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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 2016 MEETING

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OPEN SESSION

+ + + + +

FRIDAY,

MARCH 18, 2016

+ + + + +

The meeting was convened in room T-2B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:01 a.m., Philip O. Alderson, M.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

PHILIP O. ALDERSON, M.D., Chairman

FRANCIS M. COSTELLO, Agreement State
Representative

VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

RONALD D. ENNIS, M.D., Radiation Oncologist

STEVEN R. MATTMULLER, Nuclear Pharmacist

DARLENE F. METTER, M.D., Diagnostic Radiologist

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MICHAEL O'HARA, Ph.D., FDA Representative

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

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

LAURA M. WEIL, Patients' Rights Advocate

PAT B. ZANZONICO, Ph.D., Vice-Chairman

NON-VOTING: ZOUBIR OUHIB

MEMBER-SELECT: RICHARD GREEN

NRC STAFF PRESENT:

SCOTT MOORE, Acting Director, Office of Nuclear
Material Safety and Safeguards

DANIEL COLLINS, Director, Division of Material
Safety, State, Tribal and Rulemaking Programs

DOUGLAS BOLLOCK, ACMUI Designated Federal
Officer

SOPHIE HOLIDAY, ACMUI Alternate Designated
Federal Officer and ACMUI Coordinator

SAID DAIBES, Ph.D., NMSS/MSTR/MSEB

MICHAEL FULLER, NMSS/MSTR/MSEB

ESTHER R. HOUSEMAN, OGC/GCLR/RMR

DONNA-BETH HOWE, Ph.D., NMSS/MSTR/MSEB

ANGELA McINTOSH, NMSS/MSTR/MSEB

GRETCHEN RIVERA-CAPELLA, NMSS/MSTR/MSEB

KATIE TAPP, Ph.D., NMSS/MSTR/MSEB

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MEMBERS OF THE PUBLIC PRESENT:

DEBBIE BENSEN, Elekta, Inc.

BETTE BLANKENSHIP, American Association of
Physicists in Medicine

CATHERINE GILMORE-LAWLESS, Elekta, Inc.

LYNNE FAIROBENT, American Association of
Physicists in Medicine (AAPM)

CAITLIN KUBLER, Society of Nuclear Medicine and
Molecular Imaging (SNMMI)

RICHARD MARTIN, American Association of
Physicists in Medicine

CARL MELLERBY, Nordea

ERIC PERRY, Kentucky Department for Public Health

CRAIG PIERCY, Elekta, Inc.

MICHAEL PETERS, American College of Radiology

KAREN SHEEHAN, Fox Chase Cancer Center

ROBERT THOMAS, Elekta, Inc.

CINDY TOMLINSON, American Society of Radiation
Oncology (ASTRO)

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

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P R O C E E D I N G S

(8:01 a.m.)

CHAIRMAN ALDERSON: So welcome back everyone, to the second day of our spring meeting. And I'm going to -- this is Dr. Alderson, and I'm going to turn over the proceedings to Doug Bollock of the NRC.

MR. BOLLOCK: Good morning. We'll start off the morning with a presentation on our staff response to our Office of Inspector General audit of NRC's oversight of medical use of nuclear material.

So if you want me to go over a little bit of background of the audit, the audit findings, recommendations, and our response, and what we're doing moving forward.

MS. HOLIDAY: For persons on the telephone, could you please mute your phone. If your phone does not have that capability, please press Star 6. Thank you.

MR. BOLLOCK: Thank you, Sophie.

Okay, a little bit of background. So our Office of Inspector General is the NRC's internal oversight of our programs. And so they decided to audit our medical program last year.

So the audit objective was to determine if NRC's oversight of medical use of radioactive isotopes

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1 adequately protects public health and safety. So in
2 order to do that, they spoke with NRC staff here at
3 headquarters, NRC regional staff, agreement state
4 staff, and a number of licensees.

5 So the audit was completed about summer of
6 2015. And their findings were that the NRC does provide
7 adequate oversight of the medical use of radioactive
8 isotopes to protect public health and safety.

9 However, opportunities for improvement
10 exist with regard to clarification of NRC's medical
11 event reporting requirements, periodic self-assessment
12 of medical event reporting, and with providing better
13 feedback to the ACMUI.

14 So their first recommendation was to
15 clearly define the purpose of medical event reporting
16 in a publicly available document and clarify the
17 reporting requirements.

18 So during the audit they found there was
19 some confusion as to why, what the purpose of medical
20 events or reporting of medical events was. And there
21 are some differences between NRC staff, Agreement State
22 staff, within NRC regional offices. So it was pretty
23 clear that we should have one specific definition for
24 the purpose of medical events.

25 Recommendation 2 is to proactively provide

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1 all medical licensees with medical event tracking
2 trending information for lessons learned purposes.
3 And I know we spoke a little bit about that yesterday,
4 and Dr. Langhorst had some comments on that. So they
5 recognize, the OIG audit recognized that as well.

6 The third recommendation was develop and
7 implement policy and procedures that require periodic
8 assessments of NRC's approach to medical event
9 reporting. These assessments should include whether
10 the intended purpose of the reporting requirements are
11 being met and the thresholds of reporting requirements
12 are appropriate.

