Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Advisory Committee on the Medical Uses of Isotopes: Open Session

Docket Number: (n/a)

Location: Rockville, Maryland

Date: Monday, April 16, 2012

Work Order No.: NRC-1551 Pages 1-139

NEAL R. GROSS AND CO., INC.
Court Reporters and Transcribers
1323 Rhode Island Avenue, N.W.
Washington, D.C. 20005
(202) 234-4433

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

+ + + + +

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

+ + + + +

MEETING

+ + + + +

OPEN SESSION

+ + + + +

MONDAY,

APRIL 16, 2012

The meeting was convened in Room T2-B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 10:45 a.m., Bruce Thomadsen, Ph.D., ACMUI Vice Chairman, presiding.

MEMBERS PRESENT:

BRUCE THOMADSEN, Ph.D., Acting Chair

DARICE BAILEY, Agreement State Representative

MILTON GUIBERTEAU, M.D., Diagnostic Radiologist

SUSAN LANGHORST, Ph.D., Radiation Safety Officer

STEVE MATTMULLER, Nuclear Pharmacist

CHRISTOPHER PALESTRO, M.D., Nuclear Medicine Physician

JOHN SUH, M.D., Radiation Oncologist

ORHAN SULEIMAN, Ph.D., FDA Representative

MEMBERS PRESENT (Continued):

WILLIAM VAN DECKER, M.D., Nuclear Cardiologist

LAURA M. WEIL, Patients' Rights Advocate

JAMES WELSH, M.D., Radiation Oncologist

PAT ZANZONICO, Ph.D., Nuclear Medicine Physicist

NRC STAFF PRESENT:

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

CHRIS EINBERG, Designated Federal Officer

ASHLEY COCKERHAM, Alternate Designated Federal Officer

MICHAEL FULLER, Alternate Designated Federal Officer

SOPHIE HOLIDAY, Alternate ACMUI Coordinator

REGINALD AUGUSTUS, FSME/DWMEP/DURLD/SP

NEELAM BHALLA, FSME/DILR/RB-B

SUSAN CHIDAKEL, OGC/GCLR/RMR

JACKIE COOK (via telephone), RIV/DNMS/NMSB-B

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

SANDRA GABRIEL, RI/DNMS/MB

LATISCHA HANSON (via telephone), RIV/DNMS/NMSB-A

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

HARRIET KARAGIANNIS, RES/DE/RGDB

ED LOHR, FSME/DILR/RB-B

NRC STAFF PRESENT (Continued):

AARON McCRAW (via webcast), RIII/DNMS/MIB

PATRICIA PELKE (via webcast), RIII/DNMS/MLB

GRETCHEN RIVERA-CAPELLA, FSME/DMSSA/LISD/RMSB

SHIRLEY XU, FSME/DMSSA/LB

MEMBERS OF THE PUBLIC PRESENT:

DARRELL BROWN, Fox Chase Cancer Center

KEITH BROWN, University of Pennsylvania

PETER CRANE (via telephone), *No Affiliation*

ROBERT DANSEREAU, NYS Dept. of Health

MOHAN DOSS, Fox Chase Cancer Center

BRYAN EDWARDS, Fox Chase Cancer Center

LYNNE FAIROBENT, AAPM

TRACI HOLLINGSHEAD, Avera McKennan

DEEPIKA JALOTA, Bayer HealthCare Pharm.

RALPH LIETO, St. Joseph Mercy Hospital

GARY LUNGER (via webcast)

ANDREW McKINLEY, ASNC

JANETTE MERRILL, SNM

MARY E. MOORE, Philadelphia VA Medical Ctr.

DONNA MOSLEY, Fox Chase Cancer Center

MICHAEL PETERS, ACR

SOBHA PHILLIPS, Fox Chase Cancer Center

KATHRYN PRYOR, Health Physics Society

MEMBERS OF THE PUBLIC PRESENT (CONTINUED) :

JOE RODGERS, Theragenics

GLORIA ROMANELLI, ACR

KAREN SHEEHAN, Fox Chase Cancer Center

MICHAEL SHEETZ, University of Pittsburgh

MICHAEL N. STEPHENS, Florida Dept. of Health

CINDY TOMLINSON, ASTRO

RICHARD VETTER, Health Physics Society

GARY E. WILLIAMS, VA NHPP

DAVID WILLIAMSON, University of Pennsylvania

TABLE OF CONTENTS

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

(10:50 a.m.)

ACTING CHAIR THOMADSEN: Welcome to the spring ACMUI meeting. I want to thank you all for joining us. Dr. Malmud cannot be with us for medical reasons, and we send him all of our best for a speedy recovery.

And to open the program, Mr. Einberg.

MR. EINBERG: Okay. Thank you, Dr. Thomadsen. I'm not sure if we can turn up the microphone for Dr. Thomadsen, or if you could speak up, but we are getting indications from the back that you need to talk a little louder.

Good morning. I'm going to open the meeting. I'm the Designated Federal Officer for this meeting. I am pleased to welcome you to this public meeting of the Advisory Committee on the Medical Uses of Isotopes.

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

Present today as the Alternate Designated Federal Officers are Mike Fuller, who is the team leader for the Medical Radiation Safety Team, and

Ashley Cockerham, who is the coordinator for this meeting.

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 March 13, 2012, edition of the Federal Register, Volume 77, page 14837.

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

The NRC solicits the views of the Committee and values their opinions. I request that, whenever possible, we try to reach a consensus on the procedural issues that we will discuss today. But 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 who are participating today. As Dr. Thomadsen mentioned, Dr. Leon Malmud,

who is the Chairman of this Committee, is not in attendance. And I will go through the roll call right now. Dr. Bruce Thomadsen, who is the Acting Chairman for this meeting today.

ACTING CHAIR THOMADSEN: Present.

MR. EINBERG: Ms. Darice Bailey, state government representative.

MEMBER BAILEY: Present.

MR. EINBERG: Dr. Mickey Guiberteau, diagnostic radiologist.

MEMBER 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.

(No response.)

He is here today. I note that he is here. He stepped out of the room.

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: Okay. With that, we do have a quorum. And so we have at least seven members, and we can go ahead and participate -- proceed.

I now ask that the NRC staff members who are present identify themselves. I will start with the individuals in the room.

MS. HENDERSON: Pam Henderson, Acting Deputy Director.

MR. EINBERG: Thank you.

MR. FULLER: Mike Fuller, team leader, Medical Radiation Safety Team.

MR. EINBERG: Okay. I see that Dr. Sandy Gabriel is in the audience also from Region I.

MS. RIVERA-CAPELLA: Gretchen Rivera-Capella from the Medical Radiation Safety Team, NRC.

MR. EINBERG: Thank you.

MS. HOLIDAY: Sophie Holiday, also with the Medical Radiation Safety Team, NRC.

MS. COCKERHAM: Ashley Cockerham with the Medical Radiation Safety Team, NRC.

MR. EINBERG: Okay. Thank you. Are there anybody from the regions on the phone?

MS. COOK: Jackie Cook, Region IV.

MR. EINBERG: Thank you.

MS. HANSON: Latischa Hanson, Region IV, DNMS.

MR. EINBERG: Thank you. Anybody else from the regions?

(No response.)

Anybody I missed on the phone or --

(No response.)

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 that is available, and that phone number is 888-566-9152. The passcode to

access the bridge line is 23793-pound. Once again, the number is 888-566-9152. The passcode is 23793-pound.

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

At this point, I would like to turn the meeting over to Ms. Pam Henderson, who has some opening remarks she would like to make. And Ms. Henderson is the Acting Deputy Division Director for the Division of Materials Safety and State Agreements.

MS. HENDERSON: Good morning, and welcome to the spring ACMUI meeting. Brian McDermott, the Director, is representing NRC at the Organization of Agreement States Board of Directors meeting in Wisconsin, and, therefore, he is unable to be here.

In Dr. Malmud's absence, the current ACMUI Vice Chairman, Dr. Thomadsen, will act as the Chair. Thank you, Dr. Thomadsen, for acting in this capacity.

We would like to extend a warm welcome to Ms. Darice Bailey. She was appointed as the new ACMUI Agreement States representative on March 26, 2012. Ms. Bailey has been interacting with the ACMUI members and staff over email and phone for the past several

weeks, and we look forward to working with her over the course of the next four years.

We are happy to announce that Mr. Steve Mattmuller has been reappointed to serve a second term on the ACMUI. We appreciate Mr. Mattmuller's willingness to serve and for his valuable contributions to the Committee over the past four years.

On April 3rd, the Organization of Agreement States and the Conference of Radiation Control Program Directors met with the Commission to discuss medical event definitions for permanent implant brachytherapy, the expanded, increased control requirements for 10 CFR Part 37, and various other topics that impact our co-regulators in the states.

On April 24th -- next week -- NRC staff and ACMUI members and various medical stakeholders will be meeting with the Commission to discuss medical event definitions for permanent implant brachytherapy. The meeting will provide an opportunity for the Commission to receive important feedback from all interested parties before voting on the paper that is before them at this time. Dr. Welsh and Ms. Weil will be representing the ACMUI at that meeting.

On March 16th, the Commission approved the

Part 37 final rule with minor changes. Publication is expected this summer. The effective date of this new regulation will be one year after the publication date, and that is when NRC licensees will need to meet the new Part 37 requirements.

Agreement States will have three years from the date of publication to adopt compatible regulations.

During the meeting today and tomorrow, we will be covering a range of topics, including electronic signatures, patient advocacy, patient release, radium-223 chloride, medical event definitions for permanent implant brachytherapy, strontium/rubidium generators. We look forward to hearing the Committee's views on these important issues.

And with that, I will hand it back to Dr. Thomadsen.

ACTING CHAIR THOMADSEN: Thank you very much. And are there any questions from the Committee?

(No response.)

In that case, we will move on to the next presentation by Ms. Cockerham on Old Business. And that is under Tab Number 3 in your book.

MS. COCKERHAM: Good morning. For Tab

Number 3, I have new, updated handouts for you. So I'm going to pass these around. So you can pull out everything that is in your binder behind Tab 3.

And while those are going around, I will just start by saying I know a lot of these recommendations are from 2007 and '08. They seem very old and they seem to still be lingering around, but the good news is that almost all of them are included in either the permanent implant brachytherapy, the medical event definition, rulemaking that is currently undergoing, and also there is a Part 35 expanded rulemaking that is ongoing. So we are taking action on many of these items.

So for these old lists, I am actually going to go through them very quickly. I am not going to read the recommendations in detail. I can tell you for Items 2, 3, 6, 7, 8, 10, 25, all of those items are currently included in the Part 35 expanded rulemaking.

And then, when we get to Item 30, this is a recommendation for something that is in 10 CFR 35.1000. So the things that are 1000 uses, I believe the Elekta Perfexion, there is also a few items on here, if you look at Items 34 and 35, that deal with ophthalmic treatments, NeoVista, all of these things

that are Part 1000 uses are not being moved into the regulations at this time. That's why they say "open" and "delayed."

So for -- we stopped at Item 30, so for 31 I said -- 31 and 32 are both included in the Part 35 expanded rulemaking. And then for Items 34 and 35, that deals with the ophthalmic devices, and I mentioned that those will be considered for a future rulemaking, but not with the current expanded Part 35 or the current medical event definitions for permanent implant brachytherapy rulemakings.

For Items 36, 37, and that's it for that chart, those are both also included in the Part 35 expanded rulemaking.

So if we move on to 2008, Item 2 is also included in the Part 35 expanded rulemaking. And Number 5 is, as I said before, it's about Elekta Perfexion. It is not included in the current rulemakings, but it will be considered for a future rulemaking.

For Item Number 9, this deals with the abnormal occurrence criteria. And this version of the abnormal occurrence criteria was discussed during the ACMUI teleconference on December 15, 2011. The ACMUI reaffirmed this recommendation with the addition of

the letter S to physicians, and this recommendation that the NRC provide it to Research staff to propose to the Commission.

For Item 19, the Permanent Implant Brachytherapy Subcommittee report, this is currently in the permanent implant brachytherapy subcommittee proposal of the medical event definitions for permanent implant brachytherapy rulemaking.

For Item 22, this is regarding yttrium-90 microspheres. Again, this is a 10 CFR 35.1000 use, and it will be considered to be moved to rulemaking at a future time. Right now it is still in guidance phase. So this is the same as the Elekta Perfexion and the NeoVista ophthalmic device.

For Items 26 and 27, these are regarding permanent implant brachytherapy, and they are included in that rulemaking. And the last three items numbers 28, 29, and 30 are all in the Part 35 expanded rulemaking.

For 2009, Item Numbers 2 and 10 are included in the Part 35 expanded rulemaking. And for Item 9, that is just adding Dr. Welsh and Dr. Langhorst and Mr. Mattmuller to the Medical Events Subcommittee. And Dr. Suh was subsequently added in 2011, but we will get to that.

Any questions on any of these old recommendations? We are kind of seeing a trend here. It is either part of a current rulemaking, so the recommendation is under consideration, or it is a Part 1000 use, which we will consider at a future date.

Okay. So for 2010, the ACMUI will provide a list of action items for NRC staff based on the recommendations provided in the Patient Release Subcommittee report. This was still just lingering as an open item, but I know at the last meeting Dr. Langhorst stated that the Subcommittee felt it had addressed all issues in its report and that this item could be closed. And so I am just documenting that this item is now closed.

For 2011, I am actually going to start with Item Number 6. ACMUI created an action item to reevaluate its satisfaction with the reporting structure annually, and this recommendation was made in January of 2011.

So sometime this year we will need the Committee to return to this, so I guess we can put that as an agenda item for the next meeting, to evaluate its satisfaction with the reporting structure. And this deals with reporting to NRC staff

at the division level where it currently does, or reporting directly to the Commission or some sort of other option.

For Item 7, Dr. Malmud will serve as the reviewer to screen I-131 cases for the ACMUI Medical Events Subcommittee. That is just an ongoing thing. The Medical Events Subcommittee will report to us later today.

For Item 9, ACMUI recommended a three-month notice for future public stakeholder workshop meetings. I went ahead and closed this item out. The workshops are over. But I think the NRC understands that ample notice is requested for public meetings.

For Item 10, this is regarding the public stakeholder workshops. The Committee requested that we have one of those workshops in August, which was a couple of months later than I think what we had proposed. And we did in fact have it in August in Houston.

For Item 11, this deals with permanent implant brachytherapy. And the ACMUI's Permanent Implant Brachytherapy Subcommittee report was finalized on February 7, 2012. It included recommendations for post-implant dosimetry but did not separate prostate implant brachytherapy from other

types of permanent implant brachytherapy.

So I guess the point here is that this recommendation is kind of superseded by your subcommittee report. So I can actually say I had put "partially accepted," and what I will do is go ahead and close this recommendation out, since your Subcommittee report is the final statement on this.

Any questions or comments on that?

(No response.)

Okay. Item Number 12 says that we would have the next meeting. This was for last fall, so I would just close this item out so it is not lingering open. You recommended we have a September meeting, and we had a September meeting.

