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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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PAT ZANZONICO Nuclear Medicine Physicist

NRC STAFF PRESENT:

ROB LEWIS Division Director

CHRIS EINBERG Designated Federal Officer

MIKE FULLER Alt. Designated Federal Officer

ASHLEY COCKERHAM ACMUI Project Manager

MARK BANKS

NEELAM BHALLA

KATHRYN BROCK

CATHY COLLELI

KERSTUN DAY

MARC FERDAS

JAMES FIRTH

CINDY FLANNERY

SANDY GABRIEL

ROBERT HAYS (via teleconference)

MIKE HERR (via teleconference)

MERRI HORN

DONNA-BETH HOWE

VARUGHESE KURIAN

ED LOHR

JOSE MACATANGAY (via teleconference)

ANGELA McINTOSH

KEVIN NIETMANN

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STAFF MEMBERS PRESENT (CONTINUED):

KEVIN NULL (via teleconference)
PATTY PELKE
MARY JANE ROSS-LEE
LEELA SREENIVAS
GLENDA VILLAMAR (via teleconference)
JENNY WEIL
RONALD ZELAC

ALSO PRESENT:

MELISSA ALLEN	General Electric Hitachi Nuclear Energy
CURTIS ANDERSON	Mele Associates
ROY BROWN	CORAR
JANET BUKOVCAN	MDS Nordion
PETER CRANE	Unknown Affiliation
WILL DAVIDSON (via teleconference)	University of Pennsylvania
KAREN LANGLEY (via teleconference)	University of Utah
RICHARD MARTIN	ASTRO
MICHAEL PETERS	ACR
DOUG PFEIFFER	AAPM
AMANDA POTTER	AAPM

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ALSO PRESENT (CONTINUED):

LOUIS POTTERS	North Shore University Hospital and Long Island Jewish Medical Center
JANET SCHLUETER	NEI
CINDY TOMLINSON	SNM
JENNA WILKES	ASNC
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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MR. EINBERG: Thank you, Dr. Thomadsen.

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

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

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

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

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

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

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

Dr. Thomadsen?

VICE CHAIR THOMADSEN: Here.

MR. EINBERG: Dr. Darrell Fisher:

MEMBER FISHER: Here.

MR. EINBERG: Ms. Debbie Gilley?

MEMBER GILLEY: Here.

MR. EINBERG: Dr. Sue Langhorst?

MEMBER LANGHORST: Here.

MR. EINBERG: Mr. Steve Mattmuller?

MR. MATTMULLER: Here.

MR. EINBERG: Dr. Orhan Suleiman:

MEMBER SULEIMAN: Here.

MR. EINBERG: Dr. William Van Decker?

MEMBER VAN DECKER: Here.

MR. EINBERG: Dr. James Welsh?

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MEMBER WELSH: Here.

MR. EINBERG: And Dr. Pat Zanzonico?

MEMBER ZANZONICO: Here.

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

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

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

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

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

MR. FULLER: Mike Fuller, NRC.

MS. GABRIEL: Sandy Gabriel, NRC.

DR. ZELAC: Ronald Zelac, NRC.

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

MS. PELKE: Patti Pelke from Region III.

MS. BHALLA: Leelam Bhalla from

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Headquarters.

MR. EINBERG: Okay. Thank you.

MR. LOHR: Ed Lohr from Headquarters.

MR. KURIAN: Varughese Kurian from Headquarters.

MS. SREENIVAS: Leela Sreenivas, Headquarters, NRC.

MS. McINTOSH: Angela McIntosh, Headquarters.

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

MS. VILLAMAR: Glenda Villamar, NRC.

MR. EINBERG: Thank you.

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

Region III?

MR. NULL: Kevin Null in Region III.

MR. HAYS: Robert Hays, Region III.

MR. HERR: Mike Herr, Region III.

MR. MACATANGAY: Jose Macatangay, Region III.

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

(No response.)

MR. EINBERG: Okay. No participation from

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Region IV?

Did Region I come on the the line again?

(No response.)

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

(No response.)

MR. EINBERG: Okay. Thank you.

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

MS. COCKERHAM: Yes, I can do that.

Okay, is Bob Dansro on the phone?

(No response.)

MS. COCKERHAM: Will Davidson?

MR. DAVIDSON: Here.

MS. COCKERHAM: Joe Rogers?

(No response.)

MS. COCKERHAM: Steven Sutliff?

(No response.)

MS. COCKERHAM: Sandy Wolfe?

(No response.)

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

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didn't call your name?

MS. LANGLEY: Yes, Karen Langley.

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

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

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

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

MR. LEWIS: Thank you, Chris.

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

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

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

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

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

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

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

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

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

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

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

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

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be very happy to do that.

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

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

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

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

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

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

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

We have updates on medical isotopes shortages right after lunch.

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

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

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

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brachytherapy.

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

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

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

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

VICE CHAIR THOMADSEN: Thank you, Mr. Lewis.

Any questions for Mr. Lewis?

(No response.)

VICE CHAIR THOMADSEN: Okay. Thank you very much.

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MR. LEWIS: Thank you.

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

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

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

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

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

Are there any questions on the 2007 recommendations?

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

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

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

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

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

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

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

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

VICE CHAIR THOMADSEN: Please proceed.

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

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

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

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

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

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

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

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

(No response.)

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

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

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

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

Any questions on the 2008 recommendations?

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

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

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

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

MEMBER SULEIMAN: Okay.

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

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

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

Anything else on 2008?

(No response.)

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

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

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

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

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

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

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

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

MS. COCKERHAM: Okay.

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

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NRC-approved specialty boards who also certify Canadians?

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

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

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

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

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

MEMBER GUIBERTEAU: Okay. Thank you.

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

(No response.)

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

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It may have been 2005 or 2006.

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

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

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

MR. EINBERG: No.

MS. COCKERHAM: No?

MR. EINBERG: No.

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

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

(No response.)

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MS. COCKERHAM: Thank you.

VICE CHAIR THOMADSEN: Thank you.

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

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

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

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

The rulemaking would change most of the criterion that we currently have in regulation to 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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at this point.

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

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

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

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

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

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

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

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

VICE CHAIR THOMADSEN: Are there questions? Yes?

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

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

MEMBER LANGHORST: I would certainly

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encourage that because of the great changes in it.

MR. LOHR: Right.

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

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

MEMBER LANGHORST: Okay. Thank you.

VICE CHAIR THOMADSEN: Very good.

Ms. Gilley?

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

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

MEMBER GILLEY: And the next step?

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

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They have many, many options.

MR. LEWIS: The final rule.

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

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

MEMBER GILLEY: Thank you.

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

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

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

MR. LEWIS: Barring a safety issue.

MEMBER VAN DECKER: Fine.

VICE CHAIR THOMADSEN: Other questions?

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(No response.)

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

MR. LOHR: Sir?

VICE CHAIR THOMADSEN: Yes.

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

VICE CHAIR THOMADSEN: Yes.

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

VICE CHAIR THOMADSEN: Very good.

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

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

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

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

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

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

Any questions? Yes, sir?

MEMBER SULEIMAN: You were commenting about? Part 37?

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

MEMBER SULEIMAN: Oh, okay, okay.

VICE CHAIR THOMADSEN: Any other questions?

(No response.)

VICE CHAIR THOMADSEN: Thank you very much.

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

PARTICIPANT: Did you have a question?

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

(Chorus of not well.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Are there any questions?

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

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

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

MEMBER ZANZONICO: And specifically for

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

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

MEMBER ZANZONICO: Thank you.

VICE CHAIR THOMADSEN: Thank you very much.

Any other comments? Dr. Guiberteau?

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

DR. HOWE: Sixty-three?

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

Do you have --

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

MEMBER GUIBERTEAU: Yes?

MR. FULLER: Dr. Guiberteau, could you

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please move the microphone a little bit closer to you?

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

MR. FULLER: Okay.

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

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

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

MEMBER GUIBERTEAU: All right. Thank you.

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

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

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takes the same position as far as I understand.

VICE CHAIR THOMADSEN: Dr. Suleiman?

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

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

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

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agencies.

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

VICE CHAIR THOMADSEN: Dr. Welsh?

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

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

DR. HOWE: Your comment is noted.

VICE CHAIR THOMADSEN: Other comments?

Please step to the microphone.

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

VICE CHAIR THOMADSEN: Can you identify yourself again.

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

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NRC, retired.

MR. FULLER: Excuse me.

MR. CRANE: Pardon me?

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

MR. CRANE: Oh, that would help.

VICE CHAIR THOMADSEN: It's on.

MR. CRANE: Okay. Am I audible?

VICE CHAIR THOMADSEN: Yes.

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

DR. HOWE: That's the commitment.

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

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

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you clarify that please?

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

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

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

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

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

MR. CRANE: Thank you very much.

VICE CHAIR THOMADSEN: Are there any other comments?

MR. EINBERG: Excuse me?

VICE CHAIR THOMADSEN: Yes.

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

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MR. CRANE: Yes, please.

MR. EINBERG: This would be the time then.

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

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

I very much appreciate the opportunity to address this Committee. I've 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, this is it.

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

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

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time, I had seven treatments with iodine 131, two as an outpatient, 29.9 millicuries to ablate the thyroid remnant 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 it imperative it is that we ensure an ample an uninterrupted supply of it. We have, incidently, the representative of the Canadian company that manufactures I-131. We're all dependent on her. She has us on our knees.

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.

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

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

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

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

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 IAEA 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, in the 1985, 1986 major rulemaking, the NRC had correctly explained that I-131 patients could cause members of the public to receive both an

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external dose from proximity and an internal dose from contamination.

The 1997 rule 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 described the difficulty or impossibility of getting in-patient 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 in-patient 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 out-patient treatment is their only option.

Jim Luehmann of the NRC staff was present

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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 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 in-patient 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. That's somewhat different from what I heard Donna-Beth say that there were various ways that you could establish compliance with the rule.

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

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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.

"Well, 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 described this as a, "medical and

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moral issue that the NRC cannot in conscience ignore."

I actually mentioned this 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 hoe 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 bed sheets? 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

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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 word one 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 the 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 within instructions to deal with it.

The NRC's lawyers had a couple of answer 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

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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 page 39 of the brief, "The NRC's rule does not permit or encourage doctors to send treated patients to hotels."

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

Well, 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 brought by a group, the standing problem would go away. And that remains an option.

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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.

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

Now there is a listserv on Yahoo on which thousands of thyroid cancer patients ask questions pertaining to their care. Typically they are new patients looking for advice. And the old timers 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.

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

The old timers invariably tell them not to. They should 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 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 about the patient I just described? And if you wouldn't wish this on your own child, you shouldn't wish it on anyone else's either.

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Efforts have 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.

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One Commissioner says that to adopt this proposal would reverse the recent improvement in the NRC's relations with the medical 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 Commissioners 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 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 1990s because the Commission was concerned that the

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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. Don 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.

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

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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 midterm elections of 1998, in which Senator Barbara Boxer was running for reelection, 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, at that time edited by Nekita Hobson, also boasted of having contacted over a thousand Clinton-Gore donors to make similar claims about what the Administration had done to harm the interest of cancer patients.

When Ms. Hobson's terms was up, she was replace 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, Dr. Darrell Fisher, the current holder of the Patient's Rights Advocate position.

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

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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.

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

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

There was an illuminating section of an 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

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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. To which I was going to say spoken like a mensch, Dr. Malmud. And I'm sorry you're not here. I'd like to thank you in person.

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

It is 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 her 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 employee has molested a minor, you can come up with a similar rationale for not calling the police.

When you decide that other interests take

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precedence over the human beings who are the victims of mistakes or misdeed, it all too often winds up backfiring because then the whole organization is seen as corrupt rather than the individuals originally responsible. Once trust if 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 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

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

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

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. And I might interject at this point that Donna-Beth mentioned in her recitation that the NRC approach was consistent with the ICRP in affording special protection to children and pregnant mothers. ICRP 94 said that the dose limit should be 100 millirem, not 500 millirem, for children and pregnant women. And that part of the recommendation the NRC rejected. So we are not in synch with the ICRP.

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

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

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.

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

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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 300 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

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

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

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 understanding 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

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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 Chair Malmud, Acting Chairman Thomadsen, and the Committee for the opportunity to speak here today. I'll sit down unless anybody has a question to ask of me.

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

(No response.)

VICE CHAIR THOMADSEN: Thank you, Mr. Crane.

MR. CRANE: Thank you, Dr. Thomadsen.

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

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

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

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

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

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

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

Since that time, I have felt a desire to

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

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

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

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

Thank you.

VICE CHAIR THOMADSEN: Thank you, Dr.

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Fisher.

Other comments from the -- yes?

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

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

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

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

Dose-based release criteria are the ones

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

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

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

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

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

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

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

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

And there are data probably amounting to

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

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

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

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

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

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

Thank you.

VICE CHAIR THOMADSEN: Thank you.

Other comments from the Committee? Dr. Suleiman?.

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

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

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

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

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

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

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

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plausible.

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

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

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

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

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

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

VICE CHAIR THOMADSEN: Thank you, Dr. Suleiman.

We have a comment from the public.

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

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

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

So we do come out against releasing them

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

VICE CHAIR THOMADSEN: Thank you.

Mr. Lewis?

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

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

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

We take that obligation very seriously, and any information that can be provided by the Committee, by our inspection experience, by general 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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forward.

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

So thank you for that opportunity to comment.

VICE CHAIR THOMADSEN: Thank you, Mr. Lewis.

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

VICE CHAIR THOMADSEN: And I will point

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

Mr. Lewis?

