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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
(ACMUI)

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MONDAY,

MAY 24, 2010

ROCKVILLE, MARYLAND

The Advisory Committee convened at the Nuclear
Regulatory Commission, Two White Flint North, Room
T2B1, 11545 Rockville Pike, at 10:00 a.m., Bruce
Thomadsen, Acting Chair, presiding.

COMMITTEE MEMBERS PRESENT:

BRUCE THOMADSEN	Vice Chairman
	Therapy Physicist
DARRELL FISHER	Patients' Rights Advocate
DEBBIE GILLEY	State Government
MILTON GUIBERTEAU	Diagnostic Radiologist
	Representative
SUE LANGHORST	Radiation Safety Officer
STEVE MATTMULLER	Nuclear Pharmacist
ORHAN SULEIMAN	US Food & Drug Admin. (FDA)
WILLIAM VAN DECKER	Nuclear Cardiologist
JAMES WELSH	Radiation Oncologist

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1 PAT ZANZONICO Nuclear Medicine Physicist

2

3 NRC STAFF PRESENT:

4 ROB LEWIS Division Director

5 CHRIS EINBERG Designated Federal Officer

6 MIKE FULLER Alt. Designated Federal Officer

7 ASHLEY COCKERHAM ACMUI Project Manager

8 MARK BANKS

9 NEELAM BHALLA

10 KATHRYN BROCK

11 CATHY COLLELI

12 KERSTUN DAY

13 MARC FERDAS

14 JAMES FIRTH

15 CINDY FLANNERY

16 SANDY GABRIEL

17 ROBERT HAYS (via teleconference)

18 MIKE HERR (via teleconference)

19 MERRI HORN

20 DONNA-BETH HOWE

21 VARUGHESE KURIAN

22 ED LOHR

23 JOSE MACATANGAY (via teleconference)

24 ANGELA McINTOSH

25 KEVIN NIETMANN

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1 STAFF MEMBERS PRESENT (CONTINUED):

2 KEVIN NULL (via teleconference)

3 PATTY PELKE

4 MARY JANE ROSS-LEE

5 LEEA SREENIVAS

6 GLENDA VILLAMAR (via teleconference)

7 JENNY WEIL

8 RONALD ZELAC

9
10 ALSO PRESENT:

11 MELISSA ALLEN General Electric Hitachi

12 Nuclear Energy

13 CURTIS ANDERSON Mele Associates

14 ROY BROWN CORAR

15 JANET BUKOVCAN MDS Nordion

16 PETER CRANE Unknown Affiliation

17 WILL DAVIDSON (via teleconference)

18 University of Pennsylvania

19 KAREN LANGLEY (via teleconference)

20 University of Utah

21 RICHARD MARTIN ASTRO

22 MICHAEL PETERS ACR

23 DOUG PFEIFFER AAPM

24 AMANDA POTTER AAPM

1 ALSO PRESENT (CONTINUED) :

2 LOUIS POTTERS North Shore University Hospital
3 and Long Island Jewish Medical
4 Center

5 JANET SCHLUETER NEI

6 CINDY TOMLINSON SNM

7 JENNA WILKES ASNC

8 GARY WILLIAMS VA NHPP

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P R O C E E D I N G S

(10:00 a.m.)

VICE CHAIR THOMADSEN: We are going to call the meeting to order. I am Bruce Thomadsen. I will be chairing the meeting today, standing in for our Chair, Dr. Malmud with knee surgery. And I know that I will not be doing anywhere near the job that he can and ask your forbearance on that.

Darrell, would you like to say a word?

MEMBER FISHER: Yes, the Committee would like to send an acknowledgment to Dr. Malmud that we miss him today and we wish him the best with his knee replacement. And so we'll be circulating a get well card later in the meeting for members to sign.

VICE CHAIR THOMADSEN: Very good. And with that, I will turn the microphone over to Mr. Lewis.

MR. LEWIS: No, you won't.

VICE CHAIR THOMADSEN: I won't. Okay. Already I've gotten off to a bad start.

MR. LEWIS: As the Designated Official, Chris has to read our standard opening.

VICE CHAIR THOMADSEN: Oh, I'm sorry. Mr. Einberg.

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1 MR. EINBERG: Thank you, Dr. Thomadsen.

2 As the Designated Federal Officer for this
3 meeting, I'm pleased to welcome you to this
4 teleconference public meeting of the Advisory
5 Committee on the Medical Uses of Isotopes. My name is
6 Chris Einberg. I am the Chief of the Radioactive
7 Materials Safety Branch. And I have designated -- and
8 I have been designated as the Federal Officer for this
9 Advisory Committee in accordance with 10 CFR Part
10 7.11.

11 Present today as the alternate Designated
12 Federal Officer is Mike Fuller, who is the Team Leader
13 for the Medical Radiation Safety Team. Mike, can you
14 stand up please?

15 This is an announced meeting of the
16 Committee that is being held in accordance with the
17 rules and regulations of the Federal Advisory
18 Committee Act and the Nuclear Regulatory Commission.
19 The meeting was announced on April 21st, 2010 edition
20 of the Federal Register, in Volume 75, page 20869.

21 The function of the Committee is to advise
22 the staff on issues and questions that arise on the
23 medical uses of byproduct material. The Committee
24 provides counsel to the staff but does not determine
25 or direct that actual decisions of the staff or the

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1 Commission. The NRC solicits the views of the
2 Committee and values their opinions.

3 I request that whenever possible we try to
4 reach consensus on the procedural issues that we
5 discuss today. But I also recognize that there may be
6 a minority or dissenting opinions. If you have such
7 opinions, please allow them to be read into the
8 record.

9 At this point, I would like to perform a
10 roll call of the ACMUI members participating today.

11 Dr. Thomadsen?

12 VICE CHAIR THOMADSEN: Here.

13 MR. EINBERG: Dr. Darrell Fisher:

14 MEMBER FISHER: Here.

15 MR. EINBERG: Ms. Debbie Gilley?

16 MEMBER GILLEY: Here.

17 MR. EINBERG: Dr. Sue Langhorst?

18 MEMBER LANGHORST: Here.

19 MR. EINBERG: Mr. Steve Mattmuller?

20 MR. MATTMULLER: Here.

21 MR. EINBERG: Dr. Orhan Suleiman:

22 MEMBER SULEIMAN: Here.

23 MR. EINBERG: Dr. William Van Decker?

24 MEMBER VAN DECKER: Here.

25 MR. EINBERG: Dr. James Welsh?

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1 MEMBER WELSH: Here.

2 MR. EINBERG: And Dr. Pat Zanzonico?

3 MEMBER ZANZONICO: Here.

4 MR. EINBERG: And as previously noted, Dr.
5 Malmud will not be in attendance due to health issues.

6 Dr. Mickey Guiberteau is representing the
7 diagnostic radiologists. And there he is. Okay.

8 Dr. Guiberteau does not have voting
9 privileges but he will speak on behalf of the
10 diagnostic radiologists. And I would like to thank
11 him for acting in this capacity.

12 I now ask that the NRC staff members who
13 are present identify themselves. And I'll start with
14 the individuals in the room here. And then we'll turn
15 it over to the NRC staff members in the regions and on
16 the phone.

17 MS. COCKERHAM: This is Ashley Cockerham
18 with the NRC.

19 MR. FULLER: Mike Fuller, NRC.

20 MS. GABRIEL: Sandy Gabriel, NRC.

21 DR. ZELAC: Ronald Zelac, NRC.

22 MR. FERDES: Marc Ferdes, Region I Branch
23 Chief there.

24 MS. PELKE: Patti Pelke from Region III.

25 MS. BHALLA: Leelam Bhalla from

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1 Headquarters.

2 MR. EINBERG: Okay. Thank you.

3 MR. LOHR: Ed Lohr from Headquarters.

4 MR. KURIAN: Varughese Kurian from
5 Headquarters.

6 MS. SREENIVAS: Leela Sreenivas,
7 Headquarters, NRC.

8 MS. MCINTOSH: Angela McIntosh,
9 Headquarters.

10 MR. EINBERG: Okay. On the phone, is
11 there any other Headquarters staff on the phone?

12 MS. VILLAMAR: Glenda Villamar, NRC.

13 MR. EINBERG: Thank you.

14 Region I? They be on mute. We'll come
15 back to them.

16 Region III?

17 MR. NULL: Kevin Null in Region III.

18 MR. HAYS: Robert Hays, Region III.

19 MR. HERR: Mike Herr, Region III.

20 MR. MACATANGAY: Jose Macatangay, Region
21 III.

22 MR. EINBERG: Okay. Thank you. Region
23 IV?

24 (No response.)

25 MR. EINBERG: Okay. No participation from

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1 Region IV?

2 Did Region I come on the the line again?

3 (No response.)

4 MR. EINBERG: Okay. Anybody else from the
5 NRC on the line?

6 (No response.)

7 MR. EINBERG: Okay. Thank you.

8 Next we will identify members of the
9 public who are participating on the phone. Can you,
10 members of the public, Ashley, do you go through a
11 roll call on the members of the public? Or how do you
12 do that?

13 MS. COCKERHAM: Yes, I can do that.

14 Okay, is Bob Dansro on the phone?

15 (No response.)

16 MS. COCKERHAM: Will Davidson?

17 MR. DAVIDSON: Here.

18 MS. COCKERHAM: Joe Rogers?

19 (No response.)

20 MS. COCKERHAM: Steven Sutliff?

21 (No response.)

22 MS. COCKERHAM: Sandy Wolfe?

23 (No response.)

24 MS. COCKERHAM: Are there any other
25 members of the public that are on the phone if I

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1 didn't call your name?

2 MS. LANGLEY: Yes, Karen Langley.

3 MR. EINBERG: That's it, Ashley? Okay.
4 Thank you.

5 Since Dr. Malmud, the ACMUI Chairperson,
6 is unable to attend today's meeting, Dr. Thomadsen
7 will chair the meeting in his capacity as the Vice
8 Chairperson.

9 Following a discussion of each agenda
10 item, the Chair, at his option, may entertain comments
11 or questions from members of the public who are
12 participating with us today.

13 At this point, I would like to turn the
14 meeting over to Rob Lewis.

15 MR. LEWIS: Thank you, Chris.

16 Welcome back to Rockville everyone. And
17 it is good to see you all again. Particularly today I
18 would like to welcome two new members of the ACMUI.
19 The first is Dr. Pat Zanzonico, who is our new medical
20 physicist.

21 And we also have selected Dr. John Suh
22 from Cleveland Clinic as our new radiation oncologist.
23 And he brings with him a lot of gamma knife
24 experience. But we just made the selection within the
25 last few weeks. And he was unable to rearrange his

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1 schedule to be at the meeting today. But we will look
2 forward to working with him.

3 Also I would like to announce within the
4 NRC staff we have had, since the last meeting, a few
5 personnel changes.

6 Cindy Flannery, who you all know as our
7 medical team leader has moved on to the rulemaking
8 group for career broadening. And we thank Cindy for
9 all her work and her whole work with the Committee and
10 on medical issues in general. It was under her team
11 leadership that our role and relationships became a
12 lot clearer and stronger.

13 And in that regard, we have selected Mike
14 Fuller, who is over at the table on the side, to take
15 over the medical team leader duties. He comes to us
16 from the Division of Waste Management. And he will be
17 working with the Committee as we move forward as well
18 as the professional societies. And we'll get him out
19 to meet all of the key players in the near future.

20 Thank you, Dr. Thomadsen, for chairing the
21 meeting today and tomorrow.

22 We do have two vacancies on the Committee
23 as well. We have a vacant nuclear medicine physician
24 position, with is Dr. Eggli's -- the position that Dr.
25 Eggli vacated. We have a vacant diagnostic

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1 radiologist position, which is a new position added to
2 the Committee.

3 And we have done -- internally we've done
4 our paperwork and we're ready to make selections.
5 We're just going through the internal approval
6 process. And I'm sure -- famous last words -- but I'm
7 sure within the next month or so, we'll have both of
8 those positions resolved and we'll have a full
9 Committee again. So we're very looking forward to
10 that.

11 We had recently the FSME annual program
12 brief to the Commission on May 11th. Unlike past FSME
13 program briefs, this one had a particular focus on
14 medical issues. I would encourage all of the
15 Committee members or any interested members of the
16 public to review that meeting transcript or the
17 webcast, which is on the NRC public website.

18 There was a lot of discussion, as I said,
19 of medical. So it gives the status and the challenges
20 that we see before us as the NRC staff. And there was
21 a lot of discussion during the Q&A period,
22 particularly the Commission seems very interested to
23 engage the Committee, this Committee in more
24 meaningful ways. So that's welcome to us. And we
25 will accommodate the Commission in that regard. We'd

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1 be very happy to do that.

2 We do believe that the Commission will add
3 a meeting this year with the ACMUI to the fall
4 Commission meeting. So hopefully we can try to
5 coordinate the fall ACMUI meeting and the fall
6 Commission meeting so that the entire Committee can be
7 present or at least a big portion of the Committee.

8 Also this week we have another Committee
9 meeting, the Agency Action-Review Meeting. This is
10 another annual meeting that the Commission holds with
11 the NRC staff to talk about events within the last
12 year that have significant implications for health and
13 safety or for NRC's programs.

14 One of the events that will be discussed
15 in this year's AARM meeting Thursday morning is the
16 events of the Veterans Administration Philadelphia
17 Medical Center Implant Brachytherapy over the last
18 several years.

19 So the Veterans Administration has been
20 asked to the Commission briefing and deliver a
21 statement in that regard. And the NRC staff will do
22 the same on separate panels. So that may be a meeting
23 that is of great interest to the Committee to watch or
24 to get the transcript after.

25 We have a lot on the agenda today. We'll

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1 start in the morning with rulemaking status. We're
2 very close on long rulemaking that has been of long
3 interest to the Committee, which is Part 35, Medical
4 Events Definitions rule. That rule was put on hold,
5 if you will, pending our look into the VA issues and
6 events.

7 There are other rules as well. A new Part
8 35 coming after that. The rule is complete.

9 We have updates on medical isotopes
10 shortages right after lunch.

11 And we have patient-release issues right
12 before lunch. I'm sorry I skipped over that part of
13 the agenda. So we look forward to a meaningful
14 discussion on patient-release issues, which is
15 something that the Committee hasn't discussed recently
16 but was a topic of many previous ACMUI meetings in the
17 past.

18 Tomorrow we have some updates and some
19 topical issues to be presented by various Committee
20 members.

21 Since the last ACMUI meeting, there have
22 been several developments in the medical area, most
23 notably we have completed our enforcement action for
24 the Veterans Administration in Philadelphia and the
25 events that occurred there in prostate implant

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1 brachytherapy.

2 We issued a civil penalty of over 200,000
3 dollars to the VA as well as our Notice to Violation.

4 We also have had in major media outlets a
5 series of articles on medical events, primarily
6 focused on machine-produced radiation but some of them
7 include areas within the NRC's purview involving
8 byproduct material.

9 We are closely following those events and
10 working closely with the FDA and the conference
11 radiation program directors as we move forward on what
12 will be done at a federal and at a state level to take
13 a look at how machine-produced regulation is regulated
14 and how events are tracked.

15 And with that, I think my opening
16 statement is concluded. I would welcome, if the Chair
17 will permit, I will welcome at this time any questions
18 about general NRC issues on any topic if the Committee
19 would like to ask at this time.

20 VICE CHAIR THOMADSEN: Thank you, Mr.
21 Lewis.

22 Any questions for Mr. Lewis?

23 (No response.)

24 VICE CHAIR THOMADSEN: Okay. Thank you
25 very much.

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1 MR. LEWIS: Thank you.

2 VICE CHAIR THOMADSEN: And now we have a
3 review of old business by Ms. Cockerham.

4 MS. COCKERHAM: Okay. If everyone wants
5 to turn in their binders to Tab 3, I believe, there
6 should be a list of Excel sheets. I'm just going to
7 go through each item pretty quickly.

8 For items -- I'm on the 2007 ACMUI
9 recommendations and action items. For items 2, 3, 6,
10 7, and 8, all of those things are in future
11 rulemaking, which we expect to begin later this
12 summer.

13 For the next item, it's the same thing.
14 We do expect to pursue rulemaking on this summer. But
15 I would note there is a second piece of that
16 recommendation that is regarding a regulatory issue
17 summary. And that document is still in concurrence.

18 Everything else on the rest of this list
19 is also to be included during the 2010 rulemaking that
20 will commence this summer.

21 Are there any questions on the 2007
22 recommendations?

23 VICE CHAIR THOMADSEN: Please go to the
24 microphone and identify yourself.

25 MR. CRANE: Yes. My name is Peter Crane,

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1 I'm NRC retired. It's just that for those of us who
2 are not on the inside, we don't see the -- we don't
3 have the document that you are referring to. So I
4 don't know what the recommendations are.

5 And if you wouldn't mind, if it's not too
6 lengthy, running over them for the benefit for those
7 of us who don't know what they are.

8 MS. COCKERHAM: All of the handouts are
9 available in the back of the room for the members of
10 the public.

11 MR. CRANE: I'm sorry. Thanks, Ashley.

12 MS. COCKERHAM: Does that meet your needs?
13 Okay.

14 We'll go ahead and go to the 2008 ones.

15 VICE CHAIR THOMADSEN: Please proceed.

16 MS. COCKERHAM: Okay. So for 2008, for
17 items 2 and 5, these are also in the future
18 rulemaking, which will begin this summer.

19 For item 9, this is something that
20 actually we've already given the information to the
21 Office of Research. And they will take the ACMUI's
22 recommendation along with those from NRR, from the
23 reactor side of things. And they will be doing a full
24 look at the abnormal occurrence criteria. So we
25 expect for them to start looking at that in November.

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1 So maybe later this year we'll have another update on
2 that.

3 For item 19, this item is included in the
4 current rulemaking, which is on hold as Rob mentioned
5 earlier.

6 For item 22, this item is still partially
7 accepted. I think the idea is that we do eventually
8 plan to put the yttrium-90 microspheres guidance into
9 rulemaking space. However, as you all know, I'm
10 currently working on a revision to that guidance. So
11 since we're still rolling through revisions on the
12 guidance, I think we would like to wait to put that
13 into rulemaking at a later date.

14 For item 25, this is an item, I believe on
15 your sheet it says accepted. If you want to scratch
16 that out and change that to not accepted, we're
17 actually not pursuing rulemaking on this. We found
18 that there was not a need to.

19 The regions -- we had a discussion in a
20 meeting where the regions determined that the gamma
21 knife units can be put on a separate license, which
22 would cause them not to trigger this criteria, which
23 was the issue of why we pursued the rulemaking. So
24 there is no need for rulemaking. So there's no need
25 for rulemaking. So it's not that -- that's why it's

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1 not accepted. Does that make sense? Are there any
2 questions on that?

3 (No response.)

4 MS. COCKERHAM: It's no longer a problem.
5 So we don't need to fix something that doesn't need
6 fixing. Okay?

7 For item 26 and 27, both of these items
8 are included in the current rulemaking, which is on
9 hold.

10 For item 28, if you want to change -- I
11 believe it says pending on your sheets. Change that
12 to accepted. We are including this in the future
13 rulemaking. So it will begin later this year.

14 For items 29 and 30, again, they will be
15 included in the summer 2010 rulemaking.

16 Any questions on the 2008 recommendations?

17 MR. LEWIS: Since there's new members,
18 Ashley, just let me clarify that when we say accepted,
19 the NRC staff may or may not agree with the
20 Committee's recommendation. But we will enter into
21 the rulemaking process and let it play out.

22 MEMBER SULEIMAN: I have a question on 22.
23 Did the NRC have any idea which section they wanted to
24 move the yttrium-90?

25 MS. COCKERHAM: I don't think we're

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1 looking at that at this point. I'm still trying to
2 get a revision out to get interventional radiologists
3 included as authorized users.

4 MEMBER SULEIMAN: Okay.

5 MS. COCKERHAM: But it is something we
6 definitely look at in the future. For now, I'm
7 focused on getting the guidance out.

8 MEMBER SULEIMAN: Well, I'm glad because I
9 thought maybe it got ahead of us because I thought
10 maybe you guys had already made a decision.

11 MS. COCKERHAM: No. There's absolutely no
12 change on this. I just -- more than anything, I'm
13 working on the guidance. But since the guidance is
14 still evolving and I've done, I believe, four
15 revisions in the past three years, I think that
16 everyone knows that wouldn't really play out very well
17 in rulemaking space.

18 Anything else on 2008?

19 (No response.)

20 MS. COCKERHAM: If not, we'll move on to
21 2009. I think we were just talking about. This is
22 the -- item number 1 is the recommendation to revise
23 the yttrium-90 microspheres guidance to include
24 interventional radiologists. That draft -- it is in
25 concurrence. We're working on it and I hope to have

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1 it out very soon. And I know very soon is not always
2 very soon in the real world but it's very soon in the
3 NRC world. So be on the lookout for that.

4 For item 2, that is included in the future
5 rulemaking that will begin in summer 2010.

6 And then item 3, this is actually
7 superseded by item 10. So I'm just going to close out
8 this item even though it says open on the list.

9 And item 10 is accepted and it will be
10 included in the summer 2010 rulemaking.

11 MEMBER GILLEY: Ashley, are you taking
12 into consideration in your regulatory guidance the
13 changes in the sealed source and device registry for
14 Sirtex?

15 MS. COCKERHAM: I don't believe it
16 affected our guidance. But we did look at that, yes.
17 And I know what you're talking about.

18 MEMBER GUIBERTEAU: I apologize. But I
19 have a question on item 25 on the 2007.

20 MS. COCKERHAM: Okay.

21 MEMBER GUIBERTEAU: It says NRC staff
22 should revise the current regulations to include
23 Canadian-trained individuals who have passed the ABNM
24 certification examination. Will this be specific to
25 the ABNM? Or will this be open to comment by other

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1 NRC-approved specialty boards who also certify
2 Canadians?

3 MS. COCKERHAM: I will look to either Ron
4 Zelac or Donna-Beth Howe or if Glenda is on the phone
5 and wants to answer -- anyone?

6 DR. ZELAC: I'm sorry. Could you ask the
7 question again please?

8 MEMBER GUIBERTEAU: Item 25 is specific to
9 the American Board of Nuclear Medicine. But there are
10 other NRC-approved boards' certification processes
11 that also are open to Canadians who are appropriately
12 trained.

13 And my question is will this be -- will
14 this discussion be open during the rulemaking to
15 explain this if, you know, it is appropriate to these
16 other boards?

17 DR. ZELAC: I think the straight answer is
18 yes.

19 MEMBER GUIBERTEAU: Okay. Thank you.

20 MS. COCKERHAM: Okay. Any other questions
21 on the recommendations that are on these sheets?

22 (No response.)

23 MS. COCKERHAM: If not, I have one more
24 update. I believe the issue of electronic signatures
25 came up prior to the creation of these Excel sheets.

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1 It may have been 2005 or 2006.

2 And just so everyone knows, we are working
3 to -- we would like to publish a Federal Register
4 notice similar to what they did for the cesium
5 chloride where they solicited for public input very
6 early in the process before rulemaking was ever
7 started. But kind of using the rulemaking forum or
8 the tools that we have for rulemaking.

9 So we are looking in the near future to
10 publish a Federal Register notice that is asking for
11 public input on electronic signatures and how the NRC
12 could best look at that to address the issue because
13 we realize that the hospitals are moving that
14 direction.

15 So it is something we're looking at doing.
16 And anything else to add to that, Chris?

17 MR. EINBERG: No.

18 MS. COCKERHAM: No?

19 MR. EINBERG: No.

20 MS. COCKERHAM: I think that's it. So
21 that will be coming out. And it will be for public
22 comment hopefully this summer. You never know.

23 VICE CHAIR THOMADSEN: Okay. Fine. Any
24 other questions for Ms. Cockerham?

25 (No response.)

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1 MS. COCKERHAM: Thank you.

2 VICE CHAIR THOMADSEN: Thank you.

3 We now move to the current status -- the
4 status of current and future rulemaking by E. Lohr.

5 MR. LOHR: Good morning. My name is Ed
6 Lohr. And with me is my colleague, Neelam Bhalla.
7 We're from the Division of Intergovernmental Liaison
8 and Rulemaking, Branch B, which is part of the Office
9 of the Federal and State Materials and Environmental
10 Management Programs.

11 This morning we want to give you, the
12 ACMUI, an update of what the status are in the current
13 Part 35 rulemakings. Currently we have two things in
14 rulemaking that we're undertaking, one that is active,
15 and one that is about to begin: the medical event
16 definitions proposed rule and then we haven't really
17 given a title to our next Part 35, we just call it the
18 big rule at this point.

19 First I want to talk about the Part 35
20 medical event definitions proposed rule. A little
21 background, first of all, I am the actual project
22 manager for that.

23 The rulemaking would change most of the
24 criterion that we currently have in regulation to
25 determine if a medical event has occurred from a dose-

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1 based activity to an activity-based for determining
2 for permanent implant brachytherapy.

3 It would also clarify that the written
4 directive requirements are for permanent implant
5 brachytherapy and there is a proposal to add a new
6 requirement to report as a medical event when a
7 written directive is not prepared when required.

8 We actually put together this rule and we
9 published it in the Federal Register on August 6th,
10 2008. We had a 75-day comment period and this
11 Committee asked us to extend that for 18 days, which
12 we did. It closed then on November 7th, 2008.

13 During the summer and fall of 2008, as you
14 all know, a large number of medical events were
15 reported to the NRC and caused us to reevaluate the
16 proposed rule language. Based on the public comments
17 we received and the analysis of the circumstances and
18 the data from the large number of reported medical
19 events, the staff revised the proposed rule
20 significantly.

21 Based on the changes that we made to the
22 proposed rule, we've gone back to the Commission to
23 ask to re-notice or re-propose the rule to the public.
24 The Commission currently has the staff recommendations
25 and we're waiting for directions from the Commission

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1 at this point.

2 So Ashley's comment and I believe Rob's is
3 it's on hold is not really true. We're actually just
4 waiting for guidance or direction, if you will, from
5 the Commission on whether to proceed with re-proposing
6 the rule.

7 Next slide please. Our next Part 35
8 rulemaking, what we call the big one, as Ashley was
9 reading off the items earlier, you can see that we
10 have a lot of things to work on in this new rule.
11 It's based on the implementation experience basically
12 that the NRC has had since the 2002 major revision to
13 Part 35. And there's numerous changes that have been
14 proposed to be in this rulemaking.

15 All these changes have been brought to
16 this Committee and discussions and such have been
17 provided back to the NRC staff. And, of course, we
18 will see that in the rulemaking arena as well.

19 Major pieces are the Ritenour Petition and
20 the preceptor attestation requirements that has been
21 directed by the Commission for the staff to consider
22 in this rulemaking. But there's numerous other
23 pieces, as Ashley has pointed out to you.

24 We're scheduled to begin this summer. A
25 working group will be formed just as our normal

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1 process is. We hope to have a proposed rule out on
2 the street, if you will, by March of 2012. And then
3 hopefully to bring this to a final rule by September
4 of 2013.

5 Now this is a little longer than our
6 normal process but again, because there's so many
7 pieces to this, we, in rulemaking, are going to take a
8 little longer to get this out. This schedule has been
9 approved by the Commission.

10 And at this point, I'll open it up to any
11 questions that you might have.

12 VICE CHAIR THOMADSEN: Are there
13 questions? Yes?

14 MEMBER LANGHORST: Hi. Sue Langhorst.
15 You were saying on the current Part 35 rulemaking that
16 you will be taking this to the Commission. What are
17 the choices if they -- what are the choices that you
18 are presenting to them? Whether you propose it to --

19 MR. LOHR: What we have -- we, the staff,
20 we've recommended to the Commission that we re-propose
21 the rule for public comment again, for another 60-day
22 period, because it is significantly different than
23 what the public has seen on the initial rule that we
24 published in August of 2008.

25 MEMBER LANGHORST: I would certainly

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1 encourage that because of the great changes in it.

2 MR. LOHR: Right.

3 MEMBER LANGHORST: But would it be that
4 they could say no, you should publish it?

5 MR. LOHR: Well I can't speak for the
6 Commission, ma'am. They are our bosses. If they tell
7 us to republish it, we will do so. If they tell us
8 not to, we will not do so. But that is the staff
9 recommendation.

10 MEMBER LANGHORST: Okay. Thank you.

11 VICE CHAIR THOMADSEN: Very good.

12 Ms. Gilley?

13 MEMBER GILLEY: If you do get the
14 Commission's blessing on republishing it for 60 days,
15 what is the new timeline for implementation?

16 MR. LOHR: Please don't hold me to it. If
17 we are given permission to republish it by the
18 Commission, we hope to have a final rule to the
19 Commission for their consideration by December of this
20 year.

21 MEMBER GILLEY: And the next step?

22 MR. LOHR: And the next step after that
23 is, of course, the Commission then decides whether or
24 not they want us to publish the rule. And will tell
25 us so. Or they may tell us to change pieces of it.

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1 They have many, many options.

2 MR. LEWIS: The final rule.

3 MEMBER GILLEY: I kind of was looking for
4 when it would be completed -- the process be
5 completed?

6 MR. LOHR: I can't speak for the
7 Commission. There are no timelines on how long they
8 take to make those determinations.

9 MEMBER GILLEY: Thank you.

10 VICE CHAIR THOMADSEN: Other questions?
11 Hearing none -- oh, I'm sorry, Dr. Van Decker?

12 MEMBER VAN DECKER: Just the one question
13 that is always on my mind since Debbie asked about
14 timelines. And then timeline after the NRC went
15 through something like this, timeline for the states
16 with something like this.

17 MEMBER GILLEY: The states have three
18 years after NRC passes it to put it into rule. It
19 would depend on the compatibility level also but I
20 think this is Compatibility B so we would have to
21 adopt it as is within three years of NRC's effective
22 date.

23 MR. LEWIS: Barring a safety issue.

24 MEMBER VAN DECKER: Fine.

25 VICE CHAIR THOMADSEN: Other questions?

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1 (No response.)

2 VICE CHAIR THOMADSEN: Well, hearing none,
3 thank you very much. Appreciate the update.

4 MR. LOHR: Sir?

5 VICE CHAIR THOMADSEN: Yes.

6 MR. LOHR: One of my colleagues, Merri
7 Horne, is she here?

8 VICE CHAIR THOMADSEN: Yes.

9 MR. LOHR: She has a brief update on the
10 Part 37.

11 VICE CHAIR THOMADSEN: Very good.

12 MS. HORN: You all had asked for just a
13 quick update. The Commission has recently approved
14 the Part 37 proposed rule for publication. So I would
15 expect that it would be published sometime within the
16 first two weeks of June.

17 We've made the Commission-directed changes
18 to that. And it going through our process to actually
19 get signature and then to the OFR for actual
20 publication. So within the next couple of weeks we
21 should be seeing that.

22 It is 120-day public comment period so it
23 is a little bit longer than what we normally have.
24 It's a very large rule. It's almost 200 pages long.
25 So it is a very large rule.

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1 Because of the 120 days, we will be very
2 unlikely to extend the comment period beyond that.

3 We're also working on guidance document
4 that will be available for public comment during the
5 same time period or within the same time frame. It's
6 not going to be the exact same days.

7 But that document is nearing completion.
8 And there will be a couple of public meetings that
9 will be held on the guidance document. We have not
10 determined the exact dates and locations for those.
11 One of them will very likely be here in the D.C. area.
12 And the other one it is still undetermined. But we
13 will be noticing those and making the decisions on
14 those in the next couple of weeks.

15 Any questions? Yes, sir?

16 MEMBER SULEIMAN: You were commenting
17 about? Part 37?

18 MS. HORN: Part 37, it is the new security
19 requirements.

20 MEMBER SULEIMAN: Oh, okay, okay.

21 VICE CHAIR THOMADSEN: Any other
22 questions?

23 (No response.)

24 VICE CHAIR THOMADSEN: Thank you very
25 much.

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1 Ms. Howe, we now have an update on the
2 patient release.

3 PARTICIPANT: Did you have a question?

4 MR. EINBERG: Dr. Thomadsen, before we get
5 started with Dr. Howe's presentation, can member of
6 the public hear? I see that some people are straining
7 to hear a little bit?

8 (Chorus of not well.)

9 MR. EINBERG: Not well? Can the audio
10 visual staff please turn the volume up in the audience
11 section please? Testing, can you hear now? Is this
12 any better? Okay.

13 DR. HOWE: Next slide. This is just to
14 bring you up to date with where we are on patient
15 release, especially involving iodine 131.

16 As a general background for those of you
17 who are new to the ACMUI, in May of 1997, the NRC
18 issued a new patient release regulation that is dose-
19 based. And we essentially allow people to be released
20 if the patient -- if the dose from a patient to the
21 most likely person to be exposed is below a certain
22 level. Prior to that we had a 30 millicurie or 5 mR
23 per hour at a meter limit.

24 In September of 2005, we received a
25 petition for rulemaking from Peter Crane. And it was,

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1 among other things, to go back to the previous
2 activity-based regulation criteria. And it also
3 raised issues of dose to children and pregnant women.

4 And then in May of 2008, NRC denied the
5 petition but we did develop guidance and we issued a
6 IS that put that guidance out in front of the public
7 that essentially was in -- that agreed with the ICRP
8 recommendations that you need to take special concerns
9 with children and we provided that guidance in the
10 RIS.

11 And then in October of 2009 and January of
12 2010, we had two letters from Congressman Markey to
13 the NRC that asked specific questions about patient
14 release. Did the NRC want to go back and look at its
15 patient release rule over again? Were we in
16 conformance with the ICRP's and the NCRP rules?

17 NRC consistently responded in those
18 letters' responses that we felt our patient release
19 rule was adequate to protect public health and safety.
20 And that if patients were given guidance and written
21 directions and oral directions, then the probability
22 that a member of the public would be exposed in excess
23 of 500 millirem was very low.

24 Next. Okay. This is the patient release
25 requirements, just to refresh everyone. Patients can

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1 be released if a dose to any other individual from
2 exposure to the released patient is not likely to
3 exceed 5 millisieverts, 500 millirem, the patient or
4 patient's parent or guardian is provided with
5 instructions, including written instructions, so you
6 can have both oral and written, on actions recommended
7 to maintain doses to other individuals as low as
8 reasonably achievable if the total dose is going to
9 exceed one millisievert, 100 millirem.

10 And the licensee has to maintain a record
11 of the basis for authorizing the release. That record
12 could include a statement that you are following the
13 NCRP, NUREG-1556, Appendix U, or it could be specific
14 calculations for that individual patient, or it could
15 be calculations based on a group of patients, of which
16 this patient meets the same criteria as the other
17 patients.

18 So there are a number of different ways
19 that licensees can approach this requirement in the
20 records that they keep. And then we will inspect
21 those records during inspection. Okay?

22 Next. We've been looking carefully over
23 the years at the NCRP Report 155 and also the IAEA
24 Safety Series Report #63 and the ICRP Publication 94.
25 All of these documents seem to be going towards a

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1 dose-based release criteria. The actual limit on the
2 dose release criteria varies between countries. And
3 the Safety Report Series 63 is the basis, I believe,
4 for the IAEA to develop a new document that will
5 essentially supersede its current activity-based
6 because it is leaning towards the dose-based release
7 criteria.

8 And what are we doing now? Next slide.
9 Right now based on previous commitments, we are -- in
10 this case this slide says we are reviewing the need
11 for guidance. But we're actually developing guidance
12 relating the release of I-131 patients other than the
13 normal place of their residence. And so that's in the
14 process right now.

15 Are there any questions?

16 VICE CHAIR THOMADSEN: Any questions or
17 comments from the Committee? Pat Zanzonico?

18 MEMBER ZANZONICO: You emphasized or
19 specifically refer to I-131 therapies. Are these
20 rules and guidance and so forth intended to be applied
21 to other radionuclide therapies which are becoming
22 more common in practice?

23 DR. HOWE: The guidance that we've
24 developed so far has been specific to I-131.

25 MEMBER ZANZONICO: And specifically for

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1 thyroid cancer or hypothyroidism? Or, for example, I-
2 131 antibody therapy of cancer as well?

3 DR. HOWE: I believe they have been
4 primarily focusing on the sodium iodide oral
5 administrations. We would have to look at other
6 cases.

7 MEMBER ZANZONICO: Thank you.

8 VICE CHAIR THOMADSEN: Thank you very
9 much.

10 Any other comments? Dr. Guiberteau?

11 MEMBER GUIBERTEAU: There was a statement
12 -- you mentioned the IAEA 63 --

13 DR. HOWE: Sixty-three?

14 MEMBER GUIBERTEAU: -- series. In
15 February of this year, they issued a statement
16 basically reiterating -- which was unusual but they
17 reiterated a statement which I believe came from Dr.
18 Madan Rehani's area. And it was a position statement
19 reiterating the release of patients after radionuclide
20 therapy specifically addressing I-131.

21 Do you have --

22 MR. FULLER: Excuse me. I'm sorry to
23 interrupt.

24 MEMBER GUIBERTEAU: Yes?

25 MR. FULLER: Dr. Guiberteau, could you

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1 please move the microphone a little bit closer to you?

2 MEMBER GUIBERTEAU: Oh, sure, I'm sorry.

3 MR. FULLER: Okay.

4 MEMBER GUIBERTEAU: Anyway do you have any
5 background as to why they took that step in terms or
6 reiterating this? Their policy? I know there are
7 issues within the EU in terms of some variation of
8 release requirements.

9 And I wondered if -- you know some of
10 these therapies becoming unavailable in certain
11 European countries to patients who are then traveling
12 elsewhere for their treatments, whether the
13 inaccessibility of therapy might have been a
14 motivation? Or do you have any background on this?

15 DR. HOWE: I do not have any background on
16 this.

17 MEMBER GUIBERTEAU: All right. Thank you.

18 MR. LEWIS: No, I think our key person is
19 not in the audience. So we could ask if any of the
20 NRC staff have some background.

21 I would mention that the IAEA also issued
22 a draft document for Member-State comment, which the
23 NRC subsequently shared widely for public comment
24 called the International Basic Safety Standards. And
25 that document also talks about patient release and

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1 takes the same position as far as I understand.

2 VICE CHAIR THOMADSEN: Dr. Suleiman?

3 MEMBER SULEIMAN: I was involved with the
4 IAEA in that statement that came out. And my sense of
5 the underlying concern was that the variability among
6 different countries in terms of release criteria was
7 concerning some of them because it was interfering
8 with the practice of medicine where patients were not
9 being given the full medical dose because -- where you
10 had an activity restriction. And the tendency was to
11 go ahead more with the risk-based dose-based release
12 criteria.

13 There are also other issues where some
14 countries, again, will actually hold the iodine so --
15 to let it decay like in a holding tank. And the
16 consensus was that probably would actually pose as
17 more of a risk because workers are exposed to the
18 holding tank whereas there is a whole lot less risk
19 when it actually is discharged through the public, you
20 know, system.

21 So everybody has slightly different
22 criteria. But there was concern, again, by some of
23 the countries that they couldn't do -- they couldn't
24 give the appropriate dose because of some of the
25 constraints imposed by some of the regulatory

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1 agencies.

2 I definitely had a sense that they were
3 leaning more toward how we do it here in the United
4 States. And that reflects in the different documents.

5 VICE CHAIR THOMADSEN: Dr. Welsh?

6 MEMBER WELSH: Jim Welsh. I'd like to
7 follow up on Dr. Zanzonico's comment about -- or
8 question regarding whether or not this new guidance
9 that is being developed is exclusively focusing on the
10 oral sodium iodide because if it is, I might suggest
11 that it be generalized to include the other iodine
12 131-based therapies so that the guidance can be
13 relatively generalized.

14 And there might be a question of whether
15 it should include all gamma-emitting isotopes as well.
16 But at least my suggestion might be to include other
17 iodine 131-based therapies.

18 DR. HOWE: Your comment is noted.

19 VICE CHAIR THOMADSEN: Other comments?

20 Please step to the microphone.

21 MR. CRANE: Thank you. And yes, please.
22 You mentioned --

23 VICE CHAIR THOMADSEN: Can you identify
24 yourself again.

25 MR. CRANE: I'm sorry, Peter Crane, ex-

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1 NRC, retired.

2 MR. FULLER: Excuse me.

3 MR. CRANE: Pardon me?

4 MR. FULLER: Can you turn that microphone
5 -- is it turned on?

6 MR. CRANE: Oh, that would help.

7 VICE CHAIR THOMADSEN: It's on.

8 MR. CRANE: Okay. Am I audible?

9 VICE CHAIR THOMADSEN: Yes.

10 MR. CRANE: Correct me if I'm wrong but I
11 think the earlier commitment you are referring to
12 would be a memo from the staff to Region I in June of
13 2008 that said that the release of patients to hotels
14 was a not-uncommon practice, that it was not forbidden
15 by the NRC's rules, and that the staff intended to
16 provide guidance covering this issue. Am I correct
17 that that is the commitment you are referring to?

18 DR. HOWE: That's the commitment.

19 MR. CRANE: Can you tell me why this lapse
20 of two years, given that we've had New York State --
21 or New York City issue warnings to doctors not to send
22 radioactive patients to hotels. Similar things from
23 Minnesota and Washington States.

24 What happened in the intervening two years
25 that you are getting this underway just now? Could

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1 you clarify that please?

2 DR. HOWE: I think I'll pass that off to
3 Chris.

4 MR. EINBERG: The commitment was -- the
5 memo that you refer to is correct. There was an
6 internal commitment made to provide guidance in this
7 area.

8 We were advised not to develop anything
9 until the -- I believe your petition for rulemaking
10 was addressed. And until that time, we put that on
11 hold until the guidance was developed -- or until we
12 could address that.

13 MR. CRANE: I don't understand how you
14 mean until it was addressed. It was addressed in May
15 of 2008. That's when it was addressed unless you are
16 referring to the lawsuit.

17 MR. EINBERG: That's what I'm referring
18 to.

19 MR. CRANE: Thank you very much.

20 VICE CHAIR THOMADSEN: Are there any other
21 comments?

22 MR. EINBERG: Excuse me?

23 VICE CHAIR THOMADSEN: Yes.

24 MR. EINBERG: Mr. Crane, did you want to
25 read a statement?

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1 MR. CRANE: Yes, please.

2 MR. EINBERG: This would be the time then.

3 MR. LEWIS: Well, for the benefit of the
4 members of the public, we had a request in advance
5 from Mr. Crane to read a statement into the record for
6 the meeting, which we will now hear. (See Appendix A
7 for complete written statement.)

8 MR. CRANE: I may skip bits for the sake
9 of speed.

10 I very much appreciate the opportunity to
11 address this Committee. I've read a great many
12 transcripts of the Committee's meetings and I see that
13 directness and candor are the norm. I will follow
14 that example today.

15 The issue before us involves safeguarding
16 American children from the risk of radiation-caused
17 cancer. And if any subject calls for plain speaking,
18 this is it.

19 I should introduce myself. I joined the
20 NRC ten weeks after it came into existence in 1975 as
21 the assistant to then Commissioner, later Chairman
22 Marc Rowden. I joined the Office of General Counsel
23 in 1977, retired in 1979.

24 I'll skip my resume. I've also been a
25 thyroid cancer patient for 37 years. During that

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1 time, I had seven treatments with iodine 131, two as
2 an outpatient, 29.9 millicuries to ablate the thyroid
3 remnant and five as an inpatient during a recurrence
4 of cancer that began about 20 years ago.

5 No one in this room, therefore, has more
6 reason than I to appreciate the value of I-131 and how
7 it imperative it is that we ensure an ample an
8 uninterrupted supply of it. We have, incidentally,
9 the representative of the Canadian company that
10 manufactures I-131. We're all dependent on her. She
11 has us on our knees.

12 But having children who were two and four
13 when my recurrence was diagnosed, I also have reason
14 to appreciate the special risks that go with its use.

15 Second, I wish to say that the NRC has
16 always had many fine, capable, and dedicated
17 employees. I was proud to have such people as
18 colleagues. And many are my friends today.

19 I served in the trenches with some of the
20 people here. Donna-Beth will remember when we were
21 the subject of letters from Carol Marcus denouncing us
22 in letters characterized by colorful adjectives. Dr.
23 Marcus wanted me fired and I think she wanted Donna-
24 Beth fired. No?

25 DR. HOWE: No, I don't think so.

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1 MR. CRANE: Unfunded. De-funded, that was
2 it. You could come to work. You just couldn't get
3 paid.

4 But the winner was Jim Lieberman. She
5 wanted him -- he was a senior lawyer, she wanted him
6 sent to a mental hospital. She told that to the
7 Commission. He taped that letter to his office door
8 in glee.

