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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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SPRING 2014 MEETING

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OPEN SESSION

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THURSDAY,

MAY 8, 2014

+ + + + +

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

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

3 STEVEN R. MATTMULLER, Nuclear Pharmacist

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

6 JOHN J. SUH, M.D., Radiation Oncologist

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

8 LAURA M. WEIL, Patients' Rights Advocate

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

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

12

13 NRC STAFF PRESENT:

14 MICHAEL WEBER, Deputy Executive Director for
15 Operations for Materials, Waste, Research,
16 State, Tribal, and Compliance Programs

17 BRIAN HOLIAN, Acting Director, Office of Federal
18 and State Materials and Environmental Management
19 Programs

20 MARK SHAFFER, Acting Deputy Director, Office of
21 Federal and State Materials and Environmental
22 Management Programs

23 LAURA DUDES, Director, Division of Materials
24 Safety and State Agreements

25 PAMELA HENDERSON, Deputy Director, Division of

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1 Materials Safety and State Agreements
2 MICHAEL FULLER, Designated Federal Officer
3 SOPHIE HOLIDAY, Alternate Designated Federal
4 Officer, ACMUI Coordinator
5 NEELAM BHALLA, FSME/DILR/RPMB
6 DOUGLAS BOLLOCK, FSME/MSSA/RMSB
7 SUSAN CHIDAKEL, OGC/GCLR/RMR
8 ASHLEY COCKERHAM, FSME/MSSA/RMSB
9 SAID DAIBES, Ph.D., FSME/MSSA/RMSB
10 SANDRA GABRIEL, Ph.D., FSME/MSSA/RMSB
11 TOMAS HERRERA, FSME/MSSA/LB
12 DONNA-BETH HOWE, Ph.D., FSME/MSSA/RMSB
13 ED LOHR, FSME/DILR/RPMB
14 GRETCHEN RIVERA-CAPELLA, FSME/MSSA/RMSB
15 SHILLEY XU, FSME/MSSA/LB

16
17 MEMBERS OF THE PUBLIC PRESENT:

18 MAXWELL AMURAO, Columbia University Medical
19 Center
20 SUE BUNNING, Society of Nuclear Medicine and
21 Molecular Imaging
22 ROBERT DANSEREAU, New York State Department of
23 Health
24 GEORGIA HEARN, American Society of Nuclear
25 Cardiology

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1 ELIZABETH PEETZ, Mallincrokdt Pharmaceuticals
2 MICHAEL PETERS, American College of Radiology
3 DANIEL SNYDER, Geisinger Health System
4 WILLIAM SONES, Mallinkrodt Pharmaceuticals
5 MICHAEL STEPHENS, Florida Bureau for Radiation
6 Control
7 CINDY TOMLINSON, American Society for Radiation
8 Oncology
9 PAUL YURKO, Veterans Health Administration

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Adjourn

P R O C E E D I N G S

8:33 a.m.

1
2
3 VICE CHAIRMAN GUIBERTEAU: Welcome to the
4 Spring 2014 ACMUI meeting. And to start the meeting off
5 I will turn this over to Mr. Fuller who will read the
6 opening statement.

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

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

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

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

24 The function of the Committee is to advise the
25 Staff on issues and questions that arise on the medical

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1 use of byproduct material. The Committee provides
2 counsel to the staff but does not determine, nor direct
3 the actual decisions of the Staff or the Commission. The
4 NRC solicits the views of the Committee and values their
5 opinions.

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

11 At this point, I would like to perform a Roll
12 Call of the ACMUI members participating today.

13 (Roll Call.)

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

17 MS. HOLIDAY: Sophie Holiday.

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

20 DR. HOWE: Dr. Donna-Beth Howe.

21 DR. GABRIEL: Dr. Sandy Gabriel.

22 MR. BOLLOCK: Douglas Bollock.

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

1 MR. LOHR: Ed Lohr.

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

15 MR. FULLER: I would also like to add that this
16 meeting is being webcast, so other individuals may be
17 watching online. We have a bridge line available and
18 that phone number is 888-566-9152. The passcode to
19 access the bridge line is 61838#. Please put your phones
20 on mute or press *6 if your phone does not have that
21 function.