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

VICE CHAIR THOMADSEN: Thank you for that comment also.

MS. Gilley?

MEMBER GILLEY: Debbie Gilley.

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

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

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

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

Thank you.

VICE CHAIR THOMADSEN: Thank you.

Other comments from the Committee?

Dr. Zanzonico?

MEMBER ZANZONICO: Pat Zanzonico again.

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

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

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

VICE CHAIR THOMADSEN: Thank you very much.

Dr. Welsh?

MEMBER WELSH: Jim Welsh here.

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

I do have a couple of comments or questions.

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

For example, the comments made about Dr.

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

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

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

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

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that.

VICE CHAIR THOMADSEN: Thank you, Dr. Welsh.

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

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

MR. CRANE: Thank you.

For the record, this is Peter Crane.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We have the recent report from NCRP, NCRP

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130, is it? That points to the threefold increase in the amount of medical regulation -- or sixfold amount of radiation that people are getting annually from medical radiation.

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

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

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

VICE CHAIR THOMADSEN: Thank you, Mr. Crane.

MR. CRANE: Thank you.

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

Dr. Guiberteau?

MEMBER GUIBERTEAU: Yes. I believe that,

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

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

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

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treatments.

VICE CHAIR THOMADSEN: Thank you.

Dr. Welsh?

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

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

VICE CHAIR THOMADSEN: Very good.

MEMBER FISHER: Second.

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

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

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

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

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based on its comprehensive review of the data.

VICE CHAIR THOMADSEN: Very fine.

Further comments about --

MEMBER ZANZONICO: Yes.

VICE CHAIR THOMADSEN: Yes?

MEMBER ZANZONICO: Pat Zanzonico again.

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

VICE CHAIR THOMADSEN: Thank you.

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

MEMBER SULEIMAN: I'm confused because I consider myself relatively knowledgeable, but I'd like the Committee to make a concerted effort, or maybe the NRC staff could help out reviewing the current regulatory criteria both internationally and domestically. Because I think the trend is more 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 draft circulating. So I'm a little
3 bit confused as of this point in time, you know, where
4 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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patient release, reviewing available data and international recommendations and make suggestions to the NRC staff for possible changes and improvements in the release criteria. Does that capture --

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

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

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

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

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

VICE CHAIR THOMADSEN: Include states

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where saying international?

MEMBER SULEIMAN: Yes, I did.

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

Ms. Howe?

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

VICE CHAIR THOMADSEN: Absolutely.

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

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

Yes?

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

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

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

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

All in favor please say aye.

ALL: Aye.

VICE CHAIR THOMADSEN: Opposed?

Okay. It is unanimous.

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

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

Mr. Mattmuller is one.

MS. COCKERHAM: Maybe the whole Committee.

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

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

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

MS. COCKERHAM: Okay.

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

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

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

VICE CHAIR THOMADSEN: I want a subcommittee, yes.

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

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

MEMBER SULEIMAN: Okay. Fine.

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

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

VICE CHAIR THOMADSEN: Very good. Thank you.

Any further commentary on this issue?

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

We return at 1:00.

(Whereupon, at 11:5 a.m. the Advisory Committee was adjourned, to reconvene this same day at 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 crises 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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or function and physiology. And on the screen are two of our most common procedures.

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

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

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

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

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

So right now at this given time three-

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Likewise, a nuclear power plant with a

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

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

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

They've also built partial full size mock-

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

And the next potential long-term solution

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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that they desire.

Thank you.

VICE CHAIR THOMADSEN: Thank you.

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

MEMBER VAN DECKER: Van Decker.

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

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

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

In your mind do you see any intermediate

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

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

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

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

MEMBER VAN DECKER: Thank you.

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

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

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

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

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

MEMBER MATTMULLER: Okay.

MEMBER ZANZONICO: I think part of the problem is, because I know we're conducting a trial at Sloan Kettering, is that there's never definitive studies, surprisingly given the fact that its been in 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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Well, I think the transition there when a lot of this initial work was done actually at the University of Chicago, the transition from the large crystal or the thick crystal rectilinear scanners to the Anger camera was occurring. And it was technology change that really drove the use of technetium in all of these agents.

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

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

VICE CHAIR THOMADSEN: Exactly.

MEMBER GILLEY: Debbie Gilley.

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

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

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

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

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

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

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

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isotopes, that are more easily available?

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

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

MEMBER GILLEY: Thank you.

VICE CHAIR THOMADSEN: Dr. Suleiman.

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

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

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

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

VICE CHAIR THOMADSEN: Mr. Lewis?

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

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

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

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

VICE CHAIR THOMADSEN: Dr. Fisher?

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

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

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

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

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

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

MEMBER VAN DECKER: I actually have a comment.

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

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

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

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

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

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

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

Okay. Thanks.

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

Dr. Guiberteau?

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

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

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

VICE CHAIR THOMADSEN: Dr. Langhorst?

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

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

MEMBER LANGHORST: Okay.

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

MEMBER LANGHORST: And in a manageable size?

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

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

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

VICE CHAIR THOMADSEN: Thank you.

Yes, Mr. Lewis, you had a comment?

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

VICE CHAIR THOMADSEN: Okay. Fine.

And changing speakers we shall do right now.

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

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

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

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

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

MS. ROSS-LEE: Yes. Good afternoon.

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

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

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

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

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

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

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

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

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

The liquid solution reactor;

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Aqueous Homogeneous Reactors or AHR;

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

As well as accelerator-drive fission.

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

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

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

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

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

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

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

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

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

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

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

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technology.

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

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

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

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

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

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

The schedule that they had supplied to us

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

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

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

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

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

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

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

Their schedule, as I mentioned, the second

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

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

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

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

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

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

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

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

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of intent to be looking into production of moly.

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

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

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

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

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

What we're doing now. Looking at the

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

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

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

VICE CHAIR THOMADSEN: Thank you very much.

Questions for the speaker?

MEMBER ZANZONICO: This is Pat Zanzonico.

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

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

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

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

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

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

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

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

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

VICE CHAIR THOMADSEN: Dr. Langhorst.

MEMBER LANGHORST: Sue Langhorst.

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

MS. ROSS-LEE: Yes.

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

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

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

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DOE about the waste, yes.

VICE CHAIR THOMADSEN: Mr. Lewis?

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

MS. ROSS-LEE: Right.

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

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

MR. LEWIS: No.

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

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

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

MR. LEWIS: Or a commercial site.

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

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VICE CHAIR THOMADSEN: Thank you.

Mr. Mattmuller?

MEMBER MATTMULLER: Steve Mattmuller.

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

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

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

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

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

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

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

MEMBER MATTMULLER: Yes.

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

MEMBER MATTMULLER: Okay.

VICE CHAIR THOMADSEN: Thank you.

Do you still have a question, Ms. Gilley?

MEMBER GILLEY: No.

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

MEMBER VAN DECKER: Van Decker.

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

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

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

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

VICE CHAIR THOMADSEN: Dr. Langhorst.

MEMBER LANGHORST: Yes. Sue Langhorst.

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

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

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MR. LEWIS: Yes.

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

MEMBER LANGHORST: Thank you.

VICE CHAIR THOMADSEN: Dr. Suleiman?

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

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

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

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

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

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

VICE CHAIR THOMADSEN: Any other comments.

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

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

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

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

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

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

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

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

You know, I think the biggest hurdle

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

VICE CHAIR THOMADSEN: Dr. Suleiman?

MEMBER SULEIMAN: Yes. One more comment.

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

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

MS. ROSS-LEE: Reactors.

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

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

VICE CHAIR THOMADSEN: Debbie?

MEMBER GILLEY: Debbie Gilley.

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

MS. ROSS-LEE: Yes.

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

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

MEMBER GILLEY: Okay.

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

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

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February.

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

VICE CHAIR THOMADSEN: Yes, Dr. Howe?

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

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

MS. HOWE: Yes. Yes.

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

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

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

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

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

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

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

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

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

(Laughter.)

VICE CHAIR THOMADSEN: - appropriately.

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

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

MS. PELKE: Thank you, Dr. Thomadsen.

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

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

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

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

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

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

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

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

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

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

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

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80 percent of the prescribed dose.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As far as poor management/oversight of the brachytherapy program, as I mentioned probably in one of my first or second slides, the VA had contracted their services for radiation oncology to the 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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of. And they reevaluated the dose delivered to the treatment sites. And then they also had some patients that because of the recentness of their initial implant, could receive additional implants at another VA facility. And then also they suspended the privileges of one of their authorized users - actually, they suspended their whole prostate brachytherapy program back in June of 2008 as additional medical events became evident and reported.

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

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

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

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

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

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

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

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

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

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a materials licensee.

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

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

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

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

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

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

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

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

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

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

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

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

And depending on the skill of the craft or the expertise of the individuals that are implementing those procedures, you can see quite a spectrum of implementation depending on experience level of those folks.

We're also looking at our actions to assess performance improvements with the VA. And typical of any other NRC licensee that we would have where we identify escalated enforcement, they will be subject to increased inspection oversight. So, we'll be doing increased inspection activities of the VA facilities.

We'll also be accompanying their inspectors, and we'll also be looking at their event response going forward.

And then internally what we're trying to do is, you know, we're a learning organization and we're trying to get better, always trying to get better. So, we're taking a look at what we learn from these events to see how we might improve and refine some of the tools that we have available so that going

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forward we can look at maybe early precursors that could have prevented some of these in the future.

And then the last four slides are just some visual so you can see what we saw at the VAs that had adequate programs for prostate brachytherapy.

This is an example of an implant from the VA in Minneapolis. I'm using these as visuals so you can see the dramatic difference in the placement of seeds between some of these other VA facilities and what occurred at Philadelphia.

This is an implant from Cincinnati. This is an example of an implant from Philadelphia. And there's another example of an implant from Philadelphia.

And if there's any questions -

VICE CHAIR THOMADSEN: Thank you very much.

Are there questions from the Committee?

MEMBER ZANZONICO: Yes, I have several questions.

You indicate at the beginning that there were 97 of these events that rose to the level of a medical event.

That was among all the 12 VA sites?

MS. PELKE: No. The 97 that were reported were just for Philadelphia.

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MEMBER ZANZONICO: Out of a total of how many cases?

MS. PELKE: 114 patients were treated. And they did 116 treatments. Two patients were treated twice.

MEMBER ZANZONICO: And I take it, then, that there's no preemptive inspections. In other words, unless the -

MS. PELKE: Oh, yes.

MEMBER ZANZONICO: There are routine -

MS. PELKE: Yes, there's routine inspections.

MEMBER ZANZONICO: And so the Philadelphia site had not been routinely inspected -

MS. PELKE: Yes, it had been routinely inspected.

MEMBER ZANZONICO: And it passed muster?

MS. PELKE: Yes.

MEMBER ZANZONICO: Okay.

MS. PELKE: They also had two previous medical events at Philadelphia. There was one in 2003, and one in 2005. Both involved the same authorized user.

The events in 2003 were such that a number of seeds - I'm going to say about half the seeds they

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were going to implant went into the bladder.

They were subsequently retracted from the bladder, and the written directive at the time was revised to indicate the number of seeds implanted.

That was determined to not be a medical event, because the authorized user revised the written directive before completion of the treatment.

And then there was a similar event that occurred in 2005. A number of seeds, again, were implanted - erroneously implanted into the bladder. And they were removed from the bladder, the written directive was revised, and that was, again, was determined not to be a medical event.

MEMBER ZANZONICO: Now, in the case where the - you say half the seeds were placed in the bladder, but it wasn't deemed a medical event.

Was that prescription redone after the initiation of the placement of the seeds?

I mean, it almost has a sound as if they were pulling a fast one to make it not a medical event just in terms of the paperwork.

MEMBER MATTMULLER: That's one interpretation.

MS. PELKE: Yes, that is one interpretation.

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MEMBER ZANZONICO: Sounds like the only interpretation.

MS. PELKE: But I will offer the fact that we're talking about primarily one authorized user was involved in most of these treatments. That individual knew enough when seeds got into the bladder, that that was a bad thing. And that when seeds got into the bladder, that meant that you had to report. So in 2003 and 2005, events were reported.

As a result of those seeds going into the bladder, what it appears to - what appears to have happened is the individual would - the authorized user would find the prostate and would - fearing the chance that seeds could get put into the bladder, just kind of by guess - maybe that's a bad word. I'm sure it's a bad word for the physicians, but would back off to ensure that seeds wouldn't go into the bladder.

And as a result, there was a lot of erratic placement of seeds that occurred because of the fear of putting seeds into the bladder.

MEMBER ZANZONICO: It just seems that one treatment plan you showed from the VA -

MS. PELKE: Yes.

MEMBER ZANZONICO: - was just mind-boggling.

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MR. LEWIS: That was done later, though. I think that we shouldn't get involved in speculating about what happened.

I think that we have our - Patty didn't mention in her talk, but we issued our Notice of Violation with seven violations.

MS. PELKE: Yes.

MR. LEWIS: And the VA replied to us with their corrective actions for each of those. And we've dispositioned those at this point, right?

MS. PELKE: Yes. We issued a Notice of Violation with the significant enforcement action in March of this year. And the VA has paid their civil penalty.

And as I said, we're dispositioning the results of our extended condition inspections. Those were the other -

MEMBER ZANZONICO: See, what I'm trying to understand is the chronology of the detection of the initial rash of mistreatments followed by continued mistreatments and how effective the NRC's oversight or intervention was in preventing further mistreatments.

Because at least the one you showed, that was not subtle. So, I mean, were there continuing MEs as obvious, as gross as that, even after the initial

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NRC intervention?