13 And their fourth recommendation was
14 develop and implement policy and procedures to guide
15 provision of sufficiently detailed and timely feedback
16 to ACMUI from NRC staff.

17 So our staff responses, so we are, for the
18 first recommendation, we took some actions. And we
19 found what the official purpose of medical event
20 reporting was. It goes back to 1980, back when medical
21 events were called medical misadministrations. But we
22 took that statement and put it on our NRC website. We
23 put it on the medical list server, sent it out to
24 everyone on the medical list server.

25 In the current rulemaking, we are planning

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1 on adding that in the statements of consideration for
2 the current rulemaking. And what that will do is just
3 update it from, essentially, from saying medical
4 misadministrations to medical events.

5 And we also sent an RCPD letter to the
6 Agreement States. And I can read to you the official
7 -- out of the statements of consideration for the 1980
8 rule, the Commission's purpose in requiring
9 misadministration reports. The NRC was to identify
10 their causes in order to correct them and prevent the
11 recurrence.

12 The Commission was able to notify other
13 licensees if there is a possibility that they could make
14 the same errors. So that right there is the purpose,
15 to identify and correct, or to correct and prevent
16 recurrence, and to give us the ability to notify the
17 licensees of these events. And that can help them, help
18 prevent from making the same errors.

19 So the second recommendation, with our
20 second recommendation we have some medical event
21 tracking trending initiatives. Essentially, we are
22 allowing the access to the general public, as I said
23 yesterday, access to the ACMUI medical event slides. So
24 the slides that Donna-Beth provides once a year and then
25 the ACMUI, in the second meeting, provides that back to

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1 us. Those are now specifically pulled out and provided
2 on the public website.

3 There was some question. I know we, just
4 a little bit more background on that. We had some
5 discussions about how much information we'd get, you
6 know, to find the causes and any actions that were taken.
7 We do share that in the slides when it's known.
8 Sometimes it's not always known, but we do our best, if
9 it is known, to put it in those slides so the public can
10 get that, and the licensees can get that as well.

11 All right, for Recommendation 3, we'll be
12 conducting an annual self-assessment in the overall
13 effectiveness of NRC's event reporting program. So
14 even though it was specific to medical events, we
15 evaluate on a yearly basis all events as part of our
16 annual assessment review. And so as part of that, we
17 will do a separate self-assessment and looking at some
18 specifics and effectiveness of just medical or event
19 reporting in general.

20 And for the last recommendation, we have
21 updated our policy and procedures that related to our
22 work with the ACMUI. So our Policy and Procedures, 2-5,
23 basically it didn't need any updating, because that is
24 how we make a decision on what to include, basically
25 major medical policy to include ACMUI but Policy

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1 Procedure 6-15 is how we actually implement our workings
2 with the ACMUI.

3 So we've updated those procedures to
4 enhance our communications, essentially to give the
5 memos and with better rationale behind our proposed
6 actions.

7 So in the past we've always given, as Sophie
8 did yesterday, the update from all the open action items
9 but now, for anything that we either don't agree with
10 partially or don't agree completely with the ACMUI, we
11 will give in a memo format, response back to the ACMUI
12 with our reasoning why.

13 All right, any questions?

14 CHAIRMAN ALDERSON: Would anyone on the
15 Committee like to raise a question? Yes, Dr. Ennis?

16 MEMBER ENNIS: I have a few actually, if
17 that's okay.

18 CHAIRMAN ALDERSON: Yes.

19 MEMBER ENNIS: One, I had a few questions.
20 One, in terms of response from staff to us, could it be
21 more interactive, like a presentation at this type of
22 a venue rather than a memo?

23 MR. BOLLOCK: We considered, we did
24 consider that, because we have the open, we go over the
25 open action items list. Sophie goes over that. That's

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1 an opportunity to ask those questions. So we feel we
2 do have that, or you have that opportunity to ask us
3 questions there.

4 But in between the meetings twice a year,
5 you know, there's six months. Time goes on. You may
6 or may not think to ask the question then. So it's the
7 in-between we will be providing the memos, just so we
8 have, essentially you have, I guess, an official record
9 of why we decided to go one way or the other based upon
10 your recommendations.

11 But yes, I mean, we encourage open
12 communication with the ACMUI. But that was kind of the
13 rationale behind why we didn't just leave it to this
14 meeting.

15 And some other things that we are actually,
16 actually Mike and I were discussing this morning, not
17 necessarily in regards to recommendations but just some
18 of the staff actions. We may just take, five, ten
19 minutes out of the ACMUI meetings and go over what staff
20 has been working on.

21 Because some of them are based on
22 recommendations or may be tangentially associated with
23 some of the recommendations from the ACMUI. That's
24 something we plan to do. And that'll be more of the
25 informal, you know, presentation during the ACMUI

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1 meetings.

2 MEMBER ENNIS: All right, great. Yes,
3 that was mentioned. I think that would be great. So
4 I guess the question now for us would be do we want our
5 subcommittee, for example, that works on things and had
6 the reports, when we get a report back from the ACMUI
7 do want to reconvene the subcommittee just to digest
8 that response in some way? Would that be a useful
9 process?

10 CHAIRMAN ALDERSON: I don't know about
11 that. I think it would depend on the report and the
12 issue. Other people would like to comment on that
13 question? Dr. Langhorst?

