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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

(ACMUI)

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MEETING

+ + + + +

OPEN SESSION

+ + + + +

MONDAY

OCTOBER 19, 2009

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ROCKVILLE, MARYLAND

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

COMMITTEE MEMBERS:

LEON MALMUD, M.D., Chairman

BRUCE THOMADSEN, Ph.D., Vice Chairman

DOUGLAS EGGLI, M.D.

DARRELL FISHER, Ph.D.

COMMITTEE MEMBERS: (cont'd)

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WILLIAM VAN DECKER, M.D.

JAMES WELSH, M.D.

CONSULTANT TO THE COMMITTEE:

MILTON GUIBERTEAU, M.D.

NRC STAFF:

ROB LEWIS

JIM LUEHMAN

CHRIS EINBERG, Designated Federal Official

CINDY FLANNERY, Alt. Designated Federal Official

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CASSANDRA FRAZIER

SANDRA GABRIEL

DONNA-BETH HOWE, PH.D.

GRETCHEN RIVERA-CAPELLA

CARRIE SAFFORD

NRC STAFF: (cont'd)

GLENDA VILLAMAR

DARREL WIEDEMAN

MICHAEL ZEITLER

MEMBERS OF THE PUBLIC:

MELISSA ALLEN (via telephone)

CINDY TOMLINSON

DAVID BURTON

DAVID DODOO-AMOO

EIPING QUANG

GEORGE WESLEY

GLORIA ROMANELLI

JAMES ROSS (via telephone)

JOSEPH GOLDSTEIN

JOSH GOLDSTEIN

KAREN LANGLEY (via telephone)

LIN CLEGG

LYNNE FAIROBENT

MARY MOORE

MELISSA MARTIN

P. YORKO

PARKER MOORE

RANDALL SNOW

RICHARD MARTIN

MEMBERS OF THE PUBLIC: (cont'd)

VIRGIL DICKSON

TABLE OF CONTENTS

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

(10:30 a.m.)

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

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

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

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

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

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

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

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

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

I request that, whenever possible, we try to reach a consensus on the procedural issues that we discuss today. But I also recognize 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 that may be participating today. Dr. Leon Malmud, Chairman?

CHAIRMAN MALMUD: Here.

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

VICE CHAIRMAN THOMADSEN: Here.

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

MEMBER EGGLI: Here.

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

MEMBER FISHER: Here.

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

MEMBER GILLEY: Here.

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

Mr. Steve Mattmuller, Nuclear Pharmacist?

MEMBER MATTMULLER: Here.

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

MEMBER SULEIMAN: Here.

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

MEMBER VAN DECKER: Here.

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

MEMBER WELSH: Here.

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

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

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

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

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

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

MR. EINBERG: Your name?

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

MS. FLANNERY: Cindy Flannery.

DR. HOWE: Donna-Beth Howe.

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

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

MR. EINBERG: Okay. Are there any NRC

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

(No response.)

Hearing none, okay.

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

Could people on the phone please identify who is listening?

MS. LANGLEY: Karen Langley, University of Utah.

MR. EINBERG: Is there anybody else?

(No response.)

Okay. Hearing none.

Dr. Leon Malmud, the ACMUI Chairperson, will conduct today's meeting. 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 Dr. Malmud.

CHAIRMAN MALMUD: Thank you, Chris.

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

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

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

Any questions on that one?

(No response.)

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

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

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

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

Are there any questions or comments on this one?

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

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

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

MEMBER GILLEY: Thank you.

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

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

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

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

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

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

CHAIRMAN MALMUD: Yes.

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

CHAIRMAN MALMUD: Thank you for that clarification.

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

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

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

MS. FLANNERY: That is correct.

CHAIRMAN MALMUD: Thank you.

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

(No response.)

Okay. We will turn the page to the 2008 recommendations. Item Number 21, "The ACMUI formed a subcommittee to draft a set of proposed qualifications that interventional radiologists must satisfy to become authorized users for Yttrium-90 microspheres." And that subcommittee reported to the full Committee last meeting, so that item is now closed.

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

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

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

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

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

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

DR. HOWE: Not today.

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

CHAIRMAN MALMUD: Thank you.

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

CHAIRMAN MALMUD: Thank you.

MS. COCKERHAM: Any questions?

(No response.)

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

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

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

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

CHAIRMAN MALMUD: Thank you.

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

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

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

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

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

CHAIRMAN MALMUD: Question?

MS. COCKERHAM: This is Ashley. For

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

CHAIRMAN MALMUD: Did someone have a question?

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

MS. COCKERHAM: Which year?

DR. GUIBERTEAU: 2008.

MS. COCKERHAM: Okay.

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

MS. COCKERHAM: That means --

DR. GUIBERTEAU: -- that?

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

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

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

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

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

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

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

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

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

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

DR. GUIBERTEAU: But the concept has been accepted.

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

DR. GUIBERTEAU: Thank you. That helps.

MS. COCKERHAM: Okay.

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

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

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

once those 15 or 30 items, like Rob said -- well, you weren't here during the closed session -- we can only have one Part 35 rule before the Commission at a time. So once this group of 15 to 30 items goes through, it is going to take several years.

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

DR. GUIBERTEAU: Thank you.

CHAIRMAN MALMUD: Thank you.

MS. COCKERHAM: Any other questions?

(No response.)

That's all I have.

CHAIRMAN MALMUD: Thank you very much.

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

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

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

MR. LUEHMAN: Yes. My name is Jim

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

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

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

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

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

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

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

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

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

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

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

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

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

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

enforcement conference with the licensee.

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

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

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

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

Obviously, the actions we could take -- no action, notice of violation, which is -- which doesn't include a civil penalty, but it does -- it is a formal document that requires the licensee to provide us on the record their corrective actions, either the corrective actions they have taken or intend to take. And then, obviously, for the even more significant ones, you can have a notice of violation with a civil penalty.

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

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

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

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

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

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

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

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

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

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

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

systemic or programmatic matter.

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

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

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

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

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

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

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

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

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

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

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

Willful violations -- like I said, I think that these -- we consider these much more significant. There is typically an investigation by the Office of

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

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

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

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

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

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

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

The one area that we really -- that we have had increased enforcement activity in the medical area is the implementations of the increased controls. And that is getting all of the various points of the increased controls in place -- you know, agreements with local law enforcement, setting up the proper boundaries and barriers to protect particularly significant quantities of material.

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

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

We think that now we are over the hump as

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

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

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

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

And I think I have already covered that.

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

CHAIRMAN MALMUD: Thank you. Are there any questions?

MR. LUEHMAN: Okay. Debbie?

CHAIRMAN MALMUD: Yes, Debbie?

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

MR. LUEHMAN: Okay. Safety culture is not a regulation. There is a -- it's a policy statement. In fact, the Commission has recently weighed in, been provided a paper and weighed in on safety culture.

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

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

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

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

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

material.

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

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

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

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

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

CHAIRMAN MALMUD: Thank you.

Dr. Van Decker?

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

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

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

faith effort," where licensees attempted to do something.

And I think that we did have to make some adjustments, and we have, for those licensees. We have what we call the IC Toolbox, which is available to those licensees, where we have questions and answers that try to get to providing more uniformity. And I think that over a couple of rounds of inspections now in those areas we have reached some uniformity on our expectations.