For Items 13, 14, and 15, all of these items deal with attestation. And the last item deals with -- oh, they're all dealing with attestation, and they are all included in the Part 35 expanded rulemaking.

Then, we'll jump to Item 19, and Mr. Mattmuller asked the NRC staff to add ACMUI to the organizational chart on the FSME website. We are still working on this. I have identified two websites that I think the ACMUI can be added to. We just need to work through the process of going through our contractors

and getting ACMUI added to that.

I did look at the NRC website as a whole, like the public website. And there is a very high level organizational chart. It does not include organizations like the Advisory Committee on Reactor Safety or Advisory Committee on Reactor Safeguards. I believe I've got that right. And, really, it only goes down to about the office level, and there is an office level, and then there is the division level, and that's where the ACMUI reports to the division level.

So I don't think that ACMUI would be included on that chart, is that the chart that you had envisioned? I'm not sure it is or would it be more on the Office of Federal and State Programs and Environmental -- Office of Federal and State Materials and Environmental Management Programs website?

MEMBER MATTMULLER: I'm sorry. I can't keep up with your shorthand. I think the intent was greater visibility for the Committee.

MS. COCKERHAM: Okay.

MEMBER MATTMULLER: And so I will let you decide where best that can occur.

MS. COCKERHAM: Okay.

MEMBER MATTMULLER: That or work in somewhere.

MS. COCKERHAM: I guess I just wanted the Committee to know that I did look on the big picture, front page website. The NRC organizational chart, which starts with the Commissioners at the top, and then it has the Executive Director, but that chart only goes down to our Office Director.

And if this Committee reports at a division level, the Committee would not be on that page, but there are many other places it could be and I have identified two other websites where I think we could get this included. So we will be working on that.

For Item 20, Dr. Langhorst requested that NRC staff place historical documents and past ACMUI membership information on the ACMUI website. This is something we are still working on, but it is noted and it's open.

For Item 21, this is the Electronic Signature Subcommittee, and that Subcommittee will be reporting to us during that agenda item during today's meeting.

Item 22, I just closed out this item. This is the abnormal occurrence criteria. This is the teleconference that the Committee had on December 15th, so I closed out that this discussion

was tabled.

Item 23 is where Dr. Malmud added Dr. Suh to the Permanent Implant Brachytherapy Subcommittee.

Item 24, the Permanent Implant Brachytherapy Subcommittee will revise the Subcommittee report and provide it to the full Committee. And they did do this, so I have closed out this item. That October report was actually followed up by a February report, so we have moved on even since this point.

Item 26, NRC staff will provide an advance copy of the Permanent Implant Brachytherapy Subcommittee report to the Agreement States. This is because we did not have an Agreement States representative currently on the Committee. And Ms. Bailey participated in the teleconference as a member of the public on behalf of the Agreement States. So I have gone ahead and closed out this item.

Item 27, ACMUI planned to hold a spring meeting today and tomorrow. I closed this out because we're here.

This would be Item 28. I don't see a number, but it is Item 28 here. 28, 29, 30, and 31, all of these items here that I have marked closed, they are all modifications to the October Permanent

Implant Brachytherapy Subcommittee report. All of these changes were incorporated into the report, and the report was finalized on October 18th and posted to the public website. So this is just noting all of those changes that were made, so I have closed out all of those items.

And I believe this would be Item 32. ACMUI reaffirms the 2008 abnormal occurrence criteria as stated in the handout with the amendment that "S" be added to the end of "physician," which I discussed before, I think I mentioned this from a previous item. The bottom line is, the recommendations that you have made for abnormal occurrence criteria, the latest information has been provided to the Office of Research, and they are providing that to the Commission.

For the last chart, this is 2012, ACMUI recommended two changes to the Permanent Implant Brachytherapy Subcommittee report. Those two changes were made to the report and included in the final revised report that is dated February 7, 2012. And these ACMUI recommendations in that February 7th report were transmitted to the Commission in a SECY paper or a Commission paper, and that paper is SECY-12-0053.

Are there any questions on any of these recommendations or their status?

ACTING CHAIR THOMADSEN: Yes. Dr. Van Decker.

MEMBER VAN DECKER: Yes, if I could. You know, I noticed on the agenda actually that there is not an actual topic point for discussion of an update on the expanded Part 35 rulemaking, as far as what has gone on since the public meetings of last summer and our last meeting in September. Since a lot of these items are on that, can you just give us some concept of timeline of what has gone on in the last six months and where we see that playing out?

MS. COCKERHAM: Sure. Actually, Mike has a presentation on the agenda, and I believe he may discuss that. I don't know if it states that it's a rulemaking update, but it is on permanent implant brachytherapy. I don't have an agenda in front of me. Is Mike on there?

MEMBER VAN DECKER: He is on for permanent implant brachytherapy, but not for Part 35 expanded.

MS. COCKERHAM: Mike, I can ask, are you going to cover that information for the Part 35 expanded rulemaking?

MR. FULLER: This is Mike Fuller. No, it is

not on the agenda and we probably won't cover that this time. The decision was made not to add the expanded Part 35 rulemaking to this particular agenda because, really, nothing has changed much since the last meeting that we had in September. In other words, we continue to work through items the writing team is working. They are developing the preliminary rule text.

In other words, since the last meeting we haven't really tasked any milestones, so there really wasn't anything to update. We did ask that folks from our Rulemaking Division, you know, be here to answer questions throughout the course of the next day or so.

ACTING CHAIR THOMADSEN: Dr. Van Decker.

MEMBER VAN DECKER: So for an old man's memory, then, can you just remind me what your timeline for publication of a draft rule is?

MR. FULLER: These are estimates, of course, because we don't have that specified just yet in the form of, you know, formal direction from the Commission. But we are still anticipating a publication -- the publication of a draft -- I mean, of a proposed rule sometime either late this calendar year, anywhere until spring of next -- of 2013.

MEMBER VAN DECKER: Thank you, sir.

ACTING CHAIR THOMADSEN: Any other questions for Ms. Cockerham?

(No response.)

Seeing none, thank you very much for the update.

Our next presentation is by Ms. Weil on Fundamental Concepts in Patient Advocacy.

MEMBER WEIL: Thank you very much. I would like to talk about patient advocacy in general, health advocacy writ large, if you will, and to discuss for a moment my role on the ACMUI as a patient advocate. I am a non-technical non-scientific member of a technical committee, and my perspective, therefore, is unfettered by professional loyalties in the clinical realm.

And I am able perhaps to make use of my limited scientific knowledge to focus more clearly on the very zoomed-out public health issues of patient advocacy as well as the very zoomed-in patient perspective. So defining patient advocacy or health advocacy, which is the broader perspective, is often very difficult.

But one could say that a primary role is supporting individual patient choice, enabling autonomous decision-making, promoting patient and

public safety, and increasing access to health services and the quality of those health services.

There are two sets of underpinnings for this particular perspective, and I would like to borrow from the tradition of the protections of human subjects in clinical research, specifically the Belmont report, which was isolated -- which was drafted by the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research in 1979, because it was written in response to the Tuskegee syphilis study and the public outcry over the way people were treated in that particular study well into the 1970s, these three ethical principles were identified, which can be used much more broadly to define concepts of patient advocacy in the larger world of any medical encounter.

So the first principle is beneficence, which is a fairly straightforward idea of maximizing benefit and minimizing risk to patients.

The second principle of respect for persons identifies patients as autonomous beings with rights, preferences, and person-specific values, and the third principle of justice discusses equality in terms of sharing of the burdens and benefits of research in the Belmont perspective. But in the

broader patient advocacy perspective, one could interpret this to talk about the justice and equality of access to health care services in general.

The second underpinning, the concept of rights, is a more legalistic form when we start to think as rights-only in the statutory sense. Statutory rights are rights that are either legislated or codified and are enforceable by courts and law enforcement agencies.

There is a very strong tradition of grievance and redress, which supports these rights in a way that everyone understands. In the normative tradition, it is a much more flexible kind of rights. The rights represent the prevailing values in a society and are not necessarily enforceable. These are rights that are often characterized as what ought to be or what should be.

If we look at statutory rights again, an example would be the Emergency Medical Treatment and Active Labor Act, which was -- which prevents hospitals from dumping patients who have no ability to pay for emergency care. It relates only to emergency care, but it promises that every patient has the right to present to an emergency room and receive a medical evaluation and receive emergency care if needed,

without any respect to the patient's ability to pay.

This was in response to a number of incidents where patients were refused admission to emergency departments and sent down the road to the local municipal or county hospital, or to the hospital where their insurer would pay for care. And there were some deaths associated with that, including deaths to kids.

So in the normative tradition, we could look at this as an example of Rowe v. Wade. This is a statutory law that is being somewhat modified in the normative tradition by prevailing values of society. Rowe clearly stated that a woman has a right to terminate a pregnancy.

In the current discussions, this law is now being shifted a bit by local legislative and political activities to try to change that standing to match more clearly the values of local communities, states, and perhaps even of the federal law.

This third category, which I have called the Professional Codes of Ethics category, is really a category about implied rights. And I would like to cite as an example a professional Code of Ethics, the American Medical Association's Code of Medical Ethics, which puts out norms of behavior for clinicians and

the implied rights that patients have based on those norms of professional behavior.

To be specific, I would like to talk about the AMA's code about medical ethics that talks about medical errors. And I would like to quote, "Patients have a right to know when a medical error or unexpected adverse event has occurred, whether or not the patient has actually been harmed."

So while patients have no statutory right to know of a medical error that has not caused substantial injury, clearly the AMA's Code of Ethics implies that because physicians have an ethical obligation to disclose, patients, therefore, have a right to know. And there are other examples of these kinds of professional norms that imply rights to patients, but they are not enforceable in any court.

If we go back to Belmont for a moment, the Belmont report identifies respect for persons as the underlying ethical principle behind patient autonomy. And there are enablers and there are barriers to autonomy, of course, and I would like to just give a few examples.

Some of the enablers of autonomy are full information from clinicians about treatment options, transparency about how those treatment options have

been arrived at and chosen, and access to care. Barriers to autonomy would be geography and payment issues, and both of those play into that access sphere.

In rural areas, patients have very limited access to choice of provider or to perhaps centers of excellence, because there are more limited numbers of health care providers in some areas.

Insurance issues certainly play into access. Decisions about treatment options are often made based on insurance coverage rather than patient choice.

And this last category as an example, provider bias, is something that isn't often cited as a barrier to autonomy, but it is clear that health care providers have biases about treatment. They have choices that they prefer; they have reasons for recommending certain things that sometimes aren't based in clinical decision, but, rather, based on personal bias.

And some of those bias issues involve gender and racial considerations. There has been enough in the literature that describes decision-making by clinicians that is based in gender or racial considerations rather than clinical considerations

that it does have an impact on patient autonomy.

So there are issues before the ACMUI that have patient advocacy issues fairly firmly embedded in them. The first would be the permanent implant brachytherapy discussion about medical event definition.

Now, if we look at the American Medical Association's clear description of physician responsibility regarding disclosure of departures from the expected plan of care, then our medical event definition might leave patients not able to know that there has been a departure if the departure does not reach the level of medical event definition, whereas the AMA's Code of Ethics would suggest that perhaps the patient should have been told when there was a departure from what was the anticipated plan.

It is often stated that patients don't want to know, that they would prefer not to be told about what a clinician might consider a fairly insignificant departure. But there is good evidence among surveys of patients that patients do want to know, they do wish to be told, and it does affect their future medical decision-making.

So I would like to cite just a couple of surveys that have been done of patients. One is Witman

in Archives of Internal Medicine who states -- and I am going to quote -- "Virtually all patients -- 98 percent -- desired some acknowledgement of even minor errors. Patients were significantly more likely to consider litigation if the physician did not disclose the error."

Witman goes on to describe the discrepancy in litigation as being 12 percent of patients who had a discussion about the medical error with their physician were likely to take their suit to court versus 20 percent who found out about the treatment error or the adverse event on their own.

Another study, Hobgood in Academic Emergency Medicine, said that a majority of respondents wish to be informed immediately of any medical error. And they talk about this being 76 percent. And of those 76 percent, 88 percent wanted to have full disclosure of the error's extent.

Now, med mal insurers know this well, and run training programs to assist physicians in learning how to disclose medical errors and adverse events effectively, honestly, and with some degree of apology, because they know that this is protective of the physician as opposed to being an unwelcome exposure.

And I would like to pose that physician reluctance is more likely driven by a misplaced fear of litigation and a lack of models in having these discussions, because it is certainly not something that is generally taught in medical school, or it may be self-deceptions about patients' actual preferences.

Another issue that is relevant in the field of patient advocacy that has come before the ACMUI is the release of patients following 131-iodine treatment. And the concern here is patient release instructions and whether or not patients understand them.

And while I would be the last person to suggest that patients are incapable of understanding instructions, the timing of those instructions is problematic in this situation, the degree of preparation that patients have, the confusing and often contradictory instructions that patients get from even within the same facility, the problems of non-English speakers or limited English speakers, all really conspire to give me a degree of concern about whether or not the current situation is allowing patients to follow these instructions in a way that protects the public and their families.

If we were to extrapolate from the

situation with Emergency Department patients, who are equally stressed and anxious when they are discharged from the Emergency Department, we know from a study by Engel in Annals of Emergency Medicine that 78 percent of English-speaking patients -- and this doesn't even attempt to address the problem with non-English speakers -- 78 percent of patients do not understand their discharge instructions.

So it is reasonable I think to assume that iodine-131 patients are equally challenged due to stress and complications, and all of those other things, to be able to follow those instructions adequately.

The CardioGen strontium/rubidium generator issue that we are going to discuss later I believe also raises an issue about disclosure. If the patients exposed do not reach the threshold for medical event, it is questionable whether they will be told that they have been exposed to a potentially damaging isotope inadvertently.

So these are the kinds of issues that are within the realm of patient advocacy that have become -- come before this Committee. And this is a list of references that I have cited.

Thank you very much for your attention.

ACTING CHAIR THOMADSEN: Thank you very much for your presentation. Questions or comments from the Committee?

MEMBER ZANZONICO: I have a question. It is sort of a general question. There are often issues in terms of communicating with patients where there is controversy, if not out and out disagreement among themselves, regarding the level of hazard, if any. And this is certainly the case with respect to radiation controversy, like the linear non-threshold hypothesis, et cetera, et cetera.

How does one deal with that? In other words, how does one kind of candidly convey hazard or lack of hazard in the face of uncertainty or controversy among specialists in the field?

MEMBER WEIL: That's an interesting question, and you could zoom out a bit and look at regional variations of practice. Also, in that different recommendations will be made to patients depending on where they seek care, there are regional preferences, there are regional sets of beliefs, one could look at this as medicine in the normative tradition.

I don't know the answer to your question specifically. One says that medicine is an art rather

than a science, and I suspect that there is some truth to that about radiation exposure as well, the way one interprets the modeling and the numbers. I really can't answer you, but it is a very interesting issue.

