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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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OPEN MEETING

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WEDNESDAY,

October 20, 2010

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

MEMBERS PRESENT:

BRUCE THOMADSEN, Ph.D, Acting Chairman

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

DEBBIE GILLEY, State Government Representative

MILTON GUIBERTEAU, M.D., Diagnostic Radiologist

SUE LANGHORST, Ph.D, Radiation Safety Officer

STEVE MATTMULLER, Nuclear Pharmacist

CHRISTOPHER PALESTRO, M.D., Nuclear Medicine Physician

JOHN SUH, M.D., Radiation Oncologist

ORHAN SULEIMAN, Ph.D., FDA Representative

MEMBERS PRESENT: (CONT.)

WILLIAM VAN DECKER, M.D., Nuclear Cardiologist

JAMES WELSH, M.D., Radiation Oncologist

PAT ZANZONICO, Ph.D, Nuclear Medicine Physicist

NRC STAFF PRESENT:

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

CHRIS EINBERG, Designated Federal Official

MICHAEL FULLER, Alternate Designated Federal Official

ASHLEY COCKERHAM, FSME/DMSSA/LISD/RMSB

MARC FERDAS, R-I/DNMS/MB

SOPHIE HOLIDAY, FSME/DMSSA/LISD/RMSB

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

VARUGHESE KURIAN, FSME/DWMEP/DURLD

ED LOHR, FSME/DIILR/RB-B

PATRICIA PELKE, R-III/DNMS/MLB

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

ALSO PRESENT:

DAVE ADLER, ASTRO

CURTIS M. ANDERSON, Mele Associates, Inc.

PETER CRANE, UNKNOWN AFFILIATION

ALSO PRESENT: (CONT.)

JAMES A. DEYE, NIH

JENNIFER ELEE, CRCPD

JESSICA LLOYD, SNM

DAVID WALTER, OAS

MICHAEL HAGAN, DVA

JESSICA LLOYD, SNM

GLORIA ROMANELLI, ACR

ERIC SOLTYCKI, AEHN

BHADRASAIN VIKRAM, NIH

ANN WARBICK-CERONE, MDS NORDION

JENNA WILKES, ASNC

GARY E. WILLIAMS, VA NHPP

AGENDA

P R O C E E D I N G S

(1:22:36 p.m.)

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

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

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 in the Nuclear Regulatory Commission. The meeting was announced in the October 6, 2010 edition of the Federal Register, Volume 75, page

61780.

The function of the Committee is to advise the Staff on issues and questions that arise on the Medical Use Byproduct Material. The Committee provides counsel to the Staff, it 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 would request that whenever possible, we try to reach a consensus on the procedural issues that we will discuss today, but I also recognize that there may be a minority of dissenting opinions. If you have such opinions, please allow them to be read into the record.

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

MEMBER FISHER: Present.

MR. EINBERG: Ms. Debbie Gilley.

MEMBER GILLEY: Present.

MR. EINBERG: Dr. Guiberteau.

MEMBER GUIBERTEAU: Present.

MR. EINBERG: Dr. Sue Langhorst.

MEMBER LANGHORST: Present.

MR. EINBERG: Mr. Steve Mattmuller.

MEMBER MATTMULLER: Present.

MR. EINBERG: Dr. Christopher Palestro.

MEMBER PALESTRO: Present.

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

MEMBER SUH: Present.

MR. EINBERG: And welcome, as well. Dr. Orhan Suleiman.

MEMBER SULEIMAN: Present.

MR. EINBERG: Dr. William Van Decker.

MEMBER VAN DECKER: Present.

MR. EINBERG: Dr. James Welsh.

MEMBER WELSH: Present.

MR. EINBERG: Dr. Pat Zanzonico.

MEMBER ZANZONICO: Present.

MR. EINBERG: I would note that Dr. Guiberteau and Dr. Palestro do not have voting privileges at this time, but they will speak on behalf of the diagnostic radiologists and nuclear medicine physicians, respectively.

I now ask the NRC Staff members who are present to identify themselves. I'll start with the

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

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

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

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

MR. EINBERG: Ashley.

MS. COCKERHAM: Ashley Cockerham.

MS. HOLIDAY: Sophie Holiday.

MR. EINBERG: Thank you.

MR. LOHR: Ed Lohr, Rulemaking.

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

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

MS. COCKERHAM: There's nobody.

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

Following a discussion of each agenda item, the ACMUI Chairperson or Vice Chair in this case, Dr. Thomadsen, 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. Thomadsen.

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

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

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

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

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

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

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

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

We also will be doing as part of the SRM

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

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

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

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

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

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

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

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

ACTING CHAIR THOMADSEN: You may.

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

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

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

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

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

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

Subpart H is revised.

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

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

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

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

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

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

all I have.

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

MS. ELEE: I answer to lots of names.

ACTING CHAIR THOMADSEN: But not Mr. Fuller.

MS. ELEE: Not that one, no.

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

MS. ELEE: That's okay.

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

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

ACTING CHAIR THOMADSEN: Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

already have there.

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

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

very few in terms of that.

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

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

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

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

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

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

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

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

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

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

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

events.