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

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

We had to go out there and look at what

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

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

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

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

MR. EINBERG: Okay. Sorry.

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

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

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

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

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

CHAIRMAN MALMUD: Thank you. Are there other questions?

DR. GUIBERTEAU: Just to follow up on

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

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

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

CHAIRMAN MALMUD: Thank you.

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

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

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

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

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

(No response.)

If not, that completes your presentation. Thank you.

MR. LUEHMAN: Thank you.

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

MR. EINBERG: We have lunch.

CHAIRMAN MALMUD: When shall we return?

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

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

MS. COCKERHAM: Yes.

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

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

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

(1:00 p.m.)

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

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

CHAIRMAN MALMUD: Thank you.

MR. EINBERG: -- take a moment.

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

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

MS. ALLEN: Yes.

MS. COCKERHAM: Can everyone please identify themselves?

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

MR. DAVIDSON: Will Davidson from the

University of Pennsylvania.

CHAIRMAN MALMUD: Davidson from Penn.

Next?

MR. ROGERS: Joe Rogers, Therogenics Corporation.

CHAIRMAN MALMUD: Rogers, Therogenics Corporation.

Next?

MS. BOWIE: Jennifer Bowie, GE.

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

MS. BOWIE: Bowie.

CHAIRMAN MALMUD: Would you spell it, please?

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

CHAIRMAN MALMUD: Thank you.

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

MS. ALLEN: Melissa Allen, GE.

CHAIRMAN MALMUD: Melissa Allen, GE. Thank you.

Anyone else?

(No response.)

Thank you. Thank you for identifying

yourselves, and welcome to the afternoon session.

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

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

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

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

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

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

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

For our supply chain of moly, we need nuclear reactors. We need the reactors for neutrons. We need the neutrons to irradiate uranium targets to produce moly. Once irradiated, the second step is for a processor to prepare purified moly from the target. Once it is purified, it is moved on to the generator manufacturer, and the generator is our source of technetium used in nuclear medicine.

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

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

It is -- the first one, top left, is AECL. That's the NRU reactor in Canada, and the HFR in The Netherlands. I'm sorry, I can't read this, but I think it's Osiris in France, and the BR2 in Belgium, and Safari is down in South Africa. And this graphic also has added OPAL, but they have not entered the market yet.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MEMBER MATTMULLER: Right.

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

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

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

CHAIRMAN MALMUD: Thank you. Yes?

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

CHAIRMAN MALMUD: A member of the public?

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

The other thing, too, is that a lot of

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

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

CHAIRMAN MALMUD: Thank you.

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

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

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

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

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

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

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

Again, trying to get more information as

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

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

Years ago, myocardial perfusion imaging first gained widespread acceptance with thallium, but is use was replaced by the superior technetium agents. Now, as some would say, we are taking a step back in myocardial perfusion imaging.

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

breast size.

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

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

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

Substituting a PET study, such as sodium

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

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

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

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

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

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

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

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

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

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

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

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

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

their heads for a long period of time.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(Laughter.)

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

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

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

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

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

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

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

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

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

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

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

Missouri.

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

(Laughter.)

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

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

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

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

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

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

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

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

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

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

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

This is the bill that has recently been

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Thank you.

CHAIR MALMUD: Thank you, Mr. Mattmuller. Very thorough presentation. We have a couple of questions, if I may, to summarize what you have said, and then questions or questions first? Dr. Van Decker?

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

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

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

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

Do you know of any NRC or state

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

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

MEMBER VAN DECKER: Well, that is good news.

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

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

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

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

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

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

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

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

applications that do come in.

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

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

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

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

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

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

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

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

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

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

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

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

Since that one statement of them saying

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

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

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

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

MEMBER MATTMULLER: Right. Well, they are doing it now. And, actually, I think at one of the national labs, I believe in New Mexico, they do have an AHR or they used to have an operating AHR reactor. So these would not be the first to be built in the U.S. But I don't think it is operating at the moment.

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

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

CHAIR MALMUD: Dr. Suleiman?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIR MALMUD: Thank you, Dr. Suleiman.

Dr. Eggli?

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

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

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

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

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

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

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

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

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

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

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

CHAIR MALMUD: Thank you, Dr. Eggli.

Was there another comment?

MEMBER FISHER: May I?

CHAIR MALMUD: Please?

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

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

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

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

So I think Dr. Van Decker was right on

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

Thank you.

CHAIR MALMUD: Thank you.

Dr. Welsh?

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

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

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

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

agency way overblown.

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

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

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

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

CHAIR MALMUD: Thank you, Dr. Suleiman.

Another comment?

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

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

CHAIR MALMUD: Another comment?

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

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

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

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

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

(Laughter.)

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

CHAIR MALMUD: If I may, I will try as

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

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

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

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

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

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

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

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

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

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

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

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

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

are useful for administration to patients.

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

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

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

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

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

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

CHAIR MALMUD: The waste storage?

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

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

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

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

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

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

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

(Laughter.)

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

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

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

CHAIR MALMUD: So it may require some legislation?

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

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

CHAIR MALMUD: Good. That is one step forward.

Did you want to have a comment?

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

CHAIR MALMUD: Good. So they are moving.

MR. LEWIS: They are moving.

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

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

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

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

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

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

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

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

10. MEDICAL RELATED EVENTS

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

I would like to point out that each year I

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

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

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

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

find is especially interesting.

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

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

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

make just to kind of set up for the presentation.

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

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

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

going back and looking at all of their prostate procedures.

You will see that very rarely do we have one, but we did have a teletherapy event in 2008. We didn't have any this year. Most of our 35.1000 emerging technologies issues are associate with microspheres, both the TheraSpheres and also the SirSpheres microspheres.

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

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

We range between the high 30s and mid 40s. I presented those medical events. And I have given you a change from those that occurred the year earlier so you can see where we have gotten more events in one category, less events in another category.

We had essentially a bumper year in the manual brachytherapy. We had an eye applicator event. We don't normally have eye applicator events. Most of the 35.400 were in prostate brachytherapy.

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

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

Yes?

MEMBER GILLEY: Are there new slides?

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

MEMBER EGGLI: There is a change in 35.300.

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

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

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

MEMBER GILLEY: Thank you.

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

The first group would be modality 35.200.

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

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

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

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

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

having five of these. So the slide is a little bit out of date. We had one monoclonal antibody. And this is the one that they were injecting into a port. They did not visualize the port. They did not palpate the port. And when they injected the monoclonal antibodies, they did not get them into the port. So they went into subcutaneous.

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

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

intended.

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

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

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

year before.

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

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

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

Let me see where my line goes on that one. We had another case where all of the seeds were put into the prostate, but they were clumped. And, therefore, the patient got 37 percent of the D-90. I think that shows that the geometry of the positioning of the manual brachytherapy sources is really critical to delivering the dose that is prescribed for the patient. And just getting the seeds into the prostate is not sufficient to determine whether the patient has

been adequately treated.

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

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

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

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

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

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

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

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

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

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

HDRs.

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

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

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

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

This year we also had a bumper crop for

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

So that completes just my overview of the

medical events and some of the cases that weren't medical events that were reported to us in F.Y. 2009. Are there any questions or comments?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. HOWE: Yes.

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

DR. HOWE: They weren't used.

CHAIR MALMUD: Okay.

