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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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OPEN SESSION

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MONDAY,

SEPTEMBER 9, 2013

The meeting was convened in room T2-B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 11:00 a.m., Bruce Thomadsen, Ph.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

BRUCE THOMADSEN, Ph.D., Chairman

MILTON GUIBERTEAU, M.D., Vice Chairman

SUSAN M. LANGHORST, Ph.D., Radiation Safety Officer

STEVEN R. MATTMULLER, Nuclear Pharmacist

CHRISTOPHER PALESTRO, M.D., Nuclear Medicine Physician

JOHN H. SUH, M.D., Radiation Oncologist

ORHAN H. SULEIMAN, Ph.D., FDA Representative

WILLIAM A. VAN DECKER, M.D., Nuclear Cardiologist

LAURA M. WEIL, Patients' Right Advocate

JAMES S. WELSH, M.D., Radiation Oncologist

PAT B. ZANZONICO, Ph.D., Nuclear Medicine Physicist

NRC STAFF PRESENT:

LAURA DUDES, Acting Deputy Director, Office of Federal and State Materials and Environmental Management Programs

BRIAN McDERMOTT, Director, Division of Materials Safety and State Agreements

PAMELA HENDERSON, Deputy Director, Division of Materials Safety and State Agreements

CHRIS EINBERG, Chief, Radioactive Materials Safety Branch, Designated Federal Officer

MICHAEL FULLER, Medical Radiation Safety Team Leader, Alternate Designated Federal Officer

SOPHIE HOLIDAY, ACMUI Coordinator

ASHLEY COCKERHAM, Alternate Designated Federal Officer

NEELAM BHALLA, FSME/DILR/RPMB

SUSAN CHIDAKEL, OGC/GCLR/RMR

SAID DAIBES, Ph.D., FSME/DMSSA/RMSB

SARA FORSTER, R-III/DNMS/MLB

CASSANDRA FRAZIER, R-III/DNMS/MLB

LATISCHA HANSON, R-IV/DNMS/NMSB-A

MICHELLE HAMMOND, R-IV/DNMS/NMSB-B

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

ED LOHR, FSME/DILR/RPMB

ANGELA McINTOSH, FSME/DMSSA/RMSB

GRETCHEN RIVERA-CAPELLA, FSME/DMSSA/RMSB

ROBERT SUN, FSME/DMSSA/RMSB

LESTER TRIPP, R-I/DNMS/MB

SHIRLEY XU, FSME/DMSSA/LB

RONALD ZELAC, Ph.D., FSME/DMSSA/RMSB

MEMBERS OF THE PUBLIC PRESENT:

ROBERT DANSEREAU, New York State Department of Health

LYNNE FAIROBENT, American Association of Physicists in Medicine

DEBBIE GILLEY, American Association of Physicists in Medicine

RALPH LIETO, St. Joseph Mercy Health System

ANDREW McKINLEY, American Society of Nuclear Cardiology

MICHAEL PETERS, American College of Radiology

JESSE SCHOOLNIK, Society of Nuclear Medicine and Molecular Imaging

MIKE STEPHENS, Florida Bureau of Radiation

Control

CINDY TOMLINSON, American Society for Radiation Oncology

GARY E. WILLIAMS, Veterans Health Administration

T A B L E O F C O N T E N T S

P R O C E E D I N G S

11:02 a.m.

MR. EINBERG: Okay. Good morning. As the Designated Federal Officer for this meeting, I am pleased to welcome you to this public meeting of the ACMUI.

My name is Chris Einberg. I am chief of the Radioactive Material Safety Branch and I have been designated as the federal officer for this advisory committee in accordance with 10 CFR Part 7.11.

Present today as the alternate designated federal officers are Michael Fuller, Medical Radiation Safety Team leader, and Ashley Cockerham.

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

The meeting was announced in the July 10th, 2013 edition of the Federal Register, Volume 78, Page 41427 through 41428.

The function of the Committee is to advise staff on issues and questions that arise on the medical use of byproduct material.

The Committee provides counsel to the

staff, but does not determine or direct the actual decisions of the staff or the Commission. The NRC solicits the views of the Committee and values their opinions.

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

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

Dr. Bruce Thomadsen, ACMUI chairman, therapy medical physicist.

CHAIR THOMADSEN: Present.

MR. EINBERG: Dr. Mickey Guiberteau, ACMUI vice chairman, diagnostic radiologist.

VICE CHAIR GUIBERTEAU: Present.

MR. EINBERG: Dr. Sue Langhorst, radiation safety officer.

MEMBER LANGHORST: Present.

MR. EINBERG: Mr. Steve Mattmuller, nuclear pharmacist.

MEMBER MATTMULLER: Present.

MR. EINBERG: Dr. Christopher Palestro,

nuclear medicine physician.

MEMBER PALESTRO: Present.

MR. EINBERG: Dr. John Suh, radiation oncologist.

MEMBER SUH: Present.

MR. EINBERG: Dr. Orhan Suleiman, FDA representative.

MEMBER SULEIMAN: Present.

MR. EINBERG: Dr. William Van Decker, nuclear cardiologist.

MEMBER VAN DECKER: Present.

MR. EINBERG: Ms. Laura Weil, patients' rights advocate.

MEMBER WEIL: Present.

MR. EINBERG: Dr. James Welsh, radiation oncologist.

MEMBER WELSH: Present.

MR. EINBERG: Dr. Pat Zanzonico, nuclear medicine physicist.

MEMBER ZANZONICO: Present.

MR. EINBERG: We do have a quorum. So, I now ask that NRC staff members who are present to identify themselves.

I'll start with the individuals in the room here.

MR. FULLER: Mike Fuller.

DR. HOWE: Dr. Donna-Beth Howe.

MS. COCKERHAM: Ashley Cockerham.

MR. EINBERG: Theron, if you could turn the microphones on, on the tables, please.

MS. RIVERA-CAPELLA: Gretchen Rivera-Capella.

MS. HOLIDAY: Sophie Holiday.

MS. DUDES: Laura Dudes.

MS. BHALLA: Neelam Bhalla.

MR. LOHR: Ed Lohr.

MS. FORSTER: Sara Forster.

MR. EINBERG: Okay. Thank you. Also, if there's anybody from Region 1 on the line, please identify yourself now.

(No response.)

MR. EINBERG: Hearing none, we'll move to Region III. Region III, if there's anybody on the line, please identify yourself.

(No response.)

MR. EINBERG: Region IV, anybody on the line?

(No response.)

MR. EINBERG: Anybody else who has called in? NRC staff who has called in?

(No response.)

MR. EINBERG: Okay. I would also like to add that this meeting is being webcast. So, other individuals may be watching online.

We have a bridge line available and that phone number is (888) 864-0940. Once again, the number is (888) 864-0940. The passcode to access the bridge line is 73000#.

Following the discussion of each agenda item, the ACMUI chairman, Dr. Bruce Thomadsen, at his option may entertain comments or questions from members of the public who are participating with us today. We ask that one person speak at a time as this meeting is also closed caption.

At this point, I'd like to turn the meeting over to Brian McDermott, director of the Division of Materials Safety and State Agreements for a few comments.

MR. McDERMOTT: Thanks, Chris. Good morning, everybody. I'd just like to welcome everybody to this meeting of the ACMUI.

For everybody's benefit that wasn't present, the ACMUI held a teleconference back in June on the 18th to discuss the ACMUI's review of yttrium-90 microsphere medical events and we very much

appreciate the Committee's review.

The final report in that review was received on June 18th and it can be found both on the ACMUI's webpage, but also in ADAMS under ML 13175A, as in alpha, 025.

And, again, we very much appreciate ACMUI looking at those microsphere events as we did have a number of them reported in the last year.

Later on today we're going to have some conversations about the interim enforcement policy for permanent implant brachytherapy programs and also the enforcement guidance memorandum for rubidium generators. They're both fairly recent projects out of the Agency.

Tomorrow we'll have some presentations on the ViewRay licensing guidance. The presentation will be given by Megan Shober and Sandy Frazier, the co-chairs of the joint NRC and Organization of Agreement States Working Group. This guidance was released on July 24th of this year.

Also since the last ACMUI meeting, we had the annual Organization of Agreement States Meeting, which NRC had a heavy participation in, in terms of presentations. Some interesting issues in the medical arena were discussed at that meeting and that

was back on August 19th.

I would like to note that this is Dr. Van Decker's last meeting with ACMUI. He served eight years on the Committee as a nuclear cardiologist and we have a special presentation for him at the conclusion of tomorrow's meeting.

With Dr. Van Decker's departure, we will have three vacancies on the ACMUI. The positions are healthcare administrator, nuclear cardiologist and agreement state representative.

We're conducting in-person interviews looking to fill those positions in the near term. Hopefully before the next meeting of the ACMUI in-person we'll be able to have those seats filled.

Next I'll just briefly mention some changes going on at NRC. You may have heard about some of our personnel changes going on.

Mark Satorius who had been the director of the Office of Federal and State Materials and Environmental Management Programs was selected as the Executive Director for Operations.

That's our highest-ranking, non-political position in the Agency, and Mark left FSME to go on to that position on August 26th. So, we wish Mark well. I think it's a good move for Mark and a great

change, great move for the Agency.

Brian Holian, which you may have met before, Brian Holian is the deputy office director of FSME. So, he'll be temporarily filling in until a permanent replacement for Mark is identified.

While Brian is acting as our office director, Laura Dudes who is here with us today will be our acting deputy office director.

And one new one on that plate as of last week, I was asked to move to the Office of Nuclear Security and Incident Response as the deputy office director. So, that change is actually effective in an acting capacity as of today.

Pam Henderson who has been my deputy over the last year or so will be here. She'll be here with you during your afternoon session.

Pam has been an integral part of the things within the Division of Materials Safety and State Agreements since she came originally to us on a rotation, and then permanently over a year ago.

So, Pam has always been a part of the discussions and she's been here for some of your meetings as well, but she will be acting until a replacement is identified for the Division of Materials Safety and State Agreements.

One third change that's potentially down the road, we're conducting an evaluation to look at the potential reintegration of FSME with the Nuclear Materials Safety and Safeguards Office.

Now, if you go - some of you have been around for a while. You go back a few years. You know that FSME was split out of that organization and there were a number of dynamics at the time that caused that change for the Agency.

Notably, you know, the growing work that was associated with Yucca Mountain licensing, and there were also other changes that influenced the change such as bringing the - what was the Office of State and Tribal Programs in with the Materials Program staff because there is so much interaction with the States on material safety and security issues.

We're looking at that just because of, you know, the current changes in the external environment, but also to see, you know where are there synergies and is it beneficial to reintegrate those two organizations.

So, that's something that there's a working group that's been formed to look at the pros and cons of that type of merger between the two

offices. So more to come on that.

And, you know, one of the things we do is we look at opportunities to do these things. And with Mark's departure to the EDO position, Mark Satorius's departure, that leaves us short one office director. So, it's time to make it so that opportunity has the benefits to pull the organizations together. So more to come on that down the road.

And that's all I have unless there are any questions for me.

CHAIR THOMADSEN: Well, I would just like to say congratulations in your new position. And the Committee thanks you for all that you've done in working with us over the years.

MR. McDERMOTT: Thank you.

MR. EINBERG: Ashley Cockerham just reminded me to check for people who may be on the line to identify themselves.

If there is anybody on the line right now, can you please identify yourself?

(No response.)

MR. EINBERG: Well, we heard some static on there. There must be somebody on the line.

(No response.)

MR. EINBERG: Okay. I guess not. Okay. Thank you. I turn it back over to Chair Thomadsen.

CHAIR THOMADSEN: Very fine. We now have Ms. Holiday with old business.

MS. HOLIDAY: All right. Good morning, everyone. I have the pleasure of presenting old business, which is the portion of the meeting where we go over past recommendations and we discuss any NRC staff actions or ACMUI actions that have been taken or will be taken in the future.

So, we'll start back with 2007. We stuck this chart back in there. There's no changes with it. This is all included in the Part 35 extended rulemaking.

If you move on to 2008, the same thing applies here. The majority of this sheet is for the Part 35 extended rulemaking with the exception of Item Number 9 which refers to the abnormal occurrence criteria.

As you know, the ACMUI formed an Abnormal Occurrence Subcommittee and those recommendations were provided to staff. And the ACMUI Subcommittee report was then provided in staff's paper to the Office of Research. And they will provide that paper to the Commission.

Okay. Then we move on to 2009. Items 2 and 10 are in the Part 35 extended rulemaking. Item 9 is just an open action item for the Medical Events Subcommittee. That just continues on until we add members or we dissolve the subcommittee.

Oh, that's awfully hard to see. So, for 2011, I apologize for the size - thank you. Okay. For 2011 I just wanted to update you for Item Number 1.

This pertains to the patient release criteria. This is not being considered for the current rulemaking, but may be considered for future rulemaking.

For Item Number 7, this is where Dr. Malmud had agreed to serve as the reviewer to screen iodine-131 cases for the Medical Events Subcommittee.

At this time, I'd like to ask, Dr. Thomadsen, you, as the chair, if you would like to put another ACMUI member in this position.

CHAIR THOMADSEN: Yes. If Dr. Palestro agrees, I would like him to convene the subcommittee.

MEMBER PALESTRO: I'd be happy to.

MS. HOLIDAY: Thank you.

CHAIR THOMADSEN: Thank you.

MS. HOLIDAY: Okay. For Items 11, 13, 14

and 15 -

VICE CHAIR GUIBERTEAU: Excuse me. Could I clarify that?

MS. HOLIDAY: Yes.

VICE CHAIR GUIBERTEAU: Is this an appointment? Because I know Dr. Malmud did not serve on the Committee, but he agreed to review the iodine-131 issues.

MS. HOLIDAY: Right. That's correct.

VICE CHAIR GUIBERTEAU: I mean, I'm just - I think the record - is this appointing a reviewer, or a member of the Committee?

CHAIR THOMADSEN: I am appointing him to the Committee.

MS. HOLIDAY: Sure. Thank you for that distinction. Okay. So, Items 11, 13, 14 and 15 are included in the extended Part 35 rulemaking.

Item 16 also relates to the patient release - or, I'm sorry, per release limit. We have tabled this and may consider this for future rulemaking.

Item 20 is where Dr. Langhorst asked us to place historical documents on the ACMUI website and to add past information. That was discussed at the last meeting. So, this will change to closed.

And we presented you with the changes to the ACMUI webpage.

And Item 32 also relates to the AO criteria, where again we sent on the ACMUI Subcommittee's report on to Research to be included in their paper to the Commission.

Okay. Moving on to 2012, the only item that I have on the agenda here that's changed is Item 9. Not that it's changed, but just to remind you that ACMUI made the recommendation to have an annual review of the reporting structure. So, we will also have that presentation tomorrow afternoon.

Items for the chart 2013, again I apologize for the size of the chart. The majority of this, Items 1 through 14, were discussed in the ACMUI Rulemaking Subcommittee. And all these recommendations were included in staff's paper to the Commission for the proposed rulemaking.

Item 15 dealt with the ACMUI bylaws. That was tabled from the spring meeting and was discussed this morning and will be tabled for the following spring meeting. A subcommittee has been formed that will review those proposed amendments to the bylaws.

On the next page, Item 16, Dr. Langhorst,

you had requested that when we publish the proposed rulemaking in the guidance document, that they have the same docket numbers.

Staff did reach out to Admin and they have informed us that we have to have two separate docket numbers.

However, both documents will reflect each other's docket number so that they're easily accessible.

MEMBER LANGHORST: Thank you very much.

MS. HOLIDAY: You're very welcome.

Item 17 was the teleconference to discuss Y-90 microspheres medical events.

That's closed because we had that teleconference and a subcommittee report was given and delivered. And the final report was distributed on June 28th, 2013.

Item 18 also deals with the AO Subcommittee report. Again, transmitted to [be included in] a paper to Research and will be sent off to the Commission.

Item 19 is closed. That was when the ACMUI planned to hold their fall meeting on September 9th and 10th. Here we are today.

Item 20, Dr. Guiberteau asked that staff

provide the link that Ms. Weil had referred to in her ThyCa presentation. I transmitted that to the Committee on the 17th. So, that item is closed.

Item 21, in Mr. Mattmuller's presentation he asked that NRC provide regulatory relief for the decommissioning funding plan requirements for the use of germanium-68/gallium-68 generators.

Staff has taken an initial review of this and we plan to refer this on to another division in our office and they will review that recommendation and then will be able to come back with a response for you, but this is just an initial review. Dr. Zanzonico will also give a presentation on this very topic.

And then for our last item, this is a result from the Y-90 microspheres medical events teleconference that was held in June. And it's just saying that the ACMUI endorsed the report. Again, that report was finalized and distributed on June 28th, 2013.

Do you have any questions for me?

CHAIR THOMADSEN: Yes, Dr. Suh.

MEMBER SUH: There's no 2010 ACMUI recommendations and action items.