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

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

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

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

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

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

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

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

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

23 (Laughter.)

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

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

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

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

18 And the second pamphlet I have is from 1999.
19 I remember this. I was leaving a Region I job at that
20 time. I had been out in Region I for nine years, so I
21 worked with Frank Costello, and this is the Committee
22 on Veterans Affairs, U.S. House of Representatives,
23 1999 Hearing on Veterans Affairs issues and medical
24 events that we had back then. And I was paging through
25 that again this week and reliving that history, so I

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

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

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

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

16 (Laughter.)

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

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

6 (Laughter.)

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

16 (Laughter.)

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

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

1 Commission, and I was struck by the fact [inaudible] so,
2 they're all medical events. Right? I think we had 10 or
3 11, maybe 12, the number is lost, but they're all medical
4 events that we sent to Congress this year. So, at the
5 end of reading that report I was really struck about the
6 human side of the medical events.

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

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

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

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

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

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1 early and often communications on issues that arise. So,
2 with that, I think I've done the introductions. Sophie,
3 which I do have to acknowledge and thank very much for
4 all that she does for us, and she had given me some notes
5 to update you. And I know we are waiting for the Part
6 35 Rule. That is with the Commission and should be
7 published, the Draft Rule, next week' we're thinking,
8 so we'll let you know as soon as we know.

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

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

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

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

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

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

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

9 CHAIRMAN THOMADSEN: Excuse me for
10 interrupting.

11 MS. HOLIDAY: Sure.

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

16 (Laughter.)

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

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

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

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

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

12 2011, oh, 2010 you do not see because staff has
13 closed and addressed all of those recommendations that
14 came forth in 2010. For 2011, the majority of these are,
15 again, related to the current Part 35 expanded
16 rulemaking. Item 1 has to do with the Per-Release
17 Criteria. This is delayed and not included in the
18 current Part 35 rulemaking. Item 6 has to do with the
19 annual discussion from the Committee with staff on
20 evaluating their satisfaction with reporting to staff
21 versus the Commission. This item was superseded a year
22 or two later, I think in 2013, where basically the
23 Committee just said they wanted to keep having this
24 annual discussion to evaluate their satisfaction with
25 the reporting structure.

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

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

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

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

1 Proposed Expanded Part 35 Rulemaking.

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

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

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

22 Item 30, I am moving to close that item because
23 this is where we plan to have this spring meeting on May
24 8th and 9th with the backup date of 12th and 13th, and here
25 we are, so I think we can sufficiently close that item.

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

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

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

23 CHAIRMAN THOMADSEN: Dr. Langhorst.

24 MEMBER LANGHORST: It's just a housekeeping
25 thing.

1 MS. HOLIDAY: Sure.

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

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

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

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

1 there any other comments for Old Business?

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

4 MS. HOLIDAY: Thank you.

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

9 MS. HOLIDAY: Thank you.

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

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

15 (Laughter.)

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

25 Those were the majority of the comments. I'll

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

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

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

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

22 CHAIRMAN THOMADSEN: Yes, Dr. Langhorst.

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

1 agencies?

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

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

7 CHAIRMAN THOMADSEN: Dr. Suleiman.

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

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

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

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

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

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

1 please be on time, though.

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

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

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

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

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

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

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

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

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

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

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1 practice of medicine.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16 MEMBER ZANZONICO: Yes, it does. Thank you.

17 CHAIRMAN THOMADSEN: Mr. Costello.

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

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

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

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

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

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

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

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

17 MS. COCKERHAM: Thank you.

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

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

23 (Laughter.)

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

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

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

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

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

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

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

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

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

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

10 VICE CHAIRMAN GUIBERTEAU: Yes, Dr. Alderson.

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

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

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

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

6 CHAIRMAN THOMADSEN: I'm sorry. What?

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

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

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

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

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

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

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

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

25 VICE CHAIRMAN GUIBERTEAU: I think the feeling

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

12 MEMBER ALDERSON: So it was.

13 VICE CHAIRMAN GUIBERTEAU: And so it was, yes.

14 MEMBER ALDERSON: Very good. Thank you.

15 VICE CHAIRMAN GUIBERTEAU: Sue?

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

21 MEMBER ALDERSON: Okay.

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

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

5 MEMBER ALDERSON: Okay, thank you very much.

6 MEMBER LANGHORST: Thank you.

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

9 MEMBER WELSH: If I might -

10 VICE CHAIRMAN GUIBERTEAU: Yes.

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

13 (Laughter.)