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

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

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

DR. HOWE: Yes.

CHAIR MALMUD: Thank you.

Dr. Welsh?

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

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

MEMBER WELSH: 080896, the gamma knife.

DR. HOWE: The gamma knife?

MEMBER WELSH: Gamma knife event.

DR. HOWE: Yes.

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

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

MEMBER WELSH: 080896.

DR. HOWE: 896. Okay.

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

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

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

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

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

CHAIR MALMUD: Thank you.

Dr. Welsh?

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

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

CHAIR MALMUD: Thank you.

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

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

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

CHAIR MALMUD: Thank you.

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

And I wondered what the other members of the Committee might be interested as a solution that might be proprietary connectors or color-coding of these devices to maybe eliminate that as our problem. We are still seeing HDR misadministrations with wrong catheters and transfer tubes in those combinations.

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

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

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

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

CHAIR MALMUD: Debbie?

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

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

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

CHAIR MALMUD: Does that answer your question, Debbie?

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

CHAIR MALMUD: Dr. Thomadsen?

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

MEMBER GILLEY: Are the transfer tubes also?

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

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

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

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

CHAIR MALMUD: Dr. Van Decker?

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

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

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

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

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

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

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

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

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

DR. HOWE: It is how we count things. We count medical events if they come from one facility and we know they are associated as one medical event. But it may affect many patients. So for the VA Philadelphia case, we had one NMED number, but that NMED number has many, many entries in it until you get up to the 98 patients.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. HOWE: Yes.

VICE CHAIRMAN THOMADSEN: Okay.

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

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

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

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

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

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

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

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

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

CHAIR MALMUD: I would just comment that I

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

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

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

CHAIR MALMUD: Thank you, Dr. Thomadsen.

I think we have another question.

MEMBER LANGHORST: Yes. Sue Langhorst. I

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

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

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

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

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

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

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

CHAIR MALMUD: Thank you.

Dr. Howe?

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

So while we may not have statistically significant numbers, we are seeing engineering trends that are responding to difficulties people are having. And I think the NMED reports and the medical event reports are very important in the new technologies.

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

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

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

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

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

CHAIR MALMUD: Yes.

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

CHAIR MALMUD: Yes.

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

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

CHAIR MALMUD: Thank you.

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

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

DR. HOWE: I think that --

CHAIR MALMUD: Yes.

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

DR. HOWE: Orhan and myself.

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

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

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

MEMBER GILLEY: There were five of us.

CHAIR MALMUD: We have --

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

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

(Laughter.)

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

CHAIR MALMUD: Yes? Do you have a comment?

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

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

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

MS. COCKERHAM: Subcommittees are solely at your discretion.

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

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

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

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

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

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

(Laughter.)

MEMBER MATTMULLER: I second the motion.

(Laughter.)

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

(Laughter.)

CHAIR MALMUD: Thank you for having

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

MEMBER SULEIMAN: With Dr. Welsh as chair?

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

MEMBER WELSH: Thank you.

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

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

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

Who will lead off? Thank you.

11. UPDATE ON PERMANENT PROSTATE

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

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

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

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

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

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

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

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

directive.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

delivered to the treatment areas.

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

Any questions? Yes, sir?

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

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

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

MR. WIEDEMAN: That is correct.

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

MR. WIEDEMAN: That is correct.

CHAIR MALMUD: Thank you.

Other questions?

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

CHAIR MALMUD: Dr. Welsh?

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

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

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

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

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

DR. HOWE: I have a question.

CHAIR MALMUD: Dr. Howe?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Now, if you are looking at it from the sagittal view, this problem will always occur because you are advancing, you are moving the needle this way. So you move it until you hit the point and say, "Okay. This is the base." And then you adjust by retracting the needle.

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

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

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

percent of the dose delivered to the prostate.

Thank you.

CHAIR MALMUD: May I ask you your question?

DR. DODOO-AMOO: Yes, just a contribution. It is not a question. Just because I deal with this a lot, I know where the problems come up. So I am trying to contribute to how they can solve this problem.

CHAIR MALMUD: How they can solve the problem.

DR. DODOO-AMOO: The problem, yes.

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

Other comments or questions? Dr. Guiberteau?

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

And I am just curious to know in this instance, since there seemed to be an issue with training and limited experience where the failure was. First of all, were there criteria in place or were they delegated to the entity to which the department was outsourced?

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

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

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

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

DR. GUIBERTEAU: No. This is a committee

of the medical staff that does this.

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

DR. GUIBERTEAU: In the institution.

MS. FRAZIER: Right.

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

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

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

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

So the question is, since this is standard

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

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

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

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

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

CHAIR MALMUD: Thank you.

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

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

information.

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

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

And you are correct. It is not an NRC issue in terms of performing the procedure. It's a hospital credentialing issue, which is outside of the scope of the NRC. Apparently, though, it is an important point but not related to your investigation.

Dr. Eggli?

MEMBER EGGLI: Working in a department that had a VA contract for several years, the VA has a credentialing process similar to what you described.

CHAIR MALMUD: Thank you.

Dr. Welsh?

MEMBER WELSH: Jim Welsh. I am still trying to get a better understanding about how all of this could have possibly happened. And the points just raised about the questions regarding credentialing are important points that should be answered. I don't know if anybody would have the

answer to these questions, but I throw them out anyway.

Do we know if these were done via a pre-plan versus intraoperative planning? And if they were done by pre-plan, which is what I assume, we know that hormone therapy can cause a very drastic change. And do we know what fraction of these patients might have had hormonal therapy that could have led to a very different size/shape prostate during the procedure compared to when the pre-plan was done?

These are factors that come into play whenever you're looking at an outcome in terms of dosimetry that differs substantially from what was initially anticipated. And so I am just trying to figure out how this could have possibly happened if there is anything other than incompetence that could explain it, for example.

MR. WIEDEMAN: There was one case that I was aware of that there was a patient that was on hormone therapy, but that is only because it came up about the size of his prostate, which was real large. And they were trying to compensate for that.

MEMBER WELSH: But, as far as you know, it's not like all of these patients had hormone therapy because that could explain things.

CHAIR MALMUD: Dr. Welsh, your point is that the installation of the seeds itself will cause the prostate to swell because of the penetration of the prostate. And, therefore, 24 hours later is too soon to determine the dosimetry. And at the same time, hormonal therapy will shrink it and cause some change in the geometry as well? Those are the two points you were making before?

MEMBER WELSH: You are correct. The first point is that poking any organ with a bunch of needles and implanting foreign bodies is going to cause significant swelling. And that edema can occur right after the procedure, making post-implant dosimetry right after the procedure especially challenging.

But my second question was regarding the hormone therapy, which we know can cause a significant reduction in prostate volume. We intentionally do this on occasion. When the prostate is too large for implantation, we want to shrink it down.

But if we do the pre-plan before the prostate has stabilized in terms of its ultimate shrunken-down volume, you can get a very misleading pre-plan. And it could be that the prostate would be one-half the volume when you do the procedure than when you did the plan. And that can lead to

significant difficulties intraoperatively.

CHAIR MALMUD: Thank you.

Are there other questions or comments? Yes?

MR. LEWIS: Well, if I could just make an observation that all of these insights are very valuable? In terms of roles and responsibilities, what the inspectors have presented here is largely the VA's only analysis.