MS. HOLIDAY: Sure. So, actually, I think

it was maybe a year or two ago we closed all those items on 2010. So, that's why that chart is not included in this list.

CHAIR THOMADSEN: Any other questions for Ms. Holiday?

(No response.)

CHAIR THOMADSEN: Thank you very much.

MS. HOLIDAY: Thank you.

CHAIR THOMADSEN: We will move on to What is the ACMUI presentation from Ms. Cockerham.

MS. COCKERHAM: Good morning. So, this presentation, What is the ACMUI, this presentation is originally one that I gave to a group of health physicists at the NRC.

So, it included individuals from reactors, research, from the materials group, it was all across the Agency. So, not all of them knew what ACMUI stood for. So, that's why I have it spelled out here.

You guys obviously know what it is. You eat, sleep and breathe this, but that's kind of how this originated.

And it was well received. And so, we thought maybe for those who are newer on the Committee or for those who don't know its history,

and this was kind of prompted by Dr. Langhorst, she asked for some history on the ACMUI webpage. So, we were kind of building on that and that's sort of the purpose of my presentation.

So, I'm going to go over the history, talk a little bit about the organization, the purpose of the Committee, what the membership is like and meetings, how subcommittees work.

And then as you know, we totally revamped our ACMUI website. So, it's much more user-friendly and easy to find things for members of the public and for the Committee and then tell you who your contacts are.

So, taking you all the way back to 1946, this was as far back as I could find. And I was able to find this information on a DOE website. Because as you know, NRC and DOE used to be all one thing.

So, the program for distributing radioisotopes in the U.S. grew out of part of the Manhattan Project at Oak Ridge.

Individuals working on the Manhattan Project had developed the greatest technical expertise during World War II and the Manhattan Project publicly announced its program for distributing radioactive isotopes in 1946.

Medical researchers and doctors previously had limited access to radioisotopes produced from cyclotrons. However, this new distribution program also allowed access to byproduct material from the uranium chain.

Each byproduct material order had to be reviewed and approved. And for human use, each application was reviewed by a special subcommittee at Oak Ridge.

In the first year, there were over 200 orders received and nearly half of them were for human use. Over 95 percent of all requests received in 1946 were approved.

Cancer researchers initially received radioisotopes at no charge. A little bit different than the environment now, but the program was changed to an 80 percent discount after about six years.

Less than 50 practitioners were using radioisotopes in medicine at the start of the distribution program.

So, then it takes us to 1947 and Congress created the Atomic Energy Commission which transferred control from the military to the civilian sector.

The new AEC encompassed all parts of the

Manhattan Project including the subcommittee of experts who reviewed and approved the distribution of radioactive isotopes.

The first medical regulations were developed in the 1950s and the system regulated the types of uses allowed according to their hazard and known risks.

It required and provided training of those who would use the radioisotopes and it required establishment of local radioisotope committees.

Then we jump to 1959. The Oak Ridge subcommittee doing the reviews and approvals was officially named the Advisory Committee on the Medical Uses of Isotopes. The Commission established the ACMUI under the authority of the Atomic Energy Act of 1954.

Then we jump to 1974. The Energy Reorganization Act split the AEC's responsibilities between the NRC and what is now known as the DOE or Department of Energy.

The ACMUI's name, functions, reporting structure, all of that remained unchanged under the NRC.

And currently the activities of the ACMUI are subject to the Federal Advisory Committee Act

regulated by the U.S. General Services Administration and the NRC's regulations in 10 CFR Part 7.

We have been talking about this a lot recently, too. Here's an excerpt of the org chart. We have the Commission, the EDO and our office, the Office of Federal and State Materials and Environmental Management Programs.

And then we have our division where Brian is the division director. I guess Pam is our acting division director now.

And then we have the ACMUI who reports directly to Brian. And the support staff for the Advisory Committee and for all of the medical team were in that bottom box in the Radioactive Materials Safety Branch. So, that includes the Medical Radiation Safety Team. That's just a quick layout.

So, the purpose of the ACMUI is to advise staff on policy and technical issues that arise in the regulation of the medical use of byproduct material for diagnosis and therapy.

ACMUI provides specific recommendations on proposed changes to 10 CFR Part 35 and revisions to NRC guidance documents.

From 2007 to 2011 - I need to update this. I guess for all of 2012, but from 2007 to 2012

the ACMUI made over a hundred recommendations to NRC staff on various issues.

Staff accepted over 90 percent of the recommendations, but many are pending rulemaking completion for full implementation.

Only five percent of ACMUI recommendations during that same time period were not accepted. In comparison, GSA reported for fiscal year 2009 for over 900 federal advisory committees, only ten percent of recommendations have or will be fully implemented.

NRC staff values input from the medical professionals and experts on the ACMUI. I think that 90 percent number speaks volumes for your advice and input and how it is implemented through the Agency.

The ACMUI also provides technical assistance to NRC staff. For example, they can provide input on guidance documents or commission papers.

ACMUI members can raise issues on behalf of stakeholders or bring information on new technologies to the attention of NRC staff.

ACMUI members can also serve as medical consultants for specific technical issues, or to evaluate medical events that are reported to the NRC.

Since you're all here, you do know about this process. There's a formal nomination process where we publish in the *Federal Register*. And to fill vacancies, NRC staff publishes a notice in the *Federal Register* requesting nominations from interested parties.

After we receive the nominations, we convene a selection panel that includes NRC employees and an individual who is a non-NRC federal employee.

This non-NRC federal employee is always a professional who specializes in the vacancy to be filled.

So, if we had a radiation oncology opening, we would try to get someone from, say, NIH or up the road at the - what's the Army Medical Center.

PARTICIPANT: Walter Reed.

MS. COCKERHAM: Walter Reed, yes. So, typically we try to get people that are close to here to come in and sit on our panels.

The selection panel evaluates each nominee and sends the recommendation to the FSME office director.

Usually there are some interviews thrown in there and lots of other managers that are looking

over things as well.

ACMUI members serve four-year terms and they are eligible for reappointment after the four years for a second four-year term.

And ACMUI members are considered special government employees and they have L security clearances. And they also have badges.

So, these are all the positions on the ACMUI. I won't go through all of these. I think you all know very well what jobs you do the other 99.9 percent of the time that you're not here.

And expertise covers these areas. We look at diagnostic, therapeutic. We have research, patients' rights. And we have co-regulators in the agreement states and also with the FDA.

Here is your picture, I guess, from April of this year. And I've got Dr. Malmud in parentheses here, as we know he rotated off the Committee. And Ms. Bailey retired and left us as well. So, other than that, I think everyone is here.

It helps to put faces with names. For those that are working at the NRC, like I said, this was geared towards them. So, if they saw you, they would maybe know who was who.

As you know, we meet twice a year for two

days at a time. We have teleconferences any time that we need to. And one to two hours, that would be good. I don't think we've had any two-plus hour meetings recently, have we? We used to be that way. At least not the teleconferences.

And then we always look forward to trying to have an annual commission briefing. So, we will have that this year.

Subcommittees are created as needed. And they are created by the ACMUI chairman. And the majority of ACMUI work, as you know, is done in subcommittee space not necessarily while you're here meeting face to face.

Subcommittees are given a specific purpose or task usually related to one topic. They generate reports for review and discussion in a public meeting with the full committee.

Subcommittee reports are voted on and submitted to NRC as formal comments or recommendations.

And here I have listed many of the topics that have been covered. Not everyone was here in 2002, but that's when we first started, I guess, talking about training and - probably prior to that, but that's when we had a major rule coming out on

training and experience in Part 35.

And there was a subcommittee for the Novoste medical events that were reported. And we had the fingerprinting efficiency and cesium chloride issues that came up. I know Dr. Thomadsen is very familiar with those and served on those subcommittees.

We had a board certification pathway. I believe Dr. Eggli, who is no longer on that committee, headed that one up.

We've had lots of interest on patient release recently. And of high, high interest is the permanent implant brachytherapy topics. And you can see we visited in 2008, `10, `11 and `12. And more to come on that as the proposed rule works its way through the process.

And we've also looked at electronic signatures, radium-223 dichloride. The AO criteria, which Sophie mentioned, went to Research and will be submitted to the Commission.

And then we have the expanded Part 35 rulemaking which is the big rule going on right now. You guys have provided lots of input for that. And also the yttrium-90 microsphere events analysis that we just had a teleconference for.

And you also have a standing subcommittee for medical events that are reported each fiscal year to the NRC.

And here is a link to the ACMUI public webpage which we revised and updated earlier this year. Hopefully it's easier to navigate, easier to find things. And it includes all of your membership information, your biographies. If you ever need any updates or anything to that, you can always send those to Sophie and she'll get your most recent information put up there.

We also had a history section which is part of the beginning of this presentation and that takes us all the way back to the Manhattan Project. And it has a copy of our charter. All of your subcommittee reports are easily linked from there.

And meeting information which includes all the meeting summaries, the agendas, full transcripts, all that information is broken out by year and it's easy to find now.

And there's also just a generic contact submission form which goes to a box that the medical team monitors. And we assign it to the appropriate person to get a response for any questions that come in.

And obviously you guys know how to get in touch with us. But if you ever have a constituent who needs just a general question, we have a place for that.

And these are your contacts; Chris, Mike and Sophie. That's it for me.

CHAIR THOMADSEN: Any questions for Ms. Cockerham? Yes. Dr. Langhorst.

MEMBER LANGHORST: I wanted to say thank you very much for gathering this information and, yes, I do - I'm able to find things on here. It looks really good.

One question I had about the meetings - I'm trying to get to it here. The history goes back to 1993.

Is there information that goes back farther than that that's available on -

MS. COCKERHAM: We checked with HR and that was all that they had. I have some paper files that I need to turn over to Sophie. It would be a matter of going through paper files to see if there is selection panel information. And then I'm not sure even within those paper files if we would show who was selected.

I believe we're required to retain the

information for six years as far as membership goes. And so, our initial question was to HR since they maintain all of that and they went back to `93 and that's as far as it went.

So, when Jeff was here and was collecting that information, that's as far as we got with HR.

MEMBER LANGHORST: Okay. It would be nice to have the discussions that occurred in the meetings like transcripts during the formation of Part 35 and all that. So, that's one thing that would be really nice to have if it's -

MS. COCKERHAM: When did we start ADAMS stuff?

MR. McDERMOTT: 1993.

MS. COCKERHAM: I was getting ready to say you're getting into - I don't know if we have electronic copies where we could even get this stuff without going - doesn't our stuff go to the National Archive or - it goes downtown in boxes. So, that's probably why you're seeing that `93 number. The electronic age.

MS. HOLIDAY: If I can jump in just real quick, Dr. Langhorst. I do have a box of hard copy transcripts that date probably around the 1990s for some that stuff - if it's not on there. And I know

those items probably more than likely were not scanned into ADAMS. So, it's just a matter of resources.

So, when I do get time, I do plan to add those into the system and upload that. So, as information comes available and we have time to do that, then I am more than happy to add that to the website.

MEMBER LANGHORST: Well, I appreciate that effort very much.

MS. COCKERHAM: I probably have another 25 boxes to add to that.

(Laughter.)

MS. HOLIDAY: We're still transitioning.

CHAIR THOMADSEN: Dr. Van Decker.

MEMBER VAN DECKER: Yes, actually I wanted to thank you. And I wanted to point out that there's probably some utility to what you just did, you know.

Historical institutional memory is important in consistency to the stakeholder community over time and important to the thought processes that evolve over time and regulations.

So, I would start it out with my first historical comment showing how old I am and then I'll go to where I want to go.

The initial 10 CFR 35 rewrite for training and experience kicked off in 1996 at a town hall meeting in Philadelphia. I know. I was there. So, it goes back a little bit more than 2002.

And it points out that that process which was so important to the stakeholder community took eight or nine years before it came to fruition, which would have cycled everybody off the Committee during that period of time for some historical threat of where thought was going and where we were. So, there is some importance to that.

And so, collation of institutional memory and historical memory is kind of important for everyone.

And then my final comment on where that goes is obviously you have three open positions coming up and some packaging of introductory material for people to hit the ground running as far as institutional memory goes, some of the most major topics recently and some of the background on it which certainly, I think, make the Committee most effective and effective to the staff. Which from my experience from 1996 on, has been nothing but phenomenal.

CHAIR THOMADSEN: Dr. Suleiman.

MEMBER SULEIMAN: Some interesting points. There's little doubt in my mind that the transcripts of the earlier meetings are somewhere.

I've recently been looking at documents dating back to the 1940s. And so, sometimes it's surprising how ancient information is still very, very relevant. So, I think it would be important to find them or at least have some sort of a moderate level, you know, effort to find them.

Yeah, I think everything started to get electronicized about a decade or two ago and that seems to be the period, but you'd be surprised at how much stuff has been scanned in and PDF'd and is on there.

Another point just for historical purposes that I've come across, in 1963 when the FDA started to require pre-market approval of certain - for the drugs, for example, the FDA and NRC had a Memorandum of Understanding.

They basically said we don't consider these drugs - or we'll let the Atomic Energy Commission take charge of that.

But in 1975, which I always find - it's not ironic. I'm sure it's associated with the reorganization with the NRC and ERDA, Energy Research

and Development Agency, was established, but at that time they said we're going to give back to FDA the authority to require pre-market approval.

So, from `75 on FDA took back its authority to evaluate drugs prior to marketing, but prior to that it was completely AEC or completely NRC.

So, that sometimes gives you a different perspective of how different people perceive, you know, how these products have been regulated over the years.

CHAIR THOMADSEN: Dr. Welsh.

MEMBER WELSH: Thank you, Ashley, for conducting this research. I know you and I talked about two or three years ago and I was extremely interested in this in large part because of some questions that were raised to me as a member of the ASTRO History Committee, and because of the University of Wisconsin who I understand had several previous members besides me and Dr. Thomadsen. So, I wanted to try to dig that history up myself and I think you've done a much better job on it.

Therefore, I'd like, if possible, for you to refute a rumor that I might have dug up which was raised when people asked, how did someone like you

get onto the ACMUI?

And as I dug further and further into it, I heard that the original name for this committee was the Subcommittee on Human Applications within the Division of Isotopes within the Manhattan Project or Atomic Energy Commission.

And that was too long a name. So, it was shortened to the Subhuman Committee.

MS. COCKERHAM: I remember that conversation now.

(Laughter.)

MEMBER WELSH: After, we stopped all investigations into the whole subject.

MR. EINBERG: Dr. Howe has something that she'd like to say on that topic.

DR. HOWE: And that's absolutely right. It was the Subhuman Committee.

And I think one other interesting point is one reason you start to see more things on the ACMUI not only electronic, but in the late `80s, early `90s, there was a move to get new people on the ACMUI.

We had members on the ACMUI that had been on ACMUI for 18 to 20 years. So, there was a move to standardize that people would come into certain

positions and they would be here for a certain period of time. And you could be extended for a certain amount of -

MS. COCKERHAM: And I think we actually overcompensated on that. From that 18 to 20-year mark, we went to a three-year system and that wasn't long enough.

As you know, you can spend your whole first year just getting up to speed, figuring out kind of the dynamics of the Committee, what the issues are, what your position is. And then all of a sudden a year goes by and then now it's your last year.

So, having four years - I know recently we had extended terms to four years. And obviously having two back-to-back four years it seems like a long time, eight years, but I think that there is a lot to be learned and hopefully good knowledge management for that time period. Hopefully we've found a happy medium with that.

CHAIR THOMADSEN: Dr. Zanzonico.

MEMBER ZANZONICO: How is the, I mean, the composition is very logical, representative and so forth, but what mechanisms are there for expanding or changing composition.

Because one - as you were speaking and you alluded to research, one thing that came to mind was the possibility that, you know, maybe including a lab research representative as opposed to the pure clinical disciplines might be useful.

I mean, at our place and I'm sure at every academic medical center there are many, many laboratory investigators using radionuclides who are not represented on the Committee. And that might be something to consider.

MS. COCKERHAM: The mechanism is a commission paper. So, staff would write a SECY paper and it would go up through the management chain.

As an example, we added Dr. Guiberteau's position, a diagnostic radiologist. I believe Dr. Eggli had sort of made a case that he was covering one part of nuclear medicine. And although it was our expectation that he was representing another part, he wasn't necessarily bringing that perspective.

And so, he really raised that to our attention and we went to the Commission and asked to add a position.

So, the Commission has to approve positions on the Committee. And there are lots of

other things that come into play as far as the size and the scope and, you know, budgets and economic factors, things that we're not necessarily thinking about, but I think that's the balance we're trying to strike here and that's the mechanism is that it's Commission approval for each position.

CHAIR THOMADSEN: Thank you.

MS. COCKERHAM: I think it's risk-informed, too, you know. So, two radiation oncologists and different things like that.

CHAIR THOMADSEN: Any other comments?

(No response.)

CHAIR THOMADSEN: In that case, thank you very much.

MS. COCKERHAM: Thank you.