14 MEMBER LANGHORST: I think it would be very
15 important for the subcommittee to review it and provide
16 just maybe some written responses to that. Because it
17 doesn't necessarily, it may not warrant another
18 presentation. But I think it would be very helpful to
19 have the subcommittee then give an assessment for the
20 overall Committee.

21 CHAIRMAN ALDERSON: Okay. Thanks, Dr.
22 Langhorst. Did someone else have a comment on this
23 particular question?

24 VICE CHAIRMAN ZANZONICO: Oh, not on this,
25 not on the current question.

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1 CHAIRMAN ALDERSON: Anything else on Dr.
2 Ennis' suggestion?

3 (No audible response.)

4 CHAIRMAN ALDERSON: So the Committee's
5 leaving it that, obviously depending the content or
6 whatever, but they have a perhaps brief written response
7 to say this is clear, we understand, or here are a couple
8 of issues that would be useful.

9 So given that everyone seems to agree with
10 that, then we'll try to adopt that approach. Other
11 comments, Dr. Ennis?

12 MEMBER ENNIS: Yes. I just have one, I
13 guess one other. So with a more clear statement of what
14 the purpose of a medical event is, combining with our
15 conversations of yesterday, it seems like it's time to
16 really, with the new changes in, you know, the culture
17 of how you get a good quality culture and a good safety
18 culture, we really ought to move more to what Laura has
19 been talking about as an ideal.

20 And our challenge is how do we transform
21 medical events that are now really, had a significant
22 punitive component to them politically, and how can we
23 or can we transform them into the more just culture that
24 is prevalent today?

25 CHAIRMAN ALDERSON: Yes. Well, I think

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1 that's a very good question. I don't think that -- and
2 I think it's a complicated question. We're not going
3 to answer it right now.

4 MEMBER ENNIS: No, no.

5 CHAIRMAN ALDERSON: It's probably a topic
6 for a future meeting.

7 MEMBER ENNIS: Yes.

8 CHAIRMAN ALDERSON: Does anyone want to
9 comment on that before we move on?

10 MEMBER COSTELLO: Yes. I would think, to
11 the extent we could get -- I'm sorry, that's something
12 I think the Committee should take up as a whole sometime,
13 maybe in a subcommittee or wherever you'd want to do it.

14 Because a lot has happened since 1980 in
15 terms of therapy. And we've learned a lot in the
16 implementation of this. And I think maybe we can
17 probably put together a rationale that's more timely;
18 it fits better the paramedical practice.

19 CHAIRMAN ALDERSON: Good. All right, very
20 good. And we'll certainly consider that. Yes, Dr.
21 Langhorst?

22 MEMBER LANGHORST: I know a few Commission
23 briefings ago Dr. Thomadsen was talking on safety
24 culture. And I was also bringing up the idea of how NRC
25 can support or undermine a licensee's safety culture.

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1 And I really appreciated the report here.
2 On Page 15 of that report, wait a second, yes, it says,
3 ''Some stakeholders noted that NRC's approach to medical
4 event reporting is perceived to be punitive in nature.
5 Specifically stakeholders opine that the associated
6 reporting requirements are actually a deterrent to
7 self-reporting medical events.''

8 And so this is NRC's own review of how this
9 could be perceived as not supporting safety culture.
10 It's very difficult, and I know the Commissioners
11 brought it up at that point in time, well, we're the
12 regulator. Yes, we understand that. But maybe in this
13 instance can there be, because medical use is different,
14 because maybe there could be a different model of how
15 you receive medical event reporting and what you do with
16 that in the initial instance of a licensee having that
17 problem.

18 Now, maybe if there are repeated problems
19 there's another path you have to take. But can it be
20 in a way that, yes, we need this information, we'd like
21 to share as much, and maybe we could share it with the
22 community and not necessarily name names but give the
23 instance of what's happening, what led to it, how you
24 fixed it, and what the results were.

25 That could be of tremendous help to medical

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1 licensees and especially the smaller licensees that
2 maybe don't have as much resources to devote to all of
3 this. So I just ask that we help advise the NRC and the
4 NRC be open to maybe a slightly different model that we
5 could use to help support this development of a safety
6 culture between licensees and the regulators.

7 CHAIRMAN ALDERSON: Right. So I think
8 that's a fine suggestion. Yes, Mr. Costello?

9 MEMBER COSTELLO: And all the persons work
10 at the NRC.

11 CHAIRMAN ALDERSON: Yes.

12 MEMBER LANGHORST: That's why I said
13 regulators, sorry.

14 MEMBER COSTELLO: That's right. Whatever
15 percentage they said yesterday of licensees that belong
16 to the Agreement States and the approaches taken by the
17 Agreement States are not uniform with each other. In
18 fact, NRC regions aren't always uniform with each other.

19 It is a very important point, Dr. Langhorst.
20 And maybe if we do a subcommittee or something to look
21 into it, if it had recommendations that go beyond the
22 language of the purpose of the medical event, and if you
23 go into all that you talked about, you know, perhaps some
24 of these could be anonymous as far as, because of the
25 public.

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1 But I've heard the same thing from licensees
2 in our State that they don't mind reporting at all. But
3 the idea of associating their institution with a mistake
4 they have is a deterrent.