ACTING CHAIR THOMADSEN: Thank you. Any other questions? Dr. Welsh.

MEMBER WELSH: A couple of comments and questions. One, I am not sure I would agree with one of your statements, and correct me if I misunderstood what you said. But as far as disclosures and transparencies on your second-to-the-last slide, you mentioned that much of this is certainly not taught in medical school.

I'm not sure where that statement comes from, because as far as I know almost all medical school curricula in the United States do incorporate a good deal of ethical training in the curriculum now. And examples would be the courses called Patients, Ethics, and Society, and a variety of other names. But I would take issue with that particular statement.

MEMBER WEIL: Yes. And I probably wasn't clear about what I meant. What I was talking about was very few residents have an opportunity to witness an attending physician have a disclosure discussion with a patient in the hospital.

It is to say, they just don't get the chance to witness it done well, and mostly that is because those discussions, if they happen, happen in a very private way with the physician and the patient, and rarely are residents invited into that process. At least that is my experience in my hospital career.

MEMBER WELSH: I would reply that that has not been my experience. And most of the time the residents are asked to witness these types of discussions, which may happen once or twice, fortunately, during a four-year residency training program, for example. But that has not been my personal observation.

That leads me to another question, which is, in order for a physician to demonstrate competence or capability in taking care of patients in his or her chosen specialty, they must go through required training and educational experience, residency program, medical school, et cetera, and then go on to take a rigorous board of specialty board examination to become board-certified.

How does one become an adequate patient advocate? And the question comes up because I wonder how a patient advocate can truly assure that he or she represents and advocates on behalf of the patients and

truly reflects those desires and opinions of the patients.

And in the patient release controversy that is before the ACMUI, we are hearing statements that patients want this, patients want that, but it becomes confusing as to how we can know that the statements that I am reading about what patients want are truly correct. Can you enlighten us on this?

MEMBER WEIL: Well, the first rule of Advocacy in general with a capital A, I mean, not just patient advocacy but advocacy when you are representing someone, you have to take yourself as much as possible out of the equation and attempt to represent what you hear from your client or from the community that you are advocating for, and to try to actuate those desires separate from any personal bias that you might have.

Now, one only does that imperfectly, of course. But one has to attempt to do that in an impartial way.

I am not sure particularly which statements you are referring to, but I can tell you that when I talk about the iodine-131 patients I spent a long time talking to patients at the Thyroid Cancer Survivors Association's meeting in December, talking

about their experience with patient release.

I have no personal experience there, so I am not talking about my own experiences. I am talking about what patients have told me.

And the best that I could answer that question is to say that I am simply a recipient of information from patients and try to represent them in this Committee. Does that get to what you are at or is there more?

MEMBER WELSH: It does. But it raises the larger question of how reliable a patient advocate's voice can truly represent the patient's opinions at large. And to go back to the controversy at hand with the I-131 patient release issue, we hear a lot of opinions, and we hear a lot of comments that these particular assertions that are made by one person or another reflect the thyroid patients at large.

And I am left scratching my head about whether or not I can really believe that, because to my knowledge, unlike what we are trying to do in medicine, which is move towards evidence-based medicine, scientific medicine, medicine that is based on sound scientific improvement principles, I am not sure that the same is done presently in patient advocacy.

And, therefore, when I hear that most patients would like to be kept in the hospital for their I-131 treatment, I wonder if what I am hearing is truly reflecting the majority opinion of patients, or if it might be the opinion of one or two advocates that may be advocates, maybe they're not correct advocates. It leaves me questioning the whole process. I'm not sure how to solve this situation.

MEMBER WEIL: I don't think any patient advocate can presume to speak for all patients. Our job is simply to raise questions. And you're right, it's not a scientific process. It probably needs some testing in some kind of fact-gathering survey to determine what Patients with a capital P want. But I don't think that that would really solve anything.

I think one could safely say that patients want to safeguard the public from danger in this iodine-131 scenario from exposure to radiation. Whether that means they should be isolated in hospitals, whether they want to be isolated in hospitals, whether they simply want better instruction on how to protect people around them, these are all open questions.

And this advocate's role is to raise questions, not to prescribe for patients or to presume

to speak for all patients. Patients are very able to speak for themselves.

ACTING CHAIR THOMADSEN: Thank you. Any other comments?

(No response.)

Thank you, Ms. Weil.

We are running a bit ahead of schedule. Point of order, can we take up the next item, or do we break early for lunch?

MR. EINBERG: I would suggest we break for lunch early and take up the item after lunch, in case people tuned in on the conference line or members of the public want to listen in on these agenda items.

ACTING CHAIR THOMADSEN: Fine. So we stand adjourned until 1:30.

(Whereupon, at 11:43 a.m., the proceedings in the foregoing matter recessed for lunch.)

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

(1:30 p.m.)

ACTING CHAIR THOMADSEN: I would like to call the Committee back to order after lunch.

The first item of business is the report of the Electronic Signatures Subcommittee, which I chaired. You have at Tab 5 the report.

The Subcommittee was charged to look into electronic signatures, and we found that there is already a federal policy on this, which you have in the report. And the government has had standards for electronic signatures since 1999. The policy follows international protocols and was written by NIST, and it approves the use of electronic signatures for documents using passwords or PINs or the types of digitized signatures, as you might find in the supermarket checkouts.

So we find that the Subcommittee was not really necessary, that there is a policy in the government for that, and that we just recommend that the NRC recognize electronic signatures as per the government policy.

I think at this point I would ask if there was a motion by the Committee to accept and endorse the Subcommittee's report.

MEMBER WELSH: So moved.

ACTING CHAIR THOMADSEN: We have motion; Dr. Welsh has made the motion. Do we have a second

MEMBER ZANZONICO: Second it.

ACTING CHAIR THOMADSEN: We have a second by Dr. Zanzonico. Discussion?

MR. EINBERG: Yes.

ACTING CHAIR THOMADSEN: Mr. Einberg.

MR. EINBERG: I'd like to thank the Subcommittee for looking at this issue, and this is something that, you know, we have been kind of struggling with for a while to make sure that when we do implement an electronic signature policy here at the agency that it doesn't have any kind of deleterious effect with licensees and it clear and simple to implement or licensees are already using electronic signatures.

So from that standpoint, did the Subcommittee find or look at whether this law would have any kind of negative impact on licensees, or what impact would this have if we were to adopt this kind of recommendation?

ACTING CHAIR THOMADSEN: In looking at this, it seemed there would be no deleterious effects, in that you don't have to do anything in particular;

all this would be doing would be saying that the NRC could accept from any user in any record an the electronic signature as were it a written signature.

MR. EINBERG: Okay. And then, because there are electronic signature systems out there. And just so I'm clear that, you know, that this can show that they are already complying with this law.

ACTING CHAIR THOMADSEN: The policy, the federal policy, recognizes all of these softwares as being valid. But they go farther than that to acknowledge essentially any form of electronic signature over which the signer has control.

MR. EINBERG: I see. Okay.

ACTING CHAIR THOMADSEN: That's where the supermarket-type signatures apply, or if you have any other way of indicating your approval uniquely.

MR. EINBERG: Okay. So some of the things that we touched upon when the Subcommittee was formed were issues such as authentication, repudiation, data integrity, records retention and inspection. And so this law would address all of these various aspects.

ACTING CHAIR THOMADSEN: Yes.

MR. EINBERG: Okay.

ACTING CHAIR THOMADSEN: It does not address record retention. That does not seem to

be part of the charge.

MR. EINBERG: I guess we were looking at records inspection. We have a requirement to inspect hard copy records or be sure the signatures are sound even if the records are not necessarily hard copy, but to have records inspectable. And so from that standpoint we wanted to ensure that, you know, whatever we adopt is inspectable as well.

ACTING CHAIR THOMADSEN: Right. The electronic signatures would have to be maintained as any other records.

MR. EINBERG: Okay.

ACTING CHAIR THOMADSEN: For example, as far as being able to pull them up if you were being inspected.

MR. EINBERG: Okay. May I turn to the staff and see if they have any questions?

ACTING CHAIR THOMADSEN: Please.

MR. EINBERG: From the medical team, are there any questions or comments.

(No response.)

There are no questions at this time.

ACTING CHAIR THOMADSEN: Fine. Dr. Welsh.

MEMBER WELSH: So since electronic signatures have been used regularly for several years

in medical practice, they have to be compliant with certain rules, restrictions, regulations, JCAHO perhaps.

Wouldn't it be reasonable to propose that if it is used and approved by JCAHO that it could be reviewed by NRC and, if deemed acceptable, adopted rather than have NRC try to create something new and independent that would, therefore, have to be reviewed to be assured that it is JCAHO-compliant as well? Wouldn't it be easier to go the other way around?

ACTING CHAIR THOMADSEN: Do you have any reason to think there is a discrepancy with the Joint Commission policy? I would guess that they are following NIST, which is the policy that we, as a Subcommittee, have, or rather, are endorsing.

MEMBER WELSH: I think you're right.

ACTING CHAIR THOMADSEN: Dr. Langhorst.

MEMBER LANGHORST: I have a question for NRC. If when adopting this, is there a chance that NRC will accept electronic submissions for amendments and license renewals? Is that coming anytime soon?

ACTING CHAIR THOMADSEN: Mr. Einberg?

MR. EINBERG: I am not prepared to answer that right now.

MEMBER LANGHORST: That's okay. Just know I

have the question in mind.

MR. EINBERG: Okay.

MEMBER LANGHORST: As do other RSOs.

MR. EINBERG: It has been discussed, but there are no details so I am not prepared to give you a definitive answer on that.

ACTING CHAIR THOMADSEN: Any other questions or comments?

(No response.)

In that case, I will call the vote. All those in favor say aye.

(Chorus of ayes.)

Opposed, no.

(No response.)

And abstentions.

(No response.)

It is passed unanimously. Thank you very much.

Dr. Welsh, you're back up with the Medical Events Subcommittee Report.

MEMBER WELSH: Thank you, Mr. Chairman. Thanks for the opportunity to present the fiscal year 2010-2011 medical events summary.

Beginning with the 35.200 series, the diagnostic medical events, we see that there were a

total of four found in the NMED database. One case was an I-123 treatment that was contaminated with I-131. An oral I-123 capsule was given, but imaging revealed peaks for both I-131 and I-123, and it was discovered that the cap was contaminated with I-131.

A total of 380 rad to the thyroid of a child was estimated.

Another case was what is described as a technical medical event, because it was a very low dose, but it did exceed what was called for by more than 20 percent. It was actually just about 21 percent, and the discrepancy was on the order of 20 microcuries. Nonetheless, it meets the definition.

Another case was I-123 being intended. However, I-131 was administered. Five millicuries of I-131 was given instead of the I-123.

In another case, a more concerning case, an indium-111 octeotride scan was ordered, but strontium-89 was given. And this is a bit concerning, perplexing. Apparently, it is due to human error in which the strontium-90 vial, syringe was picked up and used instead of the octeotride scan. And a dose of 63 rem to the bone marrow was given.

Moving on to the 300 series, there are a total of nine medical events, but the asterisk there

indicates that a couple of cases are in the gray zone because no written directive was prepared, because the intention was diagnostic. But therapeutic isotopes or doses were administered.

There were four I-131 medical events in this category, two samarium-153 EDTMP medical events. One case was due to use of a lead syringe, which is a bit ironic in that the lead syringe has been proposed to solve one problem but may have inadvertently caused a new problem.

I can tell you that it is difficult to use the lead syringes when administering this type of treatment because you can't really see as clearly as you might need to. All of these cases were perhaps due to human error.

How an I-131 administration could be given in the absence of written directive is unclear, but this did happen.

Moving on to the 400 series, manual brachytherapy. The good news is that there haven't been any manual afterloader medical events for quite some time now. The last ones were back in 2010.

Similarly, there were no strontium-90 eye application or eye-applicator brachytherapy medical events.

And the last vascular brachytherapy event was back in 2010, but very few of these are being performed nowadays.

Unfortunately, the same pattern is not true for permanent implant brachytherapy. I don't know if we set any records this past year, but it is pretty close. Certainly, there is no difference, no major difference or major improvement in this particular area. There were 30 medical events involving 94 patients recorded, or rather, reported during this particular period.

Importantly, 81 patients in 17 medical events were reported during this period but actually occurred more than six months prior to the period in question. And some of them were as far back as 2003, and this corroborates an assertion made by the ACMUI a while back. This was a pattern that was predictable.

As far as the specifics, isotope data was not available for all the patients, but at least 18 had used palladium-103. Thirty-four at least had Iodine-125, and at least one patient involved cesium-131.

As expected, the most common cause of medical events during this timeframe was underdosing treatment site, for example, D-90 less than 80

percent. And there were at least 39 cases in this category.

The second most frequent cause, as expected, was overdose based on D-90. There were at least 18 identified, meaning that at least 60 percent, and perhaps more, of the medical events in this category were attributed to this dubious criterion of the use of D-90.

There was one I-125 normal tissue overdose due to an incorrect seed placement. There was one medical event using palladium that was a wrong dose that involved the wrong set of seeds. Two sets of seeds were ordered. The older set was implanted, even though it was for May 12, 2011, and the correct set should have been put in on June 10th.

Because this was more than a half-life difference, there was a significant underdosing because of the 17-day half-life. This probably would have been more significant if it was cesium-131, and maybe less so if it was I-25. But, nonetheless, wrong seeds qualifies as a medical event of course.

Another medical event was reported involving an aborted procedure. And this one probably should not be a medical event, because upon my review of the situation the authorized user did absolutely

the right thing.

The authorized user aborted the procedure after eight seeds were implanted, and the authorized user realized that the anatomy was going to preclude adequate placement of the lateral two columns of seeds, and, therefore, called off the procedure, because of patient's anatomy. Nonetheless, it was described as an underdose-based medical event.

There was a case involving cesium-131. That was an overdose due to administration of a full treatment of 114 gray when the prescription called for a partial treatment of 85 gray. There was another case in which the wrong activity was administered. The seeds were ordered in air karma strength but delivered in millicuries. And another overdose was due to the wrong activity entered into the software. Millicuries were entered instead of air kerma.

These are examples of what we call this morning standard or expected medical event definitions. And there are a few patients that fall into this category every so often. But it might be an opportunity for getting rid of this particular subtype of error once and for all.

ACMUI has previously recommended standardization of activity, and I think air kerma was

recommended. I don't know if it would be possible to enforce that. It was just a recommendation by the ACMUI. Societies can recommend it, but suppose if a statement came from NRC. Practitioners would listen, and everybody would use the recommended units and this type of error would go away.

There was an example of an underdose attributed to seeds that supposedly moved out of place. A procedure was done in October, but the medical event was identified almost six months later, March of the next year when the patient returned for a post-implant CT scan.

When we have intervals of this long, which are not advocated, these things can happen. And the question will always remain unanswered about whether or not the seeds truly moved or the patient's anatomy changed. Unfortunately, for this particular authorized user and medical facility, it is described as a medical event. But I personally am skeptical that seeds can truly move, but it underscores the concept of having scans done at the appropriate time for post-implant dosimetry.

