
18 for rulemaking, but it doesn't mean that we couldn't
19 be holding those workshops this spring and having them
20 focused on permanent implant brachytherapy.

21 By combining them, though, we saw the
22 added benefit of getting more public participation in
23 on the 28th, which is something that needs to happen
24 as well.

25 But, to Dr. Van Decker's point, we also

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1 recognize that that could be huge, lots and lots of
2 controversial issues trying to be spoken about maybe
3 in one day. The idea was, well, you could do separate
4 breakout sessions and things. And there are ways to
5 accommodate all of this, but, regardless of which
6 direction we go, it's going to be very big and very
7 complicated.

8 ACTING CHAIRMAN THOMADSEN: Dr. Suleiman?

9 MEMBER SULEIMAN: I need clarification for
10 the regulatory timeline. You have not published the
11 proposed rule? So you're talking about publishing the
12 proposed draft. And then you go through the public
13 comment, and then it will be final.

14 MR. FULLER: Yes. But if we have the
15 workshop -- if -- this is a big if. But if we have a
16 combined rulemaking that includes all the 28 items
17 plus proposed changes to medical event definitions for
18 permanent implant brachytherapy, then those workshops
19 that we are now on the hook to do in the Spring and
20 Summer of 2011, we could --

21 MEMBER SULEIMAN: Incorporate --

22 MR. FULLER: -- incorporate all of those
23 and get the benefit of that public and stakeholder
24 input.

25 MEMBER SULEIMAN: You want to. You could.

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1 But we would probably get lots of comments about you
2 published the proposed rule, I predict. You would get
3 so many comments. Unless you had such consensus and
4 unanimity coming out of those workshops, which I am
5 really skeptical, would happen, you would get a lot of
6 comments. And it's going to cause you to rethink,
7 saying, "We've got such a disparity of comments about
8 these proposed rules that we're going to not go with
9 the final rule." And it will continue. I mean, that
10 is my experience.

11 MR. FULLER: It's a good point.

12 MEMBER SULEIMAN: I mean, when you publish
13 a proposed rule, you go for the comment. And,
14 depending on what comes in, you get some criticism on
15 the edges, but it's generally an agreement. But then
16 you go with the final rule. But if you get a lot of
17 disagreement, then the community rises up with
18 different perspectives. You're going to go back to
19 the drawing board. That's my opinion.

20 MR. FULLER: Thank you.

21 ACTING CHAIRMAN THOMADSEN: Dr. Zelac?

22 DR. ZELAC: It's probably worth noting
23 that there's just a little bit of difference between
24 what you have heard this morning and what you've heard
25 this afternoon and our current state with respect to

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1 the revision of the permanent implant brachytherapy
2 written directive medical event reporting
3 requirements.

4 And that difference is the working group
5 that is addressing the crafting of appropriate
6 language has these two sections, 35.40 and 35.70 of
7 30.45, open.

8 And once a section is opened, there can be
9 if appropriate additional changes made that would
10 affect or could affect the entire written directive
11 and medical event reporting requirements across the
12 board. And, in fact, the proposed rule had several
13 elements like that in there, not that there is great
14 uproar about what is there now, but these had been
15 seen as improvements to the current rule in the broad
16 sense. So there are on the table and would be
17 considered in the further activities of the working
18 group putting together the revised rule, of which I am
19 a member.

20 ACTING CHAIRMAN THOMADSEN: Thank you, Dr.
21 Zelac.

22 I'm not hearing a consensus coming out of
23 the Committee. I'm also not hearing any motions from
24 the Committee as to which direction we would recommend
25 the NRC go. Is that the case? That seems to be the

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1 case. I'm sorry that we can't provide you with any
2 more guidance on this and good luck to you.

3 (Laughter.)

4 MR. FULLER: This is going to sound
5 repetitive, but we will be developing -- we owe the
6 Commission an integrated plan in March. And so we
7 will have one that you will have in draft before we go
8 to the Commission to receive your comments on. So you
9 will have another shot at it.

10 ACTING CHAIRMAN THOMADSEN: Very good.
11 Thank you.

12 We are scheduled now for a break. Please
13 be back at 3:30. We will start on time.

14 (Whereupon, the foregoing matter went off
15 the record at 2:58 p.m. and went back on the record at
16 3:29 p.m.)

17 ACTING CHAIRMAN THOMADSEN: Thank you, one
18 and all. We are going to resume with a discussion on
19 the permanent prostate brachytherapy medical events at
20 the Department of Veteran Affairs Medical Center,
21 Philadelphia.

22 Ms. Pelke?

23 MS. PELKE: Thank you very much.

24 Good afternoon, everyone. What I am
25 actually here to do is update previous presentations

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1 that we have provided of the medical events that were
2 identified at the VA Philadelphia. But, for the sake
3 of those of you who may not have heard this the first
4 time or the second time, there have been multiple
5 briefings of the ACMUI. I will go through the
6 history. (Echo from the webcast.)

7 That's a bit distracting, by the way.

8 MS. COCKERHAM: It's the webcast. And
9 it's about a 30-second delay. So we're asking them to
10 turn it off right now.

11 MS. PELKE: Thank you.

12 MS. COCKERHAM: Unless you want to hear
13 yourself.

14 MS. PELKE: I'm from the NRC Region III
15 office. I should explain that as well. I'm not from
16 headquarters, but I am part of the NRC. And I am the
17 Chief of the Nuclear Materials Licensing Branch. My
18 branch is responsible for oversight of the Master
19 Materials License that was issued to the VA.

20 So, as background, the Department of
21 Veterans Affairs, as I said, holds a Master Materials
22 License. And the Master Materials License authorizes
23 a federal organization to use radioactive material at
24 multiple sites.

25 We issue Master Materials Licenses to

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1 federal organizations. The VA has one. We also have
2 two other MMLs. The Air Force has a Master Materials
3 License as well as the Navy. And the VA has
4 established a National Radiation Security Committee.
5 And they are responsible for providing oversight of
6 the DVA's implementation of its Master Materials
7 License.

8 The National Radiation Security Committee
9 has delegated the authority for day-to-day operations
10 to the National Health Physics Program. They actually
11 are responsible for implementing the program. They
12 report up to the National Radiation Security
13 Committee.

14 The NHPP, as I said in this next bullet,
15 is responsible for issuing permits. Those are similar
16 to NRC or agreement state licenses. They conduct
17 inspections similar to NRC inspections or agreement
18 state inspections. They also are responsible for
19 event follow-up. They investigate incidents,
20 allegations, and they issue enforcement.

21 The Veterans Affairs Medical Center
22 located in Philadelphia is a permittee under the
23 Master Materials License that was issued to the
24 Department of Veterans Affairs. And as far as size of
25 their program, the Department of Veterans Affairs has

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1 approximately I would say 115 permittees or licensees.

2 The Philadelphia VA Medical Center
3 retained the services of consulting radiation oncology
4 physicians and medical physicists from the hospital at
5 the University of Pennsylvania for pre-treatment
6 planning, implant preparations, implant treatments,
7 and post-treatment planning.

8 Between 2002, February, and May of 2008, a
9 total of 114 patients were treated at the VA
10 Philadelphia. In 2002, they initiated their prostate
11 implant program. The physician responsible for the
12 implants had been trained prior to the initiation of
13 the program in 2002. And over a six-year period, they
14 conducted implants which they believed were successful
15 and met all regulatory requirements.

16 In May of 2008, the NRC was notified of a
17 medical event where the dose to the intended tissue,
18 which was the prostate, was less than 80 percent of
19 what was prescribed. And the VA established D90 as
20 their dose metric.

21 In 2008, the National Health Physics
22 Program conducted an inspection at the VA Philadelphia
23 in response to the reported medical event. As a
24 result of the inspection they performed in May, they
25 asked the permittee to go back and take a look at ten

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1 previous treatments to assess the quality of those
2 implants.

3 Based on the results of the review of
4 maybe the last 10, they asked the facility to go back
5 and look at the last 20. And because they were
6 getting more and more reports of medical events or
7 possible medical events, the VA directed the permittee
8 to evaluate the entire scope of their implant program,
9 from 2002 to 2008.

10 In addition, the program director at the
11 VA Philadelphia stood the program, suspended prostate
12 brachytherapy treatments in June of 2008.

13 Additionally, an external panel was
14 retained by the VA to evaluate the prostate implant
15 program that was being performed and had been
16 conducted at Philadelphia.

17 In July of 2008, after the NRC received
18 notification of the initial medical events and we are
19 aware of the ongoing inspection efforts of the VA and
20 NHPP, the NRC launched an independent special
21 inspection.

22 We went out and did an inspection in July
23 of 2008. And in October of 2008, we issued a
24 confirmatory action letter to the VA. Our concerns
25 were the fact that if the events that occurred at

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1 Philadelphia were such that there may be similar
2 events occurring at other VA facilities that conducted
3 prostate brachytherapy.

4 So part of the confirmatory action letter
5 was a requirement for the VA to go out and do
6 confirmatory inspections at all of the other active
7 prostate brachytherapy programs.

8 We also required in there that they
9 provide additional training to the users and medical
10 physicists on what constituted a medical event, how to
11 identify a medical event, who to report a medical
12 event to.

13 Additionally, there was also a requirement
14 in the confirmatory action letter to establish revised
15 procedures for conducting prostate implants.

16 As of December of 2009, the VA had
17 reported to the NRC a total of 97 medical events.
18 These all occurred at Philadelphia. The VA went
19 through a systematic assessment of their doses, phase
20 one -- because they looked at all of the implants that
21 were done, 114 patients, they did a phase one where
22 they initially were going back to determine whether or
23 not the intended tissue received the appropriate dose.
24 And they looked at plus or minus 20 percent of the
25 prescribed dose. Again, the metric that they were

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1 using was D90.

2 They identified medical events based on
3 their phase one criteria. And then they went back and
4 reevaluated medical events based on doses to
5 unintended organs or tissues. And in this case, they
6 were looking at the rectum with the standard volume to
7 the rectum for dosimetry at 1.33 cc. And they were
8 looking at the rectum receiving greater than 150
9 percent of the pre-treatment dose plan.

10 They looked at external tissue and made a
11 definition of periprosthetic tissue, what they would
12 be looking at. And then they also looked at dose to
13 the bladder. This was all specific to the VA at
14 Philadelphia.

15 They identified 97 medical events, as I
16 said, based on underdoses or overdoses. In this case,
17 it was underdose to the prostate of less than 80
18 percent of what was originally prescribed and then
19 medical events to doses to unintended organs or
20 tissues.

21 The causes of the medical events at
22 Philadelphia were directly attributed to incorrect
23 placement of the seeds. They had inadequate
24 procedures. They had poor management oversight of
25 contractors. And then we had inadequate training of

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1 licensee staff.

2 As far as poor management oversight of
3 contractors, the bullet that I have there, it is
4 important to recognize -- and I have said this in
5 previous presentations -- that a number of our
6 licensees contract our services. But the contracted
7 services do not relinquish the responsibility of the
8 licensee to provide oversight on what those contracted
9 services are.

10 Here at Philadelphia, there was very
11 little, if any, management oversight of the
12 contractors. And in many cases, not just in
13 Philadelphia, when a licensee contracts services, they
14 believe they're contracting experts. And they leave
15 it at that.

16 Also, we found that that training of
17 licensee staff, whether it be individuals that worked
18 for the VA Philadelphia or individuals that came over
19 and were providing contracted services, it was
20 important for the permittee to understand that the
21 procedures and expectations that they had established
22 for implementation of the prostate brachytherapy
23 program there needed to be communicated, not only to
24 their own staff but also to contracted staff and that
25 roles and responsibilities were well-defined.

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1 Again, no management oversight of the
2 brachytherapy program specifically and then also no
3 peer review. And, as far as the peer review goes, I
4 will mention that, in addition to the inspection
5 activities that we did at Philadelphia, we also went
6 out and did inspections, NRC did inspections, at the
7 other VA facilities with active prostate brachytherapy
8 programs.

9 We inspected approximately 13 other VA
10 facilities. And what we saw at the other VA
11 facilities was not consistent with what we had seen at
12 VA Philadelphia.

13 Also, the peer review seemed to be an
14 outlier at Philadelphia. When we inspected other
15 facilities -- and you may all know from your
16 professional affiliations that VAs are oftentimes
17 located very close to a major teaching institution.
18 And we saw that not only with Philadelphia but also
19 with some of the other VA's we inspected. And at the
20 other facilities we inspected, we saw that there was a
21 healthy questioning attitude and that there was peer
22 review going on. But that was lacking at
23 Philadelphia.

24 Also, there was poor placement of the
25 implant seeds. And there were no corrective actions

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1 taken. And we attributed that to lack of safety
2 culture.

3 There was not a questioning attitude by
4 the individuals involved in the implants, whether it
5 be the medical physicist, the authorized user, folks
6 from the health physics staff that were involved in
7 the procedures as well.

