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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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SPRING 2014 MEETING

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OPEN SESSION

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THURSDAY,

MAY 8, 2014

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The meeting was convened in room T-2B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:30 a.m., Bruce R. Thomadsen, Ph.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

BRUCE R. THOMADSEN, Ph.D., Chairman

MILTON J. GUIBERTEAU, M.D., Vice Chairman

PHILIP O. ALDERSON, M.D., Health Care Administrator

FRANCIS M. COSTELLO, Agreement State Representative

VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

SUSAN M. LANGHORST, Ph.D., Radiation Safety Officer
STEVEN R. MATTMULLER, Nuclear Pharmacist
CHRISTOPHER J. PALESTRO, M.D., Nuclear Medicine Physician
JOHN J. SUH, M.D., Radiation Oncologist
ORHAN H. SULEIMAN, Ph.D., FDA Representative
LAURA M. WEIL, Patients' Rights Advocate
JAMES S. WELSH, M.D., Radiation Oncologist
PAT B. ZANZONICO, Ph.D., Nuclear Medicine Physicist

NRC STAFF PRESENT:

MICHAEL WEBER, Deputy Executive Director for Operations for Materials, Waste, Research, State, Tribal, and Compliance Programs
BRIAN HOLIAN, Acting Director, Office of Federal and State Materials and Environmental Management Programs
MARK SHAFFER, Acting Deputy Director, Office of Federal and State Materials and Environmental Management Programs
LAURA DUDES, Director, Division of Materials Safety and State Agreements
PAMELA HENDERSON, Deputy Director, Division of

Materials Safety and State Agreements
MICHAEL FULLER, Designated Federal Officer
SOPHIE HOLIDAY, Alternate Designated Federal Officer, ACMUI Coordinator
NEELAM BHALLA, FSME/DILR/RPMB
DOUGLAS BOLLOCK, FSME/MSSA/RMSB
SUSAN CHIDAKEL, OGC/GCLR/RMR
ASHLEY COCKERHAM, FSME/MSSA/RMSB
SAID DAIBES, Ph.D., FSME/MSSA/RMSB
SANDRA GABRIEL, Ph.D., FSME/MSSA/RMSB
TOMAS HERRERA, FSME/MSSA/LB
DONNA-BETH HOWE, Ph.D., FSME/MSSA/RMSB
ED LOHR, FSME/DILR/RPMB
GRETCHEN RIVERA-CAPELLA, FSME/MSSA/RMSB
SHILLEY XU, FSME/MSSA/LB

MEMBERS OF THE PUBLIC PRESENT:

MAXWELL AMURAO, Columbia University Medical Center
SUE BUNNING, Society of Nuclear Medicine and Molecular Imaging
ROBERT DANSEREAU, New York State Department of Health
GEORGIA HEARN, American Society of Nuclear Cardiology

ELIZABETH PEETZ, Mallincrokdt Pharmaceuticals

MICHAEL PETERS, American College of Radiology

DANIEL SNYDER, Geisinger Health System

WILLIAM SONES, Mallinkrodt Pharmaceuticals

MICHAEL STEPHENS, Florida Bureau for Radiation Control

CINDY TOMLINSON, American Society for Radiation Oncology

PAUL YURKO, Veterans Health Administration

A G E N D A

P R O C E E D I N G S

8:33 a.m.

VICE CHAIRMAN GUIBERTEAU: Welcome to the Spring 2014 ACMUI meeting. And to start the meeting off I will turn this over to Mr. Fuller who will read the opening statement.

MS. DUDES: People here in the seats, are you hearing us okay?

MR. FULLER: Thank you, Dr. Guiberteau. As the Designated Federal Officer for this meeting, I am pleased to welcome you to this meeting of the Advisory Committee on the Medical Uses of Isotopes, or ACMUI.

My name is Michael Fuller. I am the Medical Radiation Safety Team Leader, and I have been designated as the Federal Officer for this Advisory Committee in accordance with Title 10, Code of Federal Regulations Part 7.11.

This is an announced meeting of the Committee. It is being held in accordance with the rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission. The meeting was announced in the March 11th, 2014 edition of the Federal Register.

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, nor 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 consensus on the issues that we will discuss today and tomorrow, but I also recognize that 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.

(Roll Call.)

MR. FULLER: I now ask NRC Staff members who are present here today to identify themselves. I'll start with individuals in the room.

MS. HOLIDAY: Sophie Holiday.

MR. HOLIAN: Brian Holian, Acting Director of FSME.

DR. HOWE: Dr. Donna-Beth Howe.

DR. GABRIEL: Dr. Sandy Gabriel.

MR. BOLLOCK: Douglas Bollock.

MR. FULLER: There are other NRC Staff members I see in the room, if you would please move to the microphone and introduce yourselves.

MR. LOHR: Ed Lohr.

MS. DUDES: Well, I can -- I see our Acting Deputy Director, Mark Shaffer, who is coming up to the microphone. I was going to introduce him, and I'd like to acknowledge our Deputy Executive Director for Materials, Waste, Research, State, Tribal, and Compliance Programs. That is a long title, I had to look that up this morning. They call him DEDRMWRSTC, some acronym. But, Mike Webber, thank you for joining us this morning. And, of course, I'm Laura Dudes. I'm the Director of Materials Safety and State Agreements in the Office of Federal and State Materials and Environmental Programs. We tend to have quite a few long names, but we want to include everyone so that's why we do it.

MR. FULLER: 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 888-566-9152. The passcode to access the bridge line is 61838#. Please put your phones on mute or press *6 if your phone does not have that function.

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

one person speak at a time as this meeting is also closed captioned.

At this point, I would like to turn the meeting over to Laura Dudes, Director for the Division of Materials Safety and State Agreements for her opening comments. Laura.

MS. DUDES: Thank you, Mike. Well, first of all, I just want to say good morning to everyone and welcome. I would like to welcome our new members, Frank Costello, who comes to us from the State of Pennsylvania, and also a former NRC colleague for many years. Dr. Vasken Dilsizian, welcome. And Dr. Philip Alderson. See, I was working on the names earlier today. So, welcome to you all.

I also wanted to make some comments in terms of organizational changes at the NRC. I did introduce Mark Shaffer who is the Acting Deputy Director for FSME, Brian Holian is the Acting Director. John Moses, who is not with us yet this morning, but he is the Acting Deputy Director for the Materials Safety and State Agreements Division.

I know many of you have worked closely with Chris Einberg. Chris is off on a rotational opportunity in the Office of Nuclear Security and Incident Response, so we have Doug Bollock filling in for the next eight

months. I also wanted to mention that Dr. Ron Zelac retired in January 2014 after many years of service, so we wished him farewell. And Dr. Donna-Beth Howe has been promoted to be the Senior Health Physicist in that branch, so congratulations to Donna-Beth, and I'm sure you guys will enjoy working with her as you have in the past. So, I touched on that. And before I start, Brian, did you have any opening remarks?

MR. HOLIAN: Thanks, Laura. Yes, on behalf of FSME I would just like to welcome you again. I just had a couple of comments.

One, I just love meeting new people, so before coming here, here's your trivia for today. So, I learned this from Steven, a fellow Ohioan by the way. I grew up in Ohio, and he's down near Dayton, and told me he was working at Kettering Hospital. Well, I pass through Dayton on the way to my college, so I asked him about the Wright Brothers. So we caught up on that, and then he gave me the tidbit that Kettering flew a Wright flyer. Is that right? He used to fly it over Ohio State, a Wright flag, so that's who that hospital is named after. So, there's your trivia for today.

(Laughter.)

MR. HOLIAN: So, I did come prepared for that, but I look forward to meeting many more of you. About

a year ago, I think Mark Satorius and I were here and had some opening comments. Mark has moved on to Executive Director for Operations from FSME and I've been Acting for the last nine months or so there.

You know, FSME had a cleanup day a couple of weeks ago, and I find a connection - so, I found two items I thought I'd bring along to show you from our cleanup there on the 8th floor up there. And it just highlights a little bit the importance of your work. So, if some of you are new to ACMUI you might not remember the first item. I don't know the year for this. Mike Weber will know clearly.

This was a pamphlet that was being thrown out, so I saved it, "Below Regulatory Concern". Remember that NRC program, and some of you may have views on that. So, I have that. I'll leave it around if you want to page through that. But it brings the importance of your work.

And the second pamphlet I have is from 1999. I remember this. I was leaving a Region I job at that time. I had been out in Region I for nine years, so I worked with Frank Costello, and this is the Committee on Veterans Affairs, U.S. House of Representatives, 1999 Hearing on Veterans Affairs issues and medical events that we had back then. And I was paging through that again this week and reliving that history, so I

thought it was appropriate with your meeting this week to mention those two pamphlets and mention a little bit of that history. It shows the ongoing importance of your work on this Committee, you know, to influence and inform the NRC of these types of activities.

The Commission meeting tomorrow will highlight some of the areas. I think you'll find the Commission is very interested in your work, and they themselves are touching on some of the subjects that you're touching on, on their own, so I wanted to highlight that importance.

But with that, welcome, and hope to get outside at lunchtime. It's supposed to be a good day. Thank you.

MS. DUDES: Really, yes. So, I just came [inaudible]

(Laughter.)

MS. DUDES: It would figure it was a nice day, so I just had three days of annual leave, and because this Sunday is Mother's Day, and it's also my mother's birthday and I can't make it to upstate New York, so although, you know, that's a dilemma so I just took the past three days off to spend with her instead. And we teed off yesterday morning, did the first hole, after the second hole, par 3, I teed off. I was on the green near the pin and lightning comes out of the sky. I mean,

you know, I don't know if anybody plays golf. I have clubs and balls, and I go out to the course. I'm not very good at it, but when you tee off and you see the ball and the pin, and there's lightning coming out of the sky, you think I really want to play this.

(Laughter.)

MS. DUDES: Anyway, so my mother thought better and she said, Oh come on, Laura, let's go. We need to get off the golf course, so we did. So, that was [inaudible] so, I'm coming back in. Now, I should have [inaudible] in fact, I had to leave my ball on the green, you know, because she was like let's go. It's lightning. I mean, you have metal clubs in your hand. Anyway, I don't want to take up too much time. Brian has trivia, I have my golf stories.

(Laughter.)

MS. DUDES: So, I appreciate the opportunity to meet with you and to participate. I'm new in this role. Last time you guys met I was Acting Deputy Officer Director and I sat off to the side and was able to listen to it. But I have a story.

So, we issue an annual report to Congress that lists abnormal occurrences. I'm sure you all get that and read that. So, I was reading that this past year, you know, reviewing it before we sent it up to the

Commission, and I was struck by the fact [inaudible] so, they're all medical events. Right? I think we had 10 or 11, maybe 12, the number is lost, but they're all medical events that we sent to Congress this year. So, at the end of reading that report I was really struck about the human side of the medical events.

I mean, these people are getting treatment for an illness, and I often wonder well, how many of the people that are reading about this, you know, some of their diseases are incredibly complex you know, they're not in great shape. It's very serious, so the human side of that struck me, and I sort of felt a little sad because I thought well, I'm sure some of these people may not have survived their disease, not necessarily the medical event.

So, when I talk with the medical team about our mission as Nuclear Regulatory Commission which is focused on radiation protection of the public, the occupational workers, as well as the patient, and then we have this practice of medicine that people are getting serious doses to cure them. And we don't know, I know I don't coming from 10 years, or 20 years of reactor background, but as these issues come up, I really would look to this astute body to sort of not only tell us, you know, guide us on our regulations, but also be

looking ahead to what should we be focused on, because this is the line, or the area of medical practice, and then regulation of radiation protection. We really need to make sure that as we promulgate regulations, and guidance, and other things that we're doing so for the full benefit of society, both radiation protection, but with your expertise, not necessarily crossing into an area where we don't want to be, whether it's the patient advocate's views or the medical doctor's views. So, I think, you know, I respect that role. I look forward to working with you in these areas.

Also, as I said, not just reacting and discussing things that we propose, but for this Committee to propose to the NRC areas we should be looking at, try to continue our early communications on issues. We had a very good discussion, I think it was early in 2014, with Dr. Thomadsen when we received the Part 35 SRM from the Commission, and they talked about the Medical Policy Statement. So, we were able to communicate that early. You were able to actually discuss it and we'll have a fruitful discussion on where we're going to go with that today, so I want to thank you for that.

So, two things is thank you for your advice and we're going to try and continue open communications,

early and often communications on issues that arise. So, with that, I think I've done the introductions. Sophie, which I do have to acknowledge and thank very much for all that she does for us, and she had given me some notes to update you. And I know we are waiting for the Part 35 Rule. That is with the Commission and should be published, the Draft Rule, next week' we're thinking, so we'll let you know as soon as we know.

A couple of other non-medical related items that may be of interest to you. 10 CFR Part 37, which is Category 1 and 2 Source Security Requirements, became effective on March 19th, 2014 for all NRC licenses. Agreement States will have three years to implement a comparable regulation on that.

The Conference of Radiation Control Program Directors, CRCPD meeting is the week of May 19th in Atlanta. And I think I touched on our organizational changes, so with that I'll turn it back to Dr. Thomadsen.

CHAIRMAN THOMADSEN: Thank you very much. Thank you for the comments and the reminiscences. I do remember :Below Regulatory Concern: very well.

That now brings us to Old Business, and Ms. Holiday.

MS. HOLIDAY: Okay. So, for attendees in the back, if you aren't aware, there are meeting packets

with the slides and the handouts in the very back corner, on my left, corner. So, I'll begin.

On the screen, we have the chart for 2007. For the benefit of our newest members, this part of the presentation is us simply going through the old Recommendation and Action Charts and to update the Committee on what Staff has done for the recommendations from the Committee.

CHAIRMAN THOMADSEN: Excuse me for interrupting.

MS. HOLIDAY: Sure.

CHAIRMAN THOMADSEN: But you do have in the packets in front of you the printout of what she's going through. You may not, you may be able to see better than I, the font is hard to see.

(Laughter.)

CHAIRMAN THOMADSEN: But if you can't, you may be able to read it on the fine print on the printout.

MS. HOLIDAY: Okay. So, for this chart for 2007, I'm not going to go through each one of these items. The Committee has heard me say this before, but all these items on this chart are included in the current Part 35 expanded rulemaking, that hopefully is slated to be published next week.

So, I move on to 2008. Again, the majority of

these items are also included in the Part 35 expanded rulemaking with the exception of Item 5, Item 19, and Item 22. Those are currently delayed, meaning that they are not included in the current Part 35 rulemaking, but that does not mean that Staff is not considering them.

Okay. We move on to 2009, very short. Items 2 and 10 are related to the current Part 35 expanded rulemaking. Item 9 has to do with the Medical Event Subcommittee. That was a subcommittee that Dr. Malmud created. That membership has changed as membership has changed on the Committee.

2011, oh, 2010 you do not see because staff has closed and addressed all of those recommendations that came forth in 2010. For 2011, the majority of these are, again, related to the current Part 35 expanded rulemaking. Item 1 has to do with the Per-Release Criteria. This is delayed and not included in the current Part 35 rulemaking. Item 6 has to do with the annual discussion from the Committee with staff on evaluating their satisfaction with reporting to staff versus the Commission. This item was superseded a year or two later, I think in 2013, where basically the Committee just said they wanted to keep having this annual discussion to evaluate their satisfaction with the reporting structure.

Okay. Move on to 2012. Here is that very item I was talking about, annual structure, so we will continue to have that discussion which, of course, will happen in the fall.

We move on to 2013. Like the previous years, the bulk of this has to do with the Part 35 expanded rulemaking. This was the year where we had the two teleconferences with the Committee to discuss the Draft Proposed Rule until you get down to Item 15, which has to do with the ACMUI Bylaws. We will have that discussion later on today, this afternoon after lunch. Item 21, Mr. Mattmuller asked that staff provide relief from the Decommissioning Funding Plan for the germanium-68, gallium-68 generators. We'll have a discussion from Mr. Mattmuller later on to touch on this subject again.

Number 23, as I mentioned before, the Medical Event Subcommittee membership changes according to who is on the Committee, so in 2013 Dr. Thomadsen added Dr. Palestro to that Subcommittee.

On the next page, Dr. Thomadsen created a Subcommittee to review the ACMUI Bylaws, which again we will talk about later on this afternoon. Item 25, the ACMUI recommended to reestablish the Rulemaking Subcommittee to review and address staff's response to the Subcommittee's recommendations for the Draft

Proposed Expanded Part 35 Rulemaking.

As Ms. Dudes has mentioned, we had a discussion, I believe a very fruitful discussion with Dr. Thomadsen in January of this year to discuss the SRM that was issued. Dr. Howe will give a presentation after me to give you additional details on that SRM.

Item 26 was where Dr. Thomadsen added Mr. Mattmuller to that Bylaws Subcommittee. Item 27 simply states the charges that the Subcommittee was given.

Item 29, I have this in red because this was an open item, but I'm going to say that it's delayed. Dr. Welsh had recommended that we add the topic of Physical Presence Requirements for Authorized Users for the Gamma Knife. I wasn't sure if it was the Gamma Knife or the Perfexion for discussion at this meeting; however, because we have a Commission meeting tomorrow, there wasn't adequate time to fit this on this agenda. However, if we have space on the fall agenda as in discussions with the Chairman and the Vice Chairman, then we will gladly put that on the agenda for the fall. So, it's delayed at the current time.

Item 30, I am moving to close that item because this is where we plan to have this spring meeting on May 8th and 9th with the backup date of 12th and 13th, and here we are, so I think we can sufficiently close that item.

And then I stuck in this chart, oh Gretchen, if you could make this just a tad bit bigger for me. Okay. This is 2014, for this year. The rest of the Committee may not completely be aware of this, but as Ms. Dudes said, we spoke to Dr. Thomadsen earlier this year to touch on the Medical Policy Statement. So Dr. Thomadsen, under his authority as the Chairman, formed a Subcommittee to review the existing NRC Medical Policy Statement, and to make recommendations as to whether or not staff should change this policy statement.

After Dr. Alderson became an official member on the Committee, he was then added to that Medical Policy Statement Subcommittee. Later on this morning you will have a discussion from Ms. Ashley Cockerham who is still a member of the medical team, but is now on rotation as a Technical Assistant to Ms. Laura Dudes, so she will be here to give a presentation from staff's perspective for the Medical Policy Statement. And then Dr. Thomadsen will follow-up with the Committee's or the Subcommittee's recommendations.

That concludes Old Business. Are there any questions or changes that need to be made?

CHAIRMAN THOMADSEN: Dr. Langhorst.

MEMBER LANGHORST: It's just a housekeeping thing.

MS. HOLIDAY: Sure.

MEMBER LANGHORST: I wonder, the Medical Event Subcommittee is somewhat of a standing committee. I mean, we always look at things each year, and I wonder does it stay open like you track them. I mean, if the note is to make changes in the membership of the Subcommittee, they made the changes, and then I think that should be closed so you wouldn't have to track them, necessarily. Just a suggestion.

MS. HOLIDAY: That is an absolutely wonderful suggestion, and I think great minds think alike, and I'll say that the great mind is Mr. Fuller with you, because Mr. Fuller actually brought this up with me as we were going through these charts. And I think that I wanted to bring it forth to the Committee to say that what staff would like to do is have a separate document that just lists the existing Subcommittees and the membership, and their charges, and then remove it from the Recommendation and Action Charts.

CHAIRMAN THOMADSEN: I think that would be a lot easier for us to keep track of what's going on, were that the case. Do we have any comments, Committee? I don't think we need to vote on that. I think you can just do that.

MS. HOLIDAY: Great, thank you very much. Are

there any other comments for Old Business?

CHAIRMAN THOMADSEN: Hearing none, thank you very much, Sophie.

MS. HOLIDAY: Thank you.

CHAIRMAN THOMADSEN: And I would like to second what Ms. Dudes said, that the Committee very much appreciates everything that you do for us. You go more than the extra mile.

MS. HOLIDAY: Thank you.

CHAIRMAN THOMADSEN: And that brings us to Dr. Howe with the Commission Direction on Part 35 Rulemaking Activities.