And our oversight of their analysis is through our inspection process, in which we're looking for safety issues, regulatory compliance in compliance with any commitments they have made in a license application.

We have our own independent medical consultant to verify what the VA has analyzed, but our role is that, is verification. And a lot of the comments that have been made around the table might be very valuable for VA to think about when they respond to our inspection report, but in terms of roles and responsibilities, it is not for NRC to decide -- well, it is for NRC to decide if compliance existed. It is for the licensee to provide for the safety of the patients and the workers.

CHAIR MALMUD: Thank you.

We have a question from a member of the public. Would you please introduce yourself and then your question or comment?

MS. FAIROBENT: Lynne Fairobent with AAPM. I think this might be to Rob because I think you may have answered Debbie Gilley's question earlier regarding safety culture implications.

Since one of your findings is that you determined lack of safety culture, I am curious since we are awaiting further direction, discussion, whatever, on safety culture and implications for our materials users, in lieu of the fact that there hadn't been a policy prior or during this period, how did you make a determination? And what are you judging that you found a lack of safety culture there? What are you measuring it against to determine that finding?

CHAIR MALMUD: Your question is for whom?

MS. FAIROBENT: NRC. They're all nodding to each other as to who might respond to that.

MS. FRAZIER: I will respond to that. The lack of safety culture that we are speaking of has to do with reporting radiation concerns to the appropriate individuals. And I will give you an example.

We interviewed two of the medical

physicists that were involved in the treatments. And one of the physicists indicated that he raised a concern to the authorized user physician and no action was taken by the physician. However, the physicist did not raise the concern with the radiation safety staff at the VA Philadelphia.

Another example is the other physicist also had a concern. And the concern that they had was that the physician that they worked with was underdosing the patient. Now, they raised this concern to the affiliated institution because they were consultants, but they did not raise the concern to the radiation safety staff at VA Philadelphia.

So there seemed to be no procedure in place that would cause them to raise a concern that was not taken care of by, say, the physician and raise it higher to the RSO or the radiation safety staff or the Committee or outside of the physician. So when we say, "lack of safety culture," that is what we are speaking of.

CHAIR MALMUD: Did that answer your question?

MS. FAIROBENT: Not completely. If there is noting to require that that may have existed, then how can you find action against something that they

did not do if they did not know to do it and there was no requirement requiring them to do it?

MS. FRAZIER: Well, actually, when we interviewed the radiation safety officer and the staff, they did have procedures in place that if something did not go right or if they had a problem, they were told to raise it to the radiation safety officer. But this did not take place.

CHAIR MALMUD: Thank you. Would you please once again introduce yourself and then make your comment or question?

DR. DODOO-AMOO: Again, my name is Dr. David Dodoo-Amoo.

My question is of you during your inspection because at least I saw that you were giving these after, after you had done the procedure and you are looking at files from scan. Did you take your time to follow through from the initial stage to the end, like the volume steady, all that it does from the VeriSeed to the OR, even how they receive the seed, all of those procedures? Did you follow through all of them?

Because along that line, did you check whether the equipment, the ultrasound, is even showing because if there are a lot of problems with the

ultrasound, you may not see the prostate? It is very difficult with some of these ultrasounds to see that prostate on the screen.

So did you take your time to follow through every step to the end, even after the pre/post-plan to submit all of them? Did you take your time? Because all that you have here is on paper. And that will help you to identify where the actual things were. Did you do that?

MR. WIEDEMAN: That's one of the reasons why this inspection has taken so long. We looked at every one of the cases from the pre-plan. Everyone had a pre-plan all the way through to the post-plan and then for the re-evaluation done by the new contracting physicist and oncologist.

But you have got to remember, some of these occurred back in 2003-2004. So to follow all the way through surgery, that would be totally impossible because it is past tense.

And, plus, our medical consultant has reviewed all of the medical records, the therapy follow-up on the patient, looking at PSAs and Gleason tests. So I think we have done a very thorough job in evaluating each one of these cases.

DR. DODOO-AMOO: What I was trying to ask

is you send some patient to other hospitals to reimplant. I mean, from there, you are going to look at the live procedure. What is it you are doing from the onset to the end? Did you also look at that? Because those were sent for reimplant. That is where you can also look at that and then see what is going on. Then you can see those.

I mean, you can go back to the same hospital with the same doctor because that is a problem that when you send a patient to another VA hospital, did you follow through on those patients from the beginning to the end?

MS. FRAZIER: As far as our inspection or looking at it from the regulatory side, we did follow the patients from the pre-treatment to the post-treatment.

Now, as far as the patients being the decision to have them re-treated, that is the clinical aspects of it. And we don't follow through from the clinical side just looking as far as our inspection was involved.

We do get information on the number of patients that were re-treated, but we have not gone beyond that because, really, we just had that information during our last inspection.

But just keep in mind that we are looking at the regulatory aspects of the medical events.

CHAIR MALMUD: Thank you.

We have another question from a member of the public. Please reintroduce yourself.

DR. WESLEY: Yes. I am Dr. Wesley again from the VA IG's office.

To the NRC team, do you have any indication that the kind of problems you identified extend to other VA facilities other than Philadelphia, number one? And, number two, do you have any sense that these kind of events happen in the private sector?

MS. FRAZIER: We have had medical events that have been -- at some of the other VA facilities, they have 13 total facilities that do prostate brachytherapy. And we have had medical events at the other facilities.

We have not had the numbers that we have at VA Philadelphia. So we don't believe that the VA Philadelphia is at this point an isolated issue. We are still looking into the other cases.

We have five facilities thus far that have suspended their programs based on the medical events that they have reported to NRC.

DR. WESLEY: Second half of the question, do you see these kinds of things in the private sector or is this the VA reporting a lot?

MR. WIEDEMAN: Well, I can add to that. Now, I have gone out, and I have looked at Jackson, Mississippi; Minneapolis, Minnesota; Cincinnati VA; the Seattle VA; the Reno VA. And there are other VA facilities that have very similar problems, not to the degree that Philadelphia has but very similar, similar in the sense that they have medical events.

They had physicians that disagreed to how an implant should be done. They were behind on post-implants, doing post-implant treatment plans. But they were all aware of the Philadelphia problems, and they were trying to get these problems corrected.

DR. WESLEY: That wasn't going to the question about the private sector. Do these things happen in the private sector?

MS. FRAZIER: I think we have medical events.

CHAIR MALMUD: Dr. Howe?

DR. HOWE: I've been looking at the medical events now since probably 2003. We have medical events in manual prostate brachytherapy in the private sector. When we have medical events, we may

have one or two cases at a given facility.

We have never had the level that we had at VA Philadelphia, where you are talking 80-90 percent of all the people treated for a medical event. So no, we have not had anything similar to that.

We had in other cases had a high number of medical events. And in this case, I am referring to teletherapy medical events or eye applicator medical events, where the high numbers have been as a result of a mechanical type of interpretation at the beginning of decay or generally decay. And that error has followed through for a number of years until it was identified but nothing like this in prostate.

CHAIR MALMUD: Other questions or comments? Dr. Suleiman?

MEMBER SULEIMAN: This is one of my conflicted areas where I see sometimes we'll from my agency write a simple regulation, one sentence, and defer it to the professional practice. And then you've got different professionals with different responsibilities, some ethical. And you have got a fuzzy area where it is acceptable, where you have professional disagreements. What happens when something like this happens and you swing in the other direction, you get more prescriptive, more control,

more oversight?