8 The VA took prompt action to address
9 patient care issues. They had verification, CT scans
10 performed on all patients that received prostate
11 implants. They also reevaluated the dose to the
12 treatment area. And in some cases, they determined
13 that patients should receive a re-implant. And they
14 referred those patients to other VA facilities for the
15 re-implants.

16 And they also suspended the privileges for
17 one authorized use for performing brachytherapy
18 treatments at the VA Philadelphia.

19 NRC's response to the medical events. As
20 it says here, we conducted inspections in July and
21 September of 2008 and June and August and October of
22 2009. July and September of 2008, those activities
23 were really specific to the immediacy of events that
24 were being identified between May and September at VA
25 Philadelphia.

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1 We went back in June of 2009 to evaluate
2 the dose assessment, the ongoing dose assessment that
3 was going on in Philadelphia. And we also went back
4 for that same purpose in August and October of 2009.

5 As I mentioned previously, we issued a
6 confirmatory action letter to the Department of
7 Veterans Affairs in October of 2008. We issued two
8 inspection reports as a result of our inspection
9 activities: one in March and one in November of 2009.
10 And we also issued a demand for information to one
11 physician authorized user in May of 2009.

12 We had a pre-decisional enforcement
13 conference to discuss the events that occurred at
14 Philadelphia with the VA in December of 2009. And at
15 that pre-decisional enforcement conference, there were
16 representatives not only corporately from the national
17 VA program and from the NHPP, but also there were
18 representatives there from the VA Philadelphia.

19 As a result of the violations that we
20 identified, we issued a substantial civil penalty to
21 the VA for medical events that occurred at
22 Philadelphia. And the amount is listed there,
23 227,500. We also issued a severity level 2 violation,
24 which is relatively rare in regulatory space for us.

25 We did conduct inspections at the other

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1 Department of Veterans Affairs facilities that
2 performed prostate implants. In addition to
3 conducting inspections at the other VAs that did
4 prostate brachytherapy, which we looked at that
5 inspection activity as an assessment of the extended
6 condition, which was a relatively new term for us but
7 was quite frequently used in the reactor world. When
8 a problem is found, they want to evaluate the extent
9 of the condition for corrective actions.

10 So in this case, we went out to determine
11 whether or not problems that we saw at Philadelphia
12 were consistent at the other DVA facilities. And, as
13 I mentioned previously, we saw that Philadelphia was
14 somewhat of an outlier for the VA programs.

15 In addition to those inspections, we
16 conducted an inspection at the Department of Veterans
17 Affairs of the National Health Physics Program. We
18 evaluated their responses to the medical events and
19 their inspection activities.

20 And we also conducted separate pre-
21 decisional enforcement conference that wrapped the
22 results of our extended condition inspections and the
23 results of our inspection of the National Health
24 Physics Program into one action.

25 We issued an inspection report in May. We

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1 had a pre-decisional enforcement conference in June of
2 this year. And we issued a civil penalty of \$39,000
3 relative to violations that we identified at other VA
4 facilities. There were four other VA facilities where
5 we identified violations relative to prostate
6 implants.

7 NRC actions going forward, we're looking
8 at enhanced oversight of the Department of Veterans
9 Affairs. They have instituted some global actions.
10 They have provided or established a set of standard
11 procedures. They had all of their permittees in for a
12 meeting in January of 2009 to review the procedures
13 that they had established. They discussed their
14 expectations. They met with the RSOs. And they gave
15 their permittees a period of time to assess those
16 procedures and implement the procedures.

17 Also, we are looking at actions to assess
18 our performance improvements. Whenever you find
19 program areas of this magnitude, where we spent I
20 would say well over two years of inspection time,
21 assessment time to wrap the issues up, there is a lot
22 to be gained on both sides of this situation.

23 We are looking at policies and procedures,
24 as we have probably discussed earlier in other
25 conversations on other issues, but our policies and

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1 procedures and practices related to prostate
2 brachytherapy. And we were hoping to establish
3 program enhancements going forward.

4 I actually have four slides. These are
5 all from VA facilities, but this is an example of
6 properly placed seeds that we identified at one of the
7 other VA facilities. This is VA Minnesota. This is
8 VA Cincinnati. And then we have two examples of what
9 we had seen at Philadelphia.

10 And that wraps up my presentation. And,
11 as I said, we concluded our enforcement action with
12 the VA in August. We should have final action this
13 year relative to those events.

14 ACTING CHAIRMAN THOMADSEN: Thank you very
15 much.

16 Open the floor to questions. Yes?

17 MEMBER ZANZONICO: Were they doing
18 brachytherapy at any other sites other than the
19 prostate at the Philadelphia --

20 MS. PELKE: No. That was their only --

21 MEMBER ZANZONICO: And, likewise, what
22 about other VA sites?

23 MS. PELKE: That is, the majority of what
24 we see at the other VA facilities is prostate
25 implants. Thank you.

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1 ACTING CHAIRMAN THOMADSEN: Dr. Welsh?

2 MEMBER WELSH: Thank you for the
3 presentation again. I know that we have discussed
4 this a few times. I've probably asked the same
5 question I might have asked last time.

6 There are 97 medical events. Of that,
7 what number would be categorized as medical events if
8 a different metric were used, specifically an activity
9 based metric, such as the one that the ACMUI
10 recommended in 2008? Has anybody done that from NRC,
11 as far as you are aware?

12 MS. PELKE: No. The NRC has not assessed
13 the doses based on a different metric.

14 MEMBER WELSH: Okay. From my
15 understanding, of the 97, about a dozen would be
16 categorized as medical events using the modified
17 metric that was put forth by the ACMUI.

18 That leads me to the second question,
19 which is of the 97 medical events, do you have an idea
20 of how many were identified based on phase one versus
21 phase two in your medical event criteria?

22 MS. PELKE: The majority of the medical
23 events that they identified were based on phase one
24 underdose to the prostate. And, as a result of the
25 underdose, then they went back and looked at seed

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1 positioning to make an assessment on whether or not
2 there was an overdose for unintended organ or tissue,
3 but there was not a dual report.

4 MEMBER WELSH: So the majority of these
5 were because of the dose to the prostate --

6 MS. PELKE: That's correct.

7 MEMBER WELSH: -- being 20 percent?

8 ACTING CHAIRMAN THOMADSEN: Dr.
9 Guiberteau?

10 MEMBER GUIBERTEAU: I have a question
11 here. On one of your last slides here, it says
12 "enhanced oversight by the Department of Veterans
13 Affairs." It says, "global actions instituted by
14 DVA." Does global in this sense mean throughout the
15 Veterans Affairs system?

16 MS. PELKE: Yes, yes.

17 MEMBER GUIBERTEAU: Well, I was hoping it
18 might mean two things. I see here that -- I
19 understand the violations. I understand what the NRC
20 has gone. I am also concerned about the corrective
21 actions that were taken not only by the Philadelphia
22 VA but by the DVA itself because in terms of the
23 causes of the medical events, two were obviously
24 related to the performance of the procedure and the
25 policies, but two of those are cultural in terms of

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1 quality and safety, the lack of a safety culture and
2 no peer review process, which is disturbing because
3 the two are very much aligned there in terms of
4 quality and safety.

5 And I am just wondering, in terms of
6 addressing -- since the NRC has taken such an interest
7 in a safety culture, did you get any feedback as to
8 what the DVA and particularly the Philadelphia VA are
9 doing about the cultural aspects of this issue?

10 MS. PELKE: The cultural aspects, this is
11 my opinion I am speaking from. The cultural aspects
12 are a little bit more difficult to address.

13 At Philadelphia, I will offer that they no
14 longer have an active prostate brachytherapy program.
15 We did go out and do inspections there. They do have
16 an active diagnostic program. They have an active
17 therapeutic nuclear medicine program. And we did not
18 see programs with those programs that they had in
19 place.

20 The global actions that the VA instituted,
21 they took a look and established some standard
22 procedures that they expect all of their active
23 programs to establish. They certainly give the
24 institutions some latitude to tailor those, but they
25 have some absolute criteria that they want to see in

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1 the procedures.

2 I will offer to the group -- and this may
3 open up more discussion, but part of that standardized
4 procedure was the use of D90 as a dose metric. And,
5 as a result of that, implementation of that, there
6 were some VA facilities where the authorized user
7 determined that that was not necessarily the metric
8 that that practitioner wanted to practice or institute
9 in their process and, as a result, suspended or no
10 longer conducted prostate brachytherapy within a VA.

11 Culturally the VA has done an assessment
12 of enhancing communications, fostering a
13 safety-focused environment. They certainly have open
14 door policies. They had open door policies prior to
15 that.

16 So in some cases, a safety culture can be
17 very hard to sometimes -- I'm looking at kind of
18 chipping away at the ice because depending on the
19 personalities that may be involved and how they may
20 communicate or who intuitively is asking the
21 questions, it is not something that you can
22 necessarily I think answer very easily.

23 But they certainly have their eye on the
24 ball. And they have integrated processes and really
25 reinforced processes that they already had in place

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1 with expectations.

2 They have also done a lot of work relative
3 to expectations with contracted services and how they
4 expect the permittee to manage, recognize their role
5 and responsibility and not delegate a program, even if
6 you believe it is to a group of experts. So they have
7 done a lot of work in that direction.

8 MEMBER GUIBERTEAU: And peer review?

9 MS. PELKE: Peer review, well, like I
10 said, we saw it at Philadelphia. It seemed to be an
11 outlier because the other facilities that we
12 identified, peer review was an absolute that they had
13 established that they believed was a necessity for a
14 healthy exchange of information.

15 MEMBER GUIBERTEAU: And at the
16 Philadelphia VA, was that peer review absence only
17 discernible in the brachytherapy area?

18 MS. PELKE: That's what we looked at
19 there. We don't necessarily in therapeutic nuclear
20 medicine look at peer review, nor would we absolutely
21 believe that a licensee would have a peer review for
22 diagnostic or therapeutic nuclear medicine procedures.

23 We do recognize that in therapy, with the
24 higher risk modalities, that they would have some kind
25 of peer review, whether it be internal to that

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1 organization or with an external group of experts that
2 may come in at some frequency and get together and
3 discuss cases.

4 MEMBER GUIBERTEAU: Thank you.

5 MS. PELKE: But it's a suspended program.
6 And they have no plans to reinstitute the program at
7 Philadelphia.

8 ACTING CHAIRMAN THOMADSEN: Dr. Fisher?

9 MEMBER FISHER: It looks like a very
10 appropriate regulatory study follow-up and responses.
11 I think the answer is yes, but isn't it true that
12 there was a single contractor practitioner responsible
13 for placing the seeds in each of the medical events in
14 this list or were there multiple physicians involved
15 in placing seeds?

16 MS. PELKE: There was more than one
17 physician involved.

18 ACTING CHAIRMAN THOMADSEN: Dr. Zanzonico?

19 MEMBER ZANZONICO: They did not do post-
20 implant dosimetry, post-implant CTs and/or dosimetry?

21 MS. PELKE: They did CTs. And they made
22 an assessment. The VA made a determination that after
23 the events were identified, that they went back and
24 re-CTed all the patients again to determine what CT
25 data they were going to use to evaluate a dose. So

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1 consistently there was no dose assessment done after
2 the implant was performed, even though CTs were
3 obtained.

4 MEMBER ZANZONICO: CTs were being done,
5 even prior to the sentinel event?

6 MS. PELKE: Yes.

7 MEMBER ZANZONICO: And were they used for
8 dosimetry or were they just looked at?

9 MS. PELKE: We're not sure exactly how
10 that process worked because when we launched our
11 inspection, the authorized user was no longer
12 available to answer our questions. We did make an
13 effort to interview the physicists that were involved.
14 And, there again, they're actually following their
15 directions based on what the physician's prescription.
16 So they're taking their direction from the physician.

17 MEMBER ZANZONICO: Pennsylvania is an
18 agreement state.

19 MS. PELKE: Correct.

20 MEMBER ZANZONICO: So you could not -- I
21 think I asked this question at the last meeting. You
22 could not look at the brachytherapy, prostate brachy,
23 program at any of the other U. Penn affiliated
24 facilities to see if that was a common denominator
25 somehow?

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1 MS. PELKE: Well, that would certainly be
2 true after the date Pennsylvania became an agreement
3 state, which, Mark, off the top of my head, I don't
4 recall. But we did share the information with the
5 Agreement State of Pennsylvania, what we were finding
6 at Philadelphia, because we believed that they would
7 definitely have an interest in what we were finding.

8 We also looked at the possibility of any
9 of the group affiliated with the contract services
10 from HPP if they were practicing at any other
11 NRC-regulated facility. So we did do follow-up in
12 that arena as well.

