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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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OPEN SESSION MEETING

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MONDAY, APRIL 15th, 2013

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The Open Session portion of the meeting was convened in Room T-2B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 9:30 a.m., Leon S. Malmud, M.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

LEON S. MALMUD, M.D., Chairman

BRUCE THOMADSEN, Ph.D., Vice Chairman

DARICE G. BAILEY, Agreement State Representative

MILTON GUIBERTEAU, M.D., Diagnostic Radiologist

SUSAN LANGHORST, Ph.D., Radiation Safety Officer

STEVEN MATTMULLER, Nuclear Pharmacist

CHRISTOPHER J. PALESTRO, M.D., Nuclear Medicine Physician

JOHN SUH, M.D., Radiation Oncologist

ORHAN SULEIMAN, Ph.D., FDA Representative

WILLIAM VAN DECKER, M.D., Nuclear Cardiologist

LAURA WEIL, Patients' Rights Advocate

JAMES WELSH, M.D., Radiation Oncologist

NRC STAFF PRESENT:

ALLISON MACFARLANE, Ph.D., NRC Chairman

MARK SATORIUS, Director, Office of Federal and State Materials and Environmental Management Programs

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

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

SANDRA GABRIEL, Ph.D., Acting Medical Radiation Safety Team Leader

ASHLEY COCKERHAM, ACMUI Co-Coordinator, Alternate Designated Federal Officer

SOPHIE HOLIDAY, ACMUI Co-Coordinator

NEELAM BHALLA, FSME/DILR/RPMB

SUSAN CHIDAKEL, OGC/GCLR/RMR

JIM DWYER, RI/DNMS/MB

SARA FORSTER, RIII/DNMS/MLB

CASSANDRA FRAZIER, RIIIDNMS/MLB

MICHAEL FULLER, COMM/OCM

LATISCHA HANSON, RIV/NMSB-A

VINCENT HOLAHAN, Ph.D., FSME

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

DEBORAH JACKSON, FSME/DILR

ED LOHR, FSME/DILR/RPMB

ANGELA MCINTOSH, FSME/MSSA/RMSB

KIMYATA MORGAN-BUTLER, Ph.D., FSME

KEVIN NULL, RIII/DNMS/MLB

PATTY PELKE, RIII/DNMS/MLB

GRETCHEN RIVERA-CAPELLA, FSME/MSSA/RMSB

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

MEMBERS OF THE PUBLIC:

ROBERT DANSEREAU, NY STATE DEPT OF HEALTH

WILLIAM DAVIDSON, UNIV OF PENNSYLVANIA

KAREN LANGLEY, UNIV OF UTAH

ANDREW MCKINLEY, ASNC

JOE RODGERS, THERAGENICS CORPORATION

GLORIA ROMANELLI, ACR

MICHAEL SHEETZ, UNIV OF PITTSBURGH

MICHAEL STEPHENS, FL BUREAU OF RADIATION CONTROL

CINDY TOMLINSON, ASTRO

NANCY WERSTO, FDA

PAUL YURKO, VETERANS HEALTH ADMINISTRATION

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P R O C E E D I N G S

CHAIRMAN MALMUD: Opening statements will be made by Mr. Einberg and Mr. McDermott.

MR. EINBERG: Okay, thank you, Dr. Malmud. As the designated federal officer for this meeting, I am pleased to welcome you to the public meeting of the Advisory Committee of the Medical Uses of Isotopes. My name is Chris Einberg.

I am the chief of the Radioactive Materials Safety branch, and I've been designated as the federal officer for the Advisory Committee in accordance with 10 CFR Part 7.11.

Present today as the alternate designated federal officer is Ashley Cockerham, ACMUI coordinator. This is the 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 at the March 6th, 2013 edition of the Federal Register, Volume, Page 14593. The function of the committee is to advise the staff on issues and questions that arise on the medical use of byproduct material. The committee provides counsel to the staff but does not determine or direct the actual decisions of the staff or the Commission. The NRC solicits the views of the committee and values their opinions. I request that whenever possible, we try to reach a consensus on the 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 participating today. Dr. Leon Malmud, ACMUI chairman, hospital administrator.

CHAIRMAN MALMUD: Here.

MR. EINBERG: Dr. Bruce Thomadsen, vice chairman, therapy medical physicist.

VICE CHAIRMAN THOMADSEN: Here.

MR. EINBERG: Ms. Darice Bailey, agreement state

representative.

MEMBER BAILEY: Here.

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

MEMBER GUIBERTEAU: Present.

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

MEMBER LANGHORST: Here.

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

MEMBER MATTMULLER: Here.

MR. EINBERG: Dr. Christopher Palestro, nuclear medicine, physician.

MEMBER PALESTRO: Here.

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

MEMBER SUH: Here.

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

MEMBER SULEIMAN: Here.

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

MEMBER VAN DECKER: Present.

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

MEMBER WEIL: Here.

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

MEMBER WELSH: Present.

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

MEMBER ZANZONICO: Here.

MR. EINBERG: We do have a quorum, so we can proceed. Okay. I now ask that the NRC staff members who are present to identify themselves. I'll start with the individuals in the room here.

MR. MCDERMOTT: Brian McDermott, director of the Division of Materials Safety and State Agreements and the Office of Federal and State Materials and Environmental Management Programs.

MR. EINBERG: Very good. Ashley, would you like to introduce yourself?

MS. COCKERHAM: This is Ashley Cockerham. I'm part of the Medical Radiation Safety team.

DR. GABRIEL: Sandy Gabriel, acting team leader, Medical Radiation Safety team.

MS. CHIDAKEL: Susan Chidakel, Office of General Counsel.

MS. COCKERHAM: And Sophie Holiday just stepped out. She's also part of the Medical Radiation Safety team.

MR. EINBERG: Do we have anybody from the regions on the line? Region I? Is the line open? Ashley, can you check with Theron? Is there anybody with Region I?

MS. COCKERHAM: They're currently dialing into the bridge.

MR. EINBERG: Oh, they're dialing in. Okay.

AUTOMATED OPERATOR: Your passcode has been

confirmed. Please stand by as you are joined to your conference. There are three parties in conference including you.

MR. EINBERG: Welcome to the people who are on the line. We're going through the opening remarks here. I'm doing a role call and wanted to see if there's anybody from Region I on the line, NRC staff, Region 3, or Region 4. Also is anybody from NRC staff from headquarters on the line? Dr. Zelac?

DR. ZELAC: Yes, I am on the line.

MR. EINBERG: Okay. Thank you. I would also like to add that this meeting is being webcast, so other individuals may be watching online. We have a bridge line available and that phone number is 888-864-0940. The pass code to the bridge line is 90108#. Following a discussion of each agenda item, the ACMUI Chairman, Dr. Leon Malmud, at his option, may entertain comments or questions from members of the public who are participating with us today. We ask that one person speak at a time as this meeting is also closed-captioned. At this point I would like to turn the meeting over to Mr. McDermott, director of the Division of Materials Safety and State Agreements for a few opening comments.

MR. MCDERMOTT: Thanks Chris and good morning everyone. I'd like to welcome you back to NRC for your spring 2013 in-person meeting. So it's nice to have you here and have the opportunity interact on a person-to-person basis. For our larger audience, I do want to just note that

the ACMUI did hold two public teleconferences in March to discuss the ACMUI's rulemaking subcommittee report and that the final committee report was received by NRC on April 9th, and we appreciate that. This can be found on the ACMUI webpage and also in the agency's ADAMS system.

Just looking ahead to the agenda here for the next two days, later on today we will have the opportunity to discuss the draft guidance for the proposed draft expanded Part 35 Rulemaking. This is an opportunity for the committee to understand that guidance document. And we'll also have the opportunity to hear about the AO subcommittee report as your recommendations on the AO criteria. That subcommittee was chaired by Dr. Langhorst. And this will be included in the Commission paper that's due sometime this summer, so important to make sure the committee's aligned and I understand you plan to vote on that this meeting.

Tomorrow we'll have two presentations from the National Nuclear Security Administration and the Center for Medicare and Medicaid Services in relation to Molybdenum-99 production and reimbursement policy. We'll also have a presentation on the ViewRay licensing guidance. This is the -- something the staff is working on to ensure the availability of that new technology and make sure it gets in the right place in terms of licensing. Presentation will be given tomorrow by Dr. Sandy Gabriel of the NRC and Sophie Holiday. The guidance is still pre-decisional, so we won't inform the ACMUI work public of the licensing decision at this time. It's just an update -- the working group that is

working on the guidance actually meets later this week. But that will be a good update for you all.

And then one other note since your last in-person meeting, in March this year we had the publication of the long awaited Part 37 on the security of byproduct materials, so that rule goes into place in March and a year from March is when the NRC licensees will have to be in compliance. The agreement states have an additional two years beyond that, so a total of three years to have their compatible regulations in place. Presently there's a working group that's made up of NRC staff as well as agreement state representatives working on some of the implementation details. And the key part right now is the communication plan to help get the word out. Although there's been a lot of discussion about that rulemaking over the last few years, that communication plan is part of what we do when we have significant rulemaking like that come out.

And finally, as many of you know, this is Dr. Malmud's last meeting with the ACMUI. He has provided steady and very calm leadership for the committee since 2004. He's always provided the NRC staff with reasoned advice. His service has been very much appreciated and valued by the NRC staff and Commission. And to that note, we have a special guest this morning. I'd like to introduce NRC Chairman Macfarlane.

Before you set up here for you. The Honorable Allison Macfarlane was sworn in as chairman of the U.S. Nuclear Regulatory Commission in July of 2012. She was

initially nominated by President Obama and confirmed by the Senate to a term that expires June of this year. However, just last month president Obama nominated Dr. Macfarlane for a five-year term to the Commission. Dr. Macfarlane, an expert on waste issues, holds a doctorate in geology from Massachusetts Institute of Technology and a Bachelor's Degree of science in Geology from the University of Rochester. Prior to beginning her term as the NRC's 15th chairman, Dr. Macfarlane was an associate professor of environmental science and policy at George Mason University in Fairfax, Virginia. Please join me in welcoming Chairman Macfarlane.

[applause]

NRC CHAIRMAN MACFARLANE: Thank you very much. Can you all hear me? Okay? Yeah I'm a doctor too, but of inanimate objects.

[laughter]

So it's a pleasure to join you all this morning and to be here on -- and to represent the Commission on -- to honor Dr. Leon Malmud. Dr. Malmud has made significant contributions to the ACMUI -- I'm getting used to all these acronyms here -- since his appointment in 2002. He was appointed chairman of the committee in 2004 and during that time he's overseen the Commission's -- the committee's work on a number of high priority issues of great importance to the NRC. His technical and administrative acumen, and in particular his deep understanding of the NRC's regulatory practices -- which is no small feat I can assure you -- have

made him a strong leader and an effective spokesperson for the committee in his interactions with the Commission. I should note that Dr. Malmud's work on this committee has been so well respected by his colleagues that he has served an unprecedented three terms as chairman. And under his leadership the staff has enjoyed a positive relationship with the committee and I know the staff is very, very appreciative of that. So thanks to his efforts, the committee is well placed to continue its successful work after his departure. So Dr. Malmud, on behalf of the Commission, I'd like to present you with this flag which was flown over the U.S. Capitol, and this pin which -- I'm not going to open the endless boxes, you can do that -- as tokens of NRC's great appreciation for your service. So my colleagues and I definitely want to convey our deep gratitude to all of your service.

CHAIRMAN MALMUD: Thank you

[applause]

Yeah we can do a handshake.

NRC CHAIRMAN MACFARLANE: Handshake?

CHAIRMAN MALMUD: Okay

NRC CHAIRMAN MACFARLANE: Okay? Great. Here you go! Try to keep track of this.

[laughter]

And I think you even have a letter from congress.

CHAIRMAN MALMUD: Oh. Thank you very much.

NRC CHAIRMAN MACFARLANE: You're welcome. Got it?

CHAIRMAN MALMUD: Yes. Thank you.

NRC CHAIRMAN MACFARLANE: Thank you.

CHAIRMAN MALMUD: Can I say a word or two?

NRC CHAIRMAN MACFARLANE: Please.

CHAIRMAN MALMUD: It's been a genuine honor and privilege for me to serve with this committee and your predecessor. This group represents a considerable fund of knowledge of various disciplines related to radiation patients. Every member of this committee, current and past, that I've worked with has had the best interests of the public in mind, the patients obviously, and the interaction between the NRC and us as we struggle to make the right decisions for the ultimate outcome, which is patient safety and public safety.

Each of you is a scholar in his or her own right. And it's unusual to have a committee as diverse as this one with the knowledge that all of you have, and it's truly been an honor for me. In addition to that, I would like to thank the members of the NRC staff who have made this work easier for us, who have worked earnestly to accept our opinions even when they differ, and to integrate them into final decisions that are in the best interest of patients and the public. The group here at the NRC is similarly distinguished and dedicated as all of you are. So for me it's been a joy to try and bring us all together and come to the final decisions and recommendations which are -- serve our patients and the members of the public so well. And I thank all of you for you your participation and cooperation at every level. It's been a true joy. Thank you very much.

[applause]

MR. MCDERMOTT: Thank you Dr. Malmud. So Dr. Malmud's retirement from the committee also requires that NRC appoint a new chair of the committee. As such I'd like to announce that Dr. Thomadsen has agreed to serve as chairman of the ACMUI and that Dr. Guiberteau has agreed to serve as vice chair. So I'd like to welcome you both to --

[applause]

So at the conclusion of our meeting on Tuesday, there'll be the passing of the gavel, of the baton or whatever it's going to be --

[laughter]

-- and we appreciate the [inaudible] for the committee. Now I will turn it back over to Dr. Malmud.

CHAIRMAN MALMUD: And I will turn it immediately over to Ashley Cockerham.

MS. COCKERHAM: Good morning. I am going to start with 2007. I'm just going to go through the part of the recommendations that have been updated or any items that have changed since the last meeting. So we're going to drop down to item number 35 and this says, "NRC staff should not revise 10 CFR 35.491 intended for ophthalmologists to include training and experience for the new intraocular device; this is the NeoVista device." We actually issued guidance on this in April of 2009 so this recommendation is closed. NRC decided to regulate this obviously under Part 10 CFR 35 Part 1000, and we have current guidance on this. So it's not a part of the regulations but we did consider

the ACMUI's recommendation in writing the guidance. So I'm going to close that one out for this chart.

We move on to 2008. Item number nine: This deals with the AO subcommittee report, and we're going to be discussing this item this afternoon. For item number 28, okay -- I'm going to attempt this one -- this deals with the rulemaking 10 CFR 35.65 and transmission sources. The ACMUI recommendation is the NRC staff should revise 10 CFR 35.65 to clarify it does not apply to medical uses. This is in the current rulemaking and the way it's being approached -- this recommendation is partially accepted. So the essence or the intent of the ACMUI's recommendation is in the rulemaking, but we're not removing transmission sources from 35.65. I'm going to look at Sandy Gabriel very quickly to make sure I'm following this correctly. Or Donna-Beth, if you want to go ahead.

DR. HOWE: Yes, you see in the proposed rule that the transmission sources are still in 35.65, but if they're being used for the patient, then they move to 35.500. And we've made it so that a 35.200 authorized user is automatically authorized for the use of the transmission sources under 35.500. That's in the proposed rule.

MS. COCKERHAM: Okay, so I'm seeing Dr. Langhorst shaking her head in agreement. So this is a good thing. So you're -- you agree that we incorporated the essence of what the ACMUI wanted. I'm going to mark this as partially accepted because we didn't fully accept exactly what is written here.

MEMBER LANGHORST: As I remember my one main point was to make sure that if you were approved for 35.200 that automatically got you into 35.500 if that's the path NRC was going with this.

MS. COCKERHAM: Okay. So that's reflected in the proposal -- the draft, the draft proposed rule. Is that correct?

MEMBER VAN DECKER: Dr. Howe?

DR. HOWE: No, no.

MEMBER VAN DECKER: Oh, I'm sorry. I was -- Van Decker. I was trying to ask a question of clarification since it's important. Since it's irrespective of where it sits, a 200 user .290 trainee, will be able to use GAD 153 line sources in their work under this current construct, as we put it together correct?

DR. HOWE: Yes, in some cases if the line sources are aggregated to be greater than what's in 35.65 --

MEMBER VAN DECKER: Right.

DR. HOWE: -- then they'll automatically come under 35.500. If they aren't aggregated, but they're being used on a patient, it'll come under 35.500 and the 200 user is automatically authorized. And you don't have to risk normal license.

MEMBER VAN DECKER: Can I get your last part again please? So you don't have to change --

DR. HOWE: Excuse me?

MEMBER VAN DECKER: The last part of the sentence I didn't hear.

DR. HOWE: Oh the last part of the sentence is you don't have -- if the source is eligible to be under 35.65, which has certain maximum activities, then that source does not have to be listed on a license.

MEMBER VAN DECKER: Thank you.

MS. COCKERHAM: Okay, so I'm going to update this chart to say that it is partially accepted.

MEMBER VAN DECKER: Thank you.

MS. COCKERHAM: And it is a part of the part rulemaking. Okay. Next I'm going to move to 2009. Okay, I wanted to make a point on item number two. We have a recommendation that was made at the May 7th, 2009 meeting, and this deals with parenteral administration of either beta low energy photon emission. We were -- basically we were separating out alpha. I wanted to draw to the attention that in this subcommittee report, the rulemaking subcommittee report that was submitted recently, the committee, I believe, recommended that all -- alpha, beta, everything -- be included in (G)(3), and this recommendation is saying betas in one group, alphas in another group under (G)(4). So there's just a -- just noting that there's a contradiction of two different ACMUI recommendations; so if we want to note that the subcommittee report supersedes this one, I don't know if the committee wants to retract this one, or how we want to document it, but this one's on the record. So if someone went back and looked at this and said NRC is doing a proposed rule in accordance with this recommendation, that's not your final recommendation. Does

that make sense?

CHAIRMAN MALMUD: Yes.

MS. COCKERHAM: Would you like me to just mark it as superseded or would you like me to officially -- I don't know if we officially retract them or --

CHAIRMAN MALMUD: What do you recommend we do as a committee?

MS. COCKERHAM: Some sort of indication that this is no longer your recommendation.

CHAIRMAN MALMUD: Would someone care to comment?

MEMBER ZANZONICO: Pat Zanzonico. I mean I think our intent from the subcommittee report was that they not be separated so that the lateness recommendation supersedes this one.

MS. COCKERHAM: Okay.

MEMBER ZANZONICO: So you just note that.

MS. COCKERHAM: I'm happy to do that.

CHAIRMAN MALMUD: That's noted. Thank you.

MS. COCKERHAM: Okay. For item number -- actually there's nothing to say about item number 10 that's part of the current rulemaking. Moving on to 2011, items 13, 14, and 15 are all dealing with the attestations, and these are all on the current Part 35 expanded rulemaking. Items 19, 20, and 32 -- okay, for item 19 Mr. Mattmuller had asked that NRC staff at ACMUI to the organizational chart on the FSME website. We have done that and during my website presentation we'll show you where that is on the NRC website. For item 20 Dr. Langhorst requested the NRC staff

place historical documents on the ACMUI website and also give a brief history and add ACMUI past membership. The majority of that information has also been added to the website and I'll cover that in my website presentation. For item 32, this deals with the AO criteria and this is going to be discussed later this afternoon.