9 To summarize my views, briefly I believe
10 that the NRC's deregulation of I-131 treatments in
11 1997 will someday be seen as perhaps the most radical
12 and irresponsible of all deregulations ever made in
13 the health and safety area. It violated the
14 International Basic Safety Standards established by
15 the IAEA and other international groups, not that this
16 fact was even mentioned to the Commissioners in the
17 staff memorandum proposing the change.

18 The NRC disregarded warnings from New York
19 and several other states that I-131 was a special case
20 because of its extreme radiotoxicity. The NRC also
21 reversed fields on the danger of I-131 contamination
22 and the resultant internal dose whereas only a decade
23 earlier, in the 1985, 1986 major rulemaking, the NRC
24 had correctly explained that I-131 patients could
25 cause members of the public to receive both an

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1 external dose from proximity and an internal dose from
2 contamination.

3 The 1997 rule declared internal dose to be
4 negligible. The NRC would rediscover the danger of
5 internal dose in 2008, more than four years after a
6 report from the International Commission on Radiation
7 Protection highlighted the risk to children of
8 internal exposure from patients' radioactive saliva.

9 The rule change had several effects that
10 the NRC had not foreseen. One was that insurance
11 companies would refuse to pay for inpatient treatment
12 even when the patient's family situation required it.
13 The definitive source on that is the transcript of
14 this Committee's meeting in October 2007 in which Dr.
15 Malmud and Dr. Eggli described the difficulty or
16 impossibility of getting in-patient treatment for
17 patients.

18 A second was that this would require the
19 NRC to make a choice, either enforce the rule and
20 compel providers to give in-patient treatments for
21 which they might not be compensated by insurance or
22 quietly allow many providers to ignore the rule.
23 What is the result? People are often told flatly that
24 out-patient treatment is their only option.

25 Jim Luehmann of the NRC staff was present

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1 last October at the conference of the Thyroid Cancer
2 Survivors Association held in Danvers, Massachusetts
3 at which a young woman from Arizona said that she had
4 been sent home after receiving her dose, 125
5 millicuries although she had a six month old and a
6 three year old. It is hard, she said, to keep your
7 distance from children that age.

8 I hope I'm not damaging Jim Luehmann's
9 career when I say that the patients there very much
10 appreciated that he was listening to what they had to
11 say and that since then he has been helpful to
12 patients having difficulty with insurance companies in
13 securing in-patient coverage.

14 Jim was also forthright in saying that the
15 NRC's rules require an individualized calculation of
16 the likely dose received by family members. And that
17 if the dose exceeds 500 millirem, the patient must be
18 hospitalized, no two ways about it. That's somewhat
19 different from what I heard Donna-Beth say that there
20 were various ways that you could establish compliance
21 with the rule.

22 But the NRC has passed up multiple
23 opportunities to make that clear to the licensee
24 community, and the rule is being widely ignored. Jean
25 St. Germain of Sloan-Kettering told me that her

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1 institution is punctilious in performing these case-
2 specific calculations. And if the criterion isn't
3 met, the patient is hospitalized.

4 "Is that the norm?" I asked.

5 She replied with a firm, "No."

6 "What is the norm," I asked.

7 "Well, they give them some piece of
8 paper."

9 Another young woman who came up to the
10 speaker's lectern after Jim Luehmann's presentation in
11 Danvers volunteered that her hospital had advised her
12 to go to a hotel after receiving her outpatient dose.
13 And to have her husband pick her up there the
14 following day.

15 In the last couple of years, as you may
16 know, New York City, Minnesota, and Washington State
17 have all warned licensees not to send radioactive
18 patients to hotels. New York City pointed to the not
19 implausible worst-case scenario that a pregnant hotel
20 housekeeper gets a radiation dose to her baby's
21 thyroid from contamination left in the room.

22 While the NRC was considering my petition
23 for rulemaking, I and a number of other commenters
24 mentioned the issue of patients going to hotels while
25 radioactive. I described this as a, "medical and

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1 moral issue that the NRC cannot in conscience ignore."

2 I actually mentioned this issue in three
3 separate filings. Why this stress? Because I was
4 keenly aware of an NRC operating principle that you
5 won't find among the NRC's "Principles of Good
6 Regulation," but which will be familiar to anyone who
7 knows hoe the NRC staff operates. And that is if you
8 don't have a good answer, pretend you didn't hear the
9 question. I wanted to make sure that no one later
10 claimed not to have noticed the issue.

11 Do we want radioactive patients going to
12 hotels and contaminating bathrooms and bed sheets?
13 When Minnesota issued its warning on the subject, I
14 called a regulator there who told me that the state
15 was responding to an event in Illinois in which a
16 hotel room had to be taken out of service for an
17 extended period, several months he thought, until the
18 state could certify that it was acceptable for
19 occupancy. The bathroom, the bed, and the telephone
20 had all been contaminated.

21 Of course, patients could come to the
22 hotel equipped with cleaning implements and clean up
23 after themselves just as they would at home. But it's
24 a truism that nobody ever took a rental car to a car
25 wash. By the same token, it is not reasonable to

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1 expect that patients who have just had I-131 treatment
2 will be as scrupulous in cleaning a hotel toilet
3 before they check out as they would be with a toilet
4 that their children or spouse will be using. Add to
5 that the fact that thyroid cancer patients who have
6 been off their medications in preparation for
7 treatment are likely to be feeling exhausted and
8 depleted, and not necessarily in shape for scrubbing
9 out toilets and bathtubs.

10 But when the NRC denied my petition, it
11 didn't say word one about radioactive patients in
12 hotels, despite my efforts to make sure that the issue
13 was not evaded. And it is basic administrative law
14 that agencies are supposed to deal with significant
15 issues raised in the rulemaking petition.

16 When I took the agency to the U.S. Court
17 of Appeals for the Ninth Circuit, my strongest
18 argument, therefore, was that the NRC had failed to
19 address the hotel issue. And that the case should,
20 therefore, be remanded to the NRC within instructions
21 to deal with it.

22 The NRC's lawyers had a couple of answer
23 for that. One was that the Agency had thought that I
24 had "recanted" and dropped the issue, which was patent
25 nonsense. What I had done was to file what I titled a

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1 minor correction because writing from memory while out
2 of the country, I had given an incorrect source for
3 one patient's comment about a hospital that sent all
4 its patients to the same hotel.

5 But their weightier argument was, and I
6 quote from page 39 of the brief, "The NRC's rule does
7 not permit or encourage doctors to send treated
8 patients to hotels."

9 Well, what Chris Einberg told this meeting
10 earlier, which was that it was an NRC lawyer -- maybe
11 you could you identify which one -- who said not to
12 issue this guidance on patients to hotels until the
13 lawsuit was completed, that's, to me, a highly
14 troubling fact. It's not the Office of General
15 Counsel that I knew when I worked here. It's not the
16 Office of the Solicitor that I worked for for 21
17 years. And it's a sad day.

18 Well, the court did not reach the merits
19 of the case. It bought the NRC's argument that
20 because I was not currently in treatment with I-131 or
21 on the evidence likely to be in the foreseeable
22 future, I lacked standing to be in court at all. At
23 oral argument, one of the judges suggested that if a
24 case were to brought by a group, the standing problem
25 would go away. And that remains an option.

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1 Did the court avoid the merits because it
2 was made uneasy by the Government's assurance that the
3 problem of radioactive patients in hotels was my
4 invention? We'll never know.

5 And, as I said, we now know, thanks to
6 this document that was private and internal until it
7 was released in response from Congressman Markey, that
8 OGC, in the person of an Assistant General Counsel who
9 signed off on it in April, gave the exact opposite
10 advice to Region I in the spring of 2008. And
11 Congressman Markey has asked the Inspector General to
12 investigate.

13 Now there is a listserv on Yahoo on which
14 thousands of thyroid cancer patients ask questions
15 pertaining to their care. Typically they are new
16 patients looking for advice. And the old timers
17 supply the answers. Scores of questions come in every
18 day and no one who posts a question on this listserv
19 has the slightest motivation to lie.

20 Time and again you read postings from
21 patients with small children who have been told by
22 their doctors to go to a hotel for the first couple of
23 days. Sometimes patients will volunteer that they
24 have decided on their own to go to a hotel because
25 they are concerned about exposing their children.

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1 And you'll see these discussions in which
2 they say I'm sorry, if it is a choice between
3 protecting my child and a stranger's child, my child
4 comes first. And that's human nature.

5 The old timers invariably tell them not
6 to. They should be using a room that others will be
7 occupying or cleaning with no knowledge that it is
8 contaminated. What does it say about the NRC that
9 patients are having to get this advice from other
10 patients because the NRC itself has been resolutely
11 silent on the issue to this day?

12 Is there anyone in this room who wouldn't
13 have qualms about the idea of their young child or
14 grandchild staying in a hotel room vacated a few hours
15 earlier by a patient who had just spent several days
16 after swallowing 200 or 300 or 400 millicuries of
17 iodine 131.

18 My daughter, as a college student, changed
19 beds and cleaned toilets in a Seattle youth hostel.
20 Is there anyone here who would feel comfortable about
21 having their college-age daughter quite unknowingly
22 cleaning the toilet that had been used for several
23 days about the patient I just described? And if you
24 wouldn't wish this on your own child, you shouldn't
25 wish it on anyone else's either.

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1 Efforts have been made to enlighten the
2 NRC. The State of Illinois had written in 2001 that
3 just because the NRC didn't receive reports of such
4 overexposures didn't mean they weren't happening.
5 What Illinois didn't understand was that the
6 Commission, in order to buy peace with the licensee
7 community, had essentially washed its hands of medical
8 regulation and it did not want to be confronted with
9 the evidence of how unwise and irresponsible it had
10 been to do so.

11 One need only look at the vote sheets on a
12 2002 SECY paper by which the Commission rejected, on a
13 three to two vote, the proposal to require a report to
14 the NRC whenever a released patient caused a family
15 member or other member of the public to receive a
16 radiation dose ten times in excess of allowable
17 limits. They are highly illuminating.

18 Chairman Meserve, writing in dissent, made
19 two irrefutable points. First, the Commission was
20 acting without hearing from the public. It had heard
21 only one side of the debate, the licensees'. Second,
22 without a mechanism for reporting overexposures, the
23 Commission was depriving itself of the means of
24 knowing whether its regulations were doing the job.

25 Look at the three votes on the other side.

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1 One Commissioner says that to adopt this proposal
2 would reverse the recent improvement in the NRC's
3 relations with the medical licensee community. An
4 agency that is afraid of offending the entities it is
5 supposed to regulate is an agency in trouble.

6 Another says that since the NRC wouldn't
7 do anything with information about an overexposure if
8 it received it, there is no point in receiving it in
9 the first place. That second Commissioners point was
10 that the NRC had already made clear that it wouldn't
11 penalize a licensee because a released patient
12 overexposed a member of the public. But as Chairman
13 Meserve's comments implied, what the Commission might
14 have to do, if it learned that many members of the
15 public were being overexposed, was reconsider the
16 regulations. And since that was the Commission
17 majority was utterly unwilling to consider, it needed
18 to ensure it never received such reports.

19 So who is there, except for the outvoted
20 Dick Meserve, to make the point that protecting the
21 public from harm is supposed to be among the NRC's
22 priorities? Is it, perhaps, the Patient's Rights
23 Advocate on this Committee?

24 That position was created in the early
25 1990s because the Commission was concerned that the

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1 ACMUI was weighted heavily to the licensee side and
2 there was no one to function as a kind of ombudsman
3 for patients.

4 The first to hold the post was a nurse,
5 Judith Brown, and she did a fine and conscientious
6 job. For some, too good a job. When the staff was
7 first presenting its plan of deregulating I-131, and
8 making high-dose outpatient treatment possible, Don
9 Cool was explaining the psychological benefits this
10 would have for patients by allowing a speedy return to
11 their families.

12 Ms. Brown asked, as a point of
13 information, how patients felt physically after such a
14 treatment. Don couldn't answer the question, thus
15 illuminating the fact that the staff was purporting to
16 pass judgment on the psychological condition of
17 thyroid cancer patients when it had not troubled to
18 inform itself as to their physical condition.

19 Ms. Brown also made the sensible point
20 that the proposal meant relying on the altruism of
21 patients.

22 When Ms. Brown's term ended in 1997, she
23 was replaced as Patient's Rights Advocate by Nekita
24 Hobson, a longtime public relations office for General
25 Atomics who was not Executive Director of the National

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1 Association of Cancer Patients. The NACP, despite its
2 name, was, in fact, a 501(c)(4) lobbying group,
3 created in part to lobby for the proposed Ward Valley
4 radioactive waste dump in the Mojave Desert.

5 Two weeks before the midterm elections of
6 1998, in which Senator Barbara Boxer was running for
7 reelection, the NACP issued a statement accusing
8 Senator Boxer of having delayed for "many years,
9 perhaps decades, " the search for a cure for cancer
10 because of her opposition to Ward Valley.

11 The NACP newsletter, at that time edited
12 by Nekita Hobson, also boasted of having contacted
13 over a thousand Clinton-Gore donors to make similar
14 claims about what the Administration had done to harm
15 the interest of cancer patients.

16 When Ms. Hobson's terms was up, she was
17 replace by another NACP Executive Director, Robert
18 Schenter, and when he left to join a company selling
19 radioactive isotopes, he was replaced by his former
20 assistant at the NACP, Dr. Darrell Fisher, the current
21 holder of the Patient's Rights Advocate position.

22 I have nothing personal against Dr.
23 Fisher. I am assured by Dr. Carl Paperiello, whose
24 opinion I trust implicitly, that Dr. Fisher knows his
25 isotopes after a lifetime in the field. And I do not

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1 doubt for a moment that he is a valuable asset to this
2 Committee.

3 My objection is solely that the position
4 in which he serves on this Committee should not be
5 that of Patient's Rights Advocate. That position,
6 which for 13 years has been monopolized by people from
7 the isotope-producing community, should properly be
8 held by someone from the patient community.

9 I should say I must have hit a nerve in
10 describing the NACP as I did because after I wrote a
11 letter to the Commission on the subject, somebody went
12 back and not only changed the NACP website, they
13 changed an article from the NACP newsletter from 1998
14 describing the tax status of the organization. I had
15 foreseen something on that order so I printed it out
16 first so you can see the before and after.

17 So who today speaks for the patients, the
18 tens of thousands of patients treated with
19 radiopharmaceuticals every year?

20 There was an illuminating section of an
21 ACMUI transcript not long ago when the staff briefed
22 this Committee on the events at the Philadelphia VA
23 hospital and the members, for the first time, realized
24 the magnitude of the disaster. Chairman Malmud, to
25 his credit, was plainly anguished about the fate of

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1 the patients and he made the point that the Committee
2 members were, after all, human beings and knowing what
3 they now knew, could not ignore the patients. To
4 which I was going to say spoken like a mensch, Dr.
5 Malmud. And I'm sorry you're not here. I'd like to
6 thank you in person.

7 To this one of his colleagues countered
8 that this was "getting down into the weeds," His
9 point was that it was important that the public not be
10 frightened away from a beneficial technology.

11 It is an old, old story that people think
12 this way when mistakes occur that harm individuals but
13 reflect badly on institutions, organizations, or
14 professions. If you are the Army, and a football her
15 is killed by so-called friendly fire in Afghanistan,
16 it is easy to rationalize. It was a mistake. Nothing
17 will bring him back. And if we tell the truth about
18 what happened, it could cause people to lose
19 confidence in the Army, which would be bad both for
20 the Army and for the country.

21 Likewise, if you are a religious
22 institution and discover that someone in your employee
23 has molested a minor, you can come up with a similar
24 rationale for not calling the police.

25 When you decide that other interests take

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1 precedence over the human beings who are the victims
2 of mistakes or misdeed, it all too often winds up
3 backfiring because then the whole organization is seen
4 as corrupt rather than the individuals originally
5 responsible. Once trust is forfeited in this way, it
6 may be very difficult to regain it.

7 If the American public decides that it
8 cannot depend on the NRC to protect its veterans from
9 hideous medical mistakes, or its children from
10 exposure to carcinogenic radioisotopes, will it have
11 confidence in the agency's competence and integrity in
12 the licensing and regulation of new nuclear power
13 plants?

14 One need only look at the Securities and
15 Exchange Commission to see how a once-respected
16 federal agency can do incalculable and perhaps
17 irrevocable damage to its reputation, thereby inviting
18 Congress to step in with new and more stringent
19 controls.

20 Or look at the agency which is supposed to
21 regulate offshore drilling. Already the
22 Administration has announced plans to break it up.

23 In short, I would suggest that if the NRC
24 or this Committee thinks too much about fulfilling the
25 wishes of the professional organizations of the

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1 nuclear medicine practitioners and too little about
2 what is good for patients, it could well backfire.

3 I realize that there is scientific support
4 for the patient release rules to the extent that Dr.
5 Grigsby's study of 22 patients and their families,
6 published in the Journal of the American Medical
7 Association, can be said to constitute scientific
8 support. There are a few words dropped there in the
9 written text.

10 Twenty-two patients is hardly enough, I
11 would submit, to support a deregulation of massive
12 proportions that flies in the face of the consensus of
13 the international community. And I might interject at
14 this point that Donna-Beth mentioned in her recitation
15 that the NRC approach was consistent with the ICRP in
16 affording special protection to children and pregnant
17 mothers. ICRP 94 said that the dose limit should be
18 100 millirem, not 500 millirem, for children and
19 pregnant women. And that part of the recommendation
20 the NRC rejected. So we are not in synch with the
21 ICRP.

22 We're not in synch with the basic safety
23 standards of the IAEA, which call for a maximum of 30
24 millicuries for outpatient treatment. And as you
25 probably know, most of Europe thinks that 30

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1 millicuries is too lax a standard. It tends to be in
2 the neighborhood of 12 to 15 through much of the
3 European Union and it is eight millicuries in Germany.

4 I might add that Dr. Grigsby has also told
5 the NRC that he has treated over a thousand patients
6 with I-131 and never had a case of a patient vomiting.
7 Jim Luehmann will confirm that when I reported this to
8 a roomful of thyroid cancer patients last fall, they
9 erupted in laughter.

10 The NRC has issued regulatory guidance
11 that is supposed to help licensees determine who can
12 and cannot be released. Dr. Marcus has announced that
13 this guidance is not binding, far too conservative,
14 and should be ignored. If the NRC has yet dared to
15 contradict her, I am unaware of it.

16 In 1992, incidentally, Dr. Marcus was
17 writing to the Commission that the idea of giving 400
18 millicuries of I-131 on an outpatient basis was
19 "ludicrous," unless the patient was a hermit living in
20 the wilds. I gather she thinks otherwise today.

21 Anyone who reads the thyroid cancer
22 patients' listserv, as I do, knows that the safety
23 guidance that patients receive, if they receive it all
24 all, is all over the map. What has the NRC done, in
25 the 13 years that this rule has been in effect, to

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1 ensure that patients get appropriate and consistent
2 instructions about the precautions they should take to
3 protect their families and others? Precious little.

4 It has pointed to guidance jointly
5 prepared by the NRC and the Society for Nuclear
6 Medicine in 1987. To be sure, it said, that guidance
7 was prepared in the days of the 30 millicurie maximum
8 for released patients, but that was all right. Just
9 fill in the blanks appropriately. That kind of advice
10 is worthless.

11 It's like the old joke about how to sculpt
12 an elephant. Take a block of stone and remove
13 everything that doesn't look like an elephant. It
14 tells the doctor and the patient nothing. Why in 13
15 years couldn't the NRC come up with meaningful
16 guidance, something appropriate, for example, for the
17 woman sent home to her seven year old with more than
18 300 millicuries of I-131 in her system?

19 Is it because truly appropriate guidance
20 would include precautions so extensive that people
21 would realize that outpatient treatment might not be a
22 good idea under these circumstances? I do not know.

23 So what should be done now? I, myself,
24 have never claimed to have all the answers. A return
25 to the blanket 30 millicurie standard in every case

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1 might be over regulation. It might also, at this
2 point, be under regulation given that Europe has
3 already moved to more stringent standards based on the
4 data from Chernobyl on children's susceptibility to
5 radioiodine-induced cancer.

6 And I should add Donna-Beth said that my
7 petition of September 2005 asked for a return to the
8 30-millicurie standard. I amended that in January
9 2006 and said I don't have all the answers. There may
10 be intermediate measures. There may be other ways.
11 But we do need a rulemaking that looks at this whole
12 issue in an open, sensible, scientifically sound way
13 that doesn't come to it with a preordained conclusion.
14 That was what I asked for. And that was what I did
15 not get.

16 What we need at this point is a thorough
17 reexamination of the patient release issue, fair and
18 dispassionate, without a preordained outcome. Though
19 I have not seen his letter to Congressman Markey, I
20 understanding that Aubrey Godwin, a wise and deeply
21 experienced regulator who heads Arizona's program has
22 said that such a reexamination would be timely.

23 But whether the NRC itself is capable of
24 conducting this effort is doubtful given the record of
25 the past 15 or 20 years. It is not only that this

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1 would mean confronting the agency's grave mishandling
2 of the patient release issue. It is also that the
3 analysis might lead to the conclusion that the NRC has
4 failed irretrievably in the medical area and that
5 legislation is needed to transfer these
6 responsibilities to an agency better capable of
7 discharging them. But the latter question is beyond
8 the scope of our discussion today.

9 Once again I wish to thank Chair Malmud,
10 Acting Chairman Thomadsen, and the Committee for the
11 opportunity to speak here today. I'll sit down unless
12 anybody has a question to ask of me.

13 VICE CHAIR THOMADSEN: Does any of the
14 Committee have a question for Mr. Crane?

15 (No response.)

16 VICE CHAIR THOMADSEN: Thank you, Mr.
17 Crane.

18 MR. CRANE: Thank you, Dr. Thomadsen.

19 VICE CHAIR THOMADSEN: Comments from the
20 Committee? Dr. Fisher?

21 MEMBER FISHER: Dr. Thomadsen and members
22 of the Committee, I prepared a statement in response
23 to some of the comments of Mr. Peter Crane.

24 Since my appointment in 2007 as a member
25 of this Advisory Committee and in a series of letters

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1 to the NRC Commissioners and even to U.S. Senators and
2 members of Congress, Mr. Peter Crane wrote that I have
3 affiliated with or belonged to a lobbying organization
4 for the Ward Valley Nuclear Waste Site in the Mojave
5 Desert.

6 I would like to set the record straight.
7 I have never had any involvement with that
8 organization. Period.

9 During his illness and disability with
10 myasthenia gravis, between about 2005 and 2007, I
11 assisted my friend and neighbor, Dr. Robert Schenter,
12 with his responsibilities for cancer patient
13 education. Schenter was for that time National
14 Director of a 501(c)(3) charitable foundation called
15 the National Organization of Cancer Patients and also
16 a member of this Advisory Committee as its Patients'
17 Rights Advocate. However, I was never a member of the
18 National Organization of Cancer Patients.

19 I helped Dr. Schenter on a voluntary
20 basis, at his request, when he was too ill to follow
21 up with some of the many cancer patients who contacted
22 him for educational materials. As a child, I suffered
23 with polio myelitis and also had a bone tumor
24 successfully removed.

25 Since that time, I have felt a desire to

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1 help terminally ill patients of all ages. For that
2 reason, I also volunteer with the charitable
3 organization, the Fighting Children's Cancer
4 Foundation. I help select grants to medical centers
5 for cancer research funding. And I help identify
6 needy families of children with cancer for direct
7 financial assistance. I also visit our local hospital
8 on a regular basis to spend time with patients.

9 I have lost many close friends as well as
10 my best friend and his wife to cancer. Most received
11 radiation therapy and nuclear medicine imaging as part
12 of their treatment.

13 My advocacy for patient rights is
14 voluntary and compassionate and has no other ulterior
15 motive. I typically give two to four hours per week
16 in cancer patient education, counseling, and support
17 activities. I have never affiliated with any lobbying
18 organization or industry front organization. And Mr.
19 Crane's claims to that effect are false and
20 misleading.

21 I have spoken for and will continue to
22 represent patients and patients' rights as a member of
23 this Advisory Committee.

24 Thank you.

25 VICE CHAIR THOMADSEN: Thank you, Dr.

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1 Fisher.

2 Other comments from the -- yes?

3 MEMBER ZANZONICO: Pat Zanzonico. I just
4 wanted to make a number of comments in direct response
5 to Mr. Crane's statement.

6 I certainly can't address some of the
7 administrative or what I might characterize as
8 political issues. But I'd like to address some of the
9 scientific issues that were raised.

10 The first is to emphasize the recent
11 publication of NCRP Report Number 155, which although
12 it has some differences from the current NRC rules
13 regarding patient release following radionuclide
14 therapy, essentially endorses the dose-based release
15 criteria. And I, in the interest of full disclosure,
16 I was a member of that -- of the scientific committee
17 which authored NCRP Report Number 155. And, in
18 particular, was responsible for authoring the section
19 on release criteria.

20 And the point I'd like to emphasize, I
21 think Mr. Crane has stated or implied that the primary
22 rationale for dose-based release criteria are what
23 amount to convenience and savings in funds. And I
24 think it is exactly the opposite.

25 Dose-based release criteria are the ones

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1 that are most protective of public health because
2 activity-based criteria do not ensure that members of
3 the public will not be exposed to doses that exceed
4 the regulatory limits. Only by directly estimating
5 based on the best available scientific information
6 based on patient-specific measurements and
7 calculations can one make the best estimate of what
8 the projected dose is to individuals around therapy
9 patients may be.

10 And, in fact, patients treated for
11 hypothyroidism, who have a much longer effective or
12 biological halftime of iodine and could be related at
13 an activity considerably below a 30-millicurie limit,
14 could deliver a significantly higher dose to
15 individuals around them than would a cancer patient
16 treated on an outpatient basis receiving up to several
17 hundred millicuries of I-131.

18 So the issue of whether release criteria
19 should be based on an activity threshold or a dose
20 threshold seem to me it should be self-evident that it
21 should be a dose-based threshold. And a 500 millirem
22 limit is certainly, I think, more than adequate.

23 If we were to roll this back to 100
24 millirem, one would suggest that we should warn
25 everyone living in Denver, Colorado that they are at

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1 greater risk than everyone else in the country because
2 their natural background exposure due to being at an
3 elevation of one mile, the city of Denver being at an
4 elevation of one mile, gives them an additional 100
5 millirem of background exposure.

6 So I think the issue of rolling this back
7 to 100 millirem really is not scientifically well
8 founded. Now I will say that because of the NCRP's
9 dose recommendation limits to pregnant women and
10 children of 100 millirem, that that was the dose limit
11 used in NCRP Report Number 155 in terms of exposures
12 to those cohorts.

13 But I personally do not endorse or could
14 or would defend that dose limit. But I did want to
15 clarify that possible apparent contradiction.

16 The other point is that there is far more
17 extension literature than the Grigsby paper
18 documenting the lack of dose, both external and
19 internal, to individuals around patients, family
20 members including minor family members and including
21 young children. While in principle or theoretically
22 the various scenarios Mr. Crane has outlined are not
23 altogether implausible, the data are what the data
24 are.

25 And there are data probably amounting to

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1 several hundred family members among the dozen or so
2 peer-reviewed publications, which document that
3 rarely, if ever, do family members even approach the
4 500 millirem dose limit.

5 And another point I'd like to make is the
6 citation of the Chernobyl data as a rationale for
7 requiring more stringent scrutiny and so forth of
8 radionuclide therapies performed on an outpatient
9 basis. Yes, there was a significant increase in the
10 incidence of childhood cancer following the Chernobyl
11 nuclear reactor accident. And anyone who would deny
12 that likewise is not paying attention to the
13 scientific facts in the peer-reviewed literature.

14 But those patients typically were
15 receiving doses of the order of ten to, in some
16 instances, of the order of 100 rads. So one is
17 talking about doses several orders of magnitude higher
18 than would be encountered -- frankly in even a worst-
19 case scenario of a child of a radioiodine therapy
20 parent.

21 So I think the dose-based release criteria
22 are scientifically sound, are most protective of
23 public health. And yes, there may be some refinements
24 such as addressing patients released to hotels or
25 other scenarios that might require additional

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1 guidance. But frankly, even in that case, I do not
2 think patients being released to hotels represent a
3 qualitatively different situation that cannot be
4 handled by the existing NRC paradigm in terms of use
5 of the appropriate occupancy factors and so forth.

6 So my feeling is that while the rules and
7 guidance perhaps should be revisited for the purposes
8 of refinement and improvement, as they always should
9 and in all cases, that the basic underlying concept
10 and the basic approach is, as I said, scientifically
11 sound, consistent with the available peer-reviewed
12 scientific data, and most importantly, most protective
13 of public health.

14 Thank you.

15 VICE CHAIR THOMADSEN: Thank you.

16 Other comments from the Committee? Dr.
17 Suleiman?

18 MEMBER SULEIMAN: I appreciated reading --
19 having a chance to read Mr. Crane's statement. But it
20 bothered me personally to imply that our patient
21 advocate, just because he is professionally qualified
22 shouldn't represent -- shouldn't be on this Committee.

23 I have known Dr. Fisher for a number of
24 years and I have found him, in terms of patient
25 advocates I've had the experience to interact with, to

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1 be not afraid to be critical and raise very, very
2 pertinent issues. And he is a disease survivor
3 himself.

4 So I guess having professional credentials
5 in addition to being a patient survivor, it should
6 prevent him from doing so? I mean that bothers me.

7 I also had an opportunity to talk to one
8 or two individuals mentioned in your statement. And
9 they were surprised, and I think we have to be careful
10 when we use people's names and associate with them,
11 implying that they are in agreement with whatever you
12 happen to be saying.

13 I found some of the questions -- so I
14 think there is a credibility issue here that needs to
15 be addressed. I think your concerns -- I think the
16 concerns raised should be answered scientifically. I
17 think you would be better spent devoting your
18 energies, getting a group of people to fund some sort
19 of a study with a number of institutions to follow --
20 if you think 22 patients isn't enough, initiate a
21 study. And let's get some scientific information that
22 would better clarify the concern.

23 I think some of the points are valid. But
24 I did some of the math. I did some preparation for
25 this. And I don't think they are necessarily

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1 plausible.

2 It doesn't mean there isn't room for
3 improvement. And I don't think we should, you know,
4 we should just ignore your concerns out of fact. But
5 there is an extensive body of literature on this
6 subject. And you can contribute to it in your own way
7 by helping fund and getting some of these groups to
8 pursue some of these studies.

9 And living with the consequences. I mean
10 as long as it is a scientific study that goes in and
11 monitors patients, their families, their environments,
12 after a period of time, put them into different rooms
13 and I think this would be a very easy thing to
14 address.

15 The one thing that came out of my meeting
16 at the IAEA back in January was the concern that
17 patients were actually not allowed in countries where
18 they had prescriptive regulations, they were basically
19 not allowed to undergo therapy for at least a year
20 because the hospital didn't have the space to
21 accommodate them.

22 So whether that's the regulatory agency's
23 responsibility or it's the medical authority's
24 responsibility in how you deliver care, I don't know.
25 But I think there are far more serious implications of

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1 some of these constraints that have to be considered
2 by the medical community.

3 So that bothered me the most when I heard
4 that patients were not allowed to undergo thyroid
5 treatment because they couldn't -- there wasn't space
6 in the hospital to keep them there for at least a
7 year. They delayed the treatment for a year because
8 they couldn't keep them in the hospital for a couple
9 of days.

10 VICE CHAIR THOMADSEN: Thank you, Dr.
11 Suleiman.

12 We have a comment from the public.

13 MR. PFEIFFER: Thank you, sir. I'm Doug
14 Pfeiffer, medical physicist representing the American
15 Association of Physicists in Medicine.

16 I want to say that we certainly do support
17 the current regulation for release of I-131 patients.
18 However, we were asked to respond to questions from
19 Congressman Markey regarding release to hotels.

20 And we did come out very much against that
21 practice. There is too little control. The dose
22 calculations cannot be done in nearly as coordinated a
23 manner as they can by releasing them to the patient's
24 home where there is control of the family members.

25 So we do come out against releasing them

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1 to hotels. And we ask that you consider that as you
2 are putting together your guidance.

3 VICE CHAIR THOMADSEN: Thank you.

4 Mr. Lewis?

5 MR. LEWIS: For the benefit of the
6 Committee, I would like to offer some perspective from
7 the NRC staff in your discussions.

8 Certainly, Mr. Crane has provided a very
9 thought provoking statement. And he's obviously very
10 knowledgeable on this topic and very thorough in his
11 research on this topic. And insofar as his statement
12 provides a means to further dialogue on this issue on
13 the area where there's much disagreement whether our
14 regulations and guidance are protective of public
15 health and safety, we welcome his statement.

16 Our only interest at the NRC is, of
17 course, to provide for adequate public health and
18 safety on patient release. And our obligation is to
19 provide information to the Commission so that they can
20 make a fully informed decision on the national policy
21 on this issue.

22 We take that obligation very seriously,
23 and any information that can be provided by the
24 Committee, by our inspection experience, by general
25 implementation experience with the Rule, and by the

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1 views of members of the public and we certainly
2 provide those to the Commission.

3 Much of the information has been provided
4 to the Commission in terms of the petition that was
5 mentioned, and several rounds of correspondence since
6 then on this topic with members of Congress in other
7 forums.

8 I think that what we would look for from
9 the Committee going forward is the Committee's advice
10 on the policy issues, whether our approach as
11 described by Dr. Howe towards developing guidance on
12 the hotel issue is appropriate, or whether or vehicles
13 are necessary to provide adequate protection of public
14 health safety. And once we do develop the guidance,
15 we would certainly return to the Committee to show it
16 to the Committee and receive your advice on whether
17 the guidance we have in draft is adequate. So both
18 the appropriateness and the adequacy of the guidance.

19 We do believe that going forward any views
20 of the Committee would be very welcome to the NRC
21 staff, and we would be very willing to provide those
22 to the Commission. The views of this Committee may be
23 formed, if I make a suggestion, by a subcommittee or
24 some other vehicle, but I think that this Committee
25 maybe today can have the discussion of how to move

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1 forward.

2 One last thing. Insofar as the statement
3 by Mr. Crane advances dialogue on the public health
4 and safety issues, we welcome it. And as I mentioned
5 it, insofar as the statement provided by Mr. Crane
6 questions the motive or actions of NRC or any
7 particular staff members or even Commissioners of NRC,
8 I intend to submit the statement to our Office of
9 Inspector General for any action that office deems
10 appropriate.

11 So thank you for that opportunity to
12 comment.

13 VICE CHAIR THOMADSEN: Thank you, Mr.
14 Lewis.

15 DESIGNATED FEDERAL OFFICIAL EINBERG: Dr.
16 Thomadsen, Congressman Markey's office also requested
17 that we enter his report into the record, and so I'd
18 like to read the title of the report and we'll
19 consider that report entered into the record then.
20 Congressman Markey's report is called "Radioactive
21 Roulette: How The Nuclear Regulatory Commission's
22 Cancer Patient Radiation Rules Gamble With Public
23 Health and Safety." And this is dated March 18, 2010.
24 (See Appendix B for full report.)

25 VICE CHAIR THOMADSEN: And I will point

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1 out that the members of the Committee have received
2 this report to read ahead. I believe that copies are
3 available for the general public on the table by the
4 door.

5 Mr. Lewis?

6 MR. LEWIS: And I was remiss in my
7 statement. I didn't address the patient advocate
8 position. So my apologies. But I did want to mention
9 that the NRC staff's position on the patient advocate
10 position is documented in correspondence to Mr. Crane,
11 dated June 11, 2008 and February 4th, April 24th and
12 May 20th of 2009. And in that documentation in
13 summary of it, we see no reason that Dr. Fisher isn't
14 qualified to continue as a patient advocate.

15 VICE CHAIR THOMADSEN: Thank you for that
16 comment also.

17 MS. Gilley?

18 MEMBER GILLEY: Debbie Gilley.

19 I just would like to remind NRC and the
20 Advisory Council that this is Compatibility C, this
21 patient release criteria. And that the Agreement
22 States have to maintain with Compatibility C equal to
23 what NRC has or can be more restrictive.

24 So if you look at Agreement States, you
25 may see that there is more restrictive patient release

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1 guidance out there in the Agreement States than what
2 NRC has.

3 I would also encourage to continue to keep
4 the Agreement States in the process for regulations
5 and regulatory guidance development since we do play a
6 big role in the administration of iodine-131.

7 Thank you.

8 VICE CHAIR THOMADSEN: Thank you.

9 Other comments from the Committee?

10 Dr. Zanzonico?

11 MEMBER ZANZONICO: Pat Zanzonico again.

12 I don't want to reiterate the points I've
13 made earlier with respect to Congressman's report, but
14 there is one point I just feel compelled to comment on
15 in his report in which it is repeatedly characterized
16 that the 500 millirem dose limit, the regulatory
17 limit, is repeatedly characterized as safe, implying
18 that if one receives a dose in excess of 500 millirem,
19 one has suddenly received an unsafe dose. Conversely,
20 if they remain below the 500 millirem limit, they have
21 received a safe dose. And there's simply no scientific
22 basis whatsoever for that characterization.

23 While one could argue ad nauseam about the
24 linear non-threshold hypothesis and what the
25 incremental increased cancer risk might be at that

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1 dose, again the peer review data on I-131 treated or
2 diagnosed individuals suggest a threshold of the order
3 of tens of rads, if not higher, with patients without
4 preexisting thyroid conditions from increased risk of
5 thyroid cancer. So there's simply no bases in that
6 report for characterization of a dose in excess of
7 simply 400 millirem. A regulatory benchmark is
8 unsafe.

9 VICE CHAIR THOMADSEN: Thank you very
10 much.

11 Dr. Welsh?

12 MEMBER WELSH: Jim Welsh here.

13 I appreciate the opportunity to read the
14 statement of Mr. Peter Crane and for having him read
15 this statement to us personally.

16 I do have a couple of comments or
17 questions.

18 First is that although there are several
19 important matters discussed in this statement that are
20 worthy of discussion and certainly worthy of a further
21 dialogue and guidance, I must say that the statement
22 loses some of its credibility in that there are
23 sections here that sound accusatory and antagonistic,
24 and sound like a personal attack.

25 For example, the comments made about Dr.

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1 Fisher who, as others here have already mentioned, is
2 very qualified as the patient rights advocate and has
3 been doing a good job in that role despite his
4 professional expertise and experience.

5 So my question, perhaps maybe to Mr.
6 Crane, would have been as somebody who is trying to
7 make a point in favor of patients' rights, why not
8 just contact Dr. Fisher and have that comment up here
9 for appropriate discussion and evaluation? I am
10 certain that had Dr. Fisher been informed by Mr. Crane
11 about these issues, that it would have been discussed
12 here and evaluated in an appropriate and objective
13 fashion, and with clarity. And would have been
14 brought up here for further discussion in the interest
15 of patient and public safety. That's my first point.

16 My second point related to this statement
17 is that although maybe I have not treated quite as
18 many patients as Mr. Grigsby who has treated over a
19 1,000 at the time he wrote the article or the matter
20 was discussed, maybe I've treated half that many. And
21 I, too, have not encountered much in the way of
22 vomiting after iodine-131 therapy.

23 So if the implication is that it is
24 relatively common, I would say that my personal
25 experience along with Dr. Grigsby, does not support

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1 that.

2 VICE CHAIR THOMADSEN: Thank you, Dr.
3 Welsh.

4 MR. CRANE: May I respond, since the
5 question was asked of me?

6 VICE CHAIR THOMADSEN: Please. You want
7 to step to the microphone?

8 MR. CRANE: Thank you.

9 For the record, this is Peter Crane.

10 Again, I want to make clear that I at no
11 time intended to disparage Dr. Fisher. I have never
12 said a negative word about Dr. Fisher. All you've
13 heard me say today is praise of him as a valuable
14 asset to this Committee. The endorsement of Carl
15 Paperiello, who I think enjoys immense respect and his
16 recommendation is good enough for me. My only concern
17 is that for 13 years the patient's rights advocate has
18 been associated with either the National Association
19 of Cancer Patients, or a spin-off organization, the
20 National Association of Cancer Patients Foundation.

21 Now the National Association of Cancer
22 Patients is a 501(c)(4) lobbying organization. It's
23 spelled that out on its website. It spelled it out, I
24 think it was 1998 that they created the spin-off
25 organization. And if you go to the newsletter, it's

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1 Lifelines for Issue 1 of 1998, now you get a truncated
2 version, and they say sort of bear with us as we go
3 through the legalese as we describe why we have a
4 501(c)(3) educational foundation which is in
5 partnership with the NACP, the lobbying organization.

6 So all of this was somewhat confused
7 because when the NRC announced the choice of Dr.
8 Fisher it identified him as coming from the American
9 Association of Cancer Patients, an organization which
10 doesn't exist.

11 How that erroneous message came out I
12 don't know. It was corrected after I pointed this
13 out, once, maybe twice. And where they ultimately came
14 out was to say that Dr. Fisher's association was with
15 the National -- first when I said the NACP is a
16 501(c)(4) organization, Charlie Miller wrote back to
17 me and said "Oh, no it isn't. It's 501(c)(3)." And I
18 said "Go to their website and look." He wrote back
19 to me, no, we checked with the IRS, there's probably a
20 problem with the website, which was to say that
21 Charlie knew the tax status of the NACP better than
22 the NACP did.

23 And one can imagine, perhaps, after a
24 certain number of exchanges of this kind that a
25 certain frustration builds in. But once again, I

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1 regard Dr. Fisher as an asset. But I don't think that
2 choosing Executive Directors from an organization, and
3 they've made very clear on the website that the point
4 was to lobby for Ward Valley. I believe that they --
5 I don't think they exist anymore. There's now an
6 organization called Citizens for Medical Isotopes
7 based in Richland, and I think Dr. Fisher is
8 associated with that. I think that's fine. That's
9 truth in advertising. But again, I think reaching out
10 to the patient community for an advocate would be a
11 good idea.

12 And on the question of vomiting. I think
13 if you look at websites, I think Carol Marcus has
14 estimated 30 percent of vomiting.

15 I've certainly had patients in my group
16 who reported vomiting after receiving radioiodine.

17 If you go to RadSafe, the Radiation Safety
18 Board, you see a woman whose email's address
19 identifies her as being from the Los Angeles Health
20 Department describing a case in which a released
21 patient vomited on a bus and people walked through the
22 radioactive vomit all day.

23 And I'm concerned about the fact that you
24 can have people getting caught short vomiting and
25 people cleaning up who have no knowledge that there's

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1 radioactivity present, no proper gear with which to
2 take care of it. And that I think argues among other
3 possibilities that you could examine in a rulemaking.
4 Could you have a dedicated room where people can spend
5 the first six hours or so until the risk of vomiting
6 has passed?

7 I mean, I know that when I was in NIH as a
8 patient, they told me at the first sign of nausea let
9 us know, because it was common, because we want to
10 give you an antiemetic. And it's not just that we
11 want the stuff staying in your system, it's that it's
12 a big hassle for radiation safety when you have
13 radioactive vomitus.

14 So, you know, I could give you -- I
15 realize that there is this tendency. I see it all too
16 often, to think that anything that patients contribute
17 is mere anecdote, whereas what doctors contribute is
18 scientifically valid and not to be impeached. But
19 I'll tell you, there are lots and lots of patients
20 with nausea.

21 And to address one other point. You know,
22 thyroid cancer is the most rapidly increasing cancer
23 we have. Something like 36,000 cases last year.
24 Twenty-five years ago it was 12,000.

25 We have the recent report from NCRP, NCRP

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1 130, is it? That points to the threefold increase in
2 the amount of medical regulation -- or six-fold amount
3 of radiation that people are getting annually from
4 medical radiation.

5 It just seems to me that it's a situation
6 for care and study. And if could refer to Dr.
7 Suleiman's point.

8 If I misquoted anybody, I certainly want
9 to correct the record. I don't know who I misquoted.
10 I said that I had not seen Audry Goodwin's letter. I
11 heard it described today. I did speak with
12 Gene St. Germain. I did speak with Carl Paperiello.
13 If I've misquoted any of them, I'll be happy to
14 correct the record.

15 Well, let me leave it at that. Does
16 anybody have a question I can respond to.

17 VICE CHAIR THOMADSEN: Thank you, Mr.
18 Crane.

19 MR. CRANE: Thank you.

20 VICE CHAIR THOMADSEN: So the question I
21 would like to raise o the Committee is recommendations
22 that this Committee could follow to help address the
23 issue. Recommendation or suggestions?