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

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

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

MEMBER VAN DECKER: We look alike after a

while.

(Laughter.)

ACTING CHAIR THOMADSEN: Dr. Van Decker.

MEMBER VAN DECKER: Thank you, Dr. Malmud.

(Laughter.)

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

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

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

So, here --

MS. ELEE: Are you volunteering?

MEMBER VAN DECKER: Most people would tell

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

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

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

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

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

MS. ELEE: Yes.

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

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

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

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

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

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

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

ACTING CHAIR THOMADSEN: Dr. Suleiman.

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

MS. ELEE: Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ACTING CHAIR THOMADSEN: Okay. Dr. Guiberteau.

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

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

MS. ELEE: Right.

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

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

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

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

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

ACTING CHAIR THOMADSEN: Dr. Langhorst.

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

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

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

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

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

MEMBER LANGHORST: I was just curious, yes.

MS. ELEE: Yes.

MEMBER LANGHORST: Okay. Thank you.

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

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

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

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

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

MS. ELEE: Debbie, with you all --

MEMBER GILLEY: We don't put ours on the

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

MS. ELEE: Do you give the facility names?

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

happening at another facility.

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

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

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

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

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

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

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

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

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

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

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

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

2010, Staff received another Staff Requirements Memorandum that disapproved the Staff's recommendations for the reproposed rule, and provided further direction.

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

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

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

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

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

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

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

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

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

starting point for a series of public workshops.

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

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

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

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

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

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

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

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

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Ms. Gilley?

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

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

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

ACTING CHAIRMAN THOMADSEN: Dr. Welsh?

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

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

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

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

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

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Dr. Zelac?

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

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

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

ACTING CHAIRMAN THOMADSEN: Dr. Langhorst?

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

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

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

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

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

Now, I realize that one more year is for

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

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

ACTING CHAIRMAN THOMADSEN: Mr. Einberg?

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Go ahead.

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

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

MR. FULLER: Welcome to our fire hose.

MEMBER LANGHORST: Right, right.

ACTING CHAIRMAN THOMADSEN: Dr. Guiberteau?

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

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

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

ACTING CHAIRMAN THOMADSEN: Dr. Guiberteau?

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Thank you.

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

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

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

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

approach because the AOs get reported to Congress.

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Dr. Langhorst?

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

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

MR. LEWIS: Yes, for permanent implant.

ACTING CHAIRMAN THOMADSEN: Dr. Fisher?

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

the definitions fixed to date may not be fully applicable.

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

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

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

MEMBER GUIBERTEAU: I was talking about the 28 items.

DR. HOWE: Thank you.

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

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

if we do, we should let them know.

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

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

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

MEMBER FISHER: But you could recommend.

ACTING CHAIRMAN THOMADSEN: Right.

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

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

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

ACTING CHAIRMAN THOMADSEN: And, Dr.

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Do we have

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

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

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

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

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

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

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

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

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

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

practical approach?

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

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Dr. Suleiman?

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

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

MEMBER SULEIMAN: Incorporate --

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

MEMBER SULEIMAN: You want to. You could.

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

MR. FULLER: It's a good point.

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

MR. FULLER: Thank you.

ACTING CHAIRMAN THOMADSEN: Dr. Zelac?

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Thank you, Dr. Zelac.

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

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

(Laughter.)

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

ACTING CHAIRMAN THOMADSEN: Very good. Thank you.

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

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

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

Ms. Pelke?

MS. PELKE: Thank you very much.

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

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

That's a bit distracting, by the way.

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

MS. PELKE: Thank you.

MS. COCKERHAM: Unless you want to hear yourself.

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

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

We issue Master Materials Licenses to

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

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

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

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

approximately I would say 115 permittees or licensees.

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

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

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

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

previous treatments to assess the quality of those implants.

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

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

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

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

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

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

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

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

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

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

using was D90.

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

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

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

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

licensee staff.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We did conduct inspections at the other

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

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

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

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

We issued an inspection report in May. We

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

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

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Thank you very much.

Open the floor to questions. Yes?

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Dr. Welsh?

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

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

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

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

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

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

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

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

MS. PELKE: That's correct.

MEMBER WELSH: -- being 20 percent?

ACTING CHAIRMAN THOMADSEN: Dr. Guiberteau?

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

MS. PELKE: Yes, yes.

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

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

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

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

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

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

the procedures.

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

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

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

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

with expectations.

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

MEMBER GUIBERTEAU: And peer review?

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

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

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

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

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

MEMBER GUIBERTEAU: Thank you.

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

ACTING CHAIRMAN THOMADSEN: Dr. Fisher?

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

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

ACTING CHAIRMAN THOMADSEN: Dr. Zanzonico?

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

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

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

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

MS. PELKE: Yes.

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

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

MEMBER ZANZONICO: Pennsylvania is an agreement state.

MS. PELKE: Correct.

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

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

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

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

MEMBER ZANZONICO: Do you know if Pennsylvania followed up?

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

ACTING CHAIRMAN THOMADSEN: Dr. Van Decker?