CHAIR THOMADSEN: We're running a little bit ahead. We're scheduled for the group photo at this point.

Would the photographer be ready?

MR. EINBERG: Is the photographer here, Sophie, or do you know?

MS. HOLIDAY: I believe the photographer is going to come up here at 12:00 to meet the Committee. So, if you would like, Dr. Thomadsen, I guess you could have everyone else break for lunch

now.

CHAIR THOMADSEN: That sounds like a good idea. So, officially the meeting is on break now until 1:30. And the Committee members should please hang around for the photo.

(Whereupon, the above-entitled matter went off the record at 11:46 a.m. and resumed at 1:29 p.m.)

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

1:29 p.m.

CHAIR THOMADSEN: Okay. We have Ms. Holiday who is going to make a slight correction to her presentation this morning.

MS. HOLIDAY: Thank you. For everyone's awareness, earlier this morning I gave a presentation called "Old Business." And I made an incorrect statement when going over the 2008 recommendation and action chart.

Item 28 which refers to, "staff revising 10 CFR 35.65, to clarify, it does not apply to sources used for medical use. However, NRC should not require licensees to list the transmission sources as a line item on the license. NRC staff should also revise 10 CFR 35.590 to permit the use of transmission sources under 10 CFR 35.500 by AUs meeting the training and experience requirements of 10 CFR 35.590 or 35.290."

I stated that this would be considered for future rulemaking. But in actuality, this is included in the current Part 35 rulemaking and I just wanted to get that on the record.

CHAIR THOMADSEN: Thank you very much. And speaking of the Part 35 rulemaking, here is an

update with Ms. Bhalla and Mr. Lohr.

MR. LOHR: Welcome back from lunch. I am Ed Lohr and this is Neelam Bhalla. We work in the rulemaking and project management branch. And we have the honor, if you will, of managing the Part 35 rulemaking.

Just to rehash a little bit, sometimes we forget how long these have been going on. We began the effort for the medical event rulemaking in 2006. And we merged this with what we called the expanded rulemaking in August of 2012.

And so, you hear us many times now refer to this as our expanded rulemaking. And so, this encompasses both the efforts that were independently ongoing prior to that.

The official title is Medical Use of Byproduct Material, Medical Event Definitions, Training and Experience and Clarifying Amendments.

The proposed rule package was made public on August 23rd of last month. But I do want to clarify that the package is made public, but not soliciting comments at this point.

The package was made public so that the public could be aware of the ongoing rulemaking and of course for the ACMUI discussion today, among other

things.

We will be seeking public comments on the rulemaking only if the Commission votes to publish a proposed rule. The Commission has many options, of course, on whether they would like to do that.

The Commission has scheduled a public meeting on this specific rulemaking in October. They are doing this prior to their vote on the rule. And, again, as I said, pending their approval, we will publish this in the Federal Register for public comment.

We have proposed to the Commission a 90-day comment period. The Commission can accept this recommendation from the staff, or they change it. So, today I cannot tell you exactly how long that comment period will be, but we anticipate 90 days or longer.

The medical community will be informed when the Federal Register notice has actually been published, along with the Agreement States. We send a specific letter to the Agreement States telling them that it's also available.

All of the comments that we receive if this rule is published will be considered by the NRC staff and resolved with our working group committees.

And the actual resolutions you see will be in the Federal Register Notice for the final rule.

Just one note for anybody who's looked at these, you are probably familiar we do not address question by question or comment by comment as they come in, but rather we group them together and give a general response to them.

And as of this moment in time, we are still on our tentative schedule as we presented in the past to your folks for the current - or the final rule being due to the Commission at the end of calendar year 2014.

Just as in the proposed rule, the ACMUI will be asked for and their reviews and comments will be included in the final rule package to the Commission. And this takes approximately one year after we publish the proposed rule.

There is really nothing new from the rulemaking perspective on our schedule. We're right on track and we anticipate everything to stay that way.

CHAIR THOMADSEN: Okay. Thank you. Any questions for - yes, Dr. Zanzonico.

MEMBER ZANZONICO: Does the latest draft, for lack of a better term, the one that was published

in August, did that reflect the input of the ACMUI in its report on the rulemaking?

MR. LOHR: Yes, sir, it does.

MEMBER ZANZONICO: And just a comment I was asking, I'm thinking this is such a big, complicated effort. I'm wondering if 90 days is sufficient for the community at large to provide comments. I'm thinking something like twice that length of time.

MR. LOHR: That's something, again, the Commission will make that decision.

MS. BHALLA: Generally we give about 60 days with most rulemakings. 75 is also done. 90 is like somewhat at the upper end of that time frame.

We could - and, again, it depends on, you know, if you propose to the Commission that perhaps 90 days is not enough and maybe could propose little bit longer time. But considering that 75 is kind of our norm, 90 days, we think, is adequate time.

MEMBER ZANZONICO: Even for something of this scope?

MS. BHALLA: Yes. But we could, I mean, actually -

MR. EINBERG: Just to remind you that this - the rule is already, you know, publicly available.

So, it's not out for public comment. So, people in the medical community if they wanted to get an early glimpse as to what is likely to be promulgated by the Commission, you could start reviewing already right now. But we're not soliciting comments at this time, but it's out there.

MEMBER ZANZONICO: And there will be some - so, the 90-day clock hasn't started or whatever it turns out to be. That will be some weeks, if not months, from now.

MR. EINBERG: Most likely it will be after the Commission meeting in October.

MS. BHALLA: Yeah. And the day we issue the Federal Register Notice, that's the day the clock pretty much starts. So, in that notice we say public comments will close 90 days from today.

And I think we do even put a date. So -

CHAIR THOMADSEN: Dr. Guiberteau.

VICE CHAIR GUIBERTEAU: What are the options of the Commission at this point? I mean, on October 18th providing they agree, will they approve this draft as written, or do they, I mean, I presume one of the options is to send it back for consideration, or may they change it at that meeting?

I'm just curious to know what their

options are at that time.

MR. LOHR: When the Commission votes and they send direction to the staff on to what to do, the disposition of this, they have multiple options. And it's not uncommon for them to send instruction to the staff to change particular items, language, add items, subtract items.

We are - of course we'll follow whatever instructions we get, but they also have the option to return it as they did in the medical event rule in 2010 to ask us to re-engage the community on specific items.

So, we, the staff, of course have no feel for what they're going to do, but we had hoped that we had followed their instructions and engaged the medical community in this particular rulemaking so that, you know, your views of the medical community are presented to the Commission for them to make their informed decisions.

VICE CHAIR GUIBERTEAU: Well, thank you, because I just think we need to know, you know, what to expect.

And your answer is pretty much what I expected, but I just wanted to make it clear, you know, at this point that they still have numerous

options and may well take advantage of them.

MS. BHALLA: Yeah. And Mike Fuller was here, in fact. Mike spent some - very recently Mike was with the Chairman's Office and perhaps can add to it or, you know.

MR. FULLER: No.

(Laughter.)

MR. FULLER: I apologize. I was trying to make sure that we could hear Dr. Guiberteau and Dr. Thomadsen in there as speakers. So, I missed that last bit, the last string of the conversation. So, what was the question?

MS. BHALLA: Oh, the question was that what choice the Commission would have or what - yeah, what choice the Commission would have once they start to work on the rule.

MR. FULLER: Oh, yeah. Ed is entirely correct. They have any number of options available to them and but keeping in mind that this has been going on for so many years.

I know there is a very strong interest on the part of the Commission to get this out for public comment. But, again, it's, you know, there will be an opportunity during the October 18th meeting for the ACMUI to make their opinions known as far as, you

know, the public comment period and things such as that, but what was set out in the SECY paper is reflective of the ACMUI's position on most issues, if not all.

And so, there's not a lot of - lot of controversy like we've had in the past on this particular rule. So, I wouldn't expect, you know, I would never be surprised, but it appears that this one is in pretty good shape at this point in time.

CHAIR THOMADSEN: Thank you. Dr. Van Decker.

MEMBER VAN DECKER: So, let's look at the other end other than giving extra time for comment. Saying that there's only administerial changes on October 18th or relatively buy-in, where do you foresee approximately this thing going to publication?

Is this going to take several months on your end if it comes back to you? I mean, do we see this as something that's going to come out in December-January if it goes through administerial changes? Do we see this coming out after the next ACMUI because it takes stuff within your division to get it ready to go?

MR. LOHR: Well, you need to understand

the meeting on October 18th is not when the Commission is going to vote.

MEMBER VAN DECKER: To vote, right.

MR. LOHR: They're just getting additional input from the medical community, as well as the staff, any questions they may have.

MEMBER VAN DECKER: So, it's likely it's going to be months.

MR. LOHR: They're on their own schedule to when they decide to vote on it. We hope that they will vote before the end of the year.

Once they have issued the instructions to the staff to publish a rule, we generally have it out within like three weeks on the street. It goes fairly quickly after that.

MS. BHALLA: Except I just want to add to that we have in this rule the information collection requirements. And those must be approved by the OMB, Office of Management and Budget.

So, what happens is all the rulemakings that we do, they go and they line up with this OMB's desk officer. And usually they are the ones who are behind.

And at that point, it's beyond NRC's - beyond us to control that. So, we have had some

rulemaking sitting up there for a good two, three months, four months even depending on their schedule.

So, that's one thing that we just need to, you know, keep in mind that we could be already set and, you know, ready to publish, but we may be hindered by the OMB desk clearance.

MEMBER VAN DECKER: So, my follow-up for that for what to ask is obviously I think the Committee spent a lot of years here, a lot of work on this in detail and hopefully the groundwork had been set for this to move smoothly, but we also need to recognize, right, that this is going to get a three-year grace period for the agreement states to come to Category B. So, you're really looking at 2017 implementation for the majority of the nation.

So, to keep adding six months here or six months there, we are - I may be retired by the time I see it.

So, it would be nice to kind of make sure that that, you know, kind of gets moved along, I think, from the community of stakeholders.

And then the last segue to that, obviously, is if you do get successful and move this along relatively quickly into next year, you've got three open spots here, one of which is the Agreement

State spot, that's going to have to have final consensus here.

So, from the administrative perspective making sure those seats are full, they're up to speed and the agreement states are into the buy-in of if it goes, it goes, would all be helpful in making things move.

CHAIR THOMADSEN: Thank you. Dr. Langhorst.

MEMBER LANGHORST: Yes. On the development of guidance for this rulemaking, will that be included in the update of Volume 9, 1556 Volume 9, or -

MR. LOHR: I think that Dr. Howe can possibly speak to that best.

DR. HOWE: Ashley and I are actually going to give a presentation, I believe, tomorrow on where 1556 Volume 9 is.

The guidance that goes with the rule will be independent of Volume 9 until Volume 9 is finally completed.

MEMBER LANGHORST: Okay. And so, that will be - that would be made available during the time of commenting for licensees?

DR. HOWE: The guidance that goes with the

rule is available - will be posted. The *Federal Register* Notice will go out the same day as the rule does and say where it's located. And you make your comments at the same period of time.

And then when we get to a final rule, the final guidance that goes with the rule will be published at the same time.

MEMBER LANGHORST: Thank you very much for that, because I know it can be difficult to get all that altogether and coordinated. So, I appreciate that.

CHAIR THOMADSEN: We have a comment from the public. Please state your name.

MS. FAIROBENT: Lynne Fairobent, American Association of Physicists in Medicine. I just wanted to point out a couple of things.

When the draft does go over to OMB, there is a comment period for commenting back to OMB on the data collection requirements. So, that also will add some time in there. Typically, that's a 30-day comment period. It's a very short comment period, but it is there.

The other thing, those of us who have been invited to testify on the October 18th, there are five specific questions that we have been asked

to address in our eight-minute presentations; and they are compatibility in medical event reporting for permanent implant brachytherapy, modifying training and experience attestation requirements, expanding the grandfathering to authorized status for selected board certified individuals who were not named on a license before October 25th, 2005, authorizing associate radiation safety officers in frequency of testing for molybdenum and concentration and reporting requirements for exceeding regulatory limits.

And I just wanted to mention because I think it's tangential to the Part 35 rulemaking, but I think it also hinges on it especially since we have been asked to address compatibility requirements for the permanent implant brachytherapy, there are two policy statements out for public comment right now on agreement state issues, one of which ties to compatibility, and those comment period closes September 16.

So, I think that if the Committee has not looked at those, it might be something you want to look at. Because I think whenever the direction comes out of the policy statements on the definition of compatibility, will definitely impact which

provisions of Part 35 may be determined to be Compatibility B in the future.

CHAIR THOMADSEN: Thank you for that comment. Other comments from the Committee or from the public?

(No response.)

CHAIR THOMADSEN: Hearing none, thank you very much for your presentation. And I'll just turn the chair over to Dr. Guiberteau since I'm the next presenter.

(Pause in the proceedings.)

VICE CHAIR GUIBERTEAU: Well, welcome, Dr. Thomadsen.

(Laughter.)

CHAIR THOMADSEN: I just wanted to make some comments about the Nuclear Regulatory Commission and safety culture.

You will recall that we, as a committee, reviewed the safety culture statement from the NRC a couple years ago.

And just as a summary, I have on the screen some of the features of safety culture that were included in that statement that the leadership values safety and safety actions, that problem identification and resolution are part of the

culture, there's personal accountability, there are work processes, there is continuous learning, that environment for raising concerns exist, effective safety communications are in place, there's a respectful work environment and a questioning attitude.

I want to address Item 6, Environment for Raising Concerns. And part of this comes from our concern when we talked about the statement of how the statement would be used by the NRC in the future.

And the NRC defines "a chilled work environment" as a place where employees perceive that raising safety concerns to their employers or to the NRC is being suppressed or discourages. And that's part of the Inspection Manual.

And the NRC gave a presentation at the Health Physics Society Meeting just, I think it was, last month in Madison, Wisconsin where they gave an example of workers at a facility who did not report a problem. And the speaker hypothesized that it may have been that they were afraid of retaliation and that there may have been a chilled work environment.

But more often than people being afraid of retaliation, I hear that people are afraid to report events because not of what the employers might

do, but because of what regulators might do in their employment location.

And so, it's possible that maybe the workers were afraid to report, but they were afraid to report because of potential NRC actions and that this may indeed be forming a chilled work environment.

The goal that we all should have is to learn about issues that exist and to fix the issues before they actually cause problems.

All the research in learning systems says that a non-punitive reporting environment is advantageous to being able to learn about issues that exist.

That's why we have Item Number 6 in that safety culture list. And the question would be how to best achieve this goal.

If we follow the NRC guidance to avoid a chilled workplace by not punishing facilities that identify and report problems, that's a good step.

Possibly use a reporting system like the Federal Aviation Administration where the reporters are given a bit of amnesty from the regulatory agencies from punishment as long as they have reported an issue.

This could lead to more details and more correct details being given during an investigation and better information in NMED. Openness could also facilitate concentrating on solutions rather than punishments.

In summary, following the practices of a good safety culture could be beneficial to the NRC and to the medical community.

These are the acronyms that I used and that's it. It was a very short statement, but I just wanted to bring it to the attention of the NRC staff as something to be considered.

VICE CHAIR GUIBERTEAU: Thank you, Bruce. Are there any comments from the members of the Committee or questions?

Orhan.

MEMBER SULEIMAN: I think this is sort of the heart of the whole medical error reporting issue that's, you know, out there as well is we don't have a society where people can report mistakes without implicating themselves or fearing some sort of consequences. So, I think this is maybe just a smaller subset of a bigger issue.

If that became routine practice, people would say, well, we made a mistake, I made a mistake,

identify it, learn from it and then move on, but there's always the same thing here where why would I report this when I'm not sure what's going to happen.

CHAIR THOMADSEN: Thank you very much.

MEMBER ZANZONICO: I think it is also - it's hard to disagree with anything you've said, but there's also the issue of, you know, potential litigation and the institution for which one works and, you know, their legal people and their role in, quote/unquote, protecting the institution in terms of exactly what an employee can or cannot divulge to whomever, a regulator or whomever.

So, you know, I don't have any answer or really any position, but it just does strike me that that real world consideration impacts this as well.

VICE CHAIR GUIBERTEAU: Interestingly as you bring up that topic and certainly the medical community has a long way to go in this, but there are a number of institutions and medical-legal philosophers who believe that doing the same with patients is a good practice that is admitting wrongdoing which actually goes to some kind of medication rather than the legal - the long legal processes. So, I think in general we are moving in this direction.

It has been slow, but I think it brings up some very interesting things in terms of patient advocacy, etcetera, but I think your points are very well taken.

Chris.

MR. EINBERG: Yeah, I would also just point out that during the enforcement process if the licensee itself identifies a problem, then that is taken into consideration when an enforcement action is taken.

So, problems that are self-identified receive different types of treatment in the enforcement process.

VICE CHAIR GUIBERTEAU: Any other questions? Sue.