13 But yes, certainly we would always share
14 what we find with our fellow --

15 MEMBER ZANZONICO: Do you know if
16 Pennsylvania followed up?

17 MS. PELKE: Yes. Pennsylvania went out
18 and did an inspection as well as Region I went out and
19 did an inspection.

20 ACTING CHAIRMAN THOMADSEN: Dr. Van
21 Decker?

22 MEMBER VAN DECKER: I have a doctor kind
23 of question to ask that may not even be in your
24 purview. And you don't even have to answer it. But
25 as I am listening to this, if Philadelphia VA has

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1 suspended its program and is not offering access to
2 the veterans in the Philadelphia area, how are future
3 veterans getting access to therapy in the Philadelphia
4 region? They look for an outsource contract?

5 This is not your purview, obviously, but
6 it brings up the interplay between the regulatory
7 world and the health care access world and that, you
8 know, patients need to get treated and we need to move
9 forward somehow at some point to make sure that we're
10 providing access and therapy and stuff.

11 So you don't have to answer the question.
12 I'm just wondering.

13 MS. PELKE: Well, I was going to take a
14 stab at the question. The NRC is interested in
15 quality health care being provided to patients. And
16 the VA is also interested in high quality care of
17 their veterans. So they did make arrangements.

18 I mean, that was a decision that was made,
19 I'm sure not only locally at the VA Philadelphia but
20 also at a more corporate level, on whether or not that
21 program would be reconstituted.

22 And, as I said, the director suspended the
23 program in June of 2008. And since that time, they
24 have been directing patients to other VA facilities.

25 Also, it may be helpful for you all to

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1 know that the program at Philadelphia was not very
2 active. It wasn't a major modality that they did
3 there. And therein could be part of the program.
4 Because it was an infrequently performed evolution
5 that they may have encountered the problems that they
6 did.

7 ACTING CHAIRMAN THOMADSEN: Dr. Welsh?

8 MEMBER WELSH: I'm sorry I might have
9 missed something you said, but I am very curious. So
10 I am going to ask. Do you say that because of the
11 implementation of the use of D90 for defining medical
12 events and authorized user or maybe several authorized
13 users ceased doing prostate brachytherapy for the
14 concern that D90 might be an inappropriate metric.

15 MS. PELKE: I want to try to speak and
16 clarify what I said. There are certain physicians
17 that had conducted prostate brachytherapy within the
18 VA organization prior to the standardized procedure
19 that the VA implemented fleet-wide, which established
20 D90 as a metric.

21 And, as a result of that, prior to that
22 standardized metric, the clinicians had the latitude
23 to assess different metrics for determining the
24 quality of the implant and the dose to the prostate.
25 But with this procedure, it required the use of D90.

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1 And in some cases, those clinicians chose not to do
2 implants at VA facilities because that was outside of
3 the diction they wanted to go with their practice for
4 determining quality of their implants.

5 MEMBER WELSH: So, in essence, some
6 physicians stopped doing prostate brachytherapy
7 because of this?

8 MS. PELKE: At the VA facility.

9 ACTING CHAIRMAN THOMADSEN: Any other
10 comments or questions?

11 (No response.)

12 ACTING CHAIRMAN THOMADSEN: Hearing none,
13 thank you very much. And that leads us into Dr.
14 Welsh.

15 MEMBER WELSH: Thank you, Dr. Thomadsen.

16 I will present the Permanent Implant
17 Brachytherapy Subcommittee report in a concise six
18 slide presentation here that I must thank my fellow
19 Subcommittee members for the many hours that went into
20 formulating this report.

21 So I will start out by summarizing some of
22 the key points. The Subcommittee finds that an
23 activity-based metric for the definition of medical
24 events remains preferable to any dose-based method.

25 Because of the technical difficulties,

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1 should I pause until this corrected or --

2 ACTING CHAIRMAN THOMADSEN: Well, we all
3 have the slides and the book. And I think that the
4 audience does, too. Why don't we go ahead?

5 MEMBER WELSH: So an activity-based metric
6 seems preferable. This is one of the key findings of
7 the Subcommittee. A dose-based metric is always going
8 to be fraught with numerous challenges. I'm going to
9 mention a couple of them.

10 There are volume changes associated with
11 atrophy and edema in an organization, such as genuine
12 volume changes that are not necessarily anatomic but I
13 guess what due to problems with contouring, such as
14 inter and intra contouring skills.

15 Inter-modality, identification of the
16 prostate permitters, some difficulties associated with
17 the artifacts associated with the implanted seeds,
18 result in a volume estimation that might not be
19 precise. And if the volume estimation is not precise
20 or accurate, neither can the estimated dose be.

21 So the Subcommittee also recommends
22 strongly that NRC seek specific help from stakeholders
23 for the development of an appropriate medical event
24 definition.

25 A medical event in the opinion of the

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1 Subcommittee should be something that is of genuine
2 medical significance. The definition should be
3 sensitive enough to identify potential harm to an
4 individual patient. And harm can be defined as harm
5 due to overdosing sensitive normal structures and
6 tissues or due to underdosing, to cancer, and not
7 curing the patient of their illness for which they
8 underwent the procedure in the first place.

9 Post-implant dosimetry is something that
10 the Subcommittee addressed. And we felt that
11 post-implant dosimetry is good. It's important. It
12 should be performed. But there are questions
13 surrounding the concept of using post-implant
14 dosimetry for regulatory purposes and whether or not
15 it is appropriate to impose a demand that it be
16 performed, especially within a certain time period,
17 such as the proposed 60-day time line, which remained
18 controversial.

19 One thing that the Subcommittee feels
20 strongly about is that if a patient fails to show up
21 for their post-implant dosimetry procedure, this
22 should be excluded from classification of a medical
23 event because it is beyond the control of the
24 authorized user and would fall into the category of
25 patient-related factors.

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1 The Subcommittee suggested after
2 considerable deliberation the possible creation of
3 separate categories for permanent implant
4 brachytherapy, specifically a category for implant
5 procedures which result in significant rearrangements
6 of the implant location during completion of the
7 procedure, such as brachy mesh interoperative lung
8 implants.

9 And the second category would be those
10 procedures that do not have significant rearrangement
11 of seed location on completion of the implant, such as
12 prostate or breast brachytherapy.

13 It may not be necessary to create these
14 subdivisions if the medical event definition is
15 exclusively activity or source strength-based, but if
16 a dose-based definition is entertained, this might be
17 quite appropriate.

18 One part that has come up many, many times
19 in our discussions and also reappears in the
20 repropose rule is that a dose that exceeds by 50 rem
21 to an organ or tissue 50 percent or more at the dose
22 expected could be classified as a medical event. And
23 this was something that causes a great amount of
24 consternation for some of the Subcommittee members.

25 And it must be kept in mind that 50 rem,

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1 .5 Sievert, is a very small amount compared to the
2 doses that we are prescribing, 150 Gray, for example,
3 for a prostate implant. So we are talking about less
4 than one percent of the prescribed dose.

5 Additionally, a 50 percent overdose could
6 be quite medically inconsequential if the original
7 expected dose is extremely low. As an example, if
8 we're talking about the femoral heads, the liver,
9 organs that we don't normally contour but if, for
10 whatever reason, the authorized user, medical
11 physicist, urologist, other team members decided,
12 let's contour the femoral heads in this particular
13 case, let's contour the penile wall, and the doses
14 that were calculated are on the order of a couple of
15 centiGray but actually wind up being a few centiGray,
16 you could wind up meeting the definition of medical
17 event and, yet, have no medical consequences to the
18 patient. So this is something that we feel might not
19 be appropriate to maintain.

20 And I almost hate to bring it up, but if
21 this rule were strictly applied, almost all prostate
22 brachytherapy procedures would meet this definition of
23 medical event if you looked carefully; for example, at
24 the skin on the anterior, in front of the pubic
25 symphysis. If one actually calculated that and

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1 applied this rule very rigorously, we might find that
2 the majority of prostate implant procedures that are
3 perfectly good, acceptable, nontoxic and effective
4 treatments would meet the definition. And that's
5 problematic.

6 Additionally, the units that are used in
7 these rules and repropose rules remain inconsistent
8 and confusing. And we thank Dr. Fisher for constantly
9 bringing this up. And I think it is appropriate that
10 we recommend change to appropriate units in a
11 consistent manner.

12 If a rule of this sort is to remain in the
13 repropose language, it would probably be very helpful
14 to have specific relevant area or volume specified,
15 such as x square centimeters of skin or y cubic
16 centimeters of organ 1, 2, or 3, when we are talking
17 about this, rather than the relatively vague language
18 that presently exists.

19 Finally, I would conclude by saying that
20 permanent implant brachytherapy is a proven safe,
21 effective, and efficient modality for addressing
22 cancers. And it would be improvement and a disservice
23 to the American people if this modality were to fall
24 out of favor because of overly strict regulation.

25 And the previous discussion caused me a

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1 bit of concern when I heard that some authorized users
2 are not going to offer this treatment because of a
3 concern about the use of D90 or whatever. It
4 ultimately affects the patients who perhaps can
5 benefit from this.

6 And I was disappointed to hear that some
7 of our veterans might not have access to prostate
8 brachytherapy because of this simple regulatory
9 imposition.

10 Thank you.

11 ACTING CHAIRMAN THOMADSEN: Thank you, Dr.
12 Welsh.

13 Comments from the Committee? Questions
14 for Dr. Welsh?

15 MEMBER ZANZONICO: Yes.

16 ACTING CHAIRMAN THOMADSEN: Dr. Zanzonico?

17 MEMBER ZANZONICO: This is for a point of
18 information. When you cite the 50 rem to an organ or
19 tissue, is that 50 rem for any point in the tissue or
20 organ or is it a mean tissue or organ dose or is it
21 not specified?

22 MEMBER WELSH: Not specified.

23 MEMBER ZANZONICO: It's not specified.

24 MEMBER WELSH: That's why it --

25 MEMBER ZANZONICO: So it could just be one

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1 point?

2 MEMBER WELSH: Yes.

3 MEMBER ZANZONICO: It really is
4 inconsequential.

5 MEMBER WELSH: Correct.

6 MEMBER ZANZONICO: And maybe NRC staff can
7 answer this. I agree from a deterministic point of
8 view 50 rem is trivial. Is the concern, which
9 wouldn't seem to be logical in this overpopulation,
10 possibly stochastic, I mean, future cancer induction?
11 I mean, it doesn't seem -- I can't fathom what the
12 rationale is for 50 rem being --

13 ACTING CHAIRMAN THOMADSEN: Dr. Fisher?

14 MEMBER FISHER: Yes. We think, at least
15 some members of the Committee think, that that is an
16 error in drafting the original language based on some
17 misunderstandings that the Committee has pointed out.

18 And I wanted to let Dr. Welsh know how
19 much I appreciated this very concise, accurate
20 overview of the Subcommittee's work, which was
21 extremely difficult. We didn't come to blows over
22 anything, but it was a lot of work for the
23 Subcommittee. It's a very difficult topic to tackle
24 appropriately.

25 And, Jim, I think you've done just a

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1 remarkable job of summarizing the key points that are
2 most important and presenting a very fair and accurate
3 representation of the work of this Subcommittee since
4 we last met.

5 MEMBER WELSH: I would like to respond to
6 that. Thank you, Dr. Fisher. And this opens the door
7 for a point that I did not create a slide for but I
8 think is worth discussing.

9 This is a controversial subject. And,
10 within a small Subcommittee of about a half dozen
11 people, we had a number of different opinions. One
12 can, therefore, imagine how difficult it must be for a
13 large society, such as ASTRO, AAPM, American
14 Brachytherapy Society, the NRC, to come to a
15 consensus. We could not come to a consensus on many
16 things.

17 And I should point out that the concept of
18 dose-based criteria was outvoted. And three members
19 were strongly opposed to this. There were others who
20 were ambivalent about it.

21 Two members felt very strongly that the
22 Subcommittee report should include some specific
23 recommendations regarding a dose-based method, but
24 three were so opposed to any concept of dose-based
25 metric that it was felt best not to spell out any

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1 recommendations for fear that if we did, it would be
2 misinterpreted that the Subcommittee actually endorses
3 dose-based metric and here is what we were offering.
4 The Subcommittee prefers to stay with activity-based
5 metrics for the most part.

6 One member of the Subcommittee was
7 strongly opposed to the statement that brachytherapy
8 is an art as well as a science. There are a lot of
9 different opinions on this. And we must respect each
10 individual opinion, but for the most part, the
11 Subcommittee felt that that was not inappropriate to
12 mention.

13 One member of the Subcommittee was opposed
14 to the requirement of post-implant dosimetry as a
15 basis for medical event definition. Others, two
16 others, were not opposed to the use of post-implant
17 dosimetry as definition but were opposed to the idea
18 of placing a 60-day limit.

19 And all matters related to any dose-based
20 criteria, including the inclusion of a specific
21 recommendation, were very controversial. And one
22 member was thinking that nothing dealing with dose-
23 based metrics should be included in the Subcommittee
24 report at all for fear of that misunderstanding that I
25 mentioned.

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1 So this was not an easy task. And you can
2 see that this group of people has many reasons to
3 disagree. And we sure do have that. By and large, I
4 think our report and summary summarize what we have
5 concluded.