DR. HOWE: Thank you, Dr. Thomadsen. Laura stole a lot of my thunder.

(Laughter.)

DR. HOWE: We did have the Proposed Rule. It went to the Commission, and the Commission has approved publication of the Proposed Rule. The Staff took the Commission's recommendations and incorporated them into the revised Proposed Rule. And that is currently in the process of undergoing the final processes of going over to the Commission and eventually going over to the Federal Register and getting published, and we think it will be published next week.

Those were the majority of the comments. I'll

be talking about just two of the directions that we got in the Staff Requirements Memorandum, and I'll be teeing up one of them and Ashley will be talking about that in more detail.

One of the directives was that we should update the NRC's Memorandum of Understanding with the U.S. Food and Drug Administration, and we have been in the process of updating the memorandum for a number of years, especially when we changed our name; NRC was reorganized into FSME and to the Nuclear Material Safety, NMSS offices.

We had some sticking points. We've now worked [inaudible] we're now working through the General Counsel at FDA and at NRC, and I think we're resolving most of our major issues, so we are working on revising that MOU.

And the next one is the staff's recommendation on whether to update the Policy Statement of the Medical Uses of Byproduct Material, and that's an issue that Ashley will be addressing after me. I don't see Ashley right now. Do you have any questions?

CHAIRMAN THOMADSEN: Yes, Dr. Langhorst.

MEMBER LANGHORST: Just a question on the Memorandum of Understanding. Is that something that is open for comment, or is that strictly between the two

agencies?

DR. HOWE: It's strictly between the two agencies. When we, after we've negotiated and they've signed off on it, it appears in our public website.

MEMBER LANGHORST: Okay, I was just curious. I didn't know.

CHAIRMAN THOMADSEN: Dr. Suleiman.

MEMBER SULEIMAN: Just a little bit of historical perspective. A couple of decades ago, and I lose count, but I think there was an incident where a radiation therapy unit wound up killing a patient, so you had overlapping jurisdictions. As a result of that, there were extended hearings, and I think it was Senator John Glenn who said look, you guys just need to talk to each other more. And I think out of that series of discussions, the MOU came about. Of course, what happens in the interim is you have statutes that define what you can share and what you can't share with different agencies, so that's really the sticking point. The entire intent is to communicate with each other during a safety issue where you have multiple jurisdictions, so the site doesn't get hit. I mean, they still get hit simultaneously but at least they're at least speaking to each other.

DR. HOWE: And if you're interested, the

current Memorandum of Understanding is up on the public website. If you go to the Materials, Medical, Industrial and Academic page, you'll see a link to the MOU. We found the MOU, the original that MOU signed would expire every five years. We found that extremely burdensome for both agencies, so the last time we revised it, we made it with no expiration date so that we were not faced with a deadline. So, even though it was signed a while ago it is still in effect, and it will continue to be in effect until we revise it.

CHAIRMAN THOMADSEN: Any other questions or comments? Hearing none, thank you very much, Dr. Howe. That put us just a little bit ahead of schedule for the next item which is a break. Can we go on? Is this going to be a problem for people who are calling in and expecting us to be following this schedule?

MR. FULLER: I think it's best for us to try to stay on the published schedule as much as possible for those folks who may be calling in, or listening in, or watching the webcast in accordance with the agenda. That being said, we also have another problem in that the next presenter is scheduled to be here at 10:00 for her presentation, and I do not see her in the room.

CHAIRMAN THOMADSEN: Given the confluence of events, I think we'll be on break until 10:00. Everybody

please be on time, though.

(Whereupon, the proceedings went off the record at 9:04 a.m. and went back on the record at 9:59 a.m.)

CHAIRMAN THOMADSEN: Welcome back from the break, and before we resume with the program, Mr. Fuller has a correction to make.

MR. FULLER: Thank you, Dr. Thomadsen. Once again we are reminded about the potential problems with speculating about when something may be published, when documents may be published in the Federal Register. We said early this morning we thought that the proposed rule would be published some time next week for public comment. That's the proposed rule on Part 35. On the break I was informed that that was a little premature, that it's not where we thought it was. We thought it was with the Commission. In fact, it has not gotten there yet for their five-day review; so now I think the best thing to say is that we hope and are planning on that proposed rule to be published for public comment in the Federal Register sometime soon. If I am more specific than that, I'll probably make a mistake, so considering how long it has taken to get to this point, I think it's fair to say that soon is an accurate time frame. So, again, my apologies.

CHAIRMAN THOMADSEN: Sometime before we all retire. Thank you very much for that clarification. And now we will pick up with Ms. Cockerham talking about the NRC Medical Policy Statement.

MS. COCKERHAM: Good morning, good to see all of you. I see some new faces, as well.

So, the purpose of my presentation today, part of it is to give a brief history of the Medical Policy Statement, what the previous one was, and what the current one is. As Donna-Beth discussed the Part 35 Rulemaking SRM, part of what the Commission directed staff to do in that Staff Requirements Memorandum was to look at the Medical Policy Statement. And they specifically directed staff to write a paper with recommendations on whether or not to update the current Medical Policy Statement. So, we are looking for ACMUI's input on whether or not we should update that Policy Statement, and we will include your position and recommendations in the paper that's sent to the Commission later this year.

So, a little history on Policy Statements. NRC publishes Policy Statements to cover broad areas where radiation safety is a concern. As a few examples, we have Policy Statements for consumer products, for decommissioning, medical uses, which is what we're

discussing today, we have them for nuclear fuel, radioactive waste, and also safety culture which is another one that this Committee worked on a few years ago, or actually over the past few years we've been working on it.

So, Policy Statements are not considered rules or regulations. They do allow the Commission to clarify positions regarding radiation safety issues. And Policy Statements tend to be more philosophical rather than technical, and they provide the Commission's expectations related to a particular regulatory topic for staff, licensees, and others. So, how it all started.

In 1979, based on experience, and comments, and advice from the public, other federal agencies, the States, the ACMUI, the Commission initially published its first Medical Policy Statement, and these three bullets kind of summarize what that 1979 Policy Statement looked like. And the first part is that it addressed the safety of workers and the public. Another big part is the safety of patients, and they used a risk-based approach, and further it asked for voluntary standards or compliance with these standards was inadequate. And then the third part discussed how NRC would minimize intrusion into medical judgments or the

practice of medicine.

So, what changed from 1979 to 2000, so it was in effect for those 21 years, an updated Policy Statement was finalized in 2000 and it took four years of deliberation, and that involved ACMUI and members of the public. It was our regular open process between the publishing in the Federal Register and receiving comments, public meetings, things like that. And this updated Policy Statement guides the NRC's current and future regulation of the Medical Uses of Byproduct Material.

So, from 1979 to like 2000, the first part of the Policy Statement was essentially unchanged. It's that NRC will continue to regulate the uses of radionuclides in medicine to provide for the radiation safety of workers and the general public.

For the second part they were just adamant that in patient safety that the medical use of a material is in accordance with physician directions. They kind of built on that. Another big change was with regard to the medical practice, so the language was changed from NRC will minimize intrusion to NRC will not intrude into medical judgments affecting patients except as necessary to provide for the radiation safety of workers and the general public.

And then the last piece that was added was for NRC to consider industry and professional standards that define acceptable approaches of achieving radiation safety. So, that's where we are currently.

And you saw those are kind of broad-covering areas, and we're not recommending any changes at this time, NRC Staff is not. We believe that the current Medical Policy Statement is effective and sufficiently flexible to balance the appropriate level of licensing oversight, while maintaining the radiation safety of workers, the public, and patients, while not intruding into the practice of medicine.

The staff believes that the proposed changes in the current Part 35 Rulemaking would provide the balance needed by physicians to take actions deemed medically necessary while continuing to enable the NRC to detect deficiencies in processes, procedures, and training. So, these changes that were made as a part of the Part 35 Rulemaking were all made within the current scope of the Medical Policy Statement, so there were no revisions required to make these major changes that, you know, the community and the ACMUI felt were needed.

We also raise a point that the last time the policy, or when the Policy Statement was updated starting in '96, it took four years. It was a lot of time,

a lot of resources, there's a lot that goes into it. And there were major changes, so do we want more major changes? You know, what would be the resource implications for that? So, we want to consider that.

So, as far as our path forward today, I know Dr. Thomadsen has put together a Subcommittee and has some information for NRC staff, so we're looking forward to hearing that. We will take the official ACMUI position or any recommendations that you give us and incorporate them into a Commission paper, and that will be drafted this summer. It will go to the ACMUI and to the Agreement States for review and comment, and then this fall we will finalize the paper and send it to the Commission. That's all I have for the Committee. Thank you.

CHAIRMAN THOMADSEN: Thank you very much. Any questions for Ms. Cockerham? Yes, Mr. Zanzonico.

MEMBER ZANZONICO: Pat Zanzonico, thank you. I just have sort of a philosophical issue. I have a point to what you were saying. It seems that, you know, given the broad context of Policy Statements, is there the possibility of a licensee kind of inferring from a Policy Statement something that for purpose of convenience or otherwise that might not be consistent with a particular regulation? The Policy Statements

seem to emphasize non-intrusion, facilitating medical practice, so forth and so on, and it strikes me that a licensee could potentially infer from that that something that might not be consistent with the letter of the regulations might be permissible in light of that policy. Is that an issue that ever comes up?

MS. COCKERHAM: I'd have to ask Mike as the Medical Team Leader if we've had any issues on the Medical Team that we're aware of.

MR. FULLER: Just off the top of my head I can't think of any specific examples. However, there are a lot of different opinions and philosophical positions that people take about the medical rules and so forth. Our job at NRC is to make sure that whatever we put out as a proposed rule or any of our final rules, guidance and so forth is in accordance with the Policy Statement. And part of the process like we've been going through for Part 35, the expanded rule recently, part of the process is designed to insure that when the Working Group is developing these draft rules or what eventually become proposed rules, or the rule language, if you will, part of their charge and their responsibility is to make sure that what is being proposed, what is being presented for public comment and so forth has already gone through that review, and it is in accordance with the Policy

Statement. And we have a lot of help along those lines, we have members of our Office of General Counsel, our attorneys, who help us with that, and so forth and so on.

Now, whether or not someone would then say well, this rule is not in accordance, I mean, that would be a very, very serious - that would be a statement that we would take very, very seriously, and would prompt us, especially in this upcoming anticipated proposed rule public comment time frame if somebody felt that way and made that sort of a comment, then we would take that very seriously and take it back, work it back through the process to make sure that, in fact, we had not missed something or gone off in the wrong direction. I hope that answers your question.

MEMBER ZANZONICO: Yes, it does. Thank you.

CHAIRMAN THOMADSEN: Mr. Costello.

MEMBER COSTELLO: A couple of things. Most licensees are not NRC licensees, in fact, they're Agreement State licensees. And the Policy Statement is an NRC Policy Statement, not a Policy Statement of the Agreement States. So while I believe that the Policy Statements you selected in the rules which for the most part the States adopt in a timely manner, the question as I understood you raised it, could you in a given

interaction between a licensee and the regulator, let's say during an inspection, or when the licensee was contemplating some process, it might refer to the Policy Statement and say well, it must be okay because the Policy Statement says that. And I think it would be - I think you'd have to be cautious about doing that even in an NRC State because they should refer to the regulation before they refer to the Policy Statement. And they should be even more cautious doing that in an Agreement State, which certainly has not adopted the Policy Statement.

CHAIRMAN THOMADSEN: Thank you for that comment. Any other - yes, Dr. Suleiman.

MEMBER SULEIMAN: I'm always fascinated by - I try to limit myself to the statute, the law, and then the regulations which are very prescriptive and defined. Policy, guidance, practice, they're all fuzzy, non-enforceable. So, I would think that the regulations really derive from the statute, and the policy is sort of a general, you know, sort of a sense of this is what we think. But I would think the regulation is pretty specific. And I think that policy would refer to the regulation so it could be above the regulation or below the regulation. I mean, I always taught people unless it's an enforceable regulation, the rest of it is

subject to interpretation. But, Dr. Zanzonico, you were raising the issue, could policy be used to sort of trump the regulation.

CHAIRMAN THOMADSEN: Thank you, Dr. Suleiman. Mr. Costello.

MEMBER COSTELLO: Just one further follow-up on that. I think that both the NRC and all the States are very aware that in our practices we try very hard not to intrude in the practice of medicine. And that's something when you're inspecting, it comes up more often than you may think. So, I think you'll find that all the States have adopted the philosophy that we don't intrude in the practice of medicine, but they just haven't adopted the Policy Statement as is.

CHAIRMAN THOMADSEN: Thank you. Other comments? Thank you, Ms. Cockerham.

MS. COCKERHAM: Thank you.

CHAIRMAN THOMADSEN: And since I'm the next speaker, I'm going to turn the Chair over to Dr. Guiberteau.

VICE CHAIRMAN GUIBERTEAU: Well, our next speaker is Dr. Thomadsen, who is -

(Laughter.)

VICE CHAIRMAN GUIBERTEAU: - is making his way towards a seat to make his presentation.

CHAIRMAN THOMADSEN: As you heard, we had a Subcommittee of the ACMUI, generate a statement of whether we felt there needed to be changes in the Medical Policy, which we did. Here are the members of the Subcommittee, Dr. Alderson, Dr. Guiberteau, thank you, Dr. Palestro, Dr. Suh, Dr. Welsh, and I was the Chair. You've already had the history, so I can go through these very quickly.

There were the three parts in the '79 Policy Statement stating that the NRC would regulate medical uses to protect the safety of workers and the general public. The second was that the NRC would regulate radiation safety of patients, justify it by the risk to patients, and were voluntary standards or compliance with these standards were inadequate. The third was that the NRC would minimize intrusion into the medical judgment affecting patients and into other areas additionally considered to be a part of the practice of medicine.

The change in 2000 was the NRC would continue to regulate the use of radioisotopes in medicine as necessary to provide for the regulation of the radiation safety of workers and the general public. Two, the NRC will not intrude into medical judgment affecting patients except as necessary to provide for the

radiation safety of workers and the general public. Three, the NRC will when justified by the risk to patients regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions. And, fourth, that the NRC in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety.

There have been some concerns about how the regulations are compatible with the policy, particularly, examples involving the definition of Medical Events, which this body has discussed for I don't know, how many years, several years now. And the definition has been under change in the new Part 35, and the Training and Experience Regulations, and the concern that they may have unduly affected medical practice without increasing safety. As I say, the new Part 35 seems to be addressing these concerns.

In looking at where these might encroach on medical judgment, that would mean that the regulation was in conflict with the policy. The new Part 35 seems to have brought these items into line with the policy, so the ACMUI's recommendation is that the current statement provides for Medical Uses of Radionuclides

safely for patients, subjects, staff, including general public while avoiding intrusion into the practice of medicine, and no revision is warranted at this time. That's the new part.

VICE CHAIRMAN GUIBERTEAU: Are there questions for Dr. Thomadsen from members who actually were not on the Subcommittee?

MEMBER ALDERSON: Mickey, I'd like to ask a question.

VICE CHAIRMAN GUIBERTEAU: Yes, Dr. Alderson.

MEMBER ALDERSON: Yes. And it's a question based on my late arrival to these affairs. And that is, there was a great deal of discussion, Dr. Suh made with a comment on the regulations that had to do with the placement of brachytherapy sources, especially for prostate cancer, and how that had led, unfortunately, to things that were medically appropriate being deemed medical events, and that that had been resolved. What - at least that's what I heard from some people in radiation oncology that I know.

What isn't clear to me is what that resolution was. In other words, did a policy change, did a regulation change? What changes so that the community of radiation oncologists were satisfied that no changes were required at this time?

CHAIRMAN THOMADSEN: Do you want to address that, or shall I?

MEMBER SUH: I don't know if it may be better to address all the kind of history behind it, and what was -

CHAIRMAN THOMADSEN: I'm sorry. What?

MEMBER SUH: It may be better if you address that, if you don't mind.

CHAIRMAN THOMADSEN: The problem with the previous, the old [ME] definition which has changed is the current definition, was that it was based on the dose to the prostate which is something that is very hard to control in a permanent implant. And the tolerances were tight compared to what's achievable in the clinic.

The - at least what was recommended here and maybe in the new Part 35 was looking at where the seeds were placed as opposed to the dose that they then produced, which the practitioner would have better control over. So, it was that looking at a quantity that the practitioner did not have complete control over was the intrusion into the medical practice; whereas, judging how the practitioner fulfills the intention, that is where the seeds go, was something that would be allowed under the policy, and would be the new definition in Part 35. Does that answer the question?

MEMBER ALDERSON: In part, it does. And, again, you'll forgive my newness is causing me to pursue this. But part of the question is related to what the gentleman from the FDA said just a moment ago about the fact that policy isn't enforceable and regulations and statutes are. So, my real question is, given these changes and wording in the policy that has made or is making a difference in the way that these are enforced in the field, so that the awkwardness that existed before no longer does.

CHAIRMAN THOMADSEN: You mean the change in the regulations to come in line with the policy.

MEMBER ALDERSON: Okay, maybe that's where I'm at.

CHAIRMAN THOMADSEN: Yes. See, the policy has been in place since 2000 and has not – you're recommending that it's not a change in that because as long as the regulations are compatible with the policy, you don't seem to have a problem. It's when the regulations have conflicted with the policy that that has caused problems with the medical practice.

MEMBER ALDERSON: Okay. So, the regulation has been altered in such a way that this is not a problem any more. Thank you.

VICE CHAIRMAN GUIBERTEAU: I think the feeling

here was that the policy allowed the flexibility to make regulations that were acceptable to the medical community while still protecting patients and the public. And it's the feeling of the Subcommittee, not to put words in Dr. Thomadsen's mouth, but having been on the Subcommittee there seemed to be pretty uniform agreement that it wasn't a fault of the policy, that the regulation had to be changed because it had been put in place, and when problems arise from that, that's when the - it was realized that the regulation was not clear and needed to be altered.

MEMBER ALDERSON: So it was.

VICE CHAIRMAN GUIBERTEAU: And so it was, yes.

MEMBER ALDERSON: Very good. Thank you.

VICE CHAIRMAN GUIBERTEAU: Sue?

MEMBER LANGHORST: Yes, Sue Langhorst. Dr. Alderson, just to give you a little bit more perspective, too, the - what is going to be published soon on the proposed Part 35 will be a proposed change to the regulations, which includes this.

MEMBER ALDERSON: Okay.

MEMBER LANGHORST: It will be open then for public comment, so I urge everyone that looks at these things to comment on whether they think the changes proposed, do support the policy. So, that's an

opportunity. The regulations haven't changed yet, but they're in the process. And you will learn as you're on this Committee it takes a little time to work through that whole process.

MEMBER ALDERSON: Okay, thank you very much.

MEMBER LANGHORST: Thank you.

VICE CHAIRMAN GUIBERTEAU: Any other questions for Dr. Thomadsen?

MEMBER WELSH: If I might -

VICE CHAIRMAN GUIBERTEAU: Yes.

MEMBER WELSH: - just add my perspective as the senior-most member of the Committee here.

(Laughter.)

MEMBER WELSH: Wrestled directly with the Medical Event definition for brachytherapy quite aggressively and interactively for the past seven years or so.

In the way of background, we realized that a dose-based definition versus a source placement-based definition for a medical event are two very, very different entities. A dose-based definition for brachytherapy, prostate permanent implant brachytherapy with seeds as the classic example, may be adequate for standardization in clinical trials and of value when reporting outcomes, but falls far short of

what is ideal when it comes to regulation, because it's extremely difficult to really obtain the dose that one desires based on the reality of permanent implant brachytherapy. And just to reiterate what has been said for the past seven years briefly, if you make a plan on an object that is the size of, just for the sake of example, size of a baseball, but that after the implant that target is now the size of a softball, by definition energy per unit mass, or energy per unit volume has been changed. And, therefore, your dose is off from what you planned it to be, but that doesn't mean that the implant was in any way inadequate. So, if the sources are placed where you wanted them to be, that would be a better way for regulatory purposes defining a medical event. After all, we hope that that softball will resume the size of the baseball in weeks to come, but if you take a snapshot when it's at the size different from the baseball you get an erroneous impression. So, those are some of the challenges we've had with the regulations, the rules, and the definition, and we hope that when the new rules come out you'll see that they're consistent with the policies and reflect what we have been arguing for the past seven years here. And we will await seeing what the actual published rules look like, and encourage comments if they differ from what has been recommended

by ACMUI and stakeholders.