Okay. For 2012 starting with item number three this is dealing with radium-223 dichloride. The ACMUI issued their subcommittee report and advised the NRC that it should be licensed under 35.300. And we accepted that recommendation and on January 10th we issued a memo to our regional offices transmitting the licensing decision for radium-223 dichloride. This is a publicly available document. We also issued letters to our agreement states, and to Bayer, and we published information in FSME, our office quarterly newsletter, and on the medical list server. For items five, six -- I'm sorry -- five, seven, and eight, those all deal with radium-223 dichloride so all of those will be closed as that licensing decision is final. We jump back up to number six. Dr. Malmud had asked the NRC to find data on events in which the radio pharmacy had dispensed the incorrect amount of a radiopharmaceutical or the incorrect radiopharmaceutical and we provided this information to the committee last October. For item 10, this is dealing with the abnormal occurrence, the AO subcommittee. As I've mentioned we will be discussing that this afternoon and that's also for items 11 -- so 10 and 11 are dealing with AO. And then for item 12 this was the recommendation to

have the meeting today. And we are all here. So we will close that.

For this last chart, these -- this 2013 chart is from our March -- the two March teleconferences so every item on here is regarding the current Part 35 rulemaking, and NRC staff will include the final ACMUI rulemaking report and its recommendations in a paper to the commission regarding the draft proposed expanded 10 CFR Part 35 Rulemaking. And just to note that this -- the final ACMUI report was submitted to NRC staff on April 3rd -- April 9th -- thank you, Sophie -- and it's available on the ACMUI public webpage and that's all I have for this speech. Any questions or comments or changes to any of these?

CHAIRMAN MALMUD: Are there any questions? Yes, Dr. Langhorst.

MEMBER LANGHORST: Thank you. Ashley on 2009, I just, curiosity, question number nine is about the medical event subcommittee. I just wondered why that's being carried on. I mean the subcommittee was formed and --

MS. COCKERHAM: We can close that out.

MEMBER LANGHORST: Okay.

MS. COCKERHAM: It's still an existing subcommittee but it --

MEMBER LANGHORST: Right.

MS. COCKERHAM: -- fit the membership changes as the membership changes.

MEMBER LANGHORST: Right, and I just noted that Ms. Gilley's no longer on that.

MS. COCKERHAM: Thank you.

MEMBER LANGHORST: You're welcome.

MS. COCKERHAM: We'll update that.

MEMBER LANGHORST: You're welcome.

ASHLEY COCKERHAM: Any other comments? Okay. That's all I have.

CHAIRMAN MALMUD: Any questions for Ms. Cockerham? No questions? Back to the report. You're up next?

MS. COCKERHAM: Yes.

[laughter]

CHAIRMAN MALMUD: The next item is the webpage update.

MS. COCKERHAM: Yes.

CHAIRMAN MALMUD: Which you also handle.

MS. COCKERHAM: Yes. So for the main page, basically we've condensed things down a little bit. Most of the information is still the same. The membership and history and -- or we added history, which is what Dr. Langhorst asked for. So if you look at the bulleted list on history we can go to that. And here we have some information that actually dates the ACMUI back to the Manhattan Project, so if anyone's interested in reading how you originated, all that information is contained here up through the Atomic Energy Commission, and through the NRC, and to the current name now. And here is the list of historical members, to the best of our ability [laughs]. Yeah. So we'll just keep adding to this list as individuals rotate off the committee and keep a running list of things

here. The other thing -- the main thing that we've changed here, there used to be individual links for meeting transcripts, meeting summaries, meeting agendas. All of those were listed as bullet points near the bottom of the page; now if you look on the right hand side it says related information. All of the ACMUI committee meeting and subcommittee report information is all contained on this page. So the first link is the meeting and related documents. If you click on that, it is all separated by year. This is very similar to how the Commission public meeting website looks and how the ACRS website looks. It's separated out by year, so if you put 2012 -- now we have charts where everything relating to one particular meeting is in one place. So you don't go to an agenda page that lists all of the agendas for the ACMUI. You go to which meeting you want to go to and then you would have the agenda and then the transcripts are all available, and then any meeting handouts, the e-binders that we now get, direct links to all of those. And it's all on the public website in one place.

We go back to subcommittee reports. These were all initially listed on the ACMUI home page; it said "related information" and all of the subcommittee reports were listed. Now we list them out by year and they all have titles, topics, you can see, and we'll just keep adding to this as new subcommittee reports are issued. Did we have any other major changes?

MS. HOLIDAY: Membership page.

MS. COCKERHAM: The membership page -- so the membership page, we have the lovely group photo. So we've been taking more of those as you come in so we have the most current membership on the website each time, and then you're individual bios and individual photos are all still listed here. And if you ever have any updates to your bios, changes, employment, or professional societies, things like that, it's very easy for us to update your information. You can always provide that to Sophie or to me.

I believe that's it. Any comments or questions? I know a lot of this -- oh the FSME website. Do you want to go to FSME external? Okay. While Sophie's doing that I can entertain any questions.

CHAIRMAN MALMUD: Questions for Ms. Cockerham? Dr. Langhorst?

MEMBER LANGHORST: I just want to thank you very much for all this work and I really look forward to exploring some of the history and looking at past membership. I find it very helpful in giving me a base in working with a committee and learning some of the discussions that have happened in the past. So I thank you very much for everyone's effort on that.

MS. COCKERHAM: You're welcome. I have to give credit. We had a gentleman who was here, Jeff Kowalczik, was on rotation I believe it was the last meeting, and he really was the driver for getting all this done. And then Sophie and I kind of just saw it through.

MEMBER GUIBERTEAU: I want to thank you, too. And

also on behalf of our stakeholders because I think you know websites can either be friendly or intimidating, and I think this is very nice for those who are interested, you know, in medical use of isotopes to really come on and easily find the documents that they need.

MS. COCKERHAM: Thank you.

CHAIRMAN MALMUD: Since thanks to you are being offered I want to echo those thanks. You've been an extraordinary help to me personally over the time that you were in the position that Sophie is in currently, and I want to publically thank you for having made what could have been difficult task much easier.

MS. COCKERHAM: Thank you.

MS. HOLIDAY: I don't know how to get to that to go on.

MS. COCKERHAM: Just go to Google.

[laughter]

Yeah. I wouldn't know how to navigate there from our internal website either. Under at -- go to the top -- FSME the tab, it says FSME office directory, kind of in the middle on the right. There you go. So if you look here you can see the link has already been clicked. ACMUI is now listed under our FSME directory, and it links directly to your new and improved ACMUI webpage. Over there in the back -- and if you go through this webpage and you find anything, links, you know, when you're reading or information that you think should be added that we're missing, please let us know. It's easy to add now that we kind of have the

framework and the actual pages in place, it's much easier to manage now. Okay. That's it for me.

CHAIRMAN MALMUD: Thank you.

MS. COCKERHAM: Thanks.

CHAIRMAN MALMUD: We are now 15 minutes ahead of schedule. We can take a break if that's okay with Mr. Einberg.

MR. EINBERG: Okay, that's fine.

CHAIRMAN MALMUD: In which I'll re-resume at 11:00 in order to maintain the schedule that's been shared to the public?

MR. EINBERG: Yes, sir.

CHAIRMAN MALMUD: So we will resume at 11:00 promptly. Thank you.

[break] [resume at 11:00am]

MEMBER ZANZONICO: Okay, well, I guess I'll begin then. So, good morning everyone. And what I'll be doing is kicking off. And literally, we'll just be kicking off. I understand this is intended to be an open discussion among the ACMUI and the NRC staff on the draft guidance to the 2013 proposed expanded 10 CFR 13 Rulemaking. And as I mentioned earlier, both with respect to the subcommittee report on rulemaking and on -- this being the case, I really have to extend my personal thanks to Sophie Holiday, who was really invaluable in both efforts. So, by way of introduction, and this is sort of a user's perspective, so it may not reflect rigorously the NRC's perspective, but from a user perspective, the regulatory guidance or reg

guide provides practical instructions, the emphasis on the word "practical," on compliant preparation of license applications. And so, the regulations themselves which are often, at least for me, difficult to read and interpret, define officially the why, while the reg guides describe the how. And the reg guides are indexed to the applicable regulations, to the applicable sections of the Code of Federal Regulations. And it's a resource used by licensees for regulatory compliance overall as well as license applications, because we all know the reg guides include, among other things, these invaluable model procedures for virtually all aspects of use of the medical use of radioactive materials from the point of view of radiation safety, and though we have found those model procedures to be invaluable. So as I say, I think the scope and utility of the reg guides extend well beyond license application, but to compliant performance and execution of a license, as well.

So, again, the official scope of the regulatory guide is with respect to compliant preparation of licensed applications. And in the latest reg guide, there is really very extensive documentation and forms provided on the training and experience requirements for authorized users, authorized nuclear pharmacists, authorized medical physicists and authorized radiation safety officers. It also describes the record-keeping requirements. And as I said, the model procedures, which are very often extensively relied upon by licensees for compliance implementation of

their licenses, and the draft reg guide also includes and number of sample forms. So, the reg guide we're considering at the moment consists of three parts. There's a part on medical licenses, that's Volume 9, Consolidated Guidance About Material Licenses for Medical Use Licenses. Part 2 is for commercial and radio pharmacies, that's Volume 13. And only those sections that are affected by the proposed rule, where there are changes in the proposed rule are included, and they are redlined very helpfully to identify the specific changes between the proper Part 35 in the proposed rule. And then there is a - also very helpful Part 3 with Q-and-A, questions and answers, that provides additional useful information for licensees beyond simply license preparation. So we'll use a comprehensive document complementing the proposed rule itself.

So, my overall take on looking carefully at both the proposed rule and the draft guidance, is that it really recapitulates accurately and comprehensively -- the draft guidance does -- the visions in the proposed rule, it has material on the associate RSOs, training and experience issues relating to resolution of the Ritenour petition. It indicates or documents the elimination of preceptor attestation requirements for board-certified individuals. It also changes the attestation language to now read in multiple points in the reg guide that the attester is able to independently fulfill radiation safety-related duties and it eliminates attestation to the effect of competency. A -- it also includes a seven-year rather than five-year

inspection servicing requirement for gamma stereotactic radiosurgery units. It documents the requirement for testing of every generator elution rather than the first generator elution prepare and breakthrough. The requirement for notification of the NRC by licensees of generator elutions with out of tolerance and with breakthrough. It includes the authorization for use of alpha emitters, which was recommended by the subcommittee. And also, includes information on the new activity-based definition of a medical event for permanent implant brachytherapy. These, again, are largely addressed in the question-and-answer section.

So, simply summarized, as I said, I think the draft guidance reliably recapitulates the proposed rulemaking, in that it incorporates all of the changes, as far as I can see, from the prior to the proposed rulemaking. You know, the important changes are highlighted -- are highlighted, a red line. It provides very well structured forums for training and education requirements for all authorized professionals consistent with the new attestation requirements and so forth. And, in the Q-and-A section, it includes useful supplemental information on the proposed rule or consistent with the proposed rule. But overall the NRC staff has really done a very good job in generating the draft regulatory guidance and I think it -- for the end users, for the licensees, it really is a very helpful, complete and so forth reg guide.

So, that really completes what I had to say. Here

are the usual list of abbreviations and acronyms used in the presentation. But otherwise, that concludes my formal presentation.

CHAIRMAN MALMUD: Thank you, Doctor Zanzonico. Are there comments from the staff or question? Doctor Langhorst.

MEMBER LANGHORST: Thanks, Pat, very much for that summary. I just want to express my appreciation for the NUREG documents, as one of those people who has to do licensing and having just gone through hopefully the last renewal of a license I'll ever have to do. These new reg documents are invaluable. I know, Pat, you were referring to them as regulatory guides, and those really are a little bit different section than the NUREG documents, the 1556 documents. I have a question, and maybe Doctor Howe can explain this a little bit. It's -- the first section obviously is Volume 9 and then Volume 13 is the --

[coughing]

-- [unintelligible]. Where will the question and answer section of this guidance for Part 35 -- where will that reside in these various guidance documents?

DR. HOWE: I think what we're expecting to do is to put the questions and answers up on what the medical toolkit so that they're available on the website to anyone that needs them.

MEMBER LANGHORST: It was unclear if they going to be in any of the NUREGs or not.

DR. HOWE: No, because the whole reason we came up

with the Qs and As is because they don't deal with submitting a license application, right? They deal with, well once you've got a license, how do you understand changes in the regs? So, they won't go in the NUREG Volumes 9 or 13.

MEMBER LANGHORST: Thank you for that clarification --

[coughing]

CHAIRMAN MALMUD: Other questions or comments for members of the committee? Yes, please.

MEMBER MATTMULLER: And maybe we're stealing part of Leon's thunder, but, at this point, what we saw for the proposed regulations, will those be modified at all by what our subcommittee reported on for the current regulations -- refer be -- I guess, the term would be the final proposed regulations that go into the Federal Register for official public comment?

DR. HOWE: Yeah, this document was development to match one-on-one the draft proposed that you reviewed. It does not include --

[coughing]

-- the thing concerning your recommendations. Your recommendations and other recommendations will be fed into how the proposed rule is modified, and when it goes out, then we will also have --

[coughing]

-- this to match any rules text changes that appear in the proposed rules. So, this is an early draft

proposed guidance document and it will have to match the proposed rules. And right now, we don't have a proposed rule. We're still working on comments.

MEMBER SULEIMAN: Just for -- Orhan Suleiman -- just for clarification, what we -- what this is as a draft-proposed rule that hasn't been published yet in the Federal Register.

DR. HOWE: That's correct.

MEMBER SULEIMAN: And after it's published in the Federal Register, it will still be a proposed rule for public comment, after which the NRC will take in all the input, convene, and at some point, publish a final rule.

DR. HOWE: Yes. Our intent is to publish the availability of the guidance, but when we do publish the availability of the guidance, this guidance may be revised to match the proposed rule. So, it may not be exactly what you're seeing right now. And then we have a final guidance that comes out with the final rule.

CHAIRMAN MALMUD: Thank you. Doctor Langhorst.

MEMBER LANGHORST: Thank you. I'm going to say that this will really make me look like a regulatory geek -

[laughter]

-- so I just want you guys to understand this. On the docket for the proposed rulemaking, will these guidance documents be under that same docket number or will they be in a separate document -- docket, excuse me -- docket number? I ask that because Part 37 you found the rule in one place and then you found the guidance document, if you

were lucky, in a completely different docket number. And I found that very confusing, so I hope NRC puts this all together so the commenters know where to find all the documents involved with the regulations.

CHAIRMAN MALMUD: Ms. Bhalla, do you have any insight regarding that perhaps?

MS. BHALLA: Sure. Yeah. Good morning, this is Neelam Bhalla from NRC. With regard to the docket numbers, we are pretty much bound by administration -- administrative procedures, so I'm pretty sure that the proposed rule has a -- is our docket number, I even remember the number, but the guidance is going to be under a separate docket -- separate docket number. But now that you have brought this forward, we would go back to admin and see if we can merge these. But I really have my doubts. So, I think it's set to go under a separate docket number.

MEMBER LANGHORST: At the very least -- this is Sue Langhorst again -- at the very least, make it very clear this is where you find this, and this is where you find this because I don't think it was as clear as it could have been in the Part 37 development. So, I know that's a totally different rule, but I just encourage you to make sure that the public and us, those who will be commenting on this know where to look for guidance and where to look for proposals.

DR. HOWE: I think what may help is we have control over the medical toolkit and for folks that know and use the medical toolkit, we've got a place in there for rulemaking and also for guidance. And so, we'll make sure that we have

the draft rule up there and we'll make sure we have the draft guidance up on the medical toolkit. And that way -- that's where we're planning -- that's where I'm planning on putting the draft guidance.

MEMBER LANGHORST: Thank you so very much.

CHAIRMAN MALMUD: Any other comments or questions for Dr. Howe? I just wanted to just get back to this -- initial comments you made, so my understanding then is that the draft guidance is going to be divided into two NUREGs? And then the Q&A is not going to be a hard copy document, for lack of a better term, but it will just be posted on the website.

DR. HOWE: That's our plan right now. We're -- as we indicated on our cover, we're not revising the NUREGs, the two NUREGs, right now, the medical NUREG or the commercial nuclear pharmacy NUREG because we've got another working group that's revising that for other reasons. And so, when they get to the end of their product, our supplemental information that you're reading here will be folded into it. So, there will be a NUREG guide that covers the rule and the other changes that are having to be made to the reg guide to bring them up to speed, because a lot has happened in the 10 years since they were last published. And, so that will happen for the commercial pharmacy and the medical, but the Qs and As, we do have a section on a medical toolkit that talks about Qs and As and we'll work this up on our medical toolkit so that it's publicly available at any time.

MEMBER ZANZONICO: So, that's -- this, with respect to the logistics of the rollout, because you say that updating the NUREGs is a separate effort. So, I'm sure you do this, but how do you kind of ensure that these things are rolled out simultaneously so that there's not discrepant information out there for the licensees?

DR. HOWE: We've got a separate working group that -- Ashley's actually in charge of the one for the Volume 9 for the medical licensees, and then someone else is involved for the Volume 13, the commercial nuclear pharmacy. And we've got a project manager in in FSME that's responsible for the whole thing, so we'll be working closely with them to make sure that these things come out at the same time, that at the very final part, our information as based on the final rule is inserted into the NUREG document with the other updates that they're doing.

MEMBER ZANZONICO: So there will be an old NUREG out there at the same time the new rule is in effect.

DR. HOWE: I don't think so. I think the idea is that we can't make these changes to the rule -- to the reg guide, until the rule comes into effect because then it could change again. But the other group is working on other issues and we're going to mail them at the same time. And instead of having a number of different volumes coming out, like one for this one, then two weeks later there's another one for the other one, we're going to try to merge them together so there's one revision.

MEMBER GUIBERTEAU: And Doctor Howe, when do you

anticipate that this particular document will be posting?

DR. HOWE: This particular document will be posted when the -- well, the proposed guidance will be posted at the same time that the proposed rule goes out, or within a day or two.

CHAIRMAN MALMUD: Thank you. Mr. McDermott.

MR. MCDERMOTT: I'd just like to add for everybody's benefit, the Commission's established expectations of policy for the staff relative to rulemaking that come into play here. And so, part of what you're seeing is their direction to the staff to have proposed guidance documents available at the same time the draft -- the proposal for a draft rule goes to the Commission. So, you all got the early view on it and get to provide your comments and then they may get incorporated. But -- so, it's really two steps. In the past, which remains true today, is that when the final rule is available and approved by the Commission, the final guidance has to be available. So, we're doing things a little earlier now at this proposed rule stage where we have to have both the rule text and the guidance documents coming together. So, we would not have a situation, as Dr. Zanzonico mentioned, where we get the rule out and don't have any guidance. The Commission has made sure that we understand the importance of having those two things together.

CHAIRMAN MALMUD: Thank you. Mr. Mattmuller.

MEMBER MATTMULLER: Yes. Dr. Howe, on Page 15 --

DR. HOWE: On which one are you on?

MEMBER MATTMULLER: Page 15.

DR. HOWE: Okay.

MEMBER MATTMULLER: Second paragraph in regards to production of radioactive drugs that refers to 206AA. And for the life of me, I couldn't find Appendix AA.