6 ACTING CHAIRMAN THOMADSEN: I think that
7 is an excellent description of what the Subcommittee
8 went through. Thank you for that clarification.

9 Mr. Lewis?

10 MR. LEWIS: I have a question for the
11 Subcommittee. And it involves the use of an activity-
12 based metric or source strength-based metric. How did
13 the Subcommittee or did they address the location
14 component of the place sources within the treatment
15 volume because that can -- a properly defined
16 treatment volume would poorly place seed within that
17 volume, would seemingly be something that would become
18 a medical event.

19 ACTING CHAIRMAN THOMADSEN: Dr. Welsh?

20 MEMBER WELSH: The Subcommittee
21 acknowledges that that rare, unusual, perhaps bizarre
22 situation presents a genuine problem for activity-
23 based definitions. And we wrestled with this and
24 concede that in such an unusual circumstance, the
25 dose-based criteria might be appropriate.

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1 However, if a dose-based criteria were to
2 be applied in such a situation, it might be preferable
3 to not use metrics such as D90 or dose to the target
4 organ itself but dose to sensitive adjacent tissues,
5 sensitive nearby tissues, that could be harmed on an
6 overdose.

7 In the example you present where all of
8 the seeds might be bunched together, the urethra might
9 be harmed from this. Where they are all bunched
10 together posteriorally, the rectum could receive an
11 overdose.

12 And, therefore, there was some discussion
13 about the use of dose for definition of medical events
14 but not in the way that it has been traditionally.
15 The use of dose here, rather, would be for identifying
16 potential harm to a sensitive structure. And that
17 would be the use of dose and a possible solution to
18 the problem that you describe, which most of us feel
19 would be quite unusual but not impossible.

20 ACTING CHAIRMAN THOMADSEN: Dr. Langhorst?

21 MEMBER LANGHORST: I learned a lot on the
22 Subcommittee and helped my understanding of the issues
23 greatly. But I do think we did all agree that a
24 medical event should be of medical significance. I
25 don't think we had one dissention in that regard. And

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1 so I wanted to point that out.

2 In the VA hospital review, I know that
3 they brought in a blue ribbon panel, as they called
4 it, of experts to look at their situation. And this
5 group, at least in part, is continuing to look at this
6 area in regard to any new definitions.

7 So I would hope that the NRC is getting
8 that information and bringing in those experts, too,
9 to help us in this really tough task of trying to
10 decide what is a medically significant medical event
11 and how do we define that for these brachytherapy
12 procedures.

13 ACTING CHAIRMAN THOMADSEN: Dr. Welsh?

14 MEMBER WELSH: So I will point out that we
15 had the Commission briefing in the summer and
16 discussed your points. And the staff will be meeting
17 with stakeholders, as we suggested. And hopefully we
18 would gather some valuable input. And that input will
19 be used in future repropoed rules and other language.

20 Additionally, I agree that medical event
21 definition should represent something of medical
22 significance. However, I understand the NRC's
23 perspective that a medical event might not necessarily
24 be of genuine medical significance to a patient but
25 could be used to identify trends that ultimately could

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1 lead to an event that is of medical significance.

2 So I acknowledge the traditional
3 perspective of NRC, but it raises the question that
4 has been brought up many times about terminology.
5 And, in the opinion of several, the term "medical
6 event," which was supposed to be less intimidating or
7 negative compared to misadministration, I don't think
8 it has succeeded in that particular aim.

9 I think if a patient hears that he or she
10 was subjected to a medical event from an implant
11 brachytherapy procedure, they might not interpret that
12 in the way that we originally wanted it to be
13 interpreted. The language is strong. The language is
14 interpreted in a fashion that is negative.

15 And, unlike many other areas that are
16 regulated, the medical profession is one that is
17 fraught with lawsuits. And it is feared that labeling
18 too many perfectly good medical procedures as medical
19 events could lead to a number of -- overburden the
20 NRC, the other regulatory agencies, the hospitals, and
21 lead to potential confusion in the patients that might
22 lead to seeking legal action unnecessarily.

23 ACTING CHAIRMAN THOMADSEN: Mr. Lewis.

24 MR. LEWIS: I am sympathetic to the
25 terminology, the problems maybe that terminology

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1 creates. But I want to be very clear about the NRC's
2 philosophy, regulatory philosophy, because I think it
3 is an important component of good regulatory practice,
4 that there are events that the purpose of the medical
5 events, as we have defined them, is to identify
6 situations in which an authority figure -- a doctor --
7 his instructions were not followed, or the licensee's
8 instructions were not followed.

9 And we want the licensee to investigate
10 that phenomenon, and we want perhaps the regulatory
11 agency to investigate that phenomenon before an event
12 of clinical significance happens, before a patient
13 dies, before a reactor melts down. So, really,
14 whether we call them medical events or something else,
15 the current rule says they're medical events.

16 But there are events that will need to be
17 reported to the regulator that we really have no
18 wiggle room on in terms of good regulatory practice.

19 MEMBER LANGHORST: I think, again, English
20 is involved, and medical significance doesn't mean
21 medical harm but a potential, where there are some
22 that really have little potential of a medical
23 significance. And that's what we discussed in our
24 Subcommittee and is what we mean by "medical
25 significance," not necessarily that there was harm

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1 immediately done.

2 ACTING CHAIRMAN THOMADSEN: Dr. Zanzonico.

3 MEMBER ZANZONICO: I prefer the term
4 "sentinel event," but that's not the point of my
5 question. In the draft Subcommittee report, I thought
6 you made a compelling case for the pretreatment volume
7 normalized post-treatment dosimetry as a good way of
8 characterizing the treatment actually delivered.

9 What is the down side of that? Why is
10 that not a preferred alternative as kind of a dose-
11 based metric for a medical event or not?

12 MEMBER WELSH: I believe what you are
13 referring to is the concept of normalizing to the --
14 what I call "the initial." And, in theory, it sounds
15 like a great concept. In practice, I think you could
16 ask any medical physicist, that this would be -- they
17 will tell you this would be very difficult to actually
18 implement.

19 And I've struggled with this myself, and
20 my conclusion is that "the initial" might not be as
21 useful as I initially hoped, but if the volume on
22 which the dose is estimated differs significantly from
23 "the initial," cannot draw any conclusions about
24 whether this is a medical event based on any dose-
25 based criteria.

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1 So that could be one way that "the
2 initial" could still be useful. I am not advocating
3 that we go to any dose-based criteria, but in the
4 event that the NRC elects to stick with something such
5 as D-90 or another dose-based parameter, I would argue
6 that "the initial" could still be used.

7 And the practical solution might be if the
8 volume is different from "the initial" by a certain
9 percent, you cannot accurately estimate the dose.
10 And, therefore, it should be excluded from medical
11 events based on many dose-based criteria.

12 I would ask Dr. Thomadsen if there is any
13 other ways of salvaging the "the initial" concept, but
14 I know that we've talked about it and it's not
15 something that seems to be a practical parameter with
16 the technology that we have today. Perhaps some
17 student in the future could devise something that
18 would make this implementable, but it's challenging
19 right now.

20 ACTING CHAIRMAN THOMADSEN: Well, there
21 could be -- I don't have the answer for how, but there
22 could be -- in that there have been dosimetry systems
23 developed based on how much activity should be used
24 for given volumes of targets with I-125. The memorial
25 system comes to mind readily.

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1 And something like that could maybe be
2 built into the check using a normalization back to
3 what would have been the dose with the "the initial."
4 I wouldn't write it off. Actually, this is so
5 strange, because Dr. Welsh and I had discussions about
6 this many times, where he was a strong advocate and I
7 was the opponent. And now we are sort of switching on
8 that. So I -- he is not sure how useful it is, and I
9 wouldn't give it up quite yet.

10 So, Dr. Suleiman.

11 MEMBER SULEIMAN: I think one of the
12 fundamental problems is that the physician seems to be
13 taken out of the decision making here. In other
14 words, when I see a procedure, and somebody gives --
15 we try to rely on quantitative metrics to make it
16 objective, but medicine is not just numbers, it is --
17 you've got patients with very, very different
18 situations.

19 I would argue that probably if you gave
20 twice the dose, no matter how you measure it, in a
21 therapy application it probably would be serious. I
22 would then say, "How far down do you lower it?"

23 Now, the uncertainty -- I have always felt
24 that the normal uncertainty with a specific procedure
25 is the practice of medicine, and that is where

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1 external beam therapy versus brachytherapy versus
2 radiolabel therapy, your precision and accuracy are
3 going to vary quite a bit. So one size doesn't fit
4 all.

5 I also get bothered by the whole medical
6 event definition, where 50 rem seems to be a
7 threshold. Anything below that is not reportable.
8 But that means you can screw up on a diagnostic
9 procedure and that's okay. It doesn't qualify.

10 So, and the other thing that bothered me
11 in the whole medical event criteria, which I
12 discovered this last year, was if the authorized user
13 writes the wrong numbers, and somebody executes those
14 incorrect numbers, that that's not a reportable event,
15 because the mistake was made prior to administering
16 the dose.

17 So I think taking a step back, I think the
18 system just is -- something is fundamentally wrong
19 with the whole criteria. What I would think would be
20 maybe if something doesn't look right -- and I defer
21 to the physicians doing the exam -- then you'd maybe
22 -- it would -- like a reference level or an
23 investigation level, something would flag and say,
24 "You know, we have to follow up on this. These
25 numbers don't look right," and then maybe reach a

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1 decision as to this was in fact a bad example of a
2 difficult patient.

3 But it was well within, you know, your
4 practice of medicine uncertainty. Or that expert
5 group of two or three colleagues will say, "You know,
6 this was a mistake. You shouldn't have -- there were
7 some real fundamental errors associated with that."
8 That's the only thing to me that would -- that would
9 bring more conclusive decision than just trying to
10 invoke some sort of arbitrary 20 percent, 50 percent,
11 50 rem value.

12 ACTING CHAIRMAN THOMADSEN: Yes, Mr.
13 Mattmuller.

14 MEMBER MATTMULLER: Thank you. A comment
15 and then a question. Regards to Rob's comment about
16 what the NRC is supposed to be doing, their
17 philosophy, we don't disagree with that. I think
18 where we're disagreeing is where to draw the line in
19 the sand to start looking for possible problems that
20 then do lead to more serious problems.

21 And because I keep -- I reread some of the
22 transcripts from past ACMUI meetings, and the one that
23 keeps hitting me hard is from Dr. Potter, who spoke
24 back in May of 2010.

25 And if I could repeat what he said, "But

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1 when" -- and this is in regards to the VA cases. "But
2 when you look at the clinical outcomes that the report
3 generated in terms of patients who failed treatment
4 versus patients who had excess complications, as a
5 result of the misplacement of the seeds, they really
6 weren't out of the reported realm of reported outcomes
7 of centers of excellence."

8 And he goes on to say, "Dose is
9 subjective, and the fact that there is not going to be
10 a direct correlation perhaps to toxicity or outcomes
11 just shows that it is less of a true science here."
12 So I guess, I mean, to me it seems to be very, very
13 apparent that where you have drawn the line in the
14 sand is inappropriate, that you are catching a lot of
15 cases that have no medical significance. And I think
16 what we're trying to say is you need to draw the line
17 elsewhere.

18 MR. LEWIS: I understand that.

19 ACTING CHAIRMAN THOMADSEN: Dr. Welsh.

20 MEMBER WELSH: A comment to -- with regard
21 to what Steve just said. The quote says that dose is
22 subjective. Dose shouldn't be subjective, but it is.
23 So this is an inexact science. And if we are imposing
24 regulation on an inexact aspect of this practice of
25 medicine, we are going to have some trouble.

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1 So if dose is subjective, and we impose
2 our regulations on dose, based on dose, inevitably
3 there will be complications.

4 ACTING CHAIRMAN THOMADSEN: Not arguing
5 with that. I would point out dose is not subjective,
6 but the target is subjective. And so where the dose
7 is in the target is of question. Other -- yes, Dr.
8 Zelac.

9 DR. ZELAC: Not a comment, but just a
10 relatively mundane question. In fact, two questions
11 from your presentation, and I apologize for asking in
12 this format, because hopefully the answer to both of
13 these is in the report itself. You mentioned and your
14 slide says that the 60-day requirement for doing a
15 dose assessment is controversial. Could you explain
16 that? What is controversial about it?

17 MEMBER WELSH: What was controversial is
18 the concept of using it for regulatory purposes. And
19 I think in the repropoed rule if a post-implant
20 dosimetry procedure was not done within 60 days, it
21 would be tagged as a medical event. Not everybody was
22 comfortable with imposing a 60-day rule.

23 Some of the discussion included that for
24 palladium-103, cesium-131, several half-lives have
25 transpired, and that's fine. But for iodine only one

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1 half-life has transpired at the 60-day mark, and,
2 therefore, some might say that -- and there is a lot
3 of discussion about this particular matter. But some
4 would argue that it might be more appropriate to do
5 post-implant dosimetry at a later date, and,
6 therefore, the 60-day arbitrary number is
7 controversial for that reason.