5 Now, when they tell me that there's very
6 little solace that I can give them. I can't tell them
7 they don't have to report, and I can't tell them we can
8 make them anonymous. Because that's not how it is. You
9 know, we get the report, we give it to NRC, and the
10 process moves on.

11 So if we do get a group to look into this,
12 well, we certainly want them to look into revisiting the
13 36 year-old, you know, definition of medical
14 misadministration. Maybe it can have a broader scope
15 and talk about things that you talked about, talk about
16 safety culture, and talk about ways of implementing it
17 in a way that's more likely to bring about what you're
18 trying to do. Thank you.

19 CHAIRMAN ALDERSON: Yes. Dr. Dilsizian?

20 MEMBER DILSIZIAN: Yes. I just wanted to
21 bring the clinical stress when these things happen in
22 medical misadministration.

23 The first thing we actually do, besides
24 thinking about the NRC, is call our legal counsel. So
25 just to let you know, that we, you know, while this, you

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1 know, the culture of safety is an interesting concept.
2 But the stress on the clinicians, and the patient, and
3 the hospital, and legal counsel is parallel if not more
4 stressful.

5 And so if NRC, in any way, can soften these
6 misadministration concepts that we should be reportable
7 but not necessarily a medical/legal action, it really
8 may help the physicians to report them. I'm just
9 letting you know that it's not just the NRC, it's the
10 other aspects of the medical/legal.

11 MR. BOLLOCK: If I can address some of
12 these? I think the purpose is, you know, the purpose
13 has got to remain the same. I think the purpose is
14 important that we, like I said, identify them to correct
15 and prevent recurrence and then any information we can
16 disseminate otherwise to help it from happening again.
17 I think that's, as long as we keep that as the goal, I
18 don't think that's going to change the purpose.

19 However, what you all are speaking on is how
20 do we implement that. And as, you know, Dr. Suh had a
21 presentation yesterday about the medical event
22 reporting. I think in any way that you all can help us
23 with that implementation will help.

24 You know, fortunately for us in the NRC, you
25 know, we have our regulations. If you're not in

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1 compliance with a regulation then, you know, essentially
2 you have a violation. But it's not a, it's legally
3 binding to an extent, but it's not the same things that,
4 you know -- we understand you have other concerns that
5 aren't -- our concerns is not, you know, we're not
6 directly affecting this, well, but we are affecting it
7 because of the regulations.

8 So we understand that. And we are
9 sensitive to that. And a lot of the efforts going
10 through the whole, you know, our process of we license,
11 we inspect and we enforce, and going through that, we
12 try to enforce such an inspection, and by that the
13 enforcement through performance base.

14 And how our structure works and how, you
15 know, we understand the good safety culture, and this
16 is a good safety culture going not just from the NRC
17 reactor side. We've got a good hold on that. But if
18 you look at safety culture across any industry, any
19 field, professional field, there are consistencies of
20 good safety culture. And we do understand that.

21 So, you know, you should be able to bring
22 up when a mistake is made or something without
23 repercussion. And that is always a sign of a good safety
24 culture. So hopefully that's where we could all get to.

25 But, because like you said, there are other

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1 aspects that you have to consider. We have to be open
2 to that. I think we are, you know, we as the medical
3 staff. And we can communicate that to our management.
4 And I think, with your help, we can get the
5 implementation to get it to work at the best way.

6 So, you know, my main points are the purpose
7 I don't think is going to change. But you can help us
8 with the implementation to help minimize those
9 crossovers that cause other unintended issues from our
10 part while still working together to get, you know, to
11 get the good information out so that we can prevent it.
12 And other licensees can, you know, it can prevent them
13 from having these events occur and, at the same time,
14 you know, promote a good, healthy safety culture.

15 CHAIRMAN ALDERSON: Right. So Mr. Ouhib
16 has a comment and then Dr. Langhorst will be next.

17 MR. OUHIB: Yes. I think this is a great
18 initiative. And let me go back to the purpose again.
19 So what mechanism is in place currently to actually
20 inform the users? And that is whether they are NRC
21 States, I mean, NRC-regulated States or Agreement
22 States.

23 And the second is how many cases will it take
24 to actually identify that this needs to go to users? Is
25 it two cases, is it three cases, similar.

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1 And then the other item is that unless the
2 information is accurate, it doesn't serve any purpose.
3 So that means there is, like we talked yesterday, there
4 is work that needs to be done on both sides of the aisle.
5 There's from the regulators, perhaps education and
6 training, and then from the users, them also.

7 That information is really crucial. And
8 why is it crucial? Here's why. We're trying to help
9 and assist others. This is not because we want to get
10 to the nitty gritty. You could help us prevent
11 something. And that's from both parties, that is the
12 regulator and the end user.

13 MR. BOLLOCK: So the different levels,
14 first the reporting, the reports that come in, they are
15 publicly available on our website. So, I mean, that's
16 a good and bad thing. But that's one level to get, one
17 step to get that an event happened.

18 And so that information is available for
19 other licensees, and regulators, and whomever to see
20 that and say, okay, well, this happened and hope, you
21 know, someone with a good, whatever you call it, quality
22 assurance program, what have you, would look at that and
23 say how can we make sure that this doesn't happen to us.