DR. HOWE: Oh. You were only given the parts of the reg -- of the NUREG that we revised. And so, if we did not revise Appendix AA, then you will not see it.

MEMBER MATTMULLER: Thank you for that clarification.

CHAIRMAN MALMUD: Other questions or comments?

MEMBER VAN DECKER: Yes, doctor. Van Decker. Just one more clarification because I'm trying to get straight. The proposed rule will be published, within a couple of days the proposed draft guidance is published to match the proposed rule that we've been discussing. Somewhere in the midst of all this, there's a second process looking at the NUREG. So, I assume that whatever that process is and whatever that input is is also open to comment once it gets published. And so when the proposed draft guidance document gets published a couple of days after the proposed rule, it will have both reflections of the rule plus reflections of this second process for comment at the same time? Or is it non-commentable pieces of the process?

DR. HOWE: There will be an opportunity to publicly comment on the changes that are being made to the NUREG that have nothing to do with the rulemaking.

MEMBER VAN DECKER: Okay.

DR. HOWE: That will come out at a different time. It is the final document where they merge them together. So, you'll have -- we're going to call this a supplement to those NUREGs and my feeling -- my belief is that they will stay separate so that you'll get to comment. The other ones are dealing with security and other issues that don't involve rulemaking. And they're across the board for all of our NUREGs. And so, you'll get a chance to comment on those, then you get a chance to comment on these, and then in the end, they'll merge together.

MEMBER VAN DECKER: All right.

CHAIRMAN MALMUD: Dr. Van Decker?

MEMBER VAN DECKER: I accept that as a clear clarification of where this is going.

[laughter]

MEMBER VAN DECKER: In my mind.

DR. HOWE: Anyway, okay.

CHAIRMAN MALMUD: Other comments or questions? Dr. Van Decker?

MEMBER VAN DECKER: I just have one more tangential comment, you know, I just happened to be looking through some of this and recognizing that in our attempt to be simplistic in preceptor paperwork of this 313A form, we now have a series of 313A forms relating to all the different subgroupings of training and experience, which made me nervous when I first slipped through it, but looking at the one that would reflect my constituency the most, I

think it would probably work just fine. So, as long as everyone else is satisfied with the piece of their constituency, it's okay. But, you know, for a variety of reasons, it does make things a little bit more diverse, but it's a complicated subject and I don't think this was an unreasonable way to approach it.

DR. HOWE: When we published the forms in response to the 2002 rule, we were still operating under the model that we should have one form and it should cover everybody. And we got a lot of comments that said, "This is way too confusing. I don't know what I'm supposed to do. I don't know how I'm supposed to throw it out." And so we went back and we revised the forms after 2000, and split them into the 313A series. So each type of authorized user or medical physicist or pharmacist was covered by a form that grouped similar uses. And so, that's not a new concept and we're carrying it on because we've gotten positive comments.

CHAIRMAN MALMUD: Doctor Langhorst?

MEMBER LANGHORST: In regard to the 313A forms, they are forms that you can use or you can submit the same type of information, and I know I kind of like the one that was all together because we have a lot of -- our authorized users who do a lot of different things, and so we have combined some of those in our own use of those forms and trying to meld those, so, I appreciate the forms out there. And they're very easy to fill out when you've got the simple -- I don't mean simple -- when you've got the one use, but if you have multiple uses, you have that option of combining

that -- some of that similar information.

DR. HOWE: And Sue brought out an important point. The NRC form 313, which is how do you apply for a license, that's a requirement. The use of the NRC form 313A series, are voluntary.

CHAIRMAN MALMUD: Doctor Langhorst.

MEMBER LANGHORST: Doctor Malmud, I have a logistics question. Are we going to just step through this NUREG document or are we -- should we bring up points that we don't think may be covered in what our Part 35 report suggests, or how are we to tackle this stuff?

CHAIRMAN MALMUD: It seems to me that we should bring up the questions that you have. Do we need to go through this in a stepwise fashion in part of the document?

CHAIRMAN MALMUD: Whatever your preference is.

MEMBER LANGHORST: I don't think so, but I didn't know what others' preference was.

CHAIRMAN MALMUD: Is there is preference to go through the whole document step-by-step, or just to raise questions with what's relevant to it? Dr. Zanzonico?

MEMBER ZANZONICO: Well, my preference would be not to go through the whole document --

[laughter]

-- having gone through the whole document.

[laughter]

CHAIRMAN MALMUD: We've been all waiting to hear the recommendation.

[laughter]

CHAIRMAN MALMUD: That's the answer to your question, Dr. Langhorst.

MEMBER LANGHORST: Okay, then I'm going to be leaping through my comments here to see if I have any to bring out.

CHAIRMAN MALMUD: All right. Shall we wait for you to lead?

MEMBER LANGHORST: No, you should not wait for me, please.

MEMBER MATTMULLER: Mr. Mattmuller. While we're waiting -- as you'll hear me talk tomorrow about the schedules, maybe this is why this has really stuck in my mind. But Appendix AA in 30.33, I'm not seeing Appendix AA listed in 30.33.

DR. HOWE: Are you talking about the regulations?

MEMBER MATTMULLER: Or is Appendix AA referred to an appendix in the different guide?

DR. HOWE: What page are you on and which -- are you on Part 1, 2?

MEMBER MATTMULLER: I'm still back on page 15.

DR. HOWE: But are you on Part 2? You're in the pharmacy side. I've got two page 15s. Oh, okay. Are you on Appendix C on page 15? We now have each -- Part 1 goes 1 through to the end. And Part 2 goes 1 through to the end. So I've got two page 15s.

MEMBER MATTMULLER: Sorry. This is page 15 of the document Sophie sent us two weeks ago. Production of PET radioactive drugs.

DR. HOWE: Oh, okay. That Appendix double A is the appendix in the reg guide, but we did not change --

MEMBER MATTMULLER: Change to any reg guide, okay, I'm sorry. I was looking in the regs and didn't see it.

DR. HOWE: No, it's not the regs. It's in the reg guide.

MEMBER MATTMULLER: Okay. Thank you.

CHAIRMAN MALMUD: Dr. Langhorst? Ready?

MEMBER LANGHORST: One of your recommendations that the committee made with regard to the associate radiation safety officer was to allow broad scope type A licensees to have an exemption to be able to internally approve those and list them, much like they do for authorized users, authorized nuclear pharmacists, authorized medical physicists. If the staff puts that in, then will they -- will you then also be modifying the NUREG 1556 Volume 11? I warned you it's going to be geeky, Volume 11, which has to do with broad scope licensees?

DR. HOWE: If we accept it, it would be for Part 35 broad scopes. And we address the Part 35 broad scopes in Volume 9.

MEMBER LANGHORST: The volume 9, okay.

DR. HOWE: Volume 9. So, it would stay in volume 9.

MEMBER LANGHORST: Okay. It might be worth revising when you get around to revising volume 11 someday, as I know that that references medical broad scopes sometimes, too.

DR. HOWE: It should send them over to Part 35 for things that deal with medical stuff.

MEMBER LANGHORST: Thank you.

CHAIRMAN MALMUD: Thank you, Dr. Langhorst. Did you wish to take another leave?

MEMBER LANGHORST: Yes, because I'm looking for my next comment, so I --

CHAIRMAN MALMUD: All right. While you're doing that, are there other questions from members of the committee, or comments? Although we will await your next comment, Dr. Langhorst. Oh no, Mr. Mattmuller. I'm sorry.

MEMBER MATTMULLER: We work together. I'll buy her some time. This is looking in terms of gallium 68 -- or excuse me, gallium 67, how that might be licensed in the future, because the gallium itself won't be used as is, but it will be used as part of a, in FDA terms, as a component to part of the radiopharmaceutical. And so, looking at how or why you would list it in the application, have you given any thought as to gallium 68? I'm getting my numbers mixed up. I'm sorry, gallium 68, the positron radionuclide, how that might be dealt with in the future.

CHAIRMAN MALMUD: Excuse me, for clarity, are you referring to gallium 67 sufrate or gallium 68?

MEMBER MATTMULLER: I apologize. I said 67. I mean 68. The PET rating. Investigational right now.

CHAIRMAN MALMUD: Yes. Okay. Thank you. That's the question. Sorry.

DR. HOWE: We don't necessarily regulate by

specific drugs. We regulate by medical modalities. And so, if it is being used for a modality that's currently in here, it would come under that modality. There are special cases where we put things into 1,000, that's understood. So, if it's a PET drug it's going to be used for imaging, then it would come under 200. We don't -- you would have to list the isotope, but your use would be 200. And so it wouldn't be any different. We don't list all the isotopes that are being used under 200 in the reg guide. It would be up to the licensee to list them, what they're planning on using. Does that answer your question?

MEMBER MATTMULLER: Well, actually the answer I was hoping to hear that as long as the product has FDA approval as diagnostic, that it would fit under 35.200. But the other reason I asked is because looking at the form on Page 96, there are a few individual ready nuclides that have been singled out, such as F-18, O-15, and C-11.

DR. HOWE: You list the -- you generally list the kind of the isotopes you're going to be using, but your approved use for it will be under the modalities. And you have to list some isotopes if you have a lot of them. And what page were you on for that?

MEMBER MATTMULLER: Ninety-six.

DR. HOWE: Ninety-six. And one of the things -- the reason that you're -- you have a list of F-18, is this was meant for someone that is producing a PET radioactive drug under 30 to 32J. So that's the non-commercial distribution of production. You've got the accelerator,

you're part of a consortium, and you're making it for non-commercial distribution. And the same with the Oxygen-15 and the Carbon-11, so we were listing those because you are making huge amounts of those. But if you were the recipient of it, it would probably come under any byproduct material permitted under 35.200, which is the example given above that.

CHAIRMAN MALMUD: Does that answer?

MEMBER MATTMULLER: I think so, yes.

CHAIRMAN MALMUD: Dr. Langhorst?

MEMBER LANGHORST: I'm sorry. I'm desperately trying to find the page number in the packet here versus what I had on my e-book, and it's not meshing. But, this has to do -- my question has to do with the training for staff directly involved in administration or care of patients administered byproduct material for which a written directive is required. This has to do with the vendor training required for those things under 35 --

DR. HOWE: Six hundred?

MEMBER LANGHORST: Six hundred, yes. I just asked -- and I was confused by this as we were doing our review of the proposed rule -- I think it needs some clarification and I think it would be really helpful here in the guidance document about who has to take that vendor training. I -- it's not clear to me if you're saying obviously the authorized users, the authorized medical physicists, but all of the radiation workers or operators -- I think there needs to be some additional clarification of who you're expecting

to take this vendor training prior to first use of a new unit or after manufacturer upgrades that affect operational and safety of the unit. So, I just -- I think it needs just a little bit more explanation of who all you're talking about. And I think it needs -- and I may have missed it in subsequent descriptions, but then what's your expectation of new people coming on that it doesn't have to necessarily be vendor training or you're saying it should be vendor training. I was a little confused by that and I think this part of your guidance could explain that a little bit better in your own mind. So, I give you that recommendation.

DR. HOWE: I think what I'm hearing from you is that's probably something we ought to address in our Qs and As because that's where we get into a little bit more detail about why things are done the way they are.

MEMBER LANGHORST: Okay.

DR. HOWE: Clearly in the regulations when we require vendor training, we're requiring vendor training for the authorized user and the authorized individuals, and because we don't have requirements on the other folks below, we're assuming that they're getting it. But they're not the folks we list on the license so --

MEMBER LANGHORST: Okay.

DR. HOWE: -- we would assume that you are giving vendor training to everybody that needs it.

MEMBER LANGHORST: And I'm just not clear that that's -- you're saying that clearly to me. So, I'll ask you to look at that and kind of bolster that a little bit in

whatever form you think is best.

DR. HOWE: Yeah, and that occurs more often after you've gotten your license.

MEMBER LANGHORST: Right.

DR. HOWE: So, that would be more for the Qs and As section.

MEMBER LANGHORST: Okay. Thank you. I'm going to look for my next comment. [laughs]

CHAIRMAN MALMUD: Doctor Suh.

MEMBER SUH: Yes, so, on Page 159 of this document -- I'm just looking for things that I know a little bit about, since I'm a teletherapy gamma stereotactic radiosurgery…, full inspection servicing.

DR. HOWE: [affirmative]

MEMBER SUH: It appears that this sentence was added, this is on full inspection service and replacement at intervals not to exceed five years. It says for each teletherapy, and not to exceed seven years for each gamma stereotactic radiosurgery unit. The area in red, is that new proposal then?

DR. HOWE: Yes, the area in red is the new proposal.

MEMBER SUH: Does such a similar type of proposal exist for high dose rate brachytherapy as well, in terms of when the sources should be replaced?

DR. HOWE: No, because the high rate -- high dose rate remote afterloaders, they change them frequently. And so we don't have an issue of years. I think they're -- but

we don't have a requirement for when you change and when you have to do a full service.

MEMBER SUH: Okay, because, as some of you may know, the replacement of a gamma knife radiosurgeries source is quite expensive. I mean, $800,000 to a million dollars, and I guess the only questions I have is, is it a good idea for us to put a stipulation in terms of when these sources should be replaced?

DR. HOWE: The current regulations require them to be exchanged at five years. And we felt that what we were getting were a lot of exemptions to go beyond the five years, and so we expanded it out to seven to give licensees more flexibility.

MEMBER SUH: I suspect that there may be some centers that are even beyond seven years, with the cost of replacement. Again, it's just more of a -- I just wanted to point that out.

CHAIRMAN MALMUD: Thank you. Doctor Langhorst.

MEMBER LANGHORST: I wanted to add to that that it's not only just the cost, but it's also the availability of the equipment to do that change-out. I know we are -- we had to put off ours because the equipment just wasn't available then. So, there's a lot of resources to take into account to get the slightest change planned and executed.

CHAIRMAN MALMUD: Back to you, Dr. Suleiman.

MEMBER SULEIMAN: I keep on seeing through here a reference to curies and millicuries. Is -- are you guys going to make an effort to include SI units? Just because

somebody's got to make that point, I mean.

DR. HOWE: That would be the other group that's revising the reg guides because that's a more generic question that has to go across the boards for all the reg guides, all the NUREGs.

MEMBER SULEIMAN: I mean, I know some in the scientific community or some of the societies are actually starting to remove reference to the old units. So, as a minimum, we should at least have both of them, you know.

DR. HOWE: I think for most things in here we're supposed to have both. That's the NRC. Maybe we were last.

MEMBER ZANZONICO: If I would say, look, as long as you brought up the issue of units, is there going to be a transition from the effective dose equivalents? That also seems like a dated quantity at this point.

DR. HOWE: We're not looking at that right now.

MEMBER ZANZONICO: Okay.

CHAIRMAN MALMUD: Doctor Welsh.

MEMBER WELSH: If I might ask for further clarification regarding Dr. Suh's point; if I'm reading this correctly, it is not insisting upon replacement of the cobalt at seven years. It's just advising about full inspection and servicing, correct? It is not mandating a change in the isotope at that point.

DR. HOWE: The concept is there may be parts of the gamma knife unit that can only be fully inspected and serviced when there are no sources. And so it is expected to go along with the source exchange, and with a teletherapy

unit, you don't necessarily have to exchange the sources at the five-year point, or you may exchange them earlier. But you don't -- you can do your full service and inspection without exchanging the sources. But the gamma knife, you've got to exchange all your sources to get into the areas that would be too much of a high radiation area to look at. And so, the concept is it's done at source exchange. That's what this particular test is supposed to be. Other tests that are lesser that you can do while the sources are in, you're supposed to keep doing those. But this is supposed to be your full service and inspection. And that was part of the rule change that we made.

MEMBER WELSH: So, if that is the case, then I would concur with Dr. Suh that this is a potential concern that goes beyond the monetary issue of how expensive it is to exchange the sources, because at five years or even seven years, it could be that the clinical dose rate is still acceptable for the practitioners to continue to use that gamma knife without necessarily exchanging the sources at this very expensive cost. So, I'm just wondering if five years is inappropriate, but seven years may still be a little bit restrictive.

DR. HOWE: I would take that to be a comment more on the proposed rule because we are taking the proposed rule and implementing it into guidance.

CHAIRMAN MALMUD: Dr. Langhorst.

MEMBER LANGHORST: Dr. Malmud, I didn't have any other comments that didn't touch upon what Dr. Howe had just

said, that we'd already discussed on our recommendations for the draft proposed rule.

CHAIRMAN MALMUD: Thank you. I think a member of the NRC staff did have a comment. Ms. Bhalla?

MS. BHALLA: Yeah, about the regulation that has to do with the service of the -- full service of the gamma knife or our teletherapy unit, for a five-year -- at strength now at five year, and it is to -- if you read that whole regulation, it is to assure the shutter mechanism of the unit. So, in gamma knife, the staff has determined that the beams are all -- or the sources are all fixed. And the shutter where you control the beam for where it's hitting the decease volume, is based -- is by using the plugs on the helmet. So, therefore, the shutter mechanism is like a stationary mechanism, so that when you -- your -- you are quite assured that that mechanism is still functional, even when you have gone beyond the five years. And it so happens that when exemptions came to NRC, they asked for the seven years. Seven years seemed to be a more workable solution for these -- for the gamma knives. Now if you go back to a teletherapy unit, there the source drawer mechanism, the actually -- the culmination is not a fixed system. It is a moveable system in terms of -- I think if you all -- maybe some of us can remember the teletherapy unit where the source drawer is actually coming in and out, and they're having cases of sources being stuck. So, therefore, it was always -- and that part of the servicing could only be done when the source is out. And you have a 5 curie source, I'm

just saying, even after it has decayed to one-half life, is a still -- is a very important source. So, in order to service a teletherapy unit for the source, in and out mechanism needs that source to be out. And therefore, it was decided upon way back when that this should be done, the source, that the servicing of, to ensure the shutter mechanism, needs to be done at the same time that the source is being replaced. And therefore, it was efficient. It was workable to have that source out, replace the source, and at the same time while the source is out of the unit, that they could actually go in and do the servicing of the shutter mechanism. So therefore, the -- for the teletherapy, we have still kept it as five years. But for the gamma knife, it's gone to a seven year. So, that's the long explanation for what we are doing here.

CHAIRMAN MALMUD: Thank you for the explanation. Does that answer the question? Certainly clarifies it. Is there another item you wish to present to us? That's it. Any other items? If not, thank you, Dr. Howe. Dr. Zanzonico? Are there any other items to be brought before the committee now before the break for lunch at noon? NRC staff, anything you want to mention? Sophie, Ashley, anything? Chris?

MR. EINBERG: Yeah, I would suggest that we're running considerably ahead of schedule. Right now we look towards the afternoon. The afternoon we had time allotted to discuss the rulemaking guidance further until 2:30. I would suggest that when we come back or during lunch time

we'll take a look at the agenda and see if we can move some items from tomorrow's agenda to today to fill that time slot.

CHAIRMAN MALMUD: Thank you. Then, in the meantime, we will take a break, which is scheduled to begin at noon. And we'll reconvene at 1:30. We'll reconvene in this room at 1:30.

Thank you.

[break] [resume at 1:30pm]

CHAIRMAN MALMUD: Okay, ladies and gentlemen, there are a number of changes to the agenda, and it's been distributed to you. If you'll take a look at it, you'll see that some meetings have been shifted; others have not. And Ashley can explain to you why the agenda was moved in the fashion that it has been moved.