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

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

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

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1 by ACMUI and stakeholders.

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

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

8 VICE CHAIRMAN GUIBERTEAU: Is there a second?

9 MEMBER MATTMULLER: Second.

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

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

14 (Simultaneous speaking)

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

18 (Simultaneous speaking)

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

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

25 CHAIRMAN THOMADSEN: To adopt the report. I

1 think the - what you're voting on is the recommendation
2 -

3 MEMBER ZANZONICO: The recommendation -
4 (Simultaneous speaking)

5 CHAIRMAN THOMADSEN: - provides accepting
6 right there.

7 MEMBER ZANZONICO: Okay, thank you.

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

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

17 (Simultaneous speaking)

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

25

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

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

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

5 (Laughter.)

6 VICE CHAIRMAN GUIBERTEAU: Yes?

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

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

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

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

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

14 CHAIRMAN THOMADSEN: Thank you.

15 MS. HOLIDAY: Dr. Guiberteau?

16 VICE CHAIRMAN GUIBERTEAU: Yes?

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

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

21 MS. HOLIDAY: Mr. Mattmuller. Thank you.

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

25 (Laughter.)

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

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

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

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

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

7 CHAIRMAN THOMADSEN: Thank you. Dr. Howe.

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

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

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

21 MEMBER LANGHORST: Thank you.

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

24 MEMBER LANGHORST: Thank you very much.

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

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

11 You'll see there really wasn't that much of a
12 change between where the medical events were in 2012 to
13 2013. 2012 we had medical events in 35.200, which is very
14 rare for us. Now that we have a 5 rem whole body, 50 rem
15 to an organ dose ratio which you have to exceed for
16 diagnostic. None of those involved where you're supposed
17 to get a diagnostic I-131 you get therapy. Sometimes
18 involve when you get an entire technetium generator
19 elution injected into a patient, so those are very rare,
20 so it's not unusual to have a zero in that category.

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

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

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

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1 directive.

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

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

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

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

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

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

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

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

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

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

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

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

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

1 seeds are due to poor visualization of ultrasound.

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

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

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

23 Moving into 35.600, we have the - all of our
24 35.600 medical events this year were for HDR units. We
25 didn't have any teletherapy or any GammaKnife. Six of

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

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

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

16 On the next one they -- it was an error in the
17 catheter lengths and it resulted in 1600 rad to the small
18 bowel near the bladder. And the whole dose was delivered
19 5.4 centimeters from where it should have been delivered
20 in the treatment volume.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21 (Background noise.)

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

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

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

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

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

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

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

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

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

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

1 flow.

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

14 CHAIRMAN THOMADSEN: Yes, Mr. Costello.

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

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

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

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

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

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

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

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

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

15 CHAIRMAN THOMADSEN: Dr. Dilsizian.

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

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

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

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

8 MEMBER COSTELLO: They're not reporting..

9 MEMBER DILSIZIAN: ... whole body imaging, and
10 then interpretation.

11 MEMBER COSTELLO: Right.

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

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

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

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

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

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

23 CHAIRMAN THOMADSEN: Ms. Weil.

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

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

12 CHAIRMAN THOMADSEN: Dr. Guiberteau.

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

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

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

13 CHAIRMAN THOMADSEN: Dr. Suleiman.

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

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

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

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

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

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

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

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

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

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1 Bremsstrahlung attempts for quantifying dose. Thank
2 you.

3 MEMBER ALDERSON: I'll make one further
4 comment.

5 CHAIRMAN THOMADSEN: Yes, Dr. Alderson.

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

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

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

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

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

14 (Laughter.)