24 When we see -- one of the other things that
25 we do is we evaluate. Because we get all the event

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1 reports that come in. We evaluate for a trend. If we
2 see a trend or a number of issues or issues that are
3 significant, like, that we feel are very safety
4 significant, there could be a high impact, we have
5 generic communications. It's one of our avenues.

6 So we would take the information that we
7 learned from an event or a series of events and share
8 that in a generic communication. There's different
9 levels of generic communications.

10 The first one is an information notice.
11 And that simply is just here's the information we have
12 from what has happened, and here is what you can learn
13 from it. And it's just a, you know, it's just
14 information. There's nothing that is a requirement on
15 any licensee.

16 The next level is a regulatory information
17 summary which typically doesn't, again, no requirements
18 on licensees, but it may be a little bit more in-depth.

19 And then there are other levels if we see
20 something that requires some sort of order or action.
21 There are higher levels. I've not seen any of those on
22 the material side at all. But we do have, that's kind
23 of the escalation for getting the information out and
24 what we'd expect from it.

25 CHAIRMAN ALDERSON: Dr. Langhorst?

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1 MEMBER LANGHORST: To answer your
2 question, Dr. --

3 MR. OUHIB: Zoubir.

4 MEMBER LANGHORST: Zoubir. One, you can
5 learn something from one event, because it may be very
6 valuable for your license. So I would say, you know,
7 if you could just give it for all of them, and you have
8 that consistent information, and full and accurate
9 information, that would be great.

10 Mr. Bollock, I just want to say that a safety
11 culture is not a thing that you write down and then you
12 say, okay, now we're all going to follow it. It doesn't
13 happen that way. And I know you appreciate that. It
14 is a living, breathing thing. And it's based a lot on
15 trust.

16 And so trust you have to build. And it can
17 go like that. And when there's a mistake, you have to
18 work hard on the trust that, yes, I can bring this
19 forward. And everybody agrees, yes, boy, we're really
20 sorry this happened. What can we do for this instance,
21 what can we learn, and how do we apply it every place
22 else so that we can get that valuable lesson?

23 I know licensees do that right now with the
24 information that NRC puts out. I'm not aware of any
25 Agreement States being able to put out like information.

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1 But that's helpful for my users to say, hey, this
2 happened over here. You might look at it and see what
3 we can learn from it.

4 I just would like the NRC to be open, and
5 I know Agreement States too -- when I say NRC, I mean
6 everybody, sorry, Frank -- that we continually talk
7 about this. And because medical use is different, it
8 may require a little different perspective on that give
9 and take between the regulated folks and the regulators.

10 So it's an area that I think we want to
11 explore. I think it will be very helpful to all of our
12 patients. And I just cheerlead and encourage everyone
13 to be involved in it. Thank you.

14 CHAIRMAN ALDERSON: Yes. Ms. Weil?

15 MEMBER WEIL: I totally agree with what Dr.
16 Langhorst is talking about. And it devolves down to,
17 you know, the inspector, the person who interacts with
18 the licensee.

19 And something that NRC and States could do
20 is to train those folks to enforce that those folks
21 promote this kind of a culture which is not blame, which
22 is not punitive, hopefully, which is not negative in any
23 way but rather that there's a positive spin. We're here
24 to help you, we're here to help others. And I'm sure
25 that that's not how many inspectors approach their jobs.

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1 MR. BOLLOCK: And that is a very good point.
2 And we do, like I said, you know, we do promote, as an
3 agency, that performance base. So, you know, we are
4 supposed to give credit for licensees that identify the
5 issue and correct it. And, you know, that's how we're,
6 I mean, that is the push for the NRC.

7 But you're right, it gets down to the
8 individual inspectors, whether they're an NRC regional
9 inspector or they're a State inspector. And then along
10 with that though is when we do see a non-compliance with
11 a regulation, you know, we have an obligation to identify
12 it. But then what do you do with it?

13 MR. BOLLOCK: Right. Right. And there
14 are, and now it gets to levels of enforcement, and
15 follow-up action. And this is something that, you know,
16 can be evolving. You know, it's evolved on the other
17 side of the, on the reactor side of the house. It's
18 evolved.

19 We went from completely compliance-based to
20 the performance-based. They have -- the reactor
21 oversight process has changed from purely traditional
22 enforcement to where you look at significance. And
23 they've got, you know, for violations, they have
24 non-cited violations.

25 It's basically you get a finding, they

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1 correct it, and that's it. It's in a report, it's
2 publicly available, but there's no civil penalty, you
3 know, at that point no potential civil penalty. It's
4 just a very cut and dry, here's your violation, here it
5 explains it. They have to take action to correct it,
6 and we're done. And, you know, like I said, that's
7 really the way the agency as whole is moving towards.

8 And we do, we do train our inspectors. We
9 do, you know, try to promote that for everyone. So, you
10 know, we'll continue to do that, and hopefully that will
11 help. But there is still, you know, at the end of the
12 day, if there is a non-compliance we will take some
13 action.

14 You know, whether it's just a report that
15 has a, you know, a severe Level 4 finding, you know, with
16 no civil penalties, but it's still in a report. It's
17 still publicly available. And that, in itself, could
18 have consequences in the medical community, you know.