MEMBER LANGHORST: Having been deeply involved in some of these medical event reportings and follow-ups and so on, I know we've had discussion with our NRC inspector about the frustration of admitting to what we did and what was wrong, but also having that desire to share a lot of details, but not necessarily where our name is just front and center of all of it, you know, where you can really present it in a forum for others to learn from.

And you can go into much more detail that

you don't want to do in the enforcement side of things, and that's kind of that ability to report and not have a chilling effect, not have that retribution of, boy, you did wrong and we're going to be watching you from now on.

I mean, it's, we're worse on ourselves than anybody else, but still we'd like to be able to share that with others.

I know there is efforts out there to try to get these types of lesson learned scenarios so that people can reason for themselves and understand what's going on to a little more detail than what we have currently.

The NMED system I find very interesting to read and see what happened in places, but still there is that, gee, I didn't get enough of really what happened here and it's not available to licensees.

I mean, it's an internal regulatory tool right now and I guess maybe potentially open to licensees.

So, I commend everyone who is working on this effort to try to get lessons learned out there and in a level of detail that really helps people, but still protects the entities that are reporting.

If it were easy, it would already be done. So, I'll just stop there.

CHAIR THOMADSEN: Dr. Guiberteau, you have a member of the public.

VICE CHAIR GUIBERTEAU: Yes, please.

MR. WILLIAMS: Gary Williams, Veterans Health Administration. We are in the process of beta testing an incident reporting system that would allow for individuals to make anonymous reports similar to the aircraft reporting mishap anonymous system.

We hope to get that available to our 40 locations that do primarily external vein therapy at a meeting later this month where they will be given some ideas about how they could use that system, and we'll see how it works out.

The other comment I would make is that part of the challenge from my perspective is how the NRC always uses human error as the root cause for any incident that sort of at least in the medical community is not what we use given that you want people to feel free to report.

I notice the recent information notice or RIS on HDR that came out analyzed some previous medical event circumstances. And I believe they concluded every one of them were due to human error.

So, I just do not have much comfort with the approach NRC uses with their root cause analysis and the unwarranted, in my view, conclusion that they're all due to human error. Thank you.

VICE CHAIR GUIBERTEAU: Thank you. Yes, please.

MS. TOMLINSON: Hi. Cindy Tomlinson from ASTRO. Along the same lines ASTRO has just started beta testing a radiation oncology incident learning system under the auspices of the Patient Safety Quality Improvement Act. So, it's technically a patient safety organization.

We're hopeful that full launch to the full radiation oncology community will be in the early part of 2014, but I am offering to possibly maybe present to the Committee at your spring meeting something about the PSO as we're talking about the things that we're going to be looking for and collecting. And maybe by then we'll even have some data that we can share.

But the idea of the PSO is that it's got all this information. It's collecting it in a safe environment so that physicians and other healthcare providers are not - there's no fear of liability. It can't be used in a disciplinary hearing, anything

like that.

So, that's the idea of patient safety organization is a safe - is a safe place for people to report these kinds of incidents and then analyze them on a national aggregate level.

VICE CHAIR GUIBERTEAU: Is this information as you had set it up in your - where your headquarters are, is this considered peer-protected information, or do you know?

MS. TOMLINSON: Yes, it's all protected. So, and I, I mean, I don't know how much time you want to allow me to talk about it, because I could talk for quite some time on it.

But the idea is that you enter in information, you know, it is protected, but the idea is to learn from your peers. Because especially in radiation oncology, things happen in other clinics that could be happening in your clinic and you might not necessarily know about it.

And so, it's a way for there to be sort of a national comparison, but it is safe. Any data that I see is all de-identified data. I cannot see any of it, any identifiable information.

So, I am putting ASTRO out there to give you all more information at your spring meeting if

you would so desire.

VICE CHAIR GUIBERTEAU: Thank you.

MR. EINBERG: Also this morning in the closed session I had mentioned that, you know, the NMED database may be made publicly available.

We're exploring possibilities for making that publicly available, but I wanted to give the general public the opportunity to hear that also.

As I indicated earlier, we're looking at what is sensitive information within the database that needs to be scrubbed. And so, what are the practical implications of trying to make that public.

So, we're working with our contractor out in Idaho National Labs to see if we can make that public, but, you know, the initial indications look positive. It may be possible to make NMED public.

VICE CHAIR GUIBERTEAU: Thank you. Any other comments or questions? Yes, Sophie.

MS. HOLIDAY: Sophie Holiday. I just wanted to make a quick comment. I know that Cindy Tomlinson mentioned an event database that ASTRO is developing.

As Mr. Einberg just mentioned, we're also exploring making NMED publicly available. So, staff has been made aware of several other medical event

reporting mechanisms and we considered putting that on the spring 2014 agenda, as possibly devoting half a day of the meeting to having these different organizations come in and make that presentation.

But of course the agenda hasn't really been spoken about and that would be something we would consult with the chair and the DFO about. Thank you.

VICE CHAIR GUIBERTEAU: Any other questions, comments?

(No response.)

VICE CHAIR GUIBERTEAU: Dr. Thomadsen, you are excused.

(Laughter.)

(Pause in the proceedings.)

CHAIR THOMADSEN: And that brings us to Mr. Zelac with a discussion of interim enforcement policy for permanent implant brachytherapy programs. Something this committee has lived with for a long time.

DR. ZELAC: Truer words couldn't be spoken. This is essentially the next chapter in a continuing saga that goes back at least to 2004-2005 era.

This is intended, this interim

enforcement policy, essentially, to bridge a gap - A gap between where we are now with the current regulation and where we're heading with proposed regulation with respect to permanent implant brachytherapy even reporting, primarily.

Let's see. Not the right one. Yeah. So, the first question that comes up that I'll attempt to answer is where did this come from, this interim enforcement policy?

This is one of several that the Agency has through its Office of Enforcement, but the question is, well, how did they get involved? And the answer is, the Commission.

A paper was sent up to the Commission in December - well, actually earlier, excuse me - in 2012 on recommendations for making regulatory changes with respect to permanent implant brachytherapy.

The Commission accepted those recommendations and they, in fact, are the basis for what's taking place in the proposed rule right now.

But the Commission also asked that in the interim, because there's clearly a time lag between when the Commission says this is a good idea and when it actually comes to fruition, the Commission also wanted there to be some clarity to licensees about

how they should be operating under the current rule.

And the Commission also said that based on where we're going with the current rule, it appears that there is some opportunity here for giving some enforcement discretion to inspectors who go out in the field and see certain things.

So, when the Commission provided its response to this commission paper, they gave us these two additional requirements that we were to clarify the medical event reporting for permanent implant brachytherapy under the existing rule, and secondly develop an interim enforcement policy for those licensees that use total source strength and treatment time for determining the existence of a treatment site medical event.

The objective of this interim enforcement policy was to allow staff, meaning specifically inspection staff initially, enforcement discretion both for existing and future violations of 35.3045, which is the medical event reporting requirement section.

The status of this interim enforcement policy is that it was published in the Federal Register in the early portion of July and became effective on that date.

If someone wants to look specifically at the interim enforcement policy and what it says, of course there's the Federal Register Notice on the top there, 78 FR and the page number. And I can supply it to anyone who wants it later. Or the alternative is to go to a website, www.regulations.gov, and enter the appropriate docket number and it's also available there.

The third opportunity or possibility is that you might go to what was also developed. Once the interim enforcement policy was available, it was impossible for us staff to put out the first directive that we got from the Commission, which was tell us or tell licensees and tell us how there is going to be enforcement under the existing rule and what licensees should be able to do, you know, under the existing rule to comply with it.

That was put out in the form of a regulatory issue summary that was recently published at the end of July. And, again, it references and describes and includes some excerpts from the interim enforcement policy. So, there are plenty of ways to learn more about this if you wish to.

Now, the specific enforcement discretions that are available for inspectors to consider when

they are doing an inspection, are two.

Initially it was directed by the Commission to go in one direction, which we have, and that's the first of these enforcement discretions, but another one through consideration as this was being developed, became apparent, was included in this interim enforcement policy.

The first of these discretions is to allow licensees to use as the Commission directed, total source strength and treatment time for determining the existence of a treatment site medical event. Again, conformity with the requirements of 35.3045.

The second of these enforcement discretions was to allow the total dose to the treatment site to exceed 120 percent of the prescribed dose.

Now, for those of you who are familiar with the current requirement, you know that there is a variance limit that's placed on the delivered dose. It needs to be within 20 percent plus or minus of what had been prescribed. If it isn't for the treatment site, that's one criterion for reporting - for requiring medical event reporting.

I'm going to expound on both of these.

I'm going to move ahead here. The rationale for the first one, the first discretion on source strength, is that under the existing rule there are two criteria for the treatment site dose that need to be met before it is - before a particular event - before there is an event that needs to be reported.

The first of these is that the dose has to vary. The delivered dose needs to vary from the prescribed dose by at least 50 rads to an organ or tissue.

And the second is that the variance from the prescribed dose as I mentioned already, needs to be - the variance from the prescribed dose needs to exceed 20 percent.

So, if both of those conditions are met, then you've met the criteria for a treatment site medical event report.

In fact, because we are talking therapeutic doses, these two criteria are and have always been linked together.

If you exceed the treatment site dose by 20 percent or deliver less than 80 percent of the treatment site dose, in other words, a variance in the minus direction of 20 percent, you clearly have differed from the prescribed dose by more than

50rads.

So, in fact, if you satisfy one of these conditions, the 20 percent variance condition, you have, in fact, also satisfied the 50 rads condition.

And because of that, we and the Commission felt it was appropriate that if a particular investigator were choosing to make a comparison of prescribed dose to delivered dose in terms of total source strength which is permitt4ed because the definition of "prescribed dose" in the Definition section of Part 35, 35.2, the definition of "prescribed dose" for brachytherapy is either absorbed dose or total source strength and exposure time. Either one.

So, if a particular facility chooses to make the comparison between delivered dose and prescribed dose in terms of total source strength, that should be logically acceptable, reasonable. Because, in fact, will if they exceed plus or minus 20 percent variance, automatically exceed the other condition which is greater than 50 rads.

So, that was the reasoning that went behind suggesting this discretion. And that is, in fact, the basis that was accepted by the Commission.

So, I think I've said sufficient on that.

As I'm going on, do you have any questions so they don't get lost in the muck, just let me know.

This is a lot of detailed stuff. The conclusions are simple. The concepts to get there, you know, are a little complicated.

The second discretion has to do with the magnitude of the dose to the treatment site. The current regulation again limits the variance of delivered dose from prescribed dose to be 20 percent positive.

This, in fact, limits to some degree the physician's ability to deliver optimal care to the patient since the permanent implant therapies typically have the objective of delivering as much radiation dose as possible to the treatment site without exceeding medically recognized dose limits for nearby normal tissues and structures.

So, that means the rationale were in fact, interfering with medical practice to have this limitation. What conditions can we impose for applying discretion for those investigators or clinicians that want to, in fact, disregard this upper limit? And I'll get to that in a minute.

I'm bouncing back and forth between Discretions 1 and 2, but I want to now talk about the

conditions, the specific conditions that are listed along with that interim enforcement policy for an inspector to consider when they find in the field a situation where source strength has been used to make this comparison of delivered dose to prescribed dose.

First of all, the licensee has required documented procedures. And those refer back to Part 35.41, Section 35.41, which is procedures for administrations requiring a written directive.

These procedures must specify that this comparison of prescribed dose to delivered dose is going to be made in terms of total source strength and exposure time. So, that's the first condition.

Second condition: the licensee, in fact, enters both the prescribed dose and the delivered dose into the written directive as total source strength and exposure time.

In other words, if they are operating in a total source strength and exposure time mode, they are consistent in doing this.

So, the procedures refer to doing the comparison in it. The entries in the written directive are in it. And the comparison of total source - the actual comparison of prescribed to delivered is done in terms of total source strength

and exposure time. This is the - this is basically what's being permitted and the others are tangential to that.

And finally, if, in fact, this comparison made in terms of total source strength and exposure time does indicate that there has been a dose that is not within the prescribed limits and regulations, that the licensee, in fact, reported this as a medical event.

If all of those conditions apply and if the use of total source strength and exposure time doesn't result in any misapplication of byproduct material by the licensee, then this discretion can be imposed/utilized by the inspector and not cite a violation of 35.3045.

Now we'll go back to discretion No. 2 of the dose being greater than 120 percent to the treatment site. Here the conditions are utilizing that discretion. In other words, these are things that the inspector looks for. If he or she finds it, then they can consider applying discretion. First, that the licensee is in fact using absorbed dose to compare the dose delivered to the treatment site with the prescribed dose. Why this limitation? I just said a few moments ago that prescribed dose as

defined in Part 35 can either be absorbed dose or total source strength and treatment and exposure time.

This discretion is not be exercised for licensees that use source strength and exposure time to make this comparison since it's expected that the licensee has much more control over delivery of prescribed dose when they're using source strength and exposure time than they do when they're trying to make this comparison in terms of the absorbed dose. In other words, the practitioner can have much greater control over where the seeds are placed than he or she has over the resultant dose that those seeds will deliver.

So the conditions for applying this discretion are first, absorbed dose is being used for the comparison. Secondly, if it is that the doses that normal tissues and structures in the nearby areas are receiving does not exceed the existing limitations on those doses that exist in the regulations. In other words, by allowing this discretion to have larger doses to the treatment site, you're not also trying to say, well, it's acceptable for the doses to normal tissue to correspondingly also be greater, the limitation that

exists in the regulations, which is essentially a dose that exceeds again 50 rads, but also 50 percent more than had been expected by the application.

So what this says is that the dose to normal tissues and other structures nearby can't exceed by 50 percent what had been expected based on the planned administration. If that is the case, the inspector can still consider discretion for this second condition. And finally, that in the written directive the entries that were made in the plan and afterwards, post-administration are both made in terms of absorbed dose and not total source strength.

So in summary, we have an interim enforcement policy put out by our Office of Enforcement that is available for use by inspectors. It is an interim measure, as the name would imply, between where we are now with our regulation and where we're going with the modifications as they're present currently in the proposed regulation. And it's intended to provide what seems to be reasonable flexibility above and beyond what would be currently available under a strict interpretation of the existing rule. And if you have any questions, I will attempt to answer them.

CHAIRMAN THOMADSEN: Questions? Dr.

Zanzonico?

MEMBER ZANZONICO: I have a question. So must the practitioner or a site sort of declare that they'll either use a source strength criteria for an ME, or an absorbed dose-based criteria? And maybe the radiation --

DR. ZELAC: The answer is yes.

MEMBER ZANZONICO: Because the question that raises is I'm just wondering if there might be some instances with individual patients where clinically it might be more appropriate to prescribe a treatment plan based on source strength, whereas in another instance at the discretion of the physician it might be better to prescribe it on the basis of absorbed dose. But then they're boxed in underneath this declaration.

DR. ZELAC: I understand what you're asking and I fully agree that there should be some discretion available, but I think that really comes up to what kind of information is provided with respect to that particular patient's treatment. If in fact as part of the planning for that treatment it's made clear that although our standard procedures for other patients, for example, indicate that our comparisons are going to be made in terms of total

source strength and time of exposure, which of course for permanent implants is, you know, more limited, but if in fact our standard protocol, our standard procedures speak in terms of using total source strength. But in this case we feel that absorbed dose is better. If that's documented in advance, I personally see no reason why that couldn't work.

MEMBER ZANZONICO: Right, that's my point.

DR. ZELAC: Yes.

MEMBER ZANZONICO: I don't think the physicians should have hands tied --

DR. ZELAC: No.

MEMBER ZANZONICO: -- just because they made a declaration at some point. Now you have another patient where that's not appropriate.

DR. ZELAC: The thing, too, is that you've got a licensee, but you're not talking about an individual. You're talking about a facility.

MEMBER ZANZONICO: Yes.

DR. ZELAC: Different practitioners from that facility may prefer to choose to, want to, and in fact demand to do it in one way versus the other. And, you know, so you need to have some level of discretion in this. Has to be reasonable.

MEMBER ZANZONICO: Yes.

CHAIRMAN THOMADSEN: Did that answer your question?

MEMBER ZANZONICO: Yes.

CHAIRMAN THOMADSEN: Good. Fine. Other questions? Mr. Fuller?

MR. FULLER: Just to follow on with what Ron was saying in response to Dr. Zanzonico, this really doesn't change anything. I mean currently our requirements are that you have a written program that you train your people in and you implement and so forth and so on. We don't prescribe what that program is.

So it would stand to reason that if you had a program that was written such a way that you use total source strength and treatment time as the basis for developing your written directive and assessing after the fact and so forth, except in cases where, and you fill out the reasons why you might need to have a different set of criteria -- if that's your policy and that's your procedure, and that's what you've trained your folks in, then that's what your policy is.

What this interim enforcement policy is designed to do -- as Ron has said, you know, we've

had some confusion in the past. A strict interpretation of the rules is they exist. Essentially, the requirements in 35.3045 nullify the flexibilities and the allowances in the 35.40 criteria or the rule. In other words, even though under the prescribed dose it allowed for total source strength and time, that was essentially nullified when you got to 30.45 where it talked about reporting medical events. It was only in terms of dose.