MS. PELKE: This is a retrospective look back after they suspected -

MEMBER ZANZONICO: So, everything is retro --

MS. PELKE: That's correct. Yes.

MR. LEWIS: These images were done by a panel forum to investigate the -

MEMBER ZANZONICO: Okay. So, correct me if I'm wrong. So, there was no intervention by the NRC while these 114 - over the course of these 114 treatments being delivered?

It was all after the fact?

MS. PELKE: In 2003, the VA received their master material license. At that time the VA was issued a permit for Philadelphia and was responsible for the routine inspection activities that occurred there.

Prior to that, the NRC responded to the medical event that was reported in 2003 -

MEMBER ZANZONICO: Right.

MS. PELKE: - and evaluated the circumstances. And we documented our findings there and went to the program office on the fact that the written directive said so many seeds to the prostate.

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However, in the OR the physician determined that a number of seeds were implanted into the bladder, retracted those seeds and revised the written directive.

Does this constitute a medical event?

And NRC, our Office of General Counsel, indicated, no, that did not constitute a medical event because a written directive had been revised.

MEMBER ZANZONICO: And then there were subsequent patients treated at the VA.

MS. PELKE: Yes.

MR. LEWIS: What I do think, Dr. Zanzonico, that we have the same question. Why didn't the NRC processes flush out this issue, or did they and we didn't act on it?

MEMBER ZANZONICO: Right. That's the underlying question.

MR. LEWIS: And we have in Patty's last tech slide, she talked about a lessons learned effort underway of four senior staff that were not - are knowledgeable of the issues, but weren't involved in this issue.

And their product is due to Jim Luehmann in the summertime. And I think we'll be able to have a discussion at the fall meeting about what they found

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and the path forward in terms of NRC's internal processes.

MEMBER ZANZONICO: Understood. We all have 20/20 hindsight. Just one last question.

I gather there was enhanced oversight of the other VA sites, but was there also enhanced oversight of the Hospital of UPenn site?

I mean, since they were the contractor, I would question that site as well.

MR. LEWIS: Yes.

MS. PELKE: Additional inspection has been done at University Hospital Pennsylvania. Pennsylvania became an Agreement State during this time. So, there are some activities that were still under regulation by NRC that we're looking at.

And then, yes, we informed the Agreement State through the process. And they were out with us on our exit so that they could be informed of what our findings were, as well as Region I.

MEMBER ZANZONICO: So, just one last question.

So, if there's a federal entity like the VA within an Agreement State, the federal entity, the VA, is still subject to NRC oversight even though it's within an Agreement State.

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But if it's affiliated with a nonfederal entity like UPenn, in this case, then it's subject to the Agreement State jurisdiction?

MS. PELKE: That's correct.

VICE CHAIR THOMADSEN: Dr. Suleiman.

MS. HOWE: That's not quite right.

MS. PELKE: Didn't you ask federal, if there's a federal entity?

MS. HOWE: If you're a federal facility, no matter who you align yourself with, you are still regulated by the NRC.

MEMBER ZANZONICO: Right.

MS. HOWE: Now, if you send your patients to the Agreement State hospital and they're treated at the Agreement State hospital, that Agreement State hospital is under the Agreement State.

But if your patients are treated in your hospital, they're your -

MEMBER ZANZONICO: Right. It just seems that there seems to be an opportunity for things to fall through the cracks there. If there were two different oversight agencies; one federal, one state, it just increases the possibility that something could fall through the cracks.

MS. HOWE: Well, they're not to oversight

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regulators at both sites.

MEMBER ZANZONICO: Right.

MS. HOWE: Each site has its own regulator.

MEMBER ZANZONICO: Right, but for their respected affiliated institutions.

MR. LEWIS: Well, the affiliated institution has its own license from the state.

MEMBER ZANZONICO: Right. Okay.

MR. LEWIS: So, when the physician is doing work at one, he's covered by a certain license.

MEMBER ZANZONICO: Right.

MR. LEWIS: When he's working at another, he's covered by the -

MEMBER ZANZONICO: Right. I'm just thinking out loud.

MR. LEWIS: But that is part of the problem that the contract -

MEMBER ZANZONICO: Yes, that may be part of the problem that needs to be addressed, yes.

MR. LEWIS: That's part of the issue here.

VICE CHAIR THOMADSEN: Dr. Suleiman.

MEMBER SULEIMAN: Yes, I want to get clear in my mind how the first event was picked up.

It was self-reported?

MS. PELKE: Yes.

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MEMBER SULEIMAN: Okay. And then when was the second event?

MS. PELKE: 2005. Self-reported as well.

MEMBER SULEIMAN: So, when did you realize you had an epidemic?

At what point did you realize this was a much more serious thing?

MS. PELKE: In 2008.

MEMBER SULEIMAN: And that was self-reported as well?

MS. PELKE: Yes, it was.

There was an assessment of the index case which happened in May of 2008. And as a result of that case, the NHPP required the licensee or Philadelphia to go back and look at the last ten. And when they looked at the last ten, there were some problem cases identified.

They asked them to expand that scope to about maybe 20 more. Then they suspended the program.

MEMBER SULEIMAN: Okay. So, who actually did the reporting to somebody within the VA at one of their various committees or -

MS. PELKE: The institution, Philadelphia, was responsible for looking at the events that occurred. They were reporting them to the National

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Health Physics Program, who in turn -

MEMBER SULEIMAN: No, no, no. I want all the way down to the patient. Okay.

Before it got into the institutional structure, who reported that there was a medical event?

Who made the decision that this Patient Number 2, Patient Number 3, the dose was inappropriate?

MR. LEWIS: In May of 2008?

MEMBER SULEIMAN: Okay.

MR. LEWIS: Is that your question?

MEMBER SULEIMAN: Was the physician who did it reported that?

MS. PELKE: No. It was another physician that came in and started to look at the patients that were treated there.

MEMBER SULEIMAN: And so they picked up on it symptomatically -

MS. PELKE: Yes.

MEMBER SULEIMAN: - that there was something not right?

MR. LEWIS: Not at first, but when they did the -

MEMBER SULEIMAN: Okay. Okay. Okay. So,

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it was another physician picking up on a colleague in the department.

MS. PELKE: Yes.

MR. WILLIAMS: Medical physicist.

MEMBER SULEIMAN: Was it a physicist?

VICE CHAIR THOMADSEN: Please use the microphone, please, and identify yourself.

MR. WILLIAMS: Harry Williams, Veteran's Health Administration.

A medical physicist was reviewing the patient treatment for the sentinel event in May of 2008, and identified that they had gotten the wrong seed activity. And that resulted in the initial report of a medical event.

And then after the on-site inspection by VHA, additional patient treatments were reviewed and additional medical events were identified.

Those additional medical events were not related to the circumstances of the sentinel event, but these reviews also were done by initially medical physicists from the university, but follow-up was by getting a contract medical physicist with prostate brachytherapy experience.

And so that was a rather independent review, as Patty was mentioning.

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MEMBER SULEIMAN: Okay. Okay. Thank you.

VICE CHAIR THOMADSEN: Dr. Fisher.

MEMBER FISHER: Darrell Fisher. Did the licensee contest any of the 97 medical events based on definition of "medical event"?

And if so, how is that handled by the NRC?

MS. PELKE: The VA sent us a letter in January indicating that they did not agree with the 97 medical events and that they wanted to - there was new criteria that they had established that was activity-based.

And they had proposed to retrospectively look back at all the patients that were treated at Philadelphia and use this activity-based criteria as opposed to the criteria that they had established to assess all these doses in June of 2008 that was dose-based.

And the NRC did not accept their proposal in January.

VICE CHAIR THOMADSEN: Other comments?

Dr. Welsh.

MEMBER WELSH: Just two comments in the maybe lessons learned or corrective action section.

Based on the illustrations that you've given us, the figures, which still to this day look

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very dramatic, but are not convincing to anybody who has done this because those figures, those cartoons could be drawn any way you want them to look.

If you want to make something look great, just circle the area that has the seeds in it and label that as the prostate. If you want to make something look bad, you circle another area far away from the seeds and say that's the prostate and it's a terrible implant.

So, just those cartoon illustrations still is not very convincing. But based on those illustrations assuming that they are indeed accurate, we have a process in which a written directive is written before and after a procedure.

It's possible that with the current policy, written directive could be rewritten to say that I didn't really want to give 144 gray, I wanted to give 70 gray. That's exactly what the patient got and there's no medical event, therefore.

So, that would be one conceivable way a physician could cover a medical event from being discovered.

So, it might be possible that - it might be appropriate that the pre-implant written directive should match the post-implant written directive with

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perhaps a note to specify why there is X percentage discrepancy, if there is one, just so that somebody could never say I intended to give 70 gray to this prostate and that's - therefore, it's not a medical event.

The second thing was suppose the physician does have an implant in which the penile bulb was implanted instead of the prostate, as in the very last illustration.

An unscrupulous physician could go back and during the post-implant dosimetry, perhaps, contour the area that had the seeds and say this is the prostate, it's got 144 gray just like I planned it would.

So, in the peer review process, you need to have somebody else look at that. Somebody with a lot of prostate anatomy experience to verify yea or nay whether or not this is truly the prostate that has been circled here.

Cannot be a medical physicist, in my opinion. Cannot be a radiation safety officer. Has to be a physician or anatomist who has fluency in prostate anatomy or in medical imaging.

Just two comments in the corrective action section.

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VICE CHAIR THOMADSEN: Can I ask who was it that did the contouring on those examples you gave?

MS. PELKE: The examples that I showed we received from the facility. And at the Cincinnati and I think Minneapolis, the two examples that I showed, those were done by the authorized user.

And for the Philadelphia examples that I showed you, those were not done by the authorized user. Those were done again after the treatment had occurred when they were retrospectively looking back and the physicist was working with - they brought in another physician that actually re-contoured all of the prostates.

And during that process, they took a look to see if there was a lot of variation between the physician they brought in to re-contour all the prostates and the original contours that were done by the authorized user.

And in most cases, I don't believe that there was a lot of variation. So, there was a lot of data that was generated as a result of the assessment that was done at Philadelphia.

VICE CHAIR THOMADSEN: But the contouring was not done by a physicist or radiation safety officer.

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MS. PELKE: No.

VICE CHAIR THOMADSEN: Thank you.

Dr. Howe.

MS. HOWE: I got a chance to look at most of the - a fair number of the re-contouring and the original ones.

The AU contoured his own images on the Day 1 CTs. And then the re-contoured ones were some on the Day 1, some he didn't re-contour because he thought the original physician was fine.

And then I looked to see because the question always comes up at the ACMUI as to, well, one person draws them one way, another person draws them another way.

So, they had two physicians, the authorized user, the original authorized user, and then the second individual. And I looked at the ones that were re-contoured to see if they made a difference. There were about 14.

And those that made a difference, there was almost an equal number between those that became medical events and those that didn't become medical events. Those were the ones on the edge. But for the most part, these images were contoured by the original authorized user.

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So, it was not a question of one physician drawing the circles over here and another physician drawing the circles over there.

And we pretty much went with the Day 1 CTs because the authorized user did contour those images. And he, the authorized user, is, for all intents and purposes, the gold standard unless you really missed the anatomy.

VICE CHAIR THOMADSEN: Thank you for that clarification.

Other questions?

MS. LE: I want to commend you, Patty, on taking a look at what bigger lessons can be learned from this.

And I always in my training of residents and so on in trying to describe the master license like the VA hospital, say, you know, it's somewhat like an Agreement State license or Agreement State where they self-regulate their own organization.

So, I'll look forward to hearing how NRC applies those lessons to Agreement State oversight, and especially in this time of economic challenges with a lot of state programs.

And so I commend you on looking at that and look forward to hearing what your group's thoughts

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are on that.

MS. PELKE: Well, I know that the region has some thoughts, but certainly the program office has been carrying the water on that so that we're going to be looking much broadly. Because we have the VAs master material license, of course, but we also have - the Navy and the Air Force have master material license and their programs are kind of dramatically different.

The VA is all medical, primarily. Navy and Air Force may have a little bit of medical, but they also have different primary uses.

VICE CHAIR THOMADSEN: Dr. Zelac, did you have a comment?

MR. ZELAC: Yes, I do.

It's probably worth knowing at this point that while there is a group that is in fact looking at policies and procedures and things that might be done differently based on these findings, the underlying cause, if you will, of this current issue is the fact that the rule had a flaw, and still does have a flaw.

It was intended for use in one purpose, and as you pointed out, it can be used for other purposes as well, perhaps.

That flaw, in fact, is being removed and

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timelines for making these determinations are being inserted, and that is part of the re-proposed rule. And, in fact, it's part of the proposed rule upon which the ACMUI commented. And the re-proposed rule upon which some of the members have already commented.

So, from my perspective, the real problem, in fact, has already been addressed. And the additional look at what is being done with respect to policies and procedures may add additional enhancements to this entire process.

MR. LEWIS: Dr. Thomadsen.

VICE CHAIR THOMADSEN: Yes.

MR. LEWIS: I would just like to add a thought to Ron, to Dr. Zelac.

I do agree that the medical events rule is in need of revision. But the fundamental problem in this case is the rule that existed was not complied with. And that was by the licensee and that's evidenced in our violations and the response to the violations and the civil penalty.

I think that Ron meant that, but maybe his statement could be misinterpreted to say that the NRC was the problem. But we don't have that position at all.

VICE CHAIR THOMADSEN: Dr. Welsh.

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MEMBER WELSH: Just I would like to ask Dr. Zelac if he could be specific in what you meant by there was a flaw, just so that I'm -

MR. ZELAC: Sure.