Several licensees had medical events that involved more than one patient, and one stands out very obviously. Thirty-five patients, all from the

same facility, were involved in medical events. Fourteen of these had no written directive, 20 of these had no post-implant dose recorded, and of these patients 17 didn't even have post-implant CT.

The authorized user was removed from the license, the program was permanently suspended, and perhaps this was appropriate.

But at another facility there were two medical events that were identified during a review of 12 cases done in 2008. These were both underdoses using the D-90 criteria. And, not surprisingly, to quote the NMED report, "The NRC is reviewing this event and has not yet determined that it is a reportable medical event."

Nevertheless, in December of 2008, this facility permanently terminated its program, and the last procedure was done in December of 2008. One wonders, in contrast to the previous facility that shut down, which was appropriate, whether this was perhaps unnecessary.

Perhaps the most interesting thing that came from our annual review this year were retractions. Here is an example of a retracted overdose in which the facility conducted a comprehensive review of 44 procedures done since 2003.

This particular overdose involved a D-90 that was more than 20 percent of the prescription. But the overdose was retracted and the medical event was retracted when a new post-implant dosimetry study, a post plan was generated which determined that the D-90 value no longer met the reportable criteria.

And this slide title should probably say "Underdoses," but it illustrates the same concept. Two medical events involving four patients that were based on calculated underdoses to the prostate that was believed to be due to prostate swelling. And these medical events were subsequently retracted after the team concluded that the pre-dose to the prostate was in fact within 20 percent of the prescription.

Here, are some of the details, which I won't go into, from the NMED database, that led them to state that this was due to prostate swelling. Same thing with the other event which occured due to prostate swelling. And this corroborates our point that we have been making for many years now that there can be instances in which a calculated dose to the prostate would meet the definition of "medical event" and perhaps be a perfectly good implant in reality.

Up to this point, it has been largely hypothetical. So I think these particular events are

important because they document for the first time what we have been saying for several years now. You can't have a definition that works on Monday but doesn't work on Tuesday. That is exactly what is going on here.

These so-called medical events were retracted upon repeat imaging, at a more appropriate time perhaps. Importantly, the D-90s in these cases were initially 44 percent. And that indicates to me that even our previous threshold of a D-90 of 60 percent might not really represent a true underdose if that D-90 is calculated during the adenomatous period.

And, therefore, my assertion that the use of D-90 in any form or fashion is perhaps not appropriate for regulation, and I feel stronger than ever about that assertion because of this data.

As far as Gamma Knife, there were two events, and this is where the NMED database becomes a little bit cumbersome. The Perfexion unit is Gamma Knife treatment. I include it here in the 600 series, although maybe it belongs in 1000.

A dose of 1,600 centigray was prescribed to multiple lesions, but there was erroneous labeling of one of the tumor sites resulting in delivery less than, that is, much less than what was prescribed. And

the hospital suggested that Elekta make improvements to site identification. So this is an example involving the Perfexion unit.

There was another Gamma Knife medical event involving Model C malfunction. It was reported a few months later. The patient was prescribed 2,000 centigray per lesion to 10 separate lesions. Following treatment of the third lesion, the couch failed. The physicist and the neurosurgeon entered the room and manually pulled the couch out of the unit. The physicist's badge read a dose of one millirem peak dose and two millirem superficial dose equivalent.

This one I am going to save for next year, because, and I apologize, it is from the next year's reporting period. So at least we know we will have something to talk about next year.

Moving on to other events in the 600 series, appreciate Dr. Thomadsen for putting together this table. But you can see that it looks like 12 versus eight, but when you go down to the Gamma Knife we didn't include Gamma Knife in this particular table, because some Gamma Knife is in 1000, some is in 600. There were two events there, so the difference is really 12 versus eight, not very significant.

There were no frequently encountered

problems. Two involved lung treatments. Both had problems with the dwell position identification. One patient, rather, one event involving two patients, involved the wrong length, one was the wrong transfer tube; two breast applicator problems; a lobe puncture and a SAVI catheter split; and one case in which a treatment planning problem was encountered.

There was one event in the 600 LDR remote afterloading scenario, that was a biliary treatment where the catheter shifted during treatment occurred. The patient only received 124 centigray of the intended prescription of 2000 centigray. And this was, again, a low dose rate remote afterloader procedure.

Moving on to the Part 1000, there are 11 in this category. Maybe one more for the Perfexion, three SIR-spheres, eight with the glass microspheres or TheraSpheres. Not very different from 2010, although there was a slight increase in the number of microsphere events in Part 1000 this time around.

In fact, in this table where we have LDR remote afterloader, there probably should be one there, which I included in the 600 section. And, similarly, one in the Perfexion, which I included with the Gamma Knife, which underscores some of the difficulties we have when using this NMED database

because it is kind of cumbersome. We are used to reporting things in terms of the CFR, but that is not the way the NMED database is organized at present.

Three of the TheraSphere cases are described here. One was a misread prescription, clearly human error; another involved the wrong artery, interventional team intentionally tried a different route; in another patient, there was stasis during the first fraction and pain during the second fraction, which caused the team to discontinue.

And since this is a patient-related phenomenon, one might argue that the authorized user and the team did the right thing by discontinuing the procedure. But it was deemed as a medical event.

Eight of the microsphere cases in this reporting period involved the glass microspheres. One was the wrong site due to duodenal shunting. Another was a wrong dose due to an error in ordering. Five were low doses due to technical problems, such as clumping, leaking, needle insertion into the vial, catheter problems. And one was another clear human error in which the wrong site was treated.

And I guess that is pretty much it. There might be a question, is that a gorilla? This is an 800-pound gorilla in the room that represents the

strontium/rubidium generator situation. And rather than try to do it just here, we have a special session, special set of sessions tomorrow which will address this particular topic.

So I will stop at this point.

ACTING CHAIR THOMADSEN: Thank you very much, Dr. Welsh. Do we have questions? Yes, Dr. Zanzonico.

MEMBER ZANZONICO: I am just a little confused. If you have numbers on the slide with the permanent implant prostate brachytherapies, it says 30 medical events involving 94 patients. And then, 17 medical events, 81 patients.

MEMBER WELSH: Yes.

MEMBER ZANZONICO: What I'm misunderstanding apparently is it's like more patients than medical events.

MEMBER WELSH: Yes.

MEMBER ZANZONICO: So what exactly happened? I mean, I would have thought there would have been like a one-to-one correspondence

MEMBER WELSH: No. This is not uncommon. When an institution reports a medical event, that medical event could include multiple patients within that same event. It has got something to do with the

reporting scheme or the definition.

MEMBER ZANZONICO: Okay.

MEMBER WELSH: And this is not at all uncommon.

MEMBER ZANZONICO: Okay. So that's a systemic error?

ACTING CHAIR THOMADSEN: This is systemic.

MEMBER ZANZONICO: Okay. Okay. So it's not necessarily a patient by patient accounting.

MEMBER WELSH: It is not. In some ways, it would be better if the number of medical events meant the number of patients, but this is the way it is right now.

MEMBER ZANZONICO: And so just another question. So with the proposed change in the definition of "medical event" from your Subcommittee, I gather that probably over half of those would not be medical events?

MEMBER WELSH: Perhaps more than 60 percent would not be.

MEMBER ZANZONICO: Yeah.

MEMBER WELSH: That’s because at least 60 percent of the events were only D-90 failures.

MEMBER ZANZONICO: Were based on the D-90.

MEMBER WELSH: Yes, were based on D-90.

Now, that doesn't mean that if we used the more appropriate modern definition that there wouldn't be medical events in that subset, but the use of D-90 is probably capturing many inappropriately capturing events, that is, cases that are not truly medical events.

MEMBER ZANZONICO: And one other question if I may.

ACTING CHAIR THOMADSEN: Certainly.

MEMBER ZANZONICO: What was the logic of the agency in characterizing stopping the treatment in the case of the TheraSpheres when stasis occurred? I mean, that sounds like the exactly right thing that should have been done.

MEMBER WELSH: Yes. It would seem that in that particular case, because of stasis, you can stop the procedure or perhaps because of medical concerns, such as pain. The decision should be with the authorized user and the team to discontinue the procedure.

But I think Dr. Thomadsen might be more familiar with the specifics in this case, so I will ask him.

ACTING CHAIR THOMADSEN: In the NMED database where I got the information, it didn't say

anything more than the users said it should be withdrawn, but the agency said no. That's all I can tell you. There is no justification.

MEMBER ZANZONICO: It doesn't seem to make sense.

ACTING CHAIR THOMADSEN: Yes. Dr. Langhorst.

MEMBER LANGHORST: Yes. And was that NRC regulated state or an Agreement State, or do you remember?

ACTING CHAIR THOMADSEN: It was an Agreement State.

MEMBER WELSH: I would agree that from the limited description that we have it probably shouldn't have been labeled as a medical event.

ACTING CHAIR THOMADSEN: Dr. Langhorst.

MEMBER LANGHORST: A question I have, and I don't know that it is tracked in the NMED database, and I'm still trying to learn that system, and it may be one that we might want to consider going forward on the microsphere medical events. It might be interesting to know if the authorized users are interventional radiologists or radiation oncologists.

I just thought that was a question that I had as far as, if we have any more, is there any

correlation there. So I just raise the question; not expecting anyone to be able to answer that, but for discussion.

MEMBER WELSH: I think that is a very good question that is presently not answered with the data that is in the NMED database as far as I can tell. But I think that question is important for the Y-90 microspheres as well as the I-131 thyroid treatments.

I would like to know how many events per year might be due to radiation oncologists, nuclear medicine physicians versus endocrinologists, who, as I have stated in the past, in my opinion might not have the training, well, they do not have the same degree of training in the use of ionizing radiation as the other two professionals.

It would be very difficult to answer the overall question of appropriateness of non-radiation oncologist/non-nuclear medicine physician being appropriate for being authorized user from this database, because we don't always have the denominators.

But if we could have denominators and we could see trends over years, we could answer the question of whether or not an inordinate number of medical events can be attributed to those who have

less training than those who have the detailed residency-focused training.

ACTING CHAIR THOMADSEN: I do think that it is an excellent question, and it is an issue that needs exploring. I can tell you that in the microsphere cases that there are none of those that would have anything to do with who the authorized user was.

Any other comments or questions? Mr. Einberg.

MR. EINBERG: Dr. Howe pointed out that we do not have a requirement to report who the authorized user is, and, as such, that's why it is not tracked in the NMED database.

ACTING CHAIR THOMADSEN: Thank you. Any other comments? Yes, Dr. Van Decker.

MEMBER VAN DECKER: Just since Dr. W is our denominator person, you know, obviously, there is a lot of prostate brachytherapy programs that seem to have closed here, do you have any sense, from volume of denominator, what is going on with the denominator in that category right now? And then, as an adjunct, the denominator in the sphere therapy category, is that going up, one going down, as far as denominators go?

MEMBER WELSH: It's a good question. Unfortunately, I don't have the answer for you this year. We did have the denominators last year. It is not a trivial process to obtain them. It is fairly expensive, and we have elected to collect those denominators for a more comprehensive report every other year or every two years rather than annually.

But I can tell you that my distinct impression, in the absence of proof, I must admit, it is that prostate brachytherapy continues to decrease sharply.

MEMBER ZANZONICO: Can I just follow up?

ACTING CHAIR THOMADSEN: Dr. Zanzonico.

MEMBER ZANZONICO: Is that a decrease in permanent implant brachy or to all sort of invasive or aggressive forms of treatment of prostate cancer?

MEMBER WELSH: It is probably more specific to prostate, that is, permanent prostate implant brachytherapy. There is an increase in the use of intensity-modulated radiation therapy. There are more proton therapy facilities available.

But I am not sure that prostatectomy has taken the same hit as permanent implant brachytherapy has. It may have; I just don't have the information. But I know that in the world of prostatectomy the use

of robotic surgery has perhaps kept that process going strong, whereas a number of factors, perhaps in no small part the negative publicity of medical events, has caused a noticeable decline in the use of permanent implant brachytherapy for prostate cancer.

MEMBER ZANZONICO: So it is not related necessarily to this, you know, this high profile controversy about the value of PSA and just aggressively treating prostate cancer as opposed to watchful waiting and this kind of thing that is causing it.

MEMBER WELSH: Not for this particular reporting period. In years to come it may.

MEMBER ZANZONICO: Right, it may.

MEMBER WELSH: But, there could be a sharp decrease overall, but I don't think for the periods that we are talking about presently.

ACTING CHAIR THOMADSEN: Dr. Suleiman.

MEMBER SULEIMAN: Yes. I think I will add to Dr. Zanzonico's question or answer. I think you are going to see dynamic changes, both with different alternative modalities for treatment, some of it being driven by evidence-based outcomes, some of it being driven by reimbursement rates, and a whole bunch of other factors.

So I think it is interesting to consider, I mean, safety is one of them. So if the medical event criteria could be trusted to be consistent across all modalities, it would be a real good metric to see that, you know, this modality is safer than some other modality. But I think it is good, but I don't know why. I think you are probably right about the IMRT displacing some of this.

ACTING CHAIR THOMADSEN: Thank you.

MEMBER WELSH: There is no doubt that there are financial motivations for choosing one treatment over another or directing patients in one direction or another. But I think a fact that is supported by the literature that remains clear, the fact remains that permanent implant brachytherapy is effective and, if done properly, is very safe and effective.

ACTING CHAIR THOMADSEN: Thank you, Dr. Welsh.

Now we have Mr. Fuller. Are you concerned that we are too far ahead of schedule? I see you looking at your watch.

MR. FULLER: Excuse me, Mr. Chair.

ACTING CHAIR THOMADSEN: Mr. Fuller will be talking about permanent implant brachytherapy.

MR. FULLER: Well, to answer your question,

I was looking at my watch, and we are quite ahead, well, a bit ahead of schedule. My only concern is is that sometimes people look at the agenda and they plan to join in at a particular time. And so if we get halfway through it, and so forth, I do concern myself with that. But…

ACTING CHAIR THOMADSEN: Would you prefer for us to take a break right now?

MR. FULLER: I will leave it entirely up to the Committee. It is just a sensitivity that we have, but it it is up to you.

ACTING CHAIR THOMADSEN: Right.

MR. FULLER: It is your meeting.

ACTING CHAIR THOMADSEN: We understand. Is there a sense of the Committee? Shall we try to stay on schedule for those who may be calling into this? Is there an objection to taking a break now and resuming at 3:00, when we are supposed to take up this topic?

(No response.)

Hearing none, we stand adjourned until 3:00.

(Whereupon, the proceedings in the foregoing matter went off the record at 2:12 p.m. and went back on the record at 2:58 p.m.)

ACTING CHAIR THOMADSEN: Welcome back. And

we will pick up with Mr. Fuller's presentation on the update on proposed changes related to permanent implant brachytherapy.