But what bothers me -- and I'll air it here -- is I see this all the time where we have experts running all over the place and saying they're not doing a good job, but how do you establish some sort of infrastructure -- safety culture is what you are mentioning -- where people go to the right people and not get blown off because, oh, that's just the way we do things.

And is it the physicist's responsibility? Is it the institution's responsibility? Is it the other physician's responsibility? How is this described?

And in terms of the private sector, this stuff is way, way under-reported. I mean, we know that. Adverse events just capture the tip. These are soft, soft numbers. But the point is it brings issues to the surface. And it addresses issues that could be resolved.

What are the lessons learned from this exercise? Who is going to be responsible for not over-regulating these specialists but at the same time capturing something like this before it gets on a scale that we have just observed?

MR. WIEDEMAN: That's an interesting

question because Sandy and I both interviewed the physicist and the physician. When you talk to the physician, he would say that "I relied on the medical physicist to tell me if I have a medical event."

And you go to the medical physicist. And he says, "Well, I have relied on the physician. That is a medical decision, not mine." And so we have got them both pointing fingers at each other, but neither one will assume the responsibility.

MS. FRAZIER: I just wanted to add I think the VA Philadelphia, one of their corrective actions that they have taken is to provide training to the radiation oncology staff as well as to the physicist, all new employees and trainees. What they're training their staff is the NRC regulations, how to identify a medical event, how to report and who to report the medical event to.

And also included in their training, they have an open-door policy that they have initiated. And this is for reporting concerns and suspected violations.

So I think one way that they are in a process of resolving this is to do it by training your staff.

MEMBER SULEIMAN: You see, what bothers me

is that if you had a real professional relationship among the different -- they would be communicating. And when an issue was raised, somebody would say, "Maybe they've got a point" and look into it. It shouldn't have to get to the regulatory agencies to spell something out. And I think that is the fault of the professionals themselves. I think they've got to regulate themselves in a more effective manner.

CHAIR MALMUD: Dr. Guiberteau?

DR. GUIBERTEAU: I just want to make a philosophical comment based on a lot of reading in safety cultures. I think what was just said about pointing fingers, about professionals, it isn't just the professionals. I mean, a safety culture should be pervasive in an institution.

And one of the number one causes of a failure of a safety culture, which is what the airline industry has mastered, by the way, is that it turns out to be a federation of safety subcultures, little silos. And people don't know what the people are doing.

I am just saying that is one thing that we all ought to remember, that when these things fail, it is not just because of the professionals. It is the people who work under the professionals. It is the

administrators. It is everybody. And too often we forget that.

CHAIR MALMUD: Dr. Howe?

DR. HOWE: I would just like to make a point, kind of as a tangent. This Committee has discussed many, many times about training and experience for authorized users. And they have contrasted between the alternate pathway and the Board certification pathway.

I think it is important for you to know that the individual who made all of these medical events was a Board-certified radiation oncologist and was considered an authorized user under the Subpart J criteria of Board certification. And I think that is important to keep in mind.

CHAIR MALMUD: Thank you. I don't believe anyone assumed otherwise, but thank you for the clarification.

Dr. Welsh?

MEMBER WELSH: Jim Welsh. I am sorry to belabor these minor details, but one final comment I might have regarding reconstruction of dose. I mentioned earlier that if you do the post-implant dosimetry too soon, you can be misled because of the edema that goes along with the procedure, but,

similarly, you can be misled if you do the post-implant dosimetry far too late. And, as you mentioned, some of these scans were done a year or longer afterwards.

And I just throw that out as a caveat in that there can be some atrophy in areas that are dosed and perhaps compensatory hypertrophy in areas that were underdosed, leading to a prostate that, for example, in the example you have on the slide, it could lead to a pear-shaped prostate down the road. And if you do the dosimetry at a later time point, you could be misled.

I think that is understood, but I would just bring it up since we are discussing this.

MS. FRAZIER: I think I just want to just add that the dose assessments that we have received from VA, VA Philadelphia, they had decided that they were using the next-day CT. They did do CTs on all of the patients in 2008. And then this year they were looking at those CTs versus looking at the one-day CT. And they're coming in with analysis. But they have decided to do the one-day CT, as opposed to the 2008 CT.

CHAIR MALMUD: May I ask a question as a non-radiation oncologist? What is the standard in the

United States for doing the post-therapy CTs? What number of days, weeks? Dr. Thomadsen?

VICE CHAIRMAN THOMADSEN: The recommendation, both by the ABS and new AAPM task group is for iodine at about 30 days, although there are a number of places which do maintain that it is good to do it the day of the implant, immediately following, to make sure that you have covered things and don't have major gaps or hot areas.

CHAIR MALMUD: So the standard, the recommendation, of the ABR is the next day?

VICE CHAIRMAN THOMADSEN: No. Thirty days.

CHAIR MALMUD: Thirty days.

VICE CHAIRMAN THOMADSEN: ABS. ABS, not ABR.

CHAIR MALMUD: Okay. ABS is 30 days?

VICE CHAIRMAN THOMADSEN: The American Brachytherapy Society.

CHAIR MALMUD: Thirty days?

VICE CHAIRMAN THOMADSEN: Thirty days.

CHAIR MALMUD: And how long has that standard been in place?

VICE CHAIRMAN THOMADSEN: Several years. I don't know exactly. I don't remember.

CHAIR MALMUD: Only several years.

VICE CHAIRMAN THOMADSEN: Several could be a decade.

CHAIR MALMUD: A decade.

VICE CHAIRMAN THOMADSEN: It could be five. I don't remember what it was. We could look that up, of course.

CHAIR MALMUD: Thank you.

Dr. Suleiman?

MEMBER SULEIMAN: Just a quick question. Do they not do it immediately because there is swelling in whatever? And other studies would show, I'm sure, what is the difference between the images taken immediately after, within 24 hours, and 30 days later?

VICE CHAIRMAN THOMADSEN: Bruce Thomadsen. The answer to your question have there been studies, yes. People who have done that have shown that there is not the maximal swelling immediately after that comes about a day or so later. It goes up. But there is swelling compared to a month later.

A month later you still have some swelling, but the month has been picked with iodine as a good time to do the dosimetry to represent over the year of treatment what would probably be the dosimetry

that the implant would get.

CHAIR MALMUD: Dr. Welsh?

MEMBER WELSH: If I might just add, things get a little bit complicated when we use isotopes other than iodine-125 with its 60-day half-life. For example, if you're using palladium-103 or if you're using cesium-131 with shorter half-lives, the impact of the edema on the dosimetry can be relatively more significant. And, thus, there is not a uniform time point for which post-implant dosimetry was recommended. It is isotope-dependent. And it is still debated.

CHAIR MALMUD: So if I understand what you are saying is that at this institution, they used I-125 seeds. And there is no standard for I-125 seeds.

MEMBER WELSH: The ABS recommendation is one month.

CHAIRMAN MALMUD: The ABS recommendation is one month for I-125 seeds. And was that performed at one month? No because I think you said the patients were from out of town, and they didn't schedule it. Thank you.

Any other questions regarding this issue?

(No response.)