MEMBER WELSH: - understanding completely and correctly.

MR. ZELAC: Absolutely.

The current regulation with respect to the written directive, calls in permitted implants that there be two pieces of information. That which is entered before the procedure begins, and that which is entered after the procedure is - the implant itself is done, but the procedure is not totally completed.

In both of those parts, first there is a specification of dose. There is also lacking a specification of when the procedure is completed.

The proposed rule and the re-proposed rule both insert a time factor so that it's perfectly clear and achievable for completion of the written directive.

And secondly, the re-proposed rule does not permit any modifications of what was put in there initially before the procedure began, but simply asks for completion by entering in; first, the physician; second, the date; third, the total source strength

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implanted.

MEMBER WELSH: Thanks for the clarification.

MR. POTTERS: Hi. I'm Louis Potters. I'm a radiation oncologist. I was invited to come and - and so if there are any questions, I'm a brachytherapist. I - my whole career has been in prostate brachytherapy. And to the extent that this potentially represents an outlier, the issue is of throwing the baby out with the bathwater, but clearly this represents an ethical lapse on the part of these physicians.

And as noted in the VA report, there was also a disconnect of their ability to review the post-plans. Which, in essence, would have provided them the feedback that they were not doing perhaps as well as they would have liked. So, perhaps you want to comment to the Committee on that.

And then, secondly, you commented that the NRC did not accept the activity-based, but changes that the panel had suggested as compared to the D-90. And I just wanted to know if anyone from the NRC or if you could comment on why that wasn't accepted.

MS. PELKE: The ability to do their post-plans at the Philadelphia VA was impacted for about a

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year. They had computer connectivity issues.

And during that period of time, they continued to treat patients even though they couldn't generate post-plans.

So, they would prescribe a dose, but there was no method for them to verify that the dose prescribed was delivered as intended.

I would also note that on the written directives that we looked at for Philadelphia, 160 gray was the prescribed dose. And in all cases, 160 gray with the exception of a different authorized user who prescribed 145 gray, each and every time was delivering 160 gray when, in fact, I don't know how you get a hundred percent a hundred percent of the time.

And then as far as the - that's the situation that occurred there. We looked at that issue specifically, the connectivity issue, the fact that whether or not the facilities could generate post-plans, that was a primary focus of the extended condition inspections the NRC conducted.

They with the exception of one other facility, Jackson, we did not see the connectivity issue impact their ability to generate post-plans and determine doses as dramatically as it had at

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Philadelphia and also another facility they had in Jackson.

As far as the retrospective look at the doses delivered at Philadelphia using a new criteria that the VA proposed to use with the NRC in January that was activity-based, that doesn't meet the requirements of the current rule. The current rule are dose-based. And the NRC did not accept and reject it, actually, that proposal.

Also, the VA told us the criteria they were going to use when they assessed all these doses. They started their dose assessment in July of 2008. We continue to monitor the progress of that dose assessment. In fact, that was the focus of our inspection in June of 2009.

And when we got on site at Philadelphia, it was myself, two other inspectors from Region III, and also Donna-Beth Howe was out with us as well to look at what the licensee or the permittee had been generating.

And they had generated an awful lot of data, but they didn't seem to have any process in place to systematically and methodically assess the doses and the information that they were generating.

And we had not - there was no discussion

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of we were coming up with a new criteria that's activity-based. There was no discussion about that until the VA talked about it at the Pre-Decisional Enforcement Conference that we had in December and presented their proposal.

Actually, their national director of radiation oncology, Dr. Hagen, made a fairly lengthy presentation during that conference. And then the VA put it in writing in January, and then the NRC rejected it in writing back to the VA.

MR. LEWIS: And I would just add that the technical basis for the new methodology was not provided. It was just a request to use the new methodology. That was part of our rejection as well.

But, moreover, even if we had accepted the new methodology, all of the medical events would not have been cleared. There would have still been a substantial number.

And I don't want to speculate, but our violation - it wouldn't have addressed the root causes that created our -

MR. POTTERS: No, and my asking of the question is - I'm sorry to interrupt, but my asking of the question was not necessarily in any sort of defense at all of the VA, but in terms of potential

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rule-making that the NRC or the ACMUI will be doing.

VICE CHAIR THOMADSEN: I think that may be part of the next discussion that we're going to be having here.

Dr. Welsh.

MEMBER WELSH: In follow-up to Dr. Potter's comments as long as we have an expert in prostate brachytherapy, I thought we might want to take advantage of this.

Because at this committee, we have discussed at one time the concept of making post-implant dosimetry not a nice option that shows that you have a good quality program. And if you don't do it like the VA, no big deal.

Should we consider making post-implant dosimetry a mandatory component?

And if so, is that a very difficult thing to enforce from a regulatory perspective?

So, first, I think I want Dr. Potters' opinion on whether or not in 2010 it should be the new standard, and then whether it should be regulated.

MR. POTTERS: You're putting me on the hot seat.

(Laughter.)

MR. POTTERS: I've been doing prostate seed

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implants since 1992. Post-implant CT-based analysis sort of came in around 1994-`95, using some relatively rudimentary three-dimensional treatment planning systems essentially used for external-beam delivery. And then they became a little bit more sophisticated in `97-`98.

I've been doing post-implant analysis of all my patients from 1995 on. And I use it as a learning tool for myself, I use it for trainees as a learning tool.

And the issue of dose is an important one because the intent is to achieve a minimum dose by doing the implant. And in essence, anybody can achieve a minimum dose if you overdose the prostate.

So, if all you're doing is just measuring a dose and want to achieve a certain minimum distribution of that throughout the target, whether the target is the prostate or the prostate with a small margin, you can do that quite easily.

So, the art of implantation is really to lower your hot spots, but still achieve your minimum dose requirements.

And so part of the peer, part of the chart rounds, part of your M&M within any department is to review your post-plans and take the heat from your

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colleagues and were you a little bit too hot here, were you a little bit too cold there.

Because even achieving dose minimums and lowering hot spots still doesn't take away from the heterogeneity of the dose throughout the prostate itself.

And so there's a lot of moving pieces, but clearly I think as Dr. Welsh was suggesting, I think, and as the ACR guidelines have recommended that post-implant dose - and the American Brachytherapy Society have all recommended that post-implant dosimetry be performed a hundred percent of the time.

VICE CHAIR THOMADSEN: Thank you for your comment.

Dr. Welsh, to whom were you addressing the second half of your question?

MEMBER WELSH: Well, I suppose any of the NRC staff. And I would like to just say that I was not suggesting that the regulation be in terms of evaluating things like D-90 on the post-implant dosimetry, but just perhaps a statement that 2010-2011 in order to do prostate brachytherapy using byproduct material, permanent implants, part of the program should include this step of post-implant dosimetry so that things like 90 some odd events from a single

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facility never can happen again.

VICE CHAIR THOMDSEN: So, I see Dr. Zelac has something to say.

MR. ZELAC: I'm very anxious to say something here.

This, in fact, brings us back to the discussion that we almost had this morning when we were talking about the Part 35 changes that are in place and coming up.

The proposed rule that was published for public comment and upon which we received comment, and which progress towards a final rule was held up on because of the VA, has switched from a dose-based criteria to totally - well, not entirely, but certainly in terms of the target to an activity-based criteria, a source-strength-based criteria.

Based on what occurred at the VA and the findings there, the re-proposed rule, and this is the principal reason for having the re-proposed rule, brings back in a dose-based criteria to the target.

That means that we now have in the written directive pre-implantation, a stated, if you will, target dose, intended dose, to the site.

The medical event criteria are based, and will continue to be based, on dose in part. Meaning

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that in order to make a determination as to whether or not there is a medical event, it's an obligation on the part of the licensee to determine what the resultant dose is in fact to the treatment site.

You can't make the determination that you haven't a medical event, if you don't make a determination of what the dose to the treatment is as compared to what had been stated in the pre-implantation written directive which cannot be changed.

So, what I'm basically saying is that what you are suggesting is appropriate, in fact, is already built into the re-proposed rule, and will appear if it goes forward as currently intended.

VICE CHAIR THOMADSEN: Thank you, Dr. Zelac.

Dr. Howe.

MS. HOWE: Our regulations are performance-based. And we currently have a requirement in 35.41, which is procedures for administrations requiring written directives.

And it says you will have developed, implement and maintain written procedures to provide high confidence. And "high confidence" is an important word here.

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And it goes down to say that as a minimum, your procedures will include. And one of the items is verifying that the administration is in accordance with the treatment plan and applicable in the written directive.

So, we have a performance standard that says licensees need to verify what is administered is in accordance with treatment plan written directives.

We aren't as specific as to say how you do it, but we do have an overall performance requirement right now in place that says you do have to verify. And I thought that was an important point to bring to your attention.

VICE CHAIR THOMADSEN: Thank you, Dr. Howe.

Other comments?

MR. LOHR: I'm Ed Lohr from the rule-making.

I just want to caution everybody that this is a public meeting, and the re-proposed rule is pre-decisional and not available to the public and should not be discussed in this forum.

VICE CHAIR THOMADSEN: Thank you for that clarification. Please watch yourselves.

Other comments?

MR. EINBERG: I'd like to take this

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opportunity and thank Dr. Potters for joining us at the request of the Committee, and Dr. Malmud and the Subcommittee. It was felt that we needed to supplement the expertise in the area of prostate brachytherapy.

Dr. Potters is an expert in the area. He comes from Hofstra University, the School of Medicine. And he is the chairman of the Radiation Medicine Department at the North Shore University Hospital there. And so we welcome you and we look for your input there.

And right now as you all know, we are short one radiation oncologist, and this is one of the reasons we needed to supplement our expertise in this area.

VICE CHAIR THOMADSEN: Thank you very much for that.

Other comments or questions dealing with this presentation?

If not, we should move into our next presentation which is related. This is by Dr. Welsh. A report from the Permanent Implant Brachytherapy Subcommittee.

(Off-the record comments.)

VICE CHAIR THOMADSEN: I think that means

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that you are safe to proceed, Dr. Welsh.

MEMBER WELSH: I hope so, because I didn't want to say anything that's out of line. And I do know that a lot of what I'm going to discuss here does talk about proposed rules, re-proposed rules, possibly future proposed -

VICE CHAIR THOMADSEN: Can you hold on one moment?

Can you hear Dr. Welsh in the back?

I didn't think so.

Is there a way that we can have the volume turned up?

MEMBER WELSH: Is that better?

VICE CHAIR THOMADSEN: I'm having a hard time hearing Dr. Welsh.

MS. COCKERHAM: Theron, could you turn the volume up on the mic for the presenter?

VICE CHAIR THOMADSEN: Try something.

MEMBER WELSH: Hello.

VICE CHAIR THOMADSEN: Can you hear him well now?

SPEAKER: Keep talking.

VICE CHAIR THOMADSEN: I think we're probably okay.

MEMBER WELSH: Can you hear me?

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VICE CHAIR THOMADSEN: Yes. Okay. Thank you.

MEMBER WELSH: Thank you, Dr. Thomadsen, and I appreciate the discussion we just had.

And I would start by saying that it's very useful information and it will not affect or change the opinions of my own presentation here.

This subcommittee was charged with creating a draft, providing recommendations on regulatory changes or improvements to the NRC's processes for permanent implant brachytherapy programs as an outgrowth of the investigation of the Department of Veteran Affairs' medical events.

In other words, does what we just heard about influence our opinions, our opinions on the 2008 report that was produced by the ACMUI Permanent Implant Brachytherapy Rule-Making Subcommittee?

And the answer is it generally still remains valid.

The medical events within the Department of Medical Affairs involving permanent prostate brachytherapy do not generally alter the previous subcommittee recommendations in any significant form or fashion.

In fact, in some ways we could make the

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argument that they confirm the validity of that report.

A couple of areas that might warrant a little bit of discussion, first 10 CFR 35.3045(a)(2)(ii) was discussed in the previous report. And in that report, we suggested that modern concepts of GTV, gross target volume; clinical target volume, CTV; and planning target volume, PTV, be incorporated into the definition of what was previously just called the treatment site and any new rules as described in the 2008 subcommittee report.

If we don't use modern terminology, this could lead to an excess of perfectly acceptable medical implants being mislabeled as medical events simply because we're not talking about the same thing.

So, it was recommended that modern terminology be used. And it appears that in the proposal, although the terms "GTV," "CTV" and "PTV" are not explicitly used, the concepts contained are fully conveyed.

Our subcommittee felt that there were some sections that deserved further scrutiny. Specifically 35.3045(a)(1), (a)(2)(v) and (a)(2)(vi).

Starting with (a)(1), it reads a dose that differs from the prescribed dose or dose that would

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have resulted from the prescribed dosage by more than five rem effective dose equivalent, 50 rem to an organ or tissue or 50 rem shallow dose equivalent to the skin and, and it's an important and, the following three criteria.

I'm not going to go into much detail on this particular slide because this particular section does not include permanent prostate brachytherapy. And in addition to that, it includes a Boolean and with the subsequent A, B and C not being fully appropriate.

Therefore, no suggested changes were made for 3045 (a)(1), but I throw this slide in here because it is relevant to subsequent discussion.

As far as 3045 (a)(2)(v), this is relevant for cases in which a dose exceeds five rem effective dose equivalent, 50 rem to an organ or tissue, 50 rem shallow dose equivalent to the skin as a result of wrong isotope, wrong route of administration, wrong mode of treatment, a leaking source, administration to the wrong patient.

In these situations, the subcommittee felt that classification as a medical event is perfectly valid. And, therefore, no changes in the proposed 3045 (a)(2)(v) are necessary.