MR. FULLER: Thank you, Dr. Thomadsen. It is a pleasure to be here today to provide the ACMUI with an update on the proposed changes to 10 CFR Part 35 related to permanent implant brachytherapy.

The purpose of my presentation this afternoon is to provide the ACMUI with an update on the more recent developments related to staff's proposed changes to the medical event definition for permanent implant brachytherapy.

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

In 2005, the Commission directed the staff to develop a proposed rule to modify both the written directive requirements and the medical event reporting requirements to be activity-based instead of dose-based, as had been recommended by this committee.

In 2008, the Commission approved publication of a proposed rule to amend pertinent Part 35 sections involving permanent implant brachytherapy.

However, during late summer and early fall of 2008, a substantial number of medical events involving permanent implant brachytherapy were reported to the NRC. Based on its evaluation of that information at the time, the staff believed that a number of these medical events would not have been categorized as medical events under the proposed rule. So in 2009, the Commission sought further advice from this committee and directed the staff to work with the ACMUI to provide recommendations to the commission on regulatory changes for permanent implant brachytherapy programs.

In 2010, the Commission disapproved publishing a revised proposed rule and directed the staff again to work closely with the ACMUI and others from the broader medical and stakeholder community to develop revised medical event definitions that protect the interest of patients, allow physicians the flexibility to take actions that they deem medically necessary, while continuing to enable the Agency to detect failures in process, procedure and training, as well as any misapplication of byproduct material by authorized users.

Additionally, the Commission directed staff to hold a series of stakeholder workshops to

discuss issues associated with the medical event definition, which was done last summer. I would note that these workshops that the NRC staff learned a great deal from the medical community about their needs related to the medical event definition.

On Tuesday February 7, 2012, the committee, the ACMUI, held a public teleconference and endorsed the ACMUI Permanent Implant Subcommittee report and provided NRC staff with recommendations for changes to the medical event definition for permanent implant brachytherapy.

On April 5, 2012, NRC staff provided the Commission with the staff's recommendations for changes to the medical event definition. Those recommendations were in the form of a SECY paper, specifically SECY-12-0053. The paper was made public on April 10th, which was last Tuesday, and we provided to you the entire ACMUI on that same day. This presentation will focus on the recommendations that the ACMUI provided to the staff and whether staff differed from those recommendations in our paper to the Commission.

I should make it clear that my presentation is not intended to detail the staff's recommendations but rather to go over those

recommendations that we received from the ACMUI. As I indicated in the previous slide, we only -- Our paper was only made public last Tuesday. And so in preparation for this presentation, there really wasn't enough time to even develop a presentation on the SECY paper itself. Next week, Dr. Ron Zelac will be making that specific presentation to the Commission. And it is probably appropriate that that presentation be made to the Commission as opposed to going over a great deal of detail at this point in time. And again, at the time that we were putting together this presentation, while we were very hopeful that we would have the staff's paper public at this time, we had no guarantee and I would like to thank those who helped us make that happen. There were special accommodations made on the part of the Commission last week to get this paper out and make it public right away.

So again, I will be talking about primarily what we heard from the ACMUI and how we may have differed. But then since the paper is public now, when we get to the end of the presentation and the questions and answers, I will be happy to address any questions that folks have about the staff's paper.

So, the ACMUI recommendations for the target if greater than 20 percent of the sources fall

outside the treatment site and as long as that is not resulting from patient-related causes such as edema or source migration after placement, the ACMUI recommended that this situation be defined as a medical event.

For normal tissue, there are two criteria. For neighboring structures such as the bladder or rectum and in prostate implants as an example, the dose to at least five contiguous cubic centimeters exceeds 150 percent of the dose prescribed to the clinical target volume or the planning target volume or for intra-target structures. And again using the prostate as an example, the urethra in this case, the dose to at least five contiguous centimeters exceeds 150 percent of that structure's expected dose based upon the approved pre-implant dose distribution.

Other ACMUI recommendations for what would constitute a medical event involve using the wrong radionuclide, using the wrong activity or source strength as specified in the written directive, delivered to the wrong patient, delivered directly to the wrong site or body part with the exceptions of seed migration, edema and other patient-related factors or source displacement following placement, as long as the first criteria, a few slides back, is not

violated. In other words, if less than 20 percent of the seeds are implanted outside the treatment site but at some distance from the treatment site, then a medical event has occurred.

I recall the discussion on this point when we were in Houston and I remember that there was quite a bit of consensus amongst the panelists that this situation should be considered an ME, a medical event, that is. However, I want to let folks know that I believe that the staff will have to be very careful to ensure that the rule language is crafted in a manner that makes the requirement clear, concise, and unambiguous. And I say that because in the current rule when we think in terms of wrong treatment site, which is what I think we are really getting to here, there is a dose-based criteria associated with that. So I just want to let folks know that I see this as not insurmountable because we did include it in our recommendations, but it is going to take some care on the part of the staff as we develop rule language.

Another ACMUI recommended criteria for what would constitute a medical event is delivering, using the wrong modality and finally, I mean or using the leaking sources.

Another ACMUI recommendation was that the

authorized user should provide a statement attesting that the implanted sources have been placed in accordance with the final plan distribution.

So, NRC staff recommendations. What did we do? The staff incorporated all of the ACMUI recommendations in the staff recommendations to the Commission with one exception and I will talk briefly about that exception.

One recommendation from the ACMUI's revised final report but not incorporated in staff's recommended medical event criteria involves possible bunching of implanted radioactive seeds in the treatment site, instead of being distributed as the authorized user had planned before the start of the procedure. We recommended that NRC staff require that the authorized user affirm in writing on the written directive after the implant is completed that the distribution of the sources within the treatment site was as intended per the pre-implant written directive.

The staff contends that appropriate regulation for patient protection from undeclared or unrecognized bunching exists through two existing requirements and the authorizing user affirmation is unnecessary.

One of the existing requirements is the

present 10 CFR 35.40 entitled "Written Directives" section that requires completion of the written directive after the implantation. This affords the authorized user an opportunity to acknowledge any seed bunching that may have been done intentionally or that may have been unavoidable.

The second existing requirement is in the present 10 CFR 35.41 "Procedures for Administrations Requiring a Written Directive." This section requires licensees to develop, implement, and maintain written procedures that provide high confidence that, among other things, each administration is in accordance with the written directive and, if applicable, with the treatment plan. To accomplish this objective, these written procedures have to include conducting post-implant assessment of each implant procedure. Bunching that is not declared and explained in the preceding written directive would become apparent through this assessment and follow-up medical remediation could be considered.

Moreover, this paper includes a recommended medical event criteria involving observed dose to normal tissue structures. In order to evaluate the doses to normal tissues and structures, or at least to assess whether variances from expected

results are significant, imaging to determine the positions and locations of the implanted sources is essential. Here also, bunching that is not declared and explained in the written directive would become apparent and follow-up medical remediation could be considered.

Okay, so what are the next steps? There are actually a couple that are missing on this slide. My apologies.

Okay, as I mentioned before, next week we have a Commission meeting on April 24th where staff, NRC staff as well as two members of the ACMUI and other stakeholders will be addressing the Commission on this issue and discussing the staff's recommendations. After that meeting, and one of the main purposes of that meeting is to help the Commission prepare as they get ready to vote on staff's recommendation. So after that and hopefully fairly soon, we will be receiving the Commission votes. And then typically the way that works, is once they have all voted, then based upon what they say, we get what is called a Staff's Requirement Memorandum, or an SRM. And it is in that SRM that we will be given the direction on what to do next in the form of rulemaking.

Two more points I would like to -- two more things in the process that I somehow inadvertently left off of the slides that you see but are on my slides is shortly after we get the SRM we can begin developing what is called a regulatory basis. A regulatory basis is what our rulemakers need, the folks that are specialists when it comes to developing rules and new regulations. That regulatory basis will be developed by the NRC staff or staff from the medical team and then provided and once accepted by the folks who do the rulemaking, then we can incorporate this into the expanded Part 35 rulemaking effort which is currently underway.

So then after that, we will have hopefully in a reasonable amount of time, a proposed rule. So again, our plan is and our hopes are that this will be incorporated by the end of the summer into the expanded, the ongoing expanded Part 35 rulemaking. I know we have discussed that a number of times in the past and that proposed rule should be out and again, we don't have a hard and fast date right now but our hopes are to have that late, at the very earliest, would be the very end of 2012. More likely, it would be sometime next spring, springtime of 2013.

That concludes my presentation. I am happy

to answer any questions. As I indicated before, when we put this together with had great hopes that the permanent implant brachytherapy, that the staff's recommendations to the permanent implant brachytherapy program would be public and I have had people say that they are. But that was just last Tuesday.

ACTING CHAIR THOMADSEN: Any questions for Mr. Fuller? Yes, Ms. Weil?

MEMBER WEIL: Can you help me understand the imaging requirement, which isn't really a requirement, I gather, but it is somehow implied in your slide number 11.

MR. FULLER: Yes, and let me go to our actual paper on this because I want to make sure that I get this just right.

One of the things that we did here, loud and clear from the workshops last summer, was a strong consensus that post-implant imaging should be a requirement. And so we have incorporated that. Let me see if I can find it exactly but we have incorporated that in our recommended changes to the Commission. So in fact if the Commission agrees that that should be a requirement, then that will be a new requirement.

MEMBER WEIL: And what is the nature of that imaging requirement timing-wise?

MR. FULLER: Well the timing is in our recommendations to the Commission would be within 60 days. So our understanding from what we heard during the workshops and from what we heard from this committee is that 30 days is, for the majority of cases, for I guess standard, if you will, for post-implant imaging and dosimetry. But we have also heard that there are exceptions and there are cases in which folks really can't get back exactly when they need to and so forth and so on.

So for our recommendations in the paper, we suggested a time frame of 60 days, which should give people ample time. And again, there are certainly situations where someone might not be able to get back at all and there should be or there are provisions in our recommendations as well for that.

But to get to your point and to answer your question directly, we believe that the requirement to have policies and procedures in place that provide high confidence that the procedure is conducted in accordance with the authorized user's written directive or intention, coupled with this new recommendation for post-implant imaging would provide the licensee with ample information and data to be able to make an assessment on this bunching issue.

ACTING CHAIR THOMADSEN: Dr. Zanzonico.

MEMBER ZANZONICO: So I have a question that is about the ME based on seeds implanted directly into the wrong site of the body. Now I think as you said on the slide, that would be first to sort of remote sites from the target site. So for neighboring sites or intratarget normal structures, that is accounted for by the dose-based criteria.

MR. FULLER: Right and we followed the ACMUI recommendation. In fact, both of these are ACMUI recommendations.

MEMBER ZANZONICO: Right. So this, I guess it is 4D in one of your write-ups, this refers to seeds being implanted more remote than neighboring sites.

MR. FULLER: Yes.

MEMBER ZANZONICO: And it says, this again is a little picayune but it says seeds, plural. I mean, is there some regulatory specification of number of seeds or just any seed or seeds that wind up remote from the intended target?

MR. FULLER: Right, and when we were discussing this again, I think it was discussed briefly, very briefly in New York but it was actually a topic that got quite a bit of discussion in Houston

where folks discussed the fact that any number of seeds. So I could have said seed or seeds that are implanted clearly as a mistake that that ought to constitute a medical event.

There was very, very strong agreement it seems, which actually surprised me a little bit. And when I went back over it again the next day and summarized everything, no one disagreed with me when I said this is what I thought I heard.

And so the way that we think of this and the language that has been in and around the rule for a long, long time, although not in the current rule specifically like this, we refer to these instances or these cases as wrong treatment site, which is different than normal tissue normal structure, which is in close proximity. So, I really believe that we will be able to deal with that effectively but I just wanted to remind folks that in the past, wrong treatment site has a dose-based criterion associated with it and this recommendation did not. And again, not that we can't deal with that but I think what types of questions that I expect to receive as we work on this language is that how far is far. How far away is far away? How far away is distant? Those are the things that we are going to have to wrangle with. And

again, I think we can be successful but I also think that we are going to have to be careful, that we do not write proposed rule language that ends up putting us in a situation where we now have an interpretation that was something that, you know, in other words, unintended consequences for things like this or things that I am concerned about and I think all of the medical team is a little concerned about at this point.

MEMBER ZANZONICO: Can I just follow-up? Can I just ask a question for some of the brachy specialists on the committee?

And this is completely my own ignorance but what I picture in terms of seed implantation is a seed gun or some dispenser that is inserted into tissue. Is it always, is the tip of the gun, for lack of a better term, always inserted directly into the target tissue or do you sometimes have to traverse normal structures to get the intended point of deposition into the target structure or is the target structure always exposed?

ACTING CHAIR THOMADSEN: Dr. Welsh.

MEMBER WELSH: I'll take a stab at answering that question.

You would almost always traverse some

normal tissue in order to get to your target in clinical practice. The only way around that would be with an intra-operative approach and intra-operative brachytherapy is a very different situation from what we are generally talking about here.

What we are generally talking about here alludes to primarily prostate brachytherapy. But the reason why this bullet point D is so critically important is because we have generalized beyond prostate brachytherapy. And I think the majority of us feel that if your aim is to treat the left breast and you put a seed in the right breast, even if it is one seed, you have committed an error. And if your intention is to implant the prostate and you start implanting the lung, there is a major error, whether it is one seed or how many. So in that context, wrong site is a medical event irrespective of how many seeds have placed.

MEMBER ZANZONICO: I guess what I am trying to get at is, you know envisioning simple mindedly this insertion method. Is it possible someone could be too quick on the trigger, so to speak and inadvertently deposit or insert a seed along the path of the needle near but not in the intended site and should that not or not be an ME?

MEMBER WELSH: I think I can reply to that.

ACTING CHAIR THOMADSEN: Dr. Welsh.

MEMBER WELSH: That scenario that you are describing does not uncommonly occur. With prostate brachytherapy, for example, when we withdraw the MIC applicator, the seeds can be vacuumed back out of the area that they were originally correctly implanted into and, therefore, you can have this migration effect. But I think that is very different from being quick to jump the gun when you are in completely the wrong organ. And if you are in the wrong organ, the wrong body site, there is no excuse for that. And that is why I think wrong site belongs here. But we do have to be careful when we are talking about seeds that have migrated into the perineum or into the bladder or have migrated through and wound up embolized in the lung, which does happen with prostate brachytherapy as an example. But those seeds were not directly placed in the wrong site.

MEMBER ZANZONICO: Okay. That was my concern.

ACTING CHAIR THOMADSEN: Dr. Langhorst.

MEMBER LANGHORST: The question that I have is on the attestation. And your point is that the current regulations allow the authorized user in that

final completion of the written directive clarification on what actually was able to be implanted. Is that correct?

MR. FULLER: Again, that is a piece of it. I think what we tried to describe in our paper was that there are three things that in combination makes the need, in staff's estimation, the need for a written attestation unnecessary.

So it is not just the fact that there is an opportunity for the post-implant -- completion of the written directive after implantation but before completion of the procedure, which we also have tried to clarify in the staff's recommendations.