19 But we understand that we have to work. And
20 this is why, you know, evaluate changing medical events
21 and what it takes and, you know, the aspect from the
22 medical community, we appreciate that you all bring that
23 to us.

24 CHAIRMAN ALDERSON: There's enough
25 interest around the table that I think that we should

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1 form a subcommittee on this particular issue and follow
2 it. And I don't think that, although I see other hands
3 up now, I mean, we could discuss this the rest of the
4 morning, but I think we shouldn't do that.

5 We should, in fact, have a subcommittee. And
6 then we should make it our business during the off times
7 to get together and move this issue forward. I think
8 that, Frank, you should definitely be on that committee
9 because of the State's issue. Vasken, you were
10 interested in the medical/legal side. Mr. Ouhib, would
11 you like to join that committee? I'd like at least a
12 couple of other people. Who else would, would you like
13 to be on that, Sue? Okay.

14 MEMBER LANGHORST: Can we also, because
15 this is not our issue, it's our issue. So I would like
16 a few NRC staff to be helping us.

17 CHAIRMAN ALDERSON: I think that's a great
18 idea. And --

19 (Simultaneous speaking.)

20 MEMBER LANGHORST: And I wouldn't mind
21 having maybe a person from the Office of Inspector
22 General be on that to --

23 CHAIRMAN ALDERSON: Well, we should check
24 on that. But I think the idea --

25 MEMBER LANGHORST: No.

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1 CHAIRMAN ALDERSON: I think the idea of
2 having staff engaged in this process is a very good one.
3 So, Sue, why don't you be on this subcommittee. In fact,
4 why don't you chair it? Would you like to do that?

5 MEMBER LANGHORST: I would be so honored.

6 (Laughter.)

7 CHAIRMAN ALDERSON: Wonderful. So we
8 probably need one more person on this subcommittee. Who
9 else has a passion?

10 CHAIRMAN ALDERSON: All right. So I have
11 five right now. I have you as the chair, I have Frank,
12 Vasken, Dr. Ouhib and Laura. Is that -- Dr. Ennis?

13 MEMBER ENNIS: It has to be six, right?

14 MEMBER LANGHORST: Yes.

15 MEMBER ENNIS: I'll be glad to --

16 CHAIRMAN ALDERSON: Doctor -- yes,
17 absolutely. So Ron Ennis, so you have six. That's the
18 committee.

19 MR. BOLLOCK: I think we have one too many.
20 Yes, we can only have five. Just because --

21 CHAIRMAN ALDERSON: Only have five?

22 MR. BOLLOCK: Right.

23 MEMBER ENNIS: I thought we could have six.
24 It's less than half.

25 CHAIRMAN ALDERSON: That's because of the

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1 --

2 (Simultaneous speaking.)

3 MR. BOLLOCK: Yes, we --

4 CHAIRMAN ALDERSON: That's because Mr.
5 Ouhib isn't a member yet.

6 MR. BOLLOCK: Yes, because Mr. Ouhib is not
7 a member yet.

8 CHAIRMAN ALDERSON: So we'll keep him off.
9 And when he becomes a member, he'll get on this
10 subcommittee immediately. How about that?

11 MS. HOLIDAY: Dr. Alderson, this is Sophie.
12 While Mr. Ouhib is not a full member yet, meaning he
13 doesn't have voting privileges, he can still serve as,
14 like, a consultant, like he did to Dr. Suh's
15 subcommittee.

16 CHAIRMAN ALDERSON: All right. So we'll
17 have Mr. Ouhib serve as that consultant now. And then
18 we'll have the other five people that we've named
19 comprise the committee. And it is true that I think
20 we're going to need a lot of interaction with NRC staff
21 when this committee goes forward. So we'll work with
22 Sophie to figure out how we should get that done, if
23 that's acceptable to you, Mr. Bollock.

24 MR. BOLLOCK: We'll support. But I just
25 want to make sure we understand so I know how best to

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1 support what specifically this subcommittee is going to
2 be.

3 CHAIRMAN ALDERSON: Well, the charge that
4 you all have been talking about is this culture of safety
5 and how to get there. And so we'll rely on Dr. Langhorst
6 to look at the whole issue of medical events.

7 We've spent a number of times here
8 discussing medical events, not just the culture but the
9 idea of clarity definition in addition to culture. So
10 I think one of the ways that the subcommittee can get
11 really engaged with this it so somewhat define that
12 agenda in that scope of things.

13 MEMBER LANGHORST: Yes. This is Sue
14 Langhorst. I think Dr. Suh's group is looking at
15 medical event definition, and understanding, and so on.
16 Maybe we could focus on the application of reporting and
17 that aspect of -- let me think of the exact wording and
18 get that to Sophie. And can we --

19 CHAIRMAN ALDERSON: Right. It's
20 application, implementation that's --

21 MEMBER LANGHORST: Implementation and how
22 to foster that safety culture in reporting medical
23 events, and investigating, and then not only, I guess,
24 notification of medical events and then reporting on
25 medical events.

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1 CHAIRMAN ALDERSON: So I think that's
2 actually a very good approach. One could take a very
3 superficial kind of theoretical approach and probably
4 finish that report in the next 20 minutes.

5 But the fact of the matter is that if you
6 really go into the issue to try to solve a problem that
7 has seemed resistant to solution, it then is going to
8 take a much more sophisticated and deep effort to figure
9 out how people like Burwick, for example, changed the
10 whole safety culture in medicine from a punitive one to
11 more like it is today.