24 Dr. Guiberteau?

25 MEMBER GUIBERTEAU: Yes. I believe that,

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1 rhetoric aside, Mr. Crane should be congratulated for
2 what I take as face value of his concern, as is all of
3 our concern for the safety of patients and the public,
4 as well as the access of patients to necessary
5 therapies.

6 I think that much attention has been given
7 by the radiology community from other perspectives,
8 including CT doses to children. I think it's an
9 important area. And I think our job here is to
10 balance opinion, public perception and science to come
11 up with reasonable rules. However, I think on the
12 other end I think the body of knowledge and the
13 reasonableness of the policy developed 13 years ago,
14 it has been accepted in the community as good policy.
15 I think any retreat from undue restriction or
16 rescinding the ability for us to treat patients with
17 radiopharmaceuticals, especially I-131, and release
18 them would be a detriment to the health of patients
19 and it would affect occupational dose to caregivers in
20 the hospital.

21 I think it can be done safely. I think the
22 track record illustrates this. And I would hope that
23 in refining NRC policy and guidance that this would be
24 a strong evidence for keeping the ability to treat
25 patients and increase their access to these

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1 treatments.

2 VICE CHAIR THOMADSEN: Thank you.

3 Dr. Welsh?

4 MEMBER WELSH: Well, I would agree with
5 what Dr. Guiberteau has just said. And I would like
6 to thank Mr. Crane and Congressman Markey for making
7 this important matter to our attention.

8 And I would suggest that perhaps a
9 subcommittee of this ACMUI be created to delve into
10 this in further depth and give it the appropriate time
11 and effort that it deserves.

12 VICE CHAIR THOMADSEN: Very good.

13 MEMBER FISHER: Second.

14 VICE CHAIR THOMADSEN: Oh, good. Now we
15 can talk about it.

16 We have a motion on the table that's been
17 second. We should have as part of that motion, we
18 need a charge for the subcommittee.

19 Dr. Welsh, since you've proposed the
20 subcommittee, do you have a charge in mind?

21 MEMBER WELSH: I would suggest that the
22 charge be to evaluate what has been discussed in the
23 statement by Mr. Crane and the comments by Congressman
24 Markey. And for the subcommittee to objectively
25 analyze all available data, and formulate a statement

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1 based on its comprehensive review of the data.

2 VICE CHAIR THOMADSEN: Very fine.

3 Further comments about --

4 MEMBER ZANZONICO: Yes.

5 VICE CHAIR THOMADSEN: Yes?

6 MEMBER ZANZONICO: Pat Zanzonico again.

7 I would just extend that charge to include
8 suggesting or recommending amendments to the existing
9 NRC rules and guidance, if necessary by this analyses.
10 If shown to be necessary by this analyses, but the
11 charge of this subcommittee to include offering
12 recommendations for improvement of the existing rules
13 and regulations if warranted, including the issue of
14 release of patients to hotels immediately post-
15 treatment.

16 VICE CHAIR THOMADSEN: Thank you.

17 Further comments about the charge? Yes,
18 Dr. Suleiman?

19 MEMBER SULEIMAN: I'm confused because I
20 consider myself relatively knowledgeable, but I'd like
21 the Committee to make a concerted effort, or maybe the
22 NRC staff could help out reviewing the current
23 regulatory criteria both internationally and
24 domestically. Because I think the trend is more
25 toward risk-based dose limits, and I've heard

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1 different countries are doing different things now.
2 There are a lot of drafts circulating. So I'm a
3 little bit confused as of this point in time, you
4 know, where we're going.

5 Listening to Mr. Crane I got the
6 impression we're going in the other direction. So I
7 want to know which way the wind is blowing. But my
8 sense is, as I had stated earlier, was that some of
9 these constraints actually inhibit the practice of
10 medicine, deny patients treatment in a timely manner.
11 And that's clearly the purview of the medical
12 community. And you have to balance that against the
13 variety of constraints that the different agencies do
14 and their experiences with that.

15 So, I wouldn't want peoples' opinions to
16 say this is what they do elsewhere. I'd like to know
17 what the actual numbers are in the different
18 documents. I haven't been able to find any absolute
19 prescriptive limits from the AIE. I think they're
20 tending toward risk-based criteria as well.

21 I just want to make sure that's addressed.
22 It shouldn't be a big deal.

23 VICE CHAIR THOMADSEN: Other comments?

24 What I have, then, on this charge would be
25 the subcommittee would evaluate issues raised with

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1 patient release, reviewing available data and
2 international recommendations and make suggestions to
3 the NRC staff for possible changes and improvements in
4 the release criteria. Does that capture --

5 MEMBER SULEIMAN: Clarification. Debbie,
6 would it be difficult to find out what the states do?
7 I mean, you've got the suggested state regs, but
8 that's all they are.

9 MEMBER GILLEY: You'll find 37 different
10 varieties. It's kind of the Heinz 57. Some states
11 adopt NRC's as is, and some states are more
12 restrictive. Because it's Compatibility C, so it
13 allows the states to be more restrictive than what has
14 NRC has.

15 Some states do not allow by their guidance
16 documents patients to go to hotels, or other
17 congregate living facilities. Some do not allow mass
18 transportation after receiving a dose. So you'll find
19 lots of variations along the way for the Agreement
20 States.

21 VICE CHAIR THOMADSEN: Does that have an
22 impact on your --

23 MEMBER SULEIMAN: Well, that's my
24 perspective. I mean, I --

25 VICE CHAIR THOMADSEN: Include states

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1 where saying international?

2 MEMBER SULEIMAN: Yes, I did.

3 VICE CHAIR THOMADSEN: Okay. And I think
4 we can do that.

5 Ms. Howe?

6 MS. HOWE: Dr. Thomadsen, I heard Dr.
7 Welsh and Dr. Zanzonico talking more about guidance
8 also. In other words, our criteria are in
9 regulations, but how they're implemented are in
10 guidance. And so you would not want to leave off
11 guidance in that.

12 VICE CHAIR THOMADSEN: Absolutely.

13 MEMBER GILLEY: Furthermore, guidance is
14 what I thought you said.

15 VICE CHAIR THOMADSEN: I thought we did
16 not say that. I don't remember saying that. But Dr.
17 Howe has corrected me. That is indeed what I had
18 meant to have said.

19 Yes?

20 MEMBER GILLEY: The regulations may be
21 fine. It may be the guidance document that needs the
22 work.

23 VICE CHAIR THOMADSEN: Well, I think that
24 the charge of the subcommittee would include reviewing
25 both of those and making recommendations on both of

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1 those, if that is the intention of this Committee? It
2 looks like it is.

3 Any questions or further discussion on the
4 formation of this subcommittee and its charge?
5 Hearing none, ask for a vote.

6 All in favor please say aye.

7 ALL: Aye.

8 VICE CHAIR THOMADSEN: Opposed?

9 Okay. It is unanimous.

10 Point of order. Do I need to count votes
11 on that? Okay. Very fine.

12 In that case, we next need to populate
13 this subcommittee. And I'll first ask for volunteers.

14 Mr. Mattmuller is one.

15 MS. COCKERHAM: Maybe the whole Committee.

16 VICE CHAIR THOMADSEN: Zanzonico, Dr.
17 Welsh, Dr. Fisher, Dr. Gilley and I would also serve
18 on that. So we seem to have most of the Committee,
19 that should be well representing the views of the
20 Committee.

21 MS. COCKERHAM: Dr. Thomadsen, is there
22 anyone that's not on the Committee?

23 VICE CHAIR THOMADSEN: Yes. Yes. Dr. Van
24 Decker did not put his hands up.

25 MS. COCKERHAM: Okay.

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1 VICE CHAIR THOMADSEN: Dr. Guiberteau is
2 not on the Committee.

3 I'm sorry, Dr. Suleiman was going to be on
4 the Committee, I think, wasn't he?

5 MEMBER SULEIMAN: Well, I want it to be a
6 subcommittee, so --

7 VICE CHAIR THOMADSEN: I want a
8 subcommittee, yes.

9 MEMBER SULEIMAN: So I'm willing to back
10 off so that the Committee is actually less than the
11 entire Committee, you know.

12 VICE CHAIR THOMADSEN: We already have
13 less, and I think your expertise would be useful.

14 MEMBER SULEIMAN: Okay. Fine.

15 VICE CHAIR THOMADSEN: And for a Chair,
16 now actually I would like to go to somebody who has
17 not spoken one way or another on this effort, but
18 would be involved, and that would be Dr. Langhorst.
19 As a Radiation Safety Officer representative here, it
20 seems appropriate. Would you --

21 MEMBER LANGHORST: I'd be glad to Chair
22 that subcommittee.

23 VICE CHAIR THOMADSEN: Very good. Thank
24 you.

25 Any further commentary on this issue?

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1 With that, we're actually 20 seconds ahead
2 of schedule and we're scheduled for a lunch break
3 right now.

4 We return at 1:00.

5 (Whereupon, at 11:5 a.m. the Advisory
6 Committee was adjourned, to reconvene this same day at
7 1:00 p.m.)
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A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

1:00 p.m.

VICE CHAIR THOMADSEN: Welcome back to the second session today. And we'll begin with a presentation by Steve Mattmuller on the shortage of medical isotopes.

MEMBER MATTMULLER: Good afternoon. I'm Steve Mattmuller, the nuclear pharmacists.

On several levels, we have a moly-99 crisis here in the U.S. We have a few reactors that we're dependent on for moly-99 production. And despite using half of the world's moly-99 in the U.S., we still don't have a domestic producer of moly-99.

Finally, there are efforts to reduce the use of highly enriched uranium, which is used for the production of moly. But it can be used for other nonpeaceful activities. So factors from each of these are now contributing to our worldwide shortage of moly creating a crises for our patients.

More than 16 million nuclear medicine procedures are performed each year in the U.S. that needs technetium-99m, and moly-99 is needed as the parent medical isotope used in our generators which serve as our local supply of technetium-99m.

A nuclear medicine image is based on sale

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1 or function and physiology. And on the screen are two
2 of our most common procedures.

3 The left image shows a myocardial
4 perfusion study done to diagnose coronary artery
5 disease and the yellow arrows point to areas of
6 hypoperfusion. And on the right is a bone study done
7 to diagnose metastatic bone disease. And
8 unfortunately for this patient you can see numerous
9 areas of metastatic growth to the spine and other
10 areas.

11 This graphic shows our aging collection of
12 reactors and the amount of moly-99 that they produce
13 in the world.

14 The NRU is now 52 years old and has been
15 down for repair since last May. And it was
16 responsible for about 31 percent of the world's needs.

17 The HFR is 48 years old and is responsible
18 for about 33 percent of the world's needs. And
19 unfortunately, it's gone right now. Down for repairs
20 since February for, hopefully, no more than six
21 months.

22 And just to complete to our triad of
23 trouble, the BR2 is also down for routine maintenance,
24 and we hope for no more than a month.

25 So right now at this given time three-

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1 fourths of the world's supply of moly-99 is missing.

2 This graphic also shows that there isn't a
3 single reactor in the U.S., and that we are 100
4 percent dependent on foreign reactors for our moly.
5 Also, and it may be clear from this, but the vast
6 majority of moly-99 produced by these reactors is all
7 done with highly enriched uranium or HEU.

8 There are two generator manufacturers in
9 the U.S., Covidien and Lantheus. And to try to
10 illustrate how patients are being affected, it shows
11 in this calendar from Covidien. And on this calendar
12 they try to show their availability of technetium
13 generators in the U.S. And this only represents
14 Covidien, since they have half of the U.S. market.
15 And they're also weathering this crises a little bit
16 better, or maybe a whole lot better, than Lantheus.

17 So where you see green and blue,
18 Covidien's customers are okay, but Lantheus' are still
19 struggling, even more so. But where it show orange
20 means everyone in the U.S. is suffering.

21 So for our patients their chances of
22 getting a procedure done, if it's a day that's green;
23 it's probably good. But, maybe 50 percent chance.
24 Yellow is iffy. And orange is not likely. And X is
25 slim to none.

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1 Again, this is only for departments where
2 a patient would go supplied by Covidien. If it's a
3 department that's supplied by Lantheus, their chances
4 are a lot worse.

5 It used to be that everyday in nuclear
6 medicine was a green day. And for optimal patient
7 care, everyday does need to be green.

8 As if old and broken reactors were not
9 enough, we've also had to deal with a volcano in
10 Iceland and the volcanic ash cloud has closed the
11 Amsterdam airport on a number of occasions. And this
12 is because Amsterdam is the primary airport from where
13 they fly moly-99 from Europe to the U.S. And again,
14 it also points out if we talk about the fragile chain
15 of production of moly and processing of targets, and
16 transporting the moly to the U.S., this is a weak link
17 in this complicated fragile chain.

18 In addition to volcanoes which aren't
19 always erupting, even within the past year we've had
20 instances where they were able to make the moly-99 in
21 Europe, but they couldn't get it here because of
22 weather, either closing their airport or an airport
23 here in the U.S. and, again, led to additional delays.

24 And this is the same calendar I showed you
25 earlier, but it's somewhat hard to see and the

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1 pointer, I'm sorry, doesn't work on the screen. But
2 we actually had two more weeks of orange in April
3 because of the volcanic activity in Iceland. So we had
4 two additional bad weeks in our departments.

5 Our physicians are trying to deal with
6 this as best as possible and they're choosing
7 alternate procedures that are either inferior in
8 accuracy or more expensive, or may have a higher
9 radiation dose. And again, there are no easy choices
10 as substitute as nuclear medicine procedures are based
11 on physiology first as anatomical type procedures as
12 CT or MRI. But patients are still in need and their
13 physicians still need to take care of their patients.
14 So they just provide optimal care to them.

15 Since there's no immediate solution, the
16 best we can do is try to minimize the effect it's
17 having on our patients. And for the next few slides,
18 I'll be discussing alternatives that SNM has proposed.

19 The first is to perform imaging studies
20 throughout the entire week. Traditionally, most
21 departments are on Monday through Friday. But
22 technetium is available on the weekend. And this
23 graph doesn't need to show that moly continues to
24 decay throughout the week, it doesn't end on Friday.
25 And, in fact, anyone who does have a generator now,

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1 they are using it for its maximum life of about 14
2 days. However, scheduling for weekend days is
3 challenging for everyone; patients, staff and
4 especially for cardiologist if they are needed for the
5 stress portion of a myocardial perfusion study.

6 Scheduling is difficult as despite
7 Covidien's and Lantheus's efforts, the supply is very
8 unpredictable. I mean, the calendar I showed you,
9 that was an estimate and there was disclaimer saying
10 it could change at any moment. And a lot of times, we
11 don't know how much technetium we're going to have
12 until our generator shows up that day. Because it's
13 far too often this past year we've had a number of
14 unpleasant surprises.

15 Other suggestions from the SNM is to lower
16 the administered dose. But one can only do this so
17 far as the longer the patient lies on the camera bed,
18 the greater the chance for patient movement and the
19 greater chance for degrading the image quality. And
20 this is especially true for our bone imaging patients
21 who are frequently suffering from very painful bone
22 metastases. Lying still for them can be a very
23 difficult and painful process for them.

24 Other alternate procedures, especially for
25 myocardial perfusion imaging. For a SPECT study it's

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1 usually either a rest stress study or they can reverse
2 and do it as a stress/rest depending on the
3 physician's preference for the protocol. But if they
4 do the stress portion first and it's normal, then most
5 or some physicians agree you don't need to do the rest
6 portion. So it could be skipped, and then that rest
7 dose could be saved for another patient. But not all
8 physicians are comfortable with this type of a
9 protocol.

10 Rubidium-82 is a PET myocardial perfusion
11 agent and has advantages compared to the technetium
12 study. But a department has to have a PET scanner,
13 which a lot of department don't have. And you have to
14 commit to using a rubidium-82 generator for a whole
15 year. You can't just say well I can't get a
16 technetium dose today or tomorrow, can I get rubidium
17 for those two days. You have to commit to its use for
18 a full year. So its use on a spot basis is very
19 limited.

20 Coronary angiography. Typically
21 myocardial perfusion imaging with technetium is used
22 a gatekeeper type procedure to determine whether or
23 not a patient needs coronary angiography. So a
24 physician may jump directly to this. And if that
25 happens, then a lot of patients would be getting an

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1 unnecessary procedure that is far more expensive and
2 has a much greater radiation dose to the patient.

3 Another choice could be echocardiography.
4 But it has a downside in that it doesn't have nearly
5 the same accuracy as a myocardial perfusion study.

6 And more alternatives for perfusion
7 imaging. And I'm spending time on this because this
8 accounts for our single greatest demand for
9 technetium.

10 Thallium-201 was the first widely used
11 radiopharmaceutical for myocardial perfusion imaging.
12 But there challenges to its use. Because it has a
13 much lower energy for its emission, there is far more
14 attenuation and image degradation in large patients
15 and women with large breasts. So its images are not
16 as good as technetium. There are dosimetry concerns.
17 Because it has a much longer physical and biological
18 half-life than technetium. So its dose is limited to
19 about one-tenth of what we're allowed to give a
20 patient with technetium. Hence, because of this it
21 limits what we can do in our study. A smaller dose
22 means poor accounting statistics. So we're unable to
23 do important wall motion and injection fraction
24 components, which we always do or typically do in a
25 typical technetium myocardial perfusion study.

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1 And this image shows a snapshot from a
2 dynamic study. The physician, and I did have a CINE
3 file for this where you could see the heart move in
4 and out as it beats. But my CINE file did not pass NRC
5 clearance, so I couldn't bring it in. Your IS guys
6 are tough.

7 But the physician gets to see how the
8 muscle moves in and out. And so if it's well
9 profused, it's healthy movement. It's under profused,
10 then they can also see where it's not moving where it
11 needs to. And also, they can calculate the ejection
12 fraction, which measures how efficiently the heart is
13 pumping blood throughout the patient.

14 And you also have to remember that
15 technetium was first introduced for a myocardial SPECT
16 imaging agent about 20 years ago when thallium was the
17 dominant rated pharmaceutical. And over the years its
18 use has dropped off. So in response to that,
19 manufacturers cut back in production. So even now
20 when we have a technetium shortage and in some cases
21 our only alternative is thallium, there's not thallium
22 available because the manufacturers have very limited
23 capabilities now.

24 Moving on quickly. Another alternate that
25 we can use is I-123 for thyroid imaging instead of

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1 technetium. And this is a great choice. And actually,
2 a lot of department just use I-123 instead of
3 technetium. But because thyroid procedures are
4 relatively small in number and use a relatively small
5 dose, thyroid imaging represents a very small slice of
6 the overall technetium pie.

7 Bone imaging is probably the most
8 challenging problem we have to deal with as there
9 really aren't any alternatives. There is the use of
10 sodium fluoride, F-18, but its a PET agent and it's a
11 superior procedure when you compare F-18 sodium
12 fluoride procedure to a technetium procedure. But the
13 department has to have a PET scanner. And while the
14 FDA has given its approval for the use of sodium
15 fluoride, the Centers for Medicaid and Medicare
16 services have not given its final approval. So
17 departments can't get pay, can't get reimbursement if
18 they do try to use sodium fluoride F-18 for their
19 patients.

20 The SNM Guidelines are trying their best.
21 They're trying to save a little technetium here, a
22 little bit there. Wherever we can, trying to find the
23 best alternatives. But some of these alternatives are
24 a step backwards in terms of what used to be our
25 standard of care. As a medical professional that's

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1 pretty hard to watch. We want what's best for our
2 patients and we aren't comfortable moving backwards.

3 I tried to find the right metaphor for
4 this situation. SO in a sense, we're like Michael
5 Jackson when he would moonwalk. We're facing forward,
6 but we're actually, we're moving backwards. And I'm
7 not sure this works as well as I would like it to, or
8 maybe this comparison would be better. Let's compare
9 the abundant supply of moly-99 to the strong safety
10 culture at a nuclear power plant. With an abundant
11 supply of moly-99 patients get the best tests they
12 need and subsequently have the best treatments, and
13 have the best health. A nuclear power plant with a
14 strong safety culture, with a safety culture work
15 environment operates efficiently and safely. Now a
16 poor supply of moly is like a weak safety culture at a
17 nuclear power plant, one that has a cost-conscious
18 work environment.

19 Due to the poor supply of moly-99 patients
20 won't die tomorrow, but they endure alternative
21 procedures that are not as accurate, not as safe,
22 resulting in the wrong or delayed diagnoses leading to
23 the wrong treatment or delayed treatment affecting
24 their overall health.

25 Likewise, a nuclear power plant with a

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1 cost-conscious work environment won't have a major
2 incident immediately. But over time as issues are put
3 off or ignored, major issues will develop under a
4 cost-conscious work environment, as demonstrated by
5 the significant event at the Davis-Besse Nuclear Power
6 Plant in 2002.

7 So we're in need of multiple solutions to
8 solve our crises. In the short term, we need to get
9 our reactors back online. So here's a little bit of
10 insight on how to repair a reactor 101 course.

11 And I wish i could point. But, this is a
12 model of the NRU reactor, and you can notice the
13 little man on the far right. And to give you a
14 perspective of the size. And if you move straight
15 across from him to the left in the yellow portion,
16 that's where the aluminum liner is that right now
17 they're having difficulty repairing. And the gray, of
18 course is concrete that surrounds the reactor. And it
19 surrounds it all sides, so in essence there's no
20 access to the reactor, except from the very top where
21 they have to manage their tools through a four inch
22 diameter hole, have it go down 30 feet and then has to
23 unfold so it can effect the side of the walls or work
24 on the side of the walls.

25 They've also built partial full size mock-

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1 ups of the reactors so they can design their tools and
2 plan the best repair process. As part of their mock-
3 up they've recreated models of the corroded area that
4 need to be repaired.

5 And this is an example of their weld
6 repair technique. First they spot welded on a repair
7 plate over the corroded plate, and then they've
8 covered it with additional overlapping bead welding.

9 This is another sample trial plate that
10 shows the stress from the heat of the welding process
11 and how if not done properly when it's heated or
12 cooled, can cause it to warp. And mind you, this is
13 on a fresh piece of aluminum. The actual repair is
14 going to be done on a 25 year old piece of aluminum
15 that has been in the environment of a nuclear reactor;
16 something in a far more delicate condition.

17 And from their repair page, as of the 12th
18 of this month, the team is approaching this final
19 repair very carefully as they feel they have one
20 chance to get it right. I wish that gave me a lot of
21 confidence, but it's tight.

22 Now for our friends in the Netherlands,
23 again another model of their reactor. They found
24 bubbles in the -- I'm sorry. I can't talk and point.
25 We'll not go beyond that.

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1 But last year they found bubbles in the
2 cooling water. And an inspection survey found
3 corrosion on the outside of the reducer that led to
4 gas formation. And right here are the reducers. And
5 this whole area is concrete. This area down here
6 below is actually open space. So they're fortunate
7 that they do have access area they need to repair from
8 the very bottom of the reactor. And so their best
9 repair plan is to either repair or replace the
10 existing the reducer. And this is their mock-up that
11 they too, like the Canadians, have also built to plan
12 their repair process. And the reducer is the tapered
13 part of the pipe that comes out of the circular area
14 there. And this is before they filled this area up
15 with concrete.

16 And again, this is the mock-up with
17 concrete poured and they're trying to figure out how
18 they're going to actually now remove the concrete in
19 the real reactor so they can repair the reducer.

20 This is actual repair work being done on
21 the reactor. And they had to drill out most of the
22 concrete and then remove the rest by hand by chipping
23 it with hammer and chisel, which they have done all
24 that now. And as of the 19th of this month, they're
25 now making preparation to repair the reducer.

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1 And I'll go back to their mock-up where
2 they've practiced one method of once they get to the
3 reducer, how are they going to try to fix it. And
4 it's still the mock-up.

5 Once the reducer is repaired, they'll then
6 have to replace the concrete. So here they've pumped
7 in fresh concrete, let it harden, and then they sawed
8 it in half to test their concrete replacement
9 technique.

10 Both repairs to the NRU and HFR are, of
11 course, greatly anticipated and needed. But they are
12 short-term solution to our crises, as they're both
13 very old.

14 In addition to concerns of their age, they
15 both use highly enriched uranium for moly-99 targets.
16 And the National Nuclear Safety Administration of the
17 Department of Energy is trying to make the world a bit
18 safer by minimizing the use of HEU in the world. So
19 at sometime in the future, these reactors will have to
20 undergo constantly target modifications to use LEU if
21 they want to continue producing moly-99.

22 And this is the first possible of one of
23 our long-term solutions. This is the Aqueous
24 Homogeneous reactor as proposed by Babcock and Wilcox.
25 And with the AHR it uses LEU fuel and target. It's a

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1 solution. It's one in the same as opposed to separate
2 solid target rods and fuel rods in a reactor, in a
3 typical nuclear reactor. And the moly-99 will be
4 separated from the fuel target reactor mixture and
5 then it will be returned to the reactor for additional
6 production of moly-99.

7 At a 2000 kilowatt power rating, it's less
8 than one percent of the NRU's size in terms of power,
9 so its much smaller. And it also has a large negative
10 coefficient of reactivity, which means from an
11 operational perspective it's very safe to operate.

12 And physically, you saw from
13 the prior two reactors they are multi-story type
14 structures, this is actually the size of a large
15 barrel.

16 And B&W has received \$9.1 million from DOE
17 to help promote this type of production.

18 They are on track. They've completed
19 their facility conceptual design work and they're
20 getting ready, or they plan to be ready to submit to
21 the NRC an Environmental Report by July, which is the
22 very important first step in the NRC's National
23 Environmental Policy Act process. And they hope to be
24 operational by 2014.

25 And the next potential long-term solution

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1 comes from GE Hitachi. And I'm sorry there's an error
2 in the slide. LEU is not used in this process. Stable
3 moly-98 is used as the target material that's
4 irradiated by a neutron to form moly-99.

5 But talk about coming full circle, this is
6 how moly-99 was produced for the original technetium
7 generators over 50 years ago.

8 They propose as a gel generator, which
9 would be new for us here in the U.S., but in the world
10 there are a few countries such as India and Argentina
11 that do have gel technetium generators in use right
12 now. But they're much smaller. They're 250 to 400
13 millicuries in size compared to the one the 18 curie
14 size generators that we're used to using. But GE
15 believes they have a new chemical processing
16 technology that will allow them to increase the
17 generator size to meet our needs.

18 Also, GE Hitachi along with Excelon are
19 planning to produce cobalt-60. And I think this is
20 very encouraging as it shows GE's ability to truly
21 think outside the box, or in case outside a research
22 reactor to find a source of neutrons to produce
23 isotope production.

24 For a long time solution we need passage
25 of H.R. 3276, the American Medical Isotopes Production

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1 Act of 2009, or the Markey Bill. It's passed the
2 House in November of last year, and it's passed the
3 Senate the Energy and Natural Resources Committee
4 January of this year. But it's still awaiting full
5 action from the Senate.

6 IT does put us on a timetable, though, to
7 convert reactors to LEU for production of moly-99. But
8 it does also provide funding to help develop a
9 domestic isotope production.

10 And probably most important, is it deals
11 with waste as the radioactive waste take-back
12 provision of this bill is critical for either of the
13 GE or B&W's projects to be successful.

14 Also, in past you've heard about the
15 Missouri University Research Reactor which is nearly
16 ready to produce moly-99 with LEU, but it also needs a
17 new facility to process the targets. And funds from
18 this bill would be very helpful in order to help them
19 restart their program. Because right now they're sort
20 of on a pause button.

21 So if you go back to June of last year,
22 these are Covidien's calendars. You can see the
23 differences in the colors and how green is good and
24 orange is awful. There's some overlap in October and
25 November. As you move to the right it goes from green

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1 to yellow, just to again demonstrate how this is a
2 very fluid situation for us all. It changes week-by-
3 week, sometimes day-by-day.

4 Last March was difficult, and of course
5 here in May this is the worst month we've had to date.

6 This crises, also I don't want to imply
7 just started last year in June. It's something we
8 have endured for -- actually, we've endured four
9 periods of moly-99 disruption since January of 2007.
10 So this is the fifth major disruption we've had, and
11 it's been far been the most severe and most disruptive
12 we've ever experienced.

13 One has to remember, though, that even if
14 this calendar all turns greens, and hopefully that
15 will happen, but still when it does we're still not
16 out of the wood yet, so to speak. We're still in a
17 very tenuous situation with our old reactors that use
18 HEU moly targets in foreign countries. We still need
19 to be focused on long-term solutions here in the U.S.
20 for production of moly-99. It's critical that MERV,
21 B&W and GE are successful. Just like the NRC wants
22 nuclear power plants to operate with a strong safety
23 culture, the nuclear medicine community doesn't want
24 to moonwalk with our patients anymore. We want to move
25 forward with them and give them the best level of care

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1 that they desire.

2 Thank you.

3 VICE CHAIR THOMADSEN: Thank you.

4 And comments or questions? Yes, Dr. Van
5 Decker.

6 MEMBER VAN DECKER: Van Decker.

7 Steve, thank you as always for continuing
8 to highlight what obviously is a major issue to most
9 people involved with nuclear medicine imaging, which
10 affects large volumes of patients i this nation since
11 so many of these studies have become seamless portions
12 of care for how we make some fairly high level
13 clinical decision in this nation.

14 And I think that most of us at the table
15 would also agree with you that we're very hopeful that
16 there will be a long-term solution on U.S. soil that
17 doesn't put us at risk for a variety of other things.

18 Having said that, obviously, we're
19 currently in this mix and match range right now of
20 trying to make things go short-term because of the
21 disruption issues. And the NRC has pointed out to us
22 several times that, you know, their goal is regulatory
23 issues and what they can do regulatory-wise to help
24 this crises kind of settle out.

25 In your mind do you see any intermediate

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1 solutions either in repair overseas or things the NRC
2 can be doing regulatory-wise to kind of help in this
3 situation? And what do you foresee as the long-term
4 things the NRC may need to do for long-term solutions
5 before we hear the next presentation?

6 MEMBER MATTMULLER: My first thought in
7 preparing this, or one of my initial thoughts, was to
8 be certain the NRC is aware of the severity of this
9 crises and the impact of this crises. And I can't
10 speak for the regulatory side.

11 So whenever there is a case of when there
12 are issues as far as waste, and I suppose that would
13 probably be most important to this division that our
14 Committee operates under, that it's dealt with
15 expeditiously. I'm not asking for special favors, but
16 just that it gets its full attention. Just so
17 everything can move forward quickly without an undue
18 or unnecessary barriers.

19 And I can't speak for them per se, but I
20 know in conversations with the staff here that they
21 are supportive in this.

22 MEMBER VAN DECKER: Thank you.

23 VICE CHAIR THOMADSEN: I have one
24 question. Well, first I'll say thank you very much
25 for presentation. I feel fortunate we survived the

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1 little video we saw, and I feel safer that we weren't
2 subjected to the others. But back before technetium
3 and bone scans, we used to use fluorine-18 all the
4 time. Is that no longer reimbursable, not as a PET
5 scan, but just as a flat scan?

6 MEMBER MATTMULLER: CMS has looked at the
7 use of F-18 sodium fluoride for clinical use. And
8 they've given it an maybe. And so actually we're on
9 probation, so to speak, and they're working out our
10 probationary terms as to how we might be able to use
11 F-18 sodium fluoride.

12 It's incredibly frustrating to thin that
13 while actually sodium fluoride F-18 was the very first
14 PET radiopharmaceutical approved by the FDA and now it
15 seems like we have to go through all these hoops and
16 just to get to its use again. And especially when
17 it's difficult to --

18 VICE CHAIR THOMADSEN: Well, but they have
19 30 years of history having used that.

20 MEMBER MATTMULLER: Okay.

21 MEMBER ZANZONICO: I think part of the
22 problem is, because I know we're conducting a trial at
23 Sloan Kettering, is that there's never definitive
24 studies, surprisingly given the fact that its been in
25 use for so long. There never have been definitive

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1 studies like controlled clinical studies demonstrating
2 the diagnostic efficacy of F-18 fluoride bone scanning
3 versus technetium-99m MDP. And I think a number of
4 centers, including ours, are undertaking such studies
5 to provide that information to allow it them to be
6 approved through reimbursement.

7 And I think and it's surprising, but I
8 think that's reality that once the bisphosphonates
9 became available, the tech bisphosphonates became
10 available, they were so much less expensive, et
11 cetera, et cetera, that those trials were never
12 actually conducted, even though as you say F-18
13 fluoride was the first, and probably still is the best
14 bone scanning agent.

15 VICE CHAIR THOMADSEN: If those trials
16 were never done, how did they know that the
17 bisphosphonates were as good at fluoride-18.

18 MEMBER ZANZONICO: Well, I don't know if
19 they were shown to be as good, but I think they just
20 became the standard very quickly.

21 VICE CHAIR THOMADSEN: Right.

22 MEMBER ZANZONICO: Not to go head-to-head.
23 I mean, it was like a de novo study almost.

24 MEMBER GUIBERTEAU: This is Milton
25 Guiberteau.

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1 Well, I think the transition there when a
2 lot of this initial work was done actually at the
3 University of Chicago, the transition from the large
4 crystal or the thick crystal rectilinear scanners to
5 the Anger camera was occurring. And it was technology
6 change that really drove the use of technetium in all
7 of these agents.

8 So I don't think the study was ever done.

9 With the new technology, with PET imaging,
10 these are beautiful studies but no one really knows
11 whether the sensitivity and specificity is the same.
12 And I think that's what CMS' objections are.

13 VICE CHAIR THOMADSEN: Exactly.

14 MEMBER GILLEY: Debbie Gilley.

15 I have three questions. The first one,
16 have we produced moly with LEU? I mean, have we
17 actually --

18 MEMBER MATTMULLER: Yes. Yes. University
19 of Missouri has done some test irradiations with LEU
20 plate targets. B&W hasn't. But I was going to say
21 that there's an AHR-type reactor in Russia. And they
22 have produced, or moly has always been produced in
23 this type of reactor. They've been successful in
24 separating it out and purifying it to the level that
25 it needs European pharmacopeia standards.

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1 MEMBER GILLEY: Is there any other way to
2 produce moly, other reactor?

3 MEMBER MATTMULLER: There's a number of
4 people out there who think they have the answer of
5 doing that with either a cyclotron, which is would be
6 a large cyclotron. Well, I'm sorry.

7 Well, there's two solutions with the
8 cyclotron. One is to make technetium-99m directly with
9 the cyclotron which, of course, then you have to have
10 major production everyday several times a day and it
11 would be costly that way. And there are some efforts
12 to try to generate neutrons using either a cyclotron
13 or a linear accelerator. But it's my understanding,
14 and this isn't my expertise, that it's very difficult
15 to get the density or the concentration of neutrons
16 from either a linear accelerator or a large cyclotron
17 that you have in a nuclear reactor type of
18 environment.

19 And so everyone says yes, we can make
20 moly-99. They can't seem to make a whole lot of it
21 just yet.

22 MEMBER GILLEY: And the last one is where
23 are we in research for any other diagnostic
24 pharmaceuticals that could be replaced tech? Is there
25 any efforts in research to look at other, maybe

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1 isotopes, that are more easily available?

2 MEMBER MATTMULLER: Well, some would say
3 F-18 sodium fluoride is right there, but just waiting
4 for us to use it. And from an FDA perspective, we're
5 good to go. So if we could get a little bit more
6 cooperation from CMS, that could be a big plus.

7 There are some F-18-based myocardial
8 perfusion imaging agents under research now, but
9 they're at least two, three, four years away before
10 the market ever sees that. Certainly not in time.

11 MEMBER GILLEY: Thank you.

12 VICE CHAIR THOMADSEN: Dr. Suleiman.

13 MEMBER SULEIMAN: Commercial production, I
14 don't know if the Missouri, they haven't produced
15 using LEU. I think they're just playing around with
16 that. But I think Argentina has a small reactor
17 that's been using LEU. And the Australian reactor is
18 the first large-scale reactor using LEU as a source
19 material for producing molybdenum. So they're on
20 line, but there have been some issues.

21 And all the other -- from two other
22 comments I want to make. When I first got involved in
23 this field years ago, Tech-99 was considered the ideal
24 nuclide. And I think it's really fulfilled that
25 prophesy. I mean, God made nuclides a certain way,

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1 and this one just happened to have a lot of
2 characteristics that are useful.

3 There's an awful lot of research with
4 cyclotrons, with other types of things. None of them
5 seem to produce the amount and quantities. I mean,
6 they're interesting, they're esoteric. Some of them
7 may be practical. But they all have some other
8 technical economic things that slow them down.

9 VICE CHAIR THOMADSEN: Mr. Lewis?

10 MR. LEWIS: A follow-on question to what
11 Debbie just asked is for an equivalent quality image,
12 my understanding is the occupational exposure when you
13 would use F-18 versus technetium would be much greater
14 because of the higher energy annihilation of the
15 gamma. And is this something you have a feel for, or
16 the amount by which the patient dose and the
17 occupational dose would increase if technetium image
18 was replaced with F-18?

19 MEMBER MATTMULLER: A lot of the
20 occupational exposure comes during the administration.
21 And there have been efforts, in fact a few commercial
22 firms have developed for lack, a remote administration
23 device to where once the IV is inserted into the
24 patient, they can dial in the activity to be
25 administered and push a button, and it gets measured

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1 automatically and is infused automatically into the
2 patient. So that can go a long way to reducing the
3 staff's exposure to the higher energy PET agent.

4 But you're right, with the 511 kEv
5 emission versus 144 technetium that is -- at our
6 facility we see higher exposure levels for our PET
7 technologists versus our SPECT technetium type
8 technologists. But it's still well within limits. And
9 it's manageable --

10 VICE CHAIR THOMADSEN: Dr. Fisher?

11 MEMBER FISHER: I have a follow-up to the
12 previous question from Rob Lewis.

13 If indeed it feasible to replace a
14 technetium-99m bone scan with a sodium fluoride-18
15 scan, what's the current capacity of U.S. producers of
16 Fluoride-18 to fill that gap?

17 MEMBER MATTMULLER: I would say it's
18 pretty good. I mean, going back to when F-18 was
19 first produced and supplied to the country, there were
20 three cyclotrons across the whole country, which led
21 to its demise against the wide availability of
22 technetium and every department then had their own
23 generator.

24 Now there's over a 100 cyclotrons in the
25 country producing F-18 for primary FDG production. So

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1 it's my understanding that they have additional
2 capabilities that this would not be a huge burden for
3 them. And they would also have the advantage that the
4 chemistry for sodium fluoride is much simpler and
5 easier than F-17 FDG. So what I'm trying to say for
6 an equal bombardment time that they would to to
7 produce FDG, for an equal bombardment time they could
8 actually produce more sodium fluoride because they
9 could process it and release it quicker.

10 VICE CHAIR THOMADSEN: Do you still have
11 your comment, Dr. Van Decker?

12 MEMBER VAN DECKER: I actually have a
13 comment.

14 You know, I just wanted to just point
15 something out which I think is a useful discussion.
16 You know, moly and the tech agents have now had a long
17 track record of some key issues for our health care
18 delivery. The net thing about a crisis in the U.S. is
19 that it creates a lot of intelligent people thinking
20 about a lot about alternatives to where you were. And
21 that's great.

22 I think that as we think this through, and
23 I look forward to the bright physicists and
24 radiochemists and NRC in the regulatory portion of
25 this, on a health care delivery basis we need to

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1 recognize that there's three big issues in this to
2 clinical patient care:

3 (1) Whatever production we decide on has
4 to be stable for us for a long time because we don't
5 want to be in the same position down the line for
6 exploring other issues;

7 (2) Whatever we look at as potential
8 alternatives to current isotope use has to be cost
9 effective because we come up with costs that are much
10 higher in the production method, we're going to have a
11 lot of problems going downstream because we're dealing
12 with a large number of diagnostic studies here, and;

13 The third piece of this is the production
14 method has to create an availability across the nation
15 to a wide variety of venues where patients get health
16 care.

17 And so when we think about potential
18 options to just getting out of the piece of well we're
19 lacking moly, that's been working but maybe there are
20 other alternatives which I think should be explored,
21 there is an issue to not lulling through all of this.
22 I mean, we need some type of solution that everyone
23 consensus buy into that's going to w work, and going
24 to work in the intermediate term, you know.

25 Okay. Thanks.

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1 VICE CHAIR THOMADSEN: Thank you for the
2 long view look of the problem.

3 Dr. Guiberteau?

4 MEMBER GUIBERTEAU: I think it's worth
5 noting, I think Rob Lewis' question is very pertinent
6 here. And, of course, acknowledging that Steve's
7 answer is correct. That when you're actually
8 administering dose, you're exposed to a considerable
9 concentration. But the management of patients after
10 you administer the radiopharmaceutical, particularly
11 F-18, we deal with this in PET scanning, PET CT
12 imaging, but bone scans are a rather high volume study
13 for us. So the next largest source of exposure comes
14 from the patient because the dose is in the patient to
15 technologist occupationally, as well as how to handle
16 these patients afterwards. You know, if they sit in a
17 waiting room, or in the lunchroom, or in terms of
18 their medical oncologist, if they make their
19 appointments convenient enough to go across the street
20 and visit their doctor and sit in the waiting room
21 after that. That we have, particularly with our PET
22 patients, advised the doctors not necessarily to see
23 the patients, all these PET patients on the same day.

24 So, I mean, I don't think this is really a
25 huge exposure problem, but it is a consideration in

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1 managing these patients. So if we do come F-19 bone
2 imaging, that some guidance in that area, at least in
3 the community, would be an important thing, I think.

4 VICE CHAIR THOMADSEN: Dr. Langhorst?

5 MEMBER LANGHORST: Steve, I wanted to ask
6 about the activation moly. Does this gel technology
7 get over the problem of lower specific activity from
8 that?

9 MEMBER MATTMULLER: Well, what has been
10 the concern of -- well to really answer your question,
11 I don't know. Because we're now delving to
12 proprietary information from General Electric.

13 MEMBER LANGHORST: Okay.

14 MEMBER MATTMULLER: Because if you read
15 the literature on the gel type generators that are in
16 use now, they're very, very small. I mean, in the
17 order of a couple hundred millicuries, which at this
18 point we'd be grateful to have but long-term would not
19 be a good solution for us. But GE thinks and is
20 confident that they've improved the chemistry in
21 different ways that they can get a high enough
22 concentration on the column that they can be the
23 multi-curie size generators.

24 MEMBER LANGHORST: And in a manageable
25 size?

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1 MEMBER MATTMULLER: Yes, in a manageable
2 size. Right.

3 Yes, because to add on what I didn't add,
4 the original generators when they came out, the column
5 would have been about a inch in diameter, maybe six
6 inches long. Because when it was produced in the old
7 way, the moly was not very concentrated and there was
8 a lot of cold moly-98 on the column and moly-99
9 breakthrough was a bigger concern.

10 Now the column on a fission generator is
11 about the size of my pinkie. I mean, it's much, much
12 smaller. And because they're able to produce the
13 moly-99 now from HEU targets in a much more
14 concentrated level.

15 VICE CHAIR THOMADSEN: Thank you.

16 Yes, Mr. Lewis, you had a comment?

17 MR. LEWIS: When we change speakers. I
18 have a quick announcement.

19 VICE CHAIR THOMADSEN: Okay. Fine.

20 And changing speakers we shall do right
21 now.

22 MR. LEWIS: Well, it was good that Steve
23 talked about construction and repairs, because the
24 building people have apparently seen fit to begin
25 construction behind this wall this moment. They're

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1 remodeling the cubicles. But they did say they would
2 try to keep it down.

3 And while I'm on a roll here, it was great
4 that Steve described the various technologies and
5 legislation, but of course neither the NRC nor the
6 Committee is really in a position to take a
7 promotional role on the technologies or the
8 legislation. Just offered for information only.

9 VICE CHAIR THOMADSEN: Thank you for that
10 reminder, Mr. Lewis.

11 And now we have Mary Jane Ross-Lee talking
12 about domestic production.

13 MS. ROSS-LEE: Yes. Good afternoon.

14 I am here to provide information from the
15 NRC perspective on domestic production of moly.

16 The NRC mission, as you know and I think
17 is what Rob was alluding to just before I came up, is
18 to license and regulate the civilian use of byproduct
19 source of special nuclear material. So what I'll be
20 discussing here today is what our role is in the moly
21 production.

22 Our regulatory mission covers three main
23 areas. That of reactors, commercial and research and
24 test reactors. The materials area, which is use of
25 nuclear materials in medicine, industry and academics,

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1 as well as in the waste issues of transportation,
2 storage and disposal.