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

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

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

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

25 CHAIRMAN THOMADSEN: Mr. Costello.

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

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

22 DR. HOWE: We have two.

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

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

1 working.

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

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

15 CHAIRMAN THOMADSEN: Mr. Fuller.

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

1 advice from this Committee.

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

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

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

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

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

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

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

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

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

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

22 CHAIRMAN THOMADSEN: Dr. Langhorst.

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

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

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

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

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

13 DR. HOWE: No.

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

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

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

22 CHAIRMAN THOMADSEN: Ms. Weil.

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

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

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

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

24 CHAIRMAN THOMADSEN: Dr. Alderson.

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

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

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

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

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

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

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

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

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

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

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

7 MS. FAIROBENT: Predating the motion.

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

10 MS. FAIROBENT: Yes.

11 CHAIRMAN THOMADSEN: Okay. Is that a yes?

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

14 CHAIRMAN THOMADSEN: Okay. Mr. Costello.

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

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

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

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

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

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

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

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

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

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

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

11 (Laughter.)

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

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

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

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

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

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

1 microspheres. Because it is 35.1000, regulated under
2 35.1000, we do have the ability to change, and we call
3 it guidance, and in this case guidance actually is
4 enforceable because it is under the umbrella of 35.1000.
5 So, our guidance that is published, that is out there,
6 that defines what is a medical event or under what
7 circumstances or criteria medical events need to be
8 reported to us. Then, yes, that is where I would [like]
9 for it to be focused, is our guidance in the right place
10 when it comes to reporting medical events on this issue?

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

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

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

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

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

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

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

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

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

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

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

1 MR. FULLER: Another Staff member...

2 CHAIRMAN THOMADSEN: Oh.

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

10 CHAIRMAN THOMADSEN: Thank you. Dr. Langhorst.

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

14 CHAIRMAN THOMADSEN: Please.

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

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

21 MEMBER LANGHORST: Okay, it says 135.

22 DR. HOWE: Which one are you looking...

23 (Simultaneous speaking)

24 CHAIRMAN THOMADSEN: Did you hear that?

25 MEMBER MATTMULLER: I hear voices.

1 CHAIRMAN THOMADSEN: Dr. Suleiman.

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

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

19 MEMBER WELSH: I, too, wish to shift gears a
20 little bit and ask a question to Dr. Howe regarding Slide
21 5, 35.300 Medical Events, specifically the iodine-131
22 thyroid situation.

23 DR. HOWE: Yes.

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

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

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

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

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

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

5 CHAIRMAN THOMADSEN: Dr. Guiberteau.

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

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

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

6 CHAIRMAN THOMADSEN: Dr. Dilsizian.

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

13 MEMBER WELSH: Sure. Sure.

14 MEMBER DILSIZIAN: So, I think...

15 MEMBER WELSH: Well, if I could comment. I
16 understand what you're saying. That's correct, my
17 understanding, as well. But if the Authorized User wants
18 150 millicuries, that's not diagnostic, that...

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

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

1 discrepancy...

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

5 CHAIRMAN THOMADSEN: Any other comments? Dr.
6 Palestro.

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

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

22 MEMBER MATTMULLER: Yes, that's fine.

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

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

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

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

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

19 MR. FULLER: That works for... sure.

20 MS. HOLIDAY: Dr. Thomadsen?

21 CHAIRMAN THOMADSEN: Yes.

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

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

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

9 (Laughter.)

10 (Off the record comments.)

11 CHAIRMAN THOMADSEN: Is that including the
12 Chair?

13 MS. HOLIDAY: I'm afraid it does.

14 (Off the record comments.)

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

19 MS. HOLIDAY: Yes.

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

24 MR. COSTELLO: Thank you.

25 CHAIRMAN THOMADSEN: All right. If there are no

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

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

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

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

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

7 On the bottom is a radiopharmaceutical or a
8 biomarker with nearly the same identical immunoacid
9 sequence in the important region, only here it's number
10 3-6 that gives specificity to the somatostatin
11 receptor. In the middle is the DOTA bifunctional chelate
12 so it attaches... it has two functions. One, it attaches
13 itself to the amino acid peptide, and it also chelates
14 another radionuclide. And in this case it's gallium-68.
15 And this is... can you read it? I can barely, I'm sorry,
16 is DOTA-TATE, and it's just one of the numerous
17 variations for neuroendocrine tumor imaging.