8 DR. ZELAC: Okay. I could comment, but I
9 won't in the interest of time. The second question
10 that I had relates to what you said, which doesn't
11 appear on the slide, and that has to do with -- you
12 mentioned that most brachytherapy -- prostate
13 brachytherapy implant procedures could probably be
14 deemed medical events, if one were looking at the skin
15 in the pubic area, and looking at the dose that was
16 actually delivered there compared to what had been
17 anticipated based on the implant if performed as
18 planned.

19 Now, there is a 50 percent window in which
20 you don't have a medical event. Are you saying that
21 the estimates of dose to the pubic skin area would be
22 typically off by more than 50 percent initially?

23 MEMBER WELSH: Perhaps not typically, but
24 it is not unusual for the prostate to reposition
25 itself, for slightly more seeds to be placed in the

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1 anterior than the plan called for, and meet
2 satisfactory implant by all definitions, except if you
3 were to actually estimate during the preplanning
4 procedure what the dose to the skin might be.

5 And I think that Dr. Thomadsen provided an
6 estimate of maybe somewhere around five to six gray.
7 Conceivably, the dose could be more like seven to
8 eight gray. Is that a consequence? Most likely no.
9 But it would meet the definition.

10 And the same would be true for organs that
11 we -- other organs that we don't normally contour. I
12 mentioned the penile bulb, the femoral heads, as a
13 bizarre example, the extreme example, the liver.
14 These are organs that we don't contour. But if we had
15 the technology, and made it easy to contour each and
16 every organ through some type of automated system, we
17 could keep track of those, and we would find that the
18 doses might be more than 50 rem and 50 percent more
19 than the very tiny few centigray, or whatever it might
20 be, that we initially anticipated.

21 ACTING CHAIRMAN THOMADSEN: Thank you. I
22 will follow up on that. We know from external beam
23 localization of a prostate that day to day, and even
24 during an external beam treatment if the prostate is
25 not immobilized, one centimeter differences in the

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1 depth of the prostate is not unusual, in which case if
2 you do the calculation of the dose to the skin you are
3 well over 50 percent difference just between where the
4 prostate might be from one moment to where it is the
5 next.

6 DR. ZELAC: And also exceeding the five
7 centigray --

8 ACTING CHAIRMAN THOMADSEN: Oh, yes. Yes.
9 Well exceeding -- well exceeding that. And the liver
10 is another example, as you point out, Dr. Welsh, that
11 as the prostate moves in the pelvis it can easily move
12 closer or farther from the liver.

13 DR. ZELAC: Thank you both.

14 ACTING CHAIRMAN THOMADSEN: Yes. Dr. Suh.

15 MEMBER SUH: I'm not sure this is part of
16 the mandate of the Subcommittee, but one of the --
17 just my impression is that placing of the
18 brachytherapy seeds, there is obviously some variation
19 in terms of what you are drawing as volume, are you
20 drawing as perhaps through the bladder.

21 Do you or the Subcommittee have any
22 recommendations in terms of is -- should there be some
23 type of mandated training to do prostate
24 brachytherapy, a minimum number of cases that should
25 be performed, in the hopes of trying to minimize the

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1 risk of these type of events at the Dade Hospital from
2 occurring in the future?

3 MEMBER WELSH: Yes, I think that's a very
4 important point. Somebody without proper training
5 during their residency training period probably should
6 not be doing prostate implant brachytherapy. There
7 are courses that are available -- that are available
8 for individuals who did not get this training during
9 their residency program but wish to become authorized
10 users. And of course we would recommend that such
11 training be sought before anybody attempts to do this.

12 ACTING CHAIRMAN THOMADSEN: That was
13 outside of the charge of the Subcommittee.

14 At this point, did the Subcommittee wish
15 to ask the Committee to approve the report? Dr.
16 Welsh?

17 MEMBER WELSH: As I was reading the
18 Subcommittee report, I noticed a couple of
19 typographical errors that were not apparent on the
20 computer screen but are glaringly obvious when they
21 are in paper format. Therefore, I would request an
22 opportunity to correct those typos.

23 ACTING CHAIRMAN THOMADSEN: Very fine.

24 MS. COCKERHAM: You can still vote to
25 approve the content. That's fine. We'll let you send

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1 a new copy in.

2 ACTING CHAIRMAN THOMADSEN: Do they affect
3 the substance of the report?

4 MEMBER WELSH: They do not.

5 ACTING CHAIRMAN THOMADSEN: Oh, good. Mr.
6 Lewis, was that --

7 MR. LEWIS: That was my point.

8 ACTING CHAIRMAN THOMADSEN: That was your
9 comment, too? In that case, would you like to move to
10 have the Committee approve the report?

11 MEMBER WELSH: I would put forth a motion
12 that the ACMUI as a whole approve the submitted
13 Subcommittee report.

14 MEMBER GILLEY: Second.

15 ACTING CHAIRMAN THOMADSEN: Thank you.
16 Yes.

17 MEMBER LANGHORST: Thank you. Sue
18 Langhorst. I believe that Rob said at the beginning
19 we were asked as a Subcommittee to basically freeze
20 our report at this time in light of the proposed
21 Part 35 definition not moving forward at this point.
22 And so I am a little hesitant to say we've got it all
23 done, because we really did freeze it at this point.

24 ACTING CHAIRMAN THOMADSEN: Thank you. I
25 had forgotten that. You are supposed to kick me under

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1 the table when I --

2 MEMBER LANGHORST: Sorry.

3 ACTING CHAIRMAN THOMADSEN: -- when I
4 start doing that. Ms. Cockerham.

5 MS. COCKERHAM: Just to add to that, I
6 think the reason we said freeze it at this time, and
7 something that staff had kind of discussed, is if you
8 want to vote on this report and endorse it, we'll call
9 it an interim report. We don't want to call it draft
10 if you voted on it, because it is final in that sense.

11 But we can call it an interim report, and
12 it is something that staff has committed to transmit
13 to the Commission. So we would send it to them as an
14 interim report. And then, once we do the workshops
15 and we know more about where the medical event rule is
16 going, things like that, I think we would expect a
17 final report - final final report next year. Does
18 that ease some concerns?

19 MR. LEWIS: And I think the idea here is
20 this is a very useful product for the NRC staff to
21 begin the outreach. So we would appreciate if the
22 Committee would be so inclined to give us something to
23 use to go do outreach.

24 And we would caveat in every instance we
25 get that this is not the final result, that we did

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1 have the whole rulemaking evolution, and the SRM told
2 us to go get additional input. And this is one of
3 those additional inputs. So we will appropriately
4 caveat in any way the NRC would use this report.

5 ACTING CHAIRMAN THOMADSEN: Does that
6 satisfy your --

7 MEMBER LANGHORST: I think I would like us
8 to have the ability to put that caveat in our own
9 report to say these are -- this is the status of our
10 discussion, and we offer it up for more discussion in
11 this regard.

12 ACTING CHAIRMAN THOMADSEN: Would you like
13 to amend the motion to note that this is an interim
14 report, with final report to come after stakeholder
15 input? Would that be --

16 MEMBER LANGHORST: I think that would be
17 -- I'd feel comfortable about that. I don't know
18 about the rest of the Subcommittee.

19 MEMBER GILLEY: I'm okay with it as a
20 second.

21 ACTING CHAIRMAN THOMADSEN: And Dr. Welsh?

22 MEMBER WELSH: I second that amendment,
23 and I would point out that our final product might be
24 influenced by the outcome of some of the planned
25 stakeholder meetings, too, where --

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1 MEMBER LANGHORST: Yes.

2 MEMBER WELSH: -- expert --

3 MEMBER LANGHORST: Absolutely.

4 MEMBER WELSH: -- input will be provided.

5 ACTING CHAIRMAN THOMADSEN: Dr. Suleiman.

6 MEMBER SULEIMAN: I mean, I look at this
7 report and all I see is that this is very complicated.
8 We haven't reached a definitive conclusion. So I see
9 no harm in adopting that conclusion. I don't see
10 where it is directing the NRC in any specific -- in
11 other words, it says we still have work to do.

12 MEMBER WELSH: I would like to summarize
13 it very succinctly and say that the 2008
14 recommendations are still valid. That would summarize
15 the whole report.

16 ACTING CHAIRMAN THOMADSEN: Other
17 comments?

18 (No response.)

19 In that case, we will call for a vote.
20 Those in favor of endorsing the Subcommittee's report
21 please say aye.

22 (Chorus of ayes.)

23 Those opposed? Oh. Hands only -- I
24 apologize. All in favor -- wait a second. All in
25 favor of the endorsement of the report please raise

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1 your hands.

2 MS. COCKERHAM: I have 10.

3 ACTING CHAIRMAN THOMADSEN: All opposed?
4 Is that -- how many do we have?

5 MS. COCKERHAM: I think that's correct.

6 ACTING CHAIRMAN THOMADSEN: Okay. Thank
7 you very much, Dr. Welsh.

8 MS. COCKERHAM: And no abstentions, just
9 to be clear? Okay.

10 ACTING CHAIRMAN THOMADSEN: Right. If 10
11 was -- yes, that's -- that's it.

12 We are going to move on. Dr. Fisher will
13 be discussing the patients' rights advocate's
14 responsibilities.

15 MEMBER FISHER: Thank you, Bruce. This
16 presentation is an update of one that I gave two years
17 ago in October 2008 at this Committee meeting. And we
18 are redoing it and adding to it with a slightly
19 different twist, for the benefit of our newer members
20 who were not here at that time.

21 In the previous presentation, I gave some
22 history of this Committee, that the Committee that we
23 now are members of dates back to the Manhattan
24 Project. In 1946, it was established by the Manhattan
25 Engineering District as the Interim Advisory Committee

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1 on Isotope Distribution Policy.

2 In 1947, a Subcommittee on human
3 applications was established, which was the first
4 human subjects committee in the United States, or
5 probably anywhere in the world. In 1949, the
6 Committee developed a first policy for patient
7 informed consent, which is now really very important
8 in this field.

9 In 1951, the first federal regulations on
10 isotope use in human subjects were codified into the
11 U.S. Code of Federal Regulations as 10 CFR 30.50. And
12 when the NRC was created at the split of the Atomic
13 Energy Commission, this Committee went with the NRC,
14 and hence what we have today. That was a brief
15 history.

16 Today, the NRC Advisory Committee on the
17 Medical Uses of Isotopes provides advice to the NRC on
18 policy and technical issues that arise in regulating
19 the medical use of byproduct material for medical
20 diagnosis and therapy of disease.

21 Next slide. Oh, I've got the control
22 here.

23 Patient concerns -- I'd like to go back
24 one. Let's see, how do we do this?

25 MS. COCKERHAM: You're there.

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1 MEMBER FISHER: Okay. The concerns of
2 patients are, first of all, that they get the best
3 possible medical care when faced with difficult
4 treatment decisions. We have had in my own family a
5 couple of examples where this really has come up in
6 the last three months. We want access as patients to
7 the best available medical care, and the latest
8 scientific advances. We want protection from poor
9 health practices, and we want good doctors.

10 We want good information about treatment
11 options. Patients want to be treated with dignity and
12 respect and to understand the long-term consequences
13 of disease, including, especially with cancer, quality
14 of life issues and what is it going to cost, how long
15 do I live.

16 In the community, the patients' rights
17 advocate is typically a liaison between patients and
18 health care providers to help patients obtain the best
19 possible health care. The patients' rights advocate
20 is usually a single individual, or it can be an entire
21 organization. It can be a for-profit or a non-profit.

22 The patient rights advocate in the
23 community provides educational materials and
24 counseling to help patients make wise choices in their
25 treatment decisions. Usually the organizations are

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1 non-profit, and they typically focus on one aspect of
2 health care or on a specific disease, such as today we
3 heard from the organization representing thyroid
4 cancer patients.

5 Who are the stakeholders in this process?
6 It is typically the uniformed public as patients and
7 caregivers who rely on medical practitioners for
8 health care. But it can also be -- the stakeholders
9 can also be hospital designated employee advocates.
10 Many hospitals have patient rights advocates who are
11 employees. And then there's a number of different
12 patient rights advocacy organizations.

13 Some I have listed here. This is just a
14 partial list -- for example, National Patient Advocate
15 Foundation, American Association of Kidney Patients,
16 National Breast Cancer Coalition, National Marrow
17 Donor Program, part of the patient advocacy office,
18 the Breast Cancer Task Force of the American Bar
19 Association, the Patient Action Network of the
20 American Medical Association, the National Women's
21 Health Network, etcetera, etcetera.

22 At the bottom of the list I have Us Too
23 International, which was invited to participate at the
24 previous Commission briefing. So there are many
25 stakeholders and patient rights advocacy organizations

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1 out in the community.

2 Some of these are fee-based organizations.
3 If patients want advice, they pay for it. They get
4 advice. Examples include the Houston Patient
5 Advocacy, RN Patient Advocates, AdvoConnections, The
6 Karis Group, The National Association for Rights
7 Protection and Advocacy, and so forth.