MS. COCKERHAM: Okay, this is Ashley. And previously item 15, that was going to be on the agenda for tomorrow, is going to be -- is the new item number 9. So Dr. Donna-Beth Howe is going to present on medical events. Everything tomorrow morning will remain the same. We'll take a break. What was item number 17 is now item 15. What was item 18 is now item 16. And item 16 is now item 17 but it remains at the same time. And then we'll have a closing session with Sophie, and we'll end at 12:15 instead of 2:30.

CHAIRMAN MALMUD: Thank you. And we'll move right on to the next item on the agenda, which is Dr. Howe's discussion of medical-related events.

DR. HOWE: Thank you, Dr. Malmud. Every year I

give you a -- can I get my slide? I give you a quick overview of the medical events that happened for the last fiscal year. So in the case, we're talking about Fiscal Year 2012, which ended October 1st, 2012.

The first thing I'd like to do in these presentations is give you a little bit of a perspective. Where were we in 2011 and where were we in 2012? In 2011, we had 58 medical events reported, and in 2012 we had 48. So we have a slight decrease. Now you have to keep in mind that we've got probably about 7,000 medical use licensees, so this is a very small number, so we're not really talking about statistical significance in any one of these points. And in 2011 -- and between 2011 and 2012, we have roughly two to three diagnostic medical events. That would be medical events involving radiopharmaceuticals that are used under 35.200. We have a decrease in the number of medical events for 35.300 use, which would be those requiring written directives from six in 2011 and two to 2012.

And when you look at 35.400, that's manual brachytherapy, and most of the manual brachytherapy is going to be prostate brachytherapy. And we've had a decrease from 26 down to 15. We're starting to see a tailing off of the additional medical events being reported from prostate brachytherapy as a result of heightened interest after the DA prostate brachytherapy events.

And then we get to 35.600, which are teletherapy HDR units and gamma knife units. This year, well, we're not going to see any in teletherapy but I have had one in the

past for teletherapy. And we're staying about the same from 12 in 2011 to 13 in 2012.

In 35.1000, which are the "other uses," this would include at the perfection and the yttrium microspheres in addition to some other modalities that we don't see used very often. The intravascular brachytherapy is one that we do see. Some of the others haven't gone back into use, like the gliasite, yet. Oh, we've seen an increase from 11 to 20. And I'd like to talk about that in a little bit more detail later. So that's quite a few for 35.1000 because these are devices that are not used as much as the other radiopharmaceuticals and devices.

Yes, Jim?

MEMBER WELSH: Could you explain the question mark on that slide?

DR. HOWE: This was back in the 2011. There were two that -- there was kind of a question whether they should be included with this year or maybe included with another year. I think if you go back to year 2011 notes, you'll find a better explanation.

Okay, let's look at -- now we'll look by modalities. I've also indicated patients if -- normally when we have a medical event, it's one event, one patient. In some cases, we have multiple events or we have multiple patients. And so in this case with 35.200, we had two different licensees reporting for medical events. In the first case -- and we very rarely get diagnostic medical events. In the first case, the nuclear pharmacy filled vial

label for gallium with valium, and resulted in over 5 rem doses to the patient.

In the second case -- this is the tail results of the strontium-82/rubidium-82 generator problems that evolved from Bracco Diagnostics product a year before. And when they finally completed all of the whole-body scans that they were able to do, it ended up that there were three patients out in Nevada that exceeded 5 rem whole body exposures. And that 5 rem is exclusively from the strontium contaminants.

I will say that it took us significant amount of time to get the patients identified and into the whole-body scan, and so the rubidium-82, which is the primary isotope that gives the dose. By that time was through maybe anywhere between 7, 9, or 10 half-lives. So if it wasn't picked up, that doesn't mean it wasn't there earlier.

In 35.300, most of our medical events in 35.300 are for oral sodium iodide 131. And this year's no different. We routinely have cases where two or more capsules were provided in a vial and only one of them was given to the patient. We had another case like that this year. It ends up that the medical use licensee returned the vial to the pharmacy and packaged it, did everything they were supposed to, but they must not have done measurement, because when they returned it to the pharmacy, the first thing the pharmacy notices is that there's a reading and there's still a pill left in the vial. So this is something we see happening a lot.

In another case, we had a prescription for the

prescribed dose and the written directive was 100 millicuries. But this particular licensee had changed its processing. So written directives no longer went directly the nuclear medicine; they went through an emission office. And there was also an emission order, which had signature of the authorized user but had 150 millicuries written on it. But it wasn't the written directive. And so the nuclear medicine department never got the written directive, so they gave what -- they gave -- they were intending to give 150 millicuries from the emission order, which was not a written directive. And so the licensee -- this was -- had just changed their procedures about a month or two before, and they -- this was the first I-131 that they had given. So they decided that they were going to go back to their old procedures to make sure the written directives went directly to nuclear medicine so that they would be in the department.

Okay, now we have 35.400, which is manual brachytherapy. We had 11 medical events and not all of them were prostate. We had a brachymesh medical event and the -- see if I go into detail on that one -- yes. On the brachymesh -- and then for the prostate, we had 10 medical events, but we had 22 patients. We're still seeing the tail results of -- in this case, agreement states going back and reviewing more prostate brachytherapy procedures and finding during inspection medical events that had not been reported previously. And so that's why we have more patients than reports.

For the brachymesh, the device failed. They gave

the brachymesh implantation and four days later they did a -- it was a long treatment. Four days later, they came back and did an x-ray and a sizable number of the seeds were not found on the x-ray. They started with 50; they only found 38. And they proceeded to x-ray this patient about every week after that to see what was going on. And probably within a month, all of the seeds were gone. Some of them stayed in the abdomen, but most of them disappeared. So it was a problem with device failure that the brachymesh did not hold up, and the seeds got loose. They thought the patient may have coughed some up and then that's how they got into the abdominal cavity, so -- in the abdomen, rather. So that was a first for us. We haven't had a brachymesh medical event previous to this.

And now we've got the prostate medical events. We had one licensee with multiple events. So that had 13 patients. We had another licensee that had three separate reports of one patient apiece. And then we had six separate licensees with one patient each. And we had a total of 22 patients.

We had some pretty interesting medical events here. We had a leaking I-125 seed. We don't have those very often. It ends up they -- the licensee discovered that there was a potential for leaking I-125 seeds when they were checking the packing material for the seeds that came into them, a month after they gave the procedure. So they went back and they contacted the manufacturer, and it became a "one said this, the other said that," and no one would take

responsibility. But they went back and checked the patient. Sure enough, there was an -- it was a thyroid uptake. So the leaking seed was implanted into the patient. And at this point, they haven't resolved whether it was a manufacturing problem or it was something in the transportation or the loading of the seeds; so no one is taking responsibility at this point.

Okay, now, you're going to see this coming up quite a few times in other medical events or other modalities. And it's been a long time since we really had wrong patient. But we've had -- in FY 2012, we had at least three wrong patients in different therapy events. In this case, you had two patients that were coming consecutively, but they said, one day after the other, they needed the same number of seeds. They -- the written directives were pretty similar. The does was the same. And they ended up giving the -- using the treatment plan for Patient 2 on Patient 1 days. And then they discovered it after they'd given the administration. So that's a wrong patient. Even if they got the right amount, it still would have been a wrong patient. And they also discovered they gave about 73 percent of the prescribed dose.

We have a wrong side that was -- they implanted around the penile bulb instead of the prostate. That's something we see quite frequently.

And we had one licensee that had 13 medical events. Seven of them were underdoses to the prostate, and in those seven that were underdoses, there were two

overdoses to the rectum. We also had five overdoses to the rectum. They attributed human error, and they also attributed the fact that they weren't discovered more quickly, and maybe the rest of them could have been prevented -- but the fact that they were not comparing their studies to medical event criteria.

We had a patient that passed two strands and received only 54 percent of the dose that was intended. We had one which there was a volume increase. When they did the original image, they thought the prostate was a certain volume when -- on the day of the post-surgery check, the prostate volume had doubled in size. They did another CT slightly after that, and the size of the prostate had decreased but not back to the original volume. And even when they did the second estimate, the dose to the prostate was still estimated at 62 -- 68 percent. So we had a medical event on that one.

We had three patients that were -- the procedure was performed in 2009, and they were underdoses to the prostate. And that was from the one licensee that made three different reports.

And we had also a cesium 131 underdose in 2007, which they attributed to human error. Many of these, they attributed it to the fact that the licensees were not checking to see if their procedures were in accordance with the written directive and whether they had medical events.

Okay, now we get -- yes, Dr. Malmud. No?

CHAIRMAN MALMUD: Go on, please.

DR. HOWE: Okay. Now we get to the 35.600 medical events. Most of these are HDRs. We did have a gamma knife. I always divide them into anatomical region, just for interest. And I also split them out for MammoSite or MammoSite-like procedures because that was at one time fairly new. And we seem to have a number of medical events on those types of procedures. So we've got probably the greatest variety of anatomical parts we ever had for medical events.

[laughter]

We've got the MammoSite, we've got sacral, we've got common bile duct, we have an arm, we have nose, and then we have the typical GYN medical events.

So for the MammoSite, this was another wrong patient. They had two patients, and they gave the wrong treatment to the wrong patient. Now, it ends up that they must treat their patients all very similarly because the dose and the treatment looked the same, and the problem was the wrong name on the treatment plan when they delivered it. So they were fortunate that the treatments were very similar, and so there was no medical consequence, and the person actually received about 95 percent of the dose.

In the sacral region, they tried to figure -- they calculated the planes that they were supposed to be delivering the dose to. And the difference in the planes was 3 millimeters, but when they import -- when they input the data, they put 3 centimeters. And so you had two treatment plans that were -- got a lot more dose than they

were supposed to get. So we have that kind of error. So it's one of those human errors, where they don't get the right units.

The common bile duct; they were going to give two -- they gave two fractions 4 centimeters from the desired location. They had to correct the dwell position after the catheter migrated. But when they corrected where the source was going to be, they moved it in the wrong direction. So the catheter migrated in one direction, and they should have moved the source up to fix where it was, and they moved it in the opposite direction, so they ended up nowhere near the treatment site.

We had a left arm -- I don't remember when we had an arm. And in that case, they wanted to give one treatment, and then they decided that they weren't going to give one treatment -- one treatment of 200 centigrade -- they were going to give eight fractions. And what they wanted to do was not divide the one treatment of 200 centigrade by eight, but to give eight separate fractions of 200 centigrade. And so there was a mistake by the folks there. And they thought they should be dividing by four -- by eight -- and give 24 centigrade each. Instead, they were supposed to give 200 centigrade per fraction. And it took them two fractions before they realized the mistake that they made.

Okay, and we had the sides of the nose. In this case, they were supposed to get two fractions. The dwell time was correct, but they entered the data into the system

incorrectly. And so they overdosed the treatment site. And they found their error two-thirds of the way through the procedure.

Now to the GYNs. Many times we'll have medical events but there won't be consequences that can be seen. In this case, we had a number of consequences. First one was reddening of the skin to the upper thigh. In this case, they needed a replacement catheter. The catheters that they normally use were no longer being manufactured. So they used a replacement. The replacement was a slightly larger catheter than what they were used to, so it got stuck at a constriction in the tandem. So it didn't deliver to the treatment side but delivered the HDR dose to the upper thighs. In this case, it was evenly distributed dose.

In the second case -- another case in which they did not get the source into the -- where it was supposed to be was outside of the body, and they actually saw necrotic tissue. So this is probably one of our more significant medical events in a long time. Every once in a while, we do get necrotic tissue being seen. So this was a pretty high dose to the inner thigh.

In the third case, the guide wire -- it was a drift error -- and it terminated the procedure just as it was getting started. And they weren't able to correct that, and so they had to terminate the procedure totally. So that was an underdose.

We had a case where the tandem wasn't fully inserted. So for the first fraction, the rectum received

more than it was supposed to, and then the vaginal tissue received a 70 percent overdose.

In the next one, they were using channel 1 and channel 3. They completed the run with channel 1 with no problems. And then they got an error message that channel 2 wasn't doing something right. Well, they weren't using Channel 2. So they questioned that. They tried to clear the error statement. They couldn't clear the error statement. They called the manufacturer. The manufacturer tried to talk them through things, and that didn't help. So they terminated the procedure and then they had the manufacturer come in and look at things. And they never really said what the problem was. But they appeared to claim -- to blame dust. And so now part of their corrective measures are to keep the HDR unit covered with a dust cover when it's not being in operation. So one has to infer from their corrective action of what the problem may have been.

They had a treatment planning software malfraction -- malfunction. They correctly put things into the software, but it erroneously recalculated dwell times, and it printed out an incorrect dose to the verification point. And so that's -- they went back to the manufacturer, and I think the manufacturer issued a correction warning to other folks on that.

And the last one, there was really no reason given. They expected to receive 1500 centigrade, and instead they received 1000. They did say for corrective actions that they plan on using the QA software in the

future. So that gives you a hint that maybe they were -- should have been checking, and this time they didn't check or they -- somebody checked and they just didn't use the QA software so that -- they believe that led to the problem.

Gamma knife. In this particular case, the -- there was a mechanical failure. They latch the fasteners that keep the frame or the head connected to the couch. And so when that failed, they had to terminate the procedure. I think they tightened the screws down later and they continued. So -- and that would be a conventional Gamma Knife.

So when we move into 35.1000, we see we've got a Perfexion medical event. That's the newer model of the Gamma Knife. And we've got 19 yttrium-90 microsphere medical events, which we had 21 patients. And one of the things that -- we'll be asking the ACMUI is if they would like to look into some of these yttrium-90 microsphere medical events and give us a perspective on what's going on.

Is this a statistically significant number? No. You're never going to find a statistically significant number in a medical event. There's just too few of them reported. But there are also fewer patients who are microspheres than you see for some other procedures. So, percentage-wise, they're about 0.3 percent medical event rate. That's not a large number compared to regular pharmaceuticals, but I think we would like to have the ACMUI look into this.

Okay, what happened with the Perfexion? Well, the

patient was being treated. They needed to get up. They fell. They dislodged the stereotactic frame. The licensee reattached the frame, went back, did all the things that should have done to start off the procedure. And the problem was that the treatment didn't restart at the correct location. So.

Now for our microspheres. We have a case where 10 to 15 percent of the spheres went into the spleen, the gastric fundus and the duodenum. And they believe there's potential permanent functional damage from that case. There was also incorrect positioning of the catheter. So they gave the wrong treatment site. They put it into the left hepatic artery and not the -- they put it into the right and not into the left. Once again, we've got a wrong patient. They received the dose from another patient. They labeled the doses with initials, but the technician gave the wrong vial. So the initials weren't the same. And they had expected to receive 143 millicuries. Instead they received 48 millicuries.

We had two incorrect doses prepared and delivered, and that was two treatment sites in one patient. They weren't following the protocol, so they got 40- and 27 percent less than prescribed.

Sixty-three percent of the activity remained in the device. They -- one of the manufacturers now recommends a hemostat being put on one tube. They put it on the wrong tube. It deformed the tubing and restricted the flow. Another case, 77 percent was delivered. They think the

technician who injected the microspheres failed to empty the syringe. We don't have a lot of detail on that.

Seventy-eight percent was delivered. Some adhered to the bottom of the septum. Thirty-six percent was delivered. They said the arteries were too small. It slowed the flush. And when you get a slow flush, then you don't keep the microspheres up in solution, and they settle.

Seventy-seven percent was delivered. Also, again, they were blaming low flush rate to prevent the reflux of the vessels into the stomach, and the microsphere settled in the tubing before completion of administration.

I will say we had probably a 50-50 breakdown between the two manufacturers. So between the MDS Nordion TheraSpheres and the SIRspheres. Seventy-one percent was delivered. The microspheres became lodged in the administration line at the stop cock. Seventy-one percent was delivered. They couldn't determine the cause.

Seventy-eight percent: The microspheres remained in the delivery vial. It was harder to push the plunger on three flushes. We had 76- and 56 percent delivered. Low flow rate through delivery, precipitation using low flow -- they believe there's a precipitation effect when you have low flow rates.

Seventy-one percent delivered: the aggregate of the microspheres in the delivery vial and the hub of the micro -- catheter.

Seventy-three percent delivered: flow clamp wasn't fully open in that position, and the microspheres played it

out in the flow tube.

Sixty percent delivered: They think statis occurred. We thought that there may have been vessel spasm or small fragile vessels. And it was also a slow delivery statis malfunction of system. This was TheraSphere, so TheraSpheres doesn't get -- reach statis. SIRspheres does but TheraSpheres doesn't because TheraSpheres are much smaller.

Forty-eight percent were delivered. They ended up using two vials because they couldn't get the material in the first vial. So they only got 18 percent of what was supposed to be delivered. But they changed out to another vial and they were able to get 91 percent of that. They believed it was a malfunction of the delivery plunger, and that blood backed up into the catheter on the first vial, and it ran into the overpressure valve.

Nine percent was delivered. Ninety percent of it remained in the catheter.

And then we've got two patients. The work sheets were switched. Each got the other's dose. The first reached statis at 35 percent above the prescribed dose, and the second at 56 percent less than prescribed dose. So that's another wrong patient.

And that concludes the medical events that we had for 2012. And as I said before, we have the medical events subcommittee look at things, and we're hoping this year that they will spend a little more time looking at the microsphere issues, and maybe go back a few years and see

what seems to be the issues.

Any questions? Yes, Laura.

MEMBER WEIL: I have two questions -- one you can probably get to pretty quickly. Why do you count -- why don't you count medical events per patient rather than per institution or licensee I suspect?

DR. HOWE: We generally report events as reported to our headquarters operational office. And so a licensee can call in once or they can call in multiple times. And so we tend to call -- each one's -- we'll get a different event number until we decide that maybe it's the same thing going on, and we'll tie them back to the first event. So there's really not a rhyme or reason. Many of our multiple events are due to the licensee discovering way after the fact that they've had a medical event, and then going back and looking at other patients, and so they tend to report all at one time a number of patients that were involved.

MEMBER WEIL: I wonder if representing it that way serves the purpose of protecting patients.

DR. HOWE: I will tell you that in the vast majority of the medical events we get, it's only one patient. And it's very unusual that we get multiple patients or two patients, it's unusual. But we have had medical events, especially way after the fact where we've had high application of 500 patients. And instead of having 500 individual reports, we end up with one. I don't know how to answer your question other than that.

MEMBER WEIL: Okay. So, my other question is

unanswerable, I suspect. So, given the number of medical events that are found retrospectively, can you offer any kind of a wild ballpark figure about what percentage of medical events are actually reported around the time of occurrence?

DR. HOWE: I think most of our medical events are recorded close to the occurrence time if the licensee is following the requirements in 35.40, which used to have a name. They called it the management program. But it was -- it's a program in which they're supposed to go back and assure that administrations are in accordance with the written directives. And that program used to have a number of prescriptive things in it where you were supposed to check the charts every quarter or every year. We took out the prescription part of it, and that enabled people to identify events a little more quickly.