VICE CHAIRMAN GUIBERTEAU: Thank you, Dr. Welsh. Are there any other questions or comments specifically related to the Medical Policy?

CHAIRMAN THOMADSEN: Yes, Mr. Chair. The Subcommittee would like to make the motion that the full ACMUI approve the recommendation.

VICE CHAIRMAN GUIBERTEAU: Is there a second?

MEMBER MATTMULLER: Second.

VICE CHAIRMAN GUIBERTEAU: We have a second. Some discussion on the motion?

MEMBER MATTMULLER: Can I intercept that second and ask a question.

(Simultaneous speaking)

MEMBER ZANZONICO: I'm moving to clarify, I don't think we can at the moment. I think we have to wait -

(Simultaneous speaking)

VICE CHAIRMAN GUIBERTEAU: Now the discussion needs to be directly related to the motion, that is to approve this. And if you want to ask your question now about the motion, that would be great.

MEMBER ZANZONICO: Yes. My question is, what precisely is the motion we're voting on?

CHAIRMAN THOMADSEN: To adopt the report. I

think the - what you're voting on is the recommendation -

MEMBER ZANZONICO: The recommendation -

(Simultaneous speaking)

CHAIRMAN THOMADSEN: - provides accepting right there.

MEMBER ZANZONICO: Okay, thank you.

MS. HOLIDAY: The ACMUI is recommending no changes to the current Medical Policy.

VICE CHAIRMAN GUIBERTEAU: So, the understanding with everyone here now that the clarity of this is that we are voting to accept the policy as you have it here, which recommends no change from - since the policy was revised in 2000, that no change be made – no change is necessary in the NRC Medical Policy. Any other discussion? All in favor?

(Simultaneous speaking)

MEMBER WELSH: I have a discussion point. Although I am in full agreement with everything that Dr. Thomadsen has said and everything that is in the report, I think I would be remiss if I didn't at least for the record state what I was going to say to the Commissioners last fall, but for reasons beyond our control we never had that meeting.

But as the use of byproduct material has continued to expand and broaden from provisional definition of reactor-produced literal byproduct material to accelerator-produced radioactive material and naturally occurring radioactive material, the definition has broadened. Therefore, it just seems like it's a matter of time before somebody asks the question when the Nuclear Regulatory Commission or another agency that has yet to evolve will encompass not just byproduct material but all ionizing radiation. And I look at the way the States regulate things, I look at the IAEA precedents, and I just think that with the advent of PET CT scanners and newer technologies such as the ViewRay™ and hybridized, hybrid treatments, machines, technologies that will evolve that it's going to be more and more of a challenge for the NRC to continue to regulate a technology or procedure when the byproduct aspect is not all of the ionizing radiation component that needs to be factored in when we talk about radiation safety. So, just for the record I just wanted to bring up that question or point that in an ideal world it would be nice if NRC or an agency could regulate all of ionizing radiation rather than just the byproduct aspect of ionizing radiation. And it makes a lot of sense, but I understand that it's not always practical

and could be very, very difficult to implement even if people thought this was a good idea.

VICE CHAIRMAN GUIBERTEAU: Thank you, Dr. Welsh. That would be a very expanded rulemaking --

(Laughter.)

VICE CHAIRMAN GUIBERTEAU: Yes?

MEMBER COSTELLO: But, in fact, that's what we really have for the 38 states of the union, because in the Agreement States we regulate a machine-produced radiation, you know, the LINAC and diagnostic x-ray machines, and storage units and such, and we also regulate byproduct material. So, one of the things about the Agreement State is that all encompassing, you know, regulation on radiation safety. What you don't have is, you don't have any national body that does the same thing. They do have that in the States.

VICE CHAIRMAN GUIBERTEAU: All in favor of the motion - okay. I'm sorry. Dr. Suleiman.

MEMBER SULEIMAN: I think you could argue that the FDA regulates all aspects of risk for medical products, but we clearly stay away from how it's used. I mean, we pretty much defer to - even if the label has specific information we allow the regulated medical professions, they have to be licensed to how they use it, but we don't just consider radiation risk, we

consider other risks, as well. But I think when you get into - are you talking about the user, are you talking about the products, are you just limiting this to radiation? So, I don't think you're ever going to get a simple answer.

VICE CHAIRMAN GUIBERTEAU: Any further comments? Let me look around. I need two eyes on the sides of my head. Seeing no further comments, I'll call the question. All in favor of the Committee adopting the report as presented of the Subcommittee on Medical Use Policy Statement, raise your hands. Are there any opposed? Any abstentions? Then the Subcommittee report is adopted unanimously by the Committee.

CHAIRMAN THOMADSEN: Thank you.

MS. HOLIDAY: Dr. Guiberteau?

VICE CHAIRMAN GUIBERTEAU: Yes?

MS. HOLIDAY: May I ask for the record, I have it as Dr. Thomadsen put forth the motion. Who seconded?

VICE CHAIRMAN GUIBERTEAU: I think it was Mr. Mattmuller.

MS. HOLIDAY: Mr. Mattmuller. Thank you.

VICE CHAIRMAN GUIBERTEAU: We forgot to resurrect your second, but I didn't know how far down your hand had come by the time -

(Laughter.)

CHAIRMAN THOMADSEN: And with that, we will -- thank you very much. I keep leaving that behind. We invite Dr. Howe to return to the presenter's chair to talk about Medical Events. Mr. Fuller?

MR. FULLER: Thank you, Dr. Thomadsen. We have a few minutes and in sort of response to the earlier discussion I think that Dr. Alderson had sort of started, we've been working in this expanded Part 35 Rulemaking here so long that sometimes, my apologies, we kind of short-circuit or shortcut some of the details.

When we talked about publishing the proposed rule, it is anticipated that soon we will be publishing for public comment these proposed rules, so that's sort of where we are in the process, Dr. Alderson. And it will be published for 120 days, so that will carry us through the summer.

And I want to echo some of the earlier comment, we as NRC Staff are very, very interested and would like to encourage everyone and anyone who is interested to comment during that 120-day period. This is the opportunity for us to get the feedback that we need from the public. And even though the ACMUI has had an opportunity to comment before, during this public comment period, it is yet another opportunity for folks

to really look at it closely, consider it, maybe the perspective of is it really doing what we say we're supposed to do in our policy, or any other concerns or questions that folks might have. We really, really want to encourage everyone to comment on this proposed rule. So, thank you.

CHAIRMAN THOMADSEN: Thank you. Dr. Howe.

DR. HOWE: Okay. This is part of my annual presentation on the status of Medical Events for the preceding fiscal year. I always compare the preceding fiscal year with the year before that so that you're not seeing things in a complete vacuum. And you will see that we had 48 medical events in 2012, we had 43 medical events in 2013. That's not a big difference. Yes, Sue?

MEMBER LANGHORST: I'm sorry, Dr. Howe. I just wanted to - would you say what is the fiscal year that you're talking about, what are the dates so everyone knows what that means?

DR. HOWE: The fiscal year for the U.S. Government is October 1st to September 30th.

MEMBER LANGHORST: Thank you.

DR. HOWE: So, that would be October 1st of 2012 through September 30th of 2013.

MEMBER LANGHORST: Thank you very much.

DR. HOWE: Okay. And as you look through the

different sections because the sections really reflect the modalities of medical use, 35.200 is the nuclear medicine procedures that don't require a written directive; 35.300 are the nuclear medicine procedures that do require a written directive; 35.400 is the sealed sources used for manual brachytherapy; 35.600 are the sealed sources used for either HDR, Gamma Knife, or teletherapy; and 35.1000 are those uses that don't fit into the other categories, sometimes referred to as emerging technologies.

You;ll see there really wasn;t that much of a change between where the medical events were in 2012 to 2013. 2012 we had medical events in 35.200, which is very rare for us. Now that we have a 5 rem whole body, 50 rem to an organ dose ratio which you have to exceed for diagnostic. None of those involved where you're supposed to get a diagnostic I-131 you get therapy. Sometimes involve when you get an entire technetium generator elution injected into a patient, so those are very rare, so it's not unusual to have a zero in that category.

The other thing I'd like to point out is that there are a lot of medical procedures every year, so when we're looking at 43 medical events across a number of medical specialties it's not a very large number. You are never going to get statistics out there.

Now, if you look at the specific medical events, I break them down by modality, and 35.300 are the nuclear medicine procedures that require a written directive. Normally, they're all I-131 but we did have a yttrium-90 medical event. And in this particular case, the physician wanted to administer an activity that was beyond the activity that's recommended in the package inserts for safety, so he dropped back to the package insert level. He wanted to drop back to the package insert level of 32 millicuries.

If you look at the slide you can see, and I don't know it for a fact, but it kind of looks like maybe somebody transposed the 32 and the 23, so the 23 was put on the written directive. What did they administer? They administered what the physician originally intended which was the 32, but the way our regulations are written, every once in a while we will pick up a medical event in which what was intended is what's delivered but it's not what was in the written directive. And to help reduce the number of medical events back when we looked at things in 1992 we decided that if you put things in writing then you take care of events that were happening because of speech and people misunderstanding things, so this is just one of those cases where you're caught with a human error that happens during the written

directive.

We also have things that are not medical events. When people intend to give - when they write something in the written directive which is not what they intended and that's what's given. So, it goes in both directions.

The next medical event was I-131. In this case, the physician - you have to read the TOEs on this one. If you look at the extended description that you find in the references, you'll see that there was a written directive on a form. It appears as if the form asked for a whole body scan but there was a comment section. And in the comment section it was very clear that the physician required a thyroid ablation, and the hospital was changing over to an electronic form so when they put the information in they probably looked more at the form and said oh, this is whole body scan. That went into the electronic record. It wasn't until the patient came back for the scan itself that they looked at the paper for the written directive, and the paper for the written directive had clearly indicated in the comments part that they wanted a thyroid ablation, so it was a medical event.

Moving into 35.400, we have 15 medical events with manual brachytherapy, there were 18 patients

involved. We had two gynecological medical events, and had 13 prostate reports. There were multiple patients involved in two of those. So, on the gynecological one we had packing came out, so it was a dose to the wrong treatment site, and 450 rads to the skin. On the second medical event we had one of two sources that was not correctly put in the applicator, and so it fell out in the middle of the procedure. In this particular case they found it in the linens of the bed when they changed the bedding and the nurse picked up the source with her hand and put it on the table, so the nurse received an extremity dose of 13 rem.

Now, moving into the prostate medical events. There were three patients with underdoses. The description was that first, in the first case, this is one licensee with three patients, there were very few sides - seeds were outside of the margin, but they made changes during the intraoperative to account for implant difficulties and clinical factors and they ended up looking at dose having a medical event with the three patients.

The next licensee with multiple medical events had two patients which were under doses. The physicians recognized that they were underdosed, but they did not recognize that they were medical events that needed to

be reported, so they weren't reported until a year and a half later when the physicist was looking at the records and realized that they were reportable medical events.

We had two licensees that had issues with a pubic arch, and in the first case there were five seeds of the 106 were implanted, they were unable to implant any more seeds. The corrective action for that licensee was to do a more thorough examination of the patient to make sure when they're doing the treatment planning that there are not going to be obstructions, and they will be able to deliver the procedure.

The second licensee they actually bent some of the needles as they were trying to implant 14 of the seeds and they ended up with less dose than they had expected.

We also had a treatment planning error in which the patient was supposed to receive 4500 centigray of intensity modulated therapy and then receive a lesser dose from the manual brachytherapy. The medical physicist created the treatment plan but he created the treatment plan as if there was no intensity modulated therapy and it was just a pure brachytherapy procedure, and the Authorized User signed off on it, so the written directive was incorrect. So, the corrective action is

to include the modification of the default settings. The written directive asked for 1100, the medical physicist did a treatment plan for the 14,500, and they went ahead and gave that to the patient, so it was not in accordance with the written directive.

We had multiple cases, seven different licensees where the seeds were outside of the target volume. The first slide shows a lot where I put migrated in quotes. Normally migration would not be considered a medical event but it's not clear from these descriptions and the number of seeds that moved to different places whether it was really migration or it was incorrect placing of the seeds. So, there 16 seeds that migrated to the top of the prostate in one case. The other case you had three seeds that were recovered in the operating room. There were two additional ones that were passed at home. And then when they came back and did the follow-up a month later they found that nine more seeds had migrated out of the prostate and were slightly inferior.

Then you have another licensee where the seeds migrated outside the treatment volume. And their corrective action was to use prostate stabilizers and to modify their ultrasound imaging techniques because we find a lot of the medical events with the prostate

seeds are due to poor visualization of ultrasound.

There were six seeds implanted into the perineum. In this one the licensee indicated the root cause was inadequate ultrasound image visualization, and that they had used a resident, a urology resident so the impression is that they will go to more experienced individuals. And that they were having some difficulty with the tension adjustment in the applicator.

The next licensee had 19 out of 67 seeds were put in the bladder, and they indicated that many of the seeds were not visible under ultrasound, that they continued.

The next one was 63 seeds were 3-1/2 centimeters from the site so they had incorrectly identified the treatment site. The next one was 60 percent of the intended dose was given. They claimed that there was an organ shift or incorrect needle depth, and their correction is going to be to insert the transrectal ultrasound probe to identify the base plane, so it appears as if they didn't have the base plane set where they thought it was.

Moving into 35.600, we have the - all of our 35.600 medical events this year were for HDR units. We didn't have any teletherapy or any GammaKnife. Six of

them were to the wrong site, three were with the wrong patient, and one was a stuck source.

There were wrong site. Many of the wrong site ones were - involved issues with the treatment catheters. In this case, the tip in the end of the treatment catheter were inverted in the planning system so they put the dwell positions in incorrectly and did not treat the treatment site. I've gone in order of the medical events that appeared to have a higher dose to the unintended site, so you'll see it dropping down with time.

In this particular case they identified issues that they believe were associated with a medical event for ulceration of the anterior wall of the rectum and the skin of the interior thigh.

On the next one they -- it was an error in the catheter lengths and it resulted in 1600 rad to the small bowel near the bladder. And the whole dose was delivered 5.4 centimeters from where it should have been delivered in the treatment volume.

The third one you have a high dose to the urethra, and in this case the treatment site received a very small amount of the intended dose. And the physicist selected the wrong length source guide tube and used one that was 132 centimeters instead of 119.

The next one you've got a high dose to the distal colon and the upper rectum. In this particular case the description is a little iffy, but it sounds as if they did not get the source into the person, but it deviated before it got in the person, so it stopped outside the bowel area, and then also outside the sacrum area. So, their corrective action is to review and approve the treatment catheter placement position by two attending physicians because they put it in the wrong place.

And then you've got one that was 4 centimeters from the treatment site. Once again, they had a catheter problem where they used a catheter that should have been used from a tandem. It was used on the cylinder so it was 4 centimeters longer. The corrective action is to mark the catheters for their intended use so that that doesn't happen again.

And the final - I normally keep track of those that happen with Mammosites® because they have some interesting properties. And once again, it was the same issue where they entered the wrong indexer length so they put the sources in the wrong place. They looked at what they had entered and they determined that they had a faulty source position simulator. And they've replaced that and took it out of service.

It's not usual that we get the wrong patient. Mostly in the HDRs they get the right patient, but in this case we had three cases where the wrong patient received the treatment. Some cases the procedure was very close to what the patient should have gotten, but it was the wrong name, so they just happened to be very lucky that the treatment parameters were very close.

In the first licensee, the patient received another patient's procedure. And then they had two - another licensee had two patients scheduled for the same day. The second patient received the first patient's treatment plan. The third one they administered a 700 rad fractional dose that was prepared for another patient.

And then some literally have stuck sources that end up in administration. In this particular case the source got stuck in the tube. It exposed the fie in the source, they were unable to get it retracted and they end up having to send it off to the manufacturer, and even the manufacturer's engineer couldn't dislodge it. So, that was an equipment failure.

And a lot of times licensees think that if they have equipment failure it's not a medical event. Well, if it delivers a dose that exceeds our dose limits, it is still a medical event, because they're so used to the

human factors ones that they think anything other than human factor is not a medical event.

For 35.1000 which are the other uses, are the emerging technologies, we had - and this is unusual. We had one with the I-125 seed localization procedure, and then we had 14 with the yttrium microspheres. I tend to skirt out the SirSpheres® from the TheraSpheres®. It really doesn't make a difference. One year one company has more medical events than the other. This year was SirSpheres® turn.

For the I-125 seed localization they put the seed in and the seed migrated deeper into the patient, and they were unable to retrieve the seed. And we put in the guidance for the seed localization that you have a written directive, and the written directive is intended to insure that the seeds are removed. And in this case, the seed was not removable.

They did use ultrasound to remove the tumor in the lymph node so they were unable to use the radiation probe for its intended purpose, which was to identify where the seed was and use that radiation measurement to remove - to the surgical explantation.

For SirSpheres® we - for yttrium microspheres we had 14. If you look at the slide you'll see that the numbers don't quite add up. That's because the four

included catheters really belonged under TheraSpheres® where it appears a second time.

We had a wrong site to the gastric duodenum, the stomach. This particular patient complained of abdominal pain during the procedure and five months later, and then when they did an endoscopy they identified the ulcers which were caused by the microspheres. And they indicated that at the time of the procedure they had not identified the shunting to the gastric duodenum.

We had actual wrong site where they wanted to treat the right lobe but they instead - they treated the right lobe when they intended to treat the left lobe. This was a little bit unusual in that the nuclear medicine Authorized User had intended to give two different administrations, and that's what his written directive was for. But the interventional radiologist who was - in the nuclear medicine position was not present at that time, looked at the flow studies and decided that the -

(Background noise.)

DR. HOWE: -- to the right lobe, so he gave the wrong treatment to the wrong lobe.

You have - and this is a case where the physician reported the wrong administration dose on the

written directive form. So, it was not in accordance with the written directive, but I believe it was probably in accordance what he had intended to do, so this is a second one of those today.

You have operational error. In this case, they did not put the needle down into the shielded V-shape far enough, so it did not extract all of the contents into the catheters.

You had a leaking vial. We haven't seen leaking vials for a long time, but they did have a leaking vial so their correction was to apply a bond to the top of the seal.

In this case there was resistance when they were putting - trying to flush the catheter, so they found that there was an occlusion in the catheter, but that's not the cause of the medical event. The cause of the medical event was they decided to stop the second measured dose and use another catheter, and when they did they discovered that there was a microsphere leak between the vial and the catheter, and that caused the medical event.

Now we're switching over to SirSpheres®. What we had primarily were microcatheter occlusions. And it may be that as you're getting to finer and finer treatment sites, you're getting smaller and smaller

catheters, and you're ending up with problems with the very small catheters. A lot of them have to do with kinking.

So, in the first one they only delivered 55 percent of the dose and they replaced the catheters. The next one they delivered 13 percent of the dose because the delivery system clogged. They thought they had an air bubble and they used saline flushes to try to get it out, but there was a clump that formed and clogged the line.

And in the last one we had the same licensee reporting two different medical events about a month apart, and they were all due to the same reason. They had - they were using an arterial into the arm as the location and their catheters weren't long to give a good elevation, so their corrective action was to elevate the catheters more and to induce agitation. We had buildup of microspheres in the delivery catheter. We also had another one where the outlet tubing in the microcatheter - most of it was in the outlet tubing of the delivery system. We had the radial arm, this is where the catheter was too short in the extension tubing and most of the microspheres stayed in the extension tubing. You had a catheter that was plugged during the procedure, so they were looking at the microspheres going into the catheter

flow.