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

25 Here's a comparison of early versions of the

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

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

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

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

25 With the growing interest in gallium-68, there

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

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

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

1 that demonstrate promise for the diagnosis and/or
2 treatment of rare diseases that affect fewer than
3 200,000. So, with this designation towards the
4 important clinical trial you need fewer patients.
5 Excuse me, I heard subjects in the crowd, and that's
6 correct. They would be research subjects. Application
7 fees are waived. And, also, clinical trials are
8 incredibly expensive, millions of dollars, so the
9 possibility for FDA grant funding is a huge advantage.
10 So, these are three huge advantages an Orphan Drug has
11 compared to a typical new drug and the pathway it has
12 to follow to become a new drug in the approval process
13 with the FDA.

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

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

1 country.

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

10 So, from a regulatory perspective this is our
11 issue with gallium-68, and actually it's really with
12 germanium-68, the need for financial assurance for
13 decommissioning. With the current interpretation of the
14 regs, this is where the germanium-68 possession,
15 licensees are required to get a decommissioning funding
16 plan, or a DFP. Current interpretation is currently with
17 germanium-68 as unsealed, but I would propose that's
18 possibly not quite right since the germanium-68 is a
19 solid on a solid column. The germanium-68 does have a
20 half-life of over 271 days, so it clearly exceeds the
21 120-day limit. And the problem with Appendix B is that
22 there's not a value for germanium-68 listed, so the
23 default value kicks in and it's very low. 0.1
24 microcurie. And when you multiply that by the one times
25 ten to the fifth, you only come up with 10 millicuries,

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

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

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

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

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

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

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

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

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

6 So, if you're going to talk about sources and
7 devices, of course the NRC has a regulatory guide, and
8 it's 1556. This guide describes how the use of a sealed
9 source or device is structured so that the byproduct
10 material will not breach its containment and
11 contaminate the environment. This depends largely on
12 the adequacy of the containment, the properties of the
13 sealed source or devices in withstanding the stresses
14 imposed by the environment in which they are possessed
15 and used. The environment for a generator device or
16 source such as this is sitting quietly inside a lead
17 shield on a laboratory bench or even in a hot cell. It
18 won't be moved about; it won't travel in a vehicle on
19 the highways; it won't even be moved about on a cart in
20 the laboratory. It sits and it doesn't even have any
21 moving parts. So, if you're talking about sources and
22 devices, one section in the guide is 4.9, Sources and
23 Devices for Medical Use. But these are only proof of FDA
24 approval. A couple of these we're very familiar with,
25 510(k)'s, PMAs. If you look at the list in the guide this

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

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

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

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

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

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

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1 source to be regulated. Thank you.

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

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

20 CHAIRMAN THOMADSEN: Thank you. Dr. Suleiman.

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

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

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1 clarify that.

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

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

12 MEMBER MATTMULLER: Right.

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

18 CHAIRMAN THOMADSEN: Dr. Palestro.

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

23 MEMBER MATTMULLER: As gallium-68 chloride?

24 MEMBER PALESTRO: I'm sorry?

25 MEMBER MATTMULLER: As gallium-68 chloride or

1 gallium-68 citrate?

2 MEMBER PALESTRO: Gallium-68 citrate.

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

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

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

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

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

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

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

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

16 MEMBER MATTMULLER: Right.

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

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

1 were one of the sites that got rid of it.

2 CHAIRMAN THOMADSEN: Other questions?

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

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

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

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

3 CHAIRMAN THOMADSEN: Thank you. Mr. Fuller.

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

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

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

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

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

25 MEMBER SULEIMAN: No. No different than, it

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

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

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

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

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

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

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

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

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

1 make any promises or predict where that might come out.