The other thing that I've noticed over the years is many medical events are identified the nanosecond after the administration is given. They're giving a dose to Mrs. Jones, and two seconds after they have injected it, somebody says, "Oh, hi, Mrs. Smith." And they go, "Oh," [laughs] "you know, I've got a problem here." And in the old days when we had about 400 medicals at the time because the diagnostics had a much lower threshold, that -- we saw that all the time. And I think you -- it's kind of similar here. Every once in a while, somebody will come by and they'll recognize the patient and say, "Oh, I didn't know you were in today for this." And then they start looking at it. But

I'm not sure I can give you a better answer. But I think most of us -- most of them are found. We could go back and look.

And our requirement is that they have to report the medical event within 24 hours of identification. So the identification may come at some later time.

CHAIRMAN MALMUD: Other question for Dr. Howe. Dr. Welsh.

MEMBER WELSH: So if I might continue that discussion that was brought up by Laura. I agree that the majority of events are reported relatively promptly, but in recent years, with the states going back to reviewing all the prostate brachytherapy, for example. That's been going on for the past x number of years. We have seen an increased number of medical events that are describing cases 2007, 2008, et cetera. But I think that the obligation of reporting to the NRC is being -- honored. Within a couple of days of being alerted that after 2008, the state has identified that there was a misadministration involving Patient Smith and now the obligation to report to the NRC is being kept. But I think that right now even we are in an unusual era where the states are going back and reviewing cases, case after case after case, and I think my former state of Wisconsin, there are more prostate brachytherapy cases from days in the distant past that who knows how long this situation will be going on, but I think that's the explanation for the anomaly.

DR. HOWE: I think we've also in the past as we've

done IMPEP, which are the inspection programs for the green states and for the NRC, our regions, we find that sometimes the IMPEP brings to light something that wasn't reported before, and we'll get -- all of the sudden we'll get a lot of medical events that were reported for previous years from one state or another, and you can almost, when you're doing a medical events, you can go "Oh, that state must have just had an IMPEP, because I'm seeing a number of medical events."

MEMBER WEIL: But my concern, which maybe I didn't state clearly enough, is that if all of these things are coming to light now through retrospective reviews, they weren't reported contemporaneously. They weren't reported at the time of the occurrence, so I wonder what percentage of events are not being reported now that may be discovered at some point in the future, but it's just -- it is -- granted, it's a delayed reporting, but it underlies a failure to report initially.

DR. HOWE: Yes. Except the rule is upon discovery, not upon occurrence.

MEMBER WEIL: Absolutely --

DR. HOWE: so they're meeting the letter of the law, but your concern is --

MEMBER WEIL: My concern is --

MEMBER WEIL: The patient.

DR. HOWE: The patient has to make certain decisions. It would be nice for the patient to be able to know earlier.

MEMBER WEIL: Absolutely.

DR. HOWE: But sometimes that information just doesn't come to light for a while.

CHAIRMAN MALMUD: Dr. Suleiman?

MEMBER SULEIMAN: Orhan Suleiman. Why are the states undergoing this retrospective -- is that a -- why are the states undergoing these retrospective reviews? Did I miss that, or does it just happen periodically by state?

DR. HOWE: I think when we had the VA Philadelphia Prostate Implant Brachytherapy medical advance, there was increased emphasis, or prostate brachytherapy came into more of a focal point. And so many of the states are going back and looking to see what happened in their states, and that's why we're seeing the retrospective ones.

MEMBER SULEIMAN: Thank you.

CHAIRMAN MALMUD: Do you have another question, or…

MEMBER ZANZONICO: Question. The issue of stasis with stasis is I don't think that unusual. So my question is, how uncomfortable are you that it's not being underreported or over reported? In other words, sort of a non-medical event stasis episode, just bad luck. At the time the administration, they couldn't push in all the microspheres, but everything else was done properly; that to me doesn't sound like a medical event. So any of these you think medical events? And on the other side of the coin, are people -- are their events that may qualify as medical events based on the criteria for these being unreported

because the practitioner is interpreting them as just sort of a physiologic result?

DR. HOWE: We always have that issue and that's -- one way to tell whether things are being identified at the licensee side is whether they're inspector identified. When our state inspectors go in, they do it performance-based, so they're not going to be looking in depth at everything, but if they do find in their questioning, at least looking into medical events for a certain area, they may identify there were potential medical events that weren't reported.

For stasis, we've got two different yttrium microsphere products. One product has very small microspheres, and they just don't have stasis with those microspheres. The other product has much larger microspheres and they identified early on that they weren't going to be able to get all of the activity in, and that the capillary beds would fill up. And we'd already put the TheraSpheres into 35.1000, which is the evolving technology where the other use is and when the SIRspheres came down and we realized that you would have spaces and it wasn't the licensee's fault. It was the fact that these spheres were too big to get all of them into the capillary bed. We rewrote the medical event definition for the SIRspheres to say that it was either you gave the activity you were supposed to give or stasis happened. If you wrote in the written directive, you are going to give so many millicuries or stasis for the SIRspheres, and stasis occurred, we would not consider that a medical event. Otherwise we would have

-- I think over a third of the SIRspheres are stasis, but we didn't want people to try to force the spheres in to prevent a medical event, and have them backflow into the intestinal tract and cause radiation to induce ulcers.

MEMBER ZANZONICO: So you're basically relying on the notes of the doctors saying that they couldn't deliver the whole dose because it was just physiological.

DR. HOWE: Well, I think most of them know the word stasis, and they write it in their written directive. And we don't really question that for the very larger spheres, but we get it for TheraSpheres, it's always a question because spheres are small enough they should go in and fill the capillary bed. Because they can get a lot more activity in a smaller number of spheres. They have much higher activity.

I'm not sure I answered the question.

MEMBER ZANZONICO: No, you did.

CHAIRMAN MALMUD: Doctor Welsh.

MEMBER WELSH: So, I might follow up on this point by saying that we say that the TheraSpheres being smaller, glass microspheres never experience stasis, but I've learned in medicine to really never say never, and I'm wondering what example that we talked about earlier where it might have been spasm of the vessel or a one in a million case of stasis with the smaller glass microspheres, could be an example of something that's not supposed to happen.

DR. HOWE: And I believe we've recently revised the guidance for the TheraSphere side to indicate that it's

not a medical event if you have small vessel spasm and a few other descriptors of that nature. Ashley, do you want to pipe in here?

MS. COCKERHAM: This is Ashley. That's correct.

DR. HOWE: Okay. And that's is one of the beauties of having the 35.1000 is as we find out there are more experience with things and there are things we hadn't anticipated, or licensees haven't anticipated. It's fairly easy for us to modify and come into.

CHAIRMAN MALMUD: Dr. Welsh.

MEMBER WELSH: So, that being the case, is the one example that we were talking about earlier still truly a medical event, or could it be an example where there was no true medical event?

DR. HOWE: It depends on when we change the guidance as to whether it would still be considered a medical event or not. And, you know, medical events for us is not a bad thing. If you lie about it, and then you get into escalate enforcement space, that's a bad thing; but to report one is not a bad thing for us. We will give you an additional inspection, but things happen.

CHAIRMAN MALMUD: Dr. Suleiman.

MEMBER SULIEMAN: This always bothers me because the spheres were considered medical devices. They're used for humanitarian use, so they're not used for normal, healthy individuals. The issue of the distribution is clearly not uniform, so the dosimetry is a joke as far any kind of true accurate estimate, and there's always a

question about what's normal variability in these patients. So what's -- is this, in fact, a medical event or is this just practice of medicine for that specific population of patients, and again, specifically a group that's designated for humanitarian use purposes because they're very seriously ill.

DR. HOWE: To get to your dose question, we recognized early on that people were not going to be able to calculate doses, and so we have that's part of it being in 1000, is that we recognize that if you were intending to deliver a certain activity, we do deliver what you thought was going to be some kind of dose, then we would go with the activity; so we recognize they can't measure dose, and we've taken that out of the equation for the yttrium-90 microspheres.

Only half of the patients are on humanitarian reasons. The SIRspheres folks got a full PMA, so they can be used for any medical usage. It's just the TheraSpheres that are still restricted to the humanitarian device exception.

CHAIRMAN MALMUD: Any questions for Dr. Howe? Oh, I'm sorry. Ashley, did you have your hand up?

MS. COCKERHAM: Yes.

CHAIRMAN MALMUD: Oh well, Dr. Langhorst first, please.

MEMBER LANGHORST: Dr. Howe, you mentioned about the rate of the microspheres medical events. Do you have updated numbers on the numbers that are done each year? And

I wondered -- wanted to ask our subcommittee chairman if we might want to have new numbers this year as we prepare our review.

DR. HOWE: I believe we have numbers that we can make available to the subcommittee.

MEMBER LANGHORST: Okay.

MS. COCKERHAM: So there's actually two questions. Are you talking specifically about microspheres or all medical events?

DR. HOWE: Yes.

MS. COCKERHAM: Both?

DR. HOWE: Both.

MS. COCKERHAM: For microspheres, yes we do have that information from the manufacturers and that is actually what I wanted to talk to the committee about. We touched on it earlier about having maybe a teleconference this summer to maybe look into microspheres and a little further because we have those denominator numbers. So we can talk more about that later. The other answer is we did finally get money to purchase the IMV reports, which are for all modalities, and we should have those reports very, very shortly if we don't already have them. Oh, maybe one of the two was available. Okay, we have the radiation therapy benchmark report. So it sounds like the nuclear medicine one was not available yet.

MEMBER LANGHORST: Okay. Thank you very much.

MS. COCKERHAM: Can I touch on one more thing, since I have up on the screen --

DR. HOWE: And I think up on the slides, we've got the revision that we've made to the written directive that says, "Administration must be performed in the course of the directive. If the procedure must be modified due to emergent patient conditions that prevent administration in accordance with the written directive, artery spasm or sudden change in blood pressure, then you should document such change as a written directive within 24 hours after completion, determination administration. The modification to the written directive should be included as the reason for the administration, administering the -- not administering the intended dose activity." So we've modified the guidance for that, and then we've also asked that licensees now record the amount of activity that's delivered to the treatment site.

MS. COCKERHAM: This is Ashley, I would add, this is published in June of 2012. So I'm not sure if that other medical event occurred that you were asking about, and whether or not this guidance specifically would apply.

DR. HOWE: I'd have to look.

MS. COCKERHAM: Okay.

MEMBER WELSH: I might ask if this verbiage applies equally to the glass and resin microspheres?

DR. HOWE: We did not distinguish between the two for this particular part of the guidance. Am I correct, Ashley?

MS. COCKERHAM: Correct.

CHAIRMAN MALMUD: Does that answer your question?

MEMBER WELSH: Yes, thank you.

CHAIRMAN MALMUD: Other questions for Dr. Howe? Dr. Van Decker.

MEMBER VAN DECKER: Just as an interested observer, looking at the institutions and states that have been reporting, recognizing that they shouldn't be small portions of the country concentrated, your guidance here has had reiterations of education to all providers such that we're doing the same thing across all the states right now, or we have some reason why we should have clustered reporting to some degree?

DR. HOWE: I think when we put our guidance up on the website, we --

MEMBER VAN DECKER: By some high quality performers?

DR. HOWE: We also put out on our medical listserver that we changed it. So we notified people that way. But I'm not sure we notified any other way. Many times our changes may come as a result of a request from a manufacturer, and so the manufacturer will go back and tell all of its customers the changes we have made.

MEMBER VAN DECKER: Whisper down the lane?

DR. HOWE: I think they do more than whispering. Ashley, can you --

MS. COCKERHAM: I believe, on this last revision, we probably did an agreement state letter, we call FSME letters, so we would have communicated that with the agreement states. At a bare minimum, it went out on a

listserv, because any time I revise the guidance letter it always goes on our public website.

CHAIRMAN MALMUD: Ms. Bailey, did you have your hand...

MEMBER BAILEY: I kind of got lost in some of the -- a FSME letter usually means we would send a -- very analogous, maybe just a cover letter on top of it, agreement states would go out to their licensees. So it would follow suit that all licensees received it. Now we're aware that everybody receives a stack of papers. Ours -- these kind of things often come up -- our licensees appear to be very concerned about whether something is a medical event or not, and it seems -- I can't say nine times out of 10, although it seems like a lot of phone calls. This just happened, or we just discovered this, how do we deal? And that's the time we'll end up -- we'll be going back to things like this. We'll go, "Well, that relates to that letter you received, did you apply that?" Then they can go back. So a lot of things are noticed to the states. The licensee has done their parts. Then there's a lot of going back and forth trying to make determinations, and that may be an answer to your question earlier, why states maybe go back in retrospect. IMPEP's coming up, there's a question, how many medical events did you have? And you go back and look, and you might see, oh yeah, we determined that one was, and our database doesn't indicate that we let NRC know. So a lot of it is reporting type information, but the events were worse. The regulations were put in…

DR. HOWE: Enforced?

MEMBER BAILEY: I guess for lack of a better word.

CHAIRMAN MALMUD: Thank you. Dr. Van Decker.

MEMBER VAN DECKER: My question just revolved around, you would assume there would be a bell-shaped curve from among the states where you saw reporting.

DR. HOWE: [laughs] I can't respond.

CHAIRMAN MALMUD: At this -- Dr. Welsh.

MEMBER WELSH: Dr. Howe, I don't mean to delve too much into the specifics, but that case about the arm sarcoma brachytherapy is a little perplexing to me. Did that patient not receive the full prescribed dose in the end? In other words, if the first two factions were .2 gray rather than the .25 gray, .25 rad, instead of the 2 grey, the 200 centigray, that was intended. Did you authorize the use of the device and see not compensate for those two fractions?

DR. HOWE: That information is not necessarily in the event report, but we would hope that -- having a medical event does not preclude that the physician goes back and does what needs to be done to rectify; so we would hope that they went back and decided what they needed to do to give correct doses.

MEMBER WELSH: But my question is why -- on what basis would it qualify as a medical event?

DR. HOWE: Because you've got -- we have a definition of medical event that shows if, in any given fraction, you are less than what you intended to give, then you're a medical event; and that's why I said medical events

are not necessarily bad things. Things happen, and we don't -- we've heard many statements where we hear, well you prevented us from doing the right thing. No, you can always go back and do the right thing. You may still have a medical event, but you can always go back and do the right thing. We expect you to go back and do the right thing.

MEMBER WELSH: If I could just reply to that, after being in this room for so many years, I understand that it's not considered a bad thing from the NRC's perspective, but from a patient and physician perspective, the word medical event still is perhaps misperceived as something worse than it truly is.

DR. HOWE: And I think no matter what word we pick, misadministration, medical event, whatever word we pick, will always be misunderstood.

MEMBER BAILEY: Ma'am?

CHAIRMAN MALMUD: I heard a voice.

MEMBER BAILEY: Over here.

[laughter]

MEMBER BAILEY: I have a question from our Advisory Committee relating to that. In that a medical event is not a big deal to the NRC, ergo to us, in that respect. Do you see that the medical event reporting is then used by other entities that see it as a big event? Either JCHO or the middle management, safety organizations? We're told if we report it to you, then it's a bad event in some other grouping. Is that true? Are they used otherwise negatively? That's a concern. It's an -- unintended

consequences.

CHAIRMAN MALMUD: I think we all as providers have the same concern about having medical events reported when they clinically do not appear to affect the quality of the patient care. For example, what Dr. Welsh described was correctible with an additional amount. However, if it were the third or fourth such instance in which it had not been reported, and then it was discovered retroactively that this was a pattern, the pattern could have been interrupted had a medical event been reported, even though there were no consequences to the medical event reporting except for a significant anxiety surrounding the first instance. But that might have prevented the second, third and fourth, which may have been overdoses instead of under doses or a series of events. So that's the problem that we have as providers, as physician providers. And being concerned about being overly alert -- not overly alert, but overly anxious about issues that do not affect the quality of patient care and having to deal with a considerable amount of paperwork. But as human beings we generally try to avoid pain, and the provider will generally try to prevent the pain of an investigation, even though there's no significant outcome to it. So, we're careful for the same reason we stop for red lights in the middle of the night when there's no traffic around. We just stop because those are the rules. At least I hope you do.

At any rate, I think that's the balance we've been trying to achieve and I understand Dr. Welsh's question and

I sympathize with it, not as a radiation oncologist, but as a nuclear physician in terms of reporting things that we think are inconsequential. On the other hand, when we've had events at my own institution, going back a number of years, it was a useful anxiety-provoking experience to have the NRC look at it, and those things didn't happen again.

MEMBER BAILEY: Thank you.

DR. HOWE: And it's kind of anecdotal, but back when we were receiving diagnostic medical events and we getting 400 to 500 a year, we saw a pattern in some places where the physicians were being penalized for reporting medical events so they didn't report them. And then there would be a disgruntled employee and they would report it later, and then you would have escalated enforcement action and it got a lot worse, and we have tried very hard to put out the message that a medical event is not necessarily harmful to the patient. In a medical event things happen, you have to report it. It's much worse if you don't. So…

CHAIRMAN MALMUD: Dr. Suleiman?

MEMBER SULEIMAN: I mean FDA basically takes a two-tier approach. I mean you have the severe adverse event which is death or life-threatening, which people understand is serious and then you have the adverse event, which could be anything, and is looked at sort of as a low census -- it is just early detection if you get enough of those happen, but it's an extremely imperfect process. I think we understand that. With your medical criteria you don't really have a two-tier, it's either all-or-none.

DR. HOWE: To some extent we do have a two-tier as to what we do with the information. Our medical event threshold is very low. I mean it's not harm, and it never has been harm; so we are trying to pick up the errors that may, if not corrected, lead to harm. So, you've got to report at a fairly low threshold. That doesn't mean everything is down at that low threshold; we have a number of things that are at a much higher threshold and those we categorize as abnormal occurrences and they get reported to Congress. So we do have two tiers of seriousness, but not from the reporting. We set it low enough to catch everything we think we need to catch and then we do something different with the higher ones.

CHAIRMAN MALMUD: There were some other hands. Dr. Welsh.

MEMBER WELSH: I think that this why it's so critically important to have a high quality definition for medical event. Because the reality is that, although you'll never find any proof of this because it is not going to be written, hospitals and physician groups will compete and they will take advantage of the fact that a medical event or misadministration has occurred at Hospital A down the street you and try to get the edge on them. And if Hospital A does 10 times more brachytherapy and does a great job with it but have had two medical events in the past year, Hospital B might unscrupulously take advantage of this unintended misuse of the term and misinterpretation of the term and say "our hospital has not had a medical event in the past five

years or so," even though they are not doing much brachytherapy, insinuating that in some way or another they have a better brachytherapy program. That's another unfortunate reality of human nature, and it just underscores the importance of having good medical event definition in the first place, and it is also maybe is a good segue to the next topic of abnormal occurrence, which I think, at least in my mind, is that higher threshold tier that is worthy of to keep in mind.

CHAIRMAN MALMUD: Thank you. We have a comment from Angela McIntosh.

MS. MCINTOSH: Yes, I just wanted to point out to everyone following up on Dr. Howe's comment earlier that a medical event does not necessarily indicate harm to a patient, and we try to communicate that message in the event report; there's a boilerplate statement to every reported medical event reiterating the fact that a medical event does not necessarily indicate harm to the patient. So, we do, at least that way, put it out every time that a medical event is reported, is reported to us.

CHAIRMAN MALMUD: Thank you. Dr. Welsh?

MEMBER WELSH: That would be great in an ideal world, but if then Hospital A, who has been criticized by Hospital B, because they had two medical events last year, could get that verification that these medical events are of not of importance and all those patients who are being told about let's go to Hospital B because it never had a medical event are also so informed, it would be truly valuable.