CHAIRMAN MALMUD: If not, we thank you for bringing it before us. We have been concerned about it and interested. And we appreciate the information. Thank you.

MR. WIEDEMAN: Thank you.

MS. FRAZIER: Thank you.

CHAIRMAN MALMUD: Dr. Welsh, by what percent does the volume of the prostate increase maximally after the insertion of the seeds? I know it's not uniform, but what is the most you have seen it increase?

MEMBER WELSH: I have read in the literature. I have experienced in my own practice a factor of 1.4.

CHAIRMAN MALMUD: 1.4. Total volume?

MEMBER WELSH: Yes. So if you have a volume on day zero of 50 cc, the day after the implant, after maximum --

CHAIRMAN MALMUD: Only one conversation at the table, please. Only one conversation at the table.

MEMBER WELSH: Due to the trauma of the needle insertions, due to the foreign bodies, due to the radiation, it can be 40 percent larger.

CHAIRMAN MALMUD: And is the swelling

sufficient to close off the urethra and require catheterization?

MEMBER WELSH: Yes. In my practice and many others, a Foley catheter is left in for at least the first 24 hours, but it is not at all uncommon for patients to require recatheterization after that Foley catheter is removed because of this problem.

CHAIRMAN MALMUD: So in your practice, how long do you have to keep track of those patients following therapy in the event they need to be catheterized?

MEMBER WELSH: Well, the catheter is removed the next day. And they are instructed to contact, go to an emergency room if necessary because of inability to void. But they would be in regular contact with the oncology team for the next several days and come in for routine follow-up about two weeks later.

CHAIRMAN MALMUD: Thank you very much.

We have another item on the agenda. And we'll move forward to the International Commission on Radiological Protection Publication 103 Subcommittee report and discussion. Dr. Thomadsen?

VICE CHAIRMAN THOMADSEN: Thank you.

CHAIRMAN MALMUD: Microphone.

VICE CHAIRMAN THOMADSEN: Thank you.

12. INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION (ICRP) PUBLICATION 103 SUBCOMMITTEE REPORT AND DISCUSSION

VICE CHAIRMAN THOMADSEN: At the last meeting, a subcommittee was set up with Ms. Gilley, Dr. Van Decker, and myself to look at the recommendations of the ICRP publication 103 and make a recommendation to this Committee as far as what maybe should be adopted from that.

Here is our charge, which if you just slip down to number 3 on the slide to discuss the options, consider the cost benefits, and fundamentally dues associated with revising the radiation protection framework, as presented by Dr. Cool, with regard to effective dose terminology, numerical values, occupational dose limits, dose limits for embryo and fetus, and constraints, and to identify other code 10 CFR Part 20 issues, which might arise from adoption of ICRP 103.

Terminology in radiation protection has always been a bit confusing, particularly because the actual terms used changed frequently but have little changes. And the difference in the names between quantities also does not help distinguish one quantity

from another. And moving from effective dose, rather than total effective dose, would simply both the name and the quantity at the moment, at least, with qualifications that we will be discussing through here.

One of the recommendations of ICRP is to use effective dose. And with the most to effective dose, it would be expected that licensees could calculate that. For the most part, they cannot. For the most part, a licensee will have a badge reading. And from that badge reading, if they were to calculate effective dose, they would need to know the doses to the various organs because for effective dose, you have to convert the dose given to the dose to each organ multiplied by that organ's weighing factor and add that all up to get the effective dose.

You don't have enough information to do that. Almost no licensee could do that. To demonstrate compliance, then, we would have to have something where the badge readings would stand in as a surrogate for the effective dose with the assumption that the radiation received by the badge wearer was to the whole body.

To do this; that is, allow the badge reading to be used in place of the effective dose

would require recognition of methods to convert readings to effective dose and some approximations, such as the methods of the National Council of Radiation Protection and Measurements in the report 122, which gives algorithms to try to approximate effective dose given badge readings.

The weighing factors in ICRP 103 are different form the previous, which would be ICRP 60, but the changes in the weighing factors would have very little effect in the medical community since people couldn't really use those anyways except for internal exposures.

The use of effective dose replaces the organ-specific limits in ICRP. Whereas, right now in the regulations, we have limits for organs, that goes away with just looking at effective dose.

And for a single organ irradiation, most often this would be an increased in allowed exposure, but when you don't have irradiation of a single organ, which is the most common situation here, it is probably a decrease. But you would have to go on a case-by-case basis. The subcommittee supports moving the value through the weighing factors in both the numerical values and for the items in the lists of things which are given weighing factors.

Just so that our regulations would be more compliant with the rest of the world at the moment and, as we said earlier, this is probably not going to change anything for most medical uses of radiation.

Values for occupational limits are different in ICRP 103. And if we adopted those, the occupational limits would change from the 50 millisievert per year to 20 millisievert per year. Actually, ICRP is more complicated than that.

And I put an asterisk there with a footnote to show it is actually 20 millisievert per year averaged over 5 years and less than 50 millisievert in a year and whether you would want to have this more complicated rule or just have the 20 millisievert per year would be a decision that would have to be made.

Lowering the limit for the most part would not be a problem for the medical community given the following. If badge readings were converted to effective dose, as noted before, we could use a method, such as the NCRP 122 algorithm or there are several others in the literature. If that badge reading were allowed as a surrogate for effective dose, then that would take care of one problem.

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internal exposures.

The use of effective dose replaces the organ-specific limits in ICRP. Whereas, right now in the regulations, we have limits for organs, that goes away with just looking at effective dose.

And for a single organ irradiation, most often this would be an increased in allowed exposure, but when you don't have irradiation of a single organ, which is the most common situation here, it is probably a decrease. But you would have to go on a case-by-case basis. The subcommittee supports moving the value through the weighing factors in both the numerical values and for the items in the lists of things which are given weighing factors.

Just so that our regulations would be more compliant with the rest of the world at the moment and, as we said earlier, this is probably not going to change anything for most medical uses of radiation.

Values for occupational limits are different in ICRP 103. And if we adopted those, the occupational limits would change from the 50 millisievert per year to 20 millisievert per year. Actually, ICRP is more complicated than that.

And I put an asterisk there with a footnote to show it is actually 20 millisievert per

year averaged over 5 years and less than 50 millisievert in a year and whether you would want to have this more complicated rule or just have the 20 millisievert per year would be a decision that would have to be made.

Lowering the limit for the most part would not be a problem for the medical community given the following. If badge readings were converted to effective dose, as noted before, we could use a method, such as the NCRP 122 algorithm or there are several others in the literature. If that badge reading were allowed as a surrogate for effective dose, then that would take care of one problem.

Another issue that could cause a problem for the medical community is the ALARA levels. For the most part, while the current regulations would allow 50 millisievert per year, most people assume that following ALARA, those limits should be held at about a tenth of that to 5 millisievert per year.

If that level were kept the same and moved down 2 millisieverts per has. Then that would not be a problem for most medical facilities. If it would have moved to two millisievert per year, that could be a big problem from any medial facilities, particularly for interventionalists, who frequently might be

pushing that limit.

We also noted it is clear that the badge change frequency depends on the expected reading and should be allowed to vary with the expected readings. And investigational levels should vary with the application, rather than just have a blanket investigation level for everybody in a facility.