So this is a way to fix that bridge to the new rule. You know, we have a proposed rule up to the Commission, which we'll be talking about again in October and they'll be voting on it soon. The Commission was very clear last year when they indicated that they wanted the community, the medical community to have this bridge. In other words, provide the medical community with the option of using total source strength as prescribed dose and for evaluating whether or not a medical event had occurred. Now, if a licensee desires to use an absorbed-dose-based criteria, that's entirely up to them as well.

DR. ZELAC: It is probably worth noting what I think all perfectly obvious anyway, and that's the direction that we have gone in the proposed rule

with respect to the treatment site and reporting on medical events is to eliminate dose entirely. It's been problematic from day 1. And there's certainly a reasonable alternative to it, and that's what's in the proposed rule.

So the fact that we're going in this interim to talking about source strength, total source strength as opposed to absorbed dose, is very consistent with where we're going to wind up, presumably. And I can say that with some reasonable certainty, unless the community objects strongly, because the Commission has already bought into it.

CHAIRMAN THOMADSEN: Dr. Guiberteau?

VICE-CHAIR GUIBERTEAU: Just so that the Committee, and more specifically myself, understands in terms of interim enforcement policy, are these applicable equally to the agreement states?

And the second part of my question is since I'm not sure how discretion is defined, is there an appeals process if a licensee feels that they should have been offered discretion and didn't get it?

DR. ZELAC: The answer to the first question, are Agreement State's going to be utilizing this interim enforcement policy. It's strictly up to

the particular Agreement State. It's out there. It's available. It's been made known to them very explicitly and clearly, but it's their discretion as to whether or not to use it.

The second, there's always an opportunity for appealing whatever actions might be taken in the course of an inspection for discussing it with the regulators beyond the initial report that this is what we saw, this is what you're being cited for. So, yes, certainly there is opportunity for further discussion about whether or not a particular discretion could have, should have, ought to be applied.

VICE-CHAIR GUIBERTEAU: Thank you.

CHAIRMAN THOMADSEN: Dr. Langhorst?

MEMBER LANGHORST: I wanted to share some of the comments I received from my medical physicists after reading this regulatory issue summary, just to share with the Committee. The first question they had of me was what does this say, because they found it very confusing and were not clear what was meant by what was said in here. I'm not sure I could have worked my way through it had I not been involved in the medical event, or in the Permanent Brachytherapy Subcommittee work.

If this talks about permanent implant brachytherapy, it's confusing to talk about the time of the sources being in there. It's infinity, isn't it? And if your procedure says it's permanent, isn't your time infinity? There is no other choice. So that was one level of confusion.

Also, we utilize the number of seeds method, and in 1991 in the statements of consideration when that was developed, NRC stated using total source strength and exposure time provides an easy way of specifying the total dose and simplifies a determination of a misadministration.

I think that was lost when terminology changed and medical events were defined and so on and I think somehow we lost sight, we as a community and regulators lost sight of what was originally intended. The last thing I wanted to mention was, we talk about absorbed dose and yet the dose units here are in rem and sievert rather than gray and rads. And that was confusing to my medical physicists also. So thank you very much.

CHAIRMAN THOMADSEN: Thank you. Dr. Zelac?

DR. ZELAC: If I can respond, the issue of time is it had to be included, because it's in the

current regulations. You know, anyone that's involved in any way whatsoever knows that once the seeds are there, hopefully they'll reasonably stay there. They're not going to generally be removed, so the time has no limits.

The second point having to do with the change, if you will, from source strength to dose, the 35.75 reporting requirements are general regulations that apply not only to therapy, but also to diagnostic use. And they cover all various modes of application. And it was for that reason that they had to be written in units or criteria that would apply to all the different modes of utilization and not simply to implants and particularly to permanent implants.

So because they were written in terms of dose, we now have gotten away from, as you've said -- and not with intent, but by necessity, I guess, the fact that the direction for permanent implants certainly have been -- and for temporary implants, too, the strength of the sources and the number of sources to define, if you will, the dose.

MEMBER LANGHORST: I think we'd all agree it's a confusing topic.

DR. ZELAC: I think we'd all agree that

the regulation needs some work, and that's exactly what's taking place now.

And the third thing, I can't explain it. Everything is in terms of rem and sievert. And even though clearly rads and gray would be more appropriate here, it simply wasn't there. And so the description of the current regulation had to refer to what's there, not what ought to be necessarily there.

CHAIRMAN THOMADSEN: Dr. Suleiman?

MEMBER SULEIMAN: I think one of the problems is we still see -- I see it confusion between what different professions and different people mean by "dose." And I think the absorbed dose is clearly what you plan your treatment with. Then you come up with this metric; in this case activity source strength, because you can measure that. The absorbed dose you're going to have to calculate and it's subjected to some biological variables.

The other thing that I think we continue to miss is that depending on the type of therapy, depending on the type of patients, the precision and accuracy of the methodology is going to vary. External beam therapy is extremely precise and extremely accurate. Brachytherapy, not so, because implanting the seeds and the patient's response and

inflammation and migration is going to confuse things. So if anybody thinks they can predict the absorbed dose until the entire procedure is finished, is really not accepting reality. And again, if you really talk about uncertainty, you know, let's talk about, you know, the unsealed sources.

So when we talk about dose, I think the first thing I always want to know is what are we talking about? Then my uncertainty kicks in and I say, oh, 10 percent is acceptable, or 50 percent is unacceptable. So I think unless we realize this is brachytherapy with all its limitations and whatever, we shouldn't extrapolate 20 percent to the other modalities or to the other procedures. And I see this among all specialties. When you talk about dose, they mean activity; they mean a whole variety of things. So we have to discipline ourselves and just be careful what we're talking about. And I think a large proportion of the confusion is just attributable to those metrics and how different people interpret them.

DR. ZELAC: It's actually worse than that, because in the regulation itself it's not clear what is meant by the term "dose" when it is used, and it can be used in multiple ways throughout the

regulations.

MEMBER SULEIMAN: And maybe we need to focus and really take a hammer and say this is what we mean by "dose," or these are the terms that are, you know, different. If you want to concede to the different professions and specialties, when you talk about "dose," this is what they mean, and when this group talks about "dose," this is what this group means. But when we're talking about different specialties and different therapies, I bet you if you ask the next 10 people what you mean by "dose" and not lead them, you'd probably get a whole bunch of different answers.

DR. ZELAC: Yes, and that of course if there is ever going to be any improvement of the current situation, there will at least be one revision down the road. So it's after you and I and most of the people here are long gone.

CHAIRMAN THOMADSEN: Dr. Welsh?

MEMBER WELSH: Thank you, Dr. Zelac, for the presentation, and I think you said that one of the ultimate directions that this is going in is the elimination of dose. And if that's what I heard you say, then I think that's great.

DR. ZELAC: For the treatment site, yes.

Not for the normal tissues and structures nearby or within.

MEMBER WELSH: So then for specific enforcement discretion item 2, allow the total dose to the treatment site to exceed 120 percent, it begs the question about minus 20 percent.

DR. ZELAC: I didn't mention it, but that is not included because it is felt that although permitting doses greater than 120 percent goes along with the general direction that clinicians should be thinking. Maximize the dose to the dose to the treatment site for at least portions of the treatment site for most effective treatment. You, certainly as a clinician, wouldn't want to be going in the direction and missing what you had intended by more than 20 percent. That wouldn't be an optimal -- it wouldn't be an acceptable treatment. So the discretion only applies for greater doses by a 20 percent variance than had been prescribed. It does not apply to negative, lesser doses than had been prescribed.

MEMBER WELSH: So while I can fully appreciate the logic of what you just said, I think the reality of what happens in the clinic indicates that it is the minus 20 percent that is more

problematic because of that edema that we've discussed and debated here since 2007, wherein if you take the post-implant dosimetry CT scan at an inappropriate time and the prostate gland has enlarged by 40, 50 percent, you may erroneously conclude that you have under-dosed that patient by 20 percent or more. And we still have this bit of a problem here in that 20 percent higher is exempt, but 20 percent lower, which is the majority of the issues, is not exempt.

DR. ZELAC: I don't disagree at all with what you're suggesting, but I am also indicating that for those persons that feel that this is a concern, that these are the kinds of medical event reports that they want to avoid, the option of course is discretion No. 1. Do it in terms of total source strength and you should be home free.

CHAIRMAN THOMADSEN: Dr. Welsh?

MEMBER WELSH: I have another question, and it's regarding your slide No. 7, rationale for applying discretion No. 1 source strength.

DR. ZELAC: Yes.

MEMBER WELSH: And maybe I just didn't hear or understand what you were saying about the 50 rads in this context.

DR. ZELAC: There are two criteria in 35.75 now for reporting a medical event based on the dose for the treatment site. The first of those is that the variance of dose, absorbed dose in fact, from what had been prescribed exceeds 50 rads. And the second is, okay, if it exceeds 50 rads, does it also vary from what had been prescribed? Does the delivered dose vary from what had been prescribed by more than 20 percent? Both of those are conditions which would have to be met under the current published regulation for a medical event to be reported based on the treatment site dose.

Is there a question?

MEMBER WELSH: I suppose the only comment here might be 50 rad, 0.5 gray compared to a prescription of 160 or 150, 144 gray is well under 1 percent.

DR. ZELAC: Well, but that's exactly the rationale involved in saying that if in fact you have met the second criteria, the variance criteria, you automatically can discount having to make a direct comparison on dose basis for the first criterion, because you clearly have exceeded 50 rads multi-fold.

So, you know, again, the regulation was written for any procedure that might be utilized that

required a written directive. Some of those are not intended for therapeutic purposes or diagnostic purposes. And so there was a need to have a lower-dose limit, absorbed-dose limit there in order to eliminate, you know, many diagnostic procedures from consideration as medical events because the total dose difference didn't amount to very much.

CHAIRMAN THOMADSEN: Any other questions or comments? Dr. Welsh?

MEMBER WELSH: I'd like to conclude by saying that I'm certainly not going to quibble over the 50 rads at this point. I think that we've been working on this, I've been working on this with you since 2006, 2007, and I think this is the closest we've ever come to a satisfactory resolution between the Commission, the staff and the medical stakeholders. So I applaud you for the efforts and I hope that we finally get some resolution in an efficient fashion.

DR. ZELAC: Thank you. I guess the only additional comment I'd made is that we as staff are trying to work harmoniously with our counterparts in other offices to be sure that what is done is generally what is best for everyone concerned, those in the medical community as well as regulators that

have regulations that have to be enforced.

So we try to jointly advise and inform the Commission so they can make reasonable decisions. And we also work with one another in preparing whatever it is that's going to be utilized. In this case, an interim enforcement policy that's going to be used for several years at least before we get our final rule. That was done with a great amount of input from to the Office of Enforcement to essentially get it as right as we could get it right.

CHAIRMAN THOMADSEN: Thank you very much.

DR. ZELAC: You're welcome.

CHAIRMAN THOMADSEN: Dr. Howe will now talk about the Enforcement Guidance Memorandum for the rubidium-82 generators.

DR. HOWE: Thank you, Dr. Thomadsen.

CHAIRMAN THOMADSEN: Yes. Go ahead.

DR. HOWE: What is Enforcement Guidance Memorandum 13-003? And this is the title: "It's Enforcement Guidance Memorandum: Interim Guidance for Dispositioning Violations Involving 10 C.F.R. 35.60, 10 C.F.R. 35.63 for the Calibration of Instrumentation to Measure the Activity of Rubidium-82 in the Determination of Rubidium-82 Patient Dosages."

We ended up -- well, we started with the voluntary recall of the rubidium generators because of patients receiving an excess of the strontium-82 and 85. And that caused us to go back and look extensively at what regulations apply to the rubidium radiofluoride and to see how the product meets those regulations.

And when we did that extensive review, we discovered that the main problem is that you have a very short half-life of 76 seconds for the rubidium-82. And why is that an issue for the regulation? Because of the short half-life, you have to elute the generator and inject the material directly into the patient. This precludes pre-measurement of any administration through a dose calibrator or traditional methods of measuring activity. It also means that you are delivering the dose on the fly. So a major part is there is a dose calibrator involved with this process, but it is not used in the method we normally think of as measuring activity.

And the problem we found out was that in 35.60, because you're eluting the generator, you're not receiving unit dosages. You have to measure the dosage and you have to calibrate the instrument you're using to measure the dosage in accordance to

nationally-recognized standards and calibration instructions provided by the manufacturer. And for rubidium-82 you're not using a dose calibrator to calibrate the rubidium-82. That's a secondary calibration over here.

You're actually measuring the activity of the rubidium-82 using the detector on the infusion cart, and that detector is measuring activity as it goes by in a dynamic manner. And at this particular point we don't have a nationally-recognized standard for calibrating a detector measuring in a dynamic mode. And the manufacturer's instructions were not true calibration instructions. They were constancy checks where you make a measurement with a dose calibrator of one eluent and then you check another one to see if it matches with it, with what's being measured on the dose after a certain period of time from the detector coming off of the infusion pump.

But then if you make a change because you need to adjust, there's no re-calibration of the diffusion -- infusion pump dosimetry. So it's not a true calibration. You had the calibration of the dose calibrator, but you don't have a calibration of the detector on the infusion pump.

So all of our licensees are essentially -

- if you're using rubidium-82, you're in violation of 35.60. And that's not an acceptable position. And this is the reason you don't have the nationally-recognized standards for the dynamic mode, and until such standards are developed, you cannot meet the requirements.

There is another section in 35.63, and that requires that a licensee determine the activity of a dosage administered before medical use. That's very easy with most of the other radiopharmaceuticals because you can put it in a dose calibrator, you can make the measurement, you can measure it in the syringe or vial, and then you administer it to the patient. So you've got that measurement. You can record it. You know what it is before you give it.

In this particular case, because you have a direct infusion into the patient you are not measuring the final dosage before you inject it to the patient. You're doing an incremental measurement and the infusion pump should turn off at a certain point when it believes it's reached that dose measurement. But the fluid has already gone into the patient, so technically you're not measuring it prior to administration. So because it's a dynamic process, there is really no way to meet 10 CFR 35.63.

So once again, all of our licensees using this product are in violation, and that's not acceptable.

So what we did was we looked at those requirements and we said they can't meet either one. What are we going to do about it in the short term? Well, in the short term we do not want to cite licensees for violations when there is no way that they can provide a corrective action. So we looked to see if there was something else that we could use that would kind of assure that the doses going into individuals are what they should be and will meet the current situation of how measurements are made and how the dose is administered.

So we're using enforcement discretion so that we don't issue violations for failure to comply with the requirements for the rubidium generator systems if they're not being used in accordance with 35.60 and 35.63. And we're able to use enforcement discretion because we've developed three criteria, that if the manufacturer is -- not the manufacturer, if the use licensee is following those criteria, then we can use the enforcement discretion and not issue a violation.

What are those criteria? The first criteria is essentially looking at the infusion pump

and the measurement with the radiation detector on the infusion pump. It's important for the infusion pump to deliver a constant volume. So the accuracy and the consistency of the infusion pump rate is an important factor. So we put that in as a requirement that they have a written test procedure to ensure that the infusion pump flow rate is constant and accurate. And then we put a requirement in that the radiation detector meets the manufacturer's specifications.

Now, most licensees don't have a clue as to how to make sure the infusion pump is consistent and accurate or that the radiation detector meets the manufacturer's specifications. And so we understood that and we said, okay, the licensee needs to perform the test at least every 12 months to make sure everything's functioning. And if there's a repair or a replacement, then it needs to be done again and they need to maintain records.

And because we recognized that the licensee may not have this capability, we indicated that the licensee can use the data obtained from the manufacturer, because the manufacturer is going in on a yearly basis and testing all the infusion delivery systems and is doing a radiation test of the detector

to make sure that the detector is operating correctly and also doing an electronic test of the detector to make sure it's operating. So we said, okay, as long as that's happening we'll buy into the fact that it's working the way it should be working and we let them use the manufacturer's information.

Now, in the future if there is a calibration procedure for accuracy, linearity and geometry evaluations of the detector, then the calibration procedures would have to be performed in accordance with those tests.

When we looked at the recall, one of the things that became clear is not everybody understood what they were supposed to be doing and what the measurements meant and when they were not supposed to deliver the rubidium-82 because there was too much strontium. So we put another requirement in that the authorized users -- and in our case that means the physicians. For the manufacturer, their authorized users were the technologists. But that the physicians have training in the specific rubidium generator that they have, because if the generators change, then the next manufacturer may have slightly different processes, and they need to know that. And we wanted the radiation safety officer to also have

training.

And they have to successfully complete the training with specific the manufacturer model number and they have to maintain documentation of that training.