3 The gentleman before me touched quite a
4 bit on the subject matter of technetium moly-9, so I
5 don't think I'll go into anything more on that. You
6 guys all know more about that than I can discuss.

7 Our picture today, where we're at. The
8 Canadian reactor, which produced about 40 percent of
9 the world market has been shut down since May. It
10 shows projected to start up against in August of this
11 year.

12 The Petten reactor, which was shut down in
13 February, is also showing an approximate start up of
14 about the same time.

15 The other 30 percent of the market today
16 is being supplied by reactors of South Africa, Belgium
17 and France. They are using a reactor in Poland right
18 now. It's being used to irradiate the targets from
19 Petten, which are then returned back to Petten for
20 production.

21 NNSA, which is one of the offices within
22 DOE, is looking at various proposed technologies for
23 domestic production of molybdenum. The four areas
24 that they are looking are:

25 The liquid solution reactor;

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1 Aqueous Homogeneous Reactors or AHR;

2 Neutron capture which is taking natural
3 moly and irradiating it, using low enriched uranium
4 conventional targets. Those would be used in, like, a
5 research and test reactor to produce moly;

6 As well as accelerator-drive fission.

7 The Department of Energy has signed two
8 cooperative agreements with different entities for
9 these technologies. The agreements are requiring them
10 to produce 3,000 6 day curies of moly-99 only using
11 LEU and they're to be in production by the end of
12 2013.

13 In addition and it was also touched on
14 briefly, the Markey Bill which has passed the Senate
15 Committee on Energy and Natural Resources, but is
16 currently being held up.

17 NRC, here's what I'm really to talk about,
18 where we stand and who we are.

19 We initially formed an internal working
20 group last summer to start looking at this. It
21 represented a number of multiple offices and we were
22 sort of looking at potential short-term solutions.
23 With the increase in the supply that's been able to
24 come from the foreign markets, as well as the long
25 lead time for anything domestically, we've really

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1 focused more now on what might be what we call longer
2 term solutions, or those looking at production in the
3 2013 time frame.

4 We meet monthly to talk about the issues
5 and kind of see where we stand, and try to move
6 forward on what we might see as our licensing path.

7 We also participate in a interagency
8 working group that was put together by the Office of
9 Science and Technology and Policy. There are
10 representatives in it as well as us is DOE, FDA, HHS,
11 the State. They meet approximately monthly as well.
12 And then there was also a public workshop in March
13 here they had Covidien and Lantheus in to discuss
14 molybdenum-99.

15 As an agency, we currently have received
16 four letters of intent. These are people who have
17 sent us in a letter saying we are looking at doing
18 production of molybdenum-00 here domestically.

19 One is from B&W. They are looking at this
20 liquid solution reactor, or AHR technology.

21 General Electric Hitachi, which would be
22 looking at neutron capture S rating natural moly.

23 Coqui Radiopharmaceuticals, which is a
24 company out of Puerto Rico has sent one in, and
25 they're looking at using research and test reactor

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1 technology.

2 And as well as we had a previous letter
3 from Missouri University Research Reactor. They're
4 also research and test reactor.

5 The fifth player that we're aware of is
6 this Advanced Medical Isotope Corporation or AMIC.
7 They are looking at accelerator technology. They have
8 not submitted a letter of intent to us to go into
9 production, but they have requested some regulatory
10 feedback on a potential application.

11 B&W, who their facility would be called
12 the Medical Isotope Production System, or MIPS, they
13 are one of two who have signed a cost-sharing
14 agreement with Department of Energy and NSA. They are
15 using the Los Alamos National Lab as their lead
16 support.

17 They're looking at this INVAP or Argentina
18 separation and purification design, doing some
19 research with them.

20 It would be a two-step process, but they
21 have asked for a single Part 50 license.

22 And they would be constructing and
23 operating four of these Aqueous Homogeneous Reactors
24 which are operating at about 220 kilowatts each.

25 The schedule that they had supplied to us

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1 was to have submitted a Quality Assurance Program, and
2 that will be coming in actually this month.

3 Their Environmental Report we should see
4 in June or July of this year.

5 They hope to submit a construction
6 application with preliminary Safety Analysis Report in
7 December of this year.

8 They would like to see the construction
9 permit issued in December of the following year.

10 Then they would submit their operating
11 license or final Safety Analysis Report in March of
12 2012 with an operator license in September of 2013,
13 which allow them to begin production in December of
14 2013. That is with the DOE cooperative agreement that
15 they're to be in production at that time.

16 General Electric Hitachi neutron capture,
17 they are the second entity that has signed a cost-
18 sharing cooperative agreement with DOE. They are
19 looking at irradiating natural molybdenum in existing
20 reactor.

21 They've submitted to us actually a
22 shipping package application to move these targets
23 between facilities. And in the future there would be
24 a production facility application come in.

25 Their schedule, as I mentioned, the second

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1 quarter of 2010 the shipping package application was
2 submitted, and that was just recently approved.

3 Late in this year we believe we'll see an
4 application for a processing facility.

5 And sometime in the fiscal year of 2011 we
6 would think we would see an amendment to either a
7 research and test reactor or power reactor, depending
8 on where they plan to irradiate their targets.

9 Coqui Radiopharmaceutical, which is this
10 organization out of Puerto Rico, their facility would
11 be called the Medical Molybdenum-99 Production
12 Complex, or MMPC.

13 They are proposing two non-power pool-type
14 research and test reactors, again irradiating low
15 enriched uranium targets. They would have a single
16 processing facility.

17 Their potential schedule may be as early
18 as December of this year to see the construction and
19 operating license application for this facility.

20 The last two on my list, Missouri, which
21 is MRTR, the Missouri Research and Test Reactor is an
22 existing RTR. They would be using LEU conventional
23 target technology.

24 We don't have any specifics on their
25 schedule at this time, but they had submitted a letter

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1 of intent to be looking into production of moly.

2 The Advanced Medical Isotope Corporation
3 or AMIC, again using accelerated-driven fission.
4 While we don't have a letter of intent from them,
5 they've submitted now two letters about a potential
6 application under Part 70. We believe that their next
7 step forward will be to schedule a meeting, a
8 preapplication meeting to come in and further discuss
9 technology with us.

10 Regulatory framework, where we are in
11 this. Part 50 covers power and non-power reactors,
12 production and utilization facilities would all be
13 licensed under Part 50.

14 Part 70 we do licenses for special nuclear
15 material. And Part 30 for any of the byproduct
16 material depending on location. It could be NRC or
17 Agreement States.

18 The reason that we've mentioned all of
19 these is, for instance, if you look at the B&W
20 proposal, that would be a non-power commercial
21 reactor. That would be under Part 50.

22 AMIC might come in under Part 70. So
23 that's why we've got a working group that's kind of
24 looking at all the possible path forward.

25 What we're doing now. Looking at the

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1 regulatory framework, trying to figure out where each
2 of these different proposals would fit in.

3 We've gathered a group of experienced
4 staff together. A branch has recently been formed
5 that's focusing primarily on this, as well as the
6 agency-wide working group. And we have management
7 support going forward looking at budgeting and
8 resources.

9 And so that's what I've got as far as our
10 role in this to date.

11 VICE CHAIR THOMADSEN: Thank you very
12 much.

13 Questions for the speaker?

14 MEMBER ZANZONICO: This is Pat Zanzonico.

15 I have two questions. One is, is there any
16 such thing as fast-tracking of these sorts of
17 applications given the medical issues that might
18 prevail?

19 MS. ROSS-LEE: If you mean fast-tracking
20 as in like skipping over regulations, no.

21 MEMBER ZANZONICO: No, not in that sense.
22 But in terms of moving certain applications to the
23 front of the line?

24 MS. ROSS-LEE: Well, these applications
25 would get the necessary priority on them. The best

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1 way to get an application through us quickly is when
2 we get a high quality application in. So the people
3 that are talking to us, we are emphasizing that with
4 them. What does it need to have in it? What's the
5 quality of the material? How fast can we look through
6 thing?

7 So we're fast-tracking it within the
8 regulatory framework that we can, yes. And we do
9 recognize the priority of it.

10 MEMBER ZANZONICO: And the second question
11 I have is part of their application or preapplication
12 paperwork, is there some estimate of what proportion
13 of the required need a particular installation can
14 takeover? In other words, it sounds like there's four
15 viable options and a fifth one that's less developed.
16 If each of them could provide 100 percent of the
17 capacity, or 100 percent of the need, or some such
18 thing as that, it would seem like that now there would
19 be an over supply and there wouldn't be a need for all
20 of this technology, investment, regulatory review, et
21 cetera, et cetera. Is something like that at all part
22 of the regulatory review?

23 MS. ROSS-LEE: What I believe it is a part
24 of is DOE's cooperative agreement plan. If you look
25 at their proposal, each of the technologies that

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1 they're asking is to be able to produce 50 percent of
2 the domestic market. What I believe their approach
3 is, would be, to ensure that there would be at least
4 three operating technologies, each capable of
5 producing 50 percent so were one to go down, the other
6 two would remain in operation. So they are taking a
7 look at that.

8 VICE CHAIR THOMADSEN: Dr. Langhorst.

9 MEMBER LANGHORST: Sue Langhorst.

10 One of the things that Mr. Mattmuller had
11 addressed was the waste issue.

12 MS. ROSS-LEE: Yes.

13 MEMBER LANGHORST: And so is NRC including
14 your waste regulations and how these licensees will
15 manage their waste and be able to have access to
16 proper waste disposal?

17 MS. ROSS-LEE: Well, we are looking at our
18 portion of the regulatory framework for waste, yes.
19 We can't tell DOE what to do with their waste. DOE I
20 know is looking at that, and I believe there are
21 pieces in the cooperative agreement that DOE is
22 signing that specifically addresses the waste issues.

23 We haven't been privileged to all of the
24 words that are in that cooperative agreement. But I
25 do know that the applicants have had discussions with

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1 DOE about the waste, yes.

2 VICE CHAIR THOMADSEN: Mr. Lewis?

3 MR. LEWIS: I would just add that the safe
4 handling of waste would be part of our safety review.

5 MS. ROSS-LEE: Right.

6 MR. LEWIS: And/or our environmental
7 review in our application as well. Just to be clear
8 about that.

9 MEMBER LANGHORST: And so part of that
10 would be ensuring that there was a DOE commitment to
11 take the waste that they are committed to take?

12 MR. LEWIS: No.

13 MS. ROSS-LEE: I think we need to ensure
14 that they handle their waste safely. I don't believe
15 it's --

16 MR. LEWIS: Well, it's transferred to
17 somewhere.

18 MS. ROSS-LEE: -- us to whatever DOE
19 decides.

20 MR. LEWIS: Or a commercial site.

21 MEMBER LANGHORST: Because that could be a
22 real sticky point if there really was no place to go
23 with some of this waste, and you wouldn't be able to
24 function long if you didn't have that true commitment
25 and follow-through on taking the waste.

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1 VICE CHAIR THOMADSEN: Thank you.

2 Mr. Mattmuller?

3 MEMBER MATTMULLER: Steve Mattmuller.

4 A couple of questions for you. B&W is
5 proposing this AHR-type reactor. Are there any AHR-
6 type reactors licensed in the U.S. today?

7 MS. ROSS-LEE: There is not currently.
8 There was quite a few years ago we had AHRs. And I've
9 got to think. It's probably been 30 some plus years.

10 Los Alamos, I think, probably was the last
11 one to have an AHR in operation. So we don't
12 currently have any licensed in the United States, no.

13 MEMBER MATTMULLER: Okay. And then for
14 GE's plans to irradiate targets within a power
15 reactor, what sort of challenges does that present to
16 you from a regulatory perspective?

17 MS. ROSS-LEE: Well, we haven't seen what
18 GE is proposing yet. Due to the targets in a research
19 and test reactor, will probably not be as challenging
20 because that's -- research and test reactors are
21 typically licensed to put things in and out of them
22 anyways.

23 What we're hearing is that GE is looking
24 at the TIPS, which is the Temperature in-core probes
25 that exist within reactors, in power reactors, as a

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1 place where these targets could be inserted and
2 withdrawn. It would take a license amendment to do
3 that because they would be wanting to do this at
4 operation, and that is not typically how power
5 reactors operate.

6 MEMBER MATTMULLER: Yes.

7 MS. ROSS-LEE: But I do know we have been
8 working as far as like getting cobalt-60 production.
9 So the agency has started looking at how this could
10 happen. And I would believe the moly one would
11 probably follow a very similar process to that.

12 MEMBER MATTMULLER: Okay.

13 VICE CHAIR THOMADSEN: Thank you.

14 Do you still have a question, Ms. Gilley?

15 MEMBER GILLEY: No.

16 VICE CHAIR THOMADSEN: Okay. Yes, Mr. Van
17 Decker.

18 MEMBER VAN DECKER: Van Decker.

19 And I guess there's no regulatory
20 predisposition going into this about one of these
21 methodologies versus another per se. You guys are
22 going to look against all comers and decide what the
23 licensee needs to do and the regulatory, safety and
24 environment, and then the business model of what it
25 will cost them to do that will essentially somewhat

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1 play out in this, I guess, right? I mean, we're going
2 to look at a different options and the speed coming on
3 line, kind of?

4 MS. ROSS-LEE: Yes. We have no -- we won't
5 pick a technology over another. We'll work with any
6 of the proposed applicants. We'll adequately review
7 the technologies.

8 So at this point, no, we don't have one
9 over the other. It'll probably be first in, first
10 come depending on the applications that are coming to
11 us.

12 VICE CHAIR THOMADSEN: Dr. Langhorst.

13 MEMBER LANGHORST: Yes. Sue Langhorst.

14 Another question came to mind. Will this
15 impact the licensing staff? I mean, if you get all
16 three of these, or two or three applications, do you
17 have the capacity to get those through in, as Pat
18 asked, maybe move it to the first of the line? Is
19 that going to be a big impact on the NRC staff?

20 MS. ROSS-LEE: It'll have an impact. Any
21 new work coming in would. But we've already begun the
22 process of looking at that; what would we need to do
23 to be able to get these licensed to support the
24 existing schedules? So internally the working group
25 has already taken actions and steps to be prepared --

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1 MR. LEWIS: Yes.

2 MS. ROSS-LEE: -- to review these
3 applicants as they come in.

4 MEMBER LANGHORST: Thank you.

5 VICE CHAIR THOMADSEN: Dr. Suleiman?

6 MEMBER SULEIMAN: Yes. Just a
7 clarification, as I think Rob Lewis had mentioned
8 earlier, FDA as well, I mean people come to us with
9 applications and we handle them on a case-by-case
10 basis. If the applications are prepared well, if the
11 agencies are given enough heads-up and there's been a
12 lot of proactivity on behalf of everybody in this
13 whole crises with all these multiple task groups and
14 whatever.

15 We've been hearing people way ahead of
16 time. And I don't think the regulatory agencies are
17 going to be as big a bottleneck as people are afraid
18 they are. But I think in some cases we're dealing
19 with some very different technologies. But I think
20 ultimately it's going to be marketing, practicality,
21 feasibility.

22 So, you know, some of these things are
23 exotic, they may not have a lot of through-put. PET
24 production is not the same thing as milking a
25 molybdenum generator. So a high PET through-put is

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1 what? Ten patients a day? So that's all going to
2 come into play.

3 And who knows? By the time -- you know,
4 you're dealing with two -- at least my observation
5 you're dealing with two outdated reactors. I mean,
6 they're just -- they're 50 old. I mean, that's how I
7 see it. No amount of fixing or repair. I think
8 you're either going to need new reactors or you're
9 going to need something else that's going to equal
10 that amount of through-put.

11 So I think the crises is working through,
12 but it's not finished.

13 VICE CHAIR THOMADSEN: Any other comments.

14 MEMBER MATTMULLER: I do have one more
15 question from your participation in the interagency
16 group, and maybe Orhan might be able to answer this
17 too. But have you discussed GE's gel generator?
18 Because I looked at half different -- different ways.
19 And I don't know from the FDA's perspective whether
20 they would require a new drug application for a gel
21 generator or if you have enough gray hair, one might
22 remember that one GE's divisions is Amersham. And
23 Amersham bought Medi-Physics. And Medi-Physics used
24 to make technetium generators. So I'm assuming
25 somewhere in their file cabinet they have an NDA for a

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1 fission moly generator. If they could amend that to
2 allow them to bring their gel-type generator to the
3 market quicker.

4 So the short question is: From your
5 interagency group, have the FDA people discussed at
6 all how they'll handle the GE generator?

7 MS. ROSS-LEE: I am aware that just as GE
8 has talked to us as a regulatory entity, they have
9 also met and discussed with FDA. I don't know the
10 specifics of your answer, but I do know they are in
11 discussions.

12 Part of the cooperative agreements with
13 DOE is they have been encouraging these people to
14 start to talk to us and FDA, particularly because
15 they'll have to get through both of these
16 organizations before they'll be able to actually put
17 it in the market.

18 I don't know the details of it, but I do
19 know that they have talked with FDA.

20 MS. ROSS-LEE: Could you comment from an
21 NRC perspective the biggest hurdle, Babcock & Wilcox
22 or GE would have to face with the NRC?

23 MS. ROSS-LEE: Boy, what would be our
24 biggest hurdle?

25 You know, I think the biggest hurdle

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1 they're going to have to do is really is coming up
2 with a high quality product for us to be able to get
3 the review done in the time that they need. They've
4 got a really short schedule. So if they come in and
5 there's holes in their application, if they haven't
6 addressed all the safety aspects and we need to go
7 back and continuously ask them for more information;
8 each of those iterations just puts time in the
9 schedule. And that's what I see is going to be the
10 biggest challenge. Is getting a product in right from
11 the beginning that's good quality so that we can do
12 the safety review on it.

13 VICE CHAIR THOMADSEN: Dr. Suleiman?

14 MEMBER SULEIMAN: Yes. One more comment.

15 My biggest concern is these are parallel
16 but very much related issues, is this shift to LEU
17 from HEU and all these new technologies. And the
18 ultimate issue I think is yield and how much product
19 you're going to get.

20 And so if everything was going just
21 perfectly right now and you shifted into LEU
22 technology, these reactors are not going to produce
23 the same amount. So you'd need more--

24 MS. ROSS-LEE: Reactors.

25 MEMBER SULEIMAN: Yes. So I don't know to

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1 what degree the LEU conversion when and if that's
2 mandated, will impact on this. Hopefully, by that time
3 the molybdenum production will be less of an issue.
4 But it's a big unknown.

5 VICE CHAIR THOMADSEN: Debbie?

6 MEMBER GILLEY: Debbie Gilley.

7 We've already converted the research
8 reactors over to LEU in most of the universities, have
9 we not?

10 MS. ROSS-LEE: Yes.

11 MEMBER GILLEY: Do we know any -- have any
12 idea about what their change in yield or activities
13 were based on going from HEU to LEU?

14 MEMBER MATTMULLER: Well, for
15 clarification. I think the research reactors are being
16 powered with -- they started off with HEU fuel.
17 They're now operating on LEU fuel.

18 MEMBER GILLEY: Okay.

19 MS. ROSS-LEE: The change in targets I
20 don't know. I believe the South Africans recently put
21 out a press release where they have started making
22 molybdenum with LEU, LEU targets I think. But I don't
23 know the details of that.

24 MEMBER SULEIMAN: But they've been doing
25 that, I want to say December or early January or

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1 February.

2 MS. ROSS-LEE: So I actually don't know
3 the difference in the output when you change the
4 targets.

5 VICE CHAIR THOMADSEN: Yes, Dr. Howe?

6 MS. HOWE: Just a clarification. Not all
7 of the research reactors have converted to LEU. The
8 MURR reactors do a LEU fuel. They're thinking of
9 irradiating LEU targets, but they're still at HEU --

10 MS. ROSS-LEE: Right. There are a couple
11 of reactors that are still at HEU that are in the
12 process of conversions right now.

13 MS. HOWE: Yes. Yes.

14 MS. ROSS-LEE: But what DOE is talking
15 about is the target material to produce the moly needs
16 to be made from LEU to be done domestically as opposed
17 to with HEU. So that is where the conversion is going
18 to happen.

19 And all the technologies that we're
20 looking at and the applicants we're talking to, all
21 propose to use LEU targets when they come in.

22 VICE CHAIR THOMADSEN: If there are no
23 further questions, thank you very much.

24 And we're running a little behind
25 schedule. We have considerable discussion coming

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1 after our break right now. So please try and be back
2 as close to 2:30 as possible.

3 (Whereupon, at 2:12 p.m. off the record
4 until 2:28 p.m.)

5 VICE CHAIR THOMADSEN: Well, welcome back.
6 And before we get to the next presentation, we have
7 one order of business to take care of. I think that
8 Ron has a message for the committee.

9 MR. ZELAC: Yes, indeed. I bring you
10 greetings from Chairman Malmud. As you know, he had
11 surgery a week ago. I spoke with him yesterday and he
12 is recovering. He was sorry, of course, that he could
13 not be here, but his physical condition is probably
14 going to limit his professional activities for some
15 period of time as he progresses through therapy to get
16 back on his feet, literally.

17 VICE CHAIR THOMADSEN: And for the
18 Committee, I did pick up a card to send to Dr. Malmud.
19 And if you should approve, I'll pass this around and
20 you may sign the card. If you object, you can write
21 in your minority opinion -

22 (Laughter.)

23 VICE CHAIR THOMADSEN: - appropriately.

24 And with that, I will turn the
25 presentation over to Patricia Pelke to talk about one

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1 of our favorite topics here, it seems, because it
2 keeps coming up. The prostate brachytherapy situation
3 at the Veteran's Medical Center in Philadelphia.

4 MS. PELKE: Thank you, Dr. Thomadsen.

5 My name is Patty Pelke. I'm with the NRC.
6 I'm with the Region III office. I'm a branch chief,
7 materials licensing branch. My group is responsible
8 for project management of the master material license
9 that was issued to the Department of Veteran's
10 Affairs.

11 This is the third time we have been here
12 to update you all on the status of progress with the
13 medical events that were identified at the VA facility
14 in Philadelphia.

15 For a little background, some of you may
16 have already heard this, you may know this, but I'll
17 work through this pretty quickly.

18 The Department of Veteran's Affairs has a
19 master material license. The master material license
20 is a license that authorizes a federal facility to
21 issue permits which are equivalent to NRC-specific
22 licenses. They do enforcements, they inspect and they
23 follow up on allegations for their program.

24 The Veteran's Affairs program is
25 implemented through their National Radiation Safety

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1 Committee. And they've implemented day-to-day
2 operations or delegated day-to-day operations to their
3 National Health Physics Program.

4 I've already talked about that. And the
5 Department of Veteran's Affairs was a permittee under
6 the Department of Veteran's Affairs' master material
7 license. So, a specific licensee, have you.

8 And Philadelphia had a broad-scope permit
9 that authorized both diagnostic and therapeutic uses.
10 And they had a bit of R&D there as well, I believe.

11 The Philadelphia Veteran's Affairs Medical
12 Center had retained the services of a consulting
13 group. They did their radiation oncology. And
14 radiation oncology when we talk about Veteran's
15 Affairs at Philadelphia, is limited to prostate
16 brachytherapy.

17 And the program started in 2002 in
18 Philadelphia. They treated approximately 114 patients
19 between February 2002 and May 2008.

20 I already did that. In May 2008, the
21 Philadelphia VA notified the National Health Physics
22 Program, who in turn notified the NRC of a medical
23 event that occurred where a dose of I-125, a permanent
24 prostate implant, was delivered where the dose to the
25 individual or the dose to the prostate was less than

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1 80 percent of the prescribed dose.

2 Under the master material license, the
3 National Health Physics Program responded to that
4 event. They went out and did an inspection. They
5 asked the permittee as a result of the one indexing
6 event, to take a look at ten previous treatments that
7 they had.

8 Of those ten treatments, additional
9 medical events were identified. So, the NHPP then
10 asked the Philadelphia VA to take a much more - a
11 broader brush-stroke back, and medical events
12 continued to be identified.

13 The NRC as a result of continued medical
14 events that began to be reported to us from the
15 beginning of June 2008, up through December of 2009, I
16 believe was the last time they requested a retraction,
17 in December of 2009, they reported additional medical
18 events, they reported a total of 98.

19 One was retracted as I had mentioned in
20 December of 2009. It was reported twice. One for an
21 underdose to the prostate, and one for an unintended
22 dose to an organ or tissue.

23 And for the treatments that were done at
24 Philadelphia, the dose of the unintended organs or
25 tissues, they were looking at periprostatic tissue,

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1 the rectum and as well as a dose to the prostate.

2 As a result of the medical events that
3 were identified at Philadelphia, the NRC wanted to
4 know how many other facilities the VA had that were
5 engaged in prostate brachytherapy. And we asked the
6 VA to go back and take a look at those programs, the
7 active programs they had.

8 At the time we issued a Confirmatory
9 Action Letter in 2008, the VA had identified 12 active
10 prostate brachytherapy programs.

11 And as I mentioned earlier as of December
12 of last year, they had reported a total of 97 medical
13 events.

14 The first phase of reporting for the
15 Department of Veteran's Affairs involved prostate
16 underdoses to the prostate, less than 80 percent of
17 the dose delivered.

18 Also, the Phase II looked at doses to the
19 rectum, periprostatic tissue, as I said, in the
20 bladder.

21 The VA indicated to us in, I would say,
22 June/July 2008 time frame, that the criteria they were
23 using for a dose to the prostate was D-90.

24 The medical events as well, less than 80
25 percent of the prescribed dose was delivered to the

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1 prostate. And then they looked at - we looked at
2 medical events where a dose to an unintended organ or
3 tissue exceeded our regulatory requirements.

4 As a result of the investigation that was
5 done at Philadelphia - and as I mentioned, our
6 inspection started in July of 2008. And we did - our
7 last on-site inspection at Philadelphia was October of
8 2009.

9 During that time we assessed the
10 permittee's response to the events as well as the
11 National Health Physics Program's response to the
12 events.

13 What we determined as a result of our
14 inspection activities as far as root causes for the
15 medical events, incorrect placement of seeds. We saw
16 as well as NHPP and Philadelphia as they went back,
17 erratic seed placement.

18 They also had inadequate procedures.
19 There was poor management/oversight of contractors and
20 there was inadequate training of licensee staff.

21 As far as poor management/oversight of the
22 brachytherapy program, as I mentioned probably in one
23 of my first or second slides, the VA had contracted
24 their services for radiation oncology to the
25 University Hospitals of Pennsylvania.

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1 And I can't say that this necessarily may
2 be an outlier. I believe that this might go on in a
3 number of medical institutions.

4 When you contract out the services to
5 another group, there is a misconception, maybe, that
6 you're contracting that service out to a group of
7 professionals and that contract had little oversight,
8 if any oversight.

9 Also what we saw at Philadelphia was
10 somewhat of an outlier. They didn't do any peer
11 reviews of the treatments that were performed there.
12 And as I mentioned, there was poor placement of the
13 seeds by a physician. One physician in particular.

14 And the physicists that were also working
15 with that physician had questioned placement of some
16 of the seeds. The physician responded back to the
17 physicist, but the physician continued to stand by the
18 quality of the implants that were performed there.

19 Also, we indicated that there was a lack
20 of safety culture in that safety concerns were
21 identified, but they were not raised to appropriate
22 levels within the organization to take any action.

23 The follow-up care for the patients at
24 Philadelphia, they performed follow-up CTs on all the
25 patients that were treated that they could get ahold

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1 of. And they reevaluated the dose delivered to the
2 treatment sites. And then they also had some patients
3 that because of the recentness of their initial
4 implant, could receive additional implants at another
5 VA facility. And then also they suspended the
6 privileges of one of their authorized users -
7 actually, they suspended their whole prostate
8 brachytherapy program back in June of 2008 as
9 additional medical events became evident and reported.

10 NRC's response to the events, as I
11 mentioned we conducted initial - our initial
12 inspection activity was a reactive inspection back in
13 July of 2008. We expanded that into a special
14 inspection.

15 We went back out to the site in September
16 of 2008. We were back there again in June of 2009,
17 August 2009, and October 2009.

18 We issued a Confirmatory Action Letter.
19 In that Confirmatory Action Letter we received
20 commitments from the VA about follow-up actions they
21 would take as a result of the medical events that were
22 reported at Philadelphia.

23 Those actions included standardizing their
24 procedures, taking a look back at all their other
25 active prostate brachytherapy programs to determine

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1 whether or not circumstances that we had identified at
2 Philadelphia were common to any of their other
3 facilities.

4 We issued two inspection reports. Our
5 first inspection report was in March of 2009. And
6 then we issued our last inspection report for that
7 facility in November of 2009.

8 We also issued a Demand for Information to
9 a physician last spring indicating that if that
10 individual was going to be involved in any use of
11 byproduct material, whether it be an NRC or Agreement
12 State regulated-state, that they needed to let the NRC
13 know within 72 hours. And to date, we have not
14 received any notification from that individual that
15 they've been involved with any byproduct material.

16 As a result of the violations that we
17 identified, the NRC invited the VA to a Pre-Decisional
18 Enforcement Conference in December. That Enforcement
19 Conference was held at NRC headquarters. And based on
20 the findings and the medical events that occurred, the
21 NRC issued a substantial civil penalty to Philadelphia
22 for the events that occurred at the Philadelphia VA.

23 And you can see the amount here. \$227,500
24 was the civil penalty that we issued. This is the
25 second highest civil penalty that we've ever issued to

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1 a materials licensee.

2 The previous civil penalty that had been
3 issued to a different materials licensee was several
4 years ago. Radiation Oncology Services. Some of you
5 may or may not recall that where iridium-192, HDR 10-
6 curie source was left in a patient and the patient
7 died.

8 Our response to these events, we, Region
9 III, conducted inspections at the other active
10 Department of Veteran's Affairs facilities that
11 conducted prostate brachytherapy.

12 As I mentioned when we issued our
13 Confirmatory Action Letter in October 2008, the VA
14 told us that they had 12 active prostate therapy
15 programs.

16 We also included an additional facility,
17 their renal facility, because that facility had been
18 active up until March of 2008. And we believe that
19 the last patients treated there were - their activity
20 was recent enough to the events that we identified at
21 Philadelphia for us to include that in the scope of
22 our inspections.

23 We also did an inspection at the National
24 Health Physics Program in December of 2008 to assess
25 their event response and follow-up to the events that

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1 occurred not only at Philadelphia, but also we had an
2 opportunity to assess their response to the
3 inspections that they conducted at the other VAs.

4 And as I mentioned, the results of these
5 last inspections, our extended condition inspection,
6 essentially, is what we called it, for the other 13 VA
7 facilities that conducted prostate brachytherapy, as
8 well as our inspection at the National Health Physics
9 Program, those will be wrapped up into one inspection
10 report. And that will be issued - we're looking at -
11 it will be out this week.

12 NRC actions going forward, we looked at
13 global actions that were instituted by the Department
14 of Veteran's Affairs. This was essentially as a
15 result of our Confirmatory Action Letter.

16 What we found when we went out and did our
17 extended condition inspections are that we didn't see
18 some of the issues that we saw at Philadelphia
19 prevalent throughout the rest of the VA.

20 And many of you may be familiar with VA
21 institutions. They typically align themselves with
22 another teaching institution. And we saw that with
23 the other facilities that we went out to inspect.

24 We did see that peer review was part of
25 the process. We saw a spectrum of quality of

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1 procedures. But I will also qualify the fact that
2 procedures, you can have procedures that may not be to
3 the level of detail that some folks may believe is
4 necessary.

5 And depending on the skill of the craft or
6 the expertise of the individuals that are implementing
7 those procedures, you can see quite a spectrum of
8 implementation depending on experience level of those
9 folks.

10 We're also looking at our actions to
11 assess performance improvements with the VA. And
12 typical of any other NRC licensee that we would have
13 where we identify escalated enforcement, they will be
14 subject to increased inspection oversight. So, we'll
15 be doing increased inspection activities of the VA
16 facilities.

17 We'll also be accompanying their
18 inspectors, and we'll also be looking at their event
19 response going forward.

20 And then internally what we're trying to
21 do is, you know, we're a learning organization and
22 we're trying to get better, always trying to get
23 better. So, we're taking a look at what we learn from
24 these events to see how we might improve and refine
25 some of the tools that we have available so that going

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1 forward we can look at maybe early precursors that
2 could have prevented some of these in the future.

3 And then the last four slides are just
4 some visual so you can see what we saw at the VAs that
5 had adequate programs for prostate brachytherapy.

6 This is an example of an implant from the
7 VA in Minneapolis. I'm using these as visuals so you
8 can see the dramatic difference in the placement of
9 seeds between some of these other VA facilities and
10 what occurred at Philadelphia.

11 This is an implant from Cincinnati. This
12 is an example of an implant from Philadelphia. And
13 there's another example of an implant from
14 Philadelphia.

15 And if there's any questions -

16 VICE CHAIR THOMADSEN: Thank you very much.

17 Are there questions from the Committee?

18 MEMBER ZANZONICO: Yes, I have several
19 questions.

20 You indicate at the beginning that there
21 were 97 of these events that rose to the level of a
22 medical event.

23 That was among all the 12 VA sites?

24 MS. PELKE: No. The 97 that were reported
25 were just for Philadelphia.

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1 MEMBER ZANZONICO: Out of a total of how
2 many cases?

3 MS. PELKE: 114 patients were treated. And
4 they did 116 treatments. Two patients were treated
5 twice.

6 MEMBER ZANZONICO: And I take it, then,
7 that there's no preemptive inspections. In other
8 words, unless the -

9 MS. PELKE: Oh, yes.

10 MEMBER ZANZONICO: There are routine -

11 MS. PELKE: Yes, there's routine
12 inspections.

13 MEMBER ZANZONICO: And so the Philadelphia
14 site had not been routinely inspected -

15 MS. PELKE: Yes, it had been routinely
16 inspected.

17 MEMBER ZANZONICO: And it passed muster?

18 MS. PELKE: Yes.

19 MEMBER ZANZONICO: Okay.

20 MS. PELKE: They also had two previous
21 medical events at Philadelphia. There was one in
22 2003, and one in 2005. Both involved the same
23 authorized user.

24 The events in 2003 were such that a number
25 of seeds - I'm going to say about half the seeds they

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1 were going to implant went into the bladder.

2 They were subsequently retracted from the
3 bladder, and the written directive at the time was
4 revised to indicate the number of seeds implanted.

5 That was determined to not be a medical
6 event, because the authorized user revised the written
7 directive before completion of the treatment.

8 And then there was a similar event that
9 occurred in 2005. A number of seeds, again, were
10 implanted - erroneously implanted into the bladder.
11 And they were removed from the bladder, the written
12 directive was revised, and that was, again, was
13 determined not to be a medical event.

14 MEMBER ZANZONICO: Now, in the case where
15 the - you say half the seeds were placed in the
16 bladder, but it wasn't deemed a medical event.

17 Was that prescription redone after the
18 initiation of the placement of the seeds?

19 I mean, it almost has a sound as if they
20 were pulling a fast one to make it not a medical event
21 just in terms of the paperwork.

22 MEMBER MATTMULLER: That's one
23 interpretation.

24 MS. PELKE: Yes, that is one
25 interpretation.

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1 MEMBER ZANZONICO: Sounds like the only
2 interpretation.

3 MS. PELKE: But I will offer the fact that
4 we're talking about primarily one authorized user was
5 involved in most of these treatments. That individual
6 knew enough when seeds got into the bladder, that that
7 was a bad thing. And that when seeds got into the
8 bladder, that meant that you had to report. So in
9 2003 and 2005, events were reported.

10 As a result of those seeds going into the
11 bladder, what it appears to - what appears to have
12 happened is the individual would - the authorized user
13 would find the prostate and would - fearing the chance
14 that seeds could get put into the bladder, just kind
15 of by guess - maybe that's a bad word. I'm sure it's
16 a bad word for the physicians, but would back off to
17 ensure that seeds wouldn't go into the bladder.

18 And as a result, there was a lot of
19 erratic placement of seeds that occurred because of
20 the fear of putting seeds into the bladder.

21 MEMBER ZANZONICO: It just seems that one
22 treatment plan you showed from the VA -

23 MS. PELKE: Yes.

24 MEMBER ZANZONICO: - was just mind-
25 boggling.

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1 MR. LEWIS: That was done later, though. I
2 think that we shouldn't get involved in speculating
3 about what happened.

4 I think that we have our - Patty didn't
5 mention in her talk, but we issued our Notice of
6 Violation with seven violations.

7 MS. PELKE: Yes.

8 MR. LEWIS: And the VA replied to us with
9 their corrective actions for each of those. And we've
10 dispositioned those at this point, right?

11 MS. PELKE: Yes. We issued a Notice of
12 Violation with the significant enforcement action in
13 March of this year. And the VA has paid their civil
14 penalty.

15 And as I said, we're dispositioning the
16 results of our extended condition inspections. Those
17 were the other -

18 MEMBER ZANZONICO: See, what I'm trying to
19 understand is the chronology of the detection of the
20 initial rash of mistreatments followed by continued
21 mistreatments and how effective the NRC's oversight or
22 intervention was in preventing further mistreatments.

23 Because at least the one you showed, that
24 was not subtle. So, I mean, were there continuing MES
25 as obvious, as gross as that, even after the initial

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1 NRC intervention?

2 MS. PELKE: This is a retrospective look
3 back after they suspected -

4 MEMBER ZANZONICO: So, everything is retro
5 --

6 MS. PELKE: That's correct. Yes.

7 MR. LEWIS: These images were done by a
8 panel forum to investigate the -

9 MEMBER ZANZONICO: Okay. So, correct me if
10 I'm wrong. So, there was no intervention by the NRC
11 while these 114 - over the course of these 114
12 treatments being delivered?

13 It was all after the fact?

14 MS. PELKE: In 2003, the VA received their
15 master material license. At that time the VA was
16 issued a permit for Philadelphia and was responsible
17 for the routine inspection activities that occurred
18 there.

19 Prior to that, the NRC responded to the
20 medical event that was reported in 2003 -

21 MEMBER ZANZONICO: Right.

22 MS. PELKE: - and evaluated the
23 circumstances. And we documented our findings there
24 and went to the program office on the fact that the
25 written directive said so many seeds to the prostate.

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1 However, in the OR the physician determined that a
2 number of seeds were implanted into the bladder,
3 retracted those seeds and revised the written
4 directive.

5 Does this constitute a medical event?

6 And NRC, our Office of General Counsel,
7 indicated, no, that did not constitute a medical event
8 because a written directive had been revised.

9 MEMBER ZANZONICO: And then there were
10 subsequent patients treated at the VA.

11 MS. PELKE: Yes.

12 MR. LEWIS: What I do think, Dr. Zanzonico,
13 that we have the same question. Why didn't the NRC
14 processes flush out this issue, or did they and we
15 didn't act on it?

16 MEMBER ZANZONICO: Right. That's the
17 underlying question.

18 MR. LEWIS: And we have in Patty's last
19 tech slide, she talked about a lessons learned effort
20 underway of four senior staff that were not - are
21 knowledgeable of the issues, but weren't involved in
22 this issue.

23 And their product is due to Jim Luehmann
24 in the summertime. And I think we'll be able to have
25 a discussion at the fall meeting about what they found

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1 and the path forward in terms of NRC's internal
2 processes.

3 MEMBER ZANZONICO: Understood. We all have
4 20/20 hindsight. Just one last question.

5 I gather there was enhanced oversight of
6 the other VA sites, but was there also enhanced
7 oversight of the Hospital of UPenn site?

8 I mean, since they were the contractor, I
9 would question that site as well.

10 MR. LEWIS: Yes.

11 MS. PELKE: Additional inspection has been
12 done at University Hospital Pennsylvania.
13 Pennsylvania became an Agreement State during this
14 time. So, there are some activities that were still
15 under regulation by NRC that we're looking at.

16 And then, yes, we informed the Agreement
17 State through the process. And they were out with us
18 on our exit so that they could be informed of what our
19 findings were, as well as Region I.

20 MEMBER ZANZONICO: So, just one last
21 question.

22 So, if there's a federal entity like the
23 VA within an Agreement State, the federal entity, the
24 VA, is still subject to NRC oversight even though it's
25 within an Agreement State.

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1 But if it's affiliated with a nonfederal
2 entity like UPenn, in this case, then it's subject to
3 the Agreement State jurisdiction?

4 MS. PELKE: That's correct.

5 VICE CHAIR THOMADSEN: Dr. Suleiman.

6 MS. HOWE: That's not quite right.

7 MS. PELKE: Didn't you ask federal, if
8 there's a federal entity?

9 MS. HOWE: If you're a federal facility, no
10 matter who you align yourself with, you are still
11 regulated by the NRC.

12 MEMBER ZANZONICO: Right.

13 MS. HOWE: Now, if you send your patients
14 to the Agreement State hospital and they're treated at
15 the Agreement State hospital, that Agreement State
16 hospital is under the Agreement State.

17 But if your patients are treated in your
18 hospital, they're your -

19 MEMBER ZANZONICO: Right. It just seems
20 that there seems to be an opportunity for things to
21 fall through the cracks there. If there were two
22 different oversight agencies; one federal, one state,
23 it just increases the possibility that something could
24 fall through the cracks.

25 MS. HOWE: Well, they're not to oversight

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1 regulators at both sites.

2 MEMBER ZANZONICO: Right.

3 MS. HOWE: Each site has its own regulator.

4 MEMBER ZANZONICO: Right, but for their
5 respected affiliated institutions.

6 MR. LEWIS: Well, the affiliated
7 institution has its own license from the state.

8 MEMBER ZANZONICO: Right. Okay.

9 MR. LEWIS: So, when the physician is doing
10 work at one, he's covered by a certain license.

11 MEMBER ZANZONICO: Right.

12 MR. LEWIS: When he's working at another,
13 he's covered by the -

14 MEMBER ZANZONICO: Right. I'm just
15 thinking out loud.

16 MR. LEWIS: But that is part of the problem
17 that the contract -

18 MEMBER ZANZONICO: Yes, that may be part of
19 the problem that needs to be addressed, yes.

20 MR. LEWIS: That's part of the issue here.

21 VICE CHAIR THOMADSEN: Dr. Suleiman.

22 MEMBER SULEIMAN: Yes, I want to get clear
23 in my mind how the first event was picked up.

24 It was self-reported?

25 MS. PELKE: Yes.

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1 MEMBER SULEIMAN: Okay. And then when was
2 the second event?

3 MS. PELKE: 2005. Self-reported as well.

4 MEMBER SULEIMAN: So, when did you realize
5 you had an epidemic?

6 At what point did you realize this was a
7 much more serious thing?

8 MS. PELKE: In 2008.

9 MEMBER SULEIMAN: And that was self-
10 reported as well?

11 MS. PELKE: Yes, it was.

12 There was an assessment of the index case
13 which happened in May of 2008. And as a result of
14 that case, the NHPP required the licensee or
15 Philadelphia to go back and look at the last ten. And
16 when they looked at the last ten, there were some
17 problem cases identified.

18 They asked them to expand that scope to
19 about maybe 20 more. Then they suspended the program.

20 MEMBER SULEIMAN: Okay. So, who actually
21 did the reporting to somebody within the VA at one of
22 their various committees or -

23 MS. PELKE: The institution, Philadelphia,
24 was responsible for looking at the events that
25 occurred. They were reporting them to the National

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1 Health Physics Program, who in turn -

2 MEMBER SULEIMAN: No, no, no. I want all
3 the way down to the patient. Okay.

4 Before it got into the institutional
5 structure, who reported that there was a medical
6 event?

7 Who made the decision that this Patient
8 Number 2, Patient Number 3, the dose was
9 inappropriate?

10 MR. LEWIS: In May of 2008?

11 MEMBER SULEIMAN: Okay.

12 MR. LEWIS: Is that your question?

13 MEMBER SULEIMAN: Was the physician who did
14 it reported that?

15 MS. PELKE: No. It was another physician
16 that came in and started to look at the patients that
17 were treated there.

18 MEMBER SULEIMAN: And so they picked up on
19 it symptomatically -

20 MS. PELKE: Yes.

21 MEMBER SULEIMAN: - that there was
22 something not right?

23 MR. LEWIS: Not at first, but when they did
24 the -

25 MEMBER SULEIMAN: Okay. Okay. Okay. So,

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1 it was another physician picking up on a colleague in
2 the department.