8 And the last category of stakeholders
9 might be individuals as patient counselors. That's a
10 role that I have been involved in myself personally
11 for many years -- for many years preceding my
12 involvement with this Committee.

13 So the next issue is regulation and
14 patient access to health care. In a regulatory
15 context, the factors that impact on patient rights are
16 the tradeoffs between regulations that restrict
17 availability or patient access to new treatments and
18 those that permit it.

19 The slow process for new drug or device
20 regulatory approval is an issue. And regulations that
21 may restrict hospitals' and physicians' ability to
22 provide the most effective treatments. These are the
23 issues in the regulation of health care and patient
24 access to health care. And the NRC has been very
25 positive in trying to make sure that patients are able

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1 to access the best health care provided by medical
2 isotopes.

3 At the federal level, the concept of
4 patients' rights has now become part of federal law,
5 and it is part of the Medicare and Medicaid system.
6 In 1997, President Clinton created the Advisory
7 Commission on Consumer Protection and Quality in the
8 Health Care Industry to promote and assure health care
9 quality and value and to protect consumers and
10 workers.

11 The President asked the Commission to
12 develop a patient's bill of rights, and that bill of
13 rights has a number of goals -- to strengthen consumer
14 confidence that the system is fair and responsive, to
15 reaffirm the importance of a strong relationship
16 between patients and their health care providers, to
17 reaffirm the critical role that consumers play in
18 safeguarding their own health.

19 The federal statement on patients' rights
20 has seven elements. I will just briefly mention them,
21 without reading the entire slide -- the right to
22 information, the right to choose, access to emergency
23 services, being a full partner in health care
24 decisions, health care without discrimination based on
25 multiple factors, the right to privacy, and the right

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1 to a speedy complaint resolution.

2 In turn, the patient has a responsibility
3 to the health care provider, and that is to maintain
4 good health. The reference for these federal -- these
5 codified responsibilities is 42 CFR 482.13, Code of
6 Federal Regulations.

7 That brings me around to the role of this
8 member on this Committee in the function of a
9 patient's rights, an advocate. The NRC has defined
10 this position as that person who provides technical
11 advice that helps the NRC develop useful and practical
12 medical regulations that are not overly burdensome,
13 and provides technical assistance and licensing,
14 inspection, and enforcement cases if need -- if it is
15 needed.

16 So that's the role of -- on this Committee
17 of the patient rights advocate. Also, to provide
18 consulting services to NRC staff when requested, to
19 bring key issues to the attention of staff for action,
20 but overall to be cognizant of the impacts of NRC
21 actions on patient access to health care and to
22 represent fairly the concerns of patients' rights
23 stakeholders, whether they be individuals or
24 organizations. And that is taken from the NRC
25 definition of the responsibility for this role.

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1 In terms of outreach, the Committee's
2 patient rights advocate can also be a very useful
3 liaison between the patients' rights advocacy
4 organizations, such as those that I have previously
5 listed, and the federal regulatory process. However,
6 this role is limited to the medical use of
7 radioisotopes in diagnostic and therapeutic nuclear
8 medicine.

9 So, in this role, I have made an effort to
10 contact a number of patient rights advocacy
11 organizations to inform them of this responsibility
12 and their access to the NRC through this Committee.
13 Some of those that I have spent some time with are
14 listed here -- Citizens for Medical Isotopes, the
15 Patient Advocate Foundation, Us Too International
16 Prostate Cancer Education and Support, Fighting
17 Children's Cancer Foundation, and Conservatives for
18 Patient's Rights.

19 Most of the advocacy organizations that I
20 have either talked to or tried to reach are not
21 familiar with the nuclear regulatory process or with
22 the regulations that impact the use of radioisotopes
23 in medicine. So the outreach effort is difficult for
24 that reason.

25 There are some notable exceptions, in

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1 particular Us Too International, which participated at
2 NRC request in the most recent Commissioners' briefing
3 in July. And I have noted also the ThyCa
4 representative who presented this morning at the
5 Commissioners' briefing.

6 I was impressed with testimony from Dr.
7 Houchens, David Houchens, of Columbus, Ohio. During
8 the last Commissioner brief he said, "In relation to
9 requirements for reporting medical events with
10 brachytherapy," and he represents an organization
11 concerned primarily with prostate cancer treatment.
12 It is important for doctors to use their clinical
13 judgment to provide best -- or to best treat the
14 patient.

15 In closing, I would like to state that Us
16 Too would be happy to work through the NRC Advisory
17 Committee patient rights advocate relating to issues
18 that our organization has in regards to the use of
19 medical isotopes.

20 My current plans as patient rights
21 advocate are to continue to reach outward to the
22 various patient rights advocacy organizations, to
23 continue to -- continue an outreach effort to
24 professional and scientific organizations involved in
25 patient education and counseling, to help these

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1 organizations better understand the regulatory issues
2 that affect patient access to best medical care in the
3 medical isotope area, and to provide a meaningful
4 liaison between these organizations and the Nuclear
5 Regulatory Commission.

6 So not to take up too much time, and to
7 come to a quick summary and conclusions, the most
8 important elements of the patient rights are
9 established under federal law. As I pointed out, the
10 patient rights advocate is an integral part of this
11 Nuclear Regulatory Commission Advisory Committee, and
12 has been for many years going back to the early
13 history of this Committee.

14 Most patients, caregivers, and rights
15 advocacy organizations are not well informed on the
16 medical regulatory process that they do have access to
17 the NRC through this position. However, the patient
18 rights advocate can provide a meaningful liaison
19 between the NRC and these patient rights
20 organizations.

21 So basically that is a summary of some
22 history, some federal regulations, my position,
23 responsibilities, outreach, and what we can do to help
24 facilitate the process.

25 ACTING CHAIRMAN THOMADSEN: Thank you very

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1 much, Dr. Fisher. Questions for Dr. Fisher?

2 MEMBER ZANZONICO: Now, is there any
3 mechanism or vehicle in place, like if a patient --
4 and maybe this is more of a question for the NRC staff
5 -- if a patient or someone who had some concern about
6 an isotope-related treatment, or even diagnostic
7 issue, went on the NRC website, that they would be
8 apprised of the fact that there is an independent
9 patient advocate to whom they could direct questions
10 or concerns or that sort of thing? You know, what is
11 the -- I guess the question is: what is the presence
12 of the patient advocate in terms of the NRC website or
13 publications, etcetera, etcetera?

14 MR. LEWIS: Well, some of what Dr. Fisher
15 has -- well, first of all, let me thank Dr. Fisher
16 very much for this effort, and it may have been partly
17 -- the genesis of it may have partly been a lunch
18 conversation that we had about a year ago that, you
19 know, many of you come to this meeting with -- having
20 coordinated with a professional society or the
21 agreement states and have a very distinct and
22 systematic way to bring feedback back to NRC.

23 The patient rights advocate position is
24 very unique amongst the Committee members, and it is
25 much harder to gather the collective views of many

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1 different patients' rights organizations, and what we
2 asked for Dr. Fisher to do. And thank you for looking
3 into it and for what you do to do just that. And I
4 have asked him to look at, you know, going forward how
5 we can do better for that position.

6 But I think the NRC website is not the
7 best. It could be. It's a work in progress. I think
8 I just actually had a meeting about it, and someone
9 told me there is over 300 links on the home page. And
10 in terms of website architecture, that's a bad idea,
11 and we've got people working on that. But if you do
12 go to the ACMUI page, which you can link to, believe
13 it or not, from the home page, the public home page,
14 it does describe every position, including the patient
15 rights position.

16 I'm not sure that anything that a member
17 of the public would be looking at would indicate to
18 them to call one of you. But certainly any member of
19 the public can call NRC, and we do get many, many
20 calls from concerned members of the public, or
21 letters. And we very much welcome those.

22 That's a good point. And maybe -- I'm not
23 sure that we want to open that channel. That is not
24 the purpose of the Committee members, to field calls
25 from patients. But maybe we can do better in terms of

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1 how we get a patient's info from NRC and then have the
2 NRC staff share that with Dr. Fisher to get ready for
3 the meetings.

4 Yes, Ashley.

5 MS. COCKERHAM: Just to add one more
6 thing. I flipped to the ACMUI home page, because I
7 remembered we put this up there. There is a
8 medicalquestions.resource@nrc.gov, and we do get
9 questions from patients, along with lots of other
10 questions that deal with some issues that we have
11 jurisdiction over, and some of which we do not.

12 But that's a good generic venue, and I
13 know our Office of Public Affairs, if they get a
14 specific medical question through a phone call or an
15 e-mail, they send it to that in box and that comes
16 directly to Chris's group, and that is handled by the
17 medical team. So that's another venue -- a way to
18 reach us.

19 MR. LEWIS: So we may need to close the
20 loop with Dr. Fisher to get ready for these meetings,
21 but --

22 MEMBER FISHER: I spend about four hours a
23 week in patient counseling. And I want to make sure
24 that members of this Committee understand it is not to
25 give medical advice. It is not to provide -- it is

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1 not to provide instructions on what to do to get the
2 best treatment, but, rather, it is an avenue to help
3 the patient better understand the disease and who to
4 go to for the best possible care.

5 And, like I said, it's about four hours a
6 week on average. It is something that I enjoy doing,
7 and so I -- every time I get a phone call I enjoy just
8 putting everything aside and working on that. Like I
9 said, these have come in the last two weeks primarily
10 from associates at work, members of the community, and
11 in one particular case a member of my own family
12 undergoing a second cancer treatment for a second
13 cancer following a recent procedure for a first cancer
14 of two different cell types.

15 So I would be happy also to take -- to
16 take on some additional role, if questions come
17 through the NRC through this outreach, and especially
18 from organizations involved in patient advocacy,
19 patient counseling, and patient rights.

20 ACTING CHAIRMAN THOMADSEN: Any other
21 questions?

22 (No response.)

23 Thank you again. And I'll call again on
24 Dr. Welsh to discuss novel means of medical isotope
25 production.

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1 MEMBER WELSH: Thank you, Mr. Chairman.
2 Thank you again for the opportunity to present, from
3 the emerging technology section, some new and exciting
4 information that could be of interest to us all. I
5 will specifically talk about some novel means of the
6 radioisotope production. And, as we have heard from
7 Steve Mattmuller and others today, the isotope
8 shortage is certainly a very hot topic. So we need
9 some solutions.

10 I'll start by stating the obvious. The
11 problem is that there are approximately 16 million
12 procedures in the United States alone that use
13 technetium-99M. And because of some difficulties with
14 the reactors that produce moly-99, there is an acute
15 shortage in principal user of these isotopes -- namely
16 us, the United States.

17 This shortage is due to the unreliable
18 operation of the two main reactors that supply medical
19 isotopes, namely the NRU reactor in Canada and the HFR
20 reactor in The Netherlands. These reactors are old.
21 They are becoming unreliable. And as we have seen in
22 the past few years, this is becoming a real issue.

23 Additionally, they require HEU, highly
24 enriched uranium, as feedstock, and that is another
25 problem altogether, but one that can't be ignored.

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1 Presently, the United States has no
2 ability to produce isotopes domestically, and a
3 solution is, therefore, obviously needed. Most of the
4 proposed solutions use either old existing reactors or
5 old reactor concepts. The problem that comes to mind
6 immediately is that the research reactors that might
7 be proposed for solving this problem are all quite
8 old, and are not designed for large-scale isotope
9 production. So there could be some challenges with
10 that solution.

11 Another solution that is on the table,
12 aqueous reactors, these reactors must resolve some
13 power instability concerns that have been demonstrated
14 previously, and NRC also has to determine licensing
15 strategies for liquid core reactors.

16 So I am going to pick up with the history
17 lesson from Dr. Fisher. Medical isotopes were
18 originally manufactured by non-reactor mechanisms.
19 Obviously, there was a time when we didn't have
20 nuclear reactors, but we did have applications of
21 isotopes for medical and scientific purposes.

22 The Joliot-Curies used alpha particles
23 from polonium to bombard aluminum-27 and an alpha-N
24 reaction to produce what they called radiophosphorus.
25 Radiophosphorus turned out to be P-30, phosphorous-30.

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1 Shortly afterwards, Enrico Fermi continued his work
2 with neutron bombardment and production of
3 radioisotopes, and he produced P-32, which was
4 different from P-30. But this radioactive form of
5 phosphorous was to be used to treat patients with
6 leukemia, as I will talk about shortly.

7 In 1940, the discovery of carbon-14 was
8 made through bombardment of carbon-13 through a DP
9 reaction. In contrast to the carbon-11 that was used
10 previously, which has a very short half-life, making
11 it difficult to conduct any biochemical tracer
12 experiments, Carbon-14 has a long half-life, allowing
13 it to be used for things such as the well-known
14 radiocarbon dating, but also allowing practical
15 exploration of metabolic pathways using this
16 particular isotope.