Further conditions regarding occupational limits, shielding should not have to be retrofitted to meet the new limits. Grandfathering of installations that are already built should be allowed. Otherwise you would probably have a large, an extremely large, cost to the culture, to meet the new limits with probably very little benefit.

Actually, this likely will satisfy the new limits only because people who do the shieldings usually make various conservative assumptions and probably had built in limits already. The rationale to reduce limits is not strong enough, though, to mandate additional costs for redoing the shielding.

Dose limits to the embryo and fetus would have a major effect on the medical community in that ICRP 103 recommends reducing the limit to one millisievert per term, currently have a limit of five millisievert per year per term.

This would most likely require removing staff from service at times, particularly if somebody works in a fluoroscopy environment. This could deprive patients of those expertise.

If this change occurred, it would have to be clear that a badge worn under a lead apron would apply and not a badge outside the apron that you would accept that the lead apron does attenuate most of the radiation that would go to the embryo or the fetus.

In the document that gave us our charge as to what to consider as far as the changes with ICRP 103, there are three options that should be considered. One is to change the limit to one millisievert after the declaration. And that was sort of discussed in the previous slide and the problems with that.

Another is to limit to .25 millisievert after the declaration, to keep the total below one millisievert assuming that the person has worked with radiation and has gotten some doses beforehand and look at the note for the next option, which is to make no changes in the rule.

And for both these last, we have, next slide. When we considered the dose limits for the embryo or the fetus, the limit of one millisievert per

term comes out to .11 millisieverts per month, or 11 millirem per month in the older units. This is usually right at the edge of badges', radiation badges', ability to measure the radiation.

The one millisievert itself, the limit for the term, is less than background in many places, not counting inhaled radon. One millisievert is actually less than the variation in background that we have. And there is no evidence of detrimental effects at that level or at the variations in background around that level. And so it is not clear that making the change really has any benefit to society.

Another aspect dealt with in ICRP 103 is potential exposures. For those who may not be familiar with this, a potential exposure is not one that has happened but one that could happen. And it is based on risk analysis where a facility goes through risk analysis, decides that exposures somebody might end up with due to accidents, what are the probabilities, and assign some weighted probability dose to these people already, and reduce that from their allowed limit.

The recommendation of this subcommittee is the NRC should not adopt the concept of potential exposure. The benefit is not clear. The principle is

not well-supported. Assigning variability and making assumptions to guess at potential exposures will be very difficult and very onerous for the licensee to try to accomplish. The considerable cost would not be offset by any benefits. And compliance would be hard to impossible to assess.

On the other hand, emergency exposures are dealt with, although likely, by the ICRP, which gives very little guidance but some on emergency exposures. But if the NRC is rewriting the NRC rules, it might be a good time to consider this issue and provide some guidance to users as far as what to consider in those situations. Keeping the language to allow increased exposure for caregivers and families of radioactive patients would be essential without compromising health care.

And just a couple of final points. Any changes in the rules must not be onerous or compliance will suffer. For example, if we make the doses too low, people will find it useful to keep the dosimeter in their desk, at least much of the time.

The ICRP recommendations are based on studies that have been criticized, and highly criticized, for ignoring oppositional data in studies. For example, studies by Bernard Cohen are not even

cited in the literature on which ICRP 103 based their recommendations. That leaves a suggestion for lower limits very poorly supported.

And, with that, I will close the presentation on our study and open the floor for discussion at the discretion of our Chair.

CHAIRMAN MALMUD: Dr. Van Decker?

MEMBER VAN DECKER: Thanks.

I would just like to amplify one of the concepts here, feeling mildly on ease as the surrogate clinical representative of probably the most regulated group here, being the occupational clinical exposure from sinifluoro, usually affecting mostly obviously interventional cardiology and interventional radiology, although I guess some high-volume PET facilities could touch some of these over a year.

You know, there is always this give and take of making sure that you keep productive workers productive. You know, people who are radiation-savvy have been trained to handle themselves in these situations so that you don't get yourself in a situation where you have to increase your output of experienced workers in order to match your case volume of needed procedures, especially in a field where we haven't seen dramatic abnormalities occurring with our

current limits. And I would point to the final two points on Bruce's last slide in that regard.

I did appreciate interacting with my two colleagues on the subcommittee. And after a lot of thought here, I think there is a lot to be said for the fact that the current fears of being close are usually due to external badge readings and that the use of effective dose as a more reasonable calculation of internal exposure, which may in the end be much more administratively simpler than what is going on right now and from what we know about those calculations, actually may make these calculations well within reason for this lowered standard for our annual allowed exposure I think makes sense.

And I am hopeful that those communities will find it that way as well, but I am sure there will be some discussion about it from the outside stakeholders' discussions as well.

CHAIRMAN MALMUD: Thank you, Dr. Van Decker.

Dr. Suleiman?

MEMBER SULEIMAN: I commend the committee for the report. I agree with most of the comments very strongly. I have a real problem with any regulatory limits below background radiation. I am

glad you addressed that.

I see that all the time from my colleagues at FDA who don't have a radiation background. These are our physicians. And when I explain what the natural background levels are, they say, "Why would we bother?" So I think that I am glad you addressed it and didn't ignore it.

We have had some experience in terms of monitoring organ doses and whole body doses. Our experience with some of our research protocols is that, yes, the organ doses are the constraining limit. Rarely do people exceed the whole body or in this case the effective dose limits.

That could result in higher doses. And it is possible that you may want to consider specific organ dose limits because it is possible that some organs could receive a very high dose -- let's say all the dose was in one organ -- and still be very, very well below the effective dose limit.

So I wouldn't throw the organ dose-specific constraints completely outside, but it may need some attention. And I think the ICRP addresses that like for the eye for cataract and some other issues. Otherwise I think very nice, very nice summary.

CHAIRMAN MALMUD: Thank you.

Other comments? Rob?

MR. LEWIS: Well, I am going to have to excuse myself in a few moments. A couple of thoughts. I agree with Dr. Suleiman. I thank the group for looking at this issue and the recommendations.

I am glad you mentioned cataracts because, as I understand, ICRP does address. There is a lot of anecdotal information at the current lens of the eye limit in our regulations that is not protected. And there is a lot of information that says it is protected. I think that is a key policy issue that we need to look at in terms of part 20.

Another thing, I'm surprised you mentioned in passing is caregivers. Why the NRC or any regulatory agency says a caregiver can only get 500 millirem is a question that I think we could look at closer. I am surprised, frankly, that the subcommittee didn't come out stronger on that point of why shouldn't it be a higher amount.

CHAIRMAN MALMUD: Thank you for that comment.

MR. LEWIS: Thank you.

I assume that these will be submitted as an overall Committee letter to the NRC or something in

the future?

CHAIRMAN MALMUD: Yes, it will.

MR. LEWIS: Okay.

CHAIRMAN MALMUD: Yes. Dr. Welsh?

MEMBER WELSH: I would like to just reiterate what Dr. Suleiman said, commend the subcommittee for the great job it has done and just raise the question once again, the general question, about what the purposes are of having these limitations. They are supposed to be for public safety.

The question that always rears its head when we are dealing with this particular topic is, what evidence is there that these low doses are really detrimental? And should we be arguing about one millisievert versus five millisievert when we know that the populations and areas in India, Iran, China have natural background radiations that are in some cases an order of magnitude higher than what we are talking about here? Yet, there is no evidence that these people are really harmed.