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But (a)(2)(iv) does deal with permanent prostate brachytherapy, and it reads a dose to the skin or organ or tissue other than the treatment site exceeding by 50 rem and by 50 percent or more the dose expected to that site if the administration had been carried out as specified in the pre-implantation written directive.

The subcommittee would like to reconsider the 50 rem 50 percent dose differences here. 500 rem. These minor discrepancies might be quite possible when one is considering organs that are expected to get very low doses yet still be medically acceptable because the implant was done, the goal of curing the patient of the cancer has been achieved, and there are minimal to no side effects. So, it could be very medically inconsequential.

There is no volume or area specified here, and that can lead to further confusion. So, it may be appropriate to drop this part of the medical event definition.

Perhaps that Boolean and that was in the slide I showed earlier, would be one way of keeping this section in here and making it appropriate and acceptable.

Another topic of conversation within our

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subcommittee was the concept of will one rule fit all?

For example, some of the newer permanent brachytherapy procedures could be perfectly medically acceptable and effective. In other words, an effective cancer treatment with minimal adverse effects. And as an example, the mesh implant for lung cancer. Brachymesh is one of the examples.

Because of the wording in 3045 (a)(2)(ii), some perfectly good procedures of this type could wind up classified as medical events.

A suggested change made in 2008 by the subcommittee was total source strength implanted outside the treatment site, including the gross tumor, clinical target volume, plus a variable planning margin as defined by the authorized user exceeding 20 percent of the source strength documented in the written directive.

So, if we change dose or activity to source strength in this context, some members of the subcommittee felt that this might overcome some of the issues that could arise with a newer brachytherapy procedure such as the lung permanent implant by sewn-in meshes.

But it remains possible that despite such wording, some medically acceptable permanent

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brachytherapy procedures could still wind up inappropriately classified as medical events.

It was felt that this is unlikely if the present use for absorb dose for definition of a medical event is replaced by the proposed use of activity for total source strength for defining medical events.

But there was still some discussion in the subcommittee, and therefore there was finally discussion about the possibility of creating separate categories for permanent implant brachytherapy.

As unpleasant as it might be to have more categories to regulate, should permanent prostate brachytherapy with its advanced level of sophistication and technology be separated from things like lung mesh brachytherapy?

That question was just brought up, not resolved, and that's where I will end the conversation and turn it back over to you, Chairman Thomadsen.

VICE CHAIR THOMADSEN: Thank you very much, Dr. Welsh.

Do we have questions for Dr. Welsh from the Committee?

Dr. Suleiman.

MEMBER SULEIMAN: I've got my FDA hat here.

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These are medical events. And so if the radiation was less than five rem or 50 rem, the second category and so you haven't crossed the radiation threshold, but you gave the wrong drug, you gave the wrong administration. So, it was a miss in administration. By our terminology, it wouldn't be reported.

It would have to have exceeded the five rem or 50 rem dose threshold.

MEMBER WELSH: I think that's how it is written and -

MEMBER SULEIMAN: So, how would we capture -

VICE CHAIR THOMADSEN: I believe that any of those things that you were saying, the wrong isotope, leaking source, wrong modality all would trigger -

MEMBER WELSH: Oh, okay.

VICE CHAIR THOMADSEN: - a medical event.

MEMBER WELSH: Okay.

VICE CHAIR THOMADSEN: That's not new. Those are all -

MEMBER WELSH: I misunderstood.

VICE CHAIR THOMADSEN: If you put it in the wrong patient, that's still -

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MEMBER WELSH: Yes.

VICE CHAIR THOMADSEN: Of course that's a wrong dose location, if nothing else.

Dr. Howe.

MS. HOWE: You didn't have to trigger the five rem or the 50 percent.

VICE CHAIR THOMADSEN: Can you speak a little bit louder, please?

MS. HOWE: You didn't have to trigger the dose threshold of five rem or 50 percent of what would have been given if it had been given correctly, before you can get to a medical event.

In 2002, we put a dose threshold on our medical events.

VICE CHAIR THOMADSEN: I stand corrected.

MEMBER WELSH: So then for clarification and my own edification, if you're implanting prostate brachytherapy or any type of byproduct material use and you realized at the last second that this is the wrong patient, but the patient from what you have done received less than 50 rem, it wouldn't -

MEMBER SULEIMAN: How would that be picked up otherwise?

Forget the NRC. In the hospital, in medical care, you give the wrong drug to the - you

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can't give the wrong drug to the right patient. You gave it to the patient who shouldn't be getting it.

How is that picked up in terms of a safety issue?

MEMBER WELSH: The patient could say, what are you doing to me?

MEMBER SULEIMAN: I mean professionally in terms of -

MR. POTTERS: We do intraoperative time-out. I mean, we bring the patient to the operating room for the procedure and there is a written form of - a verification.

So, at least in the way that I do it, there's written verification of isotope and what my intended prescribed dose is. That's my own internal sort of QA, but at the same time the hospital policy is to do a time-out.

We introduce the patient, his date of birth. We introduce the procedure, the dose and the isotope that's being delivered. The anesthesiologist discusses his anesthesia and allergies and the case proceeds.

MEMBER SULEIMAN: I mean, it should be picked up as a legitimate medical error so you don't repeat the mistake later on.

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MEMBER WELSH: In reality, the wrong patient is probably something that is exceedingly rare. But wrong site as in gamma knife treatments is not at all uncommon, unfortunately.

But there are in Dr. Potters' method, there is routinely used time-out procedures to verify that what you're about to do and to who you're about to do this to are appropriate and correct.

MEMBER GUIBERTEAU: In many hospitals to satisfy the Joint Commission there are committees, PIC committees, that these are reported to on a routine basis, I mean, so that you can track them.

MEMBER SULEIMAN: I mean, I'm aware of the multiple regulatory oversight that exists in society. I mean, the hospitals, the professionals, the licensed physicians, the NRC, the FDA, the companies and so on, but I just want to make sure this doesn't, you know, you don't want the NRC necessarily to pick it up if you consider that the radiation level is an acceptable level.

But the fact is if they've been given the wrong drug, it's an issue.

VICE CHAIR THOMADSEN: Dr. Zelac.

MR. ZELAC: Yes. I think it's important to keep in mind that the medial event criteria here

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applies to all medical use, not simply implants.

And the reason that there is a dose threshold for reporting a medical event is to eliminate the reporting of diagnostic doses to the wrong patients for which these thresholds would not be met, but you would in fact be reporting what amounts to therapeutic doses involving the wrong patient, etcetera because, first, that occurred, whatever the condition is, and, secondly, the dose threshold has been passed.

So, keep in mind that these thresholds are here for a specific reason to essentially only get reports of things that may have some consequences in terms of our being concerned about the protocols and procedures in place which led to this occurrence.

VICE CHAIR THOMADSEN: Thank you, Dr. Zelac.

Yes, Dr. Zanzonico.

MEMBER ZANZONICO: I may be misunderstanding something completely.

Dr. Welsh, are you recommending that for permanent implant brachytherapy, that dose-based thresholds for medical event be eliminated altogether and that they be based exclusively on activity, on implanted activity or implantation of the incorrect

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activity?

MEMBER WELSH: This was in the 2008 proposal that there be a shift from dose to activity or source strength.

MEMBER ZANZONICO: But doesn't that introduce a scenario, and it may be unrealistic, where the proper total activity is implanted, but just grossly misplaced?

Shouldn't that qualify as an ME?

MEMBER WELSH: Well, it has to be placed in the correct location. And there are a set of criteria for what is - that becomes unacceptable if too many seeds are too far away from your target. It would be classified as a medical event.

MEMBER ZANZONICO: Okay. So, my only point is this is, for lack of a better term, a geometry component as well as an activity to -

MEMBER WELSH: Yes, of course.

MEMBER ZANZONICO: - an ME.

MEMBER WELSH: Yes.

MEMBER ZANZONICO: All right.

VICE CHAIR THOMADSEN: Dr. Suleiman.

MEMBER SULEIMAN: I'm going to share how I think.

If you're doing therapy, you start out

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with the radiation absorb dose you want to deliver to the target. I won't get anymore prescriptive of that.

Then you work backward and figure out how much activity you're going to need to derive that radiation absorb dose.

So, you really can't have one without the other. If you've got the activity, it's got to be based on the target -

MEMBER WELSH: Correct.

MEMBER SULEIMAN: - absorb dose.

So, why shouldn't that information be available somewhere showing that one is related to the other or one's been calculated with - what I'm concerned about is - and I see this, I see this a lot where people get used to a certain amount of activity and then administer a certain amount of activity being a little bit more flippant. I can't think of a better word.

The patient body and anatomy are not always considered in a lot of therapeutic applications. I'm not talking about brachytherapy here, but I'm thinking more on a larger scale.

Is that a step in the wrong direction?

MEMBER WELSH: I think sticking with prostate brachytherapy, not all permanent implant

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brachytherapy, mind you, for prostate specifically we have a large body of data supporting the conventional dose is around 145 gray. So, this is typically what the prescription written directive will aim for.

Then we also have established criteria that have been authored by experts such as Dr. Potters about D-90, V-90, V-100 to help you assess whether or not the implant is rightly to achieve the stated goals.

One of the serious problems and limitations in prostate brachytherapy is that you may have a volume based on ultrasound or CT, volume is X. But as soon as you start poking that prostate gland with needles and implanting foreign bodies into it, the Volume X becomes 1.4X maybe. 40 percent larger.

And, therefore, if you were to try to determine the dose on target that is 140 percent the initial volume, you could wind up with an underestimate of what the dose truly is because your isotope will decay over time depending on which one you're using.

If it's iodine-125, for example, and a 60-day half-life, the edema and subsequent resolution of that edema might not be very consequential to the overall dose which is measured in months, used with a

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- is going to be determined by an isotope that has half-life of a couple of months.

But if you were to assess your post-implant dosimetry on Day 2, you could wind up with something that would suggest that the dose is inadequate.

And by some of the previous definitions or other people's definitions, you could wind up with an inadequate or believed to have an inadequate implant because your D-90 is low.

And it's not because in reality the implant was done technically improperly or because it's not going to be medically successful or it's going to have more side effects. It's simply because the prostate gland undergoes edema with subsequent resolution.

And, therefore, you do have to evaluate - in an ideal world, you would evaluate dose as a function of time and a dose - and a function of volume and it would be a complicated multi-variable partial differential equation.

MEMBER SULEIMAN: Okay. I understand that.

In other words, you make a first estimate based on some volume. You have to.

MEMBER WELSH: That is -

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MEMBER SULEIMAN: Knowing full well that the uncertainty, the volume is going to change for a multitude of reasons.

MEMBER WELSH: Activity will never change, but the -

MEMBER SULEIMAN: Right, right.

MEMBER WELSH: - dose might change. You get the illusion of dose being different.

MEMBER SULEIMAN: Yes.

VICE CHAIR THOMADSEN: Mr. Lewis.

MR. LEWIS: Could I ask Dr. Welsh or Dr. Potters could you explain that a little more to me?

Because what I heard, and I may be misconceiving what you intended, but in the beginning of what you said, you said that the prescribed dose is 145 gray. And we have good understanding of how many seeds would achieve that if placed properly.

In the middle part of what you said, I thought I heard you say that there's swelling and things that make the actual dose different based on seed placement.

So, to me it sounds like in your logic you had contradictory statements.

MEMBER WELSH: So, if we say that 145 gray is the goal, we can start with that. But if we assess

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the dose at Day 2, Day 3 when you still have significant edema, you could have the illusion that you're going to wind up with significantly less dose because your volume is maybe 40, 50 percent larger than on Day 1.

And if your estimated dose to the prostate was based on the volume on Day 1 and now you have a target that is 40, 50 percent larger, well, if dose is defined as energy per unit volume or energy per unit mass, which is related to volume by definition if your denominator is different, your calculation for dose is going to be different.

But in reality, what happens is that the edema comes and goes, whereas the isotope is going to continue to deliver radiation over a prolonged period of time.

For iodine-125, it's less of an issue than it is for palladium-103 and less of an issue for Cesium-131 because of this, but these are things that clinicians and physicists must take into account if we aim to truly be accurate in dose delivery.

From a clinical perspective, we know that if you aim to give 145 gray and you have a D-90 that is up there in 95 percent, chances are that you're going to have a good outcome.

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MR. POTTERS: I think another way of looking at it is this: Is that the half-life of edema, so to speak, is anywhere between two and three weeks. The effective treatment of iodine at 60-day half-life is really three half-lifes.

And so you can still deliver your 145 over the protracted period of time. If you do your post-implant analysis on Day 1 and 20, 30 percent of the patients will have measurable edema anywhere between 10, 40 percent, then the honest physician contouring that prostate will identify an underdosed gland.

Whereas if you repeat that CT in a month and redo the exact same contouring and dosimetric analysis, you'll find that actually what you've achieved is the 145.

And with palladium with a shorter half-life, it's more of a factor because one could make a theoretical argument as to whether or not you need to compensate for those patients who develop intraoperative edema or postoperative edema to account for it.

But that's more of a theoretical than a true clinical in the field type of argument, but I think that helps explain it.

MR. LEWIS: If I could just -

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VICE CHAIR THOMADSEN: Yes, Mr. Lewis.

MR. LEWIS: And I'm not trying to be difficult. I'm trying to learn.

MR. POTTERS: No, that's okay.

MR. LEWIS: Isn't that making the case that it's the dose that matters and not the activity implanted that matters?

So, why would the regulation not focus on the dose?

MR. POTTERS: Because the dose is still a component of - I think as you were saying, there's still a component of activity per cc to achieve that dose.