17 So it was E.O. Lawrence who used his
18 cyclotrons to bombard molybdenum-98 with deuterons.
19 And he thought that he might have created element 42,
20 which at the time was a glaring gap in Mendeleev's
21 Periodic Table. It was Emilio Segre who, in 1937,
22 worked with Lawrence's material and confirmed that it
23 really was element 42. He called it technetium,
24 because it didn't exist in nature. It was a
25 technological product of man.

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1 And I'd mention that he won his Nobel
2 Prize for discovery of the antiproton, because I
3 thought he got his Nobel Prize for the discovery of
4 technetium.

5 Interestingly, the brother of Earnest O.
6 Lawrence was John Lawrence, who I guess was a
7 radiation oncologist, but maybe not called that at the
8 time. He developed and administered procedures using
9 radioisotopes that were made by his brother's
10 cyclotrons.

11 For example, in 1936, he treated a 28-year
12 old leukemia patient using P-32 that was made in E.O.
13 Lawrence's cyclotrons, and some mark this as the first
14 time a radioisotope was used in the treatment of
15 disease, and, thus, the birth of nuclear medicine. So
16 this might be considered a historical milestone.

17 Shortly afterwards, it was learned that
18 iodine-131 accumulated in the thyroid, and I-131 could
19 be used to study abnormal thyroid metabolism in
20 patients with hyperthyroidism and goiter. And in
21 patients who had thyroid cancer, distant metastases
22 could be identified through scanning a patient after
23 administration of iodine-131.

24 So the term "radioisotope scanning" came
25 into use. Atomic medicine was the name for this

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1 burgeoning field. And, again, all of these procedures
2 involved isotopes that are now considered reactor-
3 produced isotopes. But none of them were available
4 through reactors at that time.

5 It wasn't until 1941 that the first
6 medical cyclotron was installed at Washington
7 University in St. Louis. And because of the interest
8 in this particular branch of medicine, it became
9 obvious that cyclotron capacity was not going to be
10 able to meet the demands, and civilian use of a
11 military nuclear reactor provided relief.

12 So picking up on what Dr. Fisher told us
13 before about the Manhattan Project, there was an
14 unprecedented expansion of radiation research,
15 expertise, and medical applications thanks to this
16 endeavor and for the first time radioisotopes actually
17 became relatively abundant. And most isotopes became
18 to be produced in nuclear reactors following World
19 War II.

20 Interestingly, in the United States, all
21 of this was kept under the secrecy of the Manhattan
22 Project. And to protect the secrecy, some absurdities
23 took place such as P-32 being produced at Oak Ridge
24 and then shipped to Berkeley, so that it looked like
25 it was coming from the University of California.

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1 The shortage of isotopes ended, by and
2 large, in 1945 when isotopes became widely available,
3 including reactor-produced isotope I-121 from Oak
4 Ridge. However, globally, particle accelerators
5 continued to provide the vast majority of isotopes for
6 medical applications until the 1950s.

7 So now, over a half a century later, one
8 has to ask, have alternatives to reactor-produced
9 isotopes evolved? And how much have they evolved in
10 this 50-year span?

11 So let me talk generally about means of
12 producing medical isotopes. The predominant method of
13 generating moly-99, and the only method that is used
14 for North American moly-99 at present is fission of U-
15 235. This is an n, f reaction. The fission involves
16 highly enriched uranium, as I mentioned before, by
17 thermal neutrons in a reactor, and this highly
18 enriched uranium is of weapons grade. It's not just
19 slightly above 20 percent. This is about 95 percent
20 U-235.

21 Roughly six percent of the total fission
22 yield is moly-99, and it is relatively pure. It is
23 relatively carrier-free, high specific activity
24 product.

25 It is possible to use low enriched uranium

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1 in a reactor, and you have heard about various
2 proposed solutions that use LEU, but that would
3 require a five times increased neutron flux, because
4 of the five time lower abundance of U-235. Perhaps
5 denser uranium foil targets would help in this regard,
6 but the proportion of undesirable fission products
7 might increase, and there could be modifications
8 necessary to the present chemical purification
9 processes that would require new FDA regulatory
10 approvals.

11 B&W and others are investigating novel
12 reactor concepts, such as the liquid LEU solution, for
13 fuel and for target. However, some have argued that
14 LEU is not going to prove to be a long-term practical
15 solution, because of the expense and the political
16 difficulties surrounding building new reactors.

17 So what are some alternatives to the
18 conventional methods, to the concept that has been
19 around for half a century? Well, photofission
20 represents one. Photofission can be used with either
21 U-235 or U-238 in a gamma f reaction, and
22 molybdenum-99 is produced. More molybdenum is
23 generated with U-235, and for either reaction, again,
24 just as in conventional fission from a reactor, six
25 percent of the yield is moly-99.

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1 However, the cross-section is relatively
2 low, and, thus, a high electron beam power is required
3 to make significant amounts of moly-99 through this
4 procedure.

5 Another alternative that is being explored
6 is accelerated -- accelerator-driven neutron sources.
7 So U-235 might undergo fission through a neutron that
8 is produced in an accelerator rather than a nuclear
9 reactor. Similarly, these neutrons could be used to
10 -- used for an n, gamma reaction involving moly-98 to
11 produce molybdenum-99.

12 Neutron capture, by enriched moly-98,
13 which incidentally constitutes approximately 24
14 percent of natural molybdenum, is the most common
15 alternative to U-235 fission right now. And this is
16 the way that one might be able to get around the need
17 for uranium targets. Again, the reactor is an n,
18 gamma reaction involving moly-98, converting it to
19 moly-99.

20 There are other non-molybdenum -- non-
21 uranium solutions that are being explored, such as
22 photoneutron reaction, gamma-n reaction, using
23 molybdenum-100.

24 Another possible neutron reaction is using
25 molybdenum-100 in an n-2n reaction, to convert

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1 molybdenum 100 to moly-99. This would employ a high
2 energy 14 MeV neutron, and this reaction does have a
3 high cross-section compared to the moly-98 n, gamma
4 reaction. But it yields a similar low specific
5 activity product.

6 Some other alternatives to neutrons
7 include a p-pn reaction involving moly-100. A proton-
8 driven reaction has been investigated. Some argue
9 that it has a relatively low cross-section, and the
10 literature is divided on this. It's interesting to
11 see the scientific debate about this. We'll have to
12 see which team is correct. But a consensus is that
13 whether it has a low cross-section or not, the
14 specific activity is not going to be high.

15 Molybdenum-100 can undergo a d-p2n
16 reaction to become moly-99. This has a high cross-
17 section, but requires very high-energy beams. So
18 there is a disadvantage there.

19 A solution that has been talked about is
20 bombarding enriched moly-100 with protons from a
21 cyclotron and directly producing technetium-99m in a
22 p, 2n reaction. So this has a large cross-section,
23 and it might work but would not be a practical
24 solution for the global shortage. It could be a
25 solution for a local metropolitan area that happens to

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1 have the technology and the need.

2 So I happened to resign from the
3 University of Wisconsin recently and learned that in
4 Madison a new and exciting technology has been
5 proposed and is being investigated, to commemorate my
6 departure I suppose.

7 (Laughter)

8 This I found to be quite fascinating. I
9 am indebted to Greg Pfeiffer for some of these slides
10 from his Phoenix Nuclear Labs organization.

11 The Morgridge Institute for Research at
12 University of Wisconsin has worked with this new
13 organization, Phoenix Nuclear, to develop what they
14 hope will be reactor-grade medical isotopes without
15 using a nuclear reactor. It employs two key aspects,
16 neutrons created by a D-T source, which is nuclear
17 fusion, and neutrons from this fusion that enter
18 aqueous low enriched uranium solution where they
19 multiply subcritically and create medical isotopes
20 through the traditional fission of uranium-235.

21 So this single device could possibly
22 produce nationally relevant quantities of molybdenum-
23 99, if it goes according to plan.

24 There are a couple of acronyms that are
25 related to this technology. SHINE is Subcritical

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1 Hybrid Intense Neutron Emitter. The hybrid refers to
2 the fusion/fission concept. And FLAME, Fusion Linear
3 Accelerator for Medicine technology, is another
4 acronym. It seems that this technology might be
5 capable of producing a high flux of neutrons, which
6 would be important for its success.

7 Basically, deuterium gas will flow into an
8 ion source, get ionized, and a DC accelerator will
9 push these ions toward the target chamber. The
10 accelerated deuterons will strike tritium, gaseous
11 phase, in the target chamber and undergo fusion,
12 creating neutrons.

13 The high efficiency supposedly has already
14 been demonstrated with greater than two times 10^9
15 neutrons per second per watt. The high-energy
16 neutrons allow for n-2n multiplication on beryllium.
17 And the only products of this part of the procedure
18 are neutrons and helium-4.

19 I'm not going to go through these
20 specifications, but I list the physical parameters
21 here and the operational parameters here, including --
22 that should say 10^{13} neutrons per second rather than
23 that typo there.

24 I won't burden you with the details here.
25 And, again, I have the physical parameters here. And

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1 the weight is approximately 20 tons in total. The
2 safety is supposedly ensured by being subcritical,
3 with the criticality monitored by in-core neutron
4 detectors. There is a negative power coefficient,
5 neutron poisons could be added to slow down the
6 reactions if the criticality exceeds what is expected,
7 and a dump tank is available if reactivity exceeds
8 safety thresholds.

9 Some key parameters include fission power
10 of 250 kilowatts, and the moly-99 production, which is
11 the bottom line here, is 2,500 six-day curies per
12 week. There shouldn't be a K there. Which happens to
13 be about 50 percent of the current U.S. demand. So if
14 this goes according to plan, they could be able to
15 produce up to 50 percent of the needs through this
16 technology.

17 Some of the benefits include absence of
18 criticality and supposedly greater safety, lack of
19 instability demonstrated with previous aqueous --
20 might be present with previous aqueous reactor
21 systems, reduced nuclear waste. Since there is no
22 true nuclear reactor, it uses low enriched uranium,
23 just barely at 19.5 percent. The aqueous process
24 should improve chemical extraction efficiency and may
25 be a simplified regulatory approval process, although

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1 that is -- that remains to be seen.

2 So as of the summer -- this past summer,
3 Phoenix Nuclear and Morgridge Institute and the
4 University of Wisconsin were seeking a Department of
5 energy grant to assist with their construction. I'm
6 not sure what the outcome is. Several partners, big
7 name partners, have been secured in negotiations, and
8 the goal is to commercialize this SHINE process by the
9 beginning of 2014.

10 So this is one of several interesting,
11 very exciting, hopefully fruitful new solutions that
12 are being proposed for the isotope shortage. But with
13 new solutions come new challenges for the NRC in terms
14 of licensing.

15 Thank you very much.

16 ACTING CHAIRMAN THOMADSEN: Thank you, Dr.
17 Welsh.

18 Dr. Van Decker.

19 MEMBER VAN DECKER: A comment and then a
20 couple of questions. My first comment would be, Dr.
21 Welsh, nine slides labeled "Brief History of Nuclear
22 Medicine" does not fulfill my North Jersey definition
23 of "brief."

24 (Laughter)

25 Having said that, you know, I think your

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1 last two pages are actually of the most interest to be
2 talked about here, and they, in my mind, take us back
3 to the question from one of the Commissioners this
4 morning when he asked, "Do you" -- or -- yes, he
5 asked, "Do you believe there is enough incentive on
6 the table for something to really happen and kind of
7 fix the problem for the end stage users here, which is
8 really hurting?"

9 You know, and in my mind -- you know, in
10 my mind, incentivization is three-fold in this
11 process. It is incentivization, are we going to go a
12 new way from what we have been before, in which case
13 that is research incentivization. And if that's the
14 case, how many models are on the table? How possible
15 are all of them? And how many are we going to fund
16 DOE-wise on a research incentivization basis to get
17 there? So that's one piece.

18 The second piece, which is what Dr. Hall
19 tried to address this morning, was on a cost per unit
20 basis is there enough in these things for these places
21 to keep themselves going once you have something in
22 place. And that depends on where our marketplace is
23 right now.

24 And then, the third piece of this
25 incentivization, which I thought Dr. Hall was going to

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1 say this morning, which he didn't, was obviously
2 regularly disincentivization. You know, a lot of
3 these vendors have been concerned that if the
4 government doesn't have some skin in the game here
5 there will be some regulatory glitch and they will
6 have, you know, a concrete or maybe a small concrete
7 Maple that is not going anywhere because of any of a
8 number of problems that come up.

9 So, you know, there is all three of those.
10 I guess your presentation kind of goes to the first of
11 those, and that's the research incentivization. And I
12 was just looking for your thoughts on how you think --
13 because societies are obviously going to write letters
14 and try to, you know, make some push here to have
15 something happen. Do you think that we should be --
16 that this process in your mind is better than some of
17 the other processes out there that will also be
18 looking for DOE funding?