Unfortunately that's never going to happen. And this abuse or taking advantage of the misinterpretation of the severity of the term is an unfortunate reality.

CHAIRMAN MALMUD: Mr. McDermott?

MR. MCDERMOTT: I just had a question to get a sense of the committee's thoughts. Angela mentioned the fact that NRC puts in a statement that says "this event may not have resulted in actual harm to the patient." If the reporting guidance and so forth were changed that the medical provider, which provides a positive statement on their assessment of whether or not this was correctible, or -- would that -- in your opinion, would that help alleviate or reduce this issue at all?

MEMBER WELSH: In my mind the answer's yes. Because from the patient's perspective, might want to know if a hospital has had a certain number of medical events is really having medical events because the definition is inappropriate or they are just doing so much brachytherapy that they are within a normal range of medical events per year for that volume, or if there is possibly something going on at that institution. If their rate is higher or if there are medical reasons to be concerned that these medical events are truly of medical consequence, I think that information would be valuable to patients. So I think that maybe it would.

DR. HOWE: If there's confusion to licensees when they have a medical event and they say, "Oh, but there was no harm to the patient." And they actually think that that

takes away the medical event, and so they think, "Well, I don't have to report this because there was no harm to the patient," or they don't have to report it because they were able to adjust things, and that ends up with an issue for us in the regulatory space. We've seen that a number of times.

CHAIRMAN MALMUD: Dr. Thomadsen?

VICE CHAIRMAN THOMADSEN: I would answer Mr. McDermott's question differently. And I would say that I would think most people would think that was just self-serving and wouldn't take it seriously. I mean they are being told these people are having events and of course the administration is going to say, "Ah, but they happen." Thank you.

CHAIRMAN MALMUD: I think we have heard both positions on the issue.

VICE CHAIRMAN THOMADSEN: Thank you.

CHAIRMAN MALMUD: May we move on to the next item, which is the AO subcommittee report?

MR. EINBNERG: Excuse me, before we move on. Ashley, did you want to talk about the medical event subcommittee telecon, or...

MS. COCKERHAM: Correct. Dr. Malmud, if we could. I gave a short presentation, it was requested by the states, to have additional information on yttrium-90 microspheres medical events. Several states have reported more than other states, and so they brought it to the NRC's attention during one of their quarterly, monthly -- it's an OAS/CRCPD phone call. So I actually spoke to that group, put together

a little one-pager that kind of summarized all of the medical events reaching around microspheres from 2007 until 2012, and I had numbers from manufacturers, as I mentioned earlier, to give me an idea of what the denominators might be. And we were wondering if the committee could maybe take a look at the yttrium-90 microspheres medical events a little further for us. I am also giving a presentation at the OAS meeting in August, and I think it would be very helpful for me to have insights from the committee to provide to the states to communicate whatever the message might be. I don't even know what the message is yet, we are just looking into them.

CHAIRMAN MALMUD: By all means.

MS. COCKERHAM: That would be Dr. Welsh's subcommittee, so I will get in touch with you more. Could we schedule a June teleconference? I believe Sophie polled the subcommittee about their availability in June for a two-hour teleconference to discuss whatever the subcommittee may find.

CHAIRMAN MALMUD: That question is addressed to Dr. Welsh?

MS. COCKERHAM: Yes.

MEMBER WELSH: I have replied regarding my availability. I don't know what the others on the subcommittee's availability is, but, I think it's a good idea.

MS. COCKERHAM: I think there's really mixed availability. We couldn't find one date where all members

were available, but where the majority of the members were available, it was the week of June 17th through 21st, from 2:00 to 4:00 p.m. So if we could pick one of the days that week. I know that Dr. Thomadsen indicated that he would be not available and he would be the chair at that time, so Dr. Guiberteau, it would kind of be at your discretion or choice as to what day would be best for you. We could pick a date and an alternate date. You don't have your calendar?

MEMBER GUIBERTEAU: No, but I think I am available every day but Monday that week.

MS. COCKERHAM: Okay. So do we want to say -- what's Tuesday's date?

MS. HOLIDAY: The 18th.

MS. COCKERHAM: Tuesday the 18th from 2:00 to 4:00 p.m. Yes, this would be a full committee meeting to discuss whatever the subcommittee's findings are.

MEMBER LANGHORST: So, the subcommittee has to come to some findings first, by June, to -- okay.

MS. COCKERHAM: And let me tell you the driver for this is that I present to OAS in August, and my slides are obviously going to be due before August, so I need to have a chance to hear from the full committee before I go in front of the states. So, Tuesday, the 18th from 2:00 to 4:00 p.m. EDT. Does anyone have …?

MEMBER LANGHORST: I'm looking desperately here.

MS. HOLIDAY: Dr. Malmud, this is Sophie. It might maybe be helpful if I indicate who did tell me that they were available on the 18th. While there will be 12

members in the committee total at the time, only nine of the 12 members indicated that they would be available on that date. That would be Dr. Suleiman, Dr. Guiberteau, Dr. Palestro, Ms. Weil, Dr. Welsh, Dr. Langhorst, Dr. Zanzonico, and Ms. Bailey, and Mr. Mattmuller.

CHAIRMAN MALMUD: Were there better days that week?

MS. HOLIDAY: Actually, this whole week, we wouldn't get everybody but we would have nine of the 12, so that would be any of the days. But then it varies on which members are actually available on those days.

CHAIRMAN MALMUD: And Dr. Langhorst?

MEMBER LANGHORST: And again, what time did you say?

CHAIRMAN MALMUD: 2:00 to 4:00.

MEMBER LANGHORST: 2:00 to 4:00 Eastern Daylight Time?

MS. HOLIDAY: Yes, ma'am.

MEMBER LANGHORST: Okay.

MS. COCKERHAM: Let's tentatively set Tuesday from 2:00 to 4:00 p.m. and then we can pick -- do we want Wednesday or Thursday as the backup day? Since I'm choosing, I'll say Thursday because we have a staff meeting on Wednesdays.

[laughter]

Is there any other driver?

CHAIRMAN MALMUD: Dr. Welsh?

MEMBER WELSH: So, I apologize. This is not

exactly what I interpreted the email to be asking. So, just for clarification the subcommittee will have to have something to present to the full committee for this day, so it's not like a subcommittee teleconference.

MS. COCKERHAM: Correct.

MEMBER WELSH: And is Dr. Thomadsen available for the subcommittee any longer? So, then we will need some restructuring of this because Dr. Thomadsen was an integral component of our subcommittee.

VICE CHAIRMAN THOMADSEN: Is there rules on the chair's participation in subcommittees?

MS. HOLIDAY: No.

MEMBER WELSH: Thank you.

MS. COCKERHAM: So, he could participate and do everything up until the actual meeting day and then you could represent his views at the meeting. Like I said, there's no preset -- I'm not presenting an issue. We are just saying we would like you to look into this and provide your medical expertise on if you think there may be issues. And what those issues might be. Only for yttrium-90 microspheres. And narrow your scope. Okay, so I am going to say Tuesday 2:00 to 4:00 p.m., Thursday as a backup 2:00 to 4:00 p.m. Dr. Thomadsen?

VICE CHAIRMAN THOMADSEN: Just will you send out to us the information that you collected on the microspheres?

MS. COCKERHAM: Absolutely.

VICE CHAIRMAN THOMADSEN: Thank you very much.

CHAIRMAN MALMUD: Okay, we will move on to the next item on the agenda. And that's the AO subcommittee report and Dr. Langhorst.

MEMBER LANGHORST: Thank you very much. I will ask if I'm willing to present my slides and then we can discuss, or if the committee would like we can discuss as I go along. I am open to either way, so, if someone wants to ask a question or get into the topic as I am presenting, I'm open to that.

CHAIRMAN MALMUD: Thank you.

MEMBER LANGHORST: Okay, thank you very much. So, this subcommittee was formed as of our last September meeting, and the charge of the subcommittee, as we have written up in our list, was to review the refined abnormal occurrence criteria and provide recommendations to the NRC staff. So, just a little background because I know whenever I come back to these topics I kind of forget, "Now where -- how did this come about?" So, in 2008, the committee made recommendation and in December of 2011 regarding its recommendation for removal of dose-based abnormal occurrence, or I will call them AO criterias, for medical licensees, that those abnormal occurrences should include significant medical harm. And after our December 2011, this was essentially the recommendation that the committee provided to NRC staff.

At our September 2012 meeting NRC staff came back with a more formal way of writing those significant medical harm, but also with a proposed refinement to add dose-based

screening criteria as listed here. The thought there was to help the staff evaluate medical events to see whether there needed to be medical consultants to review a given medical event. So it had to meet -- what they had proposed in their refinements, it had to meet these dose criteria, and I will emphasize the "and" resulted in one or more of the following significant impacts of patient health. And I say patient but please know that I always mean patient or human research subject. But I'm going to just be shortening it to patient in most cases.

So I had asked if the subcommittee's presentation to the full committee to add some additional resources so you had them handy. One was the portion of the Energy Reorganization Act of 1974 as amended covering Section 208. And this is really what defines what is meant by abnormal occurrence. So it is an unscheduled event incident or event which the Commission determines is significant from the standpoint of public health and safety. And so another resource that I asked be included was the latest policy that the Commission had approved on the AO criteria. And so in regard to medical use, if you go to appendix A, and I'm sure everyone has studied it, there is a category Roman numeral 1 that covers all licensees. And under a of that section is human exposure to radiation from licensed materials. Now this applies to all licensees and the exposure to anyone from radiation radioactive materials and so on. And so it makes sense that these kinds of exposures are not supposed to happen, that they are indication of an uncontrolled

situation of radioactive material exposure. As compared to the 10CFR Part 20 dose limits, be they for occupational dose or for public dose, the dose limits that are given for exposures to adults, exposures to a minor, or embryo fetus, they range from two to 10 times the Part 20 dose limits. Okay? And there's also a criteria said here that lists the permanent medical harm.

At the other part of the AO criteria definitions is in Roman numeral 3 Item C. And this is where medical events have been defined as to which one of the medical events should rise to the point of an abnormal occurrence. And so this is the section that we were looking at. And it is a dose-based, and this additional dose or dosage greater than 50 percent prescribed or the dose or dosages involves these mistakes or events; wrong pharmaceutical -- radiopharmaceutical, wrong route, and so on. Very similar to medical event-type criteria. Okay? Do I have everyone?

CHAIRMAN MALMUD: Appears that you do.

MEMBER LANGHORST: Thank you. I appreciate that. So the subcommittee began its review in really looking at the last five years of the AO reports. And in this you could see the AO reports follow the NRC's fiscal year. And so you can see for each of the past five years that a full number of abnormal occurrences reported. The first medical use column there is when you read each of those abnormal occurrence reports it really involved embryo fetus exposed -- unintentionally exposed when the mom received an I-131 therapy, and I will come back to that later. The next

medical use column, the AO 3-C; those are our medical events. And then the last column is all the other AOs that have been reported that had nothing to do with medical use. And you can see pretty much every year there weren't any other abnormal occurrences except for 2011.

So this is a reason why we're looking at this. It seemed like those medical events that we are reporting as abnormal occurrences seem -- that threshold seems too low.

So one of the refined proposals that the staff had given us was to retitle that section, the AO criteria Roman numeral 3C, to read for event involving patients and human research subjects. The subcommittee felt that was a correct thing to do, that it was not mistaken that that was the only AO criteria that medical licensees are subject to. They're subject to the first Roman numeral one, all licensees also. But this also further defined that this is limited to medical administration.

Now, as I noted, the ACMUI has discussed this topic several times, and in fact I think a few more times that I haven't noted. And our subcommittee discussed it yet again, and we have always come to a conclusion that dose-based screening criteria would not provide a reliable method to identified medically significant incidents in all cases. And so we recommend that should not be used. And so this is what the subcommittee presents to the committees, should be that definition of AO criteria that medical events should be measured. So the medical event involving a patient or human research subject that, as determined by consultant position

or multiple, deemed qualified by NRC or an agreement state also results -- or results in one or more of the following. And then the criteria are the same as what NRC staff proposed in their refined proposal. Unintended or unexpected permanent function, functional damage to an organ, an intended or unexpected permanent functional damage to a physiological system, a significant unexpected adverse health effect or death.

CHAIRMAN MALMUD: That's a motion. No?

MEMBER LANGHORST: No. I'm not done yet. But I see a question.

MEMBER SULEIMAN: Orhan Suleiman. I've taken the prerogative because we never decided whether or not I could interrupt you now or wait until afterwards. What if an organ received a very large dose, much higher than any of the numbers you've tossed around? And you predict that maybe that organ will die in the future but it's functioning right then and there. That would not meet your criteria.

MEMBER LANGHORST: It's an adverse health effect.

MEMBER SULEIMAN: But it hasn't occurred. The only way you can predict that it's going to occur is because you're assessing the dose, yet you just excluded dose in the previous line. It's sort of a circuitous argument that you wouldn't know until the harm was done. But you may know what the dose is, but the dose precludes you from reporting it. Am I clear?

MEMBER LANGHORST: Reporting what?

MEMBER SULEIMAN: About this is an abnormal

occurrence.

VICE CHAIRMAN THOMADSEN: I think that that's not the case because the situation was that in the medical event the, a medical consultant would be named. The medical consultant would look at the dose, say this is likely to cause harm to the patient, and that would fit this criteria -- criterion.

MEMBER SULEIMAN: So the dose wouldn't be out of the formula, but it would -- could be a medical event --

VICE CHAIRMAN THOMADSEN: It could be used -- it could be used by the medical consultant.

MEMBER LANGHORST: Right. And the medical event is still being reported. Okay? And is -- as we've discussed it's being taken very seriously, not only by the licensee but the regulators as they evaluate what it all means in this case. Okay?

CHAIRMAN MALMUD: I'm seeing other hands raised.

MEMBER LANGHORST: Thank you. The subcommittee did understand the NRC's staff concern about having a screening criteria to help them judge when a medical consultant is needed. And I know that we touched on some points at our September meeting, whether that could be made part of an AO definition for this. The subcommittee explored a criteria based on the number of events reported by a licensee in a year, or maybe a rate of events by a licensee. We could not come to any consensus on -- I think we came to a consensus that the rate probably would not be a realistic thing since we don't always have the numbers, full

numbers of what occurs per licensee, but the subcommittee could not come to a consensus on what would be the right number of events the licensee may have to report in an AO year in order to trip that criteria. We did add that discussion, a summary of that discussion, in our attachment, too. But we ultimately concluded that there was really no practical or implementable screening criteria that we could include in the AO medical event criteria definition.

CHAIRMAN MALMUD: Discussion of that point? Hearing none, move on

MEMBER LANGHORST: Okay. We did, however, as we were evaluating what things the NRC could do in a practical sense, we looked at the NRC's inspection policy regarding the use of medical consultants. And that I also -- we also concluded that is an attachment to our report that we sent to you. And we felt that that set of steps and considerations that NRC staff takes on when a medical consultant must be hired, or when a medical consultant may be hired is a practical tool that the NRC staff could use in being reasonable about hiring additional resources in evaluating that.

Just waiting for any of my subcommittee members to pipe in, but that's going to -- that's it.

Now, let me come back to our column in our table considered -- that lists the embryo fetus dosages. So in that all licensee category of Roman numeral 1 A-3, the ones that are included in that dose are when a licensee has to provide NRC notification of unintended to dose to embryo

fetus or nursing child, and that's under the 10 CFR 35.3047. And that criteria for that reporting the dose criteria is exactly the same as the abnormal occurrence dose criteria for an embryo fetus. So every time you have one of those notifications it automatically becomes an abnormal occurrence. The past five years of those AO reports included notifications of unintended dose to an embryo fetus that were due to I-131 therapy patients unknowingly being pregnant at the time of their therapy despite appropriate pre-treatment pregnancy screening. And we did not feel that it would be appropriate to change the dose in that criteria to accommodate this medical situation because it's also intended to be used if the mother were a member of the public exposed to radioactive material or radiation dose in another way.

And in addition, this unintended dose to the embryo fetus can only happen from a medical administration. So the subcommittee considered that this is not the correct place to judge whether this is an abnormal occurrence, and it should be put under the AO criteria Roman numeral 3-C. So we recommended the following: that in Roman numeral 1-A -- I'm showing my geekiness again, I can tell -- we should have an additional point that says that those criteria do not apply to events included in criteria 3, Roman numeral 3-C involving medical administrations using byproduct material to patients or human research subjects. We noted that in item Roman numeral 1B, transportation events are dealt with in a similar way.

And then to add an item two under this roman numeral 3-C, which remember is entitled "For Events Involving Patients or Human Research Subjects," notifications under 10CFR 35.3047 of an event involving an unintended dose to an embryo, fetus, or a nursing child that results in a significant adverse health impact to the embryo, fetus, or child as determined by a consultant physician deemed qualified by NRC or agreement state.

CHAIRMAN MALMUD: Any comments regarding that point?

MEMBER LANGHORST: I will make note that when you look at NRC's policy on when to hire a medical consultant, that when one of these types of notifications is received, that requires a medical consultant to review it.

And then I want to end up with -- if we want to discuss any of these points. We had three questions that we included in our attachment to some of the discussions that we had about what is the difference between medical events or notifications of embryo, fetus, or child dose versus abnormal occurrences. Could a minimum number of use-related event reports per licensee be considered as a screening criterion for abnormal occurrence definition? And then the question then if a measure of rate could be used rather than an absolute number?

Members of our abnormal occurrence subcommittee are listed here, and I thank each and every one of them for their help and for their dedication to participate in yet more teleconferences over the past couple of months. And

that completes our summary of what we present to you here.

CHAIRMAN MALMUD: Thank you, Dr. Langhorst. Now that Dr. Langhorst has completed the report, is there any discussion of her presentation? Oh, Dr. Van Decker?

MEMBER VAN DECKER: I think there should always be a hand up and there should always be someone who wasn't a member of a subcommittee speaking first. Yeah, I think that the subcommittee did a great job here. You know, I think, we struggled with this now about seven years, or eight years on intermittent discussions, and I think that the going back to the background of where we were before and trying to get where we want to be is a useful process here. You know, I think that what we were looking for was some clinical filtering to what makes clinical significance, rather than just exposure to numbers, and I think this does a great job of trying to capture that, which is exactly what we were trying to do in 2008 when we had the initial discussion, and so that's a good thing. And I think that, you know, it has a lot of common sense saying that, you know, clinical significance should be judged by, you know, clinical people involved in care, and I think that's a good piece of this, and I think trying to avoid too much in the way of absolute numbers is a good thing.

You know, as far as your three questions go, I'd just point out for question number two, when you talked about minimum number per licensee vis-à-vis our last discussion and Ashley's comment on microspheres until you have clear standard definitions and you know you're dealing

with something that's not an interpretive function from something from state to state is obviously an important piece of this, and obviously the compatibility of the states in what they define as medical event across the different issues, that gets the initial capture into an ME group, as Dr. Suleiman pointed out, from which you will take out some occasional MEs that you want to raise to a higher level; you know, I think there's some good common sense in that. But number two, I think, has to be based on everyone interpreting the same way and making sure you have a standard before you get there, and, you know, I would, you know, personally be supportive of what was presented. I think that it's a common sense approach to what's going on.