12 And so that's going to be a much more
13 difficult problem. And so with Dr. Langhorst leading
14 the team and this great team we've got, I'm sure we'll
15 get there.

16 MEMBER COSTELLO: One more question.

17 CHAIRMAN ALDERSON: One more question, and
18 then we'll move to a new subject.

19 MEMBER COSTELLO: I think I pushed it down.
20 Mr. Bollock, do you think that we have a chance of making
21 the public reports of these medical events anonymous
22 with respect to the hospitals?

23 I think maybe it's something you need to
24 talk to your legal people about. But I think that could
25 be a colossal step forward. And I know I hear from my

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1 licensees. They don't mind reporting to us really at
2 all. They don't want to see it on the cover of the
3 Philadelphia Inquirer, okay.

4 Because really, we've got reporters who
5 look at the NRC's webpage reports every single day, every
6 single day, okay. And so if I have a thing saying
7 whatever hospital has had a medical event, it could show
8 up on the next day's newspaper. So if that has a chance
9 of being approved, I think it would be a big step forward.

10 MR. BOLLOCK: I mean, I can't answer that
11 here. I think there's a possibility just knowing that
12 some of the States have restrictions on that. I believe
13 New York is one of them that they are, by statute, they're
14 not allowed to give specifics. So do I think it's
15 possible? Yes.

16 CHAIRMAN ALDERSON: Well, this is one of
17 many aspects this Committee --

18 MR. BOLLOCK: Correct.

19 CHAIRMAN ALDERSON: -- should look at. So
20 we'll proceed with that. Let's move on to a new topic.

21 MEMBER LANGHORST: As I always tell my
22 researchers, if it was easy it would have already been
23 done.

24 CHAIRMAN ALDERSON: That's correct, that's
25 exactly right. Okay. Next topic, wherever we are, Mr.

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1 Bollock. Go ahead.

2 (Laughter.)

3 MR. BOLLOCK: Next up is Sophie Holiday and
4 Eric Perry from the state of Kentucky.

5 MS. HOLIDAY: Okay. Good morning. For
6 those of you who aren't aware, my name is Sophie Holiday,
7 and I work with the medical radiation safety team.

8 MR. PERRY: And my name is Eric Perry. I
9 work for the Kentucky Department of Public Health as a
10 license reviewer and materials inspector for the
11 Agreement State Program.

12 MS. HOLIDAY: Okay. So today, thank you,
13 we're here to speak to you about the Leksell Gamma Knife
14 Icon, 10 CFR 35.1000 licensing guidance.

15 Specifically we'll touch on our working
16 group which is comprised of members from both NRC and
17 the Agreement States, give you an overview of the Icon
18 features and an overview of our licensing guidance.

19 So to start this off, I'd like to give you
20 a little bit of background. Several months ago the NRC
21 and the Organization of Agreement States Board, or the
22 OAS Board, became aware of several Agreement States who
23 had licensees that notified them that they intended to
24 purchase and install Elekta's newest gamma knife model,
25 the Icon.

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1 In addition, NRC sealed source and device
2 team informed the medical team that they were close to
3 issuing the SS&D certificate for this particular device.

4 However, I will note that Elekta had not
5 reached out to the medical team directly. So we had to
6 find out through other avenues. But the Icon was
7 already being marketed to potential licensees at the
8 point by which we found out. So this prompted the very
9 swift formation of an NRC/OAS working group to try to
10 meet the needs of the patient community.

11 So our working group was formed to complete
12 three objectives. First, to review and evaluate the
13 Icon sealed source and device certificate and any
14 relevant documentation including an owner's manual.
15 Two, determine if the Leksell Gamma Knife Perfexion Unit
16 and the Icon Unit were similar enough that they could
17 be addressed in a single 35.1000 licensing guidance
18 document. And three, if so, develop the licensing
19 guidance document accordingly, whether that be as
20 separate documents or a single document.

21 So for our working group, there were four
22 members, Eric and myself are the co-chairs. Eric is
23 from the State of Kentucky. And I'm here from NRC
24 headquarters. Our other members were Michelle Simmons
25 from NRC's Region IV and Ms. Debora Vail from the State

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1 of California.

2 We had our kickoff meeting on December 22nd
3 of 2015. We were joined by a few of the members in the
4 audience, representatives from Elekta, where they gave
5 us a presentation on the overview of the Icon as well
6 as recommendations.

7 Our working group worked very, very
8 expeditiously at a very aggressive pace. We spent about
9 three and a half weeks developing our guidance. We met
10 multiple times in a week in order to try to get guidance
11 out as soon as possible. And we completed our guidance
12 on January 22nd, 2016.

13 MR. PERRY: Thank you, Sophie. So the Icon
14 offers a number of different features over the Perfexion
15 unit. However, the source assembly and the overall
16 method of delivering the radiation dose is very similar
17 to the Perfexion; however they've added a couple of
18 features to facilitate treatment of the patients without
19 using a stereotype frame.

20 And that includes this cone beam computed
21 tomography scanner and this intrafraction motion
22 management, or what Elekta is now calling their high
23 definition motion management. And that allows the
24 system to work without the frame being rigidly attached,
25 without a frame at all and with no rigid attachment to

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1 the patient.