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

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

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

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

25 Anyway, I may regret doing this, but - I'm

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1 sorry go --

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

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

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

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

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

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

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

6 MEMBER COSTELLO: But I really mean the table.

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

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

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

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

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

25 CHAIRMAN THOMADSEN: Dr. Suleiman?

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

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

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

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

16 CHAIRMAN THOMADSEN: Dr. Langhorst?

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

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

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

3 CHAIRMAN THOMADSEN: Dr. Alderson?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19 MR. FULLER: Understood.

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

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

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

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

7 MEMBER WEIL: And the sole unit does?

8 MEMBER MATTMULLER: Yes, in essence a unit
9 does.

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

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

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

18 MEMBER MATTMULLER: And the radiation is
19 another factor.

20 MEMBER WEIL: Is that a significant factor?

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

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

3 MEMBER MATTMULLER: Right. Which is almost
4 2.8 days, right.

5 MEMBER WEIL: So you have a superior
6 therapeutic agent.

7 MEMBER MATTMULLER: In this case, we have
8 diagnostics.

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

10 MEMBER MATTMULLER: Right.

11 MEMBER WEIL: For now.

12 MEMBER MATTMULLER: Right.

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

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

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

1 for the orphan drug sets.

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

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

9 CHAIRMAN THOMADSEN: Dr. Langhorst.

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

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

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

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

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

8 MR. FULLER: Bruce, behind you.

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

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

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

16 MEMBER ALDERSON: 1000 less what?

17 MS. BUNNING: Dollars.

18 MEMBER ALDERSON: Dollars?

19 MS. BUNNING: Um-hum. Right now. And
20 octreoscan costs \$5,000.00. And this would be
21 \$1,000.00 less, as of right now.

22 MEMBER ALDERSON: Okay.

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

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

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

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

12 CHAIRMAN THOMADSEN: Ms. Langhorst.

13 MEMBER LANGHORST: It's 2013, item 21.

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

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

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

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

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

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

16 MEMBER MATTMULLER: Yes.

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

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

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

25 MEMBER ZANZONICO: Yes.

1 CHAIRMAN THOMADSEN: I need a foursome.

2 MEMBER ZANZONICO: I'd be very happy to.

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

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

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

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

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

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

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

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

8 CHAIRMAN THOMADSEN: Dr. Guiberteau?

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

14 CHAIRMAN THOMADSEN: Do you have a potential
15 name?

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

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

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

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

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

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

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

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

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

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

1 portion of it.

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

8 CHAIRMAN THOMADSEN: Would you care to join?

9 MEMBER PALESTRO: Sure I'd be happy to.

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

13 MEMBER MATTMULLER: Sure.

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

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

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

25 And the other things is this, SNMMI is one of

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

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

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

10 CHAIRMAN THOMADSEN: Do we need to do that
11 ahead?

12 MR. FULLER: We can do it later.

13 MEMBER MATTMULLER: Okay, all right.

14 MR. FULLER: We'll provide somebody.

15 CHAIRMAN THOMADSEN: Mr. Costello?

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

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

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

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

13 CHAIRMAN THOMADSEN: Good observation.
14 Thank you.

15 Dr. Zanzonico.

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

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

25 The members of the subcommittee were listed

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

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

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

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

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

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

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

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

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

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

1 some biasing.

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

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

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

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

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

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

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

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

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

25 The third task that our subcommittee had was

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

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

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

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

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

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

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

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

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

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

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

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1 presentation. Thank you.

2 CHAIRMAN THOMADSEN: Thank you Dr. Zanzonico.

3 Comments? Any questions? Dr. Langhorst?

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

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

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

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

22 MEMBER LANGHORST: Okay.

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

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

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

9 MEMBER ZANZONICO: Well let's look at that.

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

12 MEMBER ZANZONICO: Okay.

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

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

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

23 MS. HOLIDAY: There used to be.

24 MR. FULLER: So, okay.

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

1 about that?