3 MS. PELKE: Yes.

4 MR. WILLIAMS: Medical physicist.

5 MEMBER SULEIMAN: Was it a physicist?

6 VICE CHAIR THOMADSEN: Please use the
7 microphone, please, and identify yourself.

8 MR. WILLIAMS: Harry Williams, Veteran's
9 Health Administration.

10 A medical physicist was reviewing the
11 patient treatment for the sentinel event in May of
12 2008, and identified that they had gotten the wrong
13 seed activity. And that resulted in the initial
14 report of a medical event.

15 And then after the on-site inspection by
16 VHA, additional patient treatments were reviewed and
17 additional medical events were identified.

18 Those additional medical events were not
19 related to the circumstances of the sentinel event,
20 but these reviews also were done by initially medical
21 physicists from the university, but follow-up was by
22 getting a contract medical physicist with prostate
23 brachytherapy experience.

24 And so that was a rather independent
25 review, as Patty was mentioning.

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1 MEMBER SULEIMAN: Okay. Okay. Thank you.

2 VICE CHAIR THOMADSEN: Dr. Fisher.

3 MEMBER FISHER: Darrell Fisher. Did the
4 licensee contest any of the 97 medical events based on
5 definition of "medical event"?

6 And if so, how is that handled by the NRC?

7 MS. PELKE: The VA sent us a letter in
8 January indicating that they did not agree with the 97
9 medical events and that they wanted to - there was new
10 criteria that they had established that was activity-
11 based.

12 And they had proposed to retrospectively
13 look back at all the patients that were treated at
14 Philadelphia and use this activity-based criteria as
15 opposed to the criteria that they had established to
16 assess all these doses in June of 2008 that was dose-
17 based.

18 And the NRC did not accept their proposal
19 in January.

20 VICE CHAIR THOMADSEN: Other comments?

21 Dr. Welsh.

22 MEMBER WELSH: Just two comments in the
23 maybe lessons learned or corrective action section.

24 Based on the illustrations that you've
25 given us, the figures, which still to this day look

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1 very dramatic, but are not convincing to anybody who
2 has done this because those figures, those cartoons
3 could be drawn any way you want them to look.

4 If you want to make something look great,
5 just circle the area that has the seeds in it and
6 label that as the prostate. If you want to make
7 something look bad, you circle another area far away
8 from the seeds and say that's the prostate and it's a
9 terrible implant.

10 So, just those cartoon illustrations still
11 is not very convincing. But based on those
12 illustrations assuming that they are indeed accurate,
13 we have a process in which a written directive is
14 written before and after a procedure.

15 It's possible that with the current
16 policy, written directive could be rewritten to say
17 that I didn't really want to give 144 gray, I wanted
18 to give 70 gray. That's exactly what the patient got
19 and there's no medical event, therefore.

20 So, that would be one conceivable way a
21 physician could cover a medical event from being
22 discovered.

23 So, it might be possible that - it might
24 be appropriate that the pre-implant written directive
25 should match the post-implant written directive with

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1 perhaps a note to specify why there is X percentage
2 discrepancy, if there is one, just so that somebody
3 could never say I intended to give 70 gray to this
4 prostate and that's - therefore, it's not a medical
5 event.

6 The second thing was suppose the physician
7 does have an implant in which the penile bulb was
8 implanted instead of the prostate, as in the very last
9 illustration.

10 An unscrupulous physician could go back
11 and during the post-implant dosimetry, perhaps,
12 contour the area that had the seeds and say this is
13 the prostate, it's got 144 gray just like I planned it
14 would.

15 So, in the peer review process, you need
16 to have somebody else look at that. Somebody with a
17 lot of prostate anatomy experience to verify yea or
18 nay whether or not this is truly the prostate that has
19 been circled here.

20 Cannot be a medical physicist, in my
21 opinion. Cannot be a radiation safety officer. Has
22 to be a physician or anatomist who has fluency in
23 prostate anatomy or in medical imaging.

24 Just two comments in the corrective action
25 section.

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1 VICE CHAIR THOMADSEN: Can I ask who was it
2 that did the contouring on those examples you gave?

3 MS. PELKE: The examples that I showed we
4 received from the facility. And at the Cincinnati and
5 I think Minneapolis, the two examples that I showed,
6 those were done by the authorized user.

7 And for the Philadelphia examples that I
8 showed you, those were not done by the authorized
9 user. Those were done again after the treatment had
10 occurred when they were retrospectively looking back
11 and the physicist was working with - they brought in
12 another physician that actually re-contoured all of
13 the prostates.

14 And during that process, they took a look
15 to see if there was a lot of variation between the
16 physician they brought in to re-contour all the
17 prostates and the original contours that were done by
18 the authorized user.

19 And in most cases, I don't believe that
20 there was a lot of variation. So, there was a lot of
21 data that was generated as a result of the assessment
22 that was done at Philadelphia.

23 VICE CHAIR THOMADSEN: But the contouring
24 was not done by a physicist or radiation safety
25 officer.

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1 MS. PELKE: No.

2 VICE CHAIR THOMADSEN: Thank you.

3 Dr. Howe.

4 MS. HOWE: I got a chance to look at most
5 of the - a fair number of the re-contouring and the
6 original ones.

7 The AU contoured his own images on the Day
8 1 CTs. And then the re-contoured ones were some on
9 the Day 1, some he didn't re-contour because he
10 thought the original physician was fine.

11 And then I looked to see because the
12 question always comes up at the ACMUI as to, well, one
13 person draws them one way, another person draws them
14 another way.

15 So, they had two physicians, the
16 authorized user, the original authorized user, and
17 then the second individual. And I looked at the ones
18 that were re-contoured to see if they made a
19 difference. There were about 14.

20 And those that made a difference, there
21 was almost an equal number between those that became
22 medical events and those that didn't become medical
23 events. Those were the ones on the edge. But for the
24 most part, these images were contoured by the original
25 authorized user.

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1 So, it was not a question of one physician
2 drawing the circles over here and another physician
3 drawing the circles over there.

4 And we pretty much went with the Day 1 CTs
5 because the authorized user did contour those images.
6 And he, the authorized user, is, for all intents and
7 purposes, the gold standard unless you really missed
8 the anatomy.

9 VICE CHAIR THOMADSEN: Thank you for that
10 clarification.

11 Other questions?

12 MS. LE: I want to commend you, Patty, on
13 taking a look at what bigger lessons can be learned
14 from this.

15 And I always in my training of residents
16 and so on in trying to describe the master license
17 like the VA hospital, say, you know, it's somewhat
18 like an Agreement State license or Agreement State
19 where they self-regulate their own organization.

20 So, I'll look forward to hearing how NRC
21 applies those lessons to Agreement State oversight,
22 and especially in this time of economic challenges
23 with a lot of state programs.

24 And so I commend you on looking at that
25 and look forward to hearing what your group's thoughts

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1 are on that.

2 MS. PELKE: Well, I know that the region
3 has some thoughts, but certainly the program office
4 has been carrying the water on that so that we're
5 going to be looking much broadly. Because we have the
6 VAs master material license, of course, but we also
7 have - the Navy and the Air Force have master material
8 license and their programs are kind of dramatically
9 different.

10 The VA is all medical, primarily. Navy
11 and Air Force may have a little bit of medical, but
12 they also have different primary uses.

13 VICE CHAIR THOMADSEN: Dr. Zelac, did you
14 have a comment?

15 MR. ZELAC: Yes, I do.

16 It's probably worth knowing at this point
17 that while there is a group that is in fact looking at
18 policies and procedures and things that might be done
19 differently based on these findings, the underlying
20 cause, if you will, of this current issue is the fact
21 that the rule had a flaw, and still does have a flaw.

22 It was intended for use in one purpose,
23 and as you pointed out, it can be used for other
24 purposes as well, perhaps.

25 That flaw, in fact, is being removed and

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1 timelines for making these determinations are being
2 inserted, and that is part of the re-proposed rule.
3 And, in fact, it's part of the proposed rule upon
4 which the ACMUI commented. And the re-proposed rule
5 upon which some of the members have already commented.

6 So, from my perspective, the real problem,
7 in fact, has already been addressed. And the
8 additional look at what is being done with respect to
9 policies and procedures may add additional
10 enhancements to this entire process.

11 MR. LEWIS: Dr. Thomadsen.

12 VICE CHAIR THOMADSEN: Yes.

13 MR. LEWIS: I would just like to add a
14 thought to Ron, to Dr. Zelac.

15 I do agree that the medical events rule is
16 in need of revision. But the fundamental problem in
17 this case is the rule that existed was not complied
18 with. And that was by the licensee and that's
19 evidenced in our violations and the response to the
20 violations and the civil penalty.

21 I think that Ron meant that, but maybe his
22 statement could be misinterpreted to say that the NRC
23 was the problem. But we don't have that position at
24 all.

25 VICE CHAIR THOMADSEN: Dr. Welsh.

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1 MEMBER WELSH: Just I would like to ask Dr.
2 Zelac if he could be specific in what you meant by
3 there was a flaw, just so that I'm -

4 MR. ZELAC: Sure.

5 MEMBER WELSH: - understanding completely
6 and correctly.

7 MR. ZELAC: Absolutely.

8 The current regulation with respect to the
9 written directive, calls in permitted implants that
10 there be two pieces of information. That which is
11 entered before the procedure begins, and that which is
12 entered after the procedure is - the implant itself is
13 done, but the procedure is not totally completed.

14 In both of those parts, first there is a
15 specification of dose. There is also lacking a
16 specification of when the procedure is completed.

17 The proposed rule and the re-proposed rule
18 both insert a time factor so that it's perfectly clear
19 and achievable for completion of the written
20 directive.

21 And secondly, the re-proposed rule does
22 not permit any modifications of what was put in there
23 initially before the procedure began, but simply asks
24 for completion by entering in; first, the physician;
25 second, the date; third, the total source strength

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1 implanted.

2 MEMBER WELSH: Thanks for the
3 clarification.

4 MR. POTTERS: Hi. I'm Louis Potters. I'm
5 a radiation oncologist. I was invited to come and -
6 and so if there are any questions, I'm a
7 brachytherapist. I - my whole career has been in
8 prostate brachytherapy. And to the extent that this
9 potentially represents an outlier, the issue is of
10 throwing the baby out with the bathwater, but clearly
11 this represents an ethical lapse on the part of these
12 physicians.

13 And as noted in the VA report, there was
14 also a disconnect of their ability to review the post-
15 plans. Which, in essence, would have provided them
16 the feedback that they were not doing perhaps as well
17 as they would have liked. So, perhaps you want to
18 comment to the Committee on that.

19 And then, secondly, you commented that the
20 NRC did not accept the activity-based, but changes
21 that the panel had suggested as compared to the D-90.
22 And I just wanted to know if anyone from the NRC or if
23 you could comment on why that wasn't accepted.

24 MS. PELKE: The ability to do their post-
25 plans at the Philadelphia VA was impacted for about a

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1 year. They had computer connectivity issues.

2 And during that period of time, they
3 continued to treat patients even though they couldn't
4 generate post-plans.

5 So, they would prescribe a dose, but there
6 was no method for them to verify that the dose
7 prescribed was delivered as intended.

8 I would also note that on the written
9 directives that we looked at for Philadelphia, 160
10 gray was the prescribed dose. And in all cases, 160
11 gray with the exception of a different authorized user
12 who prescribed 145 gray, each and every time was
13 delivering 160 gray when, in fact, I don't know how
14 you get a hundred percent a hundred percent of the
15 time.

16 And then as far as the - that's the
17 situation that occurred there. We looked at that
18 issue specifically, the connectivity issue, the fact
19 that whether or not the facilities could generate
20 post-plans, that was a primary focus of the extended
21 condition inspections the NRC conducted.

22 They with the exception of one other
23 facility, Jackson, we did not see the connectivity
24 issue impact their ability to generate post-plans and
25 determine doses as dramatically as it had at

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1 Philadelphia and also another facility they had in
2 Jackson.

3 As far as the retrospective look at the
4 doses delivered at Philadelphia using a new criteria
5 that the VA proposed to use with the NRC in January
6 that was activity-based, that doesn't meet the
7 requirements of the current rule. The current rule
8 are dose-based. And the NRC did not accept and reject
9 it, actually, that proposal.

10 Also, the VA told us the criteria they
11 were going to use when they assessed all these doses.
12 They started their dose assessment in July of 2008.
13 We continue to monitor the progress of that dose
14 assessment. In fact, that was the focus of our
15 inspection in June of 2009.

16 And when we got on site at Philadelphia,
17 it was myself, two other inspectors from Region III,
18 and also Donna-Beth Howe was out with us as well to
19 look at what the licensee or the permittee had been
20 generating.

21 And they had generated an awful lot of
22 data, but they didn't seem to have any process in
23 place to systematically and methodically assess the
24 doses and the information that they were generating.

25 And we had not - there was no discussion

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1 of we were coming up with a new criteria that's
2 activity-based. There was no discussion about that
3 until the VA talked about it at the Pre-Decisional
4 Enforcement Conference that we had in December and
5 presented their proposal.

6 Actually, their national director of
7 radiation oncology, Dr. Hagen, made a fairly lengthy
8 presentation during that conference. And then the VA
9 put it in writing in January, and then the NRC
10 rejected it in writing back to the VA.

11 MR. LEWIS: And I would just add that the
12 technical basis for the new methodology was not
13 provided. It was just a request to use the new
14 methodology. That was part of our rejection as well.

15 But, moreover, even if we had accepted the
16 new methodology, all of the medical events would not
17 have been cleared. There would have still been a
18 substantial number.

19 And I don't want to speculate, but our
20 violation - it wouldn't have addressed the root causes
21 that created our -

22 MR. POTTERS: No, and my asking of the
23 question is - I'm sorry to interrupt, but my asking of
24 the question was not necessarily in any sort of
25 defense at all of the VA, but in terms of potential

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1 rule-making that the NRC or the ACMUI will be doing.

2 VICE CHAIR THOMADSEN: I think that may be
3 part of the next discussion that we're going to be
4 having here.

5 Dr. Welsh.

6 MEMBER WELSH: In follow-up to Dr. Potter's
7 comments as long as we have an expert in prostate
8 brachytherapy, I thought we might want to take
9 advantage of this.

10 Because at this committee, we have
11 discussed at one time the concept of making post-
12 implant dosimetry not a nice option that shows that
13 you have a good quality program. And if you don't do
14 it like the VA, no big deal.

15 Should we consider making post-implant
16 dosimetry a mandatory component?

17 And if so, is that a very difficult thing
18 to enforce from a regulatory perspective?

19 So, first, I think I want Dr. Potters'
20 opinion on whether or not in 2010 it should be the new
21 standard, and then whether it should be regulated.

22 MR. POTTERS: You're putting me on the hot
23 seat.

24 (Laughter.)

25 MR. POTTERS: I've been doing prostate seed

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1 implants since 1992. Post-implant CT-based analysis
2 sort of came in around 1994-'95, using some relatively
3 rudimentary three-dimensional treatment planning
4 systems essentially used for external-beam delivery.
5 And then they became a little bit more sophisticated
6 in '97-'98.

7 I've been doing post-implant analysis of
8 all my patients from 1995 on. And I use it as a
9 learning tool for myself, I use it for trainees as a
10 learning tool.

11 And the issue of dose is an important one
12 because the intent is to achieve a minimum dose by
13 doing the implant. And in essence, anybody can
14 achieve a minimum dose if you overdose the prostate.

15 So, if all you're doing is just measuring
16 a dose and want to achieve a certain minimum
17 distribution of that throughout the target, whether
18 the target is the prostate or the prostate with a
19 small margin, you can do that quite easily.

20 So, the art of implantation is really to
21 lower your hot spots, but still achieve your minimum
22 dose requirements.

23 And so part of the peer, part of the chart
24 rounds, part of your M&M within any department is to
25 review your post-plans and take the heat from your

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1 colleagues and were you a little bit too hot here,
2 were you a little bit too cold there.

3 Because even achieving dose minimums and
4 lowering hot spots still doesn't take away from the
5 heterogeneity of the dose throughout the prostate
6 itself.

7 And so there's a lot of moving pieces, but
8 clearly I think as Dr. Welsh was suggesting, I think,
9 and as the ACR guidelines have recommended that post-
10 implant dose - and the American Brachytherapy Society
11 have all recommended that post-implant dosimetry be
12 performed a hundred percent of the time.

13 VICE CHAIR THOMADSEN: Thank you for your
14 comment.

15 Dr. Welsh, to whom were you addressing the
16 second half of your question?

17 MEMBER WELSH: Well, I suppose any of the
18 NRC staff. And I would like to just say that I was
19 not suggesting that the regulation be in terms of
20 evaluating things like D-90 on the post-implant
21 dosimetry, but just perhaps a statement that 2010-2011
22 in order to do prostate brachytherapy using byproduct
23 material, permanent implants, part of the program
24 should include this step of post-implant dosimetry so
25 that things like 90 some odd events from a single

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1 facility never can happen again.

2 VICE CHAIR THOMDSEN: So, I see Dr. Zelac
3 has something to say.

4 MR. ZELAC: I'm very anxious to say
5 something here.

6 This, in fact, brings us back to the
7 discussion that we almost had this morning when we
8 were talking about the Part 35 changes that are in
9 place and coming up.

10 The proposed rule that was published for
11 public comment and upon which we received comment, and
12 which progress towards a final rule was held up on
13 because of the VA, has switched from a dose-based
14 criteria to totally - well, not entirely, but
15 certainly in terms of the target to an activity-based
16 criteria, a source-strength-based criteria.

17 Based on what occurred at the VA and the
18 findings there, the re-proposed rule, and this is the
19 principal reason for having the re-proposed rule,
20 brings back in a dose-based criteria to the target.

21 That means that we now have in the written
22 directive pre-implantation, a stated, if you will,
23 target dose, intended dose, to the site.

24 The medical event criteria are based, and
25 will continue to be based, on dose in part. Meaning

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1 that in order to make a determination as to whether or
2 not there is a medical event, it's an obligation on
3 the part of the licensee to determine what the
4 resultant dose is in fact to the treatment site.

5 You can't make the determination that you
6 haven't a medical event, if you don't make a
7 determination of what the dose to the treatment is as
8 compared to what had been stated in the pre-
9 implantation written directive which cannot be
10 changed.

11 So, what I'm basically saying is that what
12 you are suggesting is appropriate, in fact, is already
13 built into the re-proposed rule, and will appear if it
14 goes forward as currently intended.

15 VICE CHAIR THOMADSEN: Thank you, Dr.
16 Zelac.

17 Dr. Howe.

18 MS. HOWE: Our regulations are performance-
19 based. And we currently have a requirement in 35.41,
20 which is procedures for administrations requiring
21 written directives.

22 And it says you will have developed,
23 implement and maintain written procedures to provide
24 high confidence. And "high confidence" is an
25 important word here.

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1 And it goes down to say that as a minimum,
2 your procedures will include. And one of the items is
3 verifying that the administration is in accordance
4 with the treatment plan and applicable in the written
5 directive.

6 So, we have a performance standard that
7 says licensees need to verify what is administered is
8 in accordance with treatment plan written directives.

9 We aren't as specific as to say how you do
10 it, but we do have an overall performance requirement
11 right now in place that says you do have to verify.
12 And I thought that was an important point to bring to
13 your attention.

14 VICE CHAIR THOMADSEN: Thank you, Dr. Howe.

15 Other comments?

16 MR. LOHR: I'm Ed Lohr from the rule-
17 making.

18 I just want to caution everybody that this
19 is a public meeting, and the re-proposed rule is pre-
20 decisional and not available to the public and should
21 not be discussed in this forum.

22 VICE CHAIR THOMADSEN: Thank you for that
23 clarification. Please watch yourselves.

24 Other comments?

25 MR. EINBERG: I'd like to take this

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1 opportunity and thank Dr. Potters for joining us at
2 the request of the Committee, and Dr. Malmud and the
3 Subcommittee. It was felt that we needed to
4 supplement the expertise in the area of prostate
5 brachytherapy.

6 Dr. Potters is an expert in the area. He
7 comes from Hofstra University, the School of Medicine.
8 And he is the chairman of the Radiation Medicine
9 Department at the North Shore University Hospital
10 there. And so we welcome you and we look for your
11 input there.

12 And right now as you all know, we are
13 short one radiation oncologist, and this is one of
14 the reasons we needed to supplement our expertise in
15 this area.

16 VICE CHAIR THOMADSEN: Thank you very much
17 for that.

18 Other comments or questions dealing with
19 this presentation?

20 If not, we should move into our next
21 presentation which is related. This is by Dr. Welsh.
22 A report from the Permanent Implant Brachytherapy
23 Subcommittee.

24 (Off-the record comments.)

25 VICE CHAIR THOMADSEN: I think that means

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1 that you are safe to proceed, Dr. Welsh.

2 MEMBER WELSH: I hope so, because I didn't
3 want to say anything that's out of line. And I do
4 know that a lot of what I'm going to discuss here does
5 talk about proposed rules, re-proposed rules, possibly
6 future proposed -

7 VICE CHAIR THOMADSEN: Can you hold on one
8 moment?

9 Can you hear Dr. Welsh in the back?

10 I didn't think so.

11 Is there a way that we can have the volume
12 turned up?

13 MEMBER WELSH: Is that better?

14 VICE CHAIR THOMADSEN: I'm having a hard
15 time hearing Dr. Welsh.

16 MS. COCKERHAM: Theron, could you turn the
17 volume up on the mic for the presenter?

18 VICE CHAIR THOMADSEN: Try something.

19 MEMBER WELSH: Hello.

20 VICE CHAIR THOMADSEN: Can you hear him
21 well now?

22 SPEAKER: Keep talking.

23 VICE CHAIR THOMADSEN: I think we're
24 probably okay.

25 MEMBER WELSH: Can you hear me?

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1 VICE CHAIR THOMADSEN: Yes. Okay. Thank
2 you.

3 MEMBER WELSH: Thank you, Dr. Thomadsen,
4 and I appreciate the discussion we just had.

5 And I would start by saying that it's very
6 useful information and it will not affect or change
7 the opinions of my own presentation here.

8 This subcommittee was charged with
9 creating a draft, providing recommendations on
10 regulatory changes or improvements to the NRC's
11 processes for permanent implant brachytherapy programs
12 as an outgrowth of the investigation of the Department
13 of Veteran Affairs' medical events.

14 In other words, does what we just heard
15 about influence our opinions, our opinions on the 2008
16 report that was produced by the ACMUI Permanent
17 Implant Brachytherapy Rule-Making Subcommittee?

18 And the answer is it generally still
19 remains valid.

20 The medical events within the Department
21 of Medical Affairs involving permanent prostate
22 brachytherapy do not generally alter the previous
23 subcommittee recommendations in any significant form
24 or fashion.

25 In fact, in some ways we could make the

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1 argument that they confirm the validity of that
2 report.

3 A couple of areas that might warrant a
4 little bit of discussion, first 10 CFR
5 35.3045(a)(2)(ii) was discussed in the previous
6 report. And in that report, we suggested that modern
7 concepts of GTV, gross target volume; clinical target
8 volume, CTV; and planning target volume, PTV, be
9 incorporated into the definition of what was
10 previously just called the treatment site and any new
11 rules as described in the 2008 subcommittee report.

12 If we don't use modern terminology, this
13 could lead to an excess of perfectly acceptable
14 medical implants being mislabeled as medical events
15 simply because we're not talking about the same thing.

16 So, it was recommended that modern
17 terminology be used. And it appears that in the
18 proposal, although the terms "GTV," "CTV" and "PTV"
19 are not explicitly used, the concepts contained are
20 fully conveyed.

21 Our subcommittee felt that there were some
22 sections that deserved further scrutiny. Specifically
23 35.3045(a)(1), (a)(2)(v) and (a)(2)(vi).

24 Starting with (a)(1), it reads a dose that
25 differs from the prescribed dose or dose that would

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1 have resulted from the prescribed dosage by more than
2 five rem effective dose equivalent, 50 rem to an organ
3 or tissue or 50 rem shallow dose equivalent to the
4 skin and, and it's an important and, the following
5 three criteria.

6 I'm not going to go into much detail on
7 this particular slide because this particular section
8 does not include permanent prostate brachytherapy.
9 And in addition to that, it includes a Boolean and
10 with the subsequent A, B and C not being fully
11 appropriate.

12 Therefore, no suggested changes were made
13 for 3045 (a)(1), but I throw this slide in here
14 because it is relevant to subsequent discussion.

15 As far as 3045 (a)(2)(v), this is relevant
16 for cases in which a dose exceeds five rem effective
17 dose equivalent, 50 rem to an organ or tissue, 50 rem
18 shallow dose equivalent to the skin as a result of
19 wrong isotope, wrong route of administration, wrong
20 mode of treatment, a leaking source, administration to
21 the wrong patient.

22 In these situations, the subcommittee felt
23 that classification as a medical event is perfectly
24 valid. And, therefore, no changes in the proposed
25 3045 (a)(2)(v) are necessary.

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1 But (a)(2)(iv) does deal with permanent
2 prostate brachytherapy, and it reads a dose to the
3 skin or organ or tissue other than the treatment site
4 exceeding by 50 rem and by 50 percent or more the dose
5 expected to that site if the administration had been
6 carried out as specified in the pre-implantation
7 written directive.

8 The subcommittee would like to reconsider
9 the 50 rem 50 percent dose differences here. 500 rem.
10 These minor discrepancies might be quite possible when
11 one is considering organs that are expected to get
12 very low doses yet still be medically acceptable
13 because the implant was done, the goal of curing the
14 patient of the cancer has been achieved, and there are
15 minimal to no side effects. So, it could be very
16 medically inconsequential.

17 There is no volume or area specified here,
18 and that can lead to further confusion. So, it may be
19 appropriate to drop this part of the medical event
20 definition.

21 Perhaps that Boolean and that was in the
22 slide I showed earlier, would be one way of keeping
23 this section in here and making it appropriate and
24 acceptable.

25 Another topic of conversation within our

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1 subcommittee was the concept of will one rule fit all?

2 For example, some of the newer permanent
3 brachytherapy procedures could be perfectly medically
4 acceptable and effective. In other words, an
5 effective cancer treatment with minimal adverse
6 effects. And as an example, the mesh implant for lung
7 cancer. Brachymesh is one of the examples.

8 Because of the wording in 3045 (a)(2)(ii),
9 some perfectly good procedures of this type could wind
10 up classified as medical events.

11 A suggested change made in 2008 by the
12 subcommittee was total source strength implanted
13 outside the treatment site, including the gross tumor,
14 clinical target volume, plus a variable planning
15 margin as defined by the authorized user exceeding 20
16 percent of the source strength documented in the
17 written directive.

18 So, if we change dose or activity to
19 source strength in this context, some members of the
20 subcommittee felt that this might overcome some of the
21 issues that could arise with a newer brachytherapy
22 procedure such as the lung permanent implant by sewn-
23 in meshes.

24 But it remains possible that despite such
25 wording, some medically acceptable permanent

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1 brachytherapy procedures could still wind up
2 inappropriately classified as medical events.

3 It was felt that this is unlikely if the
4 present use for absorb dose for definition of a
5 medical event is replaced by the proposed use of
6 activity for total source strength for defining
7 medical events.

8 But there was still some discussion in the
9 subcommittee, and therefore there was finally
10 discussion about the possibility of creating separate
11 categories for permanent implant brachytherapy.

12 As unpleasant as it might be to have more
13 categories to regulate, should permanent prostate
14 brachytherapy with its advanced level of
15 sophistication and technology be separated from things
16 like lung mesh brachytherapy?

17 That question was just brought up, not
18 resolved, and that's where I will end the conversation
19 and turn it back over to you, Chairman Thomadsen.

20 VICE CHAIR THOMADSEN: Thank you very much,
21 Dr. Welsh.

22 Do we have questions for Dr. Welsh from
23 the Committee?

24 Dr. Suleiman.

25 MEMBER SULEIMAN: I've got my FDA hat here.

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1 These are medical events. And so if the
2 radiation was less than five rem or 50 rem, the second
3 category and so you haven't crossed the radiation
4 threshold, but you gave the wrong drug, you gave the
5 wrong administration. So, it was a miss in
6 administration. By our terminology, it wouldn't be
7 reported.

8 It would have to have exceeded the five
9 rem or 50 rem dose threshold.

10 MEMBER WELSH: I think that's how it is
11 written and -

12 MEMBER SULEIMAN: So, how would we capture
13 -

14 VICE CHAIR THOMADSEN: I believe that any
15 of those things that you were saying, the wrong
16 isotope, leaking source, wrong modality all would
17 trigger -

18 MEMBER WELSH: Oh, okay.

19 VICE CHAIR THOMADSEN: - a medical event.

20 MEMBER WELSH: Okay.

21 VICE CHAIR THOMADSEN: That's not new.
22 Those are all -

23 MEMBER WELSH: I misunderstood.

24 VICE CHAIR THOMADSEN: If you put it in the
25 wrong patient, that's still -

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1 MEMBER WELSH: Yes.

2 VICE CHAIR THOMADSEN: Of course that's a
3 wrong dose location, if nothing else.

4 Dr. Howe.

5 MS. HOWE: You didn't have to trigger the
6 five rem or the 50 percent.

7 VICE CHAIR THOMADSEN: Can you speak a
8 little bit louder, please?

9 MS. HOWE: You didn't have to trigger the
10 dose threshold of five rem or 50 percent of what would
11 have been given if it had been given correctly, before
12 you can get to a medical event.

13 In 2002, we put a dose threshold on our
14 medical events.

15 VICE CHAIR THOMADSEN: I stand corrected.

16 MEMBER WELSH: So then for clarification
17 and my own edification, if you're implanting prostate
18 brachytherapy or any type of byproduct material use
19 and you realized at the last second that this is the
20 wrong patient, but the patient from what you have done
21 received less than 50 rem, it wouldn't -

22 MEMBER SULEIMAN: How would that be picked
23 up otherwise?

24 Forget the NRC. In the hospital, in
25 medical care, you give the wrong drug to the - you

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1 can't give the wrong drug to the right patient. You
2 gave it to the patient who shouldn't be getting it.

3 How is that picked up in terms of a safety
4 issue?

5 MEMBER WELSH: The patient could say, what
6 are you doing to me?

7 MEMBER SULEIMAN: I mean professionally in
8 terms of -

9 MR. POTTERS: We do intraoperative time-
10 out. I mean, we bring the patient to the operating
11 room for the procedure and there is a written form of
12 - a verification.

13 So, at least in the way that I do it,
14 there's written verification of isotope and what my
15 intended prescribed dose is. That's my own internal
16 sort of QA, but at the same time the hospital policy
17 is to do a time-out.

18 We introduce the patient, his date of
19 birth. We introduce the procedure, the dose and the
20 isotope that's being delivered. The anesthesiologist
21 discusses his anesthesia and allergies and the case
22 proceeds.

23 MEMBER SULEIMAN: I mean, it should be
24 picked up as a legitimate medical error so you don't
25 repeat the mistake later on.

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1 MEMBER WELSH: In reality, the wrong
2 patient is probably something that is exceedingly
3 rare. But wrong site as in gamma knife treatments is
4 not at all uncommon, unfortunately.

5 But there are in Dr. Potters' method,
6 there is routinely used time-out procedures to verify
7 that what you're about to do and to who you're about
8 to do this to are appropriate and correct.

9 MEMBER GUIBERTEAU: In many hospitals to
10 satisfy the Joint Commission there are committees, PIC
11 committees, that these are reported to on a routine
12 basis, I mean, so that you can track them.

13 MEMBER SULEIMAN: I mean, I'm aware of the
14 multiple regulatory oversight that exists in society.
15 I mean, the hospitals, the professionals, the licensed
16 physicians, the NRC, the FDA, the companies and so on,
17 but I just want to make sure this doesn't, you know,
18 you don't want the NRC necessarily to pick it up if
19 you consider that the radiation level is an acceptable
20 level.

21 But the fact is if they've been given the
22 wrong drug, it's an issue.

23 VICE CHAIR THOMADSEN: Dr. Zelac.

24 MR. ZELAC: Yes. I think it's important to
25 keep in mind that the medial event criteria here

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1 applies to all medical use, not simply implants.

2 And the reason that there is a dose
3 threshold for reporting a medical event is to
4 eliminate the reporting of diagnostic doses to the
5 wrong patients for which these thresholds would not be
6 met, but you would in fact be reporting what amounts
7 to therapeutic doses involving the wrong patient,
8 etcetera because, first, that occurred, whatever the
9 condition is, and, secondly, the dose threshold has
10 been passed.

11 So, keep in mind that these thresholds are
12 here for a specific reason to essentially only get
13 reports of things that may have some consequences in
14 terms of our being concerned about the protocols and
15 procedures in place which led to this occurrence.

16 VICE CHAIR THOMADSEN: Thank you, Dr.
17 Zelac.

18 Yes, Dr. Zanzonico.

19 MEMBER ZANZONICO: I may be
20 misunderstanding something completely.

21 Dr. Welsh, are you recommending that for
22 permanent implant brachytherapy, that dose-based
23 thresholds for medical event be eliminated altogether
24 and that they be based exclusively on activity, on
25 implanted activity or implantation of the incorrect

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1 activity?

2 MEMBER WELSH: This was in the 2008
3 proposal that there be a shift from dose to activity
4 or source strength.

5 MEMBER ZANZONICO: But doesn't that
6 introduce a scenario, and it may be unrealistic, where
7 the proper total activity is implanted, but just
8 grossly misplaced?

9 Shouldn't that qualify as an ME?

10 MEMBER WELSH: Well, it has to be placed in
11 the correct location. And there are a set of criteria
12 for what is - that becomes unacceptable if too many
13 seeds are too far away from your target. It would be
14 classified as a medical event.

15 MEMBER ZANZONICO: Okay. So, my only point
16 is this is, for lack of a better term, a geometry
17 component as well as an activity to -

18 MEMBER WELSH: Yes, of course.

19 MEMBER ZANZONICO: - an ME.

20 MEMBER WELSH: Yes.

21 MEMBER ZANZONICO: All right.

22 VICE CHAIR THOMADSEN: Dr. Suleiman.

23 MEMBER SULEIMAN: I'm going to share how I
24 think.

25 If you're doing therapy, you start out

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1 with the radiation absorb dose you want to deliver to
2 the target. I won't get anymore prescriptive of that.

3 Then you work backward and figure out how
4 much activity you're going to need to derive that
5 radiation absorb dose.

6 So, you really can't have one without the
7 other. If you've got the activity, it's got to be
8 based on the target -

9 MEMBER WELSH: Correct.

10 MEMBER SULEIMAN: - absorb dose.

11 So, why shouldn't that information be
12 available somewhere showing that one is related to the
13 other or one's been calculated with - what I'm
14 concerned about is - and I see this, I see this a lot
15 where people get used to a certain amount of activity
16 and then administer a certain amount of activity being
17 a little bit more flippant. I can't think of a better
18 word.

19 The patient body and anatomy are not
20 always considered in a lot of therapeutic
21 applications. I'm not talking about brachytherapy
22 here, but I'm thinking more on a larger scale.

23 Is that a step in the wrong direction?

24 MEMBER WELSH: I think sticking with
25 prostate brachytherapy, not all permanent implant

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1 brachytherapy, mind you, for prostate specifically we
2 have a large body of data supporting the conventional
3 dose is around 145 gray. So, this is typically what
4 the prescription written directive will aim for.

5 Then we also have established criteria
6 that have been authored by experts such as Dr. Potters
7 about D-90, V-90, V-100 to help you assess whether or
8 not the implant is rightly to achieve the stated
9 goals.

10 One of the serious problems and
11 limitations in prostate brachytherapy is that you may
12 have a volume based on ultrasound or CT, volume is X.
13 But as soon as you start poking that prostate gland
14 with needles and implanting foreign bodies into it,
15 the Volume X becomes 1.4X maybe. 40 percent larger.

16 And, therefore, if you were to try to
17 determine the dose on target that is 140 percent the
18 initial volume, you could wind up with an
19 underestimate of what the dose truly is because your
20 isotope will decay over time depending on which one
21 you're using.

22 If it's iodine-125, for example, and a 60-
23 day half-life, the edema and subsequent resolution of
24 that edema might not be very consequential to the
25 overall dose which is measured in months, used with a

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1 - is going to be determined by an isotope that has
2 half-life of a couple of months.

3 But if you were to assess your post-
4 implant dosimetry on Day 2, you could wind up with
5 something that would suggest that the dose is
6 inadequate.

7 And by some of the previous definitions or
8 other people's definitions, you could wind up with an
9 inadequate or believed to have an inadequate implant
10 because your D-90 is low.

11 And it's not because in reality the
12 implant was done technically improperly or because
13 it's not going to be medically successful or it's
14 going to have more side effects. It's simply because
15 the prostate gland undergoes edema with subsequent
16 resolution.

17 And, therefore, you do have to evaluate -
18 in an ideal world, you would evaluate dose as a
19 function of time and a dose - and a function of volume
20 and it would be a complicated multi-variable partial
21 differential equation.

22 MEMBER SULEIMAN: Okay. I understand that.

23 In other words, you make a first estimate
24 based on some volume. You have to.

25 MEMBER WELSH: That is -

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1 MEMBER SULEIMAN: Knowing full well that
2 the uncertainty, the volume is going to change for a
3 multitude of reasons.

4 MEMBER WELSH: Activity will never change,
5 but the -

6 MEMBER SULEIMAN: Right, right.

7 MEMBER WELSH: - dose might change. You
8 get the illusion of dose being different.

9 MEMBER SULEIMAN: Yes.

10 VICE CHAIR THOMADSEN: Mr. Lewis.

11 MR. LEWIS: Could I ask Dr. Welsh or Dr.
12 Potters could you explain that a little more to me?

13 Because what I heard, and I may be
14 misconceiving what you intended, but in the beginning
15 of what you said, you said that the prescribed dose is
16 145 gray. And we have good understanding of how many
17 seeds would achieve that if placed properly.

18 In the middle part of what you said, I
19 thought I heard you say that there's swelling and
20 things that make the actual dose different based on
21 seed placement.

22 So, to me it sounds like in your logic you
23 had contradictory statements.

24 MEMBER WELSH: So, if we say that 145 gray
25 is the goal, we can start with that. But if we assess

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1 the dose at Day 2, Day 3 when you still have
2 significant edema, you could have the illusion that
3 you're going to wind up with significantly less dose
4 because your volume is maybe 40, 50 percent larger
5 than on Day 1.

6 And if your estimated dose to the prostate
7 was based on the volume on Day 1 and now you have a
8 target that is 40, 50 percent larger, well, if dose is
9 defined as energy per unit volume or energy per unit
10 mass, which is related to volume by definition if your
11 denominator is different, your calculation for dose is
12 going to be different.

13 But in reality, what happens is that the
14 edema comes and goes, whereas the isotope is going to
15 continue to deliver radiation over a prolonged period
16 of time.

17 For iodine-125, it's less of an issue than
18 it is for palladium-103 and less of an issue for
19 Cesium-131 because of this, but these are things that
20 clinicians and physicists must take into account if we
21 aim to truly be accurate in dose delivery.

22 From a clinical perspective, we know that
23 if you aim to give 145 gray and you have a D-90 that
24 is up there in 95 percent, chances are that you're
25 going to have a good outcome.

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1 MR. POTTERS: I think another way of
2 looking at it is this: Is that the half-life of
3 edema, so to speak, is anywhere between two and three
4 weeks. The effective treatment of iodine at 60-day
5 half-life is really three half-lives.

6 And so you can still deliver your 145 over
7 the protracted period of time. If you do your post-
8 implant analysis on Day 1 and 20, 30 percent of the
9 patients will have measurable edema anywhere between
10 10, 40 percent, then the honest physician contouring
11 that prostate will identify an under-dosed gland.

12 Whereas if you repeat that CT in a month
13 and redo the exact same contouring and dosimetric
14 analysis, you'll find that actually what you've
15 achieved is the 145.

16 And with palladium with a shorter half-
17 life, it's more of a factor because one could make a
18 theoretical argument as to whether or not you need to
19 compensate for those patients who develop
20 intraoperative edema or postoperative edema to account
21 for it.

22 But that's more of a theoretical than a
23 true clinical in the field type of argument, but I
24 think that helps explain it.

25 MR. LEWIS: If I could just -

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1 VICE CHAIR THOMADSEN: Yes, Mr. Lewis.

2 MR. LEWIS: And I'm not trying to be
3 difficult. I'm trying to learn.

4 MR. POTTERS: No, that's okay.

5 MR. LEWIS: Isn't that making the case that
6 it's the dose that matters and not the activity
7 implanted that matters?

8 So, why would the regulation not focus on
9 the dose?

10 MR. POTTERS: Because the dose is still a
11 component of - I think as you were saying, there's
12 still a component of activity per cc to achieve that
13 dose.

14 MEMBER SULEIMAN: The activity you can
15 control.

16 MR. POTTERS: Right.

17 MEMBER SULEIMAN: You set it as a target.
18 You're going to administer X amount of activity.
19 That's a given. You can measure it. You're
20 responsible.

21 The volume, the edema, the changing
22 dimensions, you really don't have control over that.
23 So, to penalize the user because the volume is either
24 changing ten percent or 40 percent over a 30-day
25 period of time, to me that's an inherent amount of

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1 uncertainty associated with the practice of medicine.

2 That's just - you can't get better than
3 that. So, you're talking about maybe plus or minus 20
4 percent if you take half of 140 and -

5 MR. POTTERS: And if you think of activity
6 - there's actually two points I want to make. But the
7 first is that if you think of activity per cc and you
8 go back to the VA where the actual sentinel event was
9 the ordering of the wrong activity of iodine, if the
10 radiation oncologist and the operating physicist said,
11 oops, we ordered, you know, whatever it was, 0.3
12 millicuries instead of 0.5 millicuries, and as long as
13 there was enough total activity that was there, you
14 could have avoided that sentinel event.

15 MEMBER SULEIMAN: So, when you do your
16 initial estimate, do you assume it's going to expand
17 by 10 or 20 or 40?

18 MR. POTTERS: No, I don't.

19 We published a paper to that effect almost
20 eight or nine years ago where we looked at the
21 different phases of the procedure and where edema
22 impacts and what the theoretical difference is in dose
23 and should you account for it, meaning an
24 intraoperative type of nomogram to account for the
25 changes in edema.

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1 And it turned out to be relatively
2 inconsequential in the long run, and clinically it
3 doesn't - it doesn't - the other point is in terms of
4 dose is so I predicated, you know, a little bit
5 earlier that the honest contourer will identify an
6 underdose if there's a lot of edema if you're doing
7 your plan on Day 1.

8 The problem with dose is that you - and
9 I'm not saying from an honest to dishonest, but you
10 can have - you have - these seeds create artifact on
11 CT. The delineation of the capsule of the prostate is
12 not always clear. And so you can get the guy who
13 contours, sort of connecting the dots type of contour,
14 which is going to give you a perfect D-90.

15 So, now you have the honest guy who
16 contours and spends a lot of time, plays with
17 artifact, contours the prostate, shows underdose.

18 The guy who is sort of the connect the dot
19 from artifact to artifact type contourer is going to
20 show an appropriate dose.

21 And so that's one of the reasons why dose
22 in and of itself is variable.

23 VICE CHAIR THOMADSEN: Dr. Welsh.

24 MEMBER WELSH: So, in essence, to also
25 answer your question, implanted activity is a

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1 constant. Calculation, calculated total dose is
2 actually a variable and you can come up with different
3 answers Day 1, Day 10, Day 20, Day 50.

4 And that calculated total dose is a
5 function of volume, which in turn is a function of
6 time. And that's why I think most of us are not in
7 favor of using calculated total dose or things like D-
8 90 for a criteria of medical events.

9 MS. LE: I was just going to ask Dr.
10 Potters the fact that you don't want to do dose on a
11 Day-2 scan of a prostate, you may still want to do a
12 Day-2 scan or later that one-day scan to see that you
13 have the number of seeds where you think you had
14 placed the seeds; is that correct?

15 I mean, would you -

16 MR. POTTERS: So, I -

17 MS. LE: Instead of dose, you'd be looking
18 for the number of seeds and the activity and how they
19 were implanted.

20 MR. POTTERS: Well, we x-ray patients
21 before they're discharged because of the -

22 MS. LE: Right.

23 MR. POTTERS: - need to account for all of
24 the seeds.

25 MS. LE: For the seeds.

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1 MR. POTTERS: And I think it's clear to
2 this committee that there is migration. So, one or
3 two seeds may migrate via vasculature into the pelvic
4 plexis or into the lung.

5 So, we x-ray patients before they're
6 discharged, count the seeds.

7 MS. LE: Right. And that was my point is
8 that's easy to count as going by the activity as
9 opposed to using that necessarily as a dose
10 determination.