CHAIRMAN MALMUD: Thank you, Dr. Van Decker. It looks as if you have some support from without the subcommittee. Dr. Suleiman?

MEMBER SULEIMAN: I think I'm going to agree with Dr. Van Decker that number two could -- I mean, you've already flagged it "medical event." The region of somebody says, "Well we just have a second medical event from this site, maybe a third." And I think at that point, you're just, you know, rather than come up with some descriptive criteria based on very, very poor information -- I mean, the intelligent people on the receiving end can look and say, "Well they're not related." They'll asses that -- well, that site has a bad history, that site has a good history; at that time you'll make a smart decision as to whether these need to be looked at a little more carefully, but I

think for -- to come up with some arbitrary criteria to trigger something would just add some complexity. I think, keep it simple. I mean, I think the filter through the medical consultant is good.

CHAIRMAN MALMUD: Other comments? Dr. Welsh.

MEMBER WELSH: Originally in our subcommittee conversations, we talked about the possibility of having three or more as the minimum number for which an abnormal event might be triggered, but upon further discussion it seemed to us that for something as severe as death or irreversible permanent damage, going to three or more was not in the patients' best interest, NRC's, or clinicians' best interest for this type of definition, and therefore some of us were opposed to having three or more. But now, looking at it from a completely different perspective, in light of what we were saying, what Ms. Weil said earlier about the fact that medical event is not necessarily a one-to-one correlation with one patient and one medical event, but one medical event could have 90 patients. Now we're looking at it from a different perspective and wondering if you have a minimum number of medical events -- a minimum number of patients within a medical event, if that could also be justification for an abnormal occurrence, provided the definition of "medical event" is a sound one. It makes me wonder about a number of years back, where conceivably it could be recorded as one medical event, but involving dozens of patients, should that be considered an abnormal occurrence in and of itself?

CHAIRMAN MALMUD: That's a question to you, Dr. Langhorst.

MEMBER LANGHORST: Well, as an RSO, I only thought one medical event means one patient, and if you have more than one patient, you have more than one medical event, because that's all that I've been involved with. And I did not understand that NRC will look at these things where there's multiple patients. So while we did start out, and maybe my wording here should be "medical use related event reports involving more than three or more patients." We really did -- we started out with "events" thinking -- my thought, event and patient is the exact same thing, to three or more patients, but still we could not come to a consensus as the subcommittee knows, just what is the right number. And we were aware that NRC staff felt that that was not going to be a very useful criterion to them, either, so -- and we understood that.

CHAIRMAN MALMUD: Who was next? Okay.

VICE CHAIRMAN THOMADSEN: Well -- I can -- one problem with the definition we came up with, and we talked about this, is there may be a medical event where you have a dozen patients involved, none of whom had any particular consequences, and in the world of quality control this indicates a process that is greatly out of control, and has just been lucky so far. And that type of situation would not be triggered.

MEMBER LANGHORST: I know one thing that I continue to struggle with, and I think the subcommittee did,

too, was the AO criteria under Roman numeral 4, and that's this "other events of interest" and I think that's where something like that could be brought up, but it's not clear to me that NRC staff feels comfortable in anything coming to light there except what maybe comes to light in the press. I'm not -- I'm still uncertain about it.

CHAIRMAN MALMUD: Other comments? Mr. Einberg.

MR. EINBERG: Yeah, Roman numeral 4 there, other items of interest, is a subjective criteria and we as staff have a lot of debate as to what goes in there when the annual AO report comes around, whether there is significant interest in the media, what constitutes significant interest. So that is a bit of a subjective criteria, would prefer to stay away from that. The other point I wanted to ask Dr. Langhorst, was, was there any thought given about underdose as far as getting a medical consultant for medical events, in the way it's structured now, even if you have an underdose, how you would get a medical consultant? Was that deliberated or…

MEMBER LANGHORST: I -- and please, subcommittee members jump in if you don't think I'm answering this correctly -- I do believe that the criteria used for obtaining a medical consultant in the policy, does not necessarily say that if it's under dose, you have to have a medical consultant. And we think that's a practical thing, that you could use this criteria in attachment three to reasonably say, for instance a Quadramet Samarium-153 patient, there's leakage from the administration, so they

don't get the full dosage; then you have that patient come back later and obtain that full dosage. I think that's very reasonable that the intent of the administration occurred, I think it's very reasonable to look at it as a medical event, to see what went wrong, but it's not really an abnormal occurrence. So I think your inspection manual gives you that guidance as to when you need to have a medical consultant.

MR. EINBERG: But the way the criteria -- sorry, the AO criteria that you're proposing right now would be that all medical events require a medical consultant, and so my thought is, was that the intent or -- we have our own inspection criteria, but the AO criteria would actually bump the inspector criteria here, so…

MEMBER LANGHORST: Well, again, we -- I don't know how to answer that except that we think that reasonable judgment can be used in -- when there is a medical consultant needed to evaluate these medical events. And I guess that is that point that we raised in September about whether these criteria could be separated from the AO definition, and so we think that your criteria, and you policy, and your inspection manual is a good one to judge when it's appropriate that you need to have a medical consultant.

CHAIRMAN MALMUD: Dr. Welsh?

MEMBER WELSH: If I might jump into this conversation, I'm not sure I would understand how an underdose medical event would meet the definition suggested

here of unintended, unexpected permanent functional damage to a system, to an organ, or cause death; so I think self-screening. Or am I missing something?

MR. EINBERG: The only person who can make that determination -- the NRC staff could not make that determination. A medical consultant would have to make that determination, so the point that I was driving towards is do underdosages need a medical consultant? Because it's highly -- or it may be unlikely that it would not be any significant harm to the patient.

MEMBER WELSH: So then, I suppose that my reply is my bias is given that I don't think A, B, C or D, as written by Sue, would ever be problematic. I would say that we don't need to have medical consultants review underdoses.

MEMBER GUIBERTEAU: It could be argued, however, that with the underdose they're not getting the treatment they need and there could be a significant adverse health effect.

MEMBER WELSH: Yes, of course, and I would counter immediately, that that would be a correctable situation and not permanent, as words used here in A and B --

MEMBER GUIBERTEAU: Oh no, no, no, no, no, it doesn't say that for C; if you want to put that in there, that's fine. It only says "a significant, unexpected adverse health effect," and that would depend on whether it is correctable.

CHAIRMAN MALMUD: Next was Dr. Suleiman.

MEMBER SULEIMAN: Mine will be quick, mine will be

quick.

CHAIRMAN MALMUD: Okay.

MEMBER SULEIMAN: Okay, I kind of agree with Dr. Guiberteau because -- since we're thinking conceptually, let's say it's some sort of therapeutic dose that grossly underdosed, the patient somehow leaves the country, it's not correctible by the time they catch it, and it's going to affect their health because they may not -- so, I don't want to go off on these conceptual things, but I could see that an underdosing could be life-threatening in terms of it hasn't delivered the right treatment. So I'm not saying that should go to an abnormal reporting incident, necessarily, but assuming that every underdose is going to be corrected is not a true statement.

CHAIRMAN MALMUD: I think Mr. Mattmuller was next, and then Dr. Welsh.

MEMBER MATTMULLER: Thank you. In regards to Chris's concern, I think he's suggesting -- and I think -- I agree with him that what he looks at with our criteria, that every medical event has to be evaluated by a consultant, and then if the consultant determines it meets A through D, then, boom, it becomes an AO. But Sue is also saying, "Use the criteria you have now and your policy on medical consultants to determine when a medical event needs to be reviewed by a medical consultant, and then if he decides that it meets our criteria then it becomes an AO." And I believe in here it says if it's an underdose and then it's subsequently -- well I think the example that's been bounced

around would not be considered a case that a consultant would have to review.

CHAIRMAN MALMUD: Dr. Langhorst?

MEMBER LANGHORST: When a licensee has to report a medical event, in that written report, and I believe in the notification also, but in the written report -- this is under 35.3045 and it's -- let me get the numbers right. It's D1, and I believe it's small Roman numeral 5…

MEMBER BAILEY: What page of the volume?

MEMBER LANGHORST: It's on 719 in our book. I'm sorry, Darice, I took your book. It says the licensee needs to report the effect of any on the individuals who received the administration, and if -- I mean that -- granted that's from the licensee and generally when we, at my institution, have had the unfortunate occurrence of a medical event, we ask another physician to provide that kind of assessment. I don't know if -- I had always thought that NRC put in the comment about "as determined by a consultant physician being qualified by NRC or an agreement state," that could be whether you choose that position assessment as being qualified or not.

CHAIRMAN MALMUD: Dr. Thomadsen?

VICE CHAIRMAN THOMADSEN: I'm on sort of both sides of this. For Jim, there are a lot of cases that an underdose can be made up, in which case, one would not need a consultant to come in. But there are cases -- for example, high dose rate cervix case where the dose had been less than 20 percent, yet you've already, in delivering

that, have used up the sensitivity of surrounding organs because of the difference, alpha over beta. You cannot go in and correct that dose, in which case, then maybe a consultant should brought in. So if they could not -- an underdose could not be corrected, that might be an occasion to bring in a consultant.

MEMBER WELSH: I might respond that, yes, of course we're aware that not all underdoses, and we've always used the adage that perhaps the worst complication is the recurrence of the cancer, so if an underdose has led to inappropriate or unexpected recurrence of the cancer, perhaps is it of significant medical concern. However, the wording in A and B is permanent. So underdosing should not cause permanent adverse effects to normal tissue. Underdosing also, in C, would not be unexpected to lead to a reduced tumor control probability. So I don't think that underdosing is -- there's a problem with the wording that we have here, because underdosing would not cause permanent functional damage to an organ or tissue or system, and it would not lead to unexpected sequelae.

And as an example, as far as death goes, sure, if you've underdosed and failed to cure the cancer, you're going to have some significant -- some significance. But if you think about what we were talking about earlier with the Y-90 microspheres and the potential underdosing in these medical events, these are patients who are terminally and you're not going to cure them with the Y-90 microspheres; it's palliative treatment. You can just imagine the

consequences of saying that these underdoses have resulted in patient death and are abnormal occurrences; when, in fact, that's obviously not going to be the case.

I still stand by my initial assertion that underdosing should be exempted from abnormal occurrence.

CHAIRMAN MALMUD: May I ask a question? What it would be acceptable to use the term "underdosing if not correctable" be reported? If I were a provider and I underdosed a patient, I could notify you and then I corrected it, you'd have a record that I corrected it, but it's not a significant issue. I mean I made a mistake and I fixed it, and there was no harm to the patient. So just insert those two words, "if correctable," or "if corrected" in the past tense even, by the provider. Then that eliminates that concern you would have about an underdose that's not correctable as opposed to an underdose of the example that Dr. Thomadsen mentioned, which is truly not correctible without some sequelae.

MEMBER LANGHORST: Dr. Malmud, I had to --

CHAIRMAN MALMUD: Yes, I just had to get that in before I asked [unintelligible].

MS. MCINTOSH: Actually, I'd like to respond to that and then make another comment. I think if we're to do that, we would have to -- that would require a rule change to the rule. I don't know that we could insert that in the AO policy, that the licensees would have to report whether or not it was correctible. I'm not sure about that, but I don't think so.

But the other point I wanted to make with respect to what Dr. Welsh was saying about an underdose, you know, there's no way a death could, you know, be the consequence. The staff had initially proposed those for criteria as individual separate criteria. Only one of them need be made -- or need be met to be in AO. We didn't present them as "and" statements, but "this one or this one or this one or this one." So adverse health effects does stand on its own. As the staff had presented the criteria to the committee -- now the committee is now presenting the criteria back to -- or recommending, rather, that the criteria be treated as "and" statements --

MULTIPLE SPEAKERS: No, no, no, no.

MEMBER LANGHORST: Absolutely not.

MS. MCINTOSH: So therefore, each one of those should be used separately. Only one of them need to be met.

CHAIRMAN MALMUD: Thank you for that clarification. Dr. Langhorst?

MEMBER LANGHORST: Yes. I am not certain, Dr. Malmud, where you are suggesting that wording should go. Maybe if we --

MS. MCINTOSH: As a fourth criterion, as a fifth criterion.

MEMBER LANGHORST: So you're saying as -- under this, it would be an item E, is that -- or no -- or should it be in that part B?

CHAIRMAN MALMUD: Let's for a moment, if I may, let's for a moment put aside regulation, put aside law, and

talk common sense. If I made a mistake and gave the patient half the dose I intended and then I corrected it without harm to the patient by giving the second half of dose, what's the issue? What harm has been done? Why make an issue of it? If we feel that -- if it was me in that situation, then I'm also capable of double-dosing the patient, then that's a risk; then I should be required to notify the NRC of this problem and that I corrected it. And that should be the end of it, because if it happens again, then we're going to become concerned about the behavior of the provider. But without looking at the legality, just the common sense of it, there's no harm done. I'm now turning -- please, Ms. Weil.

MEMBER WEIL: If I understand Dr. Welsh's concern, with the microspheres, you could underdose by a -- you could deliver 25 percent of the dose, a significant underdose.

CHAIRMAN MALMUD: Yes.

MEMBER WEIL: It's not correctible. And yet, it is not causing -- what we're all dancing around here is the word "negligence." It's not negligent. It's not anybody's fault. It was undeliverable for capillary for mechanics or whatever. It's a medical event. But because of the underdosing, it should not rise to the level of abnormal occurrence. So I don't know that definition, which -- I agree with you. I think that's where we need to go with this uncorrected, or correctable, however you want to phrase it, underdose. But we need to find a way to separate out those -- maybe it's just the microspheres, I don't know,

where it should be --

CHAIRMAN MALMUD: In clinical practice, it's a little bit different, and that -- let's say that there was not an adequate of the blood supply to the liver, and the microspheres went to the lungs. That is --

MEMBER WEIL: That's a different story.

CHAIRMAN MALMUD: That's a different story, we agree. But if, for some reason, in the course of the procedure, the dose wasn't delivered, but it could be augmented with a second dose, then there's -- what's the issue?

MEMBER WEIL: I don't think it can be.

CHAIRMAN MALMUD: Really?

MEMBER LANGHORST: May I --

CHAIRMAN MALMUD: Dr. Langhorst.

MEMBER LANGHORST: I want to address the issue. The issue is, did the NRC -- did they need to get a medical consultant in all cases? And in the case, as far as underdosing, if they have to do this, because they feel, with the AO criteria in this format that that trumps their policy, then they get a medical consultant, they look at it, they said this is not a problem. And so there is some expense. It may be that an agreement state that brings on that medical consultant. That's the point that we're discussing here. They're all medical events, and that should be looked at. But the question here is, is there something we can give the NRC to judge, does it need a medical consultant or not?

CHAIRMAN MALMUD: Dr. Thomadsen?

VICE CHAIRMAN THOMADSEN: Yeah. I'm not -- I definitely do not understand Mr. Einberg's comment about this trumping their policy. If we've stated that the criterion -- or criteria, I don't remember what -- the word there -- for bringing in a consultant, as specified in what you read, with the appropriate citation, then this shouldn't trump anything because we are stating that is the criteria for bringing in a consultant, and this -- the rest of this whole definition does not trigger anything if we specify that we already have the criteria in the regulation.

MEMBER LANGHORST: But the criteria is not in the regulation, it's in their policy for hiring medical consultants.

VICE CHAIRMAN THOMADSEN: Yeah.

MEMBER LANGHORST: Yeah.

VICE CHAIRMAN THOMADSEN: But you read it. You read it, it's in the regulation that you read.

CHAIRMAN MALMUD: Mr. Einberg, since we're discussing --

FEMALE SPEAKER: -- regional cycles --

MEMBER LANGHORST: Oh, by the licensee, the licensee has to report that, yeah.

VICE CHAIRMAN THOMADSEN: And they can change that if they want, but I mean, we aren't proposing anything different from your own guidance as to when you need to bring in consultants, so I don't see how it's trumping anything.

CHAIRMAN MALMUD: Mr. Einberg?

MR. EINBERG: The procedures or the -- Dr. Langhorst was, I believe, discussing or quoting from are lower level procedures, or office procedures. What we're discussing here is the AO criteria. This AO criteria is approved by the Commission, it becomes a policy, and this is what we follow. And so if your recommendation is that a medical consultant has to be brought in for all medical events, whether it's underdosage or an overdose, and that's what we follow.

But we as staff cannot come with up their own interpretation here to say, "Oh, it's an underdosage." That's not what the intent of the ACMUI was or the Commission because they're ultimately going to approve this policy.

So if it's your intent that underdoses are not evaluated or don't need to be evaluated, please, it would help the staff go forward as we try to implement this. The way it's written right now, because our staff will have to implement this, we'll get a medical consultant for every medical event. So -- and if that's your intent, that's fine, but that's the reality.

CHAIRMAN MALMUD: Dr. Welsh.

MEMBER WELSH: So if I might respond quickly, my point in bringing all this up about exempting underdosing as a category from the need for having medical consultant is because I don't believe that a medical consultant is necessary for underdosing if we use these criteria for the

definition of abnormal occurrence, with the possible exception of maybe adding the word "unanticipated death" to item D. And I just don't think that it would be a good -- it's a necessary use of medical consultant expense for underdosing to determine if a medical event is an abnormal occurrence, because we just don't think that they would qualify.

CHAIRMAN MALMUD: Mr. Mattmuller.

MEMBER MATTMULLER: A quick question for Dr. Howe, if she's still here. Okay, or maybe someone else from the staff. Using the current criteria for when you use a medical consultant, of the past medical events, how many times was the consultant brought in on evaluation of the medical events?

MR. EINBERG: Gretchen, do you happen to know what frequency we use the medical consultants?

MS. RIVERA-CAPELLA: It is -- hold on.

DR. GABRIEL: May I speak to that please?

MR. EINBERG: Dr. --

DR. GABRIEL: This is Sandy.

MR. EINBERG: Dr. Gabriel.

DR. GABRIEL: I don't have statistics, I do know that the current medical consultant use policy applies to NRC jurisdictions only. It does not apply to agreement states, however, the abnormal occurrence criterion would apply to agreement states. And as Dr. Langhorst has seen, the current NRC policy requires that for overdose-type medical events, the medical consultant is required, and when

I worked in the Region I office, we extended that to events that might have been underdosed to the treatment site, but involved an overdose to other tissue. So a significant portion of the total number of medical events do end up using a medical consultant for NRC jurisdiction.

MEMBER MATTMULLER: If I could follow up with my comment. So we're not suggesting that every medical event be reviewed by a medical consultant. We're suggesting that medical events that are reviewed per the criteria in your inspection then, then those events, as are viewed by a consultant that meet our criteria, those are the ones that become AO. Did I say that right, Jim?

MEMBER WELSH: [affirmative] Exactly.

CHAIRMAN MALMUD: Dr. Suleiman.

MEMBER SULEIMAN: I think everybody's sort of in agreement, but we're all grasping at the different parts of the elephant. I think we don't want every single medical event to be looked at by a medical consultant. I also think that underdosing significantly, that could in fact affect the outcome, and there's no way to recapture -- treated that patient. Either you've discovered a software glitch that's given a wrong dose and the patient's now in some godforsaken country that you can't get back, or it could be any number of reasons. You've underdosed significantly, and it's going to probably affect patient outcomes, so I think that would meet, you know, this criterion and get kicked up.