But that coupled with the requirement that you have policies and procedures that provide high confidence and coupled with what we are recommending as a new requirement for post-implant imaging, that those three things together make the need for a written attestation to be unnecessary.

MEMBER LANGHORST: Okay, my question is on the completion of the written directive. If a physician authorized user cannot implant all the seeds that were planned as we had talked about in one of the medical events, is that still a medical event if the physician documents that they changed their mind or

were unable to do that? Are you recognizing that that may not be a medical event? Is that -- I'm trying to get is that what you are allowing for here or am I stretching it too much?

MR. FULLER: I certainly don't want to try to get out ahead of where we might be directed. But the current recommendations from the staff really don't change any aspect of it very much. The only thing we did was clarify what was the completion of the procedure. I think you will still need to compare, in general terms, what was intended and what did you achieve. And it is really that now.

And this is really where we get ourselves in a bit of a pickle, I guess, and it is always imperfect because you are going to have some situations where you simply did not successfully complete the procedure. There are going to be other cases -- and I mean for whatever reason it was unavoidable.

You are going to have other situations where mistakes were made. And so we have to have a rule that sort of accounts for that as well. So while our direction from the Commission was that we needed provide the medical or the authorized user or the medical professionals the flexibility that they need

to be able to react to things that unforeseen. We have to provide -- We have to be accommodating to that situation.

What we want to avoid and what we will be working on when we actually develop the real language is that situation where someone simply didn't do what they really wanted to do, they recognize that they haven't and then they have changed the written directive to document what they did and not what they intended to do. And that is still something that we are struggling with and we are hoping to get more clarification.

ACTING CHAIR THOMADSEN: Dr. Suleiman.

MEMBER SULEIMAN: I have two or three questions but one of them sort of tails with yours because I am still confused.

You go in, you have got 50 seeds, arbitrary number. You wind up implanting 40 of them. You think you have put them in very randomly, very uniformly, I mean and so I think this is an enough. I would like to stop there and recalculate the dose and figure maybe you need to go back and do a second procedure. Would that be a reportable event? Or they go in and they deviate and then they say we deviated from the written directive and this is why. Would that

be a reportable medical event?

MR. FULLER: No, it shouldn't --

MEMBER SULEIMAN: Okay.

MR. FULLER: -- because again, the objective is to make sure that the dose that was delivered was what was intended, recognizing, especially in these types of manual procedures, that the medical practitioner has to have the flexibility to react to things that happen or that they find or they discover while they are in the middle of a procedure.

MEMBER SULEIMAN: Okay now my other two much more black and white questions. Wrong site. Now there is a difference between left or right, wrong patient, and unintended migration from an adjacent site. One is, I think, within that gray area of uncertainty associated with the practice of medicine and the inherent precision or lack thereof. Another one is just a flat out mistake.

And the second question, which is kind of related to that, I think I know the answer which is why I am asking it. If somebody writes the written directive wrong, puts a decimal point, is off by a factor of ten but they go ahead and administer the written dose appropriately but they are off by a

factor of ten, that is not a medical event. Correct?

MR. FULLER: That is always -- Yes, the way the rule is currently written is that if you make a mistake when you write the written directive and then you carry out the procedure in accordance with that written directive, it is not a medical event. That is true.

MEMBER SULEIMAN: That runs counter to the intent of all of this. I mean, if people make an honest mistake, they need to be able to fess up to it. A patient's health may be --

MR. FULLER: Agreed. I think -- Well I don't want to speculate. Go ahead.

MEMBER LANGHORST: I'll speculate. Sue Langhorst. It is not correct but is that where NRC can regulate? I mean, that is, again, that is the practice of medicine and maybe that is how the physician wanted to make that written directive and it may be wrong in every other circle but NRC can't regulate everything medically.

And you are right, it is not the correct thing to do for the patient and it should be looked at in another round, but does it have to be in the NRC space? You have to define it in some way.

MEMBER SULEIMAN: Well, I don't care if the

NRC doesn't regulate it as such. I would hope that somebody could assure me that that is covered by his professional practice or the hospital or something. But I would think, if nobody else is picking it up, then the NRC should pick it up.

I mean, writing a mistake that gives you -- and it is easy to do with our base ten system, you can be off by a factor of ten. And that does happen. That does get picked up periodically.

MR. FULLER: Yes, I mean I will say this about that. We do, as a matter of policy, which all of these rules have to be in compliance with -- you know, our Commission has issued a statement on the medical use of radioactive material. And it is clear that when it comes to therapy that it is okay, if you will, or appropriate in accordance with the Commission to regulate the use of this. But we are limited in that our regulations should be such that they are to ensure that what the authorized user has written in their written directive is what the other folks that they work with comply with.

In other words, licensees have to have policies and procedures in place to ensure that what the written directive says is what is ultimately carried out. And so that is the way it is currently as

a matter of policy.

So I don't know if that is entirely satisfactory but -- And again, this whole thing about the post-implant written directive completion and so forth and so on, you know again that is one of those situations which we have struggled with for many years because of the fact that we really need to be very -- We are treading a thin line there as far as getting over into regulating the practice of medicine and we have to be very careful.

ACTING CHAIR THOMADSEN: Any other questions? Dr. Welsh.

MEMBER WELSH: I don't want to belabor this point unnecessarily but I would just say that I think I disagree with Dr. Langhorst's assertion that this should not be NRC territory. Because when we are talking about written directives and deviations from the written directives, I can't think of anything else that would cover such controversies.

And in my opinion, like I said I don't want to get too far off the main point, if there is something wrong with the written directive, irrespective of whether the treatment was done in exact accordance with the mistake in the written directive or done differently, something is wrong and

I would think that that should be of interest to NRC and perhaps qualifying as a medical event. But I don't think that that is the main gist of the topic here and I don't want to stray too far.

ACTING CHAIR THOMADSEN: Dr. Langhorst.

MEMBER LANGHORST: My point is that NRC cannot, I mean, it is not how the NRC regulations are written right now. So if it is in accordance with what the written directive said, that that is where NRC space is. If the written directive is wrong, NRC does not have authority under its current regulations.

Now, granted it needs to be looked at because patient safety, correct medical procedures and so on. That still goes on in looking at what went wrong. And as an RSO, I look at those things because I consider it a near-miss and I would like to know what went wrong here and how we can make sure it is unlikely to happen again?

So my only point was NRC doesn't have that regulatory authority at this point in time. That is not to say that you should not look at the event and correct what went wrong.

ACTING CHAIR THOMADSEN: Dr. Welsh.

MEMBER WELSH: A quick response would be that I understand and I recognize the controversy and

the problem but as we saw from our medical event report this morning there were occasions where the intention was to give partial treatment and full treatment is administered for prostate brachytherapy as the example and they were flagged as medical events.

So there is precedent for treatment that is delivered that is not what was intended being a medical event. And so logically it would make sense if what is written down is not what was intended, particularly if it was followed, should be a medical event. It would seem illogical that if my intention was to give a partial treatment to the prostate because they are going to get external beam and I give a full treatment, it is a medical event, unless I have written that I -- If I have made two mistakes, it goes away but if I made one mistake it is labeled a medical event.

So there seems to be something inconsistent there that might be subject for a future discussion and examination.

ACTING CHAIR THOMADSEN: Thank you, Dr. Welsh. Any other comments? Yes, Dr. Suleiman.

MEMBER SULEIMAN: Yes, this is directed to Dr. Langhorst. So if the NRC doesn't look into it, who

would catch that factor of ten error? Okay? If NRC can't get involved, who, which agency, which professional group, which institution will hold that individual responsible for making a factor of ten mistake?

I mean if that exists, then this is a moot argument but I want to know where is the assurance that the patient is going to get the right dose or if a mistake has occurred they uncover it? I mean, if you can answer that, then I will back off.

MEMBER LANGHORST: Well, I mean I can't tell you a federal agency who would be looking at that but in looking at review of patient charts and this looks like an error, then in my institution they would look at what went wrong in having a factor of ten mistake. And it may be that we find so that a medical physicist would know to question that perhaps in the future if it was greatly outside the norm. But I can't tell you a federal agency that would be looking at that or a regulatory agency that would be looking at that. It is how you look at errors in any medical practice.

ACTING CHAIR THOMADSEN: Dr. Guiberteau.

MEMBER GUIBERTEAU: I agree with Sue. I mean, I think there is no guarantee that even if you

made this a regulation that it would be caught because physicians in practice are able to use drugs off-label at their discretion. They are able to use their judgment to apply, even if that is faulty judgment, the doses of drugs or radioactivity that they feel is appropriate. If they are in error, there are procedures in most institutions, well in fact all institutions that are accredited, in terms of peer review committees, departmental peer review committees. And almost every accredited organization requires, you know, institution requires peer review which includes chart reviews. And there are also state medical boards that cover these issues if there are breaches that come up that cannot be cured at the local level.

You know, I think it is a difficult problem. And I do understand the concern. On the other hand, I don't think that the NRC's purview or intent is to tie the hands of those of us practicing medicine. And I would strongly agree with Sue that this is not an area that we need to get into.

I think that if there is overwhelming evidence about this, that it can be addressed through various professional societies and state organizations, if you feel it isn't strenuous enough.

But I don't think we need to tie the hands of honest folks practicing medicine. A mistake is a mistake, not matter where it occurs. But on the other hand, it isn't a mistake, I think, in terms of the regulations. If it is not a mistake in terms of the regulations, I don't think that we should be involved.

ACTING CHAIR THOMADSEN: Dr. Welsh.

MEMBER WELSH: I didn't want to belabor this point but it seems like the subject is going on. I would have to strongly disagree with the statements I have just heard. And the reason is that if we are talking about written directives, this is an NRC term. And I can tell from, maybe it is just my personal experience but when I talked about written directives to hospital administrators or even other physicians who are outside the specialties represented at this table, they are clueless. And therefore, I am not confident that when there is some discrepancy within the written directive, that anybody other than the NRC or the states would be able to step up and address this particular concern.

I am not as confident that other professional organizations or other entities within hospitals or advocacy groups are going to want to tackle questions relating to an NRC definition, which

is the written directive. And outside of the NRC environment, written directive is a foreign concept to many medical practitioners and administrators.

MEMBER GUIBERTEAU: Dr. Guiberteau. As much as I understand that concern, I don't think it is grounds for the NRC to invade the practice of medicine and that is exactly what you are asking the NRC to do.

ACTING CHAIR THOMADSEN: Dr. Welsh.

MEMBER WELSH: Well I strongly disagree with that assertion because if a mistake is made, and that is we are talking about, errors in the written directive, irrespective of whether the procedure is carried out in accordance to that erroneous written directive or not, a mistake has been made. And therefore, I don't think that it is NRC encroaching on medical practice if they say a mistake has been made using, in respect to our term, the written directive, and we are going to investigate. So I am not sure that this is really encroaching on the practice of medicine but I feel that this conversation is going, encroaching on territory that might not be relevant to Mr. Fuller's initial discussion.

ACTING CHAIR THOMADSEN: Dr. Suleiman.

MEMBER SULEIMAN: Yes, my intent here was just to calibrate. I thought that somebody who is off

by a factor of ten was more dangerous than being off by misplacing the treatment field a little bit adjacent. And so I just want to be assured that somebody, people if they are going to be off by a factor of ten and there is no ramifications for that, then they may continue to not worry about it. So I think there has to be something to constrain such really wrong behavior.

Whereas, I think sometimes the imaging and the slight migration in my opinion may be over regulation; whereas, I think in this case it is almost ignoring where it is very safety related. I think I just want to hear that there are other methods that are picked up that force the user to make sure that when they write something they are doing it correctly.

I mean, that is what the whole medical physics community is around, making sure you are documenting.

MEMBER GUIBERTEAU: Again, that is what peer review is for and that is what peer review is all about. For instance, if I review a chart that Dr. Welsh has treated a patient and I look at his written directive and say my goodness, I would have treated with one and a half times this dose, is that then a mistake? You know, if he did what he wrote on the

written directive, then that is what he intended to do and what he did. Whether it agrees with my assessment of what he should have done is entirely different.

MEMBER SULEIMAN: Well I'm not saying difference of opinion. I am saying simple mathematical mistake, where somebody wrote down the wrong number.

MEMBER GUIBERTEAU: Well what if the same occurs on -- What if I write you a prescription for digitalis and I triple the dose by mistake? Who is responsible for that? It is a peer review issue if there are issues with the patient's treatment.

ACTING CHAIR THOMADSEN: Dr. Welsh?

MEMBER WELSH: I will just quickly counter that. There is a fundamental difference between a prescription which we have in prostate brachytherapy as the example and the prescription for digitalis, as you were talking about, versus the written directive, which is an NRC term, and NRC-specific issues that only the Nuclear Regulatory Commission tells us what does and does not need a written directive. And therefore, I still feel that if there is a mistake in the written directive, it remains in NRC territory and it wouldn't be outside of their purview to address this question.

The prescription would be a different

issue, however.

ACTING CHAIR THOMADSEN: There is also the problem that, to the best of my knowledge, I don't think there is 100 percent compliance with peer review for all cases.

Any other comments? Hearing none -- Oh, Dr. Van Decker.

MEMBER VAN DECKER: Well I have a tangential topic so I want to stop -- I think Dr. Guiberteau is trying to tell me his length in medicine by picking digitalis as a medicine, the foxglove plant.

Before you leave and I know I touched this point this morning and I know that this is -- and I'm not looking for exact -- There is a lot of different things going on at the same time. And can I just talk timeline for a bit? Because I am starting to see how far this is going so we all have a sense of this.

So timeline-wise, stop me at any point in time that I am incorrect because I am from North Jersey.

You are essentially telling us that we are going to go into ten months of kind of quiet here. And during that ten months we are going to see an SRM clearly on the brachytherapy piece. And I assume you

are intimating that we are going to see an SRM on the expanded Part 35 because they are coming back together to be looked at together down the line. And so therefore, that kind of has to happen before a draft proposed rule comes out next spring.

MR. FULLER: Yes, let me explain that. We have already sent the paper up over a year ago to the Commission and explained that our intention, we called it the Integrated Plan Paper and made a presentation here on that, where our intention was to include the expanded Part 35 rulemaking is underway. A lot of preliminary rule techs has already been drafted and so forth. A lot of that, there has been a lot of work done on that. The intention is to fold this into that rulemaking and then they will work together from that point. We won't need two Staff Requirements Memoranda to make that happen.

We will get an SRM after this paper is discussed and so forth. We will develop a regulatory basis and part of that regulatory basis will be to, in accordance with what we have already described in the paper to the Commission to include in that expanded Part 35. So as long as our Division of Intergovernmental Liaison and Rulemaking accept that, then that is exactly what will happen. And we can't

delay the rulemaking schedule from what we described a year or so ago.

MEMBER VAN DECKER: So then from ACMUI's perspective in October we will still kind of be in this silent building period and there may be some general discussion about the SRM but not much as far as final definitive stuff but some update.

MR. FULLER: Right.

MEMBER VAN DECKER: Then in the spring of 2013, which I will ask you to define for me as prior to ACMUI or after ACMUI, there will be a -- I know.