11 MR. POTTERS: Yes.

12 MS. LE: It's to verify your seed
13 placements and so on.

14 MR. POTTERS: Yes.

15 MS. LE: Another reason why you would want
16 to go activity versus the dose.

17 MR. POTTERS: Correct me if I'm wrong, but
18 you're still going to have the 20 percent rule.

19 MS. LE: Right.

20 MR. POTTERS: So, if 20 percent of the
21 seeds go someplace else outside of the target, that's
22 still going to be a reportable issue.

23 So, the 50 percent or the 50 of a hundred
24 seeds that wind up in a bladder is still going to
25 become a reportable event.

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1 And then I would only echo Dr. Welsh's
2 comments regarding how we define "treatment site"
3 versus what we would call the gross tumor volume or
4 the gross target volume because there are concepts now
5 with very low-risk prostate cancer of doing focal
6 brachytherapy where in fact I would only implant a
7 third or a quarter of the prostate and not the whole
8 prostate, or in a patient that has a suggestion of a
9 T3 tumor with invasion of the seminal vesicles to
10 include within the target 25, 30 percent of the
11 seminal vesicles.

12 So, it's important that any rule making
13 that's done define not necessarily the treatment site,
14 per se, but the definition of the authorized user's
15 volume that he intends to treat.

16 VICE CHAIR THOMADSEN: Dr. Suleiman.

17 MEMBER SULEIMAN: Is 20 percent too
18 restrictive?

19 MEMBER WELSH: I think that most of us felt
20 that that was the appropriate figure. We discussed it
21 here. It's been discussed with ASTRO, ACRO, American
22 Brachytherapy Society and others. And I think at this
23 point, the 20 percent figure was considered
24 acceptable.

25 MR. POTTERS: You're trying to throw us a

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1 bone, but I'm fine with 20 percent. I mean, I
2 wouldn't -

3 MEMBER SULEIMAN: No, I'm asking you. I
4 have -

5 MR. POTTERS: It shouldn't be 10 percent,
6 you know.

7 MEMBER SULEIMAN: When people tell me they
8 can get accuracy to five percent, I say absolutely
9 impossible because maybe if it was a plastic person
10 and you could target, but people react differently.

11 MR. POTTERS: Right.

12 MEMBER SULEIMAN: So, I always try to get
13 an upper estimate, 20, 30, 40 percent, yeah.

14 MR. LEWIS: I think I would like to, on
15 that note, just -- I think the premise behind your
16 question is there might be non-clinically significant
17 issues at 20 percent. And I just wanted to say, and
18 Dr. Howe taught me this, so if I don't get it right,
19 she can chime in. But there is a logic that we would
20 have a medical event threshold below the clinically
21 significant level, the same logic that we have
22 reporting requirements in other parts of the
23 regulation that aren't always over-exposures of
24 occupational dose. The idea here is that we want the
25 licensee management, and the NRC to be looking at

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1 trends, and having peer reviews and things occurring
2 before the clinically significant event were to occur.
3 So, all medical events don't, necessarily, need to be
4 clinically significant from that logical point of
5 view. And I think that's the basis, one of the bases
6 in our current regulatory approach. So, I just offer
7 that, because that was discussed, and I think that's
8 the premise behind Dr. Suleiman's remarks.

9 VICE CHAIR THOMADSEN: And contrary to
10 that, you could with less than 20 percent, or have
11 something that's quite significant.

12 MR. LEWIS: Yes.

13 VICE CHAIR THOMADSEN: Dr. Fisher.

14 MEMBER FISHER: In 2005, this Committee
15 recommended that the 20 percent criterion for defining
16 a medical event would be more reasonable if it were,
17 instead, set at the 50 percent variance level, rather
18 than 20 percent, for a total source strength
19 administered, since the 20 percent dose threshold is
20 comparable to the variation encountered in normal
21 medical practice. Just wanted to keep that guidance
22 in mind. That was according to the memo of July 19th,
23 2005 from this Committee to the NRC.

24 VICE CHAIR THOMADSEN: Thank you, Dr.
25 Fisher. Dr. Howe.

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1 MS. HOWE: I think there's another concept
2 you have to keep in mind here, and that is that
3 different physicians practice medicine in different
4 ways, so the standard of care may have a broad range.
5 But NRC staying out of the practice of medicine
6 doesn't look at how the physician practices, where
7 they are in that spectrum. To stay out of the
8 practice of medicine, we just look at what the
9 authorized user asked for, and does the facility
10 deliver what the authorized user asked for. So, you
11 may have a 20 percent variance between physicians.
12 That's not what NRC is looking for.

13 NRC is looking at once the authorized user
14 asks for something, is that delivered? And then we
15 will look at the 20 percent from what the physician
16 asked for, and we won't make a value judgment on
17 whether that original asked for was within a certain
18 range or not. I hope that helps a little.

19 VICE CHAIR THOMADSEN: Thank you for that
20 clarification, DR. Howe. Dr. Zelac.

21 MR. ZELAC: I have a question that I'd
22 like to ask to Drs. Welsh and Potters. When we're
23 talking about the variance, and what the result is
24 from what the physician had intended, 20 percent below
25 what the physician had intended, I think has been kind

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1 of accepted as reasonable, and doable. Is 20 percent
2 above what the physician had intended too tight, too
3 restrictive? I was thinking in terms of what you were
4 saying, Dr. Potters, about treating specialized areas
5 of the prostate as an example where you want to,
6 essentially, give it as much dose as you can without
7 harm to nearby critical organs.

8 There has been -- I mean, just to give you
9 the background on this, there had been some concern
10 that if the physician had expressed a dose, an
11 intended dose in terms of D-90, the D-90 was okay on
12 the low side, if you didn't meet 80 percent of your D-
13 90, there was a problem, and this should be something
14 recognized, but that exceeding the intended D-90 by
15 more than 20 percent is not so much of a problem from
16 a clinical point of view. And that perhaps either we
17 should have a higher limit on the high side than 20
18 percent, or some other approach for dealing with this
19 issue.

20 MR. POTTERS: I would be okay with that on
21 the high side. I think, like I was saying earlier,
22 the art of this is to keep your ceiling low, so if the
23 intent is to prescribe 145, 160, 125, whatever it is,
24 I mean, you shouldn't wind up too hot.

25 Now, clinically, is it less relevant that

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1 it's hot within the prostate, in terms of Grade I, II,
2 III, IV toxicity or not is something that one could
3 argue, so that maybe there's more latitude and leeway
4 on the higher side. But, personally speaking, I think
5 20 up, 20 down is going to give you a good enough
6 range.

7 VICE CHAIR THOMADSEN: Dr. Welsh, did you
8 want to respond at all?

9 MEMBER WELSH: I would agree with what Dr.
10 Potters has said, that a dose that exceeds the D-90 by
11 20 percent is unlikely to be harm to the patient,
12 might have a greater chance of curing the patient, but
13 it's not so much the dose to the prostate, itself, as
14 it is dose to the bladder, dose to the rectum, dose to
15 the urethra that travels within the prostate. If
16 those got significantly more than what we anticipated,
17 we might anticipate adverse effects to the patient.
18 But, again, I think we were hoping to get away from
19 the concept of dose for defining medical events, and
20 adhering more to the concept of administered activity.

21 VICE CHAIR THOMADSEN: This is another
22 example of where the different sites that you'd be
23 using would have different criteria, in that in a
24 breast implant as practiced in Canada with permanent
25 seed placement, a 20 percent overdose would probably

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1 have much greater significance than a 20 percent
2 under-dose.

3 MEMBER WELSH: And, as an example,
4 although it's quite uncommon of how you might have a
5 higher value than anticipated for the D-90, if you
6 were to use the older pre-planning approaches, and you
7 estimated the volume two, three weeks ahead of time,
8 did you pre-plan, but the patient is on hormone
9 therapy, and shows up in the operating room, and
10 hormone therapy has continued to cause prostate
11 shrinkage, you could wind up with a volume that might
12 be smaller than anticipated; and, therefore, you put
13 the seeds in, and you could wind up with a higher dose
14 simply because the volume is less than what you
15 expected. And, again, energy per unit volume or mass
16 defines your dose.

17 MR. ZELAC: Could I ask one more question?

18 VICE CHAIR THOMADSEN: Please.

19 MR. ZELAC: And this is a general
20 question. Is what you've just said, both of you, with
21 respect to exceeding the dose to nearby structures by
22 more than 20 percent, doesn't that speak to having a
23 criterion that considers doses to other organs and
24 tissues, critical ones, perhaps, that does exceed what
25 the estimate had been by 50 percent, which is what the

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1 rule says -

2 MR. POTTERS: I think the answer to that -
3 -in a conceptual, and a perfect world I would agree
4 with that. The reality is, is that dose is defined by
5 how one contours those organs. And given the fact
6 that there remains a tremendous degree of subjectivity
7 of how those organs are defined, and then to place
8 rulemaking on top of that would further constrain the
9 authorized user to try and conform to those doses.
10 So, I think you just -- I mean, if there was a true
11 standard where absolute dose could be measured, then I
12 would agree with you. But given the subjectivity of
13 the way that dosing is done, you're just not going to
14 see it.

15 I'd like to just make one other comment,
16 if I can indulge the Committee real quickly on the
17 idea of isotope, also, is that I want the Committee to
18 understand some of the nuances of how prostate
19 brachytherapy is done today, at least in some centers,
20 with intra operative planning and dosimetry. So, that
21 will have an impact on say the activity that I order
22 for that patient, which is separate from what the
23 intra operative planning tells me to do. So, I will
24 wind up with excess isotope that then is restored, and
25 not, necessarily, used on the patient. So, I wouldn't

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1 want to be put in a situation of having the concept of
2 over-dosing of being forced to use everything I bring
3 to the OR. So, what I generally do, what others do
4 that perform intra operative planning is to assess a
5 volume, come up with an activity per CC, order that,
6 order those sources with, perhaps, a 5 or 7 percent
7 margin intra operatively, because the setup, the
8 volume, the positioning of the patient may have a
9 slightly different volume than that which was measured
10 prior. Maybe the patient is on hormones or Avodart,
11 or some other medications, prostate is a little bit
12 smaller. And then intra operatively do the planning,
13 and that planning may call for 90 percent of the
14 activity that I've thus brought to the operating room,
15 but that achieves what I want to achieve. So, I'm
16 going to have excess activity that I give back to my
17 physicist who's in the operating room, so we're
18 signing the plan as it's being done, so we comply at
19 least with the New York State regs. And I wouldn't
20 want to be in a situation where what I order is
21 actually what I'm forced to use from an activity
22 perspective, so pre-plan, it's still -- it's intra
23 operative. It's still a pre-plan, because I haven't
24 done anything to the patient. I've just done the
25 measurements in the operating room, but I'm going to

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1 walk away -- I did a case this morning before I came
2 down here, so we left 17 seeds out of 130 that weren't
3 needed. So, any rulemaking that takes into account
4 activity should be based on a pre-plan, but it doesn't
5 have to say that the pre-plan was done a month ago, or
6 it was done two days before, or it was done 30 seconds
7 before I started implanting the patient.

8 VICE CHAIR THOMADSEN: Dr. Howe.

9 MS. HOWE: Just to follow-up with what
10 you're doing -

11 VICE CHAIR THOMADSEN: Can you speak a
12 little bit louder, please? I don't think people can
13 hear.

14 MS. HOWE: I'm trying to. Dr. Potters,
15 just to follow-up what your -

16 VICE CHAIR THOMADSEN: Is the microphone
17 on at all?

18 MS. HOWE: Yes, it is.

19 VICE CHAIR THOMADSEN: Could the audio-
20 visual people please turn up the microphone on the
21 side there, please.

22 MS. HOWE: When you're treating intra
23 operatively, what is it that tells you you're
24 finished?

25 MR. POTTERS: Okay. I'll indulge the

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1 Committee further. So, the process is that we
2 anesthetize the patient, we use the ultrasound, we
3 measure the volume of the prostate, we do the plan. I
4 use a software, I won't mention the vendor's name, but
5 I use an interactive software in the operating room,
6 and as I've mentioned, my physicist is in the
7 operating room, so that as the seeds are being loaded,
8 and they're loaded one at a -- so, I've created this
9 pre-plan, maybe it calls for 90 percent of the
10 activity, 90 percent of the seeds. I start then
11 overlaying the contoured and the dose plan with a live
12 image on the ultrasound, and I start loading the
13 seeds. And my physicist is accounting for the seeds
14 as they're being dropped. The software allows for the
15 dose calculation to be performed real time, so that
16 when I complete that plan in the operating room, I'll
17 have D-90, I'll have a V-100, I'll have a V-150, I'll
18 have urethral doses, rectal doses right then and
19 there, and I look at that before I take my gloves off,
20 and I say are we cold in any areas, in which case I
21 have the actual plan, and I can change it. So, in
22 essence, when I'm completed the case in the operating
23 room, I have a post-plan, also. I've done my post-
24 plan.

25 I still, because of ABS, and because of

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1 ASTRO and ACR, I still take a CT scan. I don't rely
2 on that 100 percent, but we've published that shows
3 that the correlation of that post-plan intra
4 operatively matches the CT, so that I don't have to
5 wait a month to tell the patient's wife that he had a
6 good implant. I can tell them right then and there
7 that the implant was successful based on the various
8 dose parameters that we use.

9 MS. HOWE: Okay. Just to follow-up on
10 that, let's say as you're starting to inject the
11 seeds, you get swelling, so what you're determining,
12 and what your computer is determining is the dose
13 based on that swollen volume.

14 MR. POTTERS: So, you're digging here, but
15 that's okay, because -

16 MS. HOWE: I'm -

17 MR. POTTERS: No, no, no, that's okay.
18 So, we published a paper on edema that looked at when
19 does edema occur? And it generally occurs after all
20 the needles are placed. It's the trauma of the
21 placement of the needles that's associated with edema.
22 So, in fact, what I do is bring the patient in, I
23 place all the needles into the prostate before I
24 contour the prostate, so that -- and then I do the
25 planning based on those contours.

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1 MS. HOWE: Okay.

2 MR. POTTERS: So, that's how I account for
3 that.

4 MS. HOWE: And I think it's important to
5 point out, as you did, in our regulations, the written
6 directive is before administration, so that could be
7 two nanoseconds before administration. It doesn't
8 have to be a month before, or some other time. So, in
9 real time planning, it can be just before you start
10 putting the seeds in.

11 MR. POTTERS: Right.

12 VICE CHAIR THOMADSEN: Other questions or
13 comments? I would like to come back to one other
14 thing, and that's dealing with the brachy mesh,
15 because I have been receiving comments from facilities
16 who are concerned that every case they do would be a
17 misadministration, because the dose they calculate
18 after they do the procedure is rarely within 20
19 percent of what they've calculated beforehand, because
20 the calculation beforehand is in a perfect geometry
21 with the patient open, and afterwards is done by CT
22 after the site has been closed. And the geometry with
23 the implant is very different in those two cases.
24 Their concern is with any dose-based calculational, or
25 any calculated dose criteria that for procedures,

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1 intra operative procedures such as this, they would
2 always be falling into the medical event arena, and
3 that would, essentially, kill the procedure. Dr.
4 Welsh.

5 MEMBER WELSH: So, again, this returns us
6 to the concept of dose-based versus activity or source
7 strength-based definitions of medical events, because
8 dose is a function of -- again, it's energy per unit
9 mass, which is, essentially, volume, and if volume has
10 changed, as in prostate brachytherapy with edema, or
11 in lung mesh brachytherapy, volume is different
12 because the cavity has bunched up, and the mesh has
13 bunched up, dose being related to volume is very
14 difficult to accurately ascertain; whereas, activity
15 and source strength is not. So, Dr. Thomadsen, in
16 your opinion, would the use of source strength or
17 activity prevent the labeling of misadministration or
18 medical event to some of the events that you were
19 talking about, specifically, your colleagues have
20 mentioned to you?

21 VICE CHAIR THOMADSEN: Yes.

22 MEMBER WELSH: So that would, then,
23 further support movement away from dose, and towards
24 activity and source strength for permanent implant
25 brachytherapy.

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1 VICE CHAIR THOMADSEN: Yes. Dr. Howe.

2 MS. HOWE: I don't know if this is
3 relevant, or not, because I don't know exactly why you
4 get difference in doses, but I do know that we have
5 had other what we consider emerging technologies,
6 where we look to see how the technology meets the
7 current requirements. And if there is a uniform area
8 in which it doesn't meet our current requirements,
9 then we'll put it in 35.1000, and we'll help to
10 identify what that area is. A specific case is, we
11 put the micro spheres in 35.1000, because you have
12 almost every medical event, almost every
13 administration would be a medical event for one type
14 of micro sphere because you go to stasis, and we
15 didn't want that to occur, so we changed what our
16 written directive was for that particular micro
17 sphere, and said that you want to deliver a certain
18 dose, or until stasis, because we knew that was a
19 common issue with that particular device and use. And
20 if you believe the brachy mesh is in the same kind of
21 area, it could go into 1000, and we could define what
22 a written directive is for it, and what a medical
23 event is for it. That is another option that is
24 available to you.

25 VICE CHAIR THOMADSEN: Yes. Although the

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1 technology involved here is not emerging, is not new,
2 has been in existence for at least 50 years, and the
3 procedure, itself, has been used in one form or
4 another for about that length of time, so I'm not sure
5 that 1000 would be the appropriate place for that.

6 Dr. Potters, you were about to say
7 something, I think.

8 MR. POTTERS: I just think the concept of
9 volume is just amplified in the lung more than, say,
10 the prostate, and you wind up with the same issue if
11 under a VATS procedure, a patient is undergo a wedge
12 resection of a localized tumor with the intent of
13 treating along the resection line, and the re-inflated
14 lung creates distortion of the mesh. That's just an
15 amplification of a change in volume relative to what
16 we're talking about, prostate edema of 10, 20, 30
17 percent. This could sometimes be more like 40 or 50
18 percent. Now, the seeds are still located within that
19 area, because it's sewn into the mesh that's there,
20 but if you created a dose definition, you would have a
21 high number of reportable events in this procedure.

22 VICE CHAIR THOMADSEN: Dr. Welsh.

23 MEMBER WELSH: So, as you mentioned, Dr.
24 Thomadsen, in response to Dr. Howe's point about lung
25 brachytherapy, this is not something that is new.

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1 This has been around for around half a century, and
2 applies to breast permanent implants, lung, pancreas,
3 even brain in rare instances. And it's come to
4 attention again because of the recently developed --
5 the one that's been marketed recently called brachy
6 mesh, which is convenient, and it's gaining in
7 popularity, and it's being investigated, data is
8 accumulating, and people are using it routinely. But
9 it does raise the question of whether or not activity
10 is a better way of defining medical events than dose,
11 and it appears that the answer is yes. And,
12 therefore, one of the Subcommittee's subjects of
13 discussion was should permanent implant prostate
14 brachytherapy, which is so sophisticated in the
15 technology, be in a separate category than the other
16 implants. It sounds like it might not be necessary.
17 I raise the question to Dr. Thomadsen. Now, in your
18 analysis of all that we've discussed, is it necessary
19 to have a separate category, or, as the title, will
20 one rule fit all, still be valid if we change to
21 activity, as we hope?

22 VICE CHAIR THOMADSEN: Well, as we've been
23 discussing here, it's been sounding like the brachy
24 mesh approach has the same -- is the same situation as
25 we've been discussing with the prostate, just a matter

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1 of degree. And the proposal of the Subcommittee
2 sounds like it would satisfy the definition for
3 medical event for both cases.

4 Oh, I'm sorry, Dr. Gilley. You're just
5 too close.

6 MEMBER GILLEY: How about micro spheres?
7 Will that fall in the same with the activity-based?
8 That's the other permanent implant that we need to
9 take into consideration that seems to be gaining
10 popularity.

11 VICE CHAIR THOMADSEN: I'd say very
12 possibly.

13 MEMBER GILLEY: Or do you want to handle
14 that as a separate rule per se for the micro spheres,
15 because I know there is migration to lung on
16 occasions, there's the health stasis process.

17 VICE CHAIR THOMADSEN: Dr. Suleiman.

18 MEMBER SULEIMAN: I have problems with
19 different protocols, different exams. The micro
20 spheres are a very different beast, you know, the
21 dosimetry is highly conjectural, in my opinion. I was
22 talking to a colleague from -- and administered
23 activity probably is a more accurate predictor,
24 because you don't know how it's distributing in the
25 liver. And my thinking of these, if the brachytherapy

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1 -- as long as these procedures are similar in
2 precision and accuracy, you could lump them together,
3 but assigning 20 percent across the board is just
4 problematic. I think some of these things have high
5 precision, high accuracy, others are just
6 guesstimates. So, I have problems with a flat out 20
7 percent, because some of these -- and the poor
8 community is struggling, is this -- can you even
9 estimate accurately the dose for some of them? So, I
10 take a more flexible approach; in other words,
11 depending on the procedure, and how accurate it is,
12 whether you'd want a 20 percent, or dispense with it.

13 VICE CHAIR THOMADSEN: Certainly, 20
14 percent dose with the micro spheres would be very hard
15 to verify one way or another.

16 MEMBER SULEIMAN: Yes, we can get in a -

17 MEMBER GILLEY: Well, realizing that it's
18 still Part 1000, but at some point in time, as
19 procedures are gaining popularity, it should have a
20 category all to itself. So, maybe that's when you
21 ought to address when we would write the written
22 directive, and the medical events criteria.

23 MEMBER WELSH: I would say I have not
24 given a whole lot of thought to this point, but my
25 feeling is that unlike prostate brachytherapy, where

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1 you're dealing with visible sources, and a finite
2 number, with the micro spheres, you have -- you're
3 dealing with millions, billions, have no idea how many
4 micro spheres there might be. They're not visible,
5 and trying to regulate them under the same set of
6 rules as prostate brachytherapy could lead to some
7 difficulty. My guess might be that it might fit with
8 radio immunotherapy better than it would fit with
9 prostate brachytherapy.

10 MEMBER ZANZONICO: And I think there are
11 sufficient safeguards developed by the practitioners
12 in terms of measuring short-circuiting to the lungs,
13 and what is or is not acceptable, as well as re-
14 embolizing certain hepatic blood vessels. I think it
15 just strikes me that the practitioners are making a
16 very good faith effort, and it's just too ill-defined
17 at this point to lend itself to rulemaking the same
18 way as prostate brachytherapy, for example.

19 VICE CHAIR THOMADSEN: Thank you very
20 much. Yes? Identify yourself, please.

21 MS. PELKE: Patty Pelke, NRC Region III,
22 back to prostate brachytherapy. Dr. Potters, you had
23 mentioned two things that I just wanted to make sure I
24 had straight before I left today. You talked about a
25 study that was done about 10 years ago relative to

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1 edema, and I was trying to get a better read on that.
2 Was it about 30 percent of patients experience edema,
3 or is it a higher percentage than that?

4 MR. POTTERS: So, the paper that I was
5 referencing was one of our publications. The other
6 authors that have published a lot on edema actually
7 come out of Jefferson, which is sort of a competing
8 institution in Philadelphia, from that that was
9 overseeing the VA.

10 Anywhere between 20 and 50 percent of the
11 patients have reported edema, as much as 5 percent to
12 50 percent, and some even higher. So, there's not a
13 good handle on it. There's also not a good handle on
14 predicting which patients are going to have more or
15 less edema, so it's not as though patients with large
16 prostates have more edema. It's not even that more
17 needle sticks, even though needle sticks is -- the
18 actual placing of the needles into the prostate is,
19 apparently, the initiating event. It's not even that
20 more needle sticks is going to cause more or less
21 edema, so it's highly variable.

22 And the paper that I was referencing that
23 we published on was, actually, it was a mathematical
24 paper looking at edema half-life relative to
25 recalculating what the dose should be, taking into

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1 account, say, Palladium with a 17-day half-life, and
2 then a 20 or 30-day edema half-life. How is that
3 impacting on dose in a patient with 30 or 40 percent
4 edema? So, it was, more or less, a mathematical
5 exercise.

6 MS. PELKE: One more question. On your
7 intra operative procedure, you talked about placing
8 all the needles first before you start dropping the
9 seeds. Is that routine for intra operative, or is
10 that just your choice?

11 MR. POTTERS: So, some of that is my
12 approach, other people are using this approach. The
13 contrary argument that's made for putting the needles
14 in first is that it creates artifact on the
15 ultrasound, which then makes contouring of the
16 prostate, and then doing your intra operative plan
17 more difficult. So, there are others that don't
18 believe that that's the best way to go, so I think
19 there is what you're going to see here is both camps
20 of intra operative type of treatment planning. And,
21 although, it may not account for edema, if you're not
22 putting the needles in, again, the concept of edema
23 and its clinical meaningfulness is something we could
24 debate without a definitive answer.

25 MS. PELKE: Thank you.

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1 VICE CHAIR THOMADSEN: Thank you. Dr.
2 Welsh.

3 MEMBER WELSH: Just to provide some
4 feedback about variability. I did not put the needles
5 in routinely during the pre-planning procedure. I
6 would do the pre-plan, and then place the needles,
7 exactly for the reason that I didn't want to be
8 planning on a gland that had the edema already in it.
9 As Dr. Potters has mentioned, we don't have the actual
10 clinical feedback data to tell which approach is
11 better. I think both of them work very well, and it
12 might be individual clinician discretion, or comfort
13 level.

14 VICE CHAIR THOMADSEN: Thank you, Dr.
15 Welsh. Is there further discussion on this issue?
16 Yes, Mr. Lewis.

17 MR. LEWIS: I just wanted to thank you for
18 the discussion. This is very enlightening to me. I
19 did want to ask about the forum to communicate the
20 Subcommittee's findings. Is the presentation here the
21 product, or will there be a written product, or a
22 letter from the Committee? Somehow, I'm trying to
23 think of how to provide the information, the
24 Committee's views, to the right people. It was clear
25 to me at the Commission briefing on the 11th that at

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1 least some of the Commissioners wanted to have the
2 Committee's views as they consider medical
3 rulemakings, presumably, this one included. They're
4 getting near term. And there are various mechanisms
5 to give them their views. Of course, we try to
6 provide the views with the SECY Paper that goes up in
7 the rulemaking, and the long history on this issue, on
8 this particular rule. But I do need a tangible path
9 forward to bring back to NRC management to provide the
10 Commission what they need.

11 VICE CHAIR THOMADSEN: Thank you for the
12 practical question. Dr. Welsh.

13 MEMBER WELSH: There is a three or four-
14 page written summary, a formal report to you from the
15 Subcommittee that I forwarded to Ashley.

16 MR. LEWIS: I guess, will it be revised in
17 light of this discussion, or is that what -

18 MR. EINBERG: And, also, we had provided
19 some additional documents, medical consultant's
20 report, and then, also, I believe the VA criteria, so
21 just in your deliberations, were those considered, or
22 do they need to be considered, as well?

23 MS. COCKERHAM: This is Ashley. I just
24 have one more thing. To formalize that Subcommittee
25 report, we would need a vote by the full Committee, so

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1 however you want to do that is fine. If you need to
2 make any revisions and look at it again at a later
3 date, and vote via email, that's fine. I think that's
4 what Rob was looking for, is like a final Subcommittee
5 report, but we wanted a good product to come to the
6 meeting with, which is what Dr. Welsh provided.

7 VICE CHAIR THOMADSEN: With the -

8 MS. COCKERHAM: Yes, or a Committee
9 report, and not a Subcommittee report.

10 VICE CHAIR THOMADSEN: Right. Would the
11 Committee recommend to the Subcommittee to provide a
12 written -- a potentially revised written version to
13 this Committee for an electronic vote to be forwarded
14 to the NRC? I'm asking is there a motion to that
15 effect.

16 MEMBER ZANZONICO: Motion.

17 VICE CHAIR THOMADSEN: Thank you. Do we
18 have a second?

19 MEMBER GILLEY: Second, if I can. I'm on
20 the Subcommittee, so I'm not sure if that's a
21 conflict.

22 VICE CHAIR THOMADSEN: I think you
23 certainly can. Now, we're open for discussion on that
24 point. Dr. Welsh, since you're chairing the
25 Subcommittee, do you have discussion on the proposal?

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1 MEMBER WELSH: So, I have taken a few
2 notes in terms of feedback, but I'd be relying mostly
3 on my memory of everything that we discussed here, and
4 the contributions from Dr. Potters, but I do believe
5 that I could edit the formal report, and resubmit it
6 to you in a timely fashion, given the feedback that
7 we've had here today.

8 VICE CHAIR THOMADSEN: Dr. Fisher.

9 MEMBER FISHER: We need to review what
10 that report states.

11 MEMBER GILLEY: Could the Subcommittee
12 review it first?

13 VICE CHAIR THOMADSEN: Well, part of the
14 motion is that it comes to the full Committee, so you
15 would certainly see that.

16 MEMBER FISHER: I'm on the Subcommittee.

17 VICE CHAIR THOMADSEN: I'm sorry, you were
18 talking about for the Subcommittee to review -

19 MEMBER FISHER: I would have to review it
20 again.

21 VICE CHAIR THOMADSEN: I'm sorry. I was
22 expecting that the Subcommittee would be working with
23 Dr. Welsh on this, although that wasn't explicitly
24 stated.

25 MEMBER FISHER: I'd like to review it

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1 before it goes to the full Committee.

2 VICE CHAIR THOMADSEN: Yes. I think that
3 that would be an internal matter for the Subcommittee,
4 and Dr. Welsh could probably whip the Subcommittee
5 into order before that.

6 MEMBER GILLEY: Submit.

7 VICE CHAIR THOMADSEN: Yes. But that's a
8 very good point, I would want to see it, also. Any
9 other -- oh, I'm sorry.

10 MEMBER ZANZONICO: There was a motion.

11 VICE CHAIR THOMADSEN: Yes.

12 MEMBER ZANZONICO: We need to vote on the
13 motion.

14 VICE CHAIR THOMADSEN: Yes, we shall, as
15 soon as everybody's done commenting.

16 MEMBER ZANZONICO: Okay.

17 VICE CHAIR THOMADSEN: Which looks like
18 that's now. Seeing no more comment, all in favor of
19 the motion say aye.

20 (Chorus of ayes.)

21 VICE CHAIR THOMADSEN: Opposed? It is
22 unanimous. Very good. I have a written report to do,
23 James. With that, any last words on the issue from
24 the NRC?

25 MR. LEWIS: Just in terms of the time

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1 frame, Ashley will work with our rulemaking people.
2 It's not a long amount of time.

3 VICE CHAIR THOMADSEN: Yes.

4 MR. LEWIS: Our rulemaking people are
5 trying to make their way to the next -

6 MS. COCKERHAM: Well, we're not quite that
7 fast.

8 MS. BHALLA: I'm Neelam Bhalla from NRC.
9 Dr. Welsh, I think if I remember correctly, last time
10 when you were discussing about the post-implant
11 verification of the dose, I thought there was a
12 discussion on what is the optimum time to do that,
13 notwithstanding the real-time ultrasound, but the,
14 let's call it the -

15 (Cough.)

16 MS. BHALLA: So, could you go over that
17 again, if that's all decided, or is the ABS still
18 looking at that?

19 MEMBER WELSH: My recommendations for NRC,
20 and the purposes of medical event definition, and
21 corrective action for VA, so that that doesn't happen
22 again, is simply that it be a requirement that post-
23 implant dosimetry be performed. And it sounds like it
24 may not have been explicit, but it's implicit already.

25 As far as when to do the post-implant

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1 dosimetry, there are statements from the American
2 Brachytherapy Society about when this could be done,
3 or should be done, but it's a function of a lot of
4 things, a lot of variables, including the isotope.
5 And I've been focusing -- we've been focusing a lot on
6 Iodine-125 today, but as Dr. Potters has mentioned,
7 Palladium has a 17-day half-life, and, therefore, your
8 window for appropriate post-implant dosimetry might be
9 a different time frame, or Cesium-131 with a 10-day
10 half-life, we published a paper very similar, a
11 mathematical analysis suggesting that there might be
12 two times that you should do the post-implant
13 dosimetry to adequately reflect the true dose to the
14 target prostate. So, I don't think that we have any
15 firm recommendations as far as NRC regulations
16 regarding the timing of post-implant dosimetry, but I
17 would ask Dr. Potters for his expert opinion on this.
18 But I'm just saying, for the purpose of regulation, I
19 don't think that we want to go into that area about
20 specifying a time frame.

21 VICE CHAIR THOMADSEN: Ms. Gilley.

22 MEMBER GILLEY: One thing you can do is
23 put it in your requirements for having a license for
24 that, and it's called your procedure. And that's one
25 way of doing it, so each individual institution or

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1 licensees could make their own criteria as to when
2 that post treatment implantation would be, and it
3 would be very much license-specific.

4 VICE CHAIR THOMADSEN: You do have a
5 problem, I would point out, that if you put in your
6 procedure that you will do the post dosimetry based on
7 a CT done 30 days later, you may have patients who do
8 not show up ever for that -

9 MEMBER GILLEY: That's patient
10 intervention.

11 VICE CHAIR THOMADSEN: As long as that's
12 considered so. Dr. Zelac.

13 MR. ZELAC: I need some clarification.
14 If, as I have gathered from the discussion, the
15 direction of the Committee, as well as the
16 Subcommittee, is to move away from there being any
17 dose-based criteria for medical event, then where does
18 the determination of the dose come in, and what's the
19 purpose of it relative to the regulation?

20 VICE CHAIR THOMADSEN: Dr. Welsh.

21 MEMBER WELSH: I would simply answer that
22 the purpose of the post-implant dosimetry in this
23 situation is not so much that we can identify medical
24 events, and regulate. But, as Dr. Potters has
25 mentioned, you get valuable feedback on the quality of

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1 your implants, and if you want the next patient to be
2 treated better than the one last week, and the patient
3 two months even better than that, this feedback is
4 very valuable. And it's part, in my opinion, of good
5 quality program to have continuous feedback on whether
6 you're doing things right, whether you could be doing
7 something better, and how you're going to do it better
8 next time.

9 And as far as the timing goes, one of the
10 realities is that sometimes patients will come a long
11 distance for an implant procedure. And I know of some
12 facilities that will do an implant before that patient
13 goes back to his original state or country. And it's
14 done kind of as a formality, that we do post-implant
15 dosimetry, but it's understood that if you're doing it
16 one day, two days afterwards, it might not be as valid
17 as if you're doing it at what ABS has recommended.
18 Again, the purpose of the post-implant dosimetry is
19 not designed for regulation for the purpose of
20 defining medical events, but simply for improving
21 quality of the program.

22 MR. ZELAC: Then it falls under the sphere
23 of medical practice?

24 MEMBER WELSH: Which is why I would not
25 recommend NRC use it in any way for defining medical

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1 events, but just simply state that it's part of the
2 requirement for getting a license, that the program
3 has to have that.

4 MR. ZELAC: I'm sorry. To me, it sounds
5 like that's medical practice, and we don't engage in
6 that. I mean, I understand the objective, and I think
7 it's well-founded, but if you're going to say that the
8 determination of dose is, essentially, for improvement
9 of the quality of the implants, that's medical
10 practice. And if we don't have any criterion for
11 determination of a medical event based on dose, then I
12 don't know that we should be putting in any medical
13 criterion, medical practice requirement into the
14 regulation.

15 VICE CHAIR THOMADSEN: Dr. Suleiman.

16 MEMBER SULEIMAN: This is an area I deal
17 with almost daily. One of the problems I've seen,
18 it's not the issue of dose, it's the issue of how you
19 calculate dose. And it's not the activity, or the
20 radiation component, it's the imaging associated with
21 the volume, volumetric determination. Aside from the
22 added amount of normal biological variability, are you
23 imaging with ultrasound, are you doing it with CT?
24 You can take images using various modalities, and get
25 different numbers all the time, so we're dealing in an

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1 area that's extremely soft, in my opinion, so it's an
2 area we're striving for. Some of the cancers, for
3 example, are extremely difficult to image, solid
4 tumors are very easy to image, so the issue, I think,
5 boils down, if you scrape away everything else, it's
6 the ability to accurately reproducibly image some sort
7 of target volume, and that practice -- it's still
8 very, very soft, it's very, very uncertain, so I've
9 always aspired toward knowing what the dose is. I
10 mean, I'm extremely biased toward that, because when
11 the dosimetry gets more precise and accurate, I
12 believe you'll see dramatic breakthroughs in some of
13 the cancer therapies with radioactivity. But just
14 because the state of the practice isn't very good,
15 maybe you shouldn't abandon it. I think in
16 brachytherapy, at least you're getting in the ball
17 park, literally. It's a soft number, but I would not
18 abandon it completely. That's where you've got this
19 give and take between administered activity, which you
20 can control very, very much so, and trying to
21 calculate the dose. You can calculate the dose five
22 different ways, if you want, using different days of
23 imaging, using different sources. So, I think you
24 have to come to grips with what level of uncertainty,
25 and what do you want to live with, so I'd focus more

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1 on the administered activity, because it's more
2 controllable. And the dosimetry is still subject to
3 image variability.

4 VICE CHAIR THOMADSEN: Dr. Welsh.

5 MEMBER WELSH: So, I'm trying to think of
6 a way to answer this dilemma that Dr. Zelac has
7 brought up. It's a bit of a challenge. I propose
8 that we get away from dose-based definitions of
9 medical events, and I'm in favor of activity or source
10 strength-based. And it sounds like there's agreement
11 on that. But I also raise the suggestion of insisting
12 that a program must have post-implant dosimetry, but
13 Dr. Zelac has pointed out that in order for that to
14 come to fruition, there has to be some justification
15 for it. And without dose-based definitions of medical
16 events, you scratch your head about what's the
17 justification.

18 I hate to -- I'm reluctant to make this
19 suggestion, but I'm going to, just for the sake of
20 discussion, that maybe rather than use the dose
21 calculated during the post-implant dosimetry in any
22 way for defining a medical event, if no post-implant
23 dosimetry is done, that could be a violation.

24 VICE CHAIR THOMADSEN: Dr. Zelac.

25 MR. ZELAC: Thinking about what the

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1 discussion was earlier, Donna Beth, Dr. Howe pointed
2 out that we do have the requirement in 35.41 for the
3 facility assuring that the procedures are of
4 appropriate quality. That could -- I think you could
5 tie this requirement that you're looking for to be in
6 the regulations to that as a subset of it, or as an
7 offshoot from it, perhaps. So, there is probably a
8 way if you massage to get what you're looking for in,
9 even without medical event involving dose.

10 MEMBER WELSH: And still stick with
11 activity or source strength-based definitions.

12 MR. ZELAC: Yes.

13 MEMBER WELSH: So, maybe that can work.

14 MR. ZELAC: I'm glad I not only raised the
15 question, but, apparently, come up with an answer, as
16 well.

17 VICE CHAIR THOMADSEN: Were everything
18 that clear. Other comments on this before we close
19 the topic? Yes, Ms. Pelke.

20 MS. PELKE: Patty, sorry. NRC Region III.
21 I just want to make sure that I understand this. What
22 you're proposing is an activity-based requirement, and
23 I'm trying to get around the fact that the activity
24 that you're going to prescribe is going to be
25 dependent on the dose you want to deliver. Is that

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1 correct?

2 VICE CHAIR THOMADSEN: That is correct.

3 MS. PELKE: Okay. So, there will be some
4 dose component to this. Right?

5 VICE CHAIR THOMADSEN: Yes.

6 MS. PELKE: Okay. And then your activity
7 is going to be based on whatever isotope you choose to
8 use, whether it be Iodine, Palladium, Cesium.

9 VICE CHAIR THOMADSEN: Right.

10 MS. PELKE: Okay.

11 MS. HOWE: Dr. Thomadsen?

12 MEMBER FISHER: Dr. Howe.

13 MS. HOWE: I would just like to point out
14 that when we look at the VA data, we find that
15 activity is not very sensitive, and that you can have
16 determined by the VA cases where you're between 90 and
17 100 percent of the seeds are identified as being in
18 the target site, and keep in mind that the authorized
19 user determines what the target site is, that those --
20 the doses, the D-90s, in this case we used D-90s
21 because that's what the facility was using as a
22 methodology for determining whether they had medical
23 events, the D-90s were not close to 80 percent. Some
24 of them were grossly below 80 percent. And if you
25 looked at the images, you saw very large cold spots,

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1 because the three-dimensional array of the seeds
2 within the prostate was such that you did not get the
3 dose you were looking for. The cloud was there, but
4 it wasn't distributed, so there's a three-dimensional
5 component here in the prostate that's very important
6 for dose. And just knowing the number of seeds put in
7 does not give you an accurate evaluation of what is
8 happening in the prostate.

9 VICE CHAIR THOMADSEN: Dr. Fisher.

10 MEMBER FISHER: I wrote this is a note to
11 Dr. Zelac, but I think it still holds. We know that
12 radiation dose is proportional to, and is a direct
13 function of the implanted activity. The radiation
14 dose to the patient for a given implant is highly
15 variable with location both within the target site,
16 and outside the target site. The assessment of post-
17 implant dose for compliance would be complex and
18 burdensome to the licensee. However, it would be
19 relatively straightforward for the licensee to
20 ascertain the total source strength implanted within
21 or outside the intended target site.

22 VICE CHAIR THOMADSEN: Dr. Howe.

23 MS. HOWE: Unfortunately, the relationship
24 between the activity and the dose is not a one-on-one
25 type of thing. If you put the seeds in an area, and

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1 you haven't distributed them the way you intended to,
2 then the calculated dose is much, much less, so you
3 don't have that one-to-one relationship that you have
4 with other implant procedures, where you have one or
5 two sources, and then you're looking at a given
6 distance.

7 MEMBER FISHER: That was my Point Two.

8 MS. HOWE: So, you don't have an accurate
9 dose to the prostate just by knowing where that you
10 have X number of seeds inside of it.

11 MR. POTTERS: I don't think you're ever
12 going to get to perfection on this.

13 MS. HOWE: I'm not talking perfection, I'm
14 talking lay-out.

15 MR. POTTERS: And I agree with that. I
16 think the other way to look at it is, and I'm not in
17 any way defending the VA practice, but when you look
18 at the clinical outcomes that the report generated in
19 terms of patients who failed treatment versus patients
20 who had excess complications as a result of the
21 misplacement of the seeds, they really weren't out of
22 the reported realm of reported outcomes of Centers of
23 Excellence, which maybe leads to the question of what
24 are we doing with prostate cancer in a general sense?
25 But that's well beyond the discussion at this table.

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1 So, if the criteria is to look at it based on
2 activity, at least activity is fixed. You can look at
3 activity in the gland, or within the target, and
4 that's pretty fixed. Dose is subjective, and the fact
5 that there's not going to be a direct correlation,
6 perhaps, to toxicity or outcomes, just shows that it's
7 less of a true science here.

8 VICE CHAIR THOMADSEN: Thank you for your
9 comments. Any other comments? In that case, we are--

10 MR. EINBERG: Did you have to vote on the
11 --oh, you already voted.

12 VICE CHAIR THOMADSEN: We did.

13 MR. EINBERG: Yes.

14 VICE CHAIR THOMADSEN: And it passed.
15 Thank you for keeping these things in mind, always
16 necessary. It's time for us to adjourn. We meet
17 again tomorrow morning at 8:00 in the same room. Good
18 night.

19 (Whereupon, the proceedings went off the
20 record at 4:55 p.m.)
21
22
23
24

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Appendix A

Statement of Peter Crane

Counsel for Special Projects, Office of General Counsel, U.S.N.R.C. (Retired)

before the

Advisory Committee on the Medical Uses of Isotopes (ACMUI)

Rockville, Maryland

May 24, 2010

I very much appreciate the opportunity to address this Committee. I have read a great many transcripts of the Committee's meetings, and I see that directness and candor are the norm. I will follow that example today. The issue before us involves safeguarding American children from the risk of radiation-caused cancer, and if any subject calls for plain speaking, that is it.

First I should introduce myself. I joined the NRC just ten weeks after it came into existence in 1975, as an assistant to then Commissioner, later Chairman, Marc Rowden. I moved to the Office of General Counsel in 1977. I was named Counsel for Special Projects in 1985 or 1986 and remained in that position until I retired in 1999. My service was continuous except for a year spent as an administrative judge with the Nuclear Claims Tribunal of the Republic of the Marshall Islands. I have thus had 35 years in which to view the ebb and flow of NRC regulation in the medical area. I was an invited speaker at a United Nations conference in Moscow in 1997, and presented a paper at a conference, sponsored by the European Commission, National Cancer Institute, and Cambridge University, at Cambridge, England, in 1998. (That talk can be found in *Radiation and Thyroid Cancer*, a book published by the European Commission in 1999.) Several years after that, I was an invited speaker at an American Thyroid Association symposium in Washington.