And then the last one we have for 35.1000 was Perfexion®. In this case we had an equipment failure while they were -- they had treated two particular lesions. They were working on the third lesion, and when they tried to give the dose to the third lesion the treatment was interrupted because of the mechanical failure. And there was a sense failure occurred and it caused the patient couch to retract and shield the door closed. And that's something you would hope that it would do in an equipment failure, but it ends up being a medical event. So, that concludes my presentation on the medical events. Any questions?

CHAIRMAN THOMADSEN: Yes, Mr. Costello.

MEMBER COSTELLO: Referring to the two cases, one on the GI shunting of microspheres, as I'm sure you know, we had a case like that in Pennsylvania just a few months ago. In looking over NMED, there have been a small number of these reported over the years. And I think the patient safety implications of these are probably greater in my view than the patient safety implications of the underdoses that are more often reported for microspheres. However, if you look at the literature, and I want to bring it to the attention of the Committee as a whole, there are those who suggest that there could

be 2 to 4 percent cases where they're shunting to the GI tract, but we get very few reports. I mean very few reports. And in the inspections that I do, I rarely see imaging of the GI tract. I see, you know, the people doing imaging for shunting to the lung, but like very rarely, not never, but very rarely, see imaging to the GI tract. I do see people are cutting off vessels that might go to the GI tract, but I don't see imaging. So, I talked to licensee representatives including some major facility in Philadelphia to suggest that none of these GI tract shuntings represent medical events because they're an accepted risk of the treatment. Okay? And I don't know, I don't know.

So, looking at your view really as to what are your thoughts of why there are so few? And, two, is my friend, the large licensee in Philadelphia, correct when he says that none of these are medical events because it's an accepted risk of the treatment?

DR. HOWE: I probably can answer all of your questions. I can give you a perspective of what we looked at and what we thought about when we developed the guidance for licensing the yttrium-90 microspheres.

We recognized at that time that because [inaudible] that shunting was an issue, that most people were aware of shunting to the lung, and that there

were recommendations in the package labeling to do a nuclear medicine procedure to see if there was shunting to the lung, and to see if that was an acceptable level of shunting, that the Authorized User would go ahead and do the procedure.

We separated the NRC licensing from following the FDA package inserts back in 1994, so we do not require licensees to look for shunting, but we wrote in there that… we put a provision in that if the physician decided there was an acceptable level of activity that could go to a shunted site, and they included that in the Written Directive, then if the material did go to that shunted site it would not be considered a medical event. Everybody knew about the lung. We also added the gastrointestinal area because we knew people weren't looking at that as much as the lung, but we wanted to kind of trigger an awareness that that was another area that could be a problem. And as you indicated, it's probably a more severe problem because you can end up with radiation-induced gastric ulcers, so very difficult to view.

MEMBER COSTELLO: I'm not really familiar with the protocols of the Committee having only been on it now for three hours, not counting the hour break. But is there a way that I can get the Committee to be

interested or take up the question of GI shunting of microspheres as to a question of is it true that they're not medical events because it's an accepted risk, or is it that this is a significant risk and maybe licensees are under-reporting it, or just what's going on because, you know, the two that you reported I think [are] from Ohio, and I think Ohio has an elevation in GI tract shunting events over the years. We had one this year. I was surprised that I never knew that GI shunting actually happened, so it's something that, you know, people use to scare people. But is it possible for me, and what's the mechanism to get the Committee to at least talk about the various issues associated with GI shunting of microspheres?

CHAIRMAN THOMADSEN: Dr. Dilsizian.

MEMBER DILSIZIAN: Yes, I'm another newcomer to the meeting. We do a lot of microspheres, I think, at the University of Maryland, and I think to me this is a clinical issue. In essence, there should be a measurement of all body, which is what we do. We should be reporting it, so it's a physician-education physician directive issue rather than an NRC issue. I mean, it's clearly understood, everybody in this room who does practice medicine knows that that's what you should be doing; so if some centers are only imaging the

lungs and not the gastric aspect of it, that's just a medical issue. I think that's just… I don't think that's an NRC issue.

MEMBER COSTELLO: But is reporting it a medical issue? Is the… if it does occur?

MEMBER DILSIZIAN: Well, that's part of the report. In essence, part of it is…

MEMBER COSTELLO: They're not reporting…

MEMBER DILSIZIAN: … whole body imaging, and then interpretation.

MEMBER COSTELLO: Right.

MEMBER DILSIZIAN: And I can extend that from this to any other imaging. You're not reporting on uptake, you're not reporting… so that's medical issue. I think that physicians should be trained to do the right thing, and that should be also part of the peer review process of the institution rather than regulation. It's just something…

CHAIRMAN THOMADSEN: Dr. Palestro, and then Ms. Weil.

MEMBER PALESTRO: Yes, you know, the microspheres have been out for several years now, and if I remember correctly when a company came to the institution, or the institutions, to train individuals the pre-treatment imaging protocol with the MAA

included not only the lungs, but the abdomen, as well. So, we follow that continuously, and all of our patients get routine imaging of the abdomen. So, I'm a little surprised to hear that that's something that you don't see very frequently. We did it both pre-treatment with the MAA, and then immediately post-treatment, as well.

MEMBER COSTELLO: I do see it, but frequently don't see it. But the real question is, if the Written Directive doesn't indicate that there will be shunting to the GI, and if there is shunting to the GI, does that constitute a medical event?

DR. HOWE: If the procedure is given in accordance with the Written Directive, and it falls within the parameters of departure from the Written Directive, the allowable departures from the Written Directive, it's not a medical event. But if the Written Directive does not include it and it occurs, then it is not in accordance with the Written Directive, and as long as it passed over the threshold barriers that are needed, then it is a Written Directive, and that's part of our regulation to capture mistakes, errors, and those kinds of issues.

CHAIRMAN THOMADSEN: Ms. Weil.

MEMBER WEIL: I think there are two issues being conflated here to a certain degree. When your licensee

talks about its part of the accepted risks of the procedure, he's talking about informed consent, and that's patient-sided. So it's not a medical error because it's part of the acceptable risks for the procedure. But then when you're talking about shunting that isn't mentioned in the Written Directive, you're talking about a regulatory issue. And it is a medical event; whereas, it may not be a medical error because it's an acceptable risk of the procedure. So, licensees may be confusing the regulatory requirement with the informed consent requirement. Is that possible?

CHAIRMAN THOMADSEN: Dr. Guiberteau.

VICE CHAIRMAN GUIBERTEAU: Well, I think that's a very good point that Ms. Laura Weil just mentioned, and I also agree with Dr. Dilsizian. I think when you look at any kind of therapy that we do, for instance, if we've given I-131 therapy to a patient with metastatic thyroid cancer who is neutropenic, you use that as part of the informed consent, and we tell them that there is a benefit here to really treating the metastasis, but also a risk, and that this risk can be managed, but there is a risk. We also do this in patients who have impaired renal function if we're treating them for bone metastasis, we tell them that there is an increased risk, and we titrate the dose, but we're going

to try to manage this for you. And I think it then becomes a decision for the patient to say well, no, I don't want my metastasis treated. We'll just have to wait until my neutropenia improves, or you treat the patient.

So, I mean, I think much of this has to do exactly with the practice of medicine, and the same is true if you see shunting, it's a matter of do you want to treat the metastasis in the liver, or do you not? And if the patient knows that they have an increased risk of GI problems because of the shunting and they make that decision, I think then they believe that it's an acceptable risk.

CHAIRMAN THOMADSEN: Dr. Suleiman.

MEMBER SULEIMAN: The implication that this is a metastatic liver cancer, and I think the original approval was for humanitarian use where basically you were dealing with a patient that didn't have any other option, so you're dealing with an extremely serious situation here. And I was trying to pull up the label.

It seems like there are an awful lot of warnings in there, and I sort of agree, this sort of shifts over into "this is medicine", you know. If you start trying to document every abnormality in a complex patient situation, I mean, this is where the medical event criteria falls apart. I mean, the same thing with

the seeds, even though seeds are… you can see them supposedly, and you can define a very fuzzy border, how do you define that border? So, how do you quantitate that? So, I think the same thing here. I guess it would depend on how serious the shunt is and how healthy or sick the patient is in the first place. I think this really… you can't go around…

MEMBER COSTELLO: Let me clarify the question. Okay? And I'll make a point of my friend from the large university in Philadelphia. I think it's an accepted risk. I think you could look on the… from -- there's no space, I think, coming up with SirSpheres®, but a few come up with TheraSpheres®, too. It mentions GI shunting, it mentions pain. I mean, I think it's a known risk of the treatment. However, it is rarely put into a Written Directive. It is rarely put that you would expect to have whatever percent shunting to the GI. So, you have a situation which it's a known risk, but it's not included in the Written Directive. So, when that happens and the patient experiences pain, experiences bleeding, should the institution say, "well, this was a risk we expected, it's not a medical event"? Or should the institution say we did mention this in the Written Directive. It's certainly more than 50 rads to the stomach I think that caused the bleeding, so it will meet

the dose criteria. And since it wasn't in the Written Directive and exceeds the dose criteria I should report it.

Some institutions have been reporting it, but I don't know if that's the whole universe of institutions that have experienced it. So to understand my question, it's not whether it's a practice of medicine, it's whether or not the fact that it's a known risk that's not documented in a Written Directive [that] necessitates the medical event when it occurs.

CHAIRMAN THOMADSEN: And I think we understand the question. There is a complication with the microspheres in that you can check for lung shunting I had with the MAA, not that that's a particularly good measure of expected lung shunting, but a lot of the shunting to the duodenum comes while there is shunting that you can tell ahead and you can coil to shut off those arteries, a lot of the shunting occurs not when… not normally, but when you fill the capillary bed to the artery you're treating then the microspheres then have a retrograde flow into the gastrointestinal artery. And that's something you can't check for ahead. And, in fact, you can't always know when it's happening. And this is a known hazard of the treatment, and it's not something I think you would want to write into the

Written Directive any more than any of the complications that are possible and known would be for the treatment, just as if you were to do for all prostate implants, the possibility that you might have a seed go into the bladder and give the bladder some dose, or a seed go into the rectum, in which case… or just the tissue outside the prostate. Covering all of those possibilities in a Written Directive would be cumbersome and inappropriate, but I understand the question you are saying. It is an item of concern that we see, we do continue to see them, and they continue to happen. Other comments? Dr. Welsh.

MEMBER WELSH: Just to amplify what you've said, Dr. Thomadsen, unlike the NAA which is tagged with technetium-99m and easily visualized, the way we visualize what has happened after the microspheres are implanted and fused, we use Bremsstrahlung imaging, which is far more challenging. And to say definitively how much, if any, and what the doses, if some, of the yttrium-90 has gone to the GI tract is very challenging with Bremsstrahlung imaging. And that's why there is this disconnect between what you see and what you get based on MAA imaging beforehand with MAA which is different from microspheres, and technetium which is different from yttrium versus the post-treatment

Bremsstrahlung attempts for quantifying dose. Thank you.

MEMBER ALDERSON: I'll make one further comment.

CHAIRMAN THOMADSEN: Yes, Dr. Alderson.

MEMBER ALDERSON: It's so basic that I hope that none of my fellow Committee members, that I make this comment, but it seems to me, I'd be surprised if there isn't a lot of shunting most of the time. I mean, you've got microspheres that have to be sized in a particular way when you're dealing with cancer where vessels don't grow in a uniform way. In fact, there is shunting within tumors, there are vessels that are large, there are vessels that are small. I'm surprised it doesn't happen all the time to some extent and, therefore, I'm just concerned that there is a real issue here because it's problematic. Perhaps, people should be instructed to write in every one of their Written Directives such as occurs on labels for things the FDA works with that there may be shunting with this particular product, and you may incur a complication, or something to that effect. But I just think this probably happens a lot.

MEMBER COSTELLO: Could I ask the Committee to take up a question as to whether shunting of microspheres to the GI such that ulcers form, if when

that occurs, is that a medical event if the Written Directive is silent on GI shunting? And if not to give the NRC advice, but give the fine Commonwealth of Pennsylvania advice, too.

CHAIRMAN THOMADSEN: That's a good question. What my tendency on that would be to assign that question as one of the points that the Medical Events Subcommittee should report this fall after they do their analysis. Would that be a reasonable task to give them? I'm hearing nothing, but seeing heads nod. Dr. Welsh, who is the Chair of that Subcommittee.

MEMBER WELSH: As the Chair of that Subcommittee, I'm not eager to take on a --

(Laughter.)

MEMBER WELSH: I think I understand the question. I think it's a good question. My opinion at the moment is that I agree with [what] Ms. Weil said, that this is more in the realm of informed consent rather than radiation regulation issue. We all know when we do this that there are medical risks associated with it, and in day-to-day practice the medical risks associated with GI complications may outweigh the radiological Written Directive violations that result in medical events. And I learned over the past seven years to strongly associate medical events which are an

NRC-defined radiological concern where it's a violation of what is written for radiation safety purposes, regulation purposes and divorce that from what is medically a concern, prostate brachytherapy being the example where this is most evident. But it is evident in this realm, as well.

And while ulceration does happen and it is a concern, it would be very challenging, I think, to try to put it into regulation for medical event definition, because what I said earlier, that it's going to be difficult to prove that there is a violation of the dose limits that were proposed based on an MAA scan, and then not demonstrated with a post-treatment Bremsstrahlung scan, but the patient has an ulcer. So, the only conclusion is that this is radiation related, but how do you really put this into effect from a regulation perspective?

I think that it remains safer to put this in the… keep this in the realm of informed consent if a procedure that has a complication rate, and some of the complications can be quite serious, including the GI complication. But my feeling right now is that that should stay outside of the NRC medical event regulatory realm and stay within medical informed consent realm.

CHAIRMAN THOMADSEN: Mr. Costello.

MEMBER COSTELLO: If I could, the problem is that it is the language of the regulation that appears to incongruously map. The language of the regulation says that a dose to unintended organs, which is more than half a gray, I guess, and is not anticipated in the Written Directive. If that were to occur that would be a medical event. And you say well, if you want to know that the microspheres caused it, in many of the events they will find the spheres in the ulcer. In fact, the one we had in Pennsylvania, we found the spheres in the ulcer. It was pretty clear that's where it came from. The patient just didn't coincidentally develop an ulcer right after having treatment. But the question is, since this was an anticipated risk, notwithstanding the fact it's not listed in the Written Directive, can it still be considered not a medical event? And, if so, what's the basis for that, because it appears to meet the language of the rule?

CHAIRMAN THOMADSEN: And if you find that a lot of… not that there aren't any teletherapy units out there now.

DR. HOWE: We have two.

CHAIRMAN THOMADSEN: We do? I thought you said last time that we didn't have any. We have two?

DR. HOWE: We have two, and they're still

working.

CHAIRMAN THOMADSEN: Excellent. Then if you do a print calculation say to a lesion in the brain and you go through the eye as well as other organs than the brain, you'd have to list each of those. And if you don't do a plant, but you just do a point dose, you don't really know those, but Dr. Guiberteau…

VICE CHAIRMAN GUIBERTEAU: Actually, I was just going to observe the comments of the Chair of the Medical Events Committee, and my feeling that I don't think I would like to overburden the Chair of the Medical Events Committee, that perhaps we could take a sense of the members here as to whether we want to undertake this question before we invest a lot of resource into it.

CHAIRMAN THOMADSEN: Mr. Fuller.

MR. FULLER: Yes, I think I agree with Dr. Guiberteau that that is perhaps a question that the full Committee could take whether it comes to us through other means or as a result of the work that's done by the Subcommittee and reported out next fall as scheduled. Just as a point of clarity, our current guidance is for what should be reported as a medical event is not included in any specific regulation, but it is in our 35.1000 guidance. So, this was done some years ago, and I'm certain it was done with input and

advice from this Committee.

But right now the way it's written is if there is… even if there is anticipated shunting and it's not captured in the Written Directive, and then it happens and it meets the dose criteria, it is required to be reported as a medical event. Now, what we would be very interested in, given this morning's conversation about the Medical Policy Statement, and how that… and also the fact that we rely heavily on this group, on this Committee, whether it comes from the Subcommittee or from the full ACMUI as a result of some work that the Medical Events Subcommittee is going to do, or if it's through some other means, if our policy, I mean our guidance, I'm sorry, 35.1000 guidance, is viewed to be perhaps in the wrong place, we would very, very much appreciate hearing that, and hearing, you know, what could we do differently, and how could it be done.

The beauty of 35.1000 is the fact that it does not require rulemaking. We can take the advice of the ACMUI, share it with our Agreement State partners and others, and we can put together a working group and fairly quickly, as opposed to the time frame that we require to change a rule. We can actually adjust some of these requirements so that we are in the right place and not interfering with the practice of medicine or

some of the other concerns that we've all been talking about.

CHAIRMAN THOMADSEN: Thank you for that clarification. Dr. Palestro, do you still have a comment you wanted to make? You had your hand up.

MEMBER PALESTRO: Yes, I had my hand up. A question that I have is, and I agree with Dr. Welsh about the difficulty in trying to sort through these Bremsstrahlung images which are only marginally interpretable, how were they able to determine a dose to the gastric duodenum and stomach? I mean, I wouldn't know how to do it.

CHAIRMAN THOMADSEN: I don't think you can. Dr. Suleiman.

MEMBER SULEIMAN: How sick are these patients, the ones with metastatic liver cancer? I mean, recently, another radiolabeled therapeutic that used to require imaging, I think we actually… the company came in and said we don't want the imaging because it doesn't really impact on the treatment. We're going to go through with it. There aren't very many other alternatives. So, again, this is really, in my opinion, I would like to weigh in on the medical thing. This clearly to me is a medical decision for a very ill patient. And the question I would ask myself is this going to benefit the

patient more even if these shunts occur? I mean, that's what I would ask myself as a patient. So that's why you have physicians that you basically better trust. I tell my colleagues this all the time, you really have to trust them because that's what they do. And this benefit/risk, we keep on forgetting the benefit of the drug. If there are other alternatives that are superior, I think you guys should weigh in. But I think this, to me, is a little straightforward.

CHAIRMAN THOMADSEN: Dr. Howe, you had your hand up, too.

DR. HOWE: I just wanted to reiterate what Mr. Fuller said. The question for the group is not is it a medical event. The question is, should it be? And when you decide whether it should be, then give us a basis if you think it shouldn't be, and we can change our guidance fairly easily. But to say it's not a medical event, we would come back and say well, yes, it meets the definition. So, that's not the question you really want to ask. The question you really want to ask is should it be, and what are your parameters?

CHAIRMAN THOMADSEN: Dr. Langhorst.

MEMBER LANGHORST: One of the things that is in NRC's regulations that I think licensees look at in this regard, too, is under 35.3045(a), it starts out, a

licensee shall report any event except for an event that results from patient intervention. And what does patient intervention mean?

DR. HOWE: It does not mean shunting. That's not the patient intervening.

MEMBER LANGHORST: Well, it's their body, so that's one area that is confusing, and you don't like regulations to be confusing.

And then I have another question on 35.1000 guidance, and being an NRC state I don't know the Agreement State requirements, but are Agreement States required to follow NRC guidance?

DR. HOWE: No.

MEMBER LANGHORST: So, 35.1000 guidance doesn't mean that will be applied uniformly across Agreement States. Is that correct?

DR. HOWE: That's correct. But it does mean it will be applied uniformly across the NRC regulated States.

MEMBER LANGHORST: Right. That, I have no question on. Thank you.

CHAIRMAN THOMADSEN: Ms. Weil.

MEMBER WEIL: I have two thoughts percolating here. One is Dr. Howe's comment should it be a medical event rather than is it, but should it be? And if the

purpose of identifying medical… or one of the purposes of identifying medical events is to identify practitioners, perhaps, or sites that have a high incidence of adverse events, then for patient protection perspective, it would be good to know if a particular site… and what's bringing this to mind is the VA with the brachytherapy incidents, has an unusual number of medical events as they're currently defined. So, that… should it be? Well, maybe yes. It's burdensome and cumbersome to have to report these things, unless it identifies a trend.