And what are we requiring in the training? We want them to know how to elute and how to do the quality control procedures to determine the rubidium-82 activity, and the strontium-82 and the strontium-85 breakthrough levels. We want them to make sure that the dose calibrator calibration procedures -- know what they are and know how to use them and use the properly. We also want them to be aware of the safety procedures for the clinical use of rubidium-82 chloride. So we've tried to identify what we think are measurable quantities and things that need to be known at the licensee's site. And for the training we will accept the generator manufacturer's training requirements.

And then there's certain tasks in that, and that's the performance of the rubidium-82 activity constancy check, and that should be also the adjustment of infusion cart readout setting, if that's necessary, and know when tests had to be required by the manufacturer. And so that gets us

into the idea that the manufacturer is now asking for tests on each generator after a certain elution volume at the beginning of each day or at some other period that's specified. And so we've tried to approach this in a method that the licensee can meet and also that will assure a safe use of the rubidium.

And our third part was as long as you have to directly infuse this into the patient, you're never going to be able to measure the activity as a unit before it's injected. And so we've said measuring the activity using the detector on the infusion cart and the printout value that the infusion cart gives you that is acceptable for the NRC to receive the enforcement discretion.

So I've just walked you through what we wrote in the Enforcement Guidance Memorandum. We sent a letter out to all the Agreement States to make them aware that we had the Enforcement Guidance Memorandum. We sent the Enforcement Guidance Memorandum to them. We gave them a link. We have just recently completed a RIS going out to our licensees, the MMLs and the Agreement States that make them aware that this Enforcement Guidance Memorandum is out there. We included it as an attachment and there's also a link to it so that

everybody knows it's there.

And you asked a question earlier about the Agreement State compatibility. The Agreement States do not have to use this Enforcement Guidance Memorandum. We think it's a good document. We think it's a reasonable approach to not having licensees in violation. So they may adopt it if they choose.

CHAIRMAN THOMADSEN: Any questions? Dr. Zanzonico?

MEMBER ZANZONICO: I have several questions. One is I think a number of sites that you use the rubidium generator don't actually have their own generator. They use a circulating generator because it's just not cost-effective for individual sites to buy it. And I believe it's the whole system that goes from site to another. So site A might use it on Monday, site 2 on Tuesday, et cetera.

So in that case, since the individual sites don't have the infusion pump or any of the components, whose responsibility is it then to demonstrate compliance with this definition?

DR. HOWE: Before the recall there were commercial pharmacies that were delivering generators and the infusion systems to different licensees on different days of the week. And the commercial

pharmacies indicated to their customers that they were not responsible for doing quality control tests. It was the medical use licensee.

Our understanding is that practice is no longer being followed, but that there is a mobile nuclear medicine process now where you have a mobile nuclear medicine licensee and that licensee takes the unit to a different medical facility. And that mobile nuclear medicine licensee is the licensee that's responsible for doing the quality control tests, because they are essentially delivering the whole thing and operating it at a different customer's site.

We've seen cases I believe out in California where they've got the big mobile van with the PET camera on it.

MEMBER ZANZONICO: So it sounds like it could be variable. In other words, if the provider of the system were to divest themselves of responsibility, then the authorized user would have to be responsible. Ideally though, the provider would take that responsibility. But someone has to be responsible.

DR. HOWE: If you have a traditional mobile nuclear medicine, you have to have an

authorized user on that mobile nuclear medicine license. That authorized user is responsible. And also the mobile nuclear medicine licensee is responsible. And they show up at a customer's site and they deliver the rubidium to them. But they are the ones responsible.

What we saw before the recall was the whole unit was delivered and the company said it's not us anymore. It's you. You've got to do everything.

MEMBER ZANZONICO: Okay. So if that's still the practice at some sites, that's still the responsibility of the AU?

DR. HOWE: It's not supposed to be the practice anymore.

MEMBER ZANZONICO: Okay.

DR. HOWE: The manufacturer is supposed to be very tightly controlling --

MEMBER ZANZONICO: Okay.

DR. HOWE: -- how its product is used, because they want to keep their product out there.

Orhan?

MEMBER SULEIMAN: This has been a real interesting case study and it's clearly not over, but the infusion system, I mean, is part and parcel with

the generator.

DR. HOWE: Yes.

MEMBER SULEIMAN: And I understand it belongs to the company. The company doesn't even give it to the sites.

DR. HOWE: That's correct.

MEMBER SULEIMAN: And I'm sure there could have been a technical solution worked out in terms of calibration, but I think what you're suggesting may in fact be a viable solution.

The question that keeps on rearing its head to me is we default to the vendor training. How do we know, how do you know, how does anybody know that the vendor training is consistent? At what point is it the trainer training somebody else and we start to get dilution of instruction? If the manufacturer does in fact initiate a training program to meet all these issues, hopefully it's spelled out. Do you pass on that? Do you say this is a qualified certified training program, or the manufacturer says this is our training program? When they've undergone this training, they get our John Hancock that we completed so many hours of training? How do we validate? How do we verify that the users have in fact been trained by the company?

DR. HOWE: NRC's policy is not to approve training programs. And so, we don't look at and evaluate the training, the manufacturer's training program. The manufacturer essentially documents that the topics are addressed and they provide written documentation that the individuals have had the training. And I guess what we do is, in our performance-based inspections, when we go to a facility, we ask the facility how they're doing things. Do they know what they're doing? We ask kind of leading questions to try to find out whether folks have absorbed what they were supposed to be absorbing from the training and they understand what it is that they're doing.

MEMBER SULEIMAN: As I recall, my memory's not perfect, but as I recall from what I heard during the entire recall was the company was saying we did the training, the site was saying we weren't trained properly and they were sort of pointing fingers at each other. And nowhere in there is there any sort of qualification that the training was conducted in the proper way. And again, from my understanding it was obvious that a lot of the sites didn't know what they were doing. But I'm not one to let the company off either, because I'm sure that

some of the accusations made against them had some validity as well.

DR. HOWE: I think what I've heard from the company is that they assumed they could go out and give training and everyone listening would absorb it and understand what was being said and would be able to go forth. And based on the FDA criteria that you gave that they had to monitor as things were coming, they began to realize that their users didn't necessarily understand. And so they had to go back out and give additional training.

And I think they've modified how they provide their training so that they have a better accountability of it, because they want to keep their product out there. And I think the recall kind of put the pressure. We want to keep it out there. We're going to go the extra mile to make sure it's there. That's the feeling that we've gotten. We've gotten the feeling that they had to go back and redesign things.

CHAIRMAN THOMADSEN: Dr. Langhorst?

MEMBER LANGHORST: I had a general question. And I appreciate all the work that went into this, because I think it is very valuable to the patients. I mean that should be the ultimate goal

for going to all these efforts.

But maybe this is a question more for Chris. How does NRC staff decide when to try to get enforcement relief like this, or not, depending on when issues are raised and problems are seen with how this is exactly meeting the regulations?

MR. EINBERG: Well, it's a collaborative effort, primarily within the medical team, and it's discussed within the medical team that meets weekly. And then in this particular instance, you know, the inability of the licensees to comply with the regulations, it could have had the negative impact of putting them out of business or not having access to this generator. So we felt that something needed to be done in this case. So, but it's a collaborative effort where we discussed things. And then if need be we'd talk to the Office of Enforcement to see what the options are for moving forward.

DR. HOWE: I think another consideration is, is it possible for a licensee to meet the regulations?

MEMBER LANGHORST: Yes.

DR. HOWE: And if most of the licensees can meet the regulations, then you probably don't go into enforcement.

MEMBER LANGHORST: Okay.

DR. HOWE: If you've got a case where none of the licensees can meet the regulation because of something unique here, then you've got to do something. And the interim enforcement is a temporary matter until we get the whole issue resolved, which may be years from now.

MEMBER LANGHORST: Yes.

DR. HOWE: So that's one of the big things. If it's 2 licensees out of 1,000 can't meet it, that's one thing.

MEMBER LANGHORST: Okay.

DR. HOWE: If it's 1,000 out of 1,000, that's something else. You kind of use the same rationale to use when you look at emerging technologies.

MEMBER LANGHORST: Yes.

DR. HOWE: Is there something unique here that you cannot meet the regulations? Is there something here that you've got to do in excess in order to be safe? So you use the same kind of thought process.

MEMBER LANGHORST: And I think Dr. Zelac might have said something along this line. Is this a challenging effort to go through and work it through

with the enforcement group, or do they understand the differences of medical use?

DR. HOWE: This one was fairly easy because we had a fairly clear message of what you couldn't meet and we came out and helped them determine what they could use to avoid violation citation.

MR. EINBERG: In the case of Ron's interim enforcement policy, that's a much more complicated topic, the one that we all struggled with. So the medical team did a lot of, you know, teaching and clarifying with the Office of Enforcement. But also, in that case that was a policy decision that was made by the Commission. So that required a SECY paper that went to the Commission. The Commission made the decision to issue this interim enforcement policy.

MEMBER LANGHORST: Well, I thank you all for all the efforts that these take, especially the complicated permanent brachytherapy one.

MEMBER ZANZONICO: One more question. In your slide 12 you indicated that all AUs as well as the radiation safety officers should receive training, but I'm thinking of sites like a private practice where the AU often is the RSO. So it's the

same individual. So how is that handled?

DR. HOWE: If the authorized user and the RSO are the same, then you're going to provide the training to that person.

MEMBER ZANZONICO: Okay.

DR. HOWE: You're going to focus on their AU issues and you're going to focus on their RSO issues.

MEMBER ZANZONICO: Right, I --

DR. HOWE: We have many licensees that are one individual.

MEMBER ZANZONICO: I didn't know if the intent of this was to have some redundancy of training, which it may be in part, but in that case, if you needed a second individual trained, named individual trained even in the instance where the AU and the RSO were the same person.

DR. HOWE: No, but we did find that in the clinics that had issues, they had radiation safety officers. They weren't the physicians. And so they needed to have the training also. So we wanted to make sure that we hit it from the physician side and the RSO side, if they were separate.

CHAIRMAN THOMADSEN: Mr. Mattmuller, did you have a question?

MEMBER MATTMULLER: Yes, a comment and a question.

CHAIRMAN THOMADSEN: All right.

MEMBER MATTMULLER: I know this is unique in that the actual dose to the patient is not measured first before it's given to the patient, but in PET we've done something very, very similar with a couple of radiopharmaceuticals that have very short half-lives, such as N-13 ammonia of 10 minutes or O-15 oxygen of 2 minutes. Not necessarily not measuring the dose, but in terms of radiopharmaceutical quality we would do a pre-production run and check the product for radiochemical purity and pyrogenicity and such, and do all that beforehand. But the actual run that we produce and then give directly to the patient, we don't have time to do that beforehand. So it's somewhat analogous to this in that we pre-check it to make sure it's working properly that morning and then subsequent doses are believed to be just meets in the criteria.

DR. HOWE: Yes, and I was going to say that we know you've got the PET oxygen and we've seen that at NIH where it's made in the basement and it's shot straight up a tube and through the pharmacy and

straight into the patient.

MEMBER MATTMULLER: Right.

DR. HOWE: So that is another use. Now, you're not going to be injecting oxygen, PET oxygen at a small clinic.

MEMBER MATTMULLER: True.

DR. HOWE: So most of those are big broads and big broads have more flexibility in trying to figure out how to meet intent of requirements.

MEMBER MATTMULLER: And then my question: In regards to the training, do you have plans to possibly make the training for -- or the training for an authorized user for this type of generator, would that be added to 35.290? Because it seems like we've got almost -- and I suppose this isn't unique -- here we're relying on training provided by a company versus if it's in 30.290 it's training as provided by a preceptor.

DR. HOWE: The interim enforcement guidance is a temporary solution. Well, it's a temporary Band-Aid. We haven't come up with the final solution on this. And I think it's clear that part of the final solution will be -- I don't want to say device-specific, but almost device-specific training, and we would have to be open to who

provides that training.

CHAIRMAN THOMADSEN: Dr. Suh?

MEMBER SUH: What kind of support is there to ensure that these enforcement guidelines, in terms of the written test procedures and training, is actually being done? Is there for like every 100 centers, I mean, like how many of them are actually being audited?

DR. HOWE: Well, in NRC space we inspect private practice licensees on a five-year basis. We inspect medical institutions, not broads, on a three-year basis. We inspect broad-scopes on a two-year basis. So our inspectors would be going out and looking at these as they go. There's not a lot of rubidium generators out there right now. I mean, there's less than 200. So, you know, it's not everywhere. And so we don't see it very often.

But we went in and inspected a rubidium generator about a week after the Enforcement Guidance Memorandum came out and the licensee was complying pretty well. They didn't understand what they were complying with, but as soon as they talked to the manufacturer, the manufacturer said, oh, yes, this is what you need and we can provide that to you. And we'd already provided the training, so the training

wasn't an issue. It was the documentation.

Have I answered your question?

MEMBER SUH: Yes.

MEMBER LANGHORST: I wanted to add onto that. I think that's an important reason why the RSO needs training or someone in the RSO office, because that's part of your responsibility to, you know, inspect your own operation and how it is in compliance with the regulations, or in this case this --

DR. HOWE: EGM?

MEMBER LANGHORST: Thank you. So and even if that person is the same, is the authorized user, too, as the RSO they have that responsibility of guess you'd say self-auditing, self-inspecting to make sure that they are in compliance and that they document that, compliance operator. So the licensee has some level of documenting that they are meeting this requirement.

CHAIRMAN THOMADSEN: Dr. Guiberteau?

VICE-CHAIR GUIBERTEAU: With respect to the 12-month frequency of really checking the physical aspects of, you know, the flow rates and the detector accuracy across different manufacturers, I mean how did you arrive at that number? Is it based

on just prior experience or is it --

DR. HOWE: In this particular case we only have one rubidium generator manufacturer and we know that they do go in every 12 months. And they send out a special team that goes out and looks at the infusion pumps, and they check them out every 12 months. And so we were able to piggyback with what they're doing.

VICE-CHAIR GUIBERTEAU: So I take it that they have found that they're consistent when they do this on a yearly basis?

DR. HOWE: Yes.

CHAIRMAN THOMADSEN: Mr. Mattmuller?

MEMBER MATTMULLER: Yes, just to address Dr. Guiberteau's concern. I mean, it's not quantitative, but on a qualitative basis when they do their first elution of the day, they're able to see the volume in the vial. So it's an eyeball test, but it's still a qualitative test that the pump is operating at the proper speed and such and they're getting the proper volume, or close to the proper volume on a daily basis. But also, again appreciate this guidance to potentially avoid any issues.

The only concern I have is that you have touched on compatibility and I never really

understand compatibility completely, but in regards to this type of document, do the typical categories fall into place and one is picked for it? And I happen to know there's an individual in the audience who might be able to comment on this, since she's back from Europe. If she would be willing to speak on this.

MS. GILLEY: Debbie Gilley, and I am not affiliated with an Agreement State anymore, so I'd probably be out of touch with what's going on in the last two years. But if you will restate your question, I will try to enlighten the Committee on those, what I might know.

MEMBER MATTMULLER: What level of compatibility would an enforcement guide of this nature have with an Agreement State?

MS. GILLEY: This would not be compatibility B. The Agreement States would not have to adopt the enforcement guide. This would either be a C or a D, and I would have to defer back to Donna-Beth if she knew which one that would be.

DR. HOWE: I'm not sure because it didn't come up. We knew that it wasn't a B. We knew that the Agreement States had flexibility in whether they wanted to use that Enforcement Guidance Memorandum or

not. And so it's not like rulemaking where you've got to identify a compatibility level for every action that you take.

MS. GILLEY: So you would have to take up whatever activity was being done by the individual Agreement State with that Agreement State.

DR. HOWE: Thank you.

CHAIRMAN THOMADSEN: Thank you. Any other -- yes, Dr. Van Decker?

MEMBER VAN DECKER: First, Dr. Howe, thank you for being consistent, and as usual providing what I consider an incredibly thoughtful and proactive presentation.

You know, the stakeholder provider community obviously also wants the product available as an option for good patient care, and so obviously, you know, we encourage and are happy with anything that improves the process for further patient care in the future.

You know, everything you laid out to me makes good general radiation safety sense, so I really like that. I mean, you know, certainly good process leads to good radioisotope clinical handling down the line, and you do what you can do to get there. I think that a lot of this has made a lot of

sense.

I did take the opportunity in the last couple of days to touch base with some of my colleagues around the nation who personally have been very involved in the service provisions. And in the words of one very smart one in the group that I've always respected greatly, he said he would consider this reasonable, customary and expected, which I thought was a good off-take of the usual CMS reasonable, customary and necessary --

(Laughter.)

MEMBER VAN DECKER: -- which you could look at as the same thing in my mind. But it's an okay thing.

I guess my only final comments on this in that regard then -- and so we appreciate it. I think that this is good and a good step in further process of creating, you know, more options and better care down the line.

I guess my quick questions are you're implicit in saying that the manufacturers kind of bought into this as far as --

DR. HOWE: Yes.