I have also been a thyroid cancer patient for 37 years.¹

¹I did not join the NRC thinking that my medical past would ever be relevant at work. But when you go to a briefing, as I did in 1983, and a senior official declares – in explaining why the NRC staff is reversing its commitment to stockpile potassium iodide – that thyroid cancer is “easily diagnosed, easily cured, no fatalities,” and you happen to know that the disease kills 1200 Americans each year, you can't help but speak up.

During that time I have had seven treatments with iodine 131: two as an outpatient, 25 years ago, to ablate what was left of my thyroid, and five as an inpatient, during a recurrence of cancer that began about 20 years ago. No one in this room, therefore, has more reason than I to appreciate the value of I-131, and how imperative it is that we ensure an ample and uninterrupted supply of it. But having children who were two and four when my recurrence was diagnosed, I also have reason to appreciate the special risks that go with its use.

Second, I wish to say that the NRC has always had many fine, capable, and dedicated employees. I was proud to have such people as colleagues, and many are my friends today.² Often it is said of an organization that it is greater than the sum of its parts; in the case of the NRC, I would say that it is sometimes *less* than the sum of its parts. I have seen very good people doing their very best, but sometimes getting overruled, or outvoted, or even misinformed or misled, and the result can be a very bad outcome. In short, the fact that I have critical things to say about the actions of the Commission, the NRC staff, and this Committee is far from being a criticism of everyone belonging to those organizations.

To summarize my views briefly, I believe that the NRC's deregulation of I-131 treatments in 1997 will someday be seen as perhaps the most radical and irresponsible of all deregulations ever made in the health and safety area. It violated the International Basic Safety Standards established by the International Atomic Energy Agency and other international groups – not that this fact was even mentioned to the Commissioners in the staff memorandum proposing the change. The NRC disregarded warnings from New York and several other states that I-131 was a special case, because of its extreme radiotoxicity. The NRC also reversed fields on the danger of I-131 contamination, and the resultant internal dose. Whereas only a decade earlier, the NRC had correctly explained that I-131 patients could cause members of the public to receive both an external dose, from proximity, and an internal dose, from contamination, the 1997 rule

²I served in the trenches with some who are here today. Dr. Donna Beth Howe will remember when Dr. Carol Marcus was denouncing both of us in letters to the Commission that were notable for the colorful adjectives employed. She wanted me fired – I can't remember about Donna Beth – but the prize went to Jim Lieberman, a senior lawyer. When Dr. Marcus wrote to the Commission demanding that he be sent to an insane asylum, he gleefully taped the letter to his office door.

declared internal dose to be negligible. (The NRC would rediscover the danger of internal dose in 2008, more than four years after a report from the International Commission on Radiation Protection highlighted the risk to children of internal exposure from patients' radioactive saliva.)

The rule change had several effects that the NRC had not foreseen. One was that insurance companies would refuse to pay for inpatient treatment, even when the patient's family situation required it. The definitive source on that is the transcript of this Committee's meeting in October 2007, in which Dr. Malmud and Dr. Eggli describe the difficulty or impossibility of getting inpatient treatment for patients. A second was that this would require the NRC to make a choice: either enforce the rule, and compel providers to give inpatient treatments for which they might not be compensated by insurance, or quietly allow many providers to ignore the rule. What is the result? People are often told, flatly, that outpatient treatment is their only option. Jim Luehmann of the NRC staff was present last October at the conference of the Thyroid Cancer Survivors' Association, held in Danvers, Massachusetts, at which a young woman from Arizona said that she had been sent home after receiving her dose (125 millicuries), although she had a six-month-old and a three-year-old. It is hard, she said, to keep your distance from children of that age.

I hope I'm not damaging Jim Luehmann's career when I say that the patients there very much appreciated that he was listening to what they had to say, and that since then, he has been helpful to patients having difficulty with insurance companies in securing inpatient coverage. Jim was also forthright in saying that the NRC's rules require an individualized calculation of the likely dose received by family members, and that if the dose exceeds 500 millirem, the patient must be hospitalized – no two ways about it.

But the NRC has passed up multiple opportunities to make that clear to the licensee community, and the rule is being widely ignored. Jean St. Germain of Sloan-Kettering told me that her institution is punctilious in performing these case-specific calculations, and if the criterion isn't met, the patient is hospitalized. "Is that the norm?" I asked. She replied with a firm "No." "What is the norm?" I asked. "Oh, they give them some piece of paper."

Another young woman who came up to the speaker's lectern after Jim Luehmann's presentation in Danvers volunteered that her hospital had advised her to go to a hotel after receiving her outpatient dose, and to have her husband pick her up there the following day.

In the last couple of years, as you may know, New York City, Minnesota, and Washington State have all warned licensees not to send radioactive patients to hotels. New York City pointed to the not implausible worst case scenario: that a pregnant hotel housekeeper gets a radiation dose to her baby's thyroid from contamination left in the room.

While the NRC was considering my petition for rulemaking, I and a number of other commenters mentioned the issue of patients going to hotels while radioactive. I had described this as "a medical and moral issue that the NRC cannot in conscience ignore." I actually mentioned the issue in three separate filings. Why this stress? Because I was keenly aware of an NRC operating principle that you won't find among the NRC's "Principles of Good Regulation," but which will be familiar to anyone who knows how the NRC staff operates. And that is: if you don't have a good answer, pretend you didn't hear the question. I wanted to make sure that no one later claimed not to have noticed the issue.

Do we want radioactive patients going to hotels and contaminating bathrooms and bedsheets? When Minnesota issued its warning on the subject, I called a regulator there, who told me that the state was responding to an event in Illinois in which a hotel room had to be taken out of service for an extended period – several months, he thought – until the state could certify that it was acceptable for occupancy. The bathroom, the bed, and the telephone had all been contaminated.

Of course, patients could come to the hotel equipped with cleaning implements and clean up after themselves, just as they would at home. But it's a truism that nobody ever took a rental car to a car wash. By the same token, it is not reasonable to expect that patients who have just had I-131 treatment will be as scrupulous in cleaning a hotel toilet before they check out as they would be with a toilet that their children or spouse will be using. Add to that the fact that thyroid cancer patients who have been off their medications in

preparation for treatment are likely to be feeling exhausted and depleted, and not necessarily in shape for scrubbing out toilets and bathtubs.

But when the NRC denied my petition, it didn't say one word about radioactive patients in hotels, despite my efforts to make sure that the issue was not evaded. And it is basic administrative law that agencies are supposed to deal with significant issues raised in a rulemaking petition.

When I took the agency to the U.S. Court of Appeals for the Ninth Circuit, my strongest argument, therefore, was that the NRC had failed to address the hotel issue, and that the case should therefore be remanded to the NRC with instructions to deal with it. The NRC's lawyers had a couple of answers for that. One was that the agency had thought that I had "recanted" and dropped the issue, which was patent nonsense. (What I had done was to file what I titled a "minor correction," because, writing from memory while out of the country, I had given an incorrect source for one patient's comment about a hospital that sent all its patients to the same hotel.) But their weightier argument was, and I quote from p. 39 of the brief, "the NRC's rule does not permit or encourage doctors to send treated patients to hotels."

If that statement was true, then it follows logically that the idea that radioactive patients were going to hotels was my invention.

The court did not reach the merits of the case. It bought the NRC's argument that because I was not currently in treatment with I-131, or, on the evidence, likely to be in the foreseeable future, I lacked standing to be in court at all. At oral argument, one of the judges suggested that if a case were to be brought by a group, the standing problem would go away. (That remains an option.) Did the court avoid the merits because it was made uneasy by the Government's assurance that the problem of radioactive patients in hotels was my invention? We'll never know.

We now know, thanks to documents obtained from the NRC by Congressman Ed Markey and his staff, that only a few months before that brief was filed, the NRC's Office of General Counsel approved an internal memorandum, replying to a request for advice from NRC Region 1, that said that the NRC's rules did *not* prohibit doctors from sending

treated patients to hotels; that this was a not uncommon practice, and that the agency would be issuing appropriate guidance on this subject. Congressman Markey has asked the NRC's Inspector General to investigate.

There is a listserv on Yahoo on which thousands of thyroid cancer patients ask questions pertaining to their care. Typically, these are new patients, looking for advice, and the oldtimers supply the answers. Scores of questions come in every day, and no one who posts a question on this listserv has the slightest motivation to lie. Time and again, you read postings from patients with small children who have been told by their doctors to go to a hotel for the first couple of days. Sometimes patients will volunteer that they have decided on their own to go to a hotel, because they are concerned about exposing their children. The oldtimers invariably tell them not to – they shouldn't be using a room that others will be occupying, or cleaning, with no knowledge that it is contaminated.

What does it say about the NRC that patients are having to get this advice from other patients, because the NRC itself has been resolutely silent on the issue to this day?

Is there anyone in this room who wouldn't have qualms about the idea of their young child or grandchild staying in a hotel room vacated a few hours earlier by a patient who had just spent several days there after swallowing 200 or 300 or 400 millicuries of iodine 131? My daughter, as a college student, changed beds and cleaned toilets in a Seattle youth hostel. Is there anyone here who would feel comfortable about having their college-age daughter, quite unknowingly, cleaning the toilet that had been used for several days by the patient I just described? If you wouldn't wish this on your own child, you shouldn't wish it on anyone else's either.

Does the Commission have a clue about what is going on in this area? The sad fact is that the Commissioners have done their best to keep themselves well insulated from knowledge of what is happening.³

³ Willful ignorance can sometimes be handy. Take the Philadelphia VA overexposures. In 2008, when the story broke, both the NRC and the VA rushed out statements, the gist of which was that both agencies had acted swiftly and decisively to address the problem as soon as they learned of it. It made for nice press releases, but the reality was that the two agencies first learned of the doctor's bungling of a prostate implant in 2003. Then he did the same thing in 2005. Wouldn't you think that this would have been an alarm bell, causing both agencies to ask themselves whether there was an incompetent at work, possibly harming many more patients? But it didn't work

Efforts had been made to enlighten the NRC. The State of Illinois had written in 2001 that just because the NRC didn't receive reports of such overexposures didn't mean they weren't happening. What Illinois didn't understand was that the Commission, in order to buy peace with the licensee community, had essentially washed its hands of medical regulation, and it did not want to be confronted with the evidence of how unwise and irresponsible it had been to do so.

One need only look at the vote sheets on a 2002 SECY paper by which the Commission rejected, on a three to two vote, the proposal to require a report to the NRC whenever a released patient caused a family member or other member of the public to receive a radiation dose ten times in excess of allowable limits. They are highly illuminating. Chairman Meserve, writing in dissent, made two irrefutable points. First, the Commission was acting without hearing from the public – it had heard only one side of the debate, the licensees'. Second, without a mechanism for reporting overexposures, the Commission was depriving itself of the means of knowing whether its regulations were doing the job.

Look at the three votes on the other side. One Commissioner says that to adopt this proposal would reverse the recent improvement in the NRC's relations with the medical

that way.

You might think that it was obvious and beyond debate that if the prescription calls for the implantation of 90 seeds in the prostate, and the doctor succeeds in getting only half of them into the prostate, while the rest have to be extracted from the bladder, or rectum, or wherever they have wound up, a "medical event" has taken place. ("Medical events" used to be called "misadministrations," until the Commission, in an effort to appease the licensee community, changed the name.) But in 2003, the ingenuity of the NRC staff, at the service of a licensee that did not want a reportable "medical event" to deal with, came to the rescue. The NRC found that if the prescription was changed in the operating room – cross out 90 seeds, write in 45 seeds – then the seeming mistake becomes a non-mistake, and does not have to be reported to the patient. Does it matter that the patient has been underdosed by fifty percent, and that his risk of a recurrence is therefore increased? Apparently not.

Then in 2005, when the same thing happened to another of this doctor's patients, the VA was in a position to say to the NRC, "You remember 2003? Well, this is the same thing, so as in 2003, it's not a medical event." And the NRC obliged.

The NRC staff, to its credit, did understand that there was a glitch in its reporting requirements that needed to be fixed. And it came to this Committee to propose a very minor tightening of the rules. What was this Committee's response? It was, as the transcripts show, to protest that any change in the reporting requirements should be in the direction of weakening them. There is an illuminating discussion in which one member proposes adoption of a statement saying that the NRC's primary role in regulating medicine should be to reduce licensees' liability. Then another member suggests that this could be seen as self-serving, so the language is tweaked, without altering the meaning. The result of all this is that the fix that the NRC staff began discussing six or seven years ago has yet to be made.

licensee community. (An agency that is afraid of offending the entities it is supposed to regulate is an agency in trouble.) Another says that since the NRC wouldn't do anything with information about an overexposure if it received it, there is no point in receiving it in the first place.

That second Commissioner's point was that the NRC had already made clear that it wouldn't penalize a licensee because a released patient overexposed a member of the public. But as Chairman Meserve's comments implied, what the Commission *might* have to do, if it learned that many members of the public were being overexposed, was reconsider the regulations. And since that was something the Commission majority was utterly unwilling to consider, it needed to ensure it never received such reports.

So who is there, except for the outvoted Dick Meserve, to make the point that protecting the public from harm is supposed to be among the NRC's priorities? Is it, perhaps, the Patient's Rights Advocate on this Committee?

That position was created in the early 1990's because the Commission was concerned that the ACMUI was weighted heavily to the licensee side, and there was no one to function as a kind of ombudsman for patients. The first to hold the post was a nurse, Judith Brown, and she did a fine and conscientious job – for some, too good a job. When the staff was first presenting its plan of deregulating I-131, and making high-dose outpatient treatment possible, Don Cool was explaining the psychological benefits this would have for patients, by allowing a speedy return to their families. Ms. Brown asked, as a point of information, how patients felt *physically* after such a treatment. Mr. Cool couldn't answer the question – thus illuminating the fact that the staff was purporting to pass judgment on the psychological condition of thyroid cancer patients when it had not troubled to inform itself as to their physical condition. Ms. Brown also made the sensible point that the proposal meant relying on the altruism of patients.⁴

⁴ Her point was well taken. Back when the proposal was first floated, NIH warned that although they always advised their released patients to avoid close contact with others for the first few days, they knew that many of their foreign patients went directly to the airport on release to board long transoceanic flights. In those days, of course, the maximum amount of I-131 that a released patient's system could contain was 30 millicuries. Today, patients may be boarding airplanes with several times that amount of I-131 in their system. I doubt that anyone in this room would be comfortable with the idea that a child or grandchild of theirs was spending six or seven hours elbow to elbow with a patient newly released after a dose of 200 millicuries or more of I-131. Again, if it's not acceptable for your child or grandchild, then it shouldn't be acceptable for anyone else's.

When Ms. Brown's term ended in 1997, she was replaced as Patient's Rights Advocate by Nekita Hobson, a longtime public relations officer for General Atomics who was now Executive Director of the National Association of Cancer Patients. The NACP, despite its name, was in fact a 501(c)(4) lobbying group, created in part to lobby for the proposed Ward Valley radioactive waste dump in the Mojave Desert. Two weeks before the mid-term elections of 1998, in which Senator Barbara Boxer was running for re-election, the NACP issued a statement accusing Senator Boxer of having delayed for "many years, perhaps decades," the search for a cure for cancer, because of her opposition to Ward Valley. The NACP newsletter also boasted of having contacted over 1000 Clinton-Gore donors to make similar claims about what the Administration had done to harm the interests of cancer patients. When Ms. Hobson's term was up, she was replaced by another NACP Executive Director, Robert Schenter, and when he left to join a company selling radioactive isotopes, he was replaced by his former assistant at the NACP, Darrell Fisher, the current holder of the Patient's Rights Advocate position.⁵

I have nothing personal against Dr. Fisher. I am assured by Dr. Carl Paperiello, whose opinion I trust implicitly, that Dr. Fisher knows his isotopes, after a lifetime in the field, and I do not doubt for a moment that he is a valuable asset to this Committee. My objection is solely that the position in which he serves on this Committee should not be that of Patient's Rights Advocate. That position, which for 13 years has been monopolized by people from the isotope producing community, should properly be held by someone from the patient community.⁶

⁵ Several years ago, the NRC staff asked the Commission for authority to name ACMUI members on its own. The Commission refused: it would make the decision. The next vacancy to come up was that of the Patient's Rights Advocate. The staff sent only a single name to the Commission, Dr. Fisher's, in a paper that failed to mention that he was Scientific Director of the Department of Energy's isotope program, failed to say who had nominated him, and failed to say who else had been nominated. (One cannot help wondering whether the staff intended, as a private joke at the Commissioners' expense, to demonstrate just how little attention they really paid to appointments to the Committee.) Not a single Commissioner's office said, "Wait a minute, don't I need a little more information?" The staff wrote to me that it would not tell me who the other candidates were, nor who nominated Dr. Fisher, and that it would not tell me, even if I filed a Freedom of Information Act request. (It made good on this promise.) From an agency that purports to be committed to "openness" as one of its "Principles of Good Regulation," this is remarkable. So how *does* the staff go about choosing its Patient's Rights Advocate? The NRC, in answers to Congressman Markey, indicated that it seeks nominations from the professional organizations with which it deals. (Perhaps in time Congress and the public will learn which ones.) It did not claim to seek nominations from patients' groups.

⁶ I must have hit a nerve in describing the NACP's history and purposes to the Commission, for sometime in 2008, after I wrote to the Commission about the Patient's Rights Advocate and its monopolization by persons

So who today speaks for the patients, the tens of thousands of patients treated with radiopharmaceuticals every year?

There was an illuminating section of ACMUI transcript, not long ago, when the staff briefed this Committee on the events at the Philadelphia VA hospital, and the members for the first time realized the magnitude of the disaster. Chairman Malmud, to his credit, was plainly anguished about the fate of the patients, and he made the point that the Committee members were, after all, human beings, and knowing what they now knew, could not ignore the patients. (Spoken like a *mensh*, Dr. Malmud.) To this, one of his colleagues countered that this was “getting down in the weeds.” His point was that it was important that the public not be frightened away from a beneficial technology.

It’s an old, old story that people think this way when mistakes occur that harm individuals but reflect badly on institutions, organizations, or professions. If you are the Army, and a football hero is killed by so-called friendly fire in Afghanistan, it is easy to rationalize: “It was a mistake, nothing will bring him back, and if we tell the truth about what happened, it could cause people to lose confidence in the Army, which would be bad both for the Army and for the country.” Likewise if you are a religious institution, and discover that someone in your employ has molested a minor, you can come up with a similar rationale for not calling the police.

When you decide that other interests take precedence over the human beings who are the victims of mistakes or misdeeds, it all too often winds up backfiring, because then the whole organization is seen as corrupt, rather than the individuals originally responsible. Once trust is forfeited in this way, it may be very difficult to regain it. If the American public decides that it cannot depend on the NRC to protect its veterans from hideous medical mistakes, or its children from exposure to carcinogenic radioisotopes, will it have confidence in the agency’s competence and integrity in the licensing and regulation of

from the NACP, the NACP’s website was altered, although the organization itself had apparently been defunct for some years. What is more, major deletions were made in an article from a 1998 issue of *Lifelines*, the NACP newsletter, some ten years after its publication. I had foreseen some such fiddle, however, and had taken the precaution of printing out the article in its original form at the time I wrote to the Commission. The before and after versions of the article make amusing reading.

new nuclear power plants?

One need only look at the Securities and Exchange Commission to see how a once respected federal agency can do incalculable and perhaps irrevocable damage to its reputation, thereby inviting Congress to step in with new and more stringent controls. Or look at the agency which is supposed to regulate offshore drilling. Already the Administration has announced plans to break it up.

In short, I would suggest that if the NRC, or this Committee, thinks too much about fulfilling the wishes of the professional organizations of the nuclear medicine practioners, and too little about what is good for patients, it could well backfire.

I realize that there is scientific support for the NRC's patient release rule, to the extent that Dr. Grigsby's study of 22 patients and their families, published in the Journal of the American Medical Association in 2000, scientific support. Twenty-two patients is hardly enough, I would submit, to support a deregulation of massive proportions, that flies in the face of the consensus of the international community. I might add that Dr. Grigsby has also told the NRC that he has treated over a thousand patients with I-131 and never had a case of a patient vomiting. Jim Luehmann will confirm that when I reported this to a roomful of thyroid cancer patients last fall, they erupted in laughter.

The NRC has issued regulatory guidance that is supposed to help licensees determine who can and cannot be released. Dr. Marcus has announced that this guidance is not binding, far too conservative, and should be ignored. If the NRC has yet dared to contradict her, I am unaware of it. In 1992, incidentally, Dr. Marcus was writing to the Commission that the idea of giving 400 millicuries of I-131 on an outpatient basis was "ludicrous," unless the patient was a hermit, living in the wilds. I gather she thinks otherwise today.⁷

Anyone who reads the thyroid cancer patients' listserv, as I do, knows that the safety

⁷ In the same year, Dr. Marcus jeered at me for suggesting that in view of the reports from Belarus of an upsurge of thyroid cancer in children exposed to radiation from the 1986 Chernobyl accident, it behooved the NRC not to make changes in its regulations which would have the effect of increasing American children's exposure to I-131. Today, of course, it is the data on childhood thyroid cancer in children affected by Chernobyl that has caused the international community to advocate sharp reductions in allowable radiation exposure to children. (See ICRP 94.) The NRC has rejected that recommendation.

guidance that patients receive – if they receive it at all – is all over the map. What has the NRC done, in the 13 years that this rule has been in effect, to ensure that patients get appropriate and consistent instructions about the precautions they should take to protect their families and others? Precious little. It has pointed to guidance jointly prepared by the NRC and the Society for Nuclear Medicine in 1987. To be sure, it said, that guidance was prepared in the days of the 30 millicurie maximum for released patients, but that was all right – just fill in the blanks appropriately.

That kind of advice is worthless. It's like the old joke about how to sculpt an elephant: take a block of stone and remove everything that doesn't look like an elephant. It tells the doctor and the patient nothing. Why, in 13 years, couldn't the NRC come up with meaningful guidance, something appropriate, for example, for the woman sent home to her seven-year-old with more than 400 millicuries of I-131 in her system? Is it because truly appropriate guidance would include precautions so extensive that people would realize that outpatient treatment might not be a good idea under these circumstances? I do not know.

So what should be done now? I myself have never claimed to have all the answers. A return to the blanket 30 millicurie standard in every case might be overregulation; it might also at this point be underregulation, given that Europe has already moved to more stringent standards, based on the data from Chernobyl on children's susceptibility to radioiodine-induced cancer.

What we need at this point is a thorough reexamination of the patient release issue, fair and dispassionate, without a preordained outcome. Though I have not seen his letter to Congressman Markey, I understand that Aubrey Godwin, a wise and deeply experienced regulator who heads Arizona's program, has said that such a reexamination would be timely. But whether the NRC itself is capable of conducting this effort is doubtful, given the record of the past 15 or 20 years. It is not only that this would mean confronting the agency's grave mishandling of the patient release issue; it is also that the analysis might lead to the conclusion that the NRC has failed irretrievably in the medical area, and that legislation is needed to transfer these responsibilities to an agency better capable of discharging them. But the latter question is beyond the scope of our discussion today.

Once again, I wish to thank Chairman Malmud and the Committee for the opportunity to speak here today.

RADIOACTIVE ROULETTE:

How the Nuclear Regulatory Commission's Cancer Patient Radiation Rules Gamble with Public Health and Safety



**A report by the Staff of Edward J. Markey (D-MA)
Chairman, Subcommittee on Energy and Environment
Energy and Commerce Committee
U.S. House of Representatives
March 18, 2010**



**EMBARGOED UNTIL THURSDAY MARCH 18, 2010
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EXECUTIVE SUMMARY

In 1997, the Nuclear Regulatory Commission (NRC), in response to a proposal initiated by its own staff, weakened its rules surrounding the release of patients treated with radioactive iodine. The rules were changed away from a system used in Europe and other countries that requires the hospitalization of patients emitting high levels of radiation in order to protect children and other members of the public from being irradiated to one that allows most treatments to be performed on a less expensive outpatient basis.

NRC's weaker, current regulations depend on the ability of medical professionals to assess the living conditions of patients and use the results of this assessment to calculate the likely radiation dose to those people the patient might come into contact with. It is unclear whether such a calculation could be accurately performed for a patient choosing to recover from treatment with radioactive iodine in a hotel, since it would be impossible to characterize every hotel's layout, or know whether the hotel staff or other hotel guests included vulnerable populations such as pregnant women or children.

Despite reports from individuals and State regulatory authorities that patients are choosing to recover from treatment with radioactive iodine in hotels – thus unwittingly exposing members of the public to radiation –the NRC has consistently refused to ban or limit this practice, and indeed, has never even issued guidance in this area to its licensees. Instead, the NRC actually twice voted to reject NRC staff proposals that would have required reports of dangerous radiation doses delivered to members of the public, through exposure to released patients, to be submitted. One such vote would have only required notification of exposures that are ten times as high as NRC's own regulatory dose limits for released patients. Rather than addressing or remedying the problem, the NRC instead chose to actively ignore it.

Of the 3,700 facilities licensed to perform treatments using radioactive iodine, the NRC directly oversees only 500 of them, with the remainder overseen by State regulators. The NRC collects no information regarding the adequacy or enforcement of its regulations in the 3,200 facilities overseen by the States. Nor does it require the States to report back instances of severe violations. Even for the remaining 500 licensees, the NRC doesn't keep sufficient records to enable it to determine whether patients chose to recover in hotels – in fact, it doesn't even track how frequently its own inspectors request additional documentation regarding regulatory compliance from licensees.

While internal NRC documents indicate a clear awareness by the NRC that some patients treated with radioactive iodine do choose to recover in hotels, and that its regulations allow for this practice to be continued, the NRC Office of General Counsel, in a brief submitted to a federal court in opposition to a citizen petition urging strengthening of the NRC regulations in this area, stated that "NRC's rule does not permit or encourage doctors to send treated patients to hotels."

In summary, rather than protect public health and safety, NRC has turned a blind eye to the radiation standards used in many other parts of the world, a deaf ear to reports of problems with its own less stringent regulations, and has consistently opposed attempts to strengthen its standards –

to the point of submitting inaccurate or misleading statements to a Federal Court. Simply put, the NRC has gambled with public health and safety.

RECOMMENDATIONS

- 1) The NRC should immediately commence a rulemaking to return to its pre-1997, dose based regulations surrounding the treatment of patients with radionuclides, and ensure that its regulations are made to be consistent with the International Commission on Radiological Protection (ICRP). Hospitalization should be mandatory for those patients who are treated with doses of I-131 above internationally accepted threshold limits.
- 2) Patients should be prohibited from recovering from such treatments in hotels, and specific written and verbal guidance in opposition to hotel release should be provided both to medical licensees and to patients.
- 3) The NRC should immediately commence a rulemaking to determine whether its current regulations for safe radiation exposure levels adequately, and in a manner consistent with international standards, protect the most vulnerable populations – pregnant women and children – and make revisions where necessary.
- 4) The NRC should aggressively enhance its oversight of medical licensees to better identify, track and respond to potential regulatory violations, including its oversight of such activities by Agreement States.
- 5) The NRC's Inspector General should investigate, and NRC should then take all appropriate action, regarding conflicting statements made by its Office of General Counsel (OGC) as to whether NRC regulations permit the release of patients to hotels. These include OGC's April 2008 concurrence with an NRC document that provided assistance to a regional office, which stated that "release to a hotel was not prohibited by the regulations," and the conflicting statement made by OGC in a legal brief submitted to the U.S. Court of Appeals for the Ninth Circuit on November 4, 2008, which inaccurately states that "NRC's rule does not permit or encourage doctors to send treated patients to hotels."

BACKGROUND AND EARLY HISTORY

Medical Practices Involving Radioactive Materials

Millions of patients are treated each year with radioactive compounds (called radionuclides) for diagnosis or treatment of diseases such as cancer. These patients can expose others around them to radiation until the radioactive material administered to them has been eliminated from their bodies or the radioactivity has decayed. The field of nuclear medicine was developed in the 1950s initially using radioactive iodine (I-131) to diagnose and then treat thyroid disease. Iodine-131 is among the most widely used radionuclides in the medical field, because of its short half-life and medical effectiveness.

Iodine is essential for proper function of the thyroid gland, which uses it to make the thyroid hormones. The thyroid is equipped with an active system or “pump” for moving iodine into its cells. Because of this property doctors are able to use I-131 treatment to successfully destroy thyroid cancer cells as well as treat an overactive thyroid, a condition called hyperthyroidism.

The thyroid cannot tell the difference between radioactive and non-radioactive iodine. It will take up radioactive iodine in whatever proportion it is available. When normal healthy cells are exposed to this radiation it can lead to cancer formation, because the same toxicity that makes I-131 capable of destroying cancer cells also makes it capable of damaging healthy thyroid cells -- damaging them to the point where it causes thyroid cancer to develop years later. Small children and babies in the womb are particularly sensitive to radiation-induced cancer as a result exposure to I-131. A stark illustration of this took place after the accident at the Chernobyl nuclear reactor, which caused numerous thyroid cancers and other thyroid disorders in Belarusian children (as well as children in other countries) due to exposure to radioactive iodine. However, exposed individuals in Poland did not experience such an increase because they ensured that prophylactic non-radioactive iodine was provided to its citizens¹.

In fact, the authoritative International Commission on Radiation Protection (ICRP), which offers recommendations for regulatory and advisory agencies to help in the management of radiological risks, warned that just one kiss from a thyroid patient treated with the radioisotope I-131 can double a child’s risk of thyroid cancer.² Additionally, in 1986, the Nuclear Regulatory Commission (NRC), which has jurisdiction over the medical uses of radioisotopes, called I-131 “The most radiotoxic byproduct material used for medical use,” and indicated that there were two ways that an I-131 patient can be dangerous to others: (1) external radiation dose, simply from being near someone emitting radiation, and (2) internal dose, from contamination, when I-131 is ingested, or inhaled, or absorbed through the skin.³

¹http://www.birdflumanual.com/resources/Self_Defense/files/Guidance%20for%20use%20of%20KI%20for%20nuclear%20emergency%20USG.pdf

² ICRP Publication 94: Release of Patients after Therapy with Unsealed Radionuclides (March, 2004)

³ 50 F.R. 30616 and 51 F.R. 36932

The Nuclear Regulatory Commission's Early Steps to Protect the Public from Radiation

There are two ways in which radiation levels can be measured. A measure of how much radioactivity is in the material administered to the patient is described in “curies (or millicuries, where one millicurie is one thousandth of a curie),” while the radiation dose that a person, such as a family member, receives from an irradiated patient is expressed in “rem”s.⁴ Converting from an amount emitted to a dose received depends on several factors including the proximity of the person receiving the dose to the patient emitting it. Thus, while it is possible to assess how much radiation is emitted by a patient if one knows how much radioactive iodine he or she received, the only way one could calculate the dose received by a member of the public, as a result of exposure to the patient, is if one also knows specific information such as how far away the member of the public was from the patient, for how long, whether the member of the public came into direct physical contact with the patient, and other factors..

To reduce the risk of exposure to others from radiation emitted from the patient, NRC maintains regulations governing the release of patients from medical care after they are given radiopharmaceuticals. Until 1997, the NRC controlled this risk by requiring patients given large doses of I-131 to remain hospitalized in radiological isolation until the level of radioactivity in their bodies dropped below 30 millicuries, consistent with international standards.⁵ Hospitalization protected members of the public from both internal radiation, caused by contamination by patients' saliva, sweat, and other bodily fluids, and external radiation, caused simply by proximity to the patient.

NRC documentation relating to this 30-millicurie release rule, the NRC stated that this “limit provides an adequate measure of public health and safety” and that the “validity of the assumptions” necessary to calculate approximate dose rates emanating from the patient to a member of the public “are tenuous.” According to NRC, in order to determine the approximate dose a person would receive from a treated patient requires making assumptions and approximations of the biological half-life of the radioactive material in the specific patient, duration of time spent near other individuals, and exact distance of household members.⁶

⁴ Note: in the International System of units, the becquerel (Bq) is the unit of radioactivity, while the dose received is expressed in sieverts (Sv)

⁵ 51 F.R. 36932

⁶ 51 FR 36945

THE 1990S: THE NRC BEGINS TO YIELD TO PRESSURE TO RELAX PROTECTIONS

Regulatory Confusion: Protection from Radiation Exposures from Patients Falls Through the Cracks

In 1987, President Reagan, in recognition of increased awareness of the hazards of radiation, especially to unborn children, approved new guidance directing federal agencies to implement the current International Commission on Radiation Protection (ICRP) recommendations, which substantially lowered acceptable radiation levels for occupational radiation protection.⁷ The President's guidance noted that the ICRP's recommendations were "now in use, in whole or substantial part, in most other countries." The Presidential guidance went further, stating that the unborn child of a radiation worker should receive a maximum of 0.5 rem during the entire period of gestation.

In 1991, the NRC, as part of new rules amending general radiation standards to incorporate these new occupational limits recommended by the President, also set dose limits for protecting members of the public from radiation of 0.1 rem and required notification of the NRC and the individual if the dose received exceeded this threshold.⁸ However, this rule did not clarify whether these new general limits on public exposure to radiation were also meant to apply to public exposures created by the release of patients treated with radioisotopes.

When the 1991 rule was promulgated, there was no discussion of whether the dose limits for the individual members of the public were intended to apply to the release of patients treated with radioisotopes.⁹ If this new 0.1 rem rule *did* apply, then patients treated with I-131 would have to remain hospitalized longer, until their radioactivity was reduced to an appropriate level. This could have caused regulatory confusion for the medical community because a patient with 30 millicuries of radioactive material in their body that was deemed releasable from the hospital under NRC regulations was likely to emit radiation at levels that would create exposure to family and others exceeding the new 0.1 rem safe limit.

Pressure to Relax the Regulations from the Medical Community Begins

Beginning in 1990, the NRC received a series of three petitions for rulemaking submitted by Dr. Carol S. Marcus (a nuclear medicine practitioner), by the American College of Nuclear Medicine (ACNM), and by the American Medical Association (AMA), requesting that the patient release rule be amended to ensure that radiation emitted by patients treated with radionuclides would not be treated the same way as radiation emitted by other sources.

These petitions went beyond a request to clarify whether the new more stringent radiation protection regulations applied to patients treated with radionuclides. The first of these petitions which was submitted by Dr. Marcus in 1991 (and then amended in 1992) requested that NRC raise the radiation dose limits to members of the public from 0.1 rem to 0.5 rem, if the exposure was

⁷ 52 F.R. 2822 (January 27, 1987). The President's Guidance noted ICRP Publications 26 and 30 which were published in 1977 and 1978.

⁸ 10 C.F.R. § 20.1301

⁹ SECY-96-100

due to patients treated with radioactive materials.¹⁰ These petitions also asserted that if the 0.1 rem exposure dose limit promulgated by the NRC in 1991 also applied to doses received as a result of patient exposure it “would be extremely expensive”¹¹ since it would require longer hospitalization of patients who could have at the time been released under NRC’s patient release rules because their systems contained under 30 millicuries.

In the original petition submitted by Dr. Marcus, she requested the elimination of the 30 millicurie rule for all radionuclides other than I-131, clearly making a distinction because of the toxicity of this isotope. However, after “discussing the issues at leisure” with “members of the NRC, Society for Nuclear Medicine”¹² and other nuclear-medicine related stakeholders, Dr. Marcus wrote an addendum to the petition that proposed to eliminate the 30 millicurie rule for I-131 as well, thereby allowing for most I-131 patients to be treated as outpatients. This new proposed change in regulations would allow for doctors to treat almost all thyroid cancer patients at their private practices as outpatients, rather than following the practices used for decades which involved the referral of these patients to hospital facilities for treatment and subsequent radiological isolation in order to protect the patients’ families and the public from radiation exposure.

Oddly, the original petition submitted by Dr. Marcus was reportedly requested by NRC staff. The NRC petition process is intended to enable members of the public to propose regulatory actions for consideration by the Commission. However, in this case, the petition process was apparently used by the NRC staff to solicit a petition that resulted in a request to weaken the Commission’s own regulations for members of the public exposed to patients treated with radiation – at the same time that the Commission was strengthening its regulations for members of the public exposed to radiation from any other source. In letters relating to the petition, Dr. Marcus explains that this was the second time in two years that the NRC staff had used a rulemaking petition from her to weaken an earlier NRC decision, describing the resulting rulemaking as an “inside job from the start.”¹³

Dr. Marcus’s petition (in both the original and amended form) also proposed to replace the 30 millicurie release limit with the very same sorts of estimated dose calculations that rely on assumptions regarding the patient’s distance from members of the public they might expose to radiation that the NRC previously deemed to be “tenuous” when it promulgated its original regulations.

1997:- NRC Gives In

In 1994, the NRC published a proposal that essentially adopted the Marcus petition to change the patient release limit from an activity-based standard of 30 millicuries (measuring the patient’s radioactivity) to a dose-based standard of 0.5 rem (calculating, based on assumptions, the predicted exposure of family or others in proximity to the patient).¹⁴ This dose-based standard also failed to take into account direct contact with the exposed individual, as would occur with a kiss or with a breastfeeding infant. This was codified on January 29, 1997, when the NRC finalized its new rule that abolished the 30

¹⁰ PRM-20-20 from Dr. Marcus was published in the FR on June 12, 1991 (56 FR 26945)

¹¹ No. 08-72973, *Peter G. Crane v. United States Nuclear Regulatory Commission* (U.S. Court of Appeals for the Ninth Circuit), Brief for Respondents (November 4, 2008),

¹² Appendix B, page 1

¹³ Appendix B, page 4

¹⁴ See 59 Fed. Reg. 30724 (June 15, 1994).

millicurie maximum limit for outpatient treatment.

The Commission's decision flew in the face of international basic safety standards, adopted just the year before by the International Atomic Energy Agency (IAEA). These standards declared that to be considered adequate, national radiation safety programs must provide for hospitalizing patients given 30 millicuries or more of I-131.¹⁵ These regulations have been adopted by most Member States of the European Union and are still the baseline approach taken by the international community, although many countries now think that 30 millicuries is too lax a standard. In the European Union, the requirement to hospitalize is usually for those receiving doses of greater than 11 to 16 millicuries, in Germany, the limit is 7 millicuries and in Japan the limit is 14 millicuries.¹⁶

In place of radiological isolation in a hospital, the new NRC rule required two things (1) that physicians perform an individualized analysis of the patient's living situation to determine how much radiation others would receive, and only release patients "not likely" to expose other individuals. (2) that medical licensees (*e.g.*, hospitals) would provide written instructions to patients on how to keep doses to others "as low as is reasonably achievable."¹⁷ This assumed the ability and willingness of newly released thyroid cancer patients – highly radioactive, ill, and under stress both from the disease and its treatment – to maintain sufficient distance from others to ensure that no other person received an external radiation dose exceeding 0.5 rem. It also assumed that physicians would have the ability to perform such a calculation about a wide variety of typical living situations expected to be utilized by their patients. However, nothing in the NRC rulemaking documents suggests that NRC considered the possibility that patients would choose to recover in hotels, with layouts and occupancies that are unknown to a physician.

In short, the Commission adopted a rule that not only assumed a significantly less stringent "safe" dose of radiation exposure than most of the rest of the world, but it additionally adopted a protocol for implementing the regulation that required physicians to make imprecise calculations related to the likely living circumstances and behaviors of patients, rather than simply setting a dose above which patients could not be released from the hospital.

¹⁵ International Basic Safety Standards (Vienna, 1996).

See http://www.pub.iaea.org/MTCD/publications/PDF/Pub1117_scr.pdf

Note: in the international System of units, the becquerel (Bq) is the unit of radioactivity. The BSS states that hospitalization should occur at 1100 MBq (Megabecquerels), which is approximately equal to 30 millicuries.

¹⁶ International Commission on Radiation Protection, ICRP Publication 94: "Release of patients after therapy with unsealed radionuclides," *Annals of the ICRP* Vol. 34(2) (March 2004), p 53.

¹⁷ <http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0075.html>

SEE NO EVIL, HEAR NO EVIL

The NRC Stamps Radiation Exposure Reports “Return to Sender” – Twice

Shortly after the NRC weakened its regulations allowing patients emitting radiation to leave the hospital, the NRC staff realized there was an inconsistency in the Commission's rules. Under another 1991 rule, in most scenarios, exposure that occurs in excess of general threshold limits must be reported to the NRC and to the individual who was exposed.¹⁸ This 1991 rule didn't explicitly refer to exposures that came about as a result of contact with or proximity to a patient treated with radioactive iodine.

On August 3, 1999 the NRC altered its guidelines that require reporting of radiation exposures to specifically exclude exposures that occurred as a result of contact with or proximity to patients treated with radioactive materials released from the hospital, – claiming that rules related to the release of patients treated with radionuclides should all reside in the same section of NRC's regulations.¹⁹ The NRC staff then put together a recommendation to revise the regulations that relate to the medical use of isotopes, proposing to add a requirement for a licensee to report events in which an individual receives a dose in excess of 0.5 rem (the limit for which a patient can be released) as a result of being exposed to a treated patient. In October 2000, the NRC Commissioners unanimously rejected this recommendation and instead told the NRC staff to develop an alternative proposal – one that would only require such notification to take place if the dose received to the individual exceeded 5 rem, or ten times NRC's patient release dose limit and 50 times NRC's more general 0.1 rem safe dose limit for members of the public.²⁰

As the NRC staff began to develop its new proposal and it engaged with stakeholders and solicited comments from Agreement States, it became clear that some States had already experienced problems related to NRC's patient release regulations.

On July 24, 2001, Joseph Klinger of the Illinois Department of Nuclear Safety wrote the NRC²¹ providing comments on the need for a reporting requirement. In Mr. Klinger's letter he responded to a comment by NRC's Advisory Committee on the Medical uses of Isotopes (ACMUI) which claimed that the “low frequency of known events and problems with rule enforcement and implementation do not justify NRC resource expenditures.”²²

“The (Illinois Nuclear Safety) Department would question the basis, including supporting data, for NRC's statements regarding the low frequency of known events associated with patient release. Simply because NRC does not keep records on such events, does not mean that such events are not occurring. Such events have occurred in Agreement States and means of addressing them have been problematic because hospitals will accept no responsibility for them....”

Mr. Klinger goes on to state that Illinois has had issues with NRC licensees who have disregarded aspects of the patient release criteria, and subsequently “rebuffed the State's inquiries

¹⁸ 10 C.F.R. § 20.2203

¹⁹ SECY-99-201

²⁰ <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2002/secy2002-0111/attachment1.pdf>

²¹ <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2002/secy2002-0111/attachment2.pdf>

²² <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2002/secy2002-0111/2002-0111scy.html>

about doses to the public.”

In discussing NRC’s claim that reporting requirements would be too onerous for the licensees and physicians, the New Jersey State Department of Environmental Protection wrote²³:

“ NRC's concerns for their rules to be less intrusive into the practice of nuclear medicine may result in them being more intrusive on the general public as a result of increased patient excreta contaminating trash which sets off radiation monitors at landfills and incinerators.”

The Washington State Department of Health also wrote to the NRC in 2001²⁴, expressing its view that the issue was not reporting of radiation exposures, but rather that the root of the problem was the 1997 rule itself. In referring to the part of the rule that requires physicians to perform an individualized calculation, the State felt that the rule allowed the physician to “adjust the assumptions made” for occupancy and other factors so that patients can be released with incredibly high levels of residual activity – even making the point that the regulation allows licenses to retroactively tweak the numbers used in the calculations to ‘prove’ that the threshold limit was not exceeded, therefore keeping the licensees in compliance with NRC regulations. This comment highlighted similar problems with the calculations that NRC itself deemed to be “tenuous” when it first codified the 30-millicurie patient release regulation.²⁵

A representative from the Alabama Department of Public Health found issue with the fact that NRC’s proposed reporting requirements (5 rem) were not equivalent with its patient release requirements (0.5 rem). Stating “this change seems to muddy the waters even further...by saying that if you exceed the specified (release) limits you don’t need to report it to the NRC. It appears to trivialize your own limits and says they are of no consequence”.²⁶

In June 2002, after considering these and other reports, the NRC staff submitted a proposed rule that would have required medical licensees, whenever they learned that a released patient had caused someone to receive a radiation dose in excess of 5 rem, or ten times NRC’s patient release dose limit and 50 times NRC’s more general 0.1 rem safe dose limit for members of the public, to report the event to NRC and the overexposed person. Even this proposal was rejected by the NRC Commissioners (by a vote of 3 to 2).