19 I mean, I note that, you know, in your
20 list of present status people, you know, Covidien and
21 B&W are obviously missing for all the obvious reasons.
22 What kind of competitive mix do we want here to have a
23 competitive marketplace versus having at least a
24 stable marketplace where everyone is together and has
25 a source? How do you see that playing out in your

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1 mind?

2 MEMBER WELSH: That's a very important set
3 of questions, and I like the way you broke down the
4 concept of incentive into three subcategories. So in
5 terms of research interest, in terms of the pure
6 intellectual stimulation, this process is great. It's
7 something fresh, it's different, and very innovative.
8 So I think that compared to some of the other
9 competing technologies that are being offered this is
10 very appealing.

11 As far as the economic aspects and the
12 financial incentives, this suffers the same
13 difficulties that all of the solutions will suffer,
14 which is at the proposed reimbursements it could be
15 very difficult to make a profit, and, therefore,
16 companies that are looking to generate profits will
17 shy away from this particular area, whether it's the
18 older technology, reactor-based solutions, or
19 innovative solutions such as this.

20 I have no idea how expensive this will be.
21 I have a feeling that it's going to be quite costly to
22 come up with all of the innovations necessary to make
23 this successful. So it could be challenging from an
24 economic perspective.

25 From a regulatory perspective, one of the

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1 slides offered by Dr. Pfieffer says that there is a
2 simplified regulatory approval process. I don't
3 understand that myself, and that's a question for NRC
4 staff. And I don't have the answer to that, but I
5 appreciate the question about the three aspects of
6 incentive.

7 And I don't see how this is going to be
8 very economically viable, but I think that it's
9 important. I think that it's fascinating from a
10 scientific and research perspective, and remains to be
11 seen if this is going to be simple or a nightmare from
12 a regulatory perspective.

13 ACTING CHAIRMAN THOMADSEN: Dr. Suleiman?

14 MEMBER SULEIMAN: Let me clarify one thing
15 when you mentioned FDA regulatory responsibilities. I
16 got involved with this issue several years ago when
17 there were rumors that FDA was going to really be a
18 regulatory bottleneck in this molybdenum shortage.
19 And I will spare you the details, but basically the --
20 there was a National Academy of Sciences report that
21 there was conflict, because I basically said, "We
22 don't think it's a big issue," and some of our critics
23 said, "This may take several years to get through the
24 FDA drug approval process."

25 And bottom line was when we finally

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1 reviewed certain aspects of this production we -- we
2 cleared those things in six days, so I felt validated.
3 I argued this point. There is a tremendous amount of
4 misinformation out there. Some of it is done for
5 political reasons, or whatever, but FDA's role is
6 basically the -- making sure that the drug quality and
7 purity, which is the technetium, all right, the
8 molybdenum is upstream. It's a raw material, it
9 transmutes.

10 We -- the manufacturer needs to be aware,
11 just like any other raw material in a final product,
12 but we focus on the drug quality and purity. And the
13 raw materials -- we have some concerns. We address
14 them. And the regulatory issue that comes up is what
15 is known as a drug master file. That is the secret
16 ingredients for Coke.

17 So how the manufacturer produces the moly
18 can be considered -- is considered proprietary. And
19 so they can share that information with us, and that's
20 basically the extent of it. But if there is a problem
21 with the drug quality and purity, obviously we may
22 want to know what is going on upstream, but that --
23 that role was blown way out of proportion.

24 Some other things that I have had the
25 opportunity -- because of that, a lot of companies

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1 have come to our door, and so we have been exposed to
2 some of these interesting, you know, approaches which
3 are all in the public literature. But for economic
4 reasons, I've got to clarify -- the radionuclidic cost
5 of a radiolabeled drug is small. The drug portion is
6 what costs a lot.

7 And I think there was a meeting earlier
8 this week at NIST where also the scanners and the
9 health care people who are reading these scans, those
10 are the big costs. So in terms of the overall cost,
11 the price of the nuclide could double or triple and it
12 is not going to have a major impact.

13 It is a free market competition out there.
14 There are also some costs associated with the waste
15 stream, and some of these technologies really reduce
16 the regulatory burden in terms of radioactive waste.

17 The last thing I want to throw out, which
18 I observed and people sort of mention it periodically,
19 but it has to do with the U.S. strategic policy in
20 terms of eliminating highly enriched uranium with low
21 enriched uranium. You mentioned it in your talk that
22 you would have to use five times as much concentrated
23 to deliver the same yield.

24 The flip side is if you go from HEU to LEU
25 you are going to reduce your output in these reactors,

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1 or whatever, by 80 percent. So if this strategy is
2 adopted, you know, somewhere down the future, the
3 shortage that we saw now is nothing, because all --
4 most of the targets, until recently, have all been
5 highly enriched uranium.

6 So there is a complex interplay here where
7 strategic nuclear nonproliferation issues are having
8 an impact on potential, you know, production costs.
9 But I think there are an awful lot of opportunities
10 out there. And I don't know how it is going to turn
11 out, but I wanted to clarify --

12 ACTING CHAIRMAN THOMADSEN: Dr. Fisher.

13 MEMBER SULEIMAN: -- our regulatory
14 bottleneck.

15 MEMBER FISHER: Yes. We don't have all
16 the information, but all of the new proposals for
17 producing moly-99 from whatever process are extremely
18 expensive compared to what we have currently been
19 anticipating from Canada from -- and, remember, the
20 moly-99 from Canada actually has two suppliers. There
21 is the reactor operated by Atomic Energy of Canada,
22 Limited.

23 Then, there is the processor, which is MDS
24 Nordion. The second -- the processing is the
25 profitable side of the business. The reactor

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1 production, using highly enriched uranium, has always
2 been a money loser for the Canadian government. It
3 has been heavily subsidized, and the great fear is --
4 from those who know is that if you -- if you change
5 the targets, as Orhan has suggested, the losses just
6 mount, the costs go up.

7 The Canadian government built two new
8 reactors, Maple 1 and Maple 2, but they didn't license
9 them for various reasons. They -- Maple 1 has
10 operated safely at about 50 percent power for many,
11 many months, and it is really very possible that they
12 could still resurrect both those reactors.

13 There is an enormous -- there is two
14 lawsuits against -- from MDS Nordion against the
15 Canadian government, and it -- and against the
16 operator of the reactor that -- or the entity AECL
17 Canada that built the Maple 1 and Maple 2. Those are
18 multi-billion dollar lawsuits still pending.

19 In my assessment, and I spent a lot of
20 time up in Canada looking at the situation, the big
21 risks are in the cost of production and the cost of
22 processing. They are two separate costs. And
23 personally I haven't seen any solutions to the supply
24 issue.

25 Incidentally, just as a footnote, out in

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1 my neighborhood we had a pretty good reactor ready to
2 go to make moly-99. That was the Fast Flux Test
3 Facility, 400-megawatt thermal modern reactor. But it
4 was essentially killed six years ago, and the main
5 reason was that Maple 1 and Maple 2 were coming
6 online. And no one could see how this reactor could
7 possibly pay for itself with 100 percent of the
8 world's supply coming from Maple 1 and Maple 2.

9 So there was a joint decision of the
10 Democrats and Republicans, up to the level of the Vice
11 President, and they drilled the core and destroyed
12 that facility, not thinking that it -- thinking they
13 were saving some money, and that it wouldn't be
14 needed. So terrible decision.

15 I mean, all of the U.S. moly-99 -- in
16 fact, the entire world need for moly-99 could have
17 been met with the Fast Flux Test Facility. It is not
18 an option any longer, and it was very frustrating, as
19 we look at the history, the need, the costs, and,
20 frankly, I just want to throw my hands up in the air.
21 I don't know what the ultimate solution is.

22 NRU reactor won't operate past 2014.
23 Well, maybe it should, you know? We just don't have
24 any other options at the moment in the foreseeable
25 future. So, yes, everything that Jim Welsh said is

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1 correct, and the other comments have been correct. It
2 is a very, very difficult long-term problem.

3 ACTING CHAIRMAN THOMADSEN: Dr. Zelac.

4 DR. ZELAC: Just a quick comment,
5 particularly since we just were hearing about Canada.
6 There was a news announcement that came out today that
7 the Canadian government, the federal government, has
8 approved four separate facilities for the production
9 of moly-99, all of them -- none of them reactor
10 related. And the funding for them will be negotiated
11 by the end of this year. One of them does in fact
12 involve moly-100 and the gamma, n reaction, with
13 accelerators.

14 ACTING CHAIRMAN THOMADSEN: Mr.
15 Mattmuller.

16 MEMBER MATTMULLER: Yes, a couple of
17 questions. In part of this slide they call it
18 neutrons in an aqueous LEU solution where they
19 multiply subcritically and create medical isotopes.
20 And that is fission of U-235.

21 So, in essence, to me I look at this in
22 simplistic terms. This is like a low power version of
23 what B&W are proposing with their AHR. So, in
24 essence, their target module is really an AHR reactor
25 with subcritical fission going on with U-235. So they

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1 are still going to have, sadly, issues in processing
2 the U-235 to pull out the moly-99 in a pure form that
3 can then be used in a technetium generator.

4 And I guess -- and I'm sad Rob had to
5 leave, but -- so I'll pick on Chris. Has the NRC seen
6 this technology? Have they been in to talk to you
7 folks as far as how would you regulate, or what would
8 you call this, and how -- do you have the license
9 category that could cover it?

10 MR. EINBERG: What I'll do is I'll defer
11 to Donna-Beth Howe. She is on the Moly Working Group
12 for the agency, and perhaps she can tell us if she has
13 seen this technology or not.

14 DR. HOWE: I don't know if I can answer
15 that question. We have talked to the -- most of the
16 groups that have cooperative agreements with DOE.
17 This group just recently got a cooperative agreement
18 with DOE. The funding is nowhere near the funding for
19 B&W or for GE Health Care.

20 Part of the issues in here, and I think
21 Jim Luehman alluded to it, is that there may be some
22 cross-boundary regulatory aspects between agreement
23 states and NRC state. But in some cases, even though
24 it is in an agreement state, it also may be an NRC
25 licensee, because if it's a Part 50 production

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1 facility it will be an NRC licensee regardless of
2 where it's located.

3 If it is an activity that includes over a
4 certain amount of special nuclear material, it will
5 also be an NRC licensee regardless of where it is
6 located. I believe this particular one comes into a
7 Part 70 type of thing. And so I will say that in
8 general terms we have a working group that Mary Jane
9 Ross-Lee talked about today, and it crosses across all
10 offices at the NRC.

11 We have individuals that routinely work
12 with special nuclear material in the Office of NMSS
13 that are on the working team and will look at issues
14 that are associated with non-reactors. This would be
15 a non-reactor. We have people from the Research
16 Reactor Group, and so they would be looking at the
17 small reactors. And we've got other folks and people
18 in Research that will be looking at all of the issues
19 that are associated.

20 So we've got a very diverse team that is
21 looking at this, and we are also encouraging all
22 individuals that believe they are going to be
23 regulated by NRC or an agreement state to come in and
24 talk to us early and get their regulatory issues
25 answered.

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1 And we have issued a number of public
2 letters to individuals that have come in -- B&W,
3 Coqui, which is a conventional research type reactor
4 to make molybdenum with LEU targets. I don't know if
5 that answers your question.

6 ACTING CHAIRMAN THOMADSEN: Any other
7 comments?

8 (No response.)

9 Thank you, Dr. Welsh.

10 Ms. Cockerham has some announcements for
11 us before we adjourn for today.

12 MS. COCKERHAM: I do. If everyone can
13 take off your nametags and leave them on the table for
14 tomorrow, I would appreciate it. And then, if you
15 have a badge that they gave you down at the security
16 desk that is like the proxy card, please give that
17 back to them when you leave today. It won't work
18 tomorrow, so you will have to pick up a new one
19 tomorrow whenever you come in.

20 The other thing is, you'll see like a
21 little bound colored -- it's the task force reports
22 that we passed out earlier. That's what Rob referred
23 to in his opening comments this morning, or this
24 afternoon, that deals with blood irradiators along
25 with a lot of other security type things.

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1 So that is yours to keep. You can have
2 it. And the last thing is I think several of you have
3 requested copies of the slides from this morning's
4 Commission briefing. I sent everyone an e-mail on
5 Monday, and it has a link to our public website. And
6 all of the slides are included there -- your slides,
7 staff, and the stakeholders.

8 So there are electronic versions that you
9 have in your e-mail box. Check for Monday. And if
10 you want a hard copy -- does everyone want hard
11 copies, or just a few people? I have them here. So
12 if you want to stop by whenever you are done, we're
13 done, you can come get this.

14 ACTING CHAIRMAN THOMADSEN: Okay. In that
15 case, we will be standing adjourned. Tomorrow morning
16 at 8:00 we have a closed session. We meet here,
17 though, at that time.

18 MS. COCKERHAM: Yes.

19 ACTING CHAIRMAN THOMADSEN: Very fine.
20 (Whereupon, at 5:52 p.m., the proceedings in the
21 foregoing matter were adjourned.)
22
23
24

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