And the second thing I'm thinking about is, isn't there an option, do you all not recall that there's an option to amend the Written Directive after the procedure in order to identify patient-specific things that caused something to be different?

DR. HOWE: That's not part of the Medical Event and Written Directive definitions right now. But we did change for the prostate brachytherapy, but not for the others. But the other thing to keep in mind, as Mr. Fuller pointed out, is the yttrium microspheres are now in 35.1000 which gives us more flexibility than having to go to rulemaking.

CHAIRMAN THOMADSEN: Dr. Alderson.

MEMBER ALDERSON: I'd like to go back to the

statement that I made a few minutes ago. I think this is totally uncontrollable. Biologically this is uncontrollable. The vessels will be of different sizes and tumors; they're totally uncontrollable; the microspheres are pre-sized. This is uncontrollable. Therefore, I would suggest that the shunting of therapeutic microspheres to a site other than the primary target should not be considered a medical event period. I make a motion to that effect, if that's appropriate.

CHAIRMAN THOMADSEN: We have a motion. Can you please repeat your motion?

MEMBER ALDERSON: Certainly. Shunting of therapeutic microspheres to a site other than the primary target should not be considered a medical event.

CHAIRMAN THOMADSEN: Do we have a second for that motion? We have a second, Dr. Welsh. Discussion on that motion? Hold on. Discussion on that motion? Dr. Suleiman.

MEMBER SULEIMAN: Well, the first thing I'd want to know… again, we're making a very blanket statement. What if the image shows that 50 or 70 percent of the blood is going to that shunt? So at that point wouldn't the physician say this is really not appropriate, most of the dose is going to go elsewhere?

So, that would contradict the very statement you're trying to impose. So, it would depend, again, on each patient's individual situation.

MEMBER ALDERSON: But that's… Yes, I agree with the example you just raised, but that's why it's not… when this happens biologically, it's not through the carelessness of the operators. It's biology. So you're doing a pre-scan and you don't go forward. But if something happens and there's a bit of shunting that goes somewhere else that you didn't know it, then you can't control that, and it should not be a medical event. That suggests that there was carelessness by the operators, that a regulation has been broken. They're trying to help a patient stay alive and there was some biological shunting.

DR. HOWE: I do believe that when the microsphere manufacturers came into the FDA they were basing a lot of what they said on the fact that this is a unique area in the liver where you're feeding into the tumor and you've got to get through the capillary bed to get the material to the other side. So the capillaries will be filled up with these microspheres, as opposed to just injecting microspheres anywhere. So, I guess my impression has been that that was built into the device, that it should go into that tumor and not go elsewhere.

MEMBER PALESTRO: But that assumes that the vessels beyond the tumor are perfectly normal vessels and normal sized. But in tumors and around tumors you get all sorts of abnormalities.

CHAIRMAN THOMADSEN: That's true. Is your comment relevant to the discussion on the motion?

MS. FAIROBENT: Predating the motion.

CHAIRMAN THOMADSEN: Right. So, we can come back to that since it's not directly…

MS. FAIROBENT: Yes.

CHAIRMAN THOMADSEN: Okay. Is that a yes?

MS. FAIROBENT: That is a yes, we can come back to it.

CHAIRMAN THOMADSEN: Okay. Mr. Costello.

MEMBER COSTELLO: A comment on the motion. I get the strong sense from the members of the Committee going back to Dr. Howe's comment that the GI shunting should not be a medical event. Okay? I think that's a clear sense that I get from the Committee. However, I don't think that the guidance and the regulations would necessarily lead us in that direction.

I would think a more helpful thing the Committee could for the NRC would be to revise the guidance, advise what's on the Written Directive so that accepted risks are not in the language of the regulation

[of] medical events. Certainly, I was saying that they're not medical events doesn't change what the regulation of the guidance says. I think we could do better, and I'll ask the NRC colleagues here, better help to the NRC if we were to recommend changes to the guidance such that it's clear that's not meant to capture the accepted risk of GI shunting.

CHAIRMAN THOMADSEN: If I can just make a statement. I think that this issue is too important to just make a snap judgment now in the length of time we've been discussing it and have for this discussion. It needs to be clarified. That's obvious, because there are two discrepant opinions in this Committee alone to let it stand. I would suggest that we remove the motion and instead set up a Task Group, I'm sorry, a Subcommittee to investigate this. With that, I would ask if the person making the motion and seconding the motion would agree to…

MEMBER ALDERSON: I'm willing to follow the Chairman's guidance.

CHAIRMAN THOMADSEN: Dr. Welsh, do you want it voted on right now, or do you want to have more thought put into a report to this Committee?

MEMBER WELSH: I, too, will follow the Chairman's guidance, and I think that the Chairman is

suggesting that we defer this to devote further thought to it than the time we have at the time.

CHAIRMAN THOMADSEN: Thank you very much. Dr. Guiberteau.

VICE CHAIRMAN GUIBERTEAU: I want to ask Mr. Fuller, wasn't… it seems to me you were asking us for more than just a sense of the Committee. You were asking us for basically a thoughtful report on this issue that would be helpful to you. Is that what I heard?

MR. FULLER: I'll take whatever I can get.

(Laughter.)

MS. DUDES: I was waiting, and I appreciated what Mike said. And I would like to echo what you're saying, a thoughtful report. When you look at the number of medical events reported that we just went through, and the very interesting discussion we just had on one type of issue, and I had the opportunity two weeks ago to present to our senior management this big graph of the Nuclear Materials Database of Events, and the numbers versus the actual activity that goes on in any given year. I just, I would ask this Committee for a thoughtful look at our event reporting guidance and broader than this issue to say are we in the right place? Are we getting the information that's needed for radiation protection for our mission versus are we doing

crossover of a line into a place where we don't want to be?

I think to say well, if it's in the Written Directive it's not a medical event, and if it's not in there, it is, doesn't seem to capture or answer any kind of question for me. So, I'd ask the entire group to not just consider this, but to consider the guidance and help us. We don't want events reported because of guidance that maybe is not actually giving us the information that we can all use and need.

VICE CHAIRMAN GUIBERTEAU: Given that it isn't that we haven't spent much time on medical events, and I think it would be helpful if the charge to whatever committee were to, subcommittee, were to take this up could be more focused. And, perhaps, after some discussion we could come back and/or maybe later in this meeting, because I think if we open up the whole thing, it's going to be very, it may be nonproductive.

And my other comment is to Mr. Fuller, and that is our sole purpose here is to provide you with advice, so you shouldn't be shy or equivocal about saying we would like your opinion in writing, and I think we can handle that. So, I mean…

MR. FULLER: Yes. Just to be clear, I agree that what we're asking for is for the yttrium-90

microspheres. Because it is 35.1000, regulated under 35.1000, we do have the ability to change, and we call it guidance, and in this case guidance actually is enforceable because it is under the umbrella of 35.1000. So, our guidance that is published, that is out there, that defines what is a medical event or under what circumstances or criteria medical events need to be reported to us. Then, yes, that is where I would [like] for it to be focused, is our guidance in the right place when it comes to reporting medical events on this issue?

But I also agree with Ms. Dudes that at any time if and we've just been through this for a multi-year process when it comes to permanent implant brachytherapy. That is actually in the regulation, specific in the regulation so it takes rulemaking to change that. And we've been through that very onerous process over the last several years, and we do appreciate, and have counted on, and relied upon the advice of this Committee in that regard.

But yes, what I would like, if the Committee is willing to accommodate this, and whatever means you feel is the most appropriate and most efficient way to do it, I would like for someone… I would like for the Committee to take a look at the yttrium-90 microsphere guidance as it exists right now when it comes to the

criteria that are in there for reporting medical events and tell us if we're in the right place or not.

CHAIRMAN THOMADSEN: Thank you very much. Now, Ms. Fairobent. Identify yourself, please.

MS. FAIROBENT: Lynne Fairobent with the American Association of Physicists in Medicine. Just two points that I would like to make based on, I think, the direction that you are going to go. One, I just would like to urge everyone to remember that Part 1000 is simply guidance. The Agreement States do not have to adopt it. And as guidance, there is typically no opportunity for public involvement and comment on that guidance before it is issued.

And while in concept Part 1000 was a great novel idea for moving forward with emerging technology to quickly get it into the regulatory scheme, I think that is some question on how this has worked. Part 1000 was never intended to be a permanent regulatory placeholder for those items that are in Part 1000. And if one goes back and reads the Statements of Consideration for when Part 1000 was developed, it was intended that once in Part 1000 after a period of time, and I would argue that we are probably past a reasonable amount of time to move something out of Part 1000, nothing that has been put into Part 1000 guidance has

ever come out of Part 1000 and been incorporated into formal rulemaking.

Secondly, in this Statements of Consideration, and I can pull it up, but in my presentation at the Organization of Agreement States meeting last year, I believe also that the Statements of Consideration for Part 1000 not only directed Staff to work with ACMUI in developing things in that area, but also the stakeholder community at large. So, those are the only two points I wanted to make. And thank you.

CHAIRMAN THOMADSEN: Thank you for reminding us of those points. If there are no other comments right this moment, I will take some time over lunch to consult and come up with an appropriate charge for this Task Group and recommended members. So, I will get back to you after lunch with that action. Dr. Howe.

DR. HOWE: Just a quick clarification. We do have provisions in the Written Directive requirements that if there is an emergent change in the patient's condition that you can change a Written Directive to an oral Written Directive and make that change in the procedure. It's a very narrow one, but that is part of our process.

CHAIRMAN THOMADSEN: Thank you very much. Yes, Mr. Fuller.

MR. FULLER: Another Staff member…

CHAIRMAN THOMADSEN: Oh.

MS. COCKERHAM: Ashley Cockerham. That was in response to Ms. Weil's question earlier about is there a provision for that. And, yes, there is. It's something that was added in June of 2012, which gets to our point of you can modify what is accepted as a medical event, provided enough microspheres, and you were able to make that change a couple of years ago.

CHAIRMAN THOMADSEN: Thank you. Dr. Langhorst.

MEMBER LANGHORST: I had a totally different question on the Medical Event Report, if we're ready to…

CHAIRMAN THOMADSEN: Please.

MEMBER LANGHORST: Okay. And please forgive me because I just don't know, and I think this question is probably directed to Dr. Welsh and Dr. Thomadsen. But on the 35.400 with the cesium seed event, I'm unfamiliar with cesium-135, and is that correct?

CHAIRMAN THOMADSEN: I assume it's cesium-137.

MEMBER LANGHORST: Okay, it says 135.

DR. HOWE: Which one are you looking…

(Simultaneous speaking)

CHAIRMAN THOMADSEN: Did you hear that?

MEMBER MATTMULLER: I hear voices.

CHAIRMAN THOMADSEN: Dr. Suleiman.

MEMBER SULEIMAN: Just one comment, it's something I felt all along. The problem with 1000 and all these different categories is with emerging technologies, we've discovered they just don't fit into any category. So, by default they go into 1000, and sometimes it's better to leave it there because if you try to fit it into one of the other categories you're really going to have to change the regulations or whatever. And since technology constantly changes, that's why I think we've had trouble with this because it's just not a very perfect paradigm. I'm not coming up with any solutions, unfortunately, but I think the reason we have these issues and this confusion is because it's just not a natural regulatory process. All these products change.

CHAIRMAN THOMADSEN: Good observation. Other comments on the medical events? Yes, Dr. Welsh.

MEMBER WELSH: I, too, wish to shift gears a little bit and ask a question to Dr. Howe regarding Slide 5, 35.300 Medical Events, specifically the iodine-131 thyroid situation.

DR. HOWE: Yes.

MEMBER WELSH: I have a hard time really understanding how something like this could happen, not

because of the confusion between the electronic versus the old-fashioned handwritten written record, but if I recall, you said that somehow or another the Authorized User wanted to give a certain type of treatment, a high-dose ablative therapy and instead a low-dose diagnostic dose was given. I just don't understand how that can happen if the Authorized User asked for something, and I'm presuming the Authorized User should or was the one who gave the therapy and was present during the therapy, how it could be that when the Authorized User looks and sees that this is supposed to be 150 millicuries but it's 5 millicuries and goes ahead in doing so. It sounds like there was some kind of disconnect, and I'm not sure that the Authorized User actually gave the treatment here. Is my understanding correct then?

DR. HOWE: I don't think we have enough detail in it, but I believe… and I indicated earlier, this is one where you've got to kind of read the tea leaves to figure out what's going on. It appears as if the Written Directive said two things. Somehow it said whole body scan, but in the comments where the physician wrote out what he wanted it was clear that the physician wanted to ablate the thyroid. So, in my mind I'm thinking maybe it was a form where you check something at one point,

you have comments elsewhere, and something got checked wrong up here, but the comments clearly showed what they wanted. And when they converted it over to the electronic they looked at one place and not the other place, and then later on when they came to do the actual scan, they had the patient already with the I-131 they got the piece of paper. And they were able to look at the piece of paper and they were able to see that there was an indication of what the physician really wanted, and that was the thyroid ablation. So, this was a very complicated one. You've got to look into the references to figure out what's going on. And we don't have the answer about referring physician and Authorized User.

MEMBER WELSH: It does sound very complicated, and I'll look forward to looking at it in further depth. But it raises the question about who was the Authorized User and why was the Authorized User not physically present to oversee an ablative, and physically administer the ablative dose of iodine and allow a 5 millicurie dose to be administered instead. It just sounds like there's so much of a disconnect that it's quite a mystery. And it raises the question of who really was the Authorized User. And, again, I don't know the details but it sometimes make me wonder if an endocrinologist asked for something and asked a nuclear

medicine or radiation oncologist physician to actually give the treatment and there was too much of a disconnect, raising the question of who really is an appropriate Authorized User for this type of therapy.

CHAIRMAN THOMADSEN: Dr. Guiberteau.

VICE CHAIRMAN GUIBERTEAU: I think one of the confusing things here may be, and I think as Dr. Howe said, we don't have all the facts. But in many hospitals and clinics the typical protocol is to do a whole body scan on a patient before you determine what sort of dose they need; that is, do they have metastasis, how much thyroid do they have left? And it's not unusual in our institution to get a physician saying I want you to ablate the thyroid. This patient is coming from another outside location. We have to review all the records, and in many cases we don't know what… you know, the patient had a tumor in the margins, they had a couple of positive nodes so we want to see if it's anywhere else. So, it wouldn't be unusual for us to call and talk to the referring physician, and as the Authorized User change that from, you know, just giving blindly the patient a dose, to actually interviewing the patient, doing a whole body scan to determine if we've got the right dose. So, this may, in part, be something that happened here. This got changed by someone along the way thinking well,

we don't do this unless we do a whole body scan first. Of course, that means you have to determine whether the patient has already had that somewhere else.

DR. HOWE: And there's no indication that that was part of this process.

CHAIRMAN THOMADSEN: Dr. Dilsizian.

MEMBER DILSIZIAN: Just to kind of address Dr. Welsh's… if it's a diagnostic study, the Authorized User doesn't have to be there, so technologists will do it. So, in this case I don't think it's an Authorized User not being appropriate. It just if it's a low-dose diagnostic study he's not there.

MEMBER WELSH: Sure. Sure.

MEMBER DILSIZIAN: So, I think…

MEMBER WELSH: Well, if I could comment. I understand what you're saying. That's correct, my understanding, as well. But if the Authorized User wants 150 millicuries, that's not diagnostic, that…

MEMBER DILSIZIAN: No, I understand. But in this case what I'm saying is, if the dose was diagnostic dose and the technologist did it, the Authorized User wasn't even present, even though that's what his wish was.

MEMBER WELSH: Right. But if it wound up being reported as a medical event, it means that there was a

discrepancy…

MEMBER DILSIZIAN: Yes, because the original intention was to have purely not diagnostic. That's where the misadministration is.

CHAIRMAN THOMADSEN: Any other comments? Dr. Palestro.

MEMBER PALESTRO: I was just going to echo Dr. Guiberteau's comment that it's entirely possible that this was designed by one or more parties to be a combination of a whole body iodine scan followed by remnant ablation. We oftentimes get requests for the iodine scan, as well as the ablation on a single prescription sheet, so without all the information in front of me, or in front of us, it would be very hard to sort through this.

CHAIRMAN THOMADSEN: And, unfortunately, we rarely have all that information. Any other comments? Hearing none, we're running a little bit behind. Mr. Mattmuller, how long do you think you actually will need? It strikes me we might have a considerable discussion following your presentation.

MEMBER MATTMULLER: Yes, that's fine.

CHAIRMAN THOMADSEN: In which case, I think we should break for lunch now and pick this up when we come back. My guess is that we probably can handle the

amendment to the bylaws in less than an hour and a half, so we're on break. Please be back at 1:30.

(Whereupon, the proceedings went off the record at 11:55 a.m. and went back on the record at 1:31 p.m.)

CHAIRMAN THOMADSEN: Welcome back, everyone. In follow-up to the conversation this morning, I am making a Subcommittee to review the microspheres guidance with respect to the medical events, and make recommendations for changes, if appropriate. The Subcommittee should report back to this Committee at our fall meeting.

The Subcommittee would consist of Dr. Guiberteau, who will Chair the Subcommittee, Dr. Alderson, Mr. Costello, Dr. Langhorst, Dr. Palestro, myself, Dr. Weil, Ms. Weil, and Dr. Welsh, and as a staff contact and resource, Dr. Howe, if that's appropriate from your point of view.

MR. FULLER: That works for… sure.

MS. HOLIDAY: Dr. Thomadsen?

CHAIRMAN THOMADSEN: Yes.

MS. HOLIDAY: This is Sophie. I'm afraid that I may have to put a hamper in your plans in that in recently attended FACA training. I've been informed that your Subcommittee membership cannot be greater

than 50 percent of the number of members on the Committee. So, that means we have to limit Subcommittee membership to six members. In case the Subcommittee puts forth a recommendation and you have seven people on that Subcommittee, the motion automatically goes through as accepted if that Subcommittee endorses it. I'm sorry.

CHAIRMAN THOMADSEN: Understood. In that case, one moment while I…

(Laughter.)

(Off the record comments.)

CHAIRMAN THOMADSEN: Is that including the Chair?

MS. HOLIDAY: I'm afraid it does.

(Off the record comments.)

CHAIRMAN THOMADSEN: The Subcommittee will consist of Dr. Guiberteau, who will Chair, Mr. Costello, Dr. Langhorst, Dr. Palestro, myself, and Dr. Welsh. Are we okay on that one?

MS. HOLIDAY: Yes.

CHAIRMAN THOMADSEN: Okay. Thank you very much. Also, following up from this morning's discussion of medical events, I'm going to be naming Mr. Costello on the Medical Event Subcommittee.

MR. COSTELLO: Thank you.

CHAIRMAN THOMADSEN: All right. If there are no

further discussions from this morning's Chair, I would like to pick up where we left off with Mr. Mattmuller who has to change the slides. Mr. Mattmuller is talking about an Update on Ga-68 Generators.

MEMBER MATTMULLER: Good afternoon. I'm Steve Mattmuller, and I'll be giving a brief update on clinical issues, on regulatory issues on gallium-68. And I'm certain you're all on the edge of your seats as this is the third talk on this subject in as many meetings.

There are four areas I'd like to cover. One is a quick review on receptor imaging and why this is such an important strategy in designing radiopharmaceuticals for diagnosis and therapy. Talk a little bit about the source of gallium-68. It comes from a germanium-68 generator which is unique for PET radionuclides in that we don't need a cyclotron. And recent developments in chemistry modules, and we've been talking somewhat on kits. And the big one, though, is the FDA Orphan Drug status. And, finally, it wouldn't be an ACMUI meeting unless we had some regulatory issues to talk about.

So, on the top of this slide is a schematic representation of the natural peptide hormone somatostatin, and that reacts with the somatostatin

receptor in the plasma membrane of different cells. And the critical area for specificity is Positions 7-10 in the far right side. This somatostatin receptor and its variants are expressed in neuroendocrine tumors or NET tumors, and a few examples would be pheochromocytoma, neuroblastoma, or cosinoid.