In the minority, then-NRC Chairman Richard Meserve²⁷ observed that “members of the public who may have received involuntary doses from the release of patients will never be informed of their exposure.” He goes on to state “We have thus ignored the very individuals who have the greatest stake in assuring that there is a reporting and notification process.”

Chairman Meserve also noted “As a result of not moving forward with this proposed regulation, the NRC will lose the insight into compliance with our regulations that the reporting

²³ <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2002/secy2002-0111/attachment2.pdf>

²⁴ <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2002/secy2002-0111/attachment2.pdf>

²⁵ 51 FR 36945

²⁶ <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2002/secy2002-0111/attachment2.pdf>

²⁷ <http://www.nrc.gov/reading-rm/doc-collections/commission/cvr/2002/2002-0111vtr.pdf>

requirements provide. We will thus not have this tool as a means to assess the effectiveness of our regulatory program.”

The Crane Petition to Strengthen Regulations

In 2005, Mr. Peter Crane, a former NRC attorney who, as a thyroid cancer patient had received multiple I-131 treatments in the 1980’s and 1990’s, filed a petition for the NRC to begin a rulemaking to partially revoke its 1997 rule.²⁸ He particularly objected to the part of the rule that allows patients to be released with more than the equivalent of 30 millicuries of I-131 in their systems, stating that the 1997 rule change:

“has had precisely the adverse effects on health and safety that were predicted at the time by States and other commenters, and that were brushed aside by the NRC. Patients treated for thyroid cancer with radioactive I-131 are now being sent home to their families under conditions that guarantee that family members would receive larger and potentially harmful doses of radiation, under uncontrolled conditions.”

In January 2006, Mr. Crane submitted further comments to the public docket for his petition.²⁹ In these comments he discussed situations in which patients treated with I-131 on an outpatient basis, take public transportation home, potentially exposing other passengers; patients who vomit after returning home or while returning home on public transportation; and patients who are advised to go to hotels, where they present a radiation hazard to other guests, the housekeepers who clean their rooms, and subsequent occupants of their rooms. This petition put particular emphasis on the hotel issue, writing:

“And what about the next hotel guest, who arrives, possibly pregnant or with small children, in a room just vacated by a radioactive patient?” Transferring the radiation burden to unsuspecting third parties represented, he wrote, “a public health issue and a moral issue that NRC cannot in conscience ignore.”

One year later, NRC’s patient release rule was discussed at a meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI).³⁰ During this meeting Dr. Douglas Eggli, a nuclear medicine physician, complained that ever since the release rule went into effect “the chances that I can get an insurance authorization for a hospitalization to isolate them, even when I have family situations that require it, it’s fighting tooth and nail with the insurance companies.”

The Chairman of the Committee Dr. Leon Malmud put it even more strongly:³¹

“... all patients are discharged upon treatment. We whisk them out the doors as fast as possible.”

²⁸ 70 FR 75752

²⁹ Docket ID: NRC-2005-0020 Comment (11) submitted by Peter G. Crane on Petition for Rulemaking PRM-35-18, Regarding Partial Revocation of the Patient Release Criteria Rule

³⁰ Transcript of the U.S. NRC Advisory Committee on the Medical Uses of Isotopes, Monday October 22, 2007

³¹ Transcript of the U.S. NRC Advisory Committee on the Medical Uses of Isotopes, Monday October 22, 2007

“There’s also an impossibility of keeping the patient in the hospital since the insurer will not cover it. The insurer will not cover it, will not cover the inpatient stay. It will cover the treatment, but not the inpatient stay.”

In 2008, NRC denied the Crane petition claiming that the patient release rule did not warrant re-examination.³² In the docket for the Crane petition, NRC stressed that those opposing the petition “doctors, medical physicists, and radiation safety officers, as well as several medical professional organizations” – “stated that reverting from the current release criteria back to the 30 millicurie (pre-1997) rule would result in additional and unnecessary healthcare costs.” NRC’s denial made no mention of the concerns related to patients being released to hotels.

Concurrent with its denial of the petition, NRC issued a non-binding “Regulatory Issue Summary (RIS)”³³ that advised its medical licensees of the International Commission on Radiation Protection (ICRP) 2004 findings³⁴, which stated that “contamination of infants and young children with saliva from a treated patient during the first few days after radioiodine therapy could result in significant doses to the child’s thyroid, and potentially raise the risk of subsequent radiation-induced thyroid cancer.” This informational summary explained that the current regulatory standards had been based on the assumption that the risks of internal doses to individuals exposed to released patients were small compared to the external exposures. However, NRC said, ICRP cautioned that the opposite was true, and that saliva from released patients “could result in significant doses to the child’s thyroid, and potentially raise the risk of subsequent radiation-induced thyroid cancer.” NRC therefore advised licensees that in implementing the current rule, they should “take into account whether the released patient may come in contact with infants or young children,” and if so, provide additional instructions. Finally, NRC said, “Licensees should also consider not releasing patients, administered I-131, whose living conditions may result in the contamination of infants and young children.”

NRC did not explain why it had waited from April 2004, when ICRP Publication 94 appeared, until May 2008, when the RIS was issued, to communicate this warning from an authoritative international safety body. NRC also did not address the question of whether infants and young children could be exposed to radiation if a patient was released to a hotel.

³² 73 F.R. 29445

³³ http://www.kdheks.gov/radiation/download/RIS_2008-11.pdf

³⁴ International Commission on Radiation Protection, ICRP Publication 94: “Release of patients after therapy with unsealed radionuclides,” Annals of the ICRP Vol. 34(2) (March 2004)

WARNINGS CONTINUE TO MOUNT, AND CONTINUE TO BE IGNORED

NRC conducts weak oversight, but even limited inspections reveal regulatory violations and policy confusion

In a response to a request for information by Congressman Edward J. Markey³⁵, the NRC indicated that of the 3,700 facilities licensed to perform treatments using radioactive iodine, the NRC directly oversees only 500 of them, with the remainder overseen by State regulators. The NRC collects no information regarding the adequacy or enforcement of its regulations in the 3,200 facilities overseen by the States. In fact, according to NRC “Agreement States do not send their inspection reports to the agency nor do they let the agency know about any violations they may cite. Violations related to patient release are not normally reported to the NRC.”

Even for the remaining 500 licensees that are under NRC ‘s direct authority, the NRC doesn’t request or retain records that would enable it to determine whether patients choose to recover in hotels. In a letter to Chairman Markey on March 5, 2010, NRC states that it “does not keep a record of how many times inspectors have requested records” as a result of observing potential deficiencies in meeting patient release criteria. NRC additionally notes that when such records are requested, they are “reviewed at the licensee’s site during the inspection.” Consequently, NRC has no way of tracking how frequently these types of violations in patient release criteria may be occurring in medical facilities across the country.

However, during the limited routine inspections NRC conducted between 2001 and 2008, it noted four licensees who violated the patient release rule. In all of these cases the licensees failed to perform the individualized analysis that is required by NRC regulations to ensure that individuals who come into contact with the patient do not receive a radiation dose above the default limit (0.5 rem). In two release cases that occurred at the Forbes Regional Hospital in Pennsylvania,’ the NRC inspector noted that the patients received doses that were 5 times higher than the pre-1997 threshold dosage, which would have required default hospitalization at 30 millicuries.³⁶

In response to these incidents, NRC issued a “Notice of Violation”³⁷ that required the licensees to take corrective actions to prevent recurrence of this patient release error. Since these facilities either claimed that they were unaware of the requirement for calculations or did not keep records for these calculations, the corrective actions were comprised of staff training sessions and education on NRC requirements as well as a commitment to keep records relating to the individualized analysis going forward.

There was no mention of whether the patients that were released by these licensees went to a hotel after their treatment, but inspectors are unlikely to request this information since NRC does

³⁵ See: U.S. NRC response to Congressman Edward Markey, March 5, 2010

³⁶ See: U.S. NRC letter to Congressman Edward Markey, March 5, 2010; Attachment 2: 10CFR 35.75 Severity Level IV Violations for I-131 therapy.

³⁷ See: U.S. NRC letter to Congressman Edward Markey, March 5, 2010; Attachment 2: 10CFR 35.75 Severity Level IV Violations for I-131 therapy.

not maintain or require licensees to maintain records regarding the destinations of released patients.

Release of Patients to Hotels: NRC Admits that It Isn't Prohibited and Realizes it Occurs

In its response to Chairman Markey's inquiry³⁸, the NRC did disclose and identify four cases involving two medical licensees in which patients were released to hotels immediately after I-131 treatment. In both cases, the patients provided written notification of their plans to stay in a hotel, and NRC inspectors only discovered the information because they had made a broader request for records from the licensees. During a 2007 inspection of MedStar Georgetown Medical Center in Washington, DC, the inspector noted that the facility had released two patients to area hotels to recover in 2006. For one of these patients the licensee justified the release to a hotel, by showing in a retroactive calculation that the likelihood of the patient exposing members of the public with doses over the threshold limit would have been low.

A similar situation occurred at the University of Virginia, where the NRC discovered during a 2008 inspection that the licensee was incorrectly performing dose calculations and as a result was releasing patients who exceeded the patient release limit. After the NRC instructed the licensee of the correct dose calculation methodology, the licensee retroactively performed the patient specific analysis and determined that it would not have been in violation of the NRC release rule since the calculated dose fell below the 0.5 rem limit (though in one case, the retroactive calculation indicated a 0.498 rem dose would have been received, barely below the regulatory limit). At this same facility, the NRC discovered that in 2007, the facility had released two I-131 patients to recover in nearby hotels. These patients, who were also sisters, shared one room in the hotel and would have contributed a combined dosage of over 0.5 rem to any guests or hotel staff.

As a result of these two inspections that occurred within a year of each other, the NRC Region 1 Division of Nuclear Materials Safety wrote to NRC headquarters³⁹ to gain clarification on whether releases to hotels were allowed under NRC regulations, and specifically whether the standard calculations that are performed as a part of the patient release process are also valid when patients are released to a hotel. The technical assistance also requested that NRC provide additional guidance for patients who go to a hotel, noting that "these types of releases are not uncommon." In fact, the technical assistance referenced a *USA Today* article that performed a survey of thyroid patients and found that 4% of the patients checked into hotels or other accommodations instead of going home and 2% of patients used public transportation after being released from the hospital. The survey also noted that only 86% of the outpatients went directly home after being treated, meaning there is plenty of opportunity for these patients to expose members of the public to radiation unwittingly.⁴⁰

³⁸ See: U.S. NRC letter to Congressman Edward Markey, March 5, 2010

³⁹ Region 1 Technical Assistance Request. November, 28, 2007. See: U.S. NRC letter to Congressman Edward Markey, March 5, 2010; Attachment 5

⁴⁰ It kills thyroid cancer, but is radiation safe? Steve Sternberg and Anthony DeBarros, *USA Today*, November 18, 2007.

On June 12, 2008, in response to this technical assistance request, the NRC informed Region 1⁴¹ that the “licensees acted in accordance with existing NRC regulations and that these regulations “do not prohibit the release of a patient to a hotel.” The NRC Office of General Counsel (OGC) reviewed and concurred with this assessment of current regulations in April, 2008.

NRC also stated in the June 12 document that it would develop additional instructions to be provided to patients released to a hotel. This guidance has yet to be developed. NRC notes in its response to Mr. Markey on March 5, 2010 that NRC staff plans to “review the guidance relating to the release of I-131 therapy patients to hotels.” However, the guidance that the NRC says it plans to review⁴² doesn’t include any mention of patient release to hotels whatsoever, making it unclear what such a review will entail.

States take matters into their own hands

Since the NRC regulations do not prohibit releases to hotels and to date the NRC has not given States or licensees any guidance in this area, some States have begun to develop and implement their own guidance, which they largely attribute to the 2004 ICRP Publication 94 that advises licenses to especially take into consideration the potential for released patients to expose infants and children to radiation. In a 2008 Minnesota Department of Health (MDH) notice to licensees, MDH warned against sending patients to hotels stating that it should not be considered an alternate means of separation from children and that the “practice has proven to cause significant exposure concerns to hotel property, housekeeping staff, and guests.”⁴³

In 2009, both the Washington State Department of Health and the New York City Office of Radiological Health sent similar letters⁴⁴ to their licensees emphasizing that the patients should not be advised to go to a hotel immediately after release. New York City explained that

“a hotel presents substantial probability of close contact with infants, young children, pregnant women, and of course the general public. In a serious and not at all implausible case, a patient could have their room or dining area cleaned by a pregnant woman who could come into very close contact with radioiodine-containing-bodily fluids.”

NRC’s Office of General Counsel Inaccurately Tells a Federal Court that Patient Release to Hotels isn’t Permitted

On July 9, 2008, Mr. Crane filed a petition for review in the U.S. Court of Appeals for the Ninth Circuit regarding the denial of his NRC petition for rulemaking. Mr. Crane argued in his brief to the court that the NRC failed to adequately address the significant safety issue of releasing treated I-131 patients from the hospital to hotels.

⁴¹ NRC June 12, 2008 Memorandum to Region 1. See U.S. NRC letter to Congressman Edward Markey, March 5, 2010; Attachment 5

⁴² http://www.kdheks.gov/radiation/download/RIS_2008-11.pdf and NUREG-1556, Volume 9 Revision 2

⁴³ MDH Information Notice 2008-04, www.health.state.mn.us/divs/eh/radiation/radioactive/infonot0408.pdf

⁴⁴ NYC Information Notice ORH 2009-01, <http://www.ci.nyc.ny.us/html/doh/downloads/pdf/radioh/radioh-Info-noticeorh.pdf> and State of Washington Information Notice, March 26, 2009; See Appendix C

In NRC's November 2008 brief to the court, the Office of General Counsel (OGC) called Mr. Crane's description of patients sent to hotels "unverifiable and unscientific." In spite of this very same office's April 2008 concurrence with NRC's opinion that release to a hotel was "not an uncommon practice" and was not prohibited by NRC regulations, this OGC filing declared to the court that: "NRC's rule does not permit or encourage doctors to send treated patients to hotels."⁴⁵

It was decided on August 19, 2009 that Mr. Crane, a thyroid cancer patient and survivor, lacked standing to bring the case because he was not currently undergoing or about to undergo treatment with radioactive iodine, and was therefore unaffected by the NRC rule. The court did not decide on the merits of the case, including Mr. Crane's claim that some radioactive patients were going to hotels and creating a hazard to other guests and hotel staff.

⁴⁵ No. 08-72973, *Peter G. Crane v. United States Nuclear Regulatory Commission* (U.S. Court of Appeals for the Ninth Circuit), Brief for Respondents (November 4, 2008), p. 39.

Appendix A – Detailed Chronology

1986- NRC issued regulations that required the hospitalization of patients with the equivalent of 30 millicuries or more of radioactive iodine 131 (I-131) in their systems. (This was consistent with the International Basic Safety Standards on radiation protection) NRC called I-131 “the most radiotoxic byproduct material used for medical use,” and indicated that there were two ways that an I-131 patient can be dangerous to others: (1) external radiation dose, simply from being near someone emitting radiation, and (2) internal dose, from contamination, when I-131 is ingested, or inhaled, or absorbed through the skin.

1987-President Reagan, in recognition of increased awareness of the hazards of radiation, especially the potential dangers to unborn children, approved new guidance directing federal agencies to implement the current International Commission on Radiation Protection (ICRP) recommendations, which stated basic principles for occupational radiation protection and recommended a safe dose of 0.5 rem for pregnant women that were occupationally exposed.¹ The President’s guidance noted that the ICRP’s recommendations were “now in use, in whole or substantial part, in most other countries.”

1991 - The NRC issued new rules amending general radiation standards and set dose limits for protecting members of the public from radiation of 0.1 rem, and required notification of the NRC and the individual if the dose received exceeded this threshold.² The rule did not explicitly specify whether these rules applied to doses given to members of the public due to exposures from patients treated with radionuclides.

1992- NRC gave public notice of the receipt of an original and amended petition submitted by Dr. Carol Marcus. The original petition requested that the 30-millicurie limit for the release of patients be eliminated for all radiopharmaceuticals except I-131, and was reportedly initiated by NRC staff. The amended petition requested elimination of the 30-millicurie limit for all radiopharmaceuticals, and recommended that patients treated with radioactive iodine be released from the hospital if a calculation performed by a physician could demonstrate that radiation received by family members or a member of the public was unlikely to exceed 0.5 rem, five times NRC’s safe radiation limit for members of the public.

March 1996- The International Atomic Energy Agency (IAEA) issued its Basic Safety Standards (BSS) entitled “Radiological Protection for Medical Exposure to Ionizing Radiation.”³ This safety guide is one part of a series of international standards based on worldwide consensus, knowledge of biological effects of radiation and principles for protection from undesirable effects. The BSS declared that to be considered adequate, national radiation safety programs must provide for hospitalizing patients given 30 millicuries or more of I-131 and that in some

¹ 52 F.R. 2822 (January 27, 1987). The President’s Guidance noted ICRP Publications 26 and 30 which were published in 1977 and 1978.

² 10 C.F.R. § 20.1301

³ International Basic Safety Standards (Vienna, 1996).

See http://www-pub.iaea.org/MTCD/publications/PDF/Pub1117_scr.pdf

countries a level of 10 millicuries is used as an example of good practice.⁴ I-131 is the only nucleotide that IAEA recommended specific standard for.

January 29, 1997- NRC adopted the amended 1992 petition and published revisions to its regulations, which authorized the immediate release of most patients treated with I-131 (or any other radioactive material) as long as the likely exposure to others would not exceed 0.5 rem, or five times NRC's own safe level for members of the public. This rule stated that for patients with more than 30 millicuries of radioactive content in their bodies, an individualized analysis of the patient's living situation was necessary to determine the likely dose to others, and as long as that dose wasn't expected to exceed 0.5 rem, the patient could be released from the hospital. The rule presented two scenarios – hospitalization, and release to one's home. It did not, however, discuss the possibility that a patient might wish to recover in a hotel, whether release to a hotel was permissible, and how such an individualized analysis might be performed for a hotel.

1998- A European Commission document entitled “Radiation Protection Following Iodine-131 therapy (exposures due to out-patients or discharged in-patients⁵)” stated that “sending patients home immediately after the administration of the radionuclide cannot be justified in most situations because both excretion and external radiation (the patient is a source) will give rise to high doses to other individuals in contact with the patient for a few days.” This risk is particularly high for infants and children who may come in contact with bodily fluids, such as saliva and sweat, as well as a treated patient's breath, all sources of I-131 radiation. “As a general rule, treatment of thyroid cancer patients using radioactive iodine will only be performed in conjunction with hospitalization of the patient.”

August 3, 1999- NRC adopted a revision to its regulations that ensured that the safe radiation levels for the public would exclude from consideration doses given to members of the public as a result of exposure to a patient treated with radionuclides, citing the 1997 regulations that governed patient release.⁶ This clarification meant that if a member of the public was exposed to more than 0.5 rem from a patient treated with radioisotopes, that exposure would not need to be reported to the NRC.⁷

October 23, 2000: The NRC unanimously rejected a staff proposal to require reporting of radiation doses of greater than 0.5 rem to members of the public as a result of exposure to a patient treated with radioisotopes⁸, even though this level was NRC's own regulatory dose limit for patients treated with radioisotopes. Instead, staff was directed to develop a proposal that would only require notification of radiation doses to members of the public of greater than 5 rem – ten times NRC's own regulatory dose limit and fifty times its safe dose level for members of the public.

⁴ Note: in the international System of units, the becquerel (Bq) is the unit of radioactivity. The BSS states that hospitalization should occur at 1100 MBq (Megabecquerels), which is approximately equal to 30 millicuries.

⁵ See http://ec.europa.eu/energy/nuclear/radioprotection/publication/doc/097_en.pdf

⁶ 10 CFR 20.1301 and SECY-99-201

⁷ <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2000/secy2000-0118/2000-0118scy.html>

⁸ See <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2002/secy2002-0111/attachment1.pdf>

2001- Illinois's Department of Nuclear Safety wrote to the NRC stating that Illinois has experienced issues with patients being released under circumstances that may cause exposure to the general public. Illinois stated that "Simply because NRC does not keep records on such events does not mean that such events are not occurring." The difficulty with these events, Illinois said, is that "hospitals will accept no responsibility for them."⁹

June 21, 2002 – In response to the October 23, 2000 direction from then-NRC Chairman Richard Meserve, NRC staff proposed an amendment to NRC's patient release regulations that would require medical licensees to notify the NRC if the licensee became aware that an individual received or is estimated to have received a dose of 5 rem -which was ten times higher than NRC's own patient release regulations dose thresholds-¹⁰ as a result of being exposed to a radioactive patient and fifty times its safe dose level for members of the public.

August 27, 2002- NRC Commissioners rejected (by a vote of 3 to 2) the staff proposal requiring that it be notified if a released patient causes a family member or member of the public to receive a dose of 5 rem - ten times higher than NRC's own patient release regulations dose thresholds and fifty times its safe dose level for members of the public.¹¹

March 2004- The International Commission on Radiation Protection (ICRP) issued Publication 94: Release of Patients after Therapy with Unsealed Radionuclides¹², which states that "contamination of infants and young children with saliva from a treated patient during the first few days after radioiodine therapy could result in significant doses to the child's thyroid, and potentially raise the risk of subsequent radiation-induced thyroid cancer." This statement was repeated in the new comprehensive radiation safety recommendations in ICRP Publication 103, The 2007 Recommendations of the International Commission on Radiological Protection,¹³ which specifically states that particular care should be taken to avoid the contamination of infants and children from patients treated with radioiodine. The ICRP recommended that the threshold for permissible radiation exposure of pregnant women and children be lowered to 0.1 rem, one fifth of what the NRC permits for patients released from the hospital. The NRC did not pass along the ICRP's warnings to its medical licensees until May 2008.

September 2, 2005- Peter Crane, a former NRC attorney and thyroid cancer patient who received multiple I-131 treatments in the 1980's and 1990's, filed a petition for rulemaking calling for partial revocation of the patient release criteria rule.¹⁴ He objected to the part of the rule that allows release of I-131 patients with 30 millicuries or more in their systems asserting that the 1997 issued rule was defective on legal and policy grounds. Mr. Crane objected to the current patient release criteria stating that it "creates unwarranted hazards as patients are sent out the door," where they may come into close contact with family members and members of the public."

⁹ See Appendix 2

¹⁰ <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2002/secy2002-0111/attachment1.pdf>

¹¹ <http://www.nrc.gov/reading-rm/doc-collections/commission/cvr/2002/2002-0111vtr.pdf>

¹² International Commission on Radiation Protection, ICRP Publication 94: "Release of patients after therapy with unsealed radionuclides," Annals of the ICRP Vol. 34(2) (March 2004)

¹³ International Commission on Radiation Protection, ICRP Publication 103: "Recommendations of the ICRP," Annals of the ICRP Vol. 37/2-4 (2007)

¹⁴ 70 FR 75752

January 30, 2006-Peter Crane submitted comments to the public docket for his petition citing concern about patients being released to hotels and unsuspecting hotel cleaning staff coming into contact with radiologically contaminated bathroom surfaces, linens, etc. The comments also note the problem of patients vomiting (in public or private spaces) after treatment and members of the public coming into contact with the radioactive vomitus.¹⁵

October 22, 2007 - The NRC's patient release rule was discussed at a meeting of the NRC's Advisory Committee on the Medical Uses of Isotopes. Dr. Douglas Eggli, a nuclear medicine physician, complained that it had become impossible to get insurance companies to pay for inpatient treatment, "even when I have family situations that require it." The committee's chairman, Dr. Leon Malmud, agreed stating: "Their wonderful insurance stops because it is no longer necessary for them to be an inpatient." As a result, he said: "All patients are discharged upon treatment. We whisk them out the doors as fast as possible."¹⁶

November 28, 2007-After an inspection revealed that patients with high doses of I-131 were knowingly discharged to a hotel, NRC's Region 1 Office made a request to NRC headquarters for technical assistance to determine whether release to a hotel was permissible under the NRC patient release rule. Referring to hotels, the technical assistance request noted that "these types of releases are not uncommon," cited some press reports on the topic, and questioned whether the required dose calculation analysis for patient release that takes into account occupancy can be performed in a valid manner for releases of patients to hotels. The Region also requested information on additional instructions to be provided to patients if they are released to hotels.¹⁷

April 23, 2008- The NRC Office of General Counsel (OGC) reviewed and approved the NRC headquarters response to the technical assistance request for NRC's Region 1 Office, which stated that "release to a hotel was not prohibited by the regulations."¹⁸

May 12, 2008- NRC issued a non-binding "Regulatory Issue Summary (RIS)" to its medical licensees, alerting them to the ICRP Publication 94 published in March 2004.¹⁹ The RIS states that "Licensees should also consider not releasing patients, administered I-131, whose living conditions may result in the contamination of infants and young children." But the report did not address the release of patients to hotels, nor did it mention anything about the mandatory requirement to calculate individualized doses to household members prior to releasing patients.

May 21, 2008- The NRC published in the Federal Register its denial of Mr. Crane's petition for rulemaking, saying that the NRC's patient release rule needed no reexamination, and citing/publishing its May 12, 2008 RIS as a means of addressing risks to infants and young

¹⁵ Docket ID: NRC-2005-0020 Comment (11) submitted by Peter G. Crane on Petition for Rulemaking PRM-35-18, Regarding Partial Revocation of the Patient Release Criteria Rule

¹⁶ Transcript of the U.S. NRC Advisory Committee on the Medical Uses of Isotopes, Monday October 22, 2007

¹⁷ Region 1 Technical Assistance Request. November, 28, 2007. See: U.S. NRC letter to Congressman Edward Markey, March 5, 2010; Attachment 5

¹⁸ NRC Safety Inspection Report Number 2007-002. Licensee: University of Virginia. See U.S. NRC letter to Congressman Edward Markey, March 5, 2010; Attachment 4

¹⁹ http://www.kdheks.gov/radiation/download/RIS_2008-11.pdf

children.²⁰ The NRC discussed and rejected the lower dose threshold for pregnant women and children urged by the ICRP.

May 28, 2008- The Minnesota Department of Health (MDH) issued a notice which advised its medical licensees of NRC's RIS and added its own warning: "MDH would discourage physicians from suggesting that patients use hotels as an alternative means of separation from infants or young children. That practice has proven to cause significant exposure concerns to hotel property, housekeeping staff, and guests."²¹

June 12, 2008 – In its response to NRC's Region 1 Office's request for technical assistance, the NRC stated that "releasing patients from a hospital to go to a hotel or other temporary accommodation is not an uncommon practice" and that current regulations do not "limit the location to which the (treated) individual must be released," and "do not prohibit the release of a patient to a hotel" To address this issue the NRC stated that "guidance for release of radiotherapy patients to hotels" and "additional instructions" to be provided to patients released to hotels "will be developed".²² This promised guidance and instructions were never developed.

July 9, 2008 – Mr. Crane filed a petition in the U.S. Court of Appeals for the Ninth Circuit to review the NRC's denial of his petition for rulemaking. Briefs were filed in the fall of 2008, in which Mr. Crane argued that the NRC failed to adequately address the significant safety issue of releasing treated I-131 patients from the hospital. The petition also addressed the inconsistencies between NRC's regulations and international safety standards.²³

November 4, 2008 – In its brief to the U.S. Court of Appeals for the Ninth Circuit in opposition to Peter Crane's petition for review of the NRC's denial of his original petition, NRC's Office of General Counsel (OGC) called Mr. Crane's description of patients sent to hotels "unverifiable and unscientific." In spite of this very same office's concurrence with the June 2008 NRC headquarters opinion that release to a hotel was not prohibited by NRC regulations, and the clear awareness on the part of the NRC that release of radioactive patients to hotels was not an uncommon practice, OGC declared to the court that: "NRC's rule does not permit or encourage doctors to send treated patients to hotels."²⁴

March 26, 2009- A notice from the State of Washington Department of Health advised its licensees to "actively discourage patient use of hotels immediately after release"²⁵

June 29, 2009 - The New York City Department of Health issued guidance to all medical licensees that specifically warned against sending patients to hotels.²⁶ It stated that "a hotel

²⁰ 73 F.R. 29445

²¹ MDH Information Notice 2008-04, www.health.state.mn.us/divs/eh/radiation/radioactive/infonot0408.pdf

²² NRC June 12, 2008 Memorandum to Region 1. See U.S. NRC letter to Congressman Edward Markey, March 5, 2010; Attachment 5

²³ No. 08-72973, *Peter G. Crane v. United States Nuclear Regulatory Commission* (U.S. Court of Appeals for the Ninth Circuit), Brief for Petitioner Peter G. Crane.

²⁴ No. 08-72973, *Peter G. Crane v. United States Nuclear Regulatory Commission* (U.S. Court of Appeals for the Ninth Circuit), Brief for Respondents (November 4, 2008), p. 39.

²⁵ See Appendix C

²⁶ <http://www.nyc.gov/html/doh/downloads/pdf/radioh/radioh-Info-noticeorh.pdf>

presents substantial probability of close contact with infants, young children, pregnant women, and of course the general public. In a serious and not at all implausible case, a patient could have their room or dining area cleaned by a pregnant woman who could come into very close contact with radioiodine-containing-bodily fluids.”

August 19, 2009 – A decision was issued in the U.S. Court of Appeals for the Ninth Circuit for Mr. Crane’s petition for review.²⁷ The court accepted the NRC’s argument that Mr. Crane, a thyroid cancer patient, lacked standing to bring the case because he was not currently undergoing or about to undergo treatment with radioactive iodine, and was therefore unaffected by the NRC rule. The court did not reach a conclusion regarding the merits of the case, including Mr. Crane’s claim that some radioactive patients were going to hotels and creating a hazard to other guests and hotel staff.

October 13, 2009- Chairman Edward J. Markey sent a letter to NRC Chairman Greg Jaczko highlighting issues with patients being released to public hotels and questioning NRC’s enforcement of patient release criteria. Mr. Markey stated: “I am concerned that current NRC regulations....may result in some unnecessary, unwitting and inappropriate exposures of individuals to dangerous levels of radiation.”²⁸

November 17, 2009- Chairman Greg Jaczko replied to Mr. Markey’s letter stating “the NRC believes the current regulation (10 CFR 35.75) provides adequate protection to members of the public, provided that adequate instructions are provided at discharge to the patient and the family members.” The letter also stated that the regulation “does not limit the location to which the individual may be released nor does it specifically address the release of patients to hotels.” The response indicated that the need to perform an individualized analysis of a patient’s living situation would also apply to those patients who go to hotels after their release from the hospital. In response to a question on protecting vulnerable populations the NRC states “there is no distinction between the dose limits that apply to other members of the public and those that apply to pregnant women and young children”.²⁹

January 14, 2010- Mr. Markey wrote another letter to NRC Chairman Jaczko, stating that he “remains extremely concerned that the Commission is abdicating its responsibility to protect the health and safety of the American people.” In discussing particular concern for patients released to hotels, where they could expose pregnant hotel workers or children of guests, he states for “hotels it would be difficult, if not impossible, to come up with credible assumptions with which to estimate the dose received by an unknown person at an unknown distance when performing the sort of individualized analysis referenced in the 1997 guidance...” Mr. Markey specifically requested an investigation into NRC’s inspection records of facilities licensed to use I-131 in medical treatments.³⁰

²⁷ <http://www.ca9.uscourts.gov/datastore/memoranda/2009/08/19/08-72973.pdf>

²⁸ http://markey.house.gov/docs/signed_isotope_nrc_letter.pdf

²⁹ http://markey.house.gov/docs/nrc_tomarkeyisotopes.pdf

³⁰ <http://markey.house.gov/docs/11410nrc.pdf>

March 5, 2010-Chairman Jaczko responded to Mr. Markey's inquiry.³¹

Notable Points:

- NRC may have recognized that pregnant women and children are different than grown men in their sensitivity to radiation and is considering possible revisions to the regulations that set dose limits for pregnant women and children. However, no timeline or process is provided for this revision.
- NRC has 3,700 I-131 licensee and Agreement State medical use facilities, but only inspects 500 of these facilities for compliance with patient release criteria, with the remaining not subject to NRC oversight. Although the remainder of these facilities are subject to State regulation and enforcement, NRC neither requests nor receive reports of any kind related to State inspections.
- The NRC noted a few examples in which enforcement actions were taken as a result of violations in patient release. These violations included the failure to perform individualized analysis before release and failure to provide written instructions to the patient on how to reduce exposures to others. This included cases in which patients were discharged to hotels.
- The NRC response declared that regulations do not prohibit doctors from sending patients to hotels and believes that physicians can reasonably calculate dose estimates for patients who go to a hotel, by using assumptions on building geometry and other factors.
- The Commission will not reconsider its decision to not be notified if harm has occurred as a result of patient exposure to the public, because the NRC is "not aware of any scenario in which a member of the public received a 0.5 rem exposure from a released patient." Since the NRC twice voted not to be told if such events occur, it is unclear how it would have become aware of such a scenario in the first place.

³¹ See: U.S. NRC letter to Congressman Edward Markey, March 5, 2010

Appendix B



'92 NOV 17 AS:53

November 9, 1992

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCHUCLA SCHOOL OF MEDICINE
HARBOR - UCLA MEDICAL CENTER
DEPARTMENT OF RADIOLOGY
1000 CARSON STREET
TORRANCE, CALIFORNIA 90509

Samuel Chilk, Secretary of the Commission
U.S. Nuclear Regulatory Commission
Docketing and Service Branch
Washington, DC 20555

Subject: Letter of Peter Crane dated 10/31/92 regarding PRM-20-
20, PRM-35-10, PRM-35-10A, and the 23 October 92
meeting of the ACMUI

Dear Mr. Chilk:

I am writing to correct the scientific mistakes and misunderstandings contained in Mr. Crane's letter of 31 Oct. 92, and to point out that certain opinions ascribed to me by Mr. Crane are grossly inaccurate. Fortunately my opinions are amply documented, in writing, in your office, so this should be quite straightforward. I recommend that Mr. Crane review my Petition dated 12/26/90, my important Addendum of 6/12/92, and my comments of 3/14/92 concerning the ACNM Petition.

My Petition was written at the request of Hal Peterson, who was embarrassed at the uncorrected errors in 10 CFR Part 20, and who urged me to "write a Petition YESTERDAY". At the time, the new Part 20 was supposed to go into effect 1 Jan 92, and we did not have many months to waste. I argued at the time that I did not want to write another petition (I wonder why?), but he insisted it was the only option open, and that is how I spent Christmas Eve, 1990. It was hastily done, and recommended honoring the methodology of NCRP no. 37, getting rid of the "30 mCi rule" for all radionuclides other than I-131, and retaining the 5 mSv maximum for members of the public from patient sources; this is in keeping with the most recent recommendations of NCRP, ICRP, and the IAEA. I recommend that Mr. Crane review this literature as well, as NRC asserts frequently that it uses such sources for its standards.

Much later, after discussing the issues at leisure in much more detail with members of NCRP, ACNP, SNM, and NRC, I wrote an Addendum covering the "30 mCi" issue. Due to the fact that the "30 mCi" value was embarrassingly based on a naive mistake by the AEC in the early 1950's and never fixed thereafter, and due also to the fact it is not mentioned anywhere in NCRP no. 37 (nor should it have been), I made a scientifically valid case for a "default" value of I-131 patient discharge which came out to 33

mCi. However, there is excellent reason to raise that number, especially for athyreotic carcinoma patients with normal renal function. NCRP no. 37 lists limits of 50 mCi for certain home situations and 80 mCi for even more restrictive home situations. Mr. Crane should familiarize himself with these qualifiers, because he is obviously unfamiliar with these long-accepted concepts. NCRP no. 37 is the law in California; the "30 mCi rule" does not exist here. We in California try to base our policies on scientifically valid health physics.

When the ACNM Petition was submitted, I used my comment opportunity to remind NRC that my Petition was drowning at the bottom of Mr. Roecklein's "in" pile, and that it needed resolution. The concept of sending patients home with 400 mCi of NaI-131 was ludicrous. Although I could theoretically concoct a situation where it could possibly be justified, there are not too many patients who would qualify as hermits in isolated areas. In any case, I stated:

"The one aspect of the petition that causes me some concern is the claim of safety of an outpatient dose of 400 mCi. I have not reviewed data supporting this argument and would appreciate the opportunity to do so. Although I'm sure that safety could be satisfied, it would appear to require some very specific circumstances".

As there are no data that could possibly support this except in highly unusual situations, the point is moot. Mr. Crane should also know that I requested that ACNP (absolutely not related in any way whatsoever to ACNM), SNM, the American College of Radiology, and Jack Goodrich, M.D., past ACMUI member, make similar points in their comment letters. I explained to the American Hospital Association that this was NOT a good way to save money, and made a presentation against the ACNM Petition at last Spring's CRCPD meeting at the request of Terry Frazee of the State of Washington.

I hope that NRC clearly understands that I am not now, nor have I ever been, a member of the ACNM nor an espouser of 400 mCi I-131 doses dispensed to patients in an uncontrolled manner. However, NRC's "30 mCi" rule is scientifically unfounded and constitutes bad physics, just as ACNM's claims are unsupported by scientific data.

All I am trying to do is challenge NRC to make an intellectually defensible, scientifically valid regulation based on best available scientific data and scientific judgment. I urge NRC to entertain only scientific discussion, and eschew scientifically

November 9, 1992
Samuel Chilk, Secretary
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for data on childhood thyroid cancer near Chernobyl. I recommend that Mr. Crane read Hull AP: Post Chernobyl childhood cancers reported. The Health Physics Newsletter, vol. 20, Nov. 1992, (cover story). There are some interesting problems with Russian "data" at this point.

Mr. Crane's naivete' concerning the first Petition I wrote in June, 1989, with Mr. McElroy's help, is surprising. Mr. Cunningham instructed Mr. McElroy to help me write the Petition. I didn't know how to write regulatory language, and it was Mr. McElroy's job to help me do that. NRC had written some very poor quality and dangerous regulations in 1987, and Mr. Cunningham realized that the language had to be fixed, and asked us to do it together. It was an "inside" job from the start. Mr. Cunningham gave us some very tough boundary conditions, but we did the best we could. This was before NRC rammed through the petitioner's "Gag Rule" without opportunity for public comment. If I were to write my own petition to change Part 35 today, with none of Mr. Cunningham's constraints, I would get rid of nearly everything in it, and upgrade education and experience criteria for nuclear medicine physicians so that NRC stopped licensing incompetent physicians who don't even know what Part 20 is, let alone the basic science necessary to comply with it. Nuclear Medicine would be subject to performance standards only. The only reason we have completely prescriptive regulation is that performance standards require thorough understanding and judgment, and NRC itself cannot seem to rise to that level. So yes, Mr. Crane, the staff "is passing judgment on a petition that the staff itself helped to write", and I did not "misspeak".

Mr. Crane is a lawyer. It is not surprising that he is thoroughly unfamiliar with the areas of nuclear medicine, nuclear pharmacy, and basic nuclear sciences, because he has never had any education, training, or experience in these fields. However, one may expect certain professional behavior from a lawyer. For openers, one would expect him to read the obvious background material on a case, so that he would be aware of the facts. It is well known that I do not deprive the NRC of my opinions on subjects involving my expertise, and a short search on Mr. Crane's part would surely have yielded the facts he so desperately lacked. Although he would not have understood my calculations, he could have asked an expert for some help. He could even have called me! He would, however, have been expected to understand the English. It is not acceptable professional behavior for an NRC lawyer to attempt to deceive NRC about the opinions of an NRC advisor and consultant, refuse to even bother with the facts, and expect NRC licensees to continue to support him with User Fees. I object to his continued employment at NRC.

uninformed nuclear hysteria from any source. NRC's independent status insures it does not have to honor outside opinion flawed by ignorance. One would hope NRC would not have to honor inside opinion flawed by ignorance, either.

Mr. Crane asks NRC to regard him somehow as a knowledgeable professional on the subject of I-131 for thyroid cancer, based on his personal experience with the disease. Having read Mr. Crane's present missive, and a previous related document at the time the Commission signed the scientifically insupportable "Quality Management" thing, let me assure you, as a knowledgeable professional on the subject of I-131 for thyroid cancer, that Mr. Crane is well-qualified to be a patient, and nothing more. For example, if Mr. Crane really had a partial thyroidectomy in 1973 and then 2 doses of 29.9 mCi each 10 and 11 years later to ablate the remnant, it is no wonder he had recurrences, and it is surprising he isn't in malpractice court. Knowing the excellence of NIH, however, I would tend to doubt the validity of his account.

As far as his story about his confinements, let me explain that one does not need "thick paper" on the floor, only absorbent material with a plastic backing. As far as "smelling strongly of seaweed", this is pure confabulation. In the first place we do not give iodine, we give iodide. Iodide does not smell like seaweed. Second, the mass of 150 mCi of I-131 is $(150)(131)(8)(24)(60)(60)(8.87 \times 10^{-17}) = 1.2$ micrograms. Normal stool contains 10-50 micrograms per day. The average person contains 30,000 micrograms of the element iodine, and another microgram or so, even if converted to a volatile form, should not make his deodorant fail. Mr. Crane's story about his contaminated computer case is indeed a physics first. "....radiation from stray drops of urine had probably penetrated the thick concrete walls of the bathroom and reached the case. A month later, the case had cooled down to the point that I could collect it from Radiation Safety." Quick, Mr. Bernero! We need at least three contracts to starving DOE labs to understand this new phenomenon. "Beta creep"? Good God! Have all our shielding calculations been for nought all these years? My Uncle Joe Fertik, who designed the 14 foot concrete vault around the very first Oak Ridge reactor after W.W. II, died last year at 94, and never knew. If a gamma ray sneaked through and hit the case it should last no more than about a picosecond at most. A month? Wow!

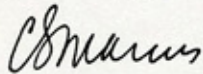
Mr. Crane makes some other interesting statements, quoting such incontrovertibly superb scientific sources as the New York Times

November 9, 1992
Samuel Chilk, Secretary
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In addition to being of no value as a nuclear expert, he is, in my opinion, behaving in an unacceptable manner for a lawyer.

Thank you for the opportunity to comment on this most informative comment letter.

Sincerely,



Carol S. Marcus, Ph.D., M.D.
Director, Nuclear Med. Outpt. Clinic
and
Assoc. Prof. of Radiological Sciences
UCLA

cc: Peter Crane
Commissioner Ivan Selin
Commissioner Gail de Planque
Commissioner Forrest Remick
Commissioner Kenneth Rogers
Commissioner James Curtiss
Hugh Thompson, Deputy EDO
Robert Bernero
Richard Cunningham
John Glenn, Ph.D.
William Parler, Chief Counsel
Joan McKeown
Peter Almond, Ph.D.
Ted Webster, Ph.D.
Gerald Pohost, M.D.
Judy Brown
Curtis Scribner, M.D.
Steve Collins
Barry Siegel, M.D.
Mel Griem, M.D.
Dan Flynn, M.D.
Capt. Wm. Briner
Mark Rotman
Myron Pollycove, M.D.

CSM:sfd

Appendix C



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
OFFICE OF RADIATION PROTECTION
111 Israel Road SE • PO Box 47827 • Olympia, Washington 98504-7827
TDD Relay Services: 1-800-833-6388

INFORMATION NOTICE

March 26, 2009

TO: All Medical Licensees Authorized Therapeutic Use of Iodine-131

FROM: C. DeMaris 
Medical Licensing

SUBJECT: Release of Therapy Patients Administered Iodine-131

[Please discourage the use of hotels following treatment. It has recently been brought to our attention that Regulatory Guide 8.39 does not specifically reference where a patient should reside when released after a therapeutic dose of Iodine-131. It is presumed that most, if not all, patients go home although there is nothing in the Guide preventing a patient from using a hotel.

A specific public complaint has been raised that a patient using a hotel immediately following release could, under certain circumstances, present an unnecessary risk of exposure to others, especially infants and children. We believe the concern is consistent with the International Commission on Radiological Protection's Publication 94, *Release of Patients after Therapy with Unsealed Radionuclides*. This publication cautions that particular care should be taken to avoid the contamination of infants and children from patients treated with radioiodine.

At present, it is our understanding that you neither advise nor encourage the use of a hotel. Nevertheless, we believe it is prudent to eliminate this potential.

We recommend that you actively discourage patient use of hotels immediately after release.

This notice requires no specific response from you. If you have any questions, I can be reached at 360-236-3223.

Thank you for your time and cooperation.