MEMBER SULEIMAN: The activity you can control.

MR. POTTERS: Right.

MEMBER SULEIMAN: You set it as a target. You're going to administer X amount of activity. That's a given. You can measure it. You're responsible.

The volume, the edema, the changing dimensions, you really don't have control over that. So, to penalize the user because the volume is either changing ten percent or 40 percent over a 30-day period of time, to me that's an inherent amount of

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uncertainty associated with the practice of medicine.

That's just - you can't get better than that. So, you're talking about maybe plus or minus 20 percent if you take half of 140 and -

MR. POTTERS: And if you think of activity - there's actually two points I want to make. But the first is that if you think of activity per cc and you go back to the VA where the actual sentinel event was the ordering of the wrong activity of iodine, if the radiation oncologist and the operating physicist said, oops, we ordered, you know, whatever it was, .3 millicuries instead of .5 millicuries, and as long as there was enough total activity that was there, you could have avoided that sentinel event.

MEMBER SULEIMAN: So, when you do your initial estimate, do you assume it's going to expand by 10 or 20 or 40?

MR. POTTERS: No, I don't.

We published a paper to that effect almost eight or nine years ago where we looked at the different phases of the procedure and where edema impacts and what the theoretical difference is in dose and should you account for it, meaning an intraoperative type of nomogram to account for the changes in edema.

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And it turned out to be relatively inconsequential in the long run, and clinically it doesn't - it doesn't - the other point is in terms of dose is so I predicated, you know, a little bit earlier that the honest contourer will identify an underdose if there's a lot of edema if you're doing your plan on Day 1.

The problem with dose is that you - and I'm not saying from an honest to dishonest, but you can have - you have - these seeds create artifact on CT. The delineation of the capsule of the prostate is not always clear. And so you can get the guy who contours, sort of connecting the dots type of contour, which is going to give you a perfect D-90.

So, now you have the honest guy who contours and spends a lot of time, plays with artifact, contours the prostate, shows underdose.

The guy who is sort of the connect the dot from artifact to artifact type contourer is going to show an appropriate dose.

And so that's one of the reasons why dose in and of itself is variable.

VICE CHAIR THOMADSEN: Dr. Welsh.

MEMBER WELSH: So, in essence, to also answer your question, implanted activity is a

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constant. Calculation, calculated total dose is actually a variable and you can come up with different answers Day 1, Day 10, Day 20, Day 50.

And that calculated total dose is a function of volume, which in turn is a function of time. And that's why I think most of us are not in favor of using calculated total dose or things like D-90 for a criteria of medical events.

MS. LE: I was just going to ask Dr. Potters the fact that you don't want to do dose on a Day-2 scan of a prostate, you may still want to do a Day-2 scan or later that one-day scan to see that you have the number of seeds where you think you had placed the seeds; is that correct?

I mean, would you -

MR. POTTERS: So, I -

MS. LE: Instead of dose, you'd be looking for the number of seeds and the activity and how they were implanted.

MR. POTTERS: Well, we x-ray patients before they're discharged because of the -

MS. LE: Right.

MR. POTTERS: - need to account for all of the seeds.

MS. LE: For the seeds.

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MR. POTTERS: And I think it's clear to this committee that there is migration. So, one or two seeds may migrate via vasculature into the pelvic plexis or into the lung.

So, we x-ray patients before they're discharged, count the seeds.

MS. LE: Right. And that was my point is that's easy to count as going by the activity as opposed to using that necessarily as a dose determination.

MR. POTTERS: Yes.

MS. LE: It's to verify your seed placements and so on.

MR. POTTERS: Yes.

MS. LE: Another reason why you would want to go activity versus the dose.

MR. POTTERS: Correct me if I'm wrong, but you're still going to have the 20 percent rule.

MS. LE: Right.

MR. POTTERS: So, if 20 percent of the seeds go someplace else outside of the target, that's still going to be a reportable issue.

So, the 50 percent or the 50 of a hundred seeds that wind up in a bladder is still going to become a reportable event.

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And then I would only echo Dr. Welsh's comments regarding how we define "treatment site" versus what we would call the gross tumor volume or the gross target volume because there are concepts now with very low-risk prostate cancer of doing focal brachytherapy where in fact I would only implant a third or a quarter of the prostate and not the whole prostate, or in a patient that has a suggestion of a T3 tumor with invasion of the seminal vesicles to include within the target 25, 30 percent of the seminal vesicles.

So, it's important that any rule-making that's done define not necessarily the treatment site, per se, but the definition of the authorized user's volume that he intends to treat.

VICE CHAIR THOMADSEN: Dr. Suleiman.

MEMBER SULEIMAN: Is 20 percent too restrictive?

MEMBER WELSH: I think that most of us felt that that was the appropriate figure. We discussed it here. It's been discussed with ASTRO, ACRO, American Brachytherapy Society and others. And I think at this point, the 20 percent figure was considered acceptable.

MR. POTTERS: You're trying to throw us a

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bone, but I'm fine with 20 percent. I mean, I wouldn't -

MEMBER SULEIMAN: No, I'm asking you. I have -

MR. POTTERS: It shouldn't be 10 percent, you know.

MEMBER SULEIMAN: When people tell me they can get accuracy to five percent, I say absolutely impossible because maybe if it was a plastic person and you could target, but people react differently.

MR. POTTERS: Right.

MEMBER SULEIMAN: So, I always try to get an upper estimate, 20, 30, 40 percent, yeah.

MR. LEWIS: I think I would like to, on that note, just -- I think the premise behind your question is there might be non-clinically significant issues at 20 percent. And I just wanted to say, and Dr. Howe taught me this, so if I don't get it right, she can chime in. But there is a logic that we would have a medical event threshold below the clinically significant level, the same logic that we have reporting requirements in other parts of the regulation that aren't always over-exposures of occupational dose. The idea here is that we want the licensee management, and the NRC to be looking at

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trends, and having peer reviews and things occurring before the clinically significant event were to occur. So, all medical events don't, necessarily, need to be clinically significant from that logical point of view. And I think that's the basis, one of the bases in our current regulatory approach. So, I just offer that, because that was discussed, and I think that's the premise behind Dr. Suleiman's remarks.

VICE CHAIR THOMADSEN: And contrary to that, you could with less than 20 percent, or have something that's quite significant.

MR. LEWIS: Yes.

VICE CHAIR THOMADSEN: Dr. Fisher.

MEMBER FISHER: In 2005, this Committee recommended that the 20 percent criterion for defining a medical event would be more reasonable if it were, instead, set at the 50 percent variance level, rather than 20 percent, for a total source strength administered, since the 20 percent dose threshold is comparable to the variation encountered in normal medical practice. Just wanted to keep that guidance in mind. That was according to the memo of July 19th, 2005 from this Committee to the NRC.

VICE CHAIR THOMADSEN: Thank you, Dr. Fisher. Dr. Howe.

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MS. HOWE: I think there's another concept you have to keep in mind here, and that is that different physicians practice medicine in different ways, so the standard of care may have a broad range. But NRC staying out of the practice of medicine doesn't look at how the physician practices, where they are in that spectrum. To stay out of the practice of medicine, we just look at what the authorized user asked for, and does the facility deliver what the authorized user asked for. So, you may have a 20 percent variance between physician. That's not what NRC is looking for.

NRC is looking at once the authorized user asks for something, is that delivered? And then we will look at the 20 percent from what the physician asked for, and we won't make a value judgment on whether that original asked for was within a certain range or not. I hope that helps a little.

VICE CHAIR THOMADSEN: Thank you for that clarification, DR. Howe. Dr. Zelac.

MR. ZELAC: I have a question that I'd like to ask to Drs. Welsh and Potters. When we're talking about the variance, and what the result is from what the physician had intended, 20 percent below what the physician had intended, I think has been kind

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of accepted as reasonable, and doable. Is 20 percent above what the physician had intended too tight, too restrictive? I was thinking in terms of what you were saying, Dr. Potters, about treating specialized areas of the prostate as an example where you want to, essentially, give it as much dose as you can without harm to nearby critical organs.

There has been -- I mean, just to give you the background on this, there had been some concern that if the physician had expressed a dose, an intended dose in terms of D-90, the D-90 was okay on the low side, if you didn't meet 80 percent of your D-90, there was a problem, and this should be something recognized, but that exceeding the intended D-90 by more than 20 percent is not so much of a problem from a clinical point of view. And that perhaps either we should have a higher limit on the high side than 20 percent, or some other approach for dealing with this issue.

MR. POTTERS: I would be okay with that on the high side. I think, like I was saying earlier, the art of this is to keep your ceiling low, so if the intent is to prescribe 145, 160, 125, whatever it is, I mean, you shouldn't wind up too hot.

Now, clinically, is it less relevant that

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it's hot within the prostate, in terms of Grade I, II, III, IV toxicity or not is something that one could argue, so that maybe there's more latitude and leeway on the higher side. But, personally speaking, I think 20 up, 20 down is going to give you a good enough range.

VICE CHAIR THOMADSEN: Dr. Welsh, did you want to respond at all?

MEMBER WELSH: I would agree with what Dr. Potters has said, that a dose that exceeds the D-90 by 20 percent is unlikely to be harm to the patient, might have a greater chance of curing the patient, but it's not so much the dose to the prostate, itself, as it is dose to the bladder, dose to the rectum, dose to the urethra that travels within the prostate. If those got significantly more than what we anticipated, we might anticipate adverse effects to the patient. But, again, I think we were hoping to get away from the concept of dose for defining medical events, and adhering more to the concept of administered activity.

VICE CHAIR THOMADSEN: This is another example of where the different sites that you'd be using would have different criteria, in that in a breast implant as practiced in Canada with permanent seed placement, a 20 percent overdose would probably

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have much greater significance than a 20 percent under-dose.

MEMBER WELSH: And, as an example, although it's quite uncommon of how you might have a higher value than anticipated for the D-90, if you were to use the older pre-planning approaches, and you estimated the volume two, three weeks ahead of time, did you pre-plan, but the patient is on hormone therapy, and shows up in the operating room, and hormone therapy has continued to cause prostate shrinkage, you could wind up with a volume that might be smaller than anticipated; and, therefore, you put the seeds in, and you could wind up with a higher dose simply because the volume is less than what you expected. And, again, energy per unit volume or mass defines your dose.

MR. ZELAC: Could I ask one more question?

VICE CHAIR THOMADSEN: Please.

MR. ZELAC: And this is a general question. Is what you've just said, both of you, with respect to exceeding the dose to nearby structures by more than 20 percent, doesn't that speak to having a criterion that considers doses to other organs and tissues, critical ones, perhaps, that does exceed what the estimate had been by 50 percent, which is what the

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rule says -

MR. POTTERS: I think the answer to that --in a conceptual, and a perfect world I would agree with that. The reality is, is that dose is defined by how one contours those organs. And given the fact that there remains a tremendous degree of subjectivity of how those organs are defined, and then to place rulemaking on top of that would further constrain the authorized user to try and conform to those doses. So, I think you just -- I mean, if there was a true standard where absolute dose could be measured, then I would agree with you. But given the subjectivity of the way that dosing is done, you're just not going to see it.

I'd like to just make one other comment, if I can indulge the Committee real quickly on the idea of isotope, also, is that I want the Committee to understand some of the nuances of how prostate brachytherapy is done today, at least in some centers, with intra operative planning and dosimetry. So, that will have an impact on say the activity that I order for that patient, which is separate from what the intra operative planning tells me to do. So, I will wind up with excess isotope that then is restored, and 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 than 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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walk away -- I did a case this morning before I came down here, so we left 17 seeds out of 130 that weren't needed. So, any rulemaking that takes into account activity should be based on a pre-plan, but it doesn't have to say that the pre-plan was done a month ago, or it was done two days before, or it was done 30 seconds before I started implanting the patient.

VICE CHAIR THOMADSEN: Dr. Howe.

MS. HOWE: Just to follow-up with what you're doing -

VICE CHAIR THOMADSEN: Can you speak a little bit louder, please? I don't think people can hear.

MS. HOWE: I'm trying to. Dr. Potters, just to follow-up what your -

VICE CHAIR THOMADSEN: Is the microphone on at all?

MS. HOWE: Yes, it is.

VICE CHAIR THOMADSEN: Could the audio-visual people please turn up the microphone on the side there, please.

MS. HOWE: When you're treating intra operatively, what is it that tells you you're finished?

MR. POTTERS: Okay. I'll indulge the

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Committee further. So, the process is that we anesthetize the patient, we use the ultrasound, we measure the volume of the prostate, we do the plan. I use a software, I won't mention the vendor's name, but I use an interactive software in the operating room, and as I've mentioned, my physicist is in the operating room, so that as the seeds are being loaded, and they're loaded one at a -- so, I've created this pre-plan, maybe it calls for 90 percent of the activity, 90 percent of the seeds. I start then overlaying the contoured and the dose plan with a live image on the ultrasound, and I start loading the seeds. And my physicist is accounting for the seeds as they're being dropped. The software allows for the dose calculation to be performed real time, so that when I complete that plan in the operating room, I'll have D-90, I'll have a V-100, I'll have a V-150, I'll have urethral doses, rectal doses right then and there, and I look at that before I take my gloves off, and I say are we cold in any areas, in which case I have the actual plan, and I can change it. So, in essence, when I'm completed the case in the operating room, I have a post-plan, also. I've done my post-plan.

I still, because of ABS, and because of

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ASTRO and ACR, I still take a CT scan. I don't rely on that 100 percent, but we've published that shows that the correlation of that post-plan intra operatively matches the CT, so that I don't have to wait a month to tell the patient's wife that he had a good implant. I can tell them right then and there that the implant was successful based on the various dose parameters that we use.