MEMBER VAN DECKER: Okay. I would reinforce Steve's comments about, quotes, "the

equivalent of compatibility B." I guess I'll be the final voice, a strong voice on that from the past '90s argument, but you know, you can't be providing services in 50 patchwork pieces in this nation to patients. You have to have some consistent way for people in training when they go from one state to another to be providing the same practice. So we have to have some way to make this within realms of reasonable, you know, consistency throughout.

My third comment would be obviously the annual scientific meeting of the American Society of Nuclear Cardiology, ASNC, is in three weeks in Chicago. So you may get some interaction from some people looking for whatever further information you can give at this point, RIS out or not, so that we can do some general education to the provider community. You know, part of all the job description of the stakeholders around the table is to bring back to your constituency stuff, as well as give input. And so, I know I can speak for my colleagues in saying we would like to do that and be piece of that.

And then the last comment I would make is just on the training piece. You know, obviously we've done manufacturer device training and radiation onc here for years and years and years, and obviously

the provider community wants to make sure that this goes well, too. And I'm sure we'll take an active interest in how this gets played out.

I would agree with your concept that this is really along the concept of device-specific training. While there is only one rubidium generator out there right now, we all know there are potential competitors and each of those devices, even though they would be rubidium, would be different in their delivery systems for proprietary methods. And so this is general 0.200 radiation safety considerations for general education of 0.290 people, but then you need some device-specific stuff in any of the realms for anything that comes up for the things we've seen. And I think that we would support that and try to be helpful in that in any way that could be possible.

So I thank you for your efforts in this.

CHAIRMAN THOMADSEN: Thank you for the comments.

Any other comments?

(No audible response.)

CHAIRMAN THOMADSEN: Thank you very much, Dr. Howe.

We have four minutes before the next presentation. I think we'll take that time for a

slight break. Maybe we can try to be back within 10 minutes and try to stick as closely to the schedule as we can with the consideration of biological necessities.

(Laughter.)

(Whereupon, at 3:22 p.m. off the record until 3:36 p.m.)

CHAIRMAN THOMADSEN: Dr. Welsh, will you please fill us in on the medical event reports for the fiscal year 2012?

MEMBER WELSH: Thank you, Dr. Thomadsen. So thank you to all the subcommittee members who participated in this annual exercise which sometimes can be quite tedious and arduous, but nonetheless we have completed this exercise.

I'm going to start with the list of events under the search that I employed, namely NMED Advanced Search, medical event details menu, therapeutic procedure. And when you do this way, you tally 69 events. And here they are. And right off the bat you can see some categories that are a bit unusual. Linear accelerator up at the top there. And then some nebulous ones. The NA/NR. And they continue to get a little bit confusing. And we see the last one, X-ray, which I was curious about

because what is that doing in this NMED database in the first place? So there are some of these categories that don't make a whole lot of sense. They're just kind of occupying some space, like specifically Linac, X-ray and NA, as quick examples.

Other things that we all observed during the event report tallying is that now Zevalin is in its own category, but Bexxar does not have its own category. There is another category, radiolabeled antibodies, which you would think should cover both, but does not. Another important point or observation was that some events from many years back will get logged into the period of your investigation so that during our 2012 event tallying we could see events that actually occurred, 2007, 2008, and finally got recorded into the system only in the past year.

Additionally, some events from the period in question may not be entered for many months. So if you think you've completed a 2012 event tally, you may find that other things can get added subsequently and your numbers are not going to be as accurate as you might think they would be. So the only way to truly conduct a search is to focus on what is reported during that fiscal year.

Additionally, since we all will be

discussing items based on how we divide topics according to 10 CFR 35, it would be nice if the database were so organized, but it is not. For example, gamma knife radiosurgery events can be problematic. Some are Part 660; others are Part 1000. The same holds true for manual brachytherapy. Many of these manual brachytherapy procedures are under 490; some are in 1000 in the form of Y-90 microspheres. So organizing things according to 10 C.F.R. 35 would be great, but it could be very challenging for those who operate the database because of how things move in and out.

So if we look at this slide that I borrowed from Dr. Howe's presentation in the spring meeting, we see that there are 11 listed under 35 Part 400, one brachy-mesh and 10 prostate events involving 22 patients. But when I did the search recently, what I initially was hoping was going to be restricted to 400 using the brachytherapy manual implant menu, I initially came up with 32.

So if Dr. Howe said that there were 11 and I said there were 32, why is there a discrepancy and what's the explanation? The simple explanation would be just to trust Dr. Howe's count rather than mine. But I did want to know exactly why I was

coming up with such a discrepancy and what can be gleaned from a detailed investigation of this.

So one of the observations that comes to the forefront immediately is that the NMED database is not in chronological order. For example, when I completed my search a month or so ago, event 130374 was the very last entry in the whole section on manual implant brachytherapy, yet it referred to an event that occurred in 2011 and therefore was to be included in our tally.

Similarly, the third-to-last event in the list was something that happened September 2012. Therefore, if I looked at what was apparently the 2012 year, finished all the 2011s, now I'm in the 2012s, and now I see everything after, it looks like it's 2013. And I don't look at the next pages and the next pages after that because apparently everything in 2012 that I'm interested is right here. I would get a wrong number because the things from 2012 can wind up way out of sequence sometimes. So this was an interesting and important observation. For an adequate search you have to look at all the pages.

Another thing that was interesting is that if you do the search, as I mentioned, advanced

search menu, medical event details, therapeutic procedures, you come up with 69 items, but not all of these are truly medical events. These are just events that are listed in NMED, and I'll talk more about that later on. Specifically, some of them can be retracted.

Additionally, some of them get added to the database well after your search has been done, and that can also lead to numbers that are discrepant with others who might be doing similar searches.

The database, as I said, is not organized along Part 35 lines. For instance, if you do a search under advanced search menu, medical event details, therapeutic procedure, brachytherapy manual implant, you'll come up with 32 items. But you have to keep in mind that this is going to include the Y-90 microspheres which are under Part 1000. You'll have to subtract those out in order to get what was truly Part 400.

So here's the bottom line tallies. In Dr. Howe's presentation we came up with a total of 52, I believe. And now it's up to 61. But it's important to keep in mind that that number there, the 61, is not all truly medical events. Some were retracted. Additionally, after Dr. Howe has

completed her search, things can get entered into the database and listed as 2012 events. Additionally, things can be out of sequence and easily missed depending on how you do the search.

The point of all of this is that this is clearly not a perfect system and these numbers here have to be taken with a grain of salt or an appropriate degree of skepticism because they are all subject to human error as well because it's a manual count. I don't know what you would call a medical practitioner who makes an error in counting events, but I don't know if that's a medical event or what, but it does explain why there's going to be a discrepancy in the numbers from one individual counter to another, and one individual count in the spring to a count in the fall.

So getting into the details, there were two medical events involving four patients involved in the Part 200 series. These were discussed earlier in the year and we've discussed them in depth elsewhere. As far as the part 35 events, there were two of them. One of them was particularly interesting and I'm going to ask Mr. Mattmuller to give us a little bit of detail on that later on, because there was an interesting explanation for what

happened in this particular event.

Focusing now on the Part 400 medical events, which can be found a variety of different ways, but the way I searched for them was under brachytherapy manual implant and then subtracting out the Y-90 microspheres. Twenty events were found. And I say here MEs, but I should point out that these are events listed in the database, not necessarily MEs as per the true definition.

Eighteen prostate permanent seed implants involving thirty-two patients. Some of them involved more than one patient. Those are listed here. The balance of them were one patient apiece. If we focus on these prostate implants, here's how they broke down. The majority were I-125, a couple palladium and cesium, and one was unspecified.

Three of them involved multiple patients, two of them with two patients each, one with thirteen patients. Twenty-three of the thirty-two total individual patient cases were under doses to the treatment site. So again, the majority of medical events in the prostate permanent implant arena were underdoses as we discussed with Dr. Zelac earlier today.

Of the underdoses where normal tissue was

not overdosed -- sorry about the typo there -- several of these patients subsequently had additional seeds placed or supplemental external beam radiation therapy as per the discretion of the treating clinician.

There were a couple of that were particularly interesting, if not truly enlightening. I can't say that any of these were able to aid in our true quest of identifying trends that can be averted, but nonetheless there are a few that are noteworthy. This particular event had all the seeds placed inferiorly to the prostate as determined on the day zero CT. This was human error because the penile bulb was mistaken for the prostate in the operating room. So the corrective action that the institution opted to take will be use fluoroscopy to verify the position of the needles in the operating room prior to implanting the seeds, and that should solve that problem.

Here are a couple of other events where the seeds were similarly placed inferior to the prostate. In one event the seeds were systematically misplaced about a centimeter inferior to the prostate. In the other event seeds were as far as 3.5 centimeters inferior to the prostate with only a

small fraction of the target getting the full prescription dose. Of note, I think both of these would qualify as medical events with the proposed definitions that we discussed an hour ago or so.

Here's another that was interesting. A survey of the packing material showed elevated readings that suggested one of the seeds might have leaked. So the patient underwent urine bioassays and thyroid counts and according to the report revealed I-125 uptake. I put in parentheses suggested simply because we don't know if that patient might have had some iodine uptake previously from another possible source, but it's extremely unlikely. There were some more doses calculated to the thyroid and the whole body that probably should not have happened. This was attributed to manufacturing error perhaps, damage in transit, damage on site at the hospital. The hospital elected to switch to a different seed manufacturer from that point on.

Here's another event wherein a patient passed 2 strands of the seeds, a total of 15 seeds. One was flushed down the toilet into the septic system. Another was brought into the hospital for proper disposal. The report mentions that the patient had a TURP, transurethral resection of

prostate, over 15 years ago, but we all know that sometimes seeds will be lost in such patients. But it's hard to predict exactly what will happen.

This might be an extreme example where 15 seeds were lost, but they were linked together in a strand. And sometimes this is going to happen, I think. I don't think that it would be appropriate to systematically say patients who have had TURP should not have this procedure. This is just a reality that goes along with seed implant in these patients.

In this particular example the wrong patient got the seeds and it was because there were back-to-back procedures on two consecutive days. The written directives were confused. The first patient got the proper treatment, but the next day the second patient received the same exact seed placement procedure as the first. In other words, his plan was the same as the patient from the day before. This resulted in a 27 percent underdose and an overdose to the urethra. Clinicians elected to place seeds to improve the irradiated coverage to the cold spots.

This one was also quite interesting in that it involved multiple patients. The Wisconsin Department of Health Services has been conducting an inspection of all cases since 2001. In this

particular event 13 patients were identified between 2005 and 2012. There was one overdose, seven underdoses. Two of those seven also had overdoses to normal tissue. And then five patients qualified based on normal tissue overdoses. The hospital had not reviewed cases against the medical event criteria and therefore it was categorized as human error. The corrective action was interesting, and that was that the authorized user will be placing all the needles from event discovery date onward, whereas in the past it was the urologist and the authorized user who were alternating the placement of the needs. Hopefully this will correct that problem.

MEMBER ZANZONICO: How common is that practice of a urologist placing implants?

MEMBER WELSH: I think it's quite common.

MEMBER ZANZONICO: Oh, it's common?

MEMBER WELSH: I think that I wouldn't be able to give you estimates, but I think that it is fairly common and depends on the institution. Probably the best solution is he or she who has the most experience in placing the needles be the one that does that. I do think that the actual deposition of the radioactive material after the needle has been placed probably should be the

authorized user, but I think the needle placement should be placed by that individual who has the most experience, and I think that varies.

In this particular event there were two patients who were underdosed in January and August of 2011. A review was subsequently performed and identified an additional 14 patients who might have gotten greater than 20 percent underdoses during the prior 3 years. The two events that were identified in question were attributed to prostate swelling between the implant and the day 15 scan. During the investigation all implant procedures were suspended and a policy and procedure revision was underway.

And this event concerned me because I wasn't sure what I was going to read afterwards and I feared that maybe that institution was going to shut down its program because of these alleged events. And that would be another example of a good therapy that is going by the wayside because of concern about events. Fortunately, it turns out that these alleged medical events, these two events reported in the NMED were determined to not be true medical events since the administered dose was actually not truly off by more than 20 percent.

Here we have these two events that were

not -- that event was not considered a true medical event. In addition to that event these two that I have on this slide here were both considered underdoses and were subsequently retracted when either subsequent post-implant dosimetry was done and found that the dose did not exceed 20 percent error or that in another example the event did not meet the Connecticut State activity based medical event criteria.

But I thought that it was interesting and instructive to note that three of the events in the system -- that if you were simply doing a count you would say, okay, there's these three medical events. But if you read the details, they're events that initially were thought to be medical events, but were subsequently retracted. And so you do have to pay attention to the detail when you're reading these things. You can't simply count them up and come up with a number.

This one was a particularly interesting case example involving an I-125 lung mesh implant. It was performed May 31st, 2012. Chest X-ray that was done a couple of months later in July 2012 showed that instead of 50 implanted seeds only 38 were visible on that chest X-ray. So they did a chest X-

ray again two days later and now instead of 38 there were only 35, and 3 of them were in the abdomen. Chest X-ray about a week later showed the number down to 25 in the lung and 9 in the abdomen. The next day after that only 13 remained in the lung and there were 17 in the abdomen. Going into August, August 4th, only six left in the lung; eight were in the abdomen. Finally on August 9th, 2012 there was one remaining in the lung and zero in the abdomen.

So the conclusion was that the patient must have been coughing up loose seeds periodically and swallowing them and they're winding up in the abdomen. So this was a very unusual example of a device failure and it was reported to the manufacturer as well as the FDA.

Among the non-prostate manual implant brachytherapies, there was one cesium-137 temporary implant using Fletcher-Suit ovoids. Thirty gray was prescribed to each ovary region. At the completion of the procedure a source was found to be missing on the left side. It was found on the IV monitor stand. It was determined that only one of the sources was correctly placed. The other one fell onto the bed and the nurse found it 12 hours later and by hand placed it on the IV stand. The patient subsequently

got treated to that left side. It was estimated that the nurse might have sustained an extremity dose of 13 rem and it was attributed to human error during the procedure and inadequate training for nursing staff. Going to Part 600, all 35.600 in 2012 totaled 17 events. Majority of these were HDR, 16 of them, with one gamma knife procedure. And the asterisk there is because not all gamma knife is in Part 600.

Here's how they broke down specifically, but as with 2011, there were no systematic errors or frequent problems. There were some length problems. Two of them where the catheter was not inserted in tandem. One endobronchial tube was used instead of an adapter. One the wrong distance used. Another not stated. Four treatment planning errors. There was one wire drift. One marker in an NG tube, nasal-gastric tube, that was mistaken for the source location. Another because of catheter slippage. One the wrong patient's plan was used and two were considered hardware or software failures. In two cases it was noted that QA was not performed and perhaps imaging before the treatment with the actual connectors or the transfer tubes could have uncovered several of these problems. As far as the gamma knife

event, it was attributed to mechanical failure, specifically the latch fastener failed.

Moving onto the 1000s, there were more in 2012 than there were in 2011. And as we discussed a few months back during our Y-90 microsphere subcommittee evaluation, nothing very specific stands out as a systematic error. But there were 11 using the glass TheraSpheres and 8 using the resin SIR-Spheres. There was on Perfexion medical event, Perfexion gamma knife medical event.

As far as the eight SIR-Spheres go, here's how the events broke down: Two involve spheres that were stuck to the septum. We've seen that plenty of times before. We've seen this wrong patient's dose medical human error-type of thing. One was attributed to retrograde flow. One was due to settling because of slow delivery. One was another human error where the wrong artery was addressed. Another one was where the wrong dose was drawn and one had no information. As far as the TheraSphere glass microspheres go, six were considered from slow flow, these various reasons here. One was a needle-in-the-vial problem. One was another classic human error: wrong patient got the dose. Another one was stasis, which one might argue

should not have been listed as a medical event. And there were two without detailed information.

As far as the other in Part 1000 with the Perfexion gamma knife, this was a computer failure after the frame was reapplied. It was listed as human error, but it's an event nevertheless.

So what were some of the general observations regarding the Part 600 and Part 1000? Well, we don't want to bash the NMED database, but it does seem like there's a paucity of useful information with sufficient detail that one can rely on to draw detailed conclusions.

I was able to use the IMV data from 2010 to put things in perspective here. We have said during the Subcommittee discussions in the past that these numbers are kind of useless if you don't have the denominators. So NRC has generously purchased these denominators here. You can see that of 924,000 radiation therapy courses 8.5 percent are not external beam radiation therapy.

And of that here's how they breakdown and here's the number of sites that report that they performed these procedures. You see radionuclide therapy is quite a small component right there at the bottom, but it does not include nuclear medicine

facilities that don't do other forms of radiation therapy.