MR. FULLER: I can tell you what our hopes are.

MEMBER VAN DECKER: Okay.

There will be a draft proposed rule which I guess most of us would be pushing to before ACMUI so that we are in the open commentary period and we have got open commentary period here with the public at that time. So that would probably be a good time for us. And then we will be in an official 90-day commentary period? Remind me again.

MR. FULLER: Well, I'm not exactly sure how long the comment period will be for, probably longer than 90 days. I will say this, is that ACMUI is in accordance with your internal procedures, you will see

a draft proposed rule and have 90 days to provide staff your comments before it is published. And so there will be a published, again, the hopes, the objectives are that it be published early to mid-spring of 2013. It might be late spring. I mean, really can't hold me down on that because there is just a ton of work that is involved and a lot of coordination with various parties.

But one of those parties that according to procedure, because this is a rulemaking-related major medical policy issue, you will get 90 days before it published to provide the staff with your comments.

MEMBER VAN DECKER: Okay.

MR. FULLER: And then once it goes into public comment period, once it is published it is public comment, probably 120 days.

MEMBER VAN DECKER: Okay. And so then the next step would be you would see final rule in fall of '13 before/after ACMUI at that point in time?

MR. FULLER: No. Our hopes are to have a final rule by the end of 2014.

MEMBER VAN DECKER: By the end of 2014. Okay and throughout this period of time OAS will be part of the discussion for Compatibility B pieces? Because here is the reminder of where we are trying to

come to closure here. If you see December 2014 as final rule and then you have three years of OAS compatibility, you are talking about a final rule in December of 2017 for any of the stuff we are talking about right now, whatever minor decisions you want to make.

You know, so then my question becomes -- Here comes the crux of my question. So when you look at these medical events between 2014 and 2017, will we get a mixture of medical events on states that have not yet transitioned using old medical event issues and NRC states using new medical event issues? And how will you track the percentage of states changing over that three-year period of time? And because I am getting older these days and I have teenagers, I wonder whether I will live to 2017 or whether they will live to 2017. It is even money right now.

(Laughter.)

MEMBER VAN DECKER: And not to be difficult, I am just trying to get a sense for where we are because you know, some of these issues over five years here or six years is going to be a lot of mixtures here and how we play into where the commentary periods they are between when they meet and what moves that along and what OAS does for three

years. Because if you look at the state turnover when Revise 35 itself went through, it was not -- as a matter of fact, it 11th hour for the majority of states.

MEMBER BAILEY: That is probably more the norm than not.

MEMBER VAN DECKER: So if 38 states aren't going to go until 2017, then we at least have got a line on what we have as a mixture in-between and that was my only point.

MR. FULLER: Point well taken. It is not something that we have not thought about and considered and deal with all the time in rulemaking.

MS. FAIROBENT: Mr. Chairman, may I ask a question?

ACTING CHAIR THOMADSEN: Yes, a member of the public, please.

MS. FAIROBENT: Lynne Fairobent with American Association of Physicists in Medicine. Mike, just to clarify to follow-up on Dr. Van Decker's timeline, when you had said you anticipate a proposed rule at the end of this calendar year to sometime in the spring of 2013, is that a public proposed rule or is that the proposed rule for the 90-day review period for ACMUI and OAS?

MR. FULLER: According to our integrated plan, which we published back I guess about a year, year and a half ago, we hope to have a proposed rule published by initially we were saying the end of 2012 but in all reality we recognize now that we are probably talking a year or so from now.

MS. FAIROBENT: Okay. So in actuality what you are really saying is you hope to have a pre-decisional proposed rule for the Advisory Committee and the Agreement States to review at the end of this calendar year, which would give them their 90 days until the spring, which could actually slip, depending on the extent of the comments received from the Advisory Committee and OAS.

So in actuality we could see a proposed rule not until the summer of 2013. So that even throws your timeline, Dr. Van Decker, out potentially longer.

I know it is all speculative.

MR. FULLER: It is very speculative at this point. I do know that there is a lot of pressure on the staff to move this along. And I don't know what else I can tell you.

MS. FAIROBENT: Okay.

MR. FULLER: There is a great deal of pressure on the staff to move this along as quickly as

possible but we have lots and lots of different procedural requirements that we have as we go through the rulemaking process.

I wish I were a rulemaking expert and then I could maybe give you a little bit more. But it is a very deliberative process that we must follow.

MS. FAIROBENT: I just wanted to be sure because I don't think that there was a sense of the fact that the 90-day period for the pre-decisional review by the advisory committee in OAS would not occur much before the end of this calendar year, if that. That is your earliest time frame, based on what you said this morning.

MR. FULLER: Yes, I mean like I said, we are going to get direction from the Commission and then we are going to ride the reg basis and once it is accepted by the Division of Intergovernmental Liaison and Rulemaking, then we can start drafting the rule language.

And so you just add that all up and you are into the fall. I mean --

MS. FAIROBENT: Okay, thanks.

MR. FULLER: Sure.

ACTING CHAIR THOMADSEN: And Dr. Welsh.

MEMBER WELSH: I might just say in closing

here that I appreciate how much stress and pressure the staff has been under and I know that this has been a topic of conversation and heated debate since I was sitting over on that side of the room. And you can see from my position at this point that it is time for me to retire. But I can see that at this stage, staff has listened to recommendations from ACMUI from the stakeholders, from the conversations during workshop discussions, and there has been a tremendous amount of work that is clearly evident in this latest SECY paper and that, from your presentation, the topic has been debated and considered since 2005 and may go on until 2017 or longer. But I applaud the staff for all the efforts that have been made and for the cooperation that I have encountered during these long periods of time since I have rotated to this present position. Thank you.

ACTING CHAIR THOMADSEN: Thank you very much. Any other comments? Hearing none, thank you very much Mr. Fuller.

MR. FULLER: Thank you.

ACTING CHAIR THOMADSEN: We now have Dr. Daibes talking on the status of the Commission paper on patient release.

DR. DAIBES: Hi. It is a pleasure to

present here today to ACMUI the status of Commission paper on patient release. My name is Said Daibes.

Our purpose here today is to provide ACMUI with a status of completion of tasks provided to staff and the SRM-COMGBJ-11-0003, data collection regarding patient release.

I am going to provide you some background so you are familiar with some of the information that has been happening now for the last year or so.

The Commission back in 2011 summer provided to the staff an SRM directing the staff to multiple tasks. The first one was to evaluate whether there are gaps in the available data on doses received by members of the public from release of patients treated with medical isotopes; and how the agency could go about collection additional data if needed, and that is, if indeed there were gaps identified; and a recommendation, as an alternative option, on the feasibility of revisiting the dose assessments used to support the 1997 patient release rulemaking. Those were three tasks identified from that SRM. And the SRM also asked for staff's recommended approach on the use of expert elicitation.

Based on the provided SRM and on the provided task, the staff went out and searched

available technical published data and indeed gaps were identified in the available empirical data that was collected and the staff concluded the following.

Since the staff has concluded that there are gaps in the available empirical data regarding doses being received by members of the public as a result of release of patients treated with medical isotopes, these gaps in the available empirical data relate to the following. Internal doses to the members of the public from close physical contact with patients or radioactive contamination from bodily fluids.

Number two, internal and external doses to members of the public from patients released to locations other than their primary residences. For example, houses, apartments, et cetera.

By identifying those gaps, staff concluded the following. They said in developing this recommendation regarding both the feasibility of collecting data for the identified gaps and whether the calculations and assumptions involved in determining whether a patient may be released should be reevaluated, the staff considered the following four options. And this was provided in a notation in both papers early this year to the Commission.

And the options are the following. And again, those options were based directly from the identified gaps in the data.

Option 1: Do not pursue any further research or data collection and do not revisit calculations and methods described in the NUREGs.

Option 2: Perform research or empirical data collection to fill identified gaps in the available data.

Option 3: As an alternative to collecting empirical data, revisit calculations and methods described in the NUREGs' guidance for patient release.

And Option 4: Perform analytical and limited empirical research/data collection and revisit calculations and methods described in the NUREGs' guidance for patient release.

Upon the submission of that paper, we recently were informed by the Commission that votes were in and that an SRM was generated on April 9th directing staff to pursue Option 4, which is this option here on the screen. And it says the following in that SRM.

The Commission has approved Option 4, which would include revisiting calculations and methods described in Agency Guidance, as well as

limited amount of analytical and empirical data collected from field measurements. As noted in Option 4, the staff should include informal discussions with experts in the field, as well as ACMUI as appropriate.

At this moment, that SRM is still in evaluation and staff is putting together a plan to pursue that data collection. At this moment that is where we are on the status of this paper. Is there any questions?

ACTING CHAIR THOMADSEN: Any questions from the committee? Dr. Langhorst.

MEMBER LANGHORST: Is the data collection anticipated to be done only by NRC staff or would NRC request proposals for others to also do data collection?

DR. DAIBES: That is under evaluation right now.

MEMBER LANGHORST: Okay.

DR. DAIBES: So that will be something that we will need to get back to the committee with that information.

ACTING CHAIR THOMADSEN: Other questions or comments? Dr. Zanzonico.

MEMBER ZANZONICO: It is not so much a question as a comment. I think given the sentiments

that this whole issue has raised, I mean it would be my recommendation, and I am speaking just for myself, not for the ACMUI, that this reevaluation with data collection would best be done through an external peer-reviewed vehicle such as a grant as opposed to an internal NRC effort.

I think the more transparent the effort is, the more satisfactory it would be to everyone concerned. And most likely, the more scientifically credible it would be as well. That is just a comment.

DR. DAIBES: Thank you.

ACTING CHAIR THOMADSEN: And can I ask a question to the NRC staff? And that is, is there a possibility that such a project could be funded for external evaluation?

MR. EINBERG: Currently, -- This is Chris Einberg. Currently the SRM directs us to gather a plan for collecting a set of data. In our internal budgeting process here we have provided the staff resources or we are planning on the staff resources and contract support for this. The Office of Research is responsible for putting this plan together. And so they are in the process of developing the plan for collection of the data.

So we will inform them of our

conversations here today and the concerns and comments that we have received.

ACTING CHAIR THOMADSEN: Very fine. Thank you.

Other questions?

MR. EINBERG: Dr. Thomadsen, there was a member of the public who maybe on the line, may wish to make a public statement. But if not, that member of the public wanted his statement put into the record. So, I would request that with your permission that we enter his written statement into the record and it will be part of the transcript that goes out.

ACTING CHAIR THOMADSEN: Please do so. And I know the members of the committee have received this, at least from discussions I have had, we have read it and are considering it.

MR. CRANE: I am the person who -- My name is Peter Crane. I am the person who filed that statement and I would appreciate the opportunity to deliver it orally.

ACTING CHAIR THOMADSEN: This has been read and is in the record. If you can, we can have just a few minutes, about three or four minutes, if you could highlight some points from that.

MR. CRANE: Very well. I guess I began by

asking whether anyone was on the committee who would be comfortable with the idea of their own daughter without her knowledge cleaning the room and bathroom of a patient who had just received an outpatient dose of 200 millicuries of I-131. Is there anyone who would be content to have their daughter doing such work?

ACTING CHAIR THOMADSEN: I don't think that the committee is going to be dealing with the hypothetical question right now. Please hit the points.

MR. CRANE: Very well, I will continue. We know as a matter -- My concern about the paper was that it reflected that changes had been made at the instigation of the ACMUI, including deletion of the staff's intent to tell the commission that it did not have confidence that members of the public were not receiving more than five millisieverts of radiation. I think it is troubling that that was taken out.

It seems to me that there is a profound medical and moral issue that patients are being sent to hotels while radioactive, that these rooms are being cleaned by housekeepers who have no awareness that they are dealing with a contamination situation. I compared it to a situation in which I know that I have got a toxic and carcinogenic mess in my basement

and instead of hiring people with hazmat suits I called the local maid service and have somebody come out because it is cheaper that way. And I don't see how that is distinguishable from the provider who sends a patient off to a hotel except that I get to see the person I am harming and the provider who sends a patient to a hotel doesn't have to.

The staff wanted to tell the Commission that I-131 can be transmitted by kissing and breastfeeding, which is perfectly true and everybody knows it. And yet the ACMUI somehow told the, persuaded the staff that it was obligated not to say this because of the terms of the SRM, which I think makes no sense.

The AMCUI has talked about doses to hotel workers but it based it on an estimation of the amount that could be absorbed from bed sheets soaked with sweat, whereas we know that saliva is a thousand times hotter, radiologically speaking, than sweat. I think that this is a gaping hole. We know from *The ASCO Post* article that patients are being sent to hotels. We know from the staff's testimony that they have in fact, that there are doctors justifying sending patients to hotels, saying it is better to do that than have them drive home with a loved one.

But the basic principle is informed consent. If you drive home with your spouse and you are the patient, the spouse is getting some benefit and is given informed consent. But there is no informed consent for the hotel worker and informed consent is just basic to the way we operate, at least in this society.

The staff wanted to speak of -- Well I'm sorry, the point is sometimes made that the patient who gets under 30 millicuries and has an intact thyroid, is getting this for hyperthyroidism, may be more of a radioactive hazard than somebody getting more than 30 millicuries but who is athyreotic. And that is true but what that calls for is for a thorough reexamination of the whole rule.

There are some valuable data points in the literature right now. Some of them to be found in the journal thyroid at the ATA, including an article by Beasley on release instructions for hyperthyroid patients who warn that small children may well receive exposure to radiation levels in excess of the limit of five milisieverts and he cites a study in which a three-year-old received 7.2 milisieverts. And bear in mind that our starting point on all of this is that our American standards, our NRC standards allow five

milisieverts, whereas, the rest of the world thinks that one millisievert is the right limit.

And as you may know, in 2008 the staff rejected the idea of the one millisievert limit in a paper that never even made its way to the Commission.

So it seems to me that -- and in addition, if you look at the regulations of one state after another, it tells them based on --

ACTING CHAIR THOMADSEN: Can you wrap this up in another minute, please?

MR. CRANE: Yes. It tells us that they should look to a pamphlet put out by the Society of Nuclear Medicine in 1987. Well, that was the days of the 30 millicurie rule. Now that we have got people being sent home with 400 millicuries, it is simply not good enough to say well look at this old guidance and change the numbers particularly.

Appropriately, I mean Dr. Zanzonico did great work in NCRP 155 in developing new guidelines. But those ought to be the basis of guidelines that are sent out to the whole world. As it is, patients and licensees are getting guidance that is all over the map, very irregular. And if you read Dr. Kloos' article, it is not clear that this guidance is even being transmitted.

I'm sorry that this is somewhat less articulate than it would have been if I had been allowed to read my statement, but I think I have made the major points I want to and I am happy to respond to any questions anybody might have.

ACTING CHAIR THOMADSEN: Thank you very much. Comments from the committee? Dr. Zanzonico.

MEMBER ZANZONICO: Pat Zanzonico. Thank you, Mr. Crane, for your comments. Just several points of clarification.