MS. HOWE: Okay. Just to follow-up on that, let's say as you're starting to inject the seeds, you get swelling, so what you're determining, and what your computer is determining is the dose based on that swollen volume.

MR. POTTERS: So, you're digging here, but that's okay, because -

MS. HOWE: I'm -

MR. POTTERS: No, no, no, that's okay. So, we published a paper on edema that looked at when does edema occur? And it generally occurs after all the needles are placed. It's the trauma of the placement of the needles that's associated with edema. So, in fact, what I do is bring the patient in, I place all the needles into the prostate before I contour the prostate, so that -- and then I do the planning based on those contours.

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MS. HOWE: Okay.

MR. POTTERS: So, that's how I account for that.

MS. HOWE: And I think it's important to point out, as you did, in our regulations, the written directive is before administration, so that could be two nanoseconds before administration. It doesn't have to be a month before, or some other time. So, in real time planning, it can be just before you start putting the seeds in.

MR. POTTERS: Right.

VICE CHAIR THOMADSEN: Other questions or comments? I would like to come back to one other thing, and that's dealing with the brachy mesh, because I have been receiving comments from facilities who are concerned that every case they do would be a misadministration, because the dose they calculate after they do the procedure is rarely within 20 percent of what they've calculated beforehand, because the calculation beforehand is in a perfect geometry with the patient open, and afterwards is done by CT after the site has been closed. And the geometry with the implant is very different in those two cases. Their concern is with any dose-based calculational, or any calculated dose criteria that for procedures,

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intra operative procedures such as this, they would always be falling into the medical event arena, and that would, essentially, kill the procedure. Dr. Welsh.

MEMBER WELSH: So, again, this returns us to the concept of dose-based versus activity or source strength-based definitions of medical events, because dose is a function of -- again, it's energy per unit mass, which is, essentially, volume, and if volume has changed, as in prostate brachytherapy with edema, or in lung mesh brachytherapy, volume is different because the cavity has bunched up, and the mesh has bunched up, dose being related to volume is very difficult to accurately ascertain; whereas, activity and source strength is not. So, Dr. Thomadsen, in your opinion, would the use of source strength or activity prevent the labeling of misadministration or medical event to some of the events that you were talking about, specifically, your colleagues have mentioned to you?

VICE CHAIR THOMADSEN: Yes.

MEMBER WELSH: So that would, then, further support movement away from dose, and towards activity and source strength for permanent implant brachytherapy.

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VICE CHAIR THOMADSEN: Yes. Dr. Howe.

MS. HOWE: I don't know if this is relevant, or not, because I don't know exactly why you get difference in doses, but I do know that we have had other what we consider emerging technologies, where we look to see how the technology meets the current requirements. And if there is a uniform area in which it doesn't meet our current requirements, then we'll put it in 35.1000, and we'll help to identify what that area is. A specific case is, we put the micro spheres in 35.1000, because you have almost every medical event, almost every administration would be a medical event for one type of micro sphere because you go to stasis, and we didn't want that to occur, so we changed what our written directive was for that particular micro sphere, and said that you want to deliver a certain dose, or until stasis, because we knew that was a common issue with that particular device and use. And if you believe the brachy mesh is in the same kind of area, it could go into 1000, and we could define what a written directive is for it, and what a medical event is for it. That is another option that is available to you.

VICE CHAIR THOMADSEN: Yes. Although the

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technology involved here is not emerging, is not new, has been in existence for at least 50 years, and the procedure, itself, has been used in one form or another for about that length of time, so I'm not sure that 1000 would be the appropriate place for that.

Dr. Potters, you were about to say something, I think.

MR. POTTERS: I just think the concept of volume is just amplified in the lung more than, say, the prostate, and you wind up with the same issue if under a VATS procedure, a patient is undergo a wedge resection of a localized tumor with the intent of treating along the resection line, and the re-inflated lung creates distortion of the mesh. That's just an amplification of a change in volume relative to what we're talking about, prostate edema of 10, 20, 30 percent. This could sometimes be more like 40 or 50 percent. Now, the seeds are still located within that area, because it's sewn into the mesh that's there, but if you created a dose definition, you would have a high number of reportable events in this procedure.

VICE CHAIR THOMADSEN: Dr. Welsh.

MEMBER WELSH: So, as you mentioned, Dr. Thomadsen, in response to Dr. Howe's point about lung brachytherapy, this is not something that is new.

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This has been around for around half a century, and applies to breast permanent implants, lung, pancreas, even brain in rare instances. And it's come to attention again because of the recently developed -- the one that's been marketed recently called brachy mesh, which is convenient, and it's gaining in popularity, and it's being investigated, data is accumulating, and people are using it routinely. But it does raise the question of whether or not activity is a better way of defining medical events than dose, and it appears that the answer is yes. And, therefore, one of the Subcommittee's subjects of discussion was should permanent implant prostate brachytherapy, which is so sophisticated in the technology, be in a separate category than the other implants. It sounds like it might not be necessary. I raise the question to Dr. Thomadsen. Now, in your analysis of all that we've discussed, is it necessary to have a separate category, or, as the title, will one rule fit all, still be valid if we change to activity, as we hope?

VICE CHAIR THOMADSEN: Well, as we've been discussing here, it's been sounding like the brachy mesh approach has the same -- is the same situation as we've been discussing with the prostate, just a matter

of degree. And the proposal of the Subcommittee sounds like it would satisfy the definition for medical event for both cases.

Oh, I'm sorry, Dr. Gilley. You're just too close.

MEMBER GILLEY: How about micro spheres? Will that fall in the same with the activity-based? That's the other permanent implant that we need to take into consideration that seems to be gaining popularity.

VICE CHAIR THOMADSEN: I'd say very possibly.

MEMBER GILLEY: Or do you want to handle that as a separate rule per se for the micro spheres, because I know there is migration to lung on occasions, there's the health stasis process.

VICE CHAIR THOMADSEN: Dr. Suleiman.

MEMBER SULEIMAN: I have problems with different protocols, different exams. The micro spheres are a very different beast, you know, the dosimetry is highly conjectural, in my opinion. I was talking to a colleague from -- and administered activity probably is a more accurate predictor, because you don't know how it's distributing in the liver. And my thinking of these, if the brachytherapy

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-- as long as these procedures are similar in precision and accuracy, you could lump them together, but assigning 20 percent across the board is just problematic. I think some of these things have high precision, high accuracy, others are just guesstimates. So, I have problems with a flat out 20 percent, because some of these -- and the poor community is struggling, is this -- can you even estimate accurately the dose for some of them? So, I take a more flexible approach; in other words, depending on the procedure, and how accurate it is, whether you'd want a 20 percent, or dispense with it.

VICE CHAIR THOMADSEN: Certainly, 20 percent dose with the micro spheres would be very hard to verify one way or another.

MEMBER SULEIMAN: Yes, we can get in a -

MEMBER GILLEY: Well, realizing that it's still Part 1000, but at some point in time, as procedures are gaining popularity, it should have a category all to itself. So, maybe that's when you ought to address when we would write the written directive, and the medical events criteria.

MEMBER WELSH: I would say I have not given a whole lot of thought to this point, but my feeling is that unlike prostate brachytherapy, where

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you're dealing with visible sources, and a finite number, with the micro spheres, you have -- you're dealing with millions, billions, have no idea how many micro spheres there might be. They're not visible, and trying to regulate them under the same set of rules as prostate brachytherapy could lead to some difficulty. My guess might be that it might fit with radio immunotherapy better than it would fit with prostate brachytherapy.

MEMBER ZANZONICO: And I think there are sufficient safeguards developed by the practitioners in terms of measuring short-circuiting to the lungs, and what is or is not acceptable, as well as re-embolizing certain hepatic blood vessels. I think it just strikes me that the practitioners are making a very good faith effort, and it's just too ill-defined at this point to lend itself to rulemaking the same way as prostate brachytherapy, for example.

VICE CHAIR THOMADSEN: Thank you very much. Yes? Identify yourself, please.

MS. PELKE: Patty Pelke, NRC Region III, back to prostate brachytherapy. Dr. Potters, you had mentioned two things that I just wanted to make sure I had straight before I left today. You talked about a study that was done about 10 years ago relative to

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edema, and I was trying to get a better read on that. Was it about 30 percent of patients experience edema, or is it a higher percentage than that?

MR. POTTERS: So, the paper that I was referencing was one of our publications. The other authors that have published a lot on edema actually come out of Jefferson, which is sort of a competing institution in Philadelphia, from that that was overseeing the VA.

Anywhere between 20 and 50 percent of the patients have reported edema, as much as 5 percent to 50 percent, and some even higher. So, there's not a good handle on it. There's also not a good handle on predicting which patients are going to have more or less edema, so it's not as though patients with large prostates have more edema. It's not even that more needle sticks, even though needle sticks is -- the actual placing of the needles into the prostate is, apparently, the initiating event. It's not even that more needle sticks is going to cause more or less edema, so it's highly variable.

And the paper that I was referencing that we published on was, actually, it was a mathematical paper looking at edema half-life relative to recalculating what the dose should be, taking into

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account, say, Palladium with a 17-day half-life, and then a 20 or 30-day edema half-life. How is that impacting on dose in a patient with 30 or 40 percent edema? So, it was, more or less, a mathematical exercise.

MS. PELKE: One more question. On your intra operative procedure, you talked about placing all the needles first before you start dropping the seeds. Is that routine for intra operative, or is that just your choice?

MR. POTTERS: So, some of that is my approach, other people are using this approach. The contrary argument that's made for putting the needles in first is that it creates artifact on the ultrasound, which then makes contouring of the prostate, and then doing your intra operative plan more difficult. So, there are others that don't believe that that's the best way to go, so I think there is what you're going to see here is both camps of intra operative type of treatment planning. And, although, it may not account for edema, if you're not putting the needles in, again, the concept of edema and its clinical meaningfulness is something we could debate without a definitive answer.

MS. PELKE: Thank you.

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VICE CHAIR THOMADSEN: Thank you. Dr. Welsh.

MEMBER WELSH: Just to provide some feedback about variability. I did not put the needles in routinely during the pre-planning procedure. I would do the pre-plan, and then place the needles, exactly for the reason that I didn't want to be planning on a gland that had the edema already in it. As Dr. Potters has mentioned, we don't have the actual clinical feedback data to tell which approach is better. I think both of them work very well, and it might be individual clinician discretion, or comfort level.

VICE CHAIR THOMADSEN: Thank you, Dr. Welsh. Is there further discussion on this issue? Yes, Mr. Lewis.

MR. LEWIS: I just wanted to thank you for the discussion. This is very enlightening to me. I did want to ask about the forum to communicate the Subcommittee's findings. Is the presentation here the product, or will there be a written product, or a letter from the Committee? Somehow, I'm trying to think of how to provide the information, the Committee's views, to the right people. It was clear 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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however you want to do that is fine. If you need to make any revisions and look at it again at a later date, and vote via email, that's fine. I think that's what Rob was looking for, is like a final Subcommittee report, but we wanted a good product to come to the meeting with, which is what Dr. Welsh provided.

VICE CHAIR THOMADSEN: With the -

MS. COCKERHAM: Yes, or a Committee report, and not a Subcommittee report.

VICE CHAIR THOMADSEN: Right. Would the Committee recommend to the Subcommittee to provide a written -- a potentially revised written version to this Committee for an electronic vote to be forwarded to the NRC? I'm asking is there a motion to that effect.

MEMBER ZANZONICO: Motion.

VICE CHAIR THOMADSEN: Thank you. Do we have a second?

MEMBER GILLEY: Second, if I can. I'm on the Subcommittee, so I'm not sure if that's a conflict.

VICE CHAIR THOMADSEN: I think you certainly can. Now, we're open for discussion on that point. Dr. Welsh, since you're chairing the Subcommittee, do you have discussion on the proposal?

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MEMBER WELSH: So, I have taken a few notes in terms of feedback, but I'd be relying mostly on my memory of everything that we discussed here, and the contributions from Dr. Potters, but I do believe that I could edit the formal report, and resubmit it to you in a timely fashion, given the feedback that we've had here today.

VICE CHAIR THOMADSEN: Dr. Fisher.

MEMBER FISHER: We need to review what that report states.

MEMBER GILLEY: Could the Subcommittee review it first?

VICE CHAIR THOMADSEN: Well, part of the motion is that it comes to the full Committee, so you would certainly see that.

MEMBER FISHER: I'm on the Subcommittee.

VICE CHAIR THOMADSEN: I'm sorry, you were talking about for the Subcommittee to review -

MEMBER FISHER: I would have to review it again.

VICE CHAIR THOMADSEN: I'm sorry. I was expecting that the Subcommittee would be working with Dr. Welsh on this, although that wasn't explicitly stated.

MEMBER FISHER: I'd like to review it

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before it goes to the full Committee.

VICE CHAIR THOMADSEN: Yes. I think that that would be an internal matter for the Subcommittee, and Dr. Welsh could probably whip the Subcommittee into order before that.

MEMBER GILLEY: Submit.

VICE CHAIR THOMADSEN: Yes. But that's a very good point, I would want to see it, also. Any other -- oh, I'm sorry.

MEMBER ZANZONICO: There was a motion.

VICE CHAIR THOMADSEN: Yes.

MEMBER ZANZONICO: We need to vote on the motion.

VICE CHAIR THOMADSEN: Yes, we shall, as soon as everybody's done commenting.

MEMBER ZANZONICO: Okay.

VICE CHAIR THOMADSEN: Which looks like that's now. Seeing no more comment, all in favor of the motion say aye.