2 Okay, so the bylaws --

3 CHAIRMAN THOMADSEN: Ms. Weil.

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

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

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

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

11 MS. HOLIDAY: Yes.

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

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

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

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

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

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

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

17 Does that make sense?

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

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

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

25 MS. HOLIDAY: So how would you submit that we

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

4 MEMBER WEIL: No, I'm asking --

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

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

10 CHAIRMAN THOMADSEN: Yes.

11 MEMBER WEIL: Thank you.

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

14 MEMBER ZANZONICO: But that was --

15 MEMBER WEIL: But that would be a group
16 decision.

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

22 MEMBER WEIL: I think so too.

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

25 MS. HOLIDAY: I think for my purposes when I

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

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

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

8 CHAIRMAN THOMADSEN: Any objections?

9 (No Answer)

10 CHAIRMAN THOMADSEN: No, none.

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

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

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

24 Are we okay with Section 1.1.1?

25 (No Answer)

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

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

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

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

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

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

1 CHAIRMAN THOMADSEN: Yes. Mr. Costello?

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

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

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

13 MS. HOLIDAY: No, not at all.

14 CHAIRMAN THOMADSEN: Ms. Weil?

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

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

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

24 MEMBER COSTELLO: But ACMUI meetings have to
25 be open.

1 MEMBER WEIL: Have to be publicly open.

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

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

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

8 CHAIRMAN THOMADSEN: You're talking about
9 1.1.2?

10 MS. HOLIDAY: Yes.

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

13 MEMBER COSTELLO: That's all meetings
14 including teleconferences.

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

17 MEMBER COSTELLO: Yeah, you take the
18 parentheses out.

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

22 CHAIRMAN THOMADSEN: I think so, yes.

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

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

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

3 CHAIRMAN THOMADSEN: That is correct.

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

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

9 MEMBER WEIL: Yeah right, just meetings.

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

13 MEMBER COSTELLO: So just strike the whole
14 parentheses.

15 CHAIRMAN THOMADSEN: The whole parenthetical
16 part.

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

20 MEMBER WEIL: Yes.

21 MS. HOLIDAY: Except under FACA.

22 CHAIRMAN THOMADSEN: Mr. Costello?

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

1 expected to participate via WebEx?

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

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

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

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

17 CHAIRMAN THOMADSEN: Yes, okay.

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

23 I see no disagreement.

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

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

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

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

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

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

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

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

25 Because this is what we attempted to do last

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

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

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

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

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

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

19 So for completeness, how many favor responding
20 off line?

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

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

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

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

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

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

25 MR. FULLER: Absolutely. I'm just saying

1 that --

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

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

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

16 CHAIRMAN THOMADSEN: Dr. Langhorst?

17 MEMBER LANGHORST: Just a suggestion, but
18 this might be relatively easy to then have a
19 teleconference or test out a webinar on just to address
20 this one question. Instead of waiting until the fall
21 --

22 CHAIRMAN THOMADSEN: Very good.

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

25 CHAIRMAN THOMADSEN: I think that that.

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

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

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

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

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

17 MEMBER WEIL: Yes.

18 CHAIRMAN THOMADSEN: Is that amenable to the
19 staff?

20 MR. FULLER: Absolutely.

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

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

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

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

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

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

16 MEMBER ALDERSON: Second.

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

20 MEMBER COSTELLO: Clarifying question?

21 CHAIRMAN THOMADSEN: And discussion? Mr.
22 Costello?

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

1 would report to the Commission through FSME? Clarify.

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

4 MEMBER COSTELLO: Okay.

5 MS. HOLIDAY: Yes.

6 MEMBER COSTELLO: Okay. I'm ready.

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

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

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

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

1 including the annual Commissioners' briefing.

2 CHAIRMAN THOMADSEN: Does that satisfy?

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

5 CHAIRMAN THOMADSEN: Okay fine. Any other
6 comments?

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

14 MS. HOLIDAY: Sure.

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

17 MEMBER ALDERSON: Yes, that's very important.

18 MS. HOLIDAY: Sure.

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

21 (Chorus of ayes)

22 CHAIRMAN THOMADSEN: Opposed?

23 (No response)

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

1 We thank you very much, Dr. Zanzonico.

2 MS. HOLIDAY: Dr. Thomadsen, may I consider
3 this our annual review of the reporting structure for
4 2014?

5 CHAIRMAN THOMADSEN: You may.

6 MS. HOLIDAY: Thank you.

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

9 MS. HOLIDAY: Great.

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

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