On the bottom is a radiopharmaceutical or a biomarker with nearly the same identical immunoacid sequence in the important region, only here it's number 3-6 that gives specificity to the somatostatin receptor. In the middle is the DOTA bifunctional chelate so it attaches… it has two functions. One, it attaches itself to the amino acid peptide, and it also chelates another radionuclide. And in this case it's gallium-68. And this is… can you read it? I can barely, I'm sorry, is DOTA-TATE, and it's just one of the numerous variations for neuroendocrine tumor imaging.

The gallium-68 radiopharmaceuticals have received probably by far the most attention in development work, but there are numerous other categories of gallium-68 radiopharmaceuticals that are also under-developed. And this is a big reason why our field is so excited about gallium-68 radiopharmaceuticals.

Here's a comparison of early versions of the

same radiopharmaceutical. On the left we have indium-111 DTPA. And indium-111 is a SPECT single photon imaging agent. On the right is the equivalent PET version with gallium-68, DOTA-TOC. The advantages are several, and you really don't have to go to medical school to see the clear differences here to appreciate them. You have better pharmacokinectics and imaging because a PET radionuclide is involved in your radiopharmaceutical, much greater sensitivity. Plus, it's also easier for the patient, for the PET version you can do it all in one day; whereas, with the SPECT agent, the indium agent innates two days, and there's also a lower radiation burden to the patient.

The other exciting aspect of gallium-68 is that it breaks the middle for most PET radionuclides. You've got the SIPOTRON. The SIPOTRON is a big heavy, expensive unit. The gallium generator now gives you the ability to have gallium-68 just about anywhere you want it. Pictured on the right is an Eckert & Ziegler generator, one of four generators available in the market now, and this is a floor model. It's not radioactive, the security guys wouldn't let me bring my germanium with me, from ITG another imaging firm, but this one is also being promoted by a company called RadioMedix based in Houston, Texas.

Design-wise the generators are very similar to what we have with the technetium generator. You have a solid cone with a solid parent radionuclide, in this case it's germanium-68, and it's eluded with an emolument, and in this case it's hydrochloric acid. But I'd like to consider that we shouldn't really look at this generator the same way as we do our other two generator systems that we're so very familiar with.

With the rubidium-82 generator it's diluted with 0.9 percent sodium chloride and it's infused directly into the patient for a myocardial perfusion imaging study. With the technetium generator it's also labeled 0.9 percent sodium chloride and the technetium can be used directly into the patient for a thyroid imaging study. In both cases, the generators produce a radiopharmaceutical, but unlike those two generators, this generator because of the acidic elution from the generator or device we might want to call it cannot be used directly in patients. Its elution only serves as a source for the gallium-68. So, hold that thought for later and we'll come back to it. Even though the Germans have called it a generator, perhaps from a regulatory sense, we should consider it something else, a source, or even a device.

With the growing interest in gallium-68, there

are two new synthesis modules that have recently been commercialized that are far simpler to operate and less expensive than previous models. One reason for this is that gallium-68 chemistry can be much simpler especially when compared to the chemistry involved with fluorine F-18 for something like FDG.

On the left is a unit by RadioMedix, excuse me, this is SmartMedix™ by RadioMedix, and that's the company from Houston, Texas. They also are selling the ITG generator. On the right is the Modular-Lab eazy by Eckert & Ziegler. Both are much simpler, easier to use reflecting the development of gallium-68 radiopharmaceuticals. These advancements are even progressing towards the development of kits, kits very much like the kits we use for our technetium products, but instead of technetium you would use gallium-68. However, the development of some of these kits is very much dependent on the bifunctional chelate that is used in the radiopharmaceutical. So, that could possibly work for some of these radiopharmaceuticals, a kit development will not proceed for all of them.

But the biggest and perhaps most important developments I'd like to talk about is the FDA Orphan Drug Program. For an Orphan Drug Program, the mission is to advance the evaluation and development of products

that demonstrate promise for the diagnosis and/or treatment of rare diseases that affect fewer than 200,000. So, with this designation towards the important clinical trial you need fewer patients. Excuse me, I heard subjects in the crowd, and that's correct. They would be research subjects. Application fees are waived. And, also, clinical trials are incredibly expensive, millions of dollars, so the possibility for FDA grant funding is a huge advantage. So, these are three huge advantages an Orphan Drug has compared to a typical new drug and the pathway it has to follow to become a new drug in the approval process with the FDA.

With this, with the Orphan Drug designation, the sponsors now get the help of the FDA in setting up their trial to make sure they're looking at the proper clinical perspectives, or issues, or conditions, and also they could get funding from the FDA to conduct this trial.

We now have two gallium-68 radiopharmaceuticals that have Orphan Drug designation, DOTA-TOC, gallium-68 DOTA-TOC and the clinical sponsor is the Society of Nuclear Medicine Molecular Imaging. And currently, last I knew, it's being investigated in two clinical sites around the

country.

The second agent, gallium-68, DOTA-TATE, the sponsor is the same company, RadioMedix; so it's in Houston, Texas. And they have clinical sites active now in five areas around the country. So, now especially for the gallium-68 radiopharmaceuticals that are used for neuroendocrine tumor imaging dramatic progress has been made in these products as they approach FDA status, approval status.

So, from a regulatory perspective this is our issue with gallium-68, and actually it's really with germanium-68, the need for financial assurance for decommissioning. With the current interpretation of the regs, this is where the germanium-68 possession, licensees are required to get a decommissioning funding plan, or a DFP. Current interpretation is currently with germanium-68 as unsealed, but I would propose that's possibly not quite right since the germanium-68 is a solid on a solid column. The germanium-68 does have a half-life of over 271 days, so it clearly exceeds the 120-day limit. And the problem with Appendix B is that there's not a value for germanium-68 listed, so the default value kicks in and it's very low. 0.1 microcurie. And when you multiply that by the one times ten to the fifth, you only come up with 10 millicuries,

which is too low because the generators themselves range from 40 to 100 millicuries.

A DFP is a big problem because it's expensive to acquire, and it's expensive to maintain on an annual basis. I really think this is unintentional because Appendix B to Part 40 was last amended in 1980, and at that time, germanium-68 not was not even regulated by the NRC. As I've said before, it's very onerous because it is expensive. And there have been a wide range of experiences by the licensees, some who already have a DFP or meet the financial test for one, it's not a problem. But as you might expect, these are at large institutions. But there were some who had germanium-68, had this generator prior to 2005, and when the DFP requirements kicked in they had to turn their generators back in because they couldn't afford the DFPs. And I have been in contact with two licensees who did have this exact experience. Up to 2005 they were fine, after 2005 they had to give the generator up. So, if you don't have a DFP it is a real barrier to be licensed for germanium-68.

So, how could they get some possible relief? How can we maybe find a tool in the NRC toolbox for a little regulatory relief? Maybe we should stop calling it a generator because maybe it's more of a device or

source as the germanium exists on a solid column sealed within a container.

Current interpretation of 30.35 triggers the DFP because it's being defined as unsealed byproduct material. So, an argument can be made that germanium-68 doesn't leave, it's sealed, while the gallium-68 does leave. It is unsealed. And disposal isn't an issue for these because in all four cases, the manufacturers take back the generator device source so the licensee doesn't have to worry about that disposal.

The other important consideration is that gallium-68 is not a radiopharmaceutical. It's really a radiopharmaceutical component that will not be used directly as-is in patients.

Now, this is a little bit busy and I apologize for it, but we're really not going to go past the DFP in the middle of the slide. This is 32.74. These are regulations for a licensee to manufacture or distribute a source or device not for a site to possess but the use is what I'd like to focus on for a moment.

One alternative for relief would be to think of it as a source or device when it's for use in 35.1000. And for new members of the Committee who have yet to memorize 10 CFR 35, 35.1000 is other medical uses of byproduct material or radiation from byproduct

material. It has a Section B that states, "U uses the material in accordance with the regulations and specific conditions the Commission considers necessary for the medical use of the material. So, there's some leeway there.

So, if you're going to talk about sources and devices, of course the NRC has a regulatory guide, and it's 1556. This guide describes how the use of a sealed source or device is structured so that the byproduct material will not breach its containment and contaminate the environment. This depends largely on the adequacy of the containment, the properties of the sealed source or devices in withstanding the stresses imposed by the environment in which they are possessed and used. The environment for a generator device or source such as this is sitting quietly inside a lead shield on a laboratory bench or even in a hot cell. It won't be moved about; it won't travel in a vehicle on the highways; it won't even be moved about on a cart in the laboratory. It sits and it doesn't even have any moving parts. So, if you're talking about sources and devices, one section in the guide is 4.9, Sources and Devices for Medical Use. But these are only proof of FDA approval. A couple of these we're very familiar with, 510(k)'s, PMAs. If you look at the list in the guide this

covers everything from a dose calibrator source to a PET scanner, and my personal favorite, a rectilinear scanner. And I'll be polite and not ask in this room who has used a rectilinear scanner.

There's also the humanitarian device exemption, and this is through the FDA how y-90 microspheres were approved. But the gallium-68 in some ways really won't be for direct medical use. It's going to be used for radiopharmaceutical preparation, so this may or may not be where it could belong or could fit in.

Also in the guide is 5.1.3, Custom Sealed Sources or Devices. It has to be under 200 millicuries, this is usually 40 to 100 millicuries, and this one is either incredibly confusing or incredibly forward-thinking. And if you read through it, the requested quantity of radioactive material in unsealed form, so I'm not quite sure why they're talking unsealed form in a guide on sealed sources or devices, or are incredibly bright and forward-thinking, NRC Staff knew that at some point someone like us might need flexibility in the future product germanium-68 solid source and its gallium-68 unsealed output.

The other somewhat complicated factor in all this is that we're not quite sure how the FDA is going to regulate this device. And it's during their approval

for gallium-68 DOTA-TOC or TATE, all they may require… I mean, because you have to remember the generator is the component and then the radiopharmaceutical is separate from being sponsored, and together the outputs from this with the radiopharmaceutical is what goes to the application to be approved, but the FDA may say well, all you need for this is a drug master file. And a drug master file, in the eyes of the FDA, usually covers chemistry, manufacturing and showing how this unit is produced. And there are some advantages of a master drug file in this case because if say ITG or Eckert & Ziegler has a DMF on file with the FDA, then… and they would have specifications as to what the product would meet as far as G-8 radiochemical purity, radionuclidic purity. Then sponsors such as the SNM or RadioMedix with their respective products could say our product works well with either of these two products, and we're going to reference their DMF.

So, we do have a recommendation that the NRC provide regulatory relief, and I hope you know I think it's still needed. As the DFP can stifle use of a very important radionuclide, gallium-68 is very hot, especially now with the Orphan status of our two radiopharmaceuticals. And perhaps the germanium-68, gallium-68 generator may now represent a new device or

source to be regulated. Thank you.

CHAIRMAN THOMADSEN: Thank you very much, Mr. Mattmuller. Questions?

MEMBER COSTELLO: I'm in total agreement that these are needed because the cost can be much higher than the cost to simply dispose of the generator. An example is we have a licensee who's alive with carbon-14, and tritium, and so forth and when he came into possession it was just below that which required financial assurance. I'm sorry, that which required financial assurance. By getting this generator, they don't have to just consider the cost disposing of the generator, the cost of decommissioning all of many, many labs which have long-lived nuclides in them. Cost of disposing of generators is trivial, actually, but not the cost of surveying and decommissioning what could be tens, 50 laboratories. And to have that decommissioning funding requirement triggered by that, it would be great to have some relief from that.

CHAIRMAN THOMADSEN: Thank you. Dr. Suleiman.

MEMBER SULEIMAN: I need to clarify what a drug master file is. It doesn't exempt or make it easier for getting approval by the agency. All a drug master file does is it insures confidentiality and proprietary information. If a company does not want how their… when

a new drug application comes in, the entire package is reviewed, but the company may be getting something from somebody else that's proprietary. So the drug master file I usually refer to as a safe deposit box, and they actually file this with the FDA. This is public information in terms of their filing, and they put… inside the safe deposit box is the family cookbook with the ingredients on how you prepare this. So, inside the drug master file is how the company makes the radionuclide. For example, or if they're manufacturing moly in the reactor, how they target the material and irradiate it, and so on. It's that proprietary process that they don't want anybody else to see, not even FDA. Once they file this DMF, they then give a letter of authorization to the agency that says we allow the FDA reviewers only to look at this as part of the application process. So, in your scenario if it's one company that let's say two or three other drug manufacturers want to access this, they would have to get authorization from the owner for the agency to look at that as part of their application process. All it does is it insures confidentiality; it doesn't mean we don't see what the process is. And when a DMF is filed, we normally do not even look at it until the actual application for which it's being referenced is looked at. So, I just want to

clarify that.

MEMBER MATTMULLER: That's fine. And that's good. I appreciate that. Thank you, Orhan. The reason I tried to… or what I was also trying to emphasize was that unlike other radiopharmaceutical products that we have and use now, they're all approved by the FDA as a radiopharmaceutical product. This device source here will not be… more than likely will not be approved by the FDA as a radiopharmaceutical.

MEMBER SULEIMAN: Well, we approve the final radiolabel, as well.

MEMBER MATTMULLER: Right.

MEMBER SULEIMAN: And what parts go into it are part of the manufacturing process, so that will get looked at during the application process, so it's not exempting it from oversight or review, it's just… it doesn't have to be reviewed on its own.

CHAIRMAN THOMADSEN: Dr. Palestro.

MEMBER PALESTRO: Yes. I have two comments. Number one, gallium-68 is being used accurately for investigation of infection and inflammation as gallium-68. So, certainly I don't know why you…

MEMBER MATTMULLER: As gallium-68 chloride?

MEMBER PALESTRO: I'm sorry?

MEMBER MATTMULLER: As gallium-68 chloride or

gallium-68 citrate?

MEMBER PALESTRO: Gallium-68 citrate.

MEMBER MATTMULLER: Right. Okay. So, in that case it still fits the model in that this comes off as gallium-68 chloride, and is reformulated to gallium citrate.

MEMBER PALESTRO: Second comment, there was a question in terms of the generators themselves. I can't tell from your presentation whether you would expect them to be in hospitals, or medical facilities, or at radiopharmaceutical companies?

MEMBER MATTMULLER: At this point I would say both. I mean, it could be in a large hospital and/or it could be at a large centralized nuclear pharmacy.

MEMBER PALESTRO: And you think it probably would not be made even in large hospitals because if you look at your molybdenum and technetium generators very few institutions, even the very large ones, use the generators any more. They depend on dose protection, say, or unit doses.

In addition to that, you've got to develop more than an indication for neuroendocrine or somatostatin separate tumor imaging to make this viable in a hospital setting. The cost is whatever it is, $40,000 for the generator with I believe about a six-month life span for

the gallium-68 generator, so I don't think that hospitals, unless they're doing large numbers of neuroendocrine imaging, are going to opt for purchasing a generator.

MEMBER MATTMULLER: I would agree completely if you just look at neuroendocrine NET imaging, but as gallium-68 citrate inflammation imaging takes off, or gallium-68 annexin for vascular issues, or countless other possible indications that people are looking at that could broaden or should broaden the use and application of gallium in all these different medical procedures or imaging tests.

MEMBER PALESTRO: Potentially, I would imagine provided that there's a simple way to complex the gallium with the compound.

MEMBER MATTMULLER: Right.

MEMBER PALESTRO: Again, because in your average hospital that's not usually done. So, once again, it brings you kind of back to the unit doses.

MEMBER MATTMULLER: True. Right. And I could easily see this existing in a centralized nuclear pharmacy. But to back up to the expense, it was… actually, one of the sites I talked to was a centralized pharmacy that had it, and they were only using it for research at that time, of course. But they

were one of the sites that got rid of it.

CHAIRMAN THOMADSEN: Other questions?

MEMBER ZANZONICO: I just have a comment following up on Dr. Palestro's point. I will represent that there's a lot of work being done using gallium-68 in connection with seed targeting with antibodies. And the significance of that, potentially, is that it opens up a whole array of applications to big diseases like breast cancer. It was just being applied in clinical trials, and prostate cancer, so forth and so on. So, the thing being is that there's potentially wide, wide applications beyond its status as an Orphan Drug. There are new questions, of course, of the radiochemistry, so forth and so on, but I think the neuroendocrine tumors are just the tip of the iceberg in terms of the potential applications of gallium-68.

MEMBER MATTMULLER: Yes. Yes and thank you for that. Because had I had more time, but those films slide along to go into that for a lot of other pharmaceuticals you can develop with gallium-68 that specific and has good targeting for specific tumor or whatever you're looking at.

I'll hurry up. You can also then -- very usually, with simple chemistry, replace the gallium-68 with something like yttrium-90. And then so you can

easily convert from a diagnostic rated pharmaceutical to a therapeutic rated pharmaceutical.

CHAIRMAN THOMADSEN: Thank you. Mr. Fuller.

MR. FULLER: Thank you. I have a question. And then also some insights on where we might could go from this.

Yes, we are well aware that we had a recommendation from the assembly rod to look into what sort of regulatory relief things -- or sort of the things that we could do to provide some sort of regulatory relief in this area. And I'll get to that.

But before I do, as far as the time frame goes, I know these are being used at some institutions now in preparation for, or in the process of some sort of trial and so forth. And you're in the process of looking for FDA and have a popular FDA approval that some of the manufacturers have.

Can you give me an idea of the time frame of when the sort of regulatory relief that you're speaking of is really going to be needed? Is it like right now? Or do we got a couple of years, or where are we?

MEMBER MATTMULLER: Orhan do you know how long it takes for something to go through the Orphan Drug Program?

MEMBER SULEIMAN: No. No different than, it

depends on -- it depends. You know I see --

MEMBER MATTMULLER: That's the answer to all of them.

MS. BUNNING: Over at our clinic, we have folks that are --

CHAIRMAN THOMADSEN: Can you step to the microphone and please identify yourself?

MS. BUNNING: -- your body, you're watching. And we do have folks around the clinic that are watching.

I'm sorry, I'm Sue Bunning. I'm from the Society of Nuclear Medicine and Molecular Imagining. And watching on camera is our folks from the clinical trials network.

In response to that, the response was yes, now. So in terms of starting to need it now.

MR. FULLER: So this is where I think we are from a regulator's perspective. Regulatory relief is a term that frankly we don't -- as regulators we don't really have that defined somewhere. But I think I understand what you're -- where you're -- what you feel like your need is.

In order to change the requirements for our licensees, it would require rulemaking. Now based upon some of the things that you gave me, these of course are some things we might could pursue. Certainly couldn't

make any promises or predict where that might come out.

But the problem as I see it right now is is that we do have this recommendation. However, that's not the best way to make this a high priority for this agency. It's a high priority for the medical team. It's a high priority for those of us who have the opportunity and the benefit of listening to these discussions.

But in an ideal situation, we would have someone apply for or possess one of these, or we would have an -- already have a licensee who's requesting through one of our regions, an amendment to their license to possess one of these and use one of these. And then raise these points and raise these issues.

That way someone has an action on their plate that they need to deal with. Then they may come to headquarters and say this is a real problem. We need to all collectively put our heads together. And it's typically what we refer to as a technical assistance request.

So that would come in to us. Then we could actually get started. So in the absence of someone actually asking us for something, it's very, very hard for us to actually start doing something.

Anyway, I may regret doing this, but – I'm

sorry go --

MEMBER COSTELLO: We have a licensee who is in a situation as describing who had -- who had no financial assurance because they carefully crafted with the licensee at requiry, you know they had many labs with small quantities of tritium and carbon-14. That this would kick them over, okay.

If you would, you know need a request, you'd do one up, because it would be silly for them, for the sake of that, to be having to come up with decommissioning plans for it might be 100 labs, okay.

But my other comment is this is an anomaly that this is even an issue. Because the dependency quantity for the, you know, gallium-68, is nothing like the risk associated with. I mean they're picking the smallest number. You know we should make it look like radium or you know, something planted.

It does not represent the risk. And I know nothing about rulemaking. I really -- is there a way you could do just a limited number in Appendix C that direct your rulemaking to say you know, for gallium-68 it's now well 100 microcuries or something?