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

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

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

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

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

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

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

Also, it may be helpful for you all to

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

ACTING CHAIRMAN THOMADSEN: Dr. Welsh?

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

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

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

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

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

MS. PELKE: At the VA facility.

ACTING CHAIRMAN THOMADSEN: Any other comments or questions?

(No response.)

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

MEMBER WELSH: Thank you, Dr. Thomadsen.

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

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

Because of the technical difficulties,

should I pause until this corrected or --

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

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

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

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

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

A medical event in the opinion of the

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

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

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

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

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

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

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

And it must be kept in mind that 50 rem,

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

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

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

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

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

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

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

And the previous discussion caused me a

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

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

Thank you.

ACTING CHAIRMAN THOMADSEN: Thank you, Dr. Welsh.

Comments from the Committee? Questions for Dr. Welsh?

MEMBER ZANZONICO: Yes.

ACTING CHAIRMAN THOMADSEN: Dr. Zanzonico?

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

MEMBER WELSH: Not specified.

MEMBER ZANZONICO: It's not specified.

MEMBER WELSH: That's why it --

MEMBER ZANZONICO: So it could just be one

point?

MEMBER WELSH: Yes.

MEMBER ZANZONICO: It really is inconsequential.

MEMBER WELSH: Correct.

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

ACTING CHAIRMAN THOMADSEN: Dr. Fisher?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Mr. Lewis?

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

ACTING CHAIRMAN THOMADSEN: Dr. Welsh?

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Dr. Langhorst?

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

so I wanted to point that out.

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

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

ACTING CHAIRMAN THOMADSEN: Dr. Welsh?

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

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

lead to an event that is of medical significance.

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

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

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

ACTING CHAIRMAN THOMADSEN: Mr. Lewis.

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

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

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

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

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

immediately done.

ACTING CHAIRMAN THOMADSEN: Dr. Zanzonico.

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

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

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

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

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

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

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

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

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

So, Dr. Suleiman.

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

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

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

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

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Yes, Mr. Mattmuller.

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

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

And if I could repeat what he said, "But

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

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

MR. LEWIS: I understand that.

ACTING CHAIRMAN THOMADSEN: Dr. Welsh.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. ZELAC: And also exceeding the five centiGray --

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

DR. ZELAC: Thank you both.

ACTING CHAIRMAN THOMADSEN: Yes. Dr. Suh.

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

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

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Very fine.

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

a new copy in.

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

MEMBER WELSH: They do not.

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

MR. LEWIS: That was my point.

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

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

MEMBER GILLEY: Second.

ACTING CHAIRMAN THOMADSEN: Thank you. Yes.

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

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

the table when I --

MEMBER LANGHORST: Sorry.

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

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Does that satisfy your --

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

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

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

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

ACTING CHAIRMAN THOMADSEN: And Dr. Welsh?

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

MEMBER LANGHORST: Yes.

MEMBER WELSH: -- expert --

MEMBER LANGHORST: Absolutely.

MEMBER WELSH: -- input will be provided.

ACTING CHAIRMAN THOMADSEN: Dr. Suleiman.

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

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

ACTING CHAIRMAN THOMADSEN: Other comments?

(No response.)

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

(Chorus of ayes.)

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

your hands.

MS. COCKERHAM: I have 10.

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

MS. COCKERHAM: I think that's correct.

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

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

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

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

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

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

on Isotope Distribution Policy.

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

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

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

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

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

MS. COCKERHAM: You're there.

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

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

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

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

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

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

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

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

out in the community.

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

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

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

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

to access the best health care provided by medical isotopes.

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

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

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

to a speedy complaint resolution.

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

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

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

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

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

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

There are some notable exceptions, in

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

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

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

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Thank you very

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

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

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

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

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

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

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

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

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

Yes, Ashley.

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

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

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Any other questions?

(No response.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

It is possible to use low enriched uranium

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

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

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

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

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

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

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

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

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

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

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

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

have the technology and the need.

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

(Laughter)

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

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

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

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

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

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

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

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

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

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

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

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

that is -- that remains to be seen.

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

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

Thank you very much.

ACTING CHAIRMAN THOMADSEN: Thank you, Dr. Welsh.

Dr. Van Decker.

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

(Laughter)

Having said that, you know, I think your

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

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

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

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

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

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

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

mind?

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

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

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

From a regulatory perspective, one of the

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

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

ACTING CHAIRMAN THOMADSEN: Dr. Suleiman?

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

And bottom line was when we finally

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

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

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

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

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

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

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Dr. Fisher.

MEMBER SULEIMAN: -- our regulatory bottleneck.

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

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

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

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

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

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

Incidentally, just as a footnote, out in

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Dr. Zelac.

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

ACTING CHAIRMAN THOMADSEN: Mr. Mattmuller.

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

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

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

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

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

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

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

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

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

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

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

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

ACTING CHAIRMAN THOMADSEN: Any other comments?

(No response.)

Thank you, Dr. Welsh.

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

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

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

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

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

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

MS. COCKERHAM: Yes.

ACTING CHAIRMAN THOMADSEN: Very fine.

(Whereupon, at 5:52 p.m., the proceedings in the foregoing matter were adjourned.)