So of 675 radiotherapy sites reporting treatment on an estimated 28,000 prostate cancer patients with permanent implants here's how they broke down: Seventy percent were I-125, twenty-nine percent were palladium and one percent used cesium. I was encouraged to see that number of 28,205 because I was fearful that we might continue to see that downward progression in the number of permanent implant brachytherapy procedures since the VA events from a number of years back, but it seems like it might have stabilized. And again, this is 2010 data.

Here's a pie chart showing how permanent seed implants fit into the rest of brachytherapy. And some of the questions and comments that were brought up during Subcommittee discussions include what kind of quality control is being done on the database? How is this event information being used by the agreement states and others? Are there other event reporting systems that are in use presently or being developed? And importantly, how can such a database be used to support licensee safety culture development to improve patient care? And an important point that is worthy of further discussion

is is the information that comes in from the states all voluntary? And if so, does that mean that the NMED database could be quite incomplete?

The numbers are probably too small to draw any kind of meaningful conclusions. We did not see any kind of very obvious trends. But the one thing that one might be able to say based on this year's analysis and prior years and the years before that we see medical events that are still due to failure to perform some basic QA, lack of verification or sloppy verification, irrespective of the verification method that should have been used. These ideas and habits should be ingrained in the community, but there perhaps will always be some very small human error that is going to cause the number here to not ever reach zero.

One other question came up about the agreement state consistency. How does the NRC assure that the agreement states are consistent wit the NRC with regard to their medical events and the reporting? But I think that looking at the denominators once again on these slides here were encouraging in that the medical events in prostate brachytherapy, as an example, are well under 1 percent, maybe under 0.1 percent. So while we go

through this exercise annually and try to identify problems that can be fixed, the fact is that even if all the events that I counted through the NMED were true medical events, the proportion of medical events compared to the total prostate brachytherapy is quite minuscule and it's a safe and effective treatment.

So I'm going to ask Mr. Mattmuller to point out the thing that he wanted to raise regarding the diagnostic event.

MEMBER MATTMULLER: You want me to go for 5 minutes or 50 minutes?

MEMBER WELSH: I'm going to leave that to our Chair.

MEMBER MATTMULLER: Okay. I'll try to be brief.

This goes back to 35.300 and it was titled, "Written Directives in the Electronic Medical Record World." And looking at this one, it sort of took me down a pathway of looking at how -- which you may not all be aware of the immense sums of money that hospitals have spent on electronic medical records, or electronic health records, depending on the abbreviation of choice -- that may or may not affect us in nuclear medicine and radiation oncology.

The first big system is akin to Windows. It's sort of all-encompassing and it's in the background. And then this system affects everybody. But then each individual department has their own module of software that's specific for their type of operation. For example, there's a module for the inpatient pharmacy and there's a separate module for the outpatient pharmacy. And likewise, there's a module for radiology that includes nuclear medicine and radiation oncology. But despite the immense expense of these modules and complexity, they still leave a lot to be desired. It's like we're in Windows 1.1, honestly, for some of these records systems. It's very difficult and expensive to do anything different from what they hand you.

One of our frustrations is that we also have a nuclear medicine information system in our hot lab for preparing, keeping track of all of our NRC records. It doesn't talk very well to this module. It can for a large of sum of money, but we haven't found that large sum of money yet. So it sounds great, but there's still some problems with these electronic records.

And as we all know, there are issues with NMED in trying to get details. And I don't know

exactly that this was done to an electronic health record issue, but it seems like the way it's structured that -- because it's actually a pathway we considered going through when our hospital took the plunge into electronic medical records. For example, all of our diagnostic procedures do go through central scheduling, but for our therapeutic procedures we still schedule those ourselves within our own department because of the complexity of them. So it sounds like they tried to do it all and ran into a snag or a snafu; regulatory terms, and have since backed away from it.

So I did do a quick non-scientific survey with a lot of my nuclear pharmacy friends around the country, and pretty much everyone's in the same situation we're at, at Kettering Medical Center in that we have a paper-written directive that stays paper the whole time. I mean, it's signed off physically by the physician and it goes into a file.

Now some sites are taking an additional step, and we're considering this at our location, to where you actually scan that written directive into the electronic medical record as a PDF file. I did find one site in Iowa where they do truly have an

electronic written directive from start to finish. They never had a paper copy. Well, I take that back. They do it all electronic and then they print out a paper copy just so they have extra backup.

So in discussing this with Dr. Welsh, this actually might be a topic for another presentation, and maybe this could be baptism for our new health care administrator, that they could explain the complexities of the new electronic medical records and the different modules throughout a hospital and how they could potentially affect us.

CHAIRMAN THOMADSEN: So noted. Put that onto the schedule.

MR. EINBERG: Should that be one of the interview questions?

CHAIRMAN THOMADSEN: That's right.

(Laughter.)

CHAIRMAN THOMADSEN: Yes. Before or after they accept.

(Laughter.)

CHAIRMAN THOMADSEN: Mr. Fuller has something to do with it.

There are no other comments if you want to make a comment right now.

MR. EINBERG: I'd like to comment on the

database, if possible.

CHAIRMAN THOMADSEN: Please.

MR. EINBERG: And thank you, Dr. Welsh. Excellent presentation and very thorough and you certainly poked the system to try to, you know, use it. And it's a complex system with many fields and especially in advanced search. I came to quite a bit of appreciation for that last week while I was out in Idaho National Labs who runs the database for us. And we had a simple query that we were trying to run, however, there's a lot of nuances to this database and an experienced user can pull out all the information that you really need on this. And Idaho National Labs has been doing this for the past 18 years. Something that we've done with a simple search, they were able to point out to us what we were doing incorrectly.

So what I'd like to offer you and the Medical Event Subcommittee is, you know, we have staff resources who can help query the database or at least reach out to Idaho National Labs to make sure that there is -- you're doing the appropriate search.

And at this point I'd like to introduce Robert Sun, who's the NMED project manager. And so,

you know, he went through your presentation also and did a very thorough analysis of all the comments and prepared some responses for each one of the comments to address why you're getting this information and so forth. And we can provide that to you or he's available right now to answer any questions you may have.

But the last thought I'd like to leave you with, you were questioning whether quality assurance was performed on this database, and there are two additional levels of quality assurance that goes into this. So it has quite an extensive quality assurance process at the Idaho National Labs. And the contractor goes out and reaches out to the agreement states as well to make sure that the data is complete. And so as you indicated, some of the data is new data that is maybe many years old. That's a function of them reaching out and also a function of the inspect process where the NRC goes out to the agreement states and does a periodic review of their programs. And I believe it's on a five-year schedule. And, you know, the agreement states, just like anybody before they're audited, they're always trying to get their records in order. And so there is oftentimes a large influx of new

data to make sure that their records are in order. So that's part of the reason that there is new data that comes in.

But that's our oversight process of the agreement states to make sure that they are reporting the appropriate information into the database.

CHAIRMAN THOMADSEN: Dr. Langhorst?

MEMBER LANGHORST: I think with the plan of potentially making NMED open to licensees and so on, it will be just another look at the database and there will be some problems that will be identified. But that's the nature of the database. I mean and when you look at it in a different way or you sort in a different way, you learn a lot more about your database, about what problems might have been identified, but then it just makes your database that much better.

And so I won't be surprised if that does come to pass and you find issues, even historical ones that maybe weren't right. Don't be discouraged.

(Laughter.)

MR. EINBERG: Absolutely. And the contractor at Idaho National Labs was grateful that we provided this feedback to them. So this will be useful feedback, you know, for them to improve their

database as well.

CHAIRMAN THOMADSEN: Dr. Suleiman?

MEMBER SULEIMAN: I think one thing that came up during our deliberations, and I want to sort of reemphasize for the record, these are just very low numbers. I mean when you realize that there are 17 or 18 million nuclear medicine procedures done annually -- and, you know, the others are obviously smaller, but you're not getting any sort of critical mass here for any of these.

I mean and they're anecdotal and we can learn from -- you know, I think probably the most important -- the biggest value you get out of this is looking at them on an individual basis and see if there are lessons learned here. But in terms of any kind of a trend -- and I think the seeds maybe were high only because of the VA incident of a few years ago. So that just sort of raises awareness. I mean that's a well-known fact. When there's publicity, you see a spike in certain types of procedures.

So these are interesting, but I don't see any upsetting kind of trend here right now, except for -- again, I think the feeling was that there just seems -- if you want to say what cuts across all of them, this lack of attention to quality control, this

failure to pay attention to some of the things that are either beneath us to do on a regular routine basis, the things that are boring. But that's where I think these sites get into trouble.

MEMBER WELSH: I'd like to follow up on what Dr. Suleiman just said with this slide here that is very valuable, and I again appreciate getting this IMV data, albeit 2010 information. But if there were 924,000 radiotherapy courses, and at the bottom you see 8.5 percent were brachytherapy radionuclide, somewhere around 75,000-80,000 cases per year.

Therefore, whether my number is correct or Dr. Howe's number from the spring is truly the correct one, we're still talking about around 0.1 percent, which indicates that we're not going to be identifying real trends, but we might be able to say that this is a relatively low event procedure. All of these are.

CHAIRMAN THOMADSEN: Dr. Guiberteau?

VICE-CHAIR GUIBERTEAU: Could you elaborate on the Part 300 medical events?

MEMBER WELSH: Oh, Part 30 were the ones that Mr. Mattmuller talked about, particularly the --

VICE-CHAIR GUIBERTEAU: You know, a little bit more information, just out of curiosity.

MEMBER WELSH: Sure. I think one of them was the admission order that was mistaken for an written directive. And another one was -- Steven?

MEMBER MATTMULLER: The first one, this one, 120548, that was a confusion of admission orders, lack of written directive, going through the central scheduling system, where 163 millicuries of iodine-131 were administered when they only wanted 100 millicuries to be administered. So it was a big overdose.

The second incident was a planned dose of 100 millicuries of iodine-131 and it was supplied in two 50-millicurie capsules. One of the capsules stuck to the plastic container, and so the patient only got one of the capsules.

Which, actually I forgot, that raises a question for staff. You guys inspect for DOT regs, right, at licensees? It seems to me that that site -- well, actually it's not clear from the NMED report that they didn't follow proper procedures for preparing that package properly to be sent back to the radiopharmacy, because if it had, they would have noticed there was 50 millicuries of iodine in here, because that would be detectable in today's packages. So it seems like there's another oops in that report

that didn't really get reported, or at least it's not described in detail in the report. But that was the second incident.

VICE-CHAIR GUIBERTEAU: So both of the events related to radioiodine therapy, is that correct?

MEMBER MATTMULLER: Yes.

VICE-CHAIR GUIBERTEAU: Okay. Thank you.

CHAIRMAN THOMADSEN: Dr. Suh?

MEMBER SUH: I mean obviously it's been shown the instance of these events is very small. You're looking at less than 0.1 percent. But if someone wanted to learn -- like you mentioned lessons learned from these various events, these 62 events, or whatever number you want to use. Is there a mechanism that someone could actually learn from it? I just want to get an idea of what type of events occurred for prostate implant, or what kind of events occurred for TheraSphere. I mean is there a way to manufacture and we can get easy access to this?

MEMBER WELSH: Well, if you mean somebody -- lay public? Some member of the lay public wanted to --

MEMBER SUH: Just like a physician. Let's say I'm someone in training and I may go out in

the real world. You know, an authorized user. I just want to get a sense of --

MEMBER WELSH: Well, I think that unless you have access to the NMED database yourself, you rely on the reports that we generate twice a year, one by Dr. Howe and the other one by myself. And then you could comb through those. And I know individuals have contacted me and said is there anything that you can share about this type of an event or that type of an event? We're wondering if we should introduce it at our hospital, or etcetera.

So I think that that is one mechanism wherein a physician can get more information, because our reports are made available to the public on the Web site.

MR. EINBERG: In addition, there's the NMED Annual Report as well. And so that's a compilation of all the different types of events out there. And there's descriptions of the events of interest. So that's a good resource as well.

But unless you have access to the database as a, you know, ACMUI member or an Agreement State or NRC employee, you really don't have access as a member of the public to that information, you

know, to do your own kind of queries.

MEMBER SUH: It's not so much a query. Just in terms of trying to educate the next generation of, you know, physician users. I think if you were to -- and my suspicion at least is that if you were to hold training programs, particularly in radiation oncology, you know, what kind of events are occurring, they probably don't have a good sense of that.

MEMBER WELSH: Well, I think as an example of how the information could be used by a physician or for educational purposes there was an abstract presented at last year's ASTRO meeting based on the annual exercise that is done here. And the point of the abstract was that a number of prostate medical events were evaluated and subsequently found to be not medical events when a repeat CT scan was done and the volume was different on that repeat scan and the dose was not the underdose to the prostate that it was initially believed it was.

And the point of that was that the medical event definition should not be good on Monday, but not on Tuesday. And therefore, the medical event definition deserved revision. So that would be an example of information or scientific

publications or presentations that were based on material that was discussed here.

MR. EINBERG: If I may, additionally we ask the contractor once a year to do a special trending study or a special analysis study. And if there's something of interest, you know, if there is, you know, for instance an increase of -- outside of a medical area, an increase of radiography events, overexposures, then we may ask to do a special study on that.

I believe the VA was the source of a special study. And this gets fed into our Agency Action Review Meeting. And so if there is a, you know, special study that the Committee here would like, then we can get our contractor to, you know, focus on something as well.

CHAIRMAN THOMADSEN: And we have a comment from the public.

MS. FAIROBENT: Two things. Lynne Fairobent with AAPM. Dr. Welsh, on the IMV data did you also or did NRC also purchase nuclear medicine data so that we might know the denominators for microspheres, or did they only purchase the therapy seeds?

MEMBER WELSH: The information that I saw

was on external -- all radiotherapy courses and it included these here.

MS. FAIROBENT: Okay.

MEMBER WELSH: And this was the information that I had at my disposal.

CHAIRMAN THOMADSEN: The answer is from Ms. Cockerham.

MS. COCKERHAM: And Sophie can confirm this. It depends on if the report is available or not. I don't know exactly what we bought. I know also that these reports range in the thousands of dollars. And so typically we buy excerpts of the report. So sometimes they're right, sometimes they're not. It also depends on budgeting. And I think we had to pick and choose which reports we could get at the particular time based on the available budget.

MS. FAIROBENT: Yes.

MS. COCKERHAM: So I don't know exactly yes or no for nuclear medicine, but I know there are multiple reports that we need to put all of this together.

MS. FAIROBENT: Yes, I was really curious on the denominators for the microspheres.

MS. COCKERHAM: And interesting thing

about that is we know the denominators for the microspheres from another source, and they don't necessarily match up exactly here. And I don't believe that they're -- you're not able to separate them out in this group, are you?

CHAIRMAN THOMADSEN: I think the answer is no you can't. And because they're done in different facilities by different people they sort of wash down the cracks between the reports.

MS. COCKERHAM: When I was looking -- we did the actual Y-90 event analysis. I peeked -- we didn't have this 2010. I had the 2007 version that we used for the previous analysis for the Subcommittee. And when I looked at it, I couldn't really get the numbers out of there. And I knew what the numbers were. So it was a matter of are they in here? Can I find them? It wasn't easy to extract.

MS. FAIROBENT: Thanks, Ashley. If the Committee is going to look at electronic records, AAPM -- as part of their training for the Conference of Radiation Control Program Director's Meeting in 2010, we did include electronic records, at least as it applies potentially in brachytherapy. So we'd be happy to update that if you wanted us to, also, if you're doing that topic.

CHAIRMAN THOMADSEN: Thank you. Dr. Langhorst?

MEMBER LANGHORST: I just wanted to remind people because this confused me no end as I was a newbie on the Committee, but NMED stands for Nuclear Material Events Database. And it's not just medical. Even though it sounds like it is, it isn't. So there's a lot of sorting to do to just get to the medical, the events that deal with medical use.

CHAIRMAN THOMADSEN: Dr. Welsh?

MEMBER WELSH: And to that point, when you're doing a search, as Dr. Thomadsen and I discussed through email, there are several ways to get to the same end point. I think, Bruce, you used a method that was a different approach than the one I did where I went to advanced search, medical event details menu, therapeutic procedure. I think you did advance search, general event info, event type medical and then event date and had fewer challenges with things being out of sequence than I did. But I guess the point is that there may be many ways of skinning the cat, but there's a lot of cats in there, too.

(Laughter.)

CHAIRMAN THOMADSEN: Mr. Einberg, did you

have another --

MR. EINBERG: Yes, Sophie pointed out, to get back to Dr. Suh's point as far as the public availability of some of this information -- she reminded me that we do have an event notification reporting system on our public Web site. Now [inaudible] that, but, you know, all the events coming in. We post them on the public Web site. They're held for five days before being publicly released. But that is a source of the event information as well.

CHAIRMAN THOMADSEN: Thank you. Any other comments?

(No audible response.)

CHAIRMAN THOMADSEN: Hearing none, today's session is done and we'll meet here again tomorrow at 8:30 in the morning.

(Whereupon, the meeting was adjourned at 4:34 p.m. to reconvene at 8:30 the next day.)