MR. FULLER: To answer your question is I believe that all of those things are possibilities. But as I said, the problem that we have is that we haven't

received -- I mean I don't -- I think the best way, in other words, again the easiest and most direct way is some change to the rule.

That makes it real clear and quick and people can find those reasons and so --

MEMBER COSTELLO: But I really mean the table.

MR. FULLER: Right, but that other work is the table.

MEMBER COSTELLO: But that's all they need, one number.

MR. FULLER: I understand, but if -- it really needs to start with somebody asking us to provide some sort of relief or something. I mean we have to have something that we can take action on. An actual licensing action or an actual direction you know, something like that.

MS. BANNING: Hi, Sue Bunning again, SNMMI. An additional point. At the Clinical Trials Network, according to them, there are at least six sites right now that have the gallium generators, but that we plan to file new app -- a new drug application status by the end of 2014.

So we're filing by the end of 2014 and there's six sites now using the gallium generator.

CHAIRMAN THOMADSEN: Dr. Suleiman?

MEMBER SULEIMAN: Again, just a clarification. I think I used this analogy, and I'll invoke it here.

When people say will this get approved? I come back and I say it's like asking am I going to pass this course if I enroll in it. So it really depends on the quality of the application, the specifics. It undergoes review and it depends on what questions the people find.

So you're never going to get an answer that says this is going to get -- that it will even get approved. It may find some hurdle during the process.

So, the fact that a potential pathway exists, just doesn't mean it's going to sail through. So I think, but at least there may be some opportunity there.

CHAIRMAN THOMADSEN: Dr. Langhorst?

MEMBER LANGHORST: And I think Mr. Mattmuller mentioned this in his talk, but some of the places that use this generator have to have a decommissioning funding plan. We have one. And so this was no big deal just to add that to -- well it's already added to our license, just to use this in our license.

But it's the unfairness of that default by you that has to be applied to the germanium-68 because it just doesn't appear in that table as a discrete number.

And that's what limits it to use at other licensees that don't have a DFP already.

CHAIRMAN THOMADSEN: Dr. Alderson?

MEMBER ALDERSON: Yes, just a point of clarification because I'm not familiar with this particular generator. So and I don't want to -- neither do I want to waste the time of the Committee. But I'd like to know why you know, what is so exciting about it that's caused this to come forward?

I mean the SNMMI is here speaking up for it. You're speaking up for it. What is people's involvement? What is this doing that other -- you know I saw the one you know, antidotal example, sure.

And -- but I don't see data, so you know, why are we interested in this and what is your interest in it and so forth?

MEMBER MATTMULLER: Well there's the one active image is only there because of lack of time. In some of our previous talks, we've gone into that subject and so there are numerous other applications even. And Pat has spoken on this also. We have a tag team going here.

So he'll probably be back here in September I guess. But, and I appreciate your comments Mike. But it's my understanding if we were to revise the quantity

in that table that has to go through the whole typical regulatory review process. Or is there an expedited way that that could be revised in a shorter time frame maybe?

MR. FULLER: Well I'm not a rulemaking expert on that. But I can certainly get you an answer you know, before the end of the day. But as it stands, my understanding is that this is -- this is part of the rule.

And so there might be some -- there may be some ways to speed the process and so forth. But it's -- it is a deliberative, public involved process that we follow to make changes like this.

You know, and the other thing I would mention sort of similar to what Dr. Alderson said you know, we have heard some of these concerns before. But what we would need in addition to the statements is the data.

I mean yes, it's burdensome, but compared to what -- in other words what does -- what would it actually cost? And what would it mean in the way of you know, what percentage of that decommissioning funding plan cost, you know how does that compare to the revenues and so forth?

So those are the types of details that would need to be considered and understood. A kind of -- I

mean while I believe everything that folks tell me, a claim of regulatory burden or financial burden and so forth, is something that would need to be backed up with numbers.

MEMBER COSTELLO: The problem with Appendix C is really intended to be a risk-based thing in which numbers of greater risk or smaller numbers like strontium-90 has a smaller number than tritium does. If you were to choose a number for gallium-68 based on risk, you would certainly not choose the number that's there now.

I think the data that can prove that would not be hard to come by. I mean, it's just because of history that an accelerated and produced isotope at the time the regulations was developed. It wasn't there.

But if it was based on whether to have the other isotope to check, then you would never choose that number that it's at now, which is the default number.

MR. FULLER: Understood.

CHAIRMAN THOMADSEN: Any other comments or questions regarding this? Ms. Weil.

MEMBER WEIL: Just can you put this into perspective for me. The other radiopharmaceuticals that are used that this would be replacing, indium I supposed being one of them. These are produced by

generators in the facility, or are they ordered in a different way?

MEMBER MATTMULLER: The indium, the example of comparison with indium is produced on the accelerator, but it's produced by a larger manufacture, in fact.

MEMBER WEIL: And the sole unit does?

MEMBER MATTMULLER: Yes, in essence a unit does.

MEMBER WEIL: Now in terms of cost per dose, how does this square up?

MEMBER MATTMULLER: The cost per dose? Well I'm sure it's going to be more expensive then the indium dose. But then you have time savings, convenience to the patient, far better information.

MEMBER WEIL: And the reduction of the radiation, --

MEMBER MATTMULLER: And the radiation is another factor.

MEMBER WEIL: Is that a significant factor?

MEMBER MATTMULLER: Let's see, I don't know if I brought that with me, but I can either find it, let's see -- the half point that gallium-68 is 68 minutes. With the panel, the remaining 68. The remaining 68 is 271 days.

MEMBER WEIL: So it's significant to this sort of being.

MEMBER MATTMULLER: Right. Which is almost 2.8 days, right.

MEMBER WEIL: So you have a superior therapeutic agent.

MEMBER MATTMULLER: In this case, we have diagnostics.

MEMBER WEIL: Not this diagnostic, I'm sorry.

MEMBER MATTMULLER: Right.

MEMBER WEIL: For now.

MEMBER MATTMULLER: Right.

MEMBER WEIL: And it theoretically isn't being used because of regulatory barriers or it just?

MEMBER MATTMULLER: Well I would say right now because it's at the investigational level at large institutions like Washington, like Sloan Kettering. I happen to be at Kettering, which is the poor cousin to Sloan Kettering. They're of the same family.

But this would be an issue for us at our place. Because we're actively looking at getting into the gallium-68 business. But this would be an actual cost that could be a deal breaker for us because, especially right now with more under lying tumor imaging, it's a very small patient population. That's why it qualifies

for the orphan drug sets.

MEMBER WEIL: And in terms of, I don't know if you know the answer to this, in terms of reimbursement, will facilities get reimbursed for the increased expense at the moment of offering this particular… applied for?

MEMBER MATTMULLER: We always have that hope, yes. It's never guaranteed, but we do.

CHAIRMAN THOMADSEN: Dr. Langhorst.

MEMBER LANGHORST: I wanted to try to help answer Ms. Weil's question there. The – it's not just decommissioning of this generator, it's decommissioning of your whole license.

And for instance Washington University or Jewish Hospital just decommissioned a few buildings and our decommissioning costs to just have an outside contractor come in and do that survey was about, I believe it was around $120,000.00 just to have them come in. That didn't count all the time; we had to do showing all the history and everything.

So it's not just the cost for having a decommissioning funding plan and so on for that generator. It then encompasses your whole license. And so the reimbursement's not going to pay for you know, your decommissioning that carbon-14 lab.

MEMBER WEIL: No, it's not. Thank you.

MEMBER LANGHORST: So that's, that's the dilemma. And it's not warranted because the germanium-68 is not that risky. It's just it wasn't in the original table. It has to go to a default value, which by nature is a very low number. And this is the rock and a hard place that they're in right now.

MR. FULLER: Bruce, behind you.

MS. BUNNING: Sue Bunning again with SNMMI. Based on some data that we've seen, the gallium scan is approximately 1000 less than octreoscan as of right now.

MEMBER ALDERSON: Would you say that again. I'm sorry, I didn't…

MS. BUNNING: The gallium scan is approximately 1000 less than octreoscan.

MEMBER ALDERSON: 1000 less what?

MS. BUNNING: Dollars.

MEMBER ALDERSON: Dollars?

MS. BUNNING: Um-hum. Right now. And octreoscan costs $5,000.00. And this would be $1,000.00 less, as of right now.

MEMBER ALDERSON: Okay.

MS. DUDES: Well as a point, and I'm sure Sophie will keep me in line as a -- in the fact of order of a map. So I'm looking at the first sentence on this

slide and it says ACMUI has a recommendation that the NRC provide regulatory relief.

Have we -- and I'm, as the new person here, so did we receive a written paper that provides this recommendation with a… the cost benefit? And I mean I -- what Ms. Weil said resonates that if there is such superior diagnostic product, that is not being used because of a regulatory issue that there may not be a lot of purpose for.

You know to have that recommendation in writing to us, and do we have that?

CHAIRMAN THOMADSEN: Ms. Langhorst.

MEMBER LANGHORST: It's 2013, item 21.

MS. DUDES: Yes. I was looking through this and I left my readers upstairs.

MEMBER LANGHORST: It's 2013 ACMUI recommendation in Table 21.

MS. DUDES: Okay, so but within that, it's beyond the recommendation that's in the Table. There's a substantive paper or classification regarding you know, those key points. The superior product that for you know, the cost benefit -- the benefit to the patients or medical providers, and then -- I mean that's something that I think is more action-able for us to take.

This is the Committee that advises us and I think I said this morning that I'd like you to advise us on where we should be going, not just where we're at. To have that in front of you know, is a catalyst. I can't say that it would jump all priorities, but you know, it's a catalyst for action.

So I mean if there is something that can be provided from the Committee to us with the types of things that have come up in this discussion, I think it is a burning platform so to speak, to move forward if that is the Committee's intention.

CHAIRMAN THOMADSEN: Then having been asked that, I want to designate a subcommittee to write the justifications for this to provide for the NRC. And Mr. Mattmuller, will you serve on that as chair?

MEMBER MATTMULLER: Yes.

CHAIRMAN THOMADSEN: Dr. Langhorst will you serve on that as --

MEMBER LANGHORST: Wait a minute -- yes, I'll help another subcommittee.

CHAIRMAN THOMADSEN: And Mr. Costello. I think that three sounds like a fine number without pushing it. Dr. Zanzonico, would you like to join them as number four?

MEMBER ZANZONICO: Yes.

CHAIRMAN THOMADSEN: I need a foursome.

MEMBER ZANZONICO: I'd be very happy to.

CHAIRMAN THOMADSEN: Very fine. Okay. To effect that plus in the flow, Dr. Guiberteau.

VICE CHAIRMAN GUIBERTEAU: Might we want an end user on this? I mean since we have talked and the question has been raised about the urgency here that, I mean nothing against the people on it, but generally since this is -- had known in increasing medical imaging applications, that we might want someone on the Committee who can represent the interest of the user community, licensees?

MEMBER MATTMULLER: Would we be able to have a representative from the SNMMI since they're intimately involved in this as a sponsor?

CHAIRMAN THOMADSEN: And that's a question that I'll turn over to Ms. Holiday. Can you have outside people as consultants?

MS. HOLIDAY: The answer is yes and no. The only thing that yes, SNMMI can designate an individual to serve on a working group, or in this case, a subcommittee.

However, because SNMMI is a professional organization and not an NRC employee, if we have sensitive internal information that is distributed,

that individual would not be privy to that information. And that's, as I said before, is a strong if. You just don't know.

So would you have to sit someone in that position where they could be left out in the dark because they don't have the information that the rest of the subcommittee members have.

CHAIRMAN THOMADSEN: Dr. Guiberteau?

VICE CHAIRMAN GUIBERTEAU: I was thinking more in terms of a practicing imaging physician on our Committee who could also serve as the liaison in terms of expressing the concerns that we heard today from the members of SNMMI present.

CHAIRMAN THOMADSEN: Do you have a potential name?

VICE CHAIRMAN GUIBERTEAU: Well I would think -- I know three of them here, Drs. Palestro, Alderson, Dr. Dilsizian. I mean all of whom are practicing clear physicians. And perhaps maybe not our cardiology representative.

CHAIRMAN THOMADSEN: I'm not sure that that would satisfy your point of having an end user.

VICE CHAIRMAN GUIBERTEAU: Well I'm talking about end user being someone who is using the gallium-68 to image patients. Because I thought the whole issue

here is that this is a growing need by the imaging community. So it seems to me that someone who does -- actually does this procedure, might be a good person to have on the subcommittee to express their feelings on that portion.

CHAIRMAN THOMADSEN: Do any of the aforementioned use this material?

MEMBER DILSIZIAN: This is still under investigation. Thus that's the only clinical experience you're going to get.

VICE CHAIRMAN GUIBERTEAU: Well but to be fair, we do use the indium often times. We do see them on different patients. We have to bring them back two or three days. We have to know that the radiation exposure has to create and we do see the potential advantage of that of potential radiation half life.

I think a potential possibility of the radiation advocate maybe Ms. Weil can be on it, so.

CHAIRMAN THOMADSEN: Well with that, the imagers who have not used the gallium, but have used the indium in its place, serve to -- to serve the function you were thinking of?

VICE CHAIRMAN GUIBERTEAU: Yes. Well I mean and you know, this being a replacement for that, I mean it raises the whole question of you know, the urgency

portion of it.

So I think that as both you know, Dr. Palestro is a… you know, can I speak to the Society of Nuclear Medicine for many years as a member. And you know, being active in it, I think perhaps he would be a person who could represent that sort of faction of the stakeholders in this particular instance.

CHAIRMAN THOMADSEN: Would you care to join?

MEMBER PALESTRO: Sure I'd be happy to.

CHAIRMAN THOMADSEN: Okay. So we have a fifth and I think we'll cut it at that. Any other comments? Thank you Mr. Mattmuller.

MEMBER MATTMULLER: Sure.

CHAIRMAN THOMADSEN: Oh, I'm sorry, Dr. Howe.

DR. HOWE: I just have two things that you might want to consider. One is as you were talking about the information that we would need to go forward. If we're talking about rulemaking, we would need something called a regulatory basis. And there's specific information that is required in the regulatory basis that would make the process go faster later.

And so I think your subcommittee should be aware of what the regulatory basis is and the type of information that is needed for it.

And the other things is this, SNMMI is one of

the sponsors. And you may have to be careful about conflict of interest.

CHAIRMAN THOMADSEN: Well we did have a name in from them, so that would be the judge of that one. Thank you of course for those reminders. And I will try to map out a more detailed charge with your input and will mention it tomorrow.

MEMBER MATTMULLER: Do we need to identify an NRC staff person for our Committee?

CHAIRMAN THOMADSEN: Do we need to do that ahead?

MR. FULLER: We can do it later.

MEMBER MATTMULLER: Okay, all right.

MR. FULLER: We'll provide somebody.

CHAIRMAN THOMADSEN: Mr. Costello?

MEMBER COSTELLO: One last comment on this. This is an issue that will come up again in the future. It happens to be coming up with the places right now. But you know, referring to Appendix B of Part 30, which gallium was originally designed to -- so we could have a late radiant material. It wasn't designed with financial assurance in mind at all.

We sort of glommed onto it going to develop the requirement for financial assurance because it was a convenient table. Well, there are more isotopes then

are listed there. And I just, the range is a little bit insult, it is in some clever light, it is with these other isotopes that are developed. They're not on here.

And once again, we'll be treating them as though they were plutonium or strontium-90, or much more hazardous then they really are. I'm a little upset with this, is there some way you could address this, and I don't know if there is in a generic light, so we don't have to do this by isotope by isotope as it comes up. And finally it's just -- the problem isn't this particular isotope, the problem is the table is old.

CHAIRMAN THOMADSEN: Good observation. Thank you.

Dr. Zanzonico.

MEMBER ZANZONICO: Good afternoon everyone. We have convened a subcommittee, or the ACMUI convened a subcommittee to look at the draft amendment to the ACMUI bylaws and several related issues.

So I'm going to present the draft report submitted to the NRC staff. And I'm going to review with you, the recommendations of our subcommittee. I could keep us on schedule. I don't anticipate a lot of impassioned debate about bylaws.

The members of the subcommittee were listed

here. And I first have to acknowledge and apologize in that in some inexplicable way. Ms. Weil was inadvertently not included on the thread of emails on the various iterations of the report and so forth. And so she didn't have the opportunity to provide input. And I do apologize for that.

So the task of the subcommittee was as follows -- to review and identify potential additional amendments to the amended ACMUI bylaws, the original draft was in September 2013.

And the work of our subcommittee actually expanded somewhat beyond that limited scope to include the task two, three and four, discuss and make recommendations to the ACMUI reporting structure, discuss and make recommendations for possible budgeting for an additional face to face meeting such as we're having now, and consideration of the feasibility of conducting web-based meetings.

So I'll address these tasks in turn starting with the amended ACMUI bylaws. And highlight some of the issues we identified, or think we identified that may be problematic in the draft bylaws.

First as has been pointed out on a number of occasions that have been in these meetings and deliberations, sometime NRC legal counsel review is

required in terms of the propriety of ACMUI recommendations. And we therefore recommend that that be incorporated explicitly in the bylaws.

That on some occasion there may be a need for legal counsel review which might trump in some instances our deliberations. And we think that should be acknowledged as I said, explicitly in the bylaws.

There is also an item in the bylaws indicating that webcasting of meetings was required. And at least it appears to be a requirement. And we thought it might be helpful to provide some exemption to that as a requirement in the event that the technical or other reasons, webcasting did not happen to be possible in a particular instance.

So rather than not go forward with the meeting with the ACMUI membership assembled, that we could format the bylaws in such a way that it would be possible to go forward nonetheless if that were not possible.

There was another issue which essentially related the biasing of the discussions by the ACMUI by the ACMUI Chair and it included language to the effect that the ACMUI Chair, if unwilling influencing and biasing an ongoing discussion, that the ACMUI Chair could be essentially disenfranchised. In other words, no longer leading the discussion and thereby avoiding

some biasing.

In the end, trying to remedy that became more problematic then the language as it currently stands. So we decided to recommend leaving Section 1.3.5 in the bylaws as is.

Another issue was term limits. In the bylaws it says ACMUI membership is limited to two four-year terms. But we know in the case of our last chairman, Dr. Malmud, he served three terms for example.

So there is a mechanism for such exemptions. But it's not specified explicitly in the draft bylaws. And given that these things can and do occur, there should be some language referred to exemptions beyond the current two four-year terms.

This slide's atypical to see if our address is tasked to. This is the ACMUI reporting structure. The current reporting structure is on the left-hand side -- the left-hand side of the slide, where the ACMUI reports ultimately to the Commission, but through a series of intermediaries within the NRC.

The alternative as shown on the right, would be for the ACMUI to report directly to the Commission. So the question is should we remain the current reporting structure through NRC staff and so forth, or recommend reporting directly to the Commission.

Now obviously, we can add some light that there are advantages and disadvantages to both possibilities. The -- certainly as we've heard, reporting directly to the Commissioners would likely entail a greater time and effort commitment by the ACMUI membership. Perhaps a generation of more documentation generation, holding of more meetings, so forth and so on.

And among the -- our ACMUI, among our subcommittee members, we were hard pressed to identify a changeable benefit. There's some I guess philosophical or aesthetic benefit to reporting directly to the Commission. But really we can't identify a tangible benefit at present.

The current reporting structure frankly seems to be working well. The NRC staff is responsive. We think our recommendation is ultimately reaching the Commission in an unfiltered forum, so forth and so on.

And so based on those considerations, we recommend maintaining the current reporting structure. But also maintaining the annual review of reporting structure if and when the current reporting structure appears to become ineffective or whatever. And we also recommend importantly maintaining our annual briefing to the NRC Commission, as will occur tomorrow.

The third task that our subcommittee had was

with respect to additional face-to-face meetings. And again, we maintain retaining the status quo, that is the current schedule of two face-to-face meetings per year at NRC headquarters here.

We feel that there is ample time for uninterrupted, frank discussion. That meetings at six month intervals allow reasonably, timely attention to new issues as they arise.