So if we were to extend this concept to its fullest extent, we would say that somebody who lives in an area around the Gulf states in this country might have to have a different annual limit

than somebody who lives in the Rocky Mountain states because of the natural background rivaling the numbers that we're talking here.

Hopefully the argument will never be carried to that ultimate foolishness, but I bring it up because it is something that always has to be thought of when we are talking about such low numbers.

CHAIRMAN MALMUD: Thank you.

Dr. Eggli?

MEMBER EGGLI: You actually don't have to go as far as India. You get to central Pennsylvania, and it's three times the limit proposed here.

The other thing is I think the sensitivities to radiation are a public perception issue. ICRP is dominated by in a large sense I think a European perspective, where public sensitivities to issues related to radiation are much greater than they are in the United States.

So I think that, in fact, what we are talking about is not necessarily always radiation safety but the politics of perception. And to do something that will cause more harm than good by lowering levels to unreasonable limits does not really accomplish the goal of protecting the public.

Certainly with occupational workers, it is

clearly true that someone whose livelihood depends on being a radiation worker is going to take off their badge and put it away if they are approaching these limits. There is just no question about that. It is going to happen.

You know, if you are engaging in the safest practice you can and your practice takes you towards what is now an unreasonably low limit, you will take off your badge and you will put it away.

So I think that we need to resist the pressure to follow suit with the Europeans simply because they face different political pressures than we do in the United States.

CHAIRMAN MALMUD: Thank you, Dr. Eggli.

MEMBER FISHER: Yes. Thank you. The subcommittee should be commended for doing a pretty thorough job of analyzing the problem. One comment I would like to add is that in many institutions, we have institutional limits that are far lower than those required under the current part 20, 10 CFR part 20, and sometimes a factor of ten lower.

So the impact of changing the basic radiation protection limit for some institutions is going to be to drive the regulations down below background. I mean, it could have that effect.

I also agree that the anti-nuclear community will perceive these limits as being limits at which radiation damage is dangerous or radiation exposure is harmful. So we have to be somewhat careful in the setting of radiation limits.

That said, I think the committee has made some pretty good recommendations.

CHAIRMAN MALMUD: Thank you.

You have had three accolades thus far. That is a record for the day, Dr. Thomadsen.

VICE CHAIRMAN THOMADSEN: Maybe I should quit.

(Laughter.)

CHAIRMAN MALMUD: Dr. Eggli?

MEMBER EGGLI: Well, I didn't give the committee an accolade in my first comment. I will. But I would like to cycle back to what Rob said about the caregiver limit. I think that would be the only area of the subcommittee report where I would wonder if sticking -- because we have had the conversation before of the current limit not being adequate in many situations for caregivers.

So do we want to maintain a limit that we ourselves have said in many cases may be inadequate?

CHAIRMAN MALMUD: Dr. Thomadsen?

VICE CHAIRMAN THOMADSEN: One reason we didn't talk about the caregiver is that in ICRP 103, that is not really different. That didn't change. And so we didn't address that.

If we are bringing up caregivers quite outside of the scope of ICRP 103, I have very definite feelings. And I think there is a very definite need to address that issue.

We are just starting MIVG I-131 treatments where the parents take care of children who have 800 millicuries of I-131 on board. They need special limits on them. And with the increase of these types of therapies, this is something that is required for patient care. That was not an issue as part of this docket.

CHAIRMAN MALMUD: Dr. Suleiman?

MEMBER SULEIMAN: Yes. And I want a clarifying point also. I think the caregivers are neither occupational nor public. I think they warrant a special category.

VICE CHAIRMAN THOMADSEN: Yes.

MEMBER SULEIMAN: But I thought we had discussed this in the past.

CHAIRMAN MALMUD: Malmud. We did discuss the issue of caregivers when there was a case that

came to our attention of a daughter who was caring for a terminally ill mother who had received a high dose of I-131. And the daughter refused to separate herself physically from her mother and, therefore, received an estimated excess radiation burden.

We felt very empathetic with the daughter in the care of her mother. The issue there, as I recall, was not with the daughter's behavior, which was unapproved of but, nevertheless, understandable, but with the manner in which it was reported or not reported in a delayed manner to the NRC regional office. But our sympathy was with the institution.

So the issue comes back to us again with respect to loosening the regulations for caregivers. And that might be a subject to be handled separately.

Dr. Howe, you are looking at me. Did I recall correctly the issue?

DR. HOWE: You recall that one correctly, but we also had another case for the MIVG for the infants. In that, I believe we set up a policy for essentially granting exemptions quickly if that was needed.

I do think that if the NRC is thinking about revising part 20 and they're looking at this NCRP, we have an issue with putting caregivers into

part 20 that was going to be delayed based on using the exemption.

So it would be a good time to talk about it and try to get it into regulatory space.

CHAIRMAN MALMUD: Good. So something may come out of that as well. Who is going to be handling that?

DR. HOWE: It won't be the medical group because it's part 20. It will be another group. I think Dr. Cool will be a major player in it. And so we just have to make sure he is plugged in.

CHAIRMAN MALMUD: Rob, thank you.

MR. LEWIS: Thank you.

CHAIRMAN MALMUD: Is there a motion for adjournment? Dr. Suleiman, is there a motion for adjournment?

MEMBER SULEIMAN: I so move.

CHAIRMAN MALMUD: Dr. Suleiman moves. I see we have another hand raised.

MS. COCKERHAM: Can I make two quick announcements? In your binders, look behind tab 18. There is a calendar. Please check your calendars tonight to determine your availability for the next meeting. There are dates on that calendar that are already circled that are available for you to meet.

And then the second one is everyone please take your name tags off and set them on the table so you will have them tomorrow.

CHAIRMAN MALMUD: Ashley, we want to thank you for a very well-organized first day of this meeting. If tomorrow goes as well, it will be perfect.

MS. COCKERHAM: Thank you. I will tell Gretchen thank you, too. I think she already stepped out.

CHAIRMAN MALMUD: Oh, we have one more comments from Dr. Welsh.

MEMBER WELSH: Actually, tomorrow we are scheduled to break relatively early for an ACMUI meeting. But when will we know if we are really going to be aiming to finish up at 11:30 or not for those of us who might want to change our travel plans?

DR. HOWE: There is also the issue of drug testing.

MEMBER WELSH: Yes.

MS. COCKERHAM: Well, one, the meeting may or may not run late. You know how these meetings go. And, two, we do have the issue of drug testing, which is scheduled for 1:00 p.m. tomorrow for those who will be subject to drug testing. We will have that either

tomorrow morning or at lunch.

MR. EINBERG: I think we can probably work with it and let you know in the morning.

CHAIRMAN MALMUD: Ashley, you don't mean at lunch because the agenda says meeting is over at 11:30.

MS. COCKERHAM: Yes. You would know at 11:30 because that is more than an hour.

CHAIRMAN MALMUD: Okay.

MS. COCKERHAM: The form says an hour before testing. But, like Chris said, I think we can talk to admin. They have been very accommodating so far with your drug testing. So we should be able to tell you first thing in the morning.

CHAIRMAN MALMUD: Thank you. The meeting is adjourned. Thank you.

(Whereupon, the foregoing matter was recessed at 5:01 p.m., to be reconvened on Tuesday, October 20, 2009, at 8:00 a.m.)