(Chorus of ayes.)

VICE CHAIR THOMADSEN: Opposed? It is unanimous. Very good. I have a written report to do, James. With that, any last words on the issue from the NRC?

MR. LEWIS: Just in terms of the time

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frame, Ashley will work with our rulemaking people. It's not a long amount of time.

VICE CHAIR THOMADSEN: Yes.

MR. LEWIS: Our rulemaking people are trying to make their way to the next -

MS. COCKERHAM: Well, we're not quite that fast.

MS. BHALLA: I'm Neelam Bhalla from NRC. Dr. Welsh, I think if I remember correctly, last time when you were discussing about the post-implant verification of the dose, I thought there was a discussion on what is the optimum time to do that, notwithstanding the real-time ultrasound, but the, let's call it the -

(Cough.)

MS. BHALLA: So, could you go over that again, if that's all decided, or is the ABS still looking at that?

MEMBER WELSH: My recommendations for NRC, and the purposes of medical event definition, and corrective action for VA, so that that doesn't happen again, is simply that it be a requirement that post-implant dosimetry be performed. And it sounds like it may not have been explicit, but it's implicit already.

As far as when to do the post-implant

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dosimetry, there are statements from the American Brachytherapy Society about when this could be done, or should be done, but it's a function of a lot of things, a lot of variables, including the isotope. And I've been focusing -- we've been focusing a lot on Iodine-125 today, but as Dr. Potters has mentioned, Palladium has a 17-day half-life, and, therefore, your window for appropriate post-implant dosimetry might be a different time frame, or Cesium-131 with a 10-day half-life, we published a paper very similar, a mathematical analysis suggesting that there might be two times that you should do the post-implant dosimetry to adequately reflect the true dose to the target prostate. So, I don't think that we have any firm recommendations as far as NRC regulations regarding the timing of post-implant dosimetry, but I would ask Dr. Potters for his expert opinion on this. But I'm just saying, for the purpose of regulation, I don't think that we want to go into that area about specifying a time frame.

VICE CHAIR THOMADSEN: Ms. Gilley.

MEMBER GILLEY: One thing you can do is put it in your requirements for having a license for that, and it's called your procedure. And that's one way of doing it, so each individual institution or

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licensees could make their own criteria as to when that post treatment implantation would be, and it would be very much license-specific.

VICE CHAIR THOMADSEN: You do have a problem, I would point out, that if you put in your procedure that you will do the post dosimetry based on a CT done 30 days later, you may have patients who do not show up ever for that -

MEMBER GILLEY: That's patient intervention.

VICE CHAIR THOMADSEN: As long as that's considered so. Dr. Zelac.

MR. ZELAC: I need some clarification. If, as I have gathered from the discussion, the direction of the Committee, as well as the Subcommittee, is to move away from there being any dose-based criteria for medical event, then where does the determination of the dose come in, and what's the purpose of it relative to the regulation?

VICE CHAIR THOMADSEN: Dr. Welsh.

MEMBER WELSH: I would simply answer that the purpose of the post-implant dosimetry in this situation is not so much that we can identify medical events, and regulate. But, as Dr. Potters has mentioned, you get valuable feedback on the quality of

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your implants, and if you want the next patient to be treated better than the one last week, and the patient two months even better than that, this feedback is very valuable. And it's part, in my opinion, of good quality program to have continuous feedback on whether you're doing things right, whether you could be doing something better, and how you're going to do it better next time.

And as far as the timing goes, one of the realities is that sometimes patients will come a long distance for an implant procedure. And I know of some facilities that will do an implant before that patient goes back to his original state or country. And it's done kind of as a formality, that we do post-implant dosimetry, but it's understood that if you're doing it one day, two days afterwards, it might not be as valid as if you're doing it at what ABS has recommended. Again, the purpose of the post-implant dosimetry is not designed for regulation for the purpose of defining medical events, but simply for improving quality of the program.

MR. ZELAC: Then it falls under the sphere of medical practice?

MEMBER WELSH: Which is why I would not recommend NRC use it in any way for defining medical

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events, but just simply state that it's part of the requirement for getting a license, that the program has to have that.

MR. ZELAC: I'm sorry. To me, it sounds like that's medical practice, and we don't engage in that. I mean, I understand the objective, and I think it's well-founded, but if you're going to say that the determination of dose is, essentially, for improvement of the quality of the implants, that's medical practice. And if we don't have any criterion for determination of a medical event based on dose, then I don't know that we should be putting in any medical criterion, medical practice requirement into the regulation.

VICE CHAIR THOMADSEN: Dr. Suleiman.

MEMBER SULEIMAN: This is an area I deal with almost daily. One of the problems I've seen, it's not the issue of dose, it's the issue of how you calculate dose. And it's not the activity, or the radiation component, it's the imaging associated with the volume, volumetric determination. Aside from the added amount of normal biological variability, are you imaging with ultrasound, are you doing it with CT? You can take images using various modalities, and get different numbers all the time, so we're dealing in an

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area that's extremely soft, in my opinion, so it's an area we're striving for. Some of the cancers, for example, are extremely difficult to image, solid tumors are very easy to image, so the issue, I think, boils down, if you scrape away everything else, it's the ability to accurately reproducibly image some sort of target volume, and that practice -- it's still very, very soft, it's very, very uncertain, so I've always aspired toward knowing what the dose is. I mean, I'm extremely biased toward that, because when the dosimetry gets more precise and accurate, I believe you'll see dramatic breakthroughs in some of the cancer therapies with radioactivity. But just because the state of the practice isn't very good, maybe you shouldn't abandon it. I think in brachytherapy, at least you're getting in the ball park, literally. It's a soft number, but I would not abandon it completely. That's where you've got this give and take between administered activity, which you can control very, very much so, and trying to calculate the dose. You can calculate the dose five different ways, if you want, using different days of imaging, using different sources. So, I think you have to come to grips with what level of uncertainty, and what do you want to live with, so I'd focus more

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on the administered activity, because it's more controllable. And the dosimetry is still subject to image variability.

VICE CHAIR THOMADSEN: Dr. Welsh.

MEMBER WELSH: So, I'm trying to think of a way to answer this dilemma that Dr. Zelac has brought up. It's a bit of a challenge. I propose that we get away from dose-based definitions of medical events, and I'm in favor of activity or source strength-based. And it sounds like there's agreement on that. But I also raise the suggestion of insisting that a program must have post-implant dosimetry, but Dr. Zelac has pointed out that in order for that to come to fruition, there has to be some justification for it. And without dose-based definitions of medical events, you scratch your head about what's the justification.

I hate to -- I'm reluctant to make this suggestion, but I'm going to, just for the sake of discussion, that maybe rather than use the dose calculated during the post-implant dosimetry in any way for defining a medical event, if no post-implant dosimetry is done, that could be a violation.

VICE CHAIR THOMADSEN: Dr. Zelac.

MR. ZELAC: Thinking about what the

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discussion was earlier, Donna Beth, Dr. Howe pointed out that we do have the requirement in 35.41 for the facility assuring that the procedures are of appropriate quality. That could -- I think you could tie this requirement that you're looking for to be in the regulations to that as a subset of it, or as an offshoot from it, perhaps. So, there is probably a way if you massage to get what you're looking for in, even without medical event involving dose.

MEMBER WELSH: And still stick with activity or source strength-based definitions.

MR. ZELAC: Yes.

MEMBER WELSH: So, maybe that can work.

MR. ZELAC: I'm glad I not only raised the question, but, apparently, come up with an answer, as well.

VICE CHAIR THOMADSEN: Were everything that clear. Other comments on this before we close the topic? Yes, Ms. Pelke.

MS. PELKE: Patty, sorry. NRC Region III. I just want to make sure that I understand this. What you're proposing is an activity-based requirement, and I'm trying to get around the fact that the activity that you're going to prescribe is going to be dependent on the dose you want to deliver. Is that

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correct?

VICE CHAIR THOMADSEN: That is correct.

MS. PELKE: Okay. So, there will be some dose component to this. Right?

VICE CHAIR THOMADSEN: Yes.

MS. PELKE: Okay. And then your activity is going to be based on whatever isotope you choose to use, whether it be Iodine, Palladium, Cesium.

VICE CHAIR THOMADSEN: Right.

MS. PELKE: Okay.

MS. HOWE: Dr. Thomadsen?

MEMBER FISHER: Dr. Howe.

MS. HOWE: I would just like to point out that when we look at the VA data, we find that activity is not very sensitive, and that you can have determined by the VA cases where you're between 90 and 100 percent of the seeds are identified as being in the target site, and keep in mind that the authorized user determines what the target site is, that those -- the doses, the D-90s, in this case we used D-90s because that's what the facility was using as a methodology for determining whether they had medical events, the D-90s were not close to 80 percent. Some of them were grossly below 80 percent. And if you looked at the images, you saw very large cold spots,

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because the three-dimensional array of the seeds within the prostate was such that you did not get the dose you were looking for. The cloud was there, but it wasn't distributed, so there's a three-dimensional component here in the prostate that's very important for dose. And just knowing the number of seeds put in does not give you an accurate evaluation of what is happening in the prostate.

VICE CHAIR THOMADSEN: Dr. Fisher.

MEMBER FISHER: I wrote this is a note to Dr. Zelac, but I think it still holds. We know that radiation dose is proportional to, and is a direct function of the implanted activity. The radiation dose to the patient for a given implant is highly variable with location both within the target site, and outside the target site. The assessment of post-implant dose for compliance would be complex and burdensome to the licensee. However, it would be relatively straightforward for the licensee to ascertain the total source strength implanted within or outside the intended target site.

VICE CHAIR THOMADSEN: Dr. Howe.

MS. HOWE: Unfortunately, the relationship between the activity and the dose is not a one-on-one type of thing. If you put the seeds in an area, and

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you haven't distributed them the way you intended to, then the calculated dose is much, much less, so you don't have that one-to-one relationship that you have with other implant procedures, where you have one or two sources, and then you're looking at a given distance.

MEMBER FISHER: That was my Point Two.

MS. HOWE: So, you don't have an accurate dose to the prostate just by knowing where that you have X number of seeds inside of it.

MR. POTTERS: I don't think you're ever going to get to perfection on this.

MS. HOWE: I'm not talking perfection, I'm talking lay-out.

MR. POTTERS: And I agree with that. I think the other way to look at it is, and I'm not in any way defending the VA practice, but when you look at the clinical outcomes that the report generated in terms of patients who failed treatment versus patients who had excess complications as a result of the misplacement of the seeds, they really weren't out of the reported realm of reported outcomes of Centers of Excellence, which maybe leads to the question of what are we doing with prostate cancer in a general sense? But that's well beyond the discussion at this table.

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So, if the criteria is to look at it based on activity, at least activity is fixed. You can look at activity in the gland, or within the target, and that's pretty fixed. Dose is subjective, and the fact that there's not going to be a direct correlation, perhaps, to toxicity or outcomes, just shows that it's less of a true science here.

VICE CHAIR THOMADSEN: Thank you for your comments. Any other comments? In that case, we are--

MR. EINBERG: Did you have to vote on the --oh, you already voted.

VICE CHAIR THOMADSEN: We did.

MR. EINBERG: Yes.

VICE CHAIR THOMADSEN: And it passed. Thank you for keeping these things in mind, always necessary. It's time for us to adjourn. We meet again tomorrow morning at 8:00 in the same room. Good night.

(Whereupon, the proceedings went off the record at 4:55 p.m.)

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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]

[1] I 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

[2] I 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]

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[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

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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]

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[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 *mensch*, 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

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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.

Appendix B

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 citizens [1].

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]

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[1] http://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

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[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 millcurie 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.

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[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 NRC[21] 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

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[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 wrote[23]:

> " 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 2001[24], 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 Meserve [27] 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

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[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."

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[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 findings[34], 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 <u>not</u> 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.

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[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. Markey [35], 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 inquiry[38], 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 headquarters[39] 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]

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[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 1[41] 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 review[42]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 letters[44] 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.

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[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

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[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-patients[5])" 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 radioisotopes[8], 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.

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[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 Radionuclides[12], 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."

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[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 <u>not</u> 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

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[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

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[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]

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[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/nrcltomarkeyisotopes.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 <u>not</u> reconsider its decision to <u>not</u> 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

DOCKET NUMBER
PETITION RULE PRM 3-5-10A
(57 FR 21043)

UNIVERSITY OF CALIFORNIA, LOS ANGELES UCLA

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USNRC

'92 NOV 17 A8:53

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

UCLA SCHOOL OF MEDICINE
HARBOR - UCLA MEDICAL CENTER
DEPARTMENT OF RADIOLOGY
1000 CARSON STREET
TORRANCE, CALIFORNIA 90509

November 9, 1992

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 <u>other than</u> 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 <u>I am not now, nor have I ever been, a member of the ACNM</u> 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.

<u>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</u>. I urge NRC to entertain only scientific discussion, and eschew scientifically

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 <u>own</u> 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.

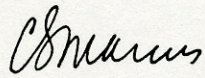
As far as his story about his confinements, let me explain that one does not need "thick paper" on the floor, only absorbent material with a plastic backing. As far as "smelling strongly of seaweed", this is pure confabulation. In the first place we do not give iodine, we give iodide. Iodide does not smell like seaweed. Second, the mass of 150 mCi of I-131 is $(150)(131)(8)(24)(60)(60)(8.87\times10^{-17}) = 1.2$ 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 <u>month</u> ? Wow!

Mr. Crane makes some other interesting statements, quoting such incontrovertibly superb scientific sources as the New York Times

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.
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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.