And an advantage of face-to-face meetings, not that there was any possibility raised of cutting back on those, but we were going to emphasize nonetheless, that advantages of face-to-face meetings is sort of promoting and nurturing camaraderie, collegiality, et cetera, et cetera. Not only among the members of the ACMUI itself, but between the ACMUI membership and the staff.

It's much more difficult to become enraged or angry with someone when you see them face-to-face then when they're just a name on an email. We think that there are tangible benefits we feel to maintaining face-to-face meetings on a regular basis.

Now the other side of that coin, which is task four, is the regularization of web-based conferencing like web applications or go to meeting. And certainly I think for any of us who have used that technology, and

it's probably most of us, if not all of us, definitely, it's now a mature, reliable, inexpensive, universally available, easy to use technology.

I mean from a technical point of view, there's no down side to web-based meetings. It's applicable to all desk tops and even mobile platforms. And it's certainly superior we think to sort of old style, audio only conferencing. You can see another attendee's desktop computer, their display and vice versa.

And so it seems there's no reason not to use web-based conferencing as needed. But importantly as a compliment to, but not replacement for, face-to-face meetings.

So we just want to avoid the slippery slope syndrome where there's a possibility that, especially given the savings and money, where web-based meetings might be viewed as a viable replacement for regular face-to-face meetings.

And this is just a slide of our abbreviations and acronyms used here. We do have -- we did prepare a draft report, which includes this background. And actually makes our recommendations on each of these points in a formal way.

And that's included in the e-binder that was distributed to all the ACMUI members. That is my

presentation. Thank you.

CHAIRMAN THOMADSEN: Thank you Dr. Zanzonico.

Comments? Any questions? Dr. Langhorst?

MEMBER LANGHORST: Thank you. I just wanted to ask on -- in our packet here, we have the draft report, and then there's a mark-up of the bylaws. Was that the old markup?

MEMBER ZANZONICO: The -- I asked Sophie that, and my understanding is that the version, the redlined version in the handout incorporates a number of these recommendations. But I don't know if it includes all of them.

MS. HOLIDAY: Dr. Langhorst, to answer your question, I believe that the mark-up that you see in your packet, which I am going to pull up on the screen for the Committee and the attendees to see, incorporates the original changes that were proposed in September.

And the blue part, which you'll see once I pull it up on the screen, should incorporate all of the suggestions that the subcommittee made during their deliberations.

MEMBER LANGHORST: Okay.

MEMBER ZANZONICO: Well, incorporated most -- many of the recommendations were essentially related to changing will, the word "will" to "should". So it built

in flexibility so that you know if something for example could not be technically doable, it would not prevent a meeting from going forward.

MEMBER LANGHORST: But the reason I ask is because the markup on what the Chair is allowed to do and stuff, seemed like there were changes. And you said that you all decided that you weren't recommending any changes. And that's what --

MEMBER ZANZONICO: Well let's look at that.

MEMBER LANGHORST: That's what confused me, so.

MEMBER ZANZONICO: Okay.

MS. HOLIDAY: So, for our purposes, it might be beneficial to go in order through the bylaws and see if the Committee is amenable to what we have on the screen. And then we'll eventually get to that piece about the Chair part. If you're okay with that.

CHAIRMAN THOMADSEN: Mr. Fuller, you have a comment?

MR. FULLER: Just I was going to ask a question, if there's a microphone available for Sophie from where's she's sitting.

MS. HOLIDAY: There used to be.

MR. FULLER: So, okay.

MS. HOLIDAY: I will join you up here, how

about that?

Okay, so the bylaws --

CHAIRMAN THOMADSEN: Ms. Weil.

MS. HOLIDAY: I'm sorry, go ahead.

MEMBER WEIL: Well I just wanted to make a comment that if Sophie's got something to say first.

MS. HOLIDAY: No, I was going to get into it, but please.

MEMBER WEIL: This is the reporting structure here. The first blue marking yes?

MS. HOLIDAY: Yes.

MEMBER WEIL: So, on the flow chart that shows the existing structure, the slide that represents the recommendation. It's a little different then from the way it's stated here.

We ultimately in the flow chart report to the Commission. Here it says that we report to NRC staff in the Division of Material Safety and State Agreements, FSME, et cetera, period.

MS. HOLIDAY: Sure. So just a little bit of clarification. Dr. Zanzonico's chart, which I provided to him, so I will go ahead and take the blame on that and apologize.

What we were trying to convey is that the ACMUI, unlike the ACRS reports to staff and not to the

Commission. So the hierarchy is that the ACMUI advises staff. You all officially report to Ms. Dudes as the Director of the Division of Material Safety and State Agreements.

And we're of course, a part of FSME. And FSME then has to report through the other channels, the EDO, and then communication has been sent from the EDO's office to the Commission.

So what Dr. Zanzonico was trying to say is that the Committee's advice and your unfettered views and comments, such as your patient release reports, your permanent brachy implant reports, we provide that to the Commission when staff provides their paper to the Commission, it clearly states that this is ACMUI's position. It's ACMUI's advice to staff, which is ultimately given to the Commission.

Does that make sense?

MEMBER WEIL: It makes sense, and I just would like to go on record as objecting to that structure. Because I think this Committee should report through staff to the Commission.

MS. HOLIDAY: That's what the Committee does.

MEMBER WEIL: It does, but that's not what that says.

MS. HOLIDAY: So how would you submit that we

change this? This says that ACMUI provides independent advice to the staff in this Division. Are you asking for us to add a piece in there that says --

MEMBER WEIL: No, I'm asking --

CHAIRMAN THOMADSEN: Are you asking to have what's crossed out not crossed out? Because that would then say to the Commission and to the NRC staff.

MEMBER WEIL: I guess so. I guess I'm objecting to the change.

CHAIRMAN THOMADSEN: Yes.

MEMBER WEIL: Thank you.

MS. HOLIDAY: Okay. We will reject that strike out then.

MEMBER ZANZONICO: But that was --

MEMBER WEIL: But that would be a group decision.

MEMBER ZANZONICO: Well I agree, that was the -- that was my inference. A working inference, that was my understanding based on those -- the reported structure in the diagrams. And I think there's a significant difference --

MEMBER WEIL: I think so too.

MEMBER ZANZONICO: Between including or not including that strike out, yes.

MS. HOLIDAY: I think for my purposes when I

was preparing changes to the bylaws, I guess as an NRC staff person here, I understood that that's what it meant. But --

MEMBER WEIL: But that's not what it says.

MS. HOLIDAY: But that's not what it says. So for clarification purposes, we will remove the strike out if the full Committee agrees with that change.

CHAIRMAN THOMADSEN: Any objections?

(No Answer)

CHAIRMAN THOMADSEN: No, none.

MS. HOLIDAY: Okay. So the next change in blue is just ACMUI, the work ACMUI was left out. I don't think that there are any objections to that. It just clearly identifies ACMUI and not just members. Okay.

So then we move down to Section 1, scheduling and time of meetings. 1.1.1, the changes are pretty minor. It just changed the word meetings to ACMUI meetings. The following spring is un-capitalized. Fall is un-capitalized.

We inserted the terms annually for the meeting with the Commission. Unless the Chair or the designated Chair of the ACMUI declines, or the Commission declines.

Are we okay with Section 1.1.1?

(No Answer)

MS. HOLIDAY: Okay. Moving on to 1.1.2, in the past, I don't know if I said this. So these bylaws have not been amended since 2006. So there is a lot of terminology that has to be updated, which was our initial position for updating the bylaws to begin with.

So we took out the word special. We understand the Section to include all meetings, whether that be teleconferences or subcommittee meetings or full committee meetings, will be open to the public, except for meetings or portions of meetings in which matters are discussed that are exempt from public disclosure under FACA, or appropriate rules or statutes.

I'm seeing a look on Ms. Weil's face.

MEMBER WEIL: Well just all meetings except. Are subcommittee meetings ever open to the public?

MS. HOLIDAY: So FACA does not require us to make subcommittee meetings open. But we left the term in there in the event that a subcommittee wished to broadcast their meeting publically.

So that would be the part where it says are exempt from public disclosure under FACA, because those are. But in the event that a subcommittee wished to open it up to the public, they could do that if it was not senstive internal information.

CHAIRMAN THOMADSEN: Yes. Mr. Costello?

MEMBER COSTELLO: If the subcommittee is essentially having a conference call to discuss let's say gallium-68 generators, right, would that subcommittee's conference call a necessity be open to the public?

MS. HOLIDAY: Right. So what I'm saying is that subcommittee meetings do not have to be open to the public. They are not required to be open to the public.

MEMBER COSTELLO: So if we have a conference call to discuss those generators, we don't have to notice it?

MS. HOLIDAY: No, not at all.

CHAIRMAN THOMADSEN: Ms. Weil?

MEMBER WEIL: That's really not what this says. This says that subcommittee meetings will be open to the public unless there is stuff that is exempt from public disclosure.

MR. FULLER: Could you go up and see the --

MEMBER WEIL: So what you want to do instead of will be, you should just say may be. If you want subcommittee meetings to be potentially open to the public if the subcommittee so chooses.

MEMBER COSTELLO: But ACMUI meetings have to be open.

MEMBER WEIL: Have to be publicly open.

MEMBER COSTELLO: Yes, but I think subcommittee meetings I think normally will not be open.

MEMBER WEIL: But this says they will be open right now, unless there's non-public information.

MEMBER COSTELLO: I know, I know, I don't think that's our function.

CHAIRMAN THOMADSEN: You're talking about 1.1.2?

MS. HOLIDAY: Yes.

CHAIRMAN THOMADSEN: That's ACMUI meetings, not subcommittee meetings.

MEMBER COSTELLO: That's all meetings including teleconferences.

CHAIRMAN THOMADSEN: Yes, I know, we should probably just take that out of there.

MEMBER COSTELLO: Yeah, you take the parentheses out.

MS. HOLIDAY: So, would we just like to say ACMUI meetings, including teleconferences, and strike and subcommittee meetings?

CHAIRMAN THOMADSEN: I think so, yes.

MS. HOLIDAY: Are you happy with that to Ms. Weil?

MEMBER WEIL: Yes, because it doesn't say that

a subcommittee meeting couldn't be open to the public, if that's what your intention was.

CHAIRMAN THOMADSEN: That is correct.

MS. HOLIDAY: Right. Right. And this is a fruitful conversation for us because this is language that was in the existing 2006 bylaws.

VICE CHAIR GUIBERTEAU: Why do we need to include teleconference on there? I think we can --

MEMBER WEIL: Yeah right, just meetings.

VICE CHAIR GUIBERTEAU: Because if it's an ACMUI meeting, it doesn't matter how we have it, it could be a WebEx meeting.

MEMBER COSTELLO: So just strike the whole parentheses.

CHAIRMAN THOMADSEN: The whole parenthetical part.

MS. HOLIDAY: Okay. So it will just read ACMUI meetings will be open to the public except for meetings, da, da, da, da, da.

MEMBER WEIL: Yes.

MS. HOLIDAY: Except under FACA.

CHAIRMAN THOMADSEN: Mr. Costello?

MEMBER COSTELLO: If we're to open a WebEx meeting to the public, would that be up to them as a teleconference meeting? Or would the public be

expected to participate via WebEx?

CHAIRMAN THOMADSEN: I'm sorry, I didn't --

MEMBER COSTELLO: I'm sorry. If we had a WebEx meeting, okay. Would that be open that only the public could participate via WebEx, or would that mean the public would participate via teleconference? Because a number -- outnumber the public who could participate via WebEx would be a smaller population I would think.

CHAIRMAN THOMADSEN: Actually I think now days it wouldn't be. Most of the WebEx and GoToMeetings that I've been on have also had a call in number that somebody could use. I don't see that that, I mean I know we have to have that sort of thing.

MEMBER COSTELLO: I think we could, because if somebody stays at home, they may not have it.

CHAIRMAN THOMADSEN: Yes, okay.

MS. HOLIDAY: Okay, so for 1.1.2 it will read ACMUI meetings will be open to the public except for meetings or portions of meetings in which matters are discussed that are exempt from public disclosure under FACA or other appropriate rules or statutes.

I see no disagreement.

CHAIRMAN THOMADSEN: Good. Oh, Mr. Fuller, yes?

MR. FULLER: I'm just a little curious here. Was the intent when we put this on the agenda, to go through this line by line by line.

Or if this is what we asked the -- this is what the subcommittee was asked to do, make the recommendations to the full Committee in a public quorum, I did not realize that we were going take this time to then go through, because this was all provided in advance.

But so I'm just trying to understand the process here. We're going to talk about every word in the bylaws during the next hour or so?

CHAIRMAN THOMADSEN: To tell you the truth, I did not expect this either. I expected that we would terminate with the ends of the report. And that we would then go on off line to look at this and have input from the Committee on the draft that was here.

I didn't expect us to go through line by line this meeting. I don't think we have the time either.

MR. FULLER: So I don't think so.

MS. HOLIDAY: The reason that we blocked out two hours, and two hours we were convinced -- originally had two hours, which would have been sufficient time to discuss the line by line.

Because this is what we attempted to do last

time, or the last two meetings and we were unable to do that. But we did try to do it in a closed session. But since then, we've learned that -- these bylaws, there's nothing that really allows us to do that in closed space.

So that's why it's in an open session, not for offline discussion, if that makes sense.

CHAIRMAN THOMADSEN: Let me -- let me poll the Committee.

MR. FULLER: I just wanted to ask the question.

CHAIRMAN THOMADSEN: And ask how many would like to – I'm going to give you two opinions to either continue with this now. Or to look through this off line, make comments and I will designate how that would happen, to which we would add this to the fall meeting as a two hour -- a two hour block.

Now, first question, how many would favor continuing now?

So for completeness, how many favor responding off line?

Okay. In that case, what I would suggest is everybody looking through this and send edited comments with track changes to me. I will try to consolidate that and we'll bring this up, highlighting those issues that people don't agree on at the next meeting.

I think that would cut the time too going through stuff that everybody would agree on.

MR. FULLER: Now just a quick -- I understand what Sophie's saying, under the FACA regulations, this must be done ultimately in a public forum. But having the deliberation and wordsmithing going on, I think it's probably not a re --

In other words, ultimately, the full Committee's going to have to consider the recommended changes of the subcommittee in the public forum. And then either accept them or reject them. Adopt them or not. But to go through and actually say well I think there should be a comma there and things like that, I don't think that is an expectation of the FACA requirements.

CHAIRMAN THOMADSEN: That's where we keep to required.

VICE CHAIR GUIBERTEAU: I like this so far, but I'm not -- I heard something that you said that I was not comfortable with. And that is, I do believe that when this Committee approves the changes that are accepted by whomever is going to field our comments, that we do have a chance to look at them again. And not just have the recommendation voted up or down.

MR. FULLER: Absolutely. I'm just saying

that --

VICE CHAIR GUIBERTEAU: Somebody may feel very strongly about something that wasn't accepted. And then convince us in this meeting that they were correct.

MR. FULLER: Absolutely. All I'm saying is I don't think there's an expectation that this full Committee further this process of going word by word by word in the public forum.

You could have a presentation like you had today and be -- and because you were prepared and had read everything before hand, there might be something that you strongly disagree with, and you want to bring that up also in a public forum and have that deliberated and discussed. Absolutely, yes.

CHAIRMAN THOMADSEN: Dr. Langhorst?

MEMBER LANGHORST: Just a suggestion, but this might be relatively easy to then have a teleconference or test out a webinar on just to address this one question. Instead of waiting until the fall --

CHAIRMAN THOMADSEN: Very good.

MEMBER LANGHORST: Or taking a big chunk of time in the fall.

CHAIRMAN THOMADSEN: I think that that.

MR. FULLER: We certainly have a lot of time for the fall meeting to do.

MS. HOLIDAY: Yes. I was going to say I think that's preferable. Because as our fall agenda stands right now, it's getting pretty full.

CHAIRMAN THOMADSEN: Oh, yes. Also I don't think this is something that you would have a great deal of interest in the public to call and listen to that.

Very fine, so, the procedure, people look through this, make notes of things that they would like to change, or that they object to. Send them to me. I'll send a consolidated version out. I may ask the staff to help me with that.

We will then set up a teleconference of some sort to go through this. Is that amenable to the Committee?

MEMBER WEIL: Yes.

CHAIRMAN THOMADSEN: Is that amenable to the staff?

MR. FULLER: Absolutely.

MEMBER ZANZONICO: Can I just speak? Can I just make a statement? I refer to our -- actually as I outlined four tasks for the subcommittee. Only one of which dealt specifically with the bylaws. I think we disposed of that for the time being.

Do we need to have a vote regarding the recommendations of the other three tasks? Which were the -- the second task is and recommendation for that was to maintain the current ACMUI reporting structure.

The third task, the resolution ultimately -- or the recommendation ultimately was to maintain current two face-to-face meetings annually. And the third recommendation was to endorse essentially web-based meetings as needed, but not in place of the two annual face-to-face meetings.

Could we collectively vote to approve those three recommendations and get those off of the table?

CHAIRMAN THOMADSEN: I will assume that you just made a Motion?

MEMBER ZANZONICO: Yes, I've made the Motion.

MEMBER ALDERSON: Second.

CHAIRMAN THOMADSEN: Just for the record, it doesn't need a second because it's coming from a subcommittee of this organization.

MEMBER COSTELLO: Clarifying question?

CHAIRMAN THOMADSEN: And discussion? Mr. Costello?

MEMBER COSTELLO: You said maintain the current reporting structure. Is the current reporting structure one that would report to FSME, or one that

would report to the Commission through FSME? Clarify.

MEMBER ZANZONICO: In my report, I think they're reporting to the Commission through FSME.

MEMBER COSTELLO: Okay.

MS. HOLIDAY: Yes.

MEMBER COSTELLO: Okay. I'm ready.

CHAIRMAN THOMADSEN: Thank you for the clarification request. Any other discussion? Dr. Welsh?

MEMBER WELSH: Yes. Regarding the same point. Reporting scheme. I know we discussed this last -- or maybe it was two years ago, and the recommendation was as it is today, to maintain the status quo.

But I think I said at that time that the status quo was working very well. Not because of the scheme, but because of the individual people. And I think I recommended that the question be raised intermittently maybe on an annual or biannual basis. Just to make sure that the individuals who are a part of the scheme are still satisfying our needs to make sure that the ultimate message gets to the Commission.

MEMBER ZANZONICO: Right, no exactly. The actual recommendation with respect to the reporting structure was including the annual review. And

including the annual Commissioners' briefing.

CHAIRMAN THOMADSEN: Does that satisfy?

MEMBER WELSH: If that's the way it's stated, then yes, it does satisfy.

CHAIRMAN THOMADSEN: Okay fine. Any other comments?

MEMBER ALDERSON: Just a brief comment. As someone who has not spent as much time with this as all of you have, it would be very useful for what you've asked us to do, if we got a color coded you know, version of that with all the appropriate determinates of what a particular color means. Because it's not all together clear to me now.

MS. HOLIDAY: Sure.

CHAIRMAN THOMADSEN: And in a Word version so that you could insert comments.

MEMBER ALDERSON: Yes, that's very important.

MS. HOLIDAY: Sure.

CHAIRMAN THOMADSEN: Thank you. Other comments? Hearing none, all in favor say aye.

(Chorus of ayes)

CHAIRMAN THOMADSEN: Opposed?

(No response)

CHAIRMAN THOMADSEN: Good. Was there any opposition? Okay. So it's a passed amendment.

We thank you very much, Dr. Zanzonico.

MS. HOLIDAY: Dr. Thomadsen, may I consider this our annual review of the reporting structure for 2014?

CHAIRMAN THOMADSEN: You may.

MS. HOLIDAY: Thank you.

CHAIRMAN THOMADSEN: I think we just, not unless we affirm with that. We affirm.

MS. HOLIDAY: Great.

CHAIRMAN THOMADSEN: That brings us to the end of the open portion of our program for today. And we have a break to go to. The Committee can appoint the Committee and staff who work with these.

(Whereupon, the open session went off the record at 3:03 p.m.)