The analysis on the dosimetry to hotel workers that was published in the ACMUI report actually was not limited to exposure from perspiration. In fact, it included conservative assumptions about the amount of activity excreted in urine into bed sheets, really unrealistically conservative assumptions. And with those, the projected doses to hotel workers, specifically housekeepers taking care of those rooms was well, well under 100 millirem.

The issue you raise about informed consent is well taken but it puts them under scenario that should people moving to Denver be given informed consent that they will receive annual doses of 100 millirem greater than individuals in the rest of the

country. I think it is a matter of quantitation. Yes, the doses to hotel workers will be non-zero but they will be well under the projected doses, I should say the projected doses will be well under doses to other cohorts in the country from natural and other sources that probably do not receive informed consent. And again, I am thinking of individuals living in Denver and other parts of the country where there is higher cosmic radiation background, higher naturally occurring radioactivity in soil and so forth and so on. So it really is a matter of scale.

One could, of course, go to one extreme and say anyone who gets any dose beyond a population average should be informed consent but it becomes really impractical. All one can and should do, I think is make the best technical judgment as to what projected doses are and even do it conservatively so. And then make a judgment whether those projected doses warrant or do not warrant informed consent. And I think that is what has been done up to this point in the case of radionuclide therapy patients who are released from hospitals.

ACTING CHAIR THOMADSEN: Thank you, very much Dr. Zanzonico.

MR. CRANE: If I could respond to that Dr.

Zanzonico. First, BEIR VII says that the argument about Denver and background radiation is irrelevant and gives an explanation for that.

But as far as the bed sheets, it seems to me that the amount of urine that is going to be deposited in the bed sheet is trifling compared to the amount of urine that is going to be put into a toilet. And if you grant that urine is taken into account, why not count the toilet and why not count the sink? We know about saliva. We know also that a lot of common household products cause radioiodine to volatilize, so people can be inhaling.

What is the reason for not taking into consideration toilets?

ACTING CHAIR THOMADSEN: Thank you very much, Mr. Crane but we are not going to have a debate on this right now.

MR. CRANE: And just one last point. Okay, suppose it is under 100 millirem --

ACTING CHAIR THOMADSEN: Mr. Crane?

MR. CRANE: -- for the hotel worker who does it once.

ACTING CHAIR THOMADSEN: Mr. Crane?

MR. CRANE: But suppose he does it ten times.

ACTING CHAIR THOMADSEN: Thank you very much for your comments, Mr. Crane. We are not having a debate on this issue right now. We are talking about getting more information in order to look into issues about this.

Other questions to Dr. Said Daibes about the proposals?

(No audible response.)

ACTING CHAIR THOMADSEN: Hearing none, thank you very much.

DR. DAIBES: Thank you.

ACTING CHAIR THOMADSEN: And Dr. Welsh, we are up to you again.

MEMBER WELSH: Thank you, Mr. Chairman. Thanks again for the opportunity to discuss matters before you today.

This will be a far less heavy subject than the one we just reviewed and is strictly for informational purposes. It is an interesting subject and I will keep it strictly at a qualitative level for this presentation today.

I have to thank my scientific colleagues who have worked with me on this particular presentation and subject and introduced me to this fascinating possible scientific observation.

We know that radioactivity supposedly decays with a very predictable exponential function. And from an educational website dealing with radioactivity, it specifically says that no operation, physical or chemical, has ever been shown to change the rate at which radionuclide decays and this statement in some form or fashion can be found in this book, *Radiations from Radioactive Substances* by these very well-known and respected authors, Rutherford, Chadwick, and Ellis.

But we do know that there are some exceptions. And the exceptions that come to mind immediately are those involving electron capture, where the chemistry can affect the half-life and the affect is relatively small on the order of 0.2 to maybe 0.8 percent in most cases. But to pick a more extreme example, beryllium-7 in hydrated form compared to beryllium oxide where it is covalently bonded to highly electronegative element that is going to be pulling its electrons away and therefore making the electron less accessible for electron capture, the difference in half-life is on the order of 1.5 percent.

Interestingly, isomeric transitions, including technetium-99m are another category of

isotopes in which half-life changes can occur due to chemical environment. And in fact technetium-99m was the first metastable isotope that ever demonstrated observable half-life change due to the chemical environment. It is about 0.3 percent different in sodium or potassium protactinate in physiological saline versus technetium sulfide as an example.

But these are due to electron capture and isomeric transmissions where conversion electrons may be less available or covalently bonds and make electron capture less possible.

But in contrast to those two examples of decay via electron capture and gamma versus internal conversion, there might be another exception to this general law. And recent studies have suggested decays of some isotopes might follow anomalous or demonstrate various variations that are unexpected. And these observations now raise the question of whether such variations could have clinical relevance that has previously been unrecognized in temporary brachytherapy, teletherapy and gamma knife radiosurgery.

So where did all this come from? It actually stems from my flight back from an ACMUI meeting in which I picked up a *Popular Science*

magazine read it on the flight and it said that while looking for sources of random numbers, researchers found disagreement in measured decay rates, which is odd for something that is supposed to be a physical constant. Well, apparently they looked further into a collective data and came across further surprises, including long-term observations of decays of certain isotopes demonstrating small seasonal variations so that the decay was slower and slightly faster in the winter than in the summer. So radioactivity is stronger in the winter.

So I thought this was scientifically fascinating but I was fully prepared to dump it until I came across some further information about a coronal mass ejection, which was basically a large solar flare in February of 2011 that meant more than just an attractive aurora borealis. It meant that certain radioisotopes will show a decrease in radioactive decay. I thought that truly is scientifically interesting from the perspective of someone involved in nuclear physics and nuclear medicine.

So I read on further and found another article that discussed the scientists at Purdue noticing the decay rate of an isotope that dropped during the solar flare and dropped actually before the

solar flare did.

So it could be useful in an early warning of an impending solar storm. That could be relevant to astronaut health. But then I thought well that is very interesting because I am a health practitioner and this is interesting nuclear physics but the phrase medical isotope caught my attention. So I decided I must read a little bit more.

And the bottom line here where it says when doctors determine the proper dose of radioactivity to treat a cancer patient, is what really hooked me. And when these popular scientific magazines mentioned this aspect, I decided it is time to go ahead and read the papers in greater detail.

So upon a more detailed examination, I learned that scientists evaluated databases that were required in a number of institutions and they found significant discrepancies in the measured decay rates. So rather than go into the details, I will just mention that there are a number of papers that show quite large discrepancies that were difficult to dismiss simply on the basis of errors in measurement. In fact, I think in this particular paper the bottom line in this abstract says that the seasonal differences of approximately 0.5 percent can be

present between winter and summer months. So it is quite fascinating.

Then the team from Purdue went ahead and evaluated things in further depth and observed similar phenomena. The published literature provides support of this hypothesis and some of these graphs can be quite striking in terms of demonstrating a seasonable variability. This is demonstrating a periodicity with a timescale and thousands of days. And here is the paper that talked about that particular December 2006 solar flare.

A further study by these teams, indicated that the swings seemed to be in sync with the earth's elliptical orbit so that the decay rates oscillated as a function of distance from the sun. And looking at further data, they found an interesting recurring pattern over 33 days, which was surprising to them because the sun rotates with a period of 28 days and this was a little bit longer than that. But they astutely pointed out that the core spins at slightly different rate than the surface does. So this raises the possibility of neutrinos, solar neutrinos being to blame.

Well, that is hard to believe, given the cross-section of neutrinos as they interact with

matter of any sort but it is amenable to investigation. A sphere should have a greater internal flux of neutrinos if radioactive, a radioactive sphere, than a radioactive foil sample. So the investigators decided to see if the half-life of a radionuclide depends on its shape. And this, if true, would be of great interest to medical physicists and radiation oncologists because the geometry of our sources, sealed sources varies widely.

Some members of the same team who proposed this phenomenon, went on to test this particular hypothesis and they found that when comparing a sphere of gold 198 with a thin foil of gold-198 that despite the differences in neutrino flux, that there was really no significant difference in decay rate.

But this did not solve the problem because an inherent challenge with this particular experiment is that the neutrinos that were proposed to cause the phenomenon in the first place were solar neutrinos and they were different from the electron antineutrinos in the gold-198. We know that solar neutrinos which supposedly exhibit a flavor and mass state oscillation that accounts for the solar neutrino deficit might have a slightly different effect on radioactivity than electron antineutrinos. So that was a possible way

around it.

But there are other more serious challenges to this hypothesis. One is where the observed variations in decay rate simply caused by changes in response of the experimental apparatus between summer and winter versus the isotope decaying themselves. So this was examined. And in this particular paper, the team evaluated this question in greater depth and concluded that it was quite unlikely that the observed differences could be attributed to temperature or humidity changes or any other environmental changes in the detection systems.

Another criticism or challenge to the team came from radioisotope thermoelectric generator data. Radium-226 decays by alpha emission but it demonstrates an annual periodicity. So, does this phenomenon apply to alpha as well as beta? If true, Cooper should have been able to demonstrate a fluctuation in the power of output of the NASA Cassini satellite because that satellite which was launched in 1997 reached Saturn in 2004, approached as close as Venus and as far from the sun as Saturn, yet the plutonium-238, an alpha emitter with a half-life of 88 years did not show any seasonal variation for variability with proximity to the sun.

So the response to this was that plutonium-238 and radium-226 are both alpha emitters but radium-226 that was studied was in secular equilibrium. In about 200 years, a sample of radium-226 will have about 42 percent of its photon emission due to beta decaying daughter products and the ionization chamber is not going to discriminate where those photons are coming from. So, while radium 226 decays by alpha decay, the daughters which contribute significantly to what was being measured do decay by a beta mechanism and these were perhaps demonstrating the annual cycle. But in contrast, the plutonium in the RTG was not in secular equilibrium and, therefore, no non-alpha emitting daughters were contributing to any meaningful degree and, therefore, the variation was not observed.

Well, another challenge was put forth and an experiment conducted by Norman and colleagues that calculated ratio between two different types of decay, beta and alpha, for example, and that would be expected to cancel out any changes in equipment between summer and winter. And it was assumed that if there was an annual variation, it would affect different decay processes differently and, therefore, the ratios would change but when looking at these

particular sets of isotopes, there was no change annually.

The reply to this is that while americium-241 as an example decays primarily by alpha, it is possible that like the radium-226 example, its decay products which decay via beta mechanisms would be subject to the annual influence but a more important and legitimate point may be that different radionuclides are inherently different.

And in beta decay, some may show this variability, others may not. And if one looks further into this subject, you will see that although electron capture half-lives, isotopes which decay via electron capture in some cases showed variability as a function of chemical state but others do not. Beryllium-7 as I mentioned in the early slides demonstrates such a change in half-life, if it is electrons are bonded, whereas potassium-40 seems less susceptible to this particular type of phenomenon. So it is reasonable to assume that the same thing would be true for beta decay susceptible to this particular type of variability.

So in summary here, anomalous variations have been characterized by strong annual periodicities, as well as short duration deviations.

And it is the short duration deviations from the apparent decay rate that persists for hours or days that could be of significant concern to radiation oncology.

The annual periodicity has been observed in 14 radionuclides thus far, including this set of isotopes that are used in radiation oncology. But the annual oscillation amplitude varies from nuclide to nuclide and is typically less than 0.5 percent and would never be of clinical relevance. On the other hand, the short duration deviations which have been observed only in a small number of radionuclides thus far but including cobalt-60, strontium/yttrium-90 and radium-226 could have more important clinical ramifications. Preliminary analysis of these short duration deviations suggests changes in apparent half-life that can persist for up to two days at a time. And therefore, this could affect HDR or Gamma Knife efficacy if delivered during this window.

It remains unknown whether such short duration decay rate variations exist in other commonly used medical isotopes like the ones listed here. And it also remains uncertain whether short duration variability if it does exist in these isotopes results in any clinically relevant dosimetric changes. But

preliminary investigations show flat regions in the decay curve. Flat regions are called short duration deviations that can be as significant as 600 percent in terms of a change in apparent half-life and that can last as long as two decades.

So if the treatment happened to be given during a period where the half-life differed by as much as 600 percent, one could anticipate that the dosimetry could indeed be affected.

And of interest, some of the raw data that was used in coming to these conclusions was acquired during calibration sequences and precision measurements or in establishing references. These are procedures that are quite commonly done by medical physicists and very familiar to medical physicists. Therefore, additional investigations could include not just analysis of archived data but careful evaluation of existing calibration data from gamma knife units, from HDR units, from active clinics that are sampling at frequencies that might be sufficient to detect any such rate variations.

So at this point, I will stop the discussion, aside from showing some of these slides from some of the papers that have been published. You can see that the variability here, which is kind of

odd, is plotted out in other studies and analyses and in some cases, it can be very striking. And here is the data from that 2006 solar flare. You can see the count rate dropping right before the flare, which opens up the subject of this so-called helioradiology, where you could use this type of information to determine if a solar flare which could be of health significance to astronauts is on its way.

And here you can see differences in the calculated half-lives during these flat periods where in one situation the calculated half-life might be estimated at several-fold the calculations in other areas of the curve.

So I will stop it at this point.

ACTING CHAIR THOMADSEN: Thank you very much, Dr. Welsh. Comments or questions for Dr. Welsh? Dr. Zanzonico.

MEMBER ZANZONICO: Well Dr. Welsh, you elevated the nerdiness of this committee.

(Laughter.)

MEMBER ZANZONICO: And the question I have, you would think if this is related to a solar flare phenomena there would be a geographic effect as well. In other words, the magnitude of these effects would differ in different parts of the earth. Is there any

evidence of that? In other words, closer to the North or South -- North Pole in particular, a more pronounced effect than near the equator?

MEMBER WELSH: Thus far, no. And it is being investigated but if it were neutrino-based, you might not expect to see such a variation. These neutrinos can go through the entire planet quite readily. But if it is neutrino-based it is hard to understand how it possibly could make sense because the cross-sections are just so minuscule.

It is subject of investigation and thus far there is no clear answer to your question but there have been proposed new particles, things called nutellas, I think, that I will refrain from discussing in any depth here. But there is no shortage of interesting proposed mechanisms but more data is required.

ACTING CHAIR THOMADSEN: Any other questions or comments? Yes, Dr. Weil?

MEMBER WEIL: No.

ACTING CHAIR THOMADSEN: In that case, any last words from the staff for today?

MR. EINBERG: Yes, thank you Dr. Welsh for the presentation.

I would ask the committee to be sure to

check their calendars for upcoming meetings and go to Tab 14. Tomorrow we will be discussing the next ACMUI meeting. So be prepared to look at your calendars and see if you have any conflicts. So let's just serve it as a reminder.

And I thank the committee for all the interesting presentations and discussion today. And we will reconvene tomorrow morning at eight o'clock.

ACTING CHAIR THOMADSEN: We stand adjourned.

(Whereupon, at 4:46 p.m., the foregoing meeting was adjourned to reconvene on Tuesday, April 17, 2012 at 8:00 a.m.)