How you decide when to call in the consultant or not, I really don't know, but I think, again, the staff --

if you're not sure, you bring in the consultant. If it looks like it's pretty black and white and you're in consensus internally, you know, at that point you kick it up to an AO. But for us to sort of micro dictate, you know, call in a medical consultant each and every time, I think we want to give you some flexibility.

MS. COCKERHAM: This is Ashley --

CHAIRMAN MALMUD: Who was -- Ashley?

MS. COCKERHAM: This is Ashley. Gretchen looked at the medical consultant use, and it's about five a year.

MR. EINBERG: For NRC states?

MS. COCKERHAM: For NRC states.

MEMBER LANGHORST: I think we've touched upon how difficult it is to define this in the AO criteria to give you a screening tool. We've suggested that maybe you may look at your policy as something practical to implement it, and in assessing this, but you can't put all of that policy into AO criteria, and I'm not sure we could adequately put underdosing in there in a agreeable way. I -- it's not an easy thing to deal with.

CHAIRMAN MALMUD: Dr. Guiberteau.

MEMBER GUIBERTEAU: I understand this conundrum because it is difficult for the staff to be able to decide whether something rises to the occasion of a consultant or not, but I'm just wondering if perhaps the medical events committee, which does have physicians on it could assist you in sorting these out in terms of -- many of these case on their face would not rise to the occasions of an abnormal

occurrence, so I don't think you have any reason to go forward with a medical consultant on things that are pretty obvious. But it might be possible for a committee of -- this committee -- subcommittee of this committee to review them, and I don't think it would take a lot of time, and take out the ones that if you want to report these to Congress as abnormal occurrences, could help decide if the committee needs more information or more help.

CHAIRMAN MALMUD: Mr. Einberg.

MR. EINBERG: I think that's a possible solution. However, the concern I have with that is that, you know, we have the annual report to Congress that has to be submitted in a timely fashion and it has its own deadlines. If we wait for the Medical Events Subcommittee to determine which ones should be screened and which shouldn't, it would need to be more on a more real-time basis working with the subcommittee rather than waiting to have the twice-a-year full committee meetings. And so that's part of the practical implementation aspects of working a solution like that.

The other aspect is that if you felt a client make a statement within your subcommittee report that the staff could use their own screening -- or determination of their policies or procedures for underdosages, then we could leave it up to discretion of the staff there to come up with something, in perhaps with consultation from ACMUI to determine something like that. We would need something in the report as written right now to give us that flexibility

to do so.

CHAIRMAN MALMUD: Dr. Welsh.

MEMBER WELSH: Just to underscore the complexity of this, heard earlier today that are a number of Y-90 microsphere medical events this year. Many of them were underdoses. All of these patients will soon unfortunately die because this not curative treatment; it is failure to treatment. Conceivably these underdoses could be misconstrued as abnormal occurrences because of item D, death. And I think -- I don't have an answer for it other than to say perhaps, I think we should change it to say unanticipated death, but I think it underscores the complexity of all of this, why I am leaning towards to steering clear of underdosing as being a criteria for abnormal occurrence definition.

MEMBER SULEIMAN: I think this is an example of why you got to consider the source. I think radio-labeled dosimetry isn't an exact science at this point. So the precision and accuracy of 25- or 50 percent to me would be completely acceptable as practice of medicine.

If you are talking about 50 percent underdosing in terms of external radiation therapy dose, I don't think there's a person here who would consider that within the normal realm of practice, that would be a the gross underestimate of the dose. I think considering the source you could make a very binomial decision on that.

So that's one of the problems with the whole reporting criteria, is you try to lump every medical

procedure into this quantitative metric where 10 percent or 15 percent, or whatever. Whereas, again, with radiolabeled therapies, we're not there yet. With external beam therapy, it's the closest thing to a science-based cancer treatment. The others are still developing.

CHAIRMAN MALMUD: Dr. Palestro.

MEMBER PALESTRO: Yeah. You know, the subcommittee on various teleconferences and emails grappled with this problem. We were unable to come up with any criteria that we felt that the NRC could use -- screening criteria to determine whether medial consultant should be identified. And I think that this ongoing discussion here, at least for me, just confirms that fact that we're are unable to establish any well-defined specific criteria when a consultant should be called, and I think that I would not want to try to implement that even with the underdosing, because it's certainly is very easy to say, well, we know these people, virtually all, are going to be dead within a short time. That's probably true most of time, but not necessarily all the time, and I think the best way to manage it, though it maybe not the least expensive way, is to have a consultant review these cases on an individual basis, and let them make that decision because they are nominally the experts and they can review all the data.

CHAIRMAN MALMUD: Dr. Langhorst.

MEMBER LANGHORST: I wanted to pose a question to Mr. Einberg. Because you state it's an acceptable to have a consultant, however the wording is now, an agreement state

or NRC, for medical events in order to -- agreement states would NRC feel compelled to order a medical consultant to review those? Or would you rely on the medical consultant that the agreement state has used?

MR. EINBERG: The agreement states would have the authority to choose their own, that's all.

MEMBER LANGHORST: Thank you.

CHAIRMAN MALMUD: May I ask a question of Dr. Welsh, please? Dr. Welsh, are you concerned about the hiring of the medical consultant, and the expense, or are you concerned about the anxiety and fear in the patient who's told that this is being investigated?

MEMBER WELSH: Of course both.

CHAIRMAN MALMUD: Which is the dominant concern?

MEMBER WELSH: For the conversation at hand right now, it is the expense of the medical consultant because I'm talking about the underdosing possibly being exempted from abnormal occurrence criteria. And so for that conversation, I'm focusing on avoiding unnecessary expense and time of medical consultants because of significant complexity and the conundrum that will be presented in the example I just gave about all those Y-90 cases this morning, which will likely -- the patients likely will be dead, but if -- I don't think that they deserve consideration for abnormal event -- abnormal occurrences, and I think that that expense could be avoided, so that's why I'm focusing primarily on that aspect.

CHAIRMAN MALMUD: So you're concerned about the

expense, but let's say that a medical consultant were brought in, and he or she took a look at the incident and said, this is just one of the risks of practice, it's just handled by a letter in the same way you might be asked to review a potential lawsuit against someone and you say there's no basis for it in your opinion, versus spending hours and hours going through the entire case and so on.

The expense of that consultant is there, but it's not necessarily an extensive review if it's cut and dried, obvious corrected problem. If, on the other hand, the consultant feels that it's a significant issue, then it would be pursued. I think the problem the NRC has is that once it's labeled as a medical event, then their staff at the lower level that would begin to deal with this are obligated to pursue it. And -- because they're not going to make that judgment. We're having difficulty making that judgment, with all this expertise at this table. They can't be expected to do that. So they're -- the NRC, I suspect, is looking for the guidance from us as to where the line is to be drawn, and it sounds as if that there are unintended risks from an underdose that can't be corrected. Do I understand that that can happen? There are unintended risks from an underdose that cannot be corrected, and therefore, even though the patient's outcome is predictable, namely that he or she will die of a disease, that patient hasn't given adequate opportunity for prolonged life prior to dying, whether that's a matter of months or years. That patient has lost that opportunity, and therefore was not

afforded the advantage of the therapy that was being offered. That patient did not get optimal care in that situation, and then -- because it was not corrected.

So these are questions which we struggle with, and NRC's looking for guidance. And Dr. Langhorst has come up with this document which is an opinion of a number of experts in the area who happen to be members of this larger committee. We don't seem to be able to come to more of a specific recommendation than that which Dr. Langhorst has presented as an outcome of the committee, so eloquently expressed by Dr. Palestro. Dr. Welsh.

MEMBER WELSH: My quick reply to that would be that if we look at the criteria A, B, C, and D, C says a significant unexpected adverse health effect, and I would argue that if you grossly underdose a patient, it would not be unexpected that the malignancy will return, and therefore still unconvinced that the underdosing deserves to be screened and put into the abnormal occurrence criteria.

CHAIRMAN MALMUD: Thank you. Mr. Mattmuller.

MEMBER MATTMULLER: I would think it will because, remember, we start with medical events. And then the next filter is when a medical consultant is used per current NRC guidelines that we've got attached in our report. And our -- it's policy and use of medical consultants. To your knowledge, has a medical consultant ever been brought in on an underdose medical event? This is a question to Dr. Howe.

MR. EINBERG: Or Dr. Gabriel.

DR. GABRIEL: Current NRC guidance allows the NRC

regions to call in a medical consultant --

CHAIRMAN MALMUD: I'm not sure that -- can the court reporter hear you?

COURT REPORTER: Is it Howe or --

CHAIRMAN MALMUD: Dr. Gabriel. Dr. Gabriel.

DR. GABRIEL: Current NRC guidance allows the regions to make use of a consultant in situations other than the ones in which a consultant is required if they believe it to be appropriate. You know, if there are some unusual questions.

MEMBER MATTMULLER: Right, so I agree. It's possible, given extenuating circumstances, but not on a routine basis. So I think we've got a level of protection in there already -- protection's the wrong word -- criteria in there to avoid underdosing if that means going to an AO level, or even being reviewed by a consultant before it could even be considered an AO.

MEMBER WELSH: My quick reply to that --

CHAIRMAN MALMUD: Okay, you first, and then Mr. Einberg.

MEMBER WELSH: I would agree 100 percent with you, had we had this conversation in the morning before Dr. Howe's presentation. Of all those, underdosing Y90 medical events, because some of those patients have very limited life expectancies, and some of them died naturally because natural history, some will die perhaps because of the underdosing, but bringing in a medical consultant to determine whether or not that death, which is item D here,

is due to A or B, what we just said, I think is going to be a serious problem that will not have an answer, but could be a waste of resources.

CHAIRMAN MALMUD: Well, Steve, I mean, Dr. Welsh, if I may. If the patient -- the patient -- it's a matter of informed consent. If the patient is told before the therapy, irrespective of the radiation issue, that this is a palliative therapy, that what's being offered to you is the possibility of an extended life, but not necessarily profoundly extended. And then the therapy is applied incorrectly, and they do not benefit from the opportunity of extended number of months or days or weeks. They've been denied that which could have been given to them had the therapy been delivered properly. And the risk is that there may be, certainly not represented at this table, but there may be someone who doesn't do this correctly and repeats the same error, and it involves the use of radiation and therefore, even though there was informed consent, that yes, the patient and the family understand this palliative care, death is inevitable, this is for prolonged quality of life or prolonged number of days of life, and hasn't been offered the therapy. It's not death that's the issue, it's the fact that the patient was denied the opportunity. Dr. Welsh?

MEMBER WELSH: So my reply to that would be item C, which is significant unexpected adverse health effect. And I would argue that underdosing of what could lead to lack of palliation and perhaps lack of prolongation of life, as would be expected if the treatment were given properly,

but if the treatment were significantly underdosed, this would not be unexpected, and therefore the verbiage here takes that into account.

CHAIRMAN MALMUD: I'll allow someone else to comment on that. Mr. Einberg?

MR. EINBERG: Yes, I wanted to get back to the point that Mr. Mattmuller was making regarding that the NRC has the procedures in place to determine when a medical consultant should be used. If we go back, how this discussion came about is we're looking for that threshold criteria as to when medical consultants should be used. And so what's in place right now, we don't feel comfortable with, and we're looking to revise the AO criteria for -- we do not want to fall back onto the existing, you know, procedure that we have in place right now for determining when a medical consultant should be used. Unless it's deliberate that you're clear in your committee report or subcommittee report as to when that should be, and so it's kind of a circular argument. You know, what comes first in bargaining?

CHAIRMAN MALMUD: Ms. Weil.

MS. WEIL: I would like to second Dr. Guiberteau's suggestion, and perhaps explore why this is not logistically feasible. If we as a committee are here to advise staff, then why could not ad hoc -- I mean, quickly mobilized medical events subcommittees be used using the medical expertise in this room to determine whether or not a medical consultant is needed?

CHAIRMAN MALMUD: Mr. Einberg.

MR. EINBERG: Certainly is a possibility to -- rather have an ad hoc committee or then all of the physicians here can serve as medical consultants to us, as some of them do. So that's an opportunity to -- if one of the members of the committee wanted to serve in that capacity to do evaluations, that's a possible solution as well. Now, just to clarify, we're not opposed to hiring a medical consultant for all cases if that's the case. The cost associated with it -- while there is a cost associated, would the prudent stewards of the ratepayer's money or the taxpayer's money -- if necessary, it's not that much of a cost to be honest.

CHAIRMAN MALMUD: Dr. Suleiman.

MEMBER SULEIMAN: I've come up with two very specific plausible scenarios, okay? Let's say in comes the yttrium, underdosed, I would think any group would say the uncertainty in that type of procedure is high, I wouldn't worry about it, it was within the normal practice of medicine. Scenario number two, in our outpatient world where we have a lot of people coming from other countries, somebody -- some patient comes in, they undergo a pretty high tech external beam therapeutic procedure. For whatever reasons, the software glitches, the site doesn't figure it out till maybe two or three days later when this person has now left the country and is off someplace else and is in no position to come back. At that point I think an analysis would show: either number one, you should hold onto the

patient long enough to verify the dose, or there should be some checks and balances for your software to make sure the equipment is working right.

So here's a case you've underdosed, and I think in today's world is a very plausible scenario, so why wouldn't that be considered serious enough? It wouldn't necessarily reflect on the facility, though it could to some degree, but it also could involve the manufacturer because there could be some equipment problems there. So not calling it an abnormal occurrence would deny that mistake the opportunity to be analyzed and figure out some procedures that would prevent it from happening in the future. So I think underdosing could be a reportable abnormal occurrence.

CHAIRMAN MALMUD: Ms. Bailey.

MEMBER BAILEY: What you just described sounded like down here at the medical event end, not at the abnormal occurrence which is just a policy with what we report to Congress. So they miss the software glitch, and underdose, perhaps is a medical event. I think the question is do you then want to hire a consultant to decide if that goes over to the group we report to Congress?

MEMBER SULEIMAN: Well the way I'd do the consulting hiring was there'd either be strong consensus among the NRC staff that they don't need to do it, which would be a pretty straight decision, there'd be a strong consensus to hire a consultant. And if there was a split decision I'd probably still opt to go ahead and hire a consultant. So I think you have the -- some flexibility

there.

CHAIRMAN MALMUD: Is there more discussion regarding the presentation that Dr. Langhorst has made to us on behalf of that subcommittee? If not --

MEMBER LANGHORST: Can I do a -- just a little summary?

CHAIRMAN MALMUD: Please do.

MEMBER LANGHORST: I understand, again, the NRC's need for some clear cut criteria they can apply to decide whether there's need for a medical consultant or not. I don't think that we can add anything to our definition in the AO criteria policy that can clearly give you that and cover every occurrence. We understand that you don't feel comfortable in the -- in the procedures that you have. At lower level they seem very reasonable to us, but I understand that if you define your AO criteria like this, it seems like you have to have a medical consultant every time. And maybe that's as good as we can get. But there was -- I think we can all agree there's just not something that we can readily say will fit in here to give you a screening tool.

CHAIRMAN MALMUD: Dr. Thomadsen.

VICE CHAIRMAN THOMADSEN: Well, could we put in something about using the physicians in this committee to determine whether you should hire a consultant for abnormal occurrence? Would that alleviate the problem? I mean, that could be written in.

MEMBER LANGHORST: But wouldn't it be reasonable

that they just use you as a medical consultant to evaluate this? I mean, that seems very expedient, we're on the hook.

VICE CHAIRMAN THOMADSEN: How would they want to handle that?

MR. EINBERG: In some regards, we'll need to get a -- if as written, we'll need to get a medical consultant, regardless. Now, whether we interject another step in there to determine whether a medical consultant is necessary, they're already serving in capacity as a medical consultant to make that determination. So I'm not sure whether it would be useful or not, so -- but you certainly could write it into a report if the committee felt it was necessary.

CHAIRMAN MALMUD: Dr. Thomadsen, did you...

VICE CHAIRMAN THOMADSEN: I don't think the committee feels that it's necessary. We're trying to treat the NRC staff, not ourselves.

MR. EINBERG: I don't see the need for it.

VICE CHAIRMAN THOMADSEN: Okay.

CHAIRMAN MALMUD: So, Dr. -- oh, excuse me, Dr. Welsh?

MEMBER WELSH: Yes, I have a question for Sue regarding a slide that's currently there. Would it be of any help for item D to say unanticipated or unexpected death in light of some of the conversation we've had about underdosing and given that we have not come to a consensus about underdosing being excluded? Death that is unexpected or unanticipated might clarify this.

MEMBER LANGHORST: I am not sure I can answer that

for you. I think it makes it sound unclear if you say anything other than death.

CHAIRMAN MALMUD: Dr. Guiberteau.

MEMBER GUIBERTEAU: It seems to me the operative word here is results in. Really doesn't matter after that. If we -- the whole point of all this, with the medical consultants and this language, is to connect the event with the complications here, and I think results already does that, so I don't think we need to, you know, really qualify death there. So I mean, to me, it already says what it needs to say. The issue here is, you know, I think we're stuck on, is the medical consultant issue. And I just wanted to ask Chris, do you have any suggestions?

MR. EINBERG: Mr. McDermott here just brought up the suggestion, if the subcommittee likes the language that's in the procedure right now, the NRC's internal procedure, could that be added as a footnote to the subcommittee report that this is when you would use the medical consultant?

MEMBER LANGHORST: I believe we said that, but --

[laughter]

[talking simultaneously]

MEMBER LANGHORST: -- say that four or five more times in there. That's what we think we're saying. That's what we think we're saying.

CHAIRMAN MALMUD: Dr. Langhorst, is your summary that we see now a motion?

MEMBER LANGHORST: I have not heard any difference

as far as what we've put forward for the report, so I would so move.

CHAIRMAN MALMUD: Is there a second to the motion?

MEMBER PALESTRO: Second.

CHAIRMAN MALMUD: It's been seconded by Dr. Palestro. Is there further discussion of the motion? Hearing none, all in favor, please say "aye."

MULTIPLE SPEAKERS: Aye.

CHAIRMAN MALMUD: Any opposed? Any abstentions? Thank you Dr. Langhorst and the members of your committee for a yeoman's job. Thank you.

MR. EINBERG: On behalf of the NRC, thank you [inaudible].

[laughter]

[inaudible commentary]

CHAIRMAN MALMUD: Is there a statement from --

MR. MCDERMOTT: Yes.

CHAIRMAN MALMUD: Oh. Mr. McDermott.

MR. MCDERMOTT: Yes, I just wanted to inform the committee and the members of our audience, that news is reporting two explosions in Boston in the vicinity of Boston Marathon finish line. They're reporting injuries and just wanted you to be aware of that.

CHAIRMAN MALMUD: Thank you.

MS. COCKERHAM: I was reading that they reported three deaths.

MR. MCDERMOTT: There's three deaths reported.

CHAIRMAN MALMUD: Thank you for informing us,

we'll check the news when we get out of here. And tomorrow we will meet again at 8:00. The first item on the agenda tomorrow is 10 CFR Part 35 rulemaking update with Ms. Bhalla and Ed Lohr. We look forward to that, and then agenda as you can see has been abbreviated, so that if you want to make alternate travel plans, you may have the opportunity to do so, although your -- that's up to you. See you all tomorrow.

[Whereupon, the proceedings were concluded at 5:00pm]