2 So as you can see here on the left, we've
3 got a picture of the stereotactic frames that were used,
4 have to be used with the Perfexion and can be used with
5 the Icon. And the other picture shows them setting up
6 for a frameless therapy where they use a plastic mask,
7 a thermoplastic mask, and the mask adapter to immobilize
8 the patient and also monitoring for movement.

9 Right here you see a more close-up view of
10 that. And this was borrowed from Elekta's
11 presentation.

12 So the patient lays on the couch. They have
13 a marker on their nose and two fixed markers on the
14 patient couch, and an infrared camera that monitors the
15 relative position of those three markers and can monitor
16 that within about, you know, a point, I believe they said
17 0.3 millimeters of movement causes a pause in the
18 deliverance of the dose. And so the patient is
19 repositioned to the proper location, and then the dose,
20 the treatment can continue.

21 And this kind of shows that. I know that's
22 hard to see, but what that shows is kind of what the user
23 gets from the system, from the monitoring system.

24 So the picture on the right, you can see the
25 red line on the little screen. When the relative motion

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1 exceeds that threshold, that's when therapy is paused,
2 until they basically reset and movement stops. And they
3 can resume the therapy. And it monitors continuously.
4 And it's kind of interesting.

5 One thing I didn't talk about, and I meant
6 to earlier, what goes along with this is the cone beam
7 CT scanner so that they can image the patient just prior
8 to therapy and do a proper transformation of the
9 treatment volume, from a patient-specific coordinate
10 system to the Leksell coordinate system, so that the
11 patient is properly positioned relative to the focal
12 point of the unit.

13 And so there's not necessarily -- you don't
14 have to do the imaging, the MR imaging with the fiducial
15 box and things of that nature prior to treatment. It
16 simplifies the process, also allows for a fractionated
17 delivery of the dose which is a pretty big step in gamma
18 radiosurgery.

19 Because now if you have areas that may be
20 close to areas that you don't want to give an excessive
21 radiation dose to, you can break that therapy up into
22 multiple fractions and thereby reduce the dose to
23 surrounding tissue.

24 MS. HOLIDAY: Okay. So moving on to an
25 overview of the licensing guidance. I would like to start

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1 by saying members on the Committee were provided with
2 the licensing guidance when the working group completed
3 its work in January of this year.

4 So what the working group decided to do was
5 to create a single licensing guidance document that
6 merged both the licensing commitments for the Perfexion
7 unit and the Icon unit. And as such, the working group
8 attempted to marry the guidance such that all the
9 requirements for the Perfexion unit are applicable to
10 the Icon unit.

11 This does not mean that licensees who have
12 a Perfexion unit but are not upgrading to the Icon unit,
13 meaning that they are just retaining their Perfexion
14 unit as is, they do not have to do anything to amend their
15 license.

16 But if they are licensees who do want to
17 upgrade their unit to the Icon unit, meaning they get
18 the cone beam CT, and the IFMM or the HDMM system, and
19 the thermoplastic frameless mask, then there would be
20 additional requirements for the Icon unit. But as Eric
21 stated, the Icon unit can use both the stereotactic frame
22 and the frameless mask option.

23 Our guidance also incorporates, as you
24 heard from Katie's presentation yesterday, general
25 formatting and language that is included in all 35.1000

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1 licensing guidance documents that were issued after
2 2013.

3 So what is the current status of our 35.1000
4 guidance? As I stated, we provided the guidance to the
5 ACMUI. And I would like to note that typically NRC gives
6 the ACMUI 60-days to review and comment on our license
7 guidance document.

8 However, I had a conversation with both the
9 ACMUI chair and vice-chair in December to discuss the
10 guidance. And since, basically, there are no
11 significant technical departures, meaning the Icon
12 essentially has the Perfexion core, meaning none of the
13 radiation sources are changing, we just have these
14 additional components, the cone beam CT, the IFMM system
15 and the thermoplastic mask, they agreed that it was okay
16 to forego the standard 60-day review period.

17 So thank you to the ACMUI for accommodating
18 this. So we were able to get the guidance out to the
19 Agreement States and the regions ahead of time so that
20 we would be able to, again, meet the needs of the patient
21 community.

22 We did receive some comments from an ACMUI
23 member, so we do appreciate those comments. And the
24 working group is also resolving your comments, Dr.
25 Langhorst.

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1 So in February, just last month, on February
2 22nd, we provided the guidance to the NRC regions for
3 a 30-day review comment period. We also sent the
4 guidance to the Agreement States on February 25th, just
5 a few days later, for their review and comments.

6 Currently, we have received maybe three or
7 four sets of comments. And we've already begun to
8 review and respond to those comments.

9 Once the working group resolves all of the
10 comments, in approximately three to four weeks, the
11 guidance will have to move through the general
12 concurrence scheme, meaning through management and
13 legal counsel review.

14 With that, we expect the guidance to be
15 issued in early summer of 2016. I would also like to
16 note, as I said earlier, we pursued a very aggressive
17 schedule with developing this license guidance
18 document.

19 Typically, working groups that are
20 assembled to address 35.1000 guidance documents take
21 between six to nine months alone to develop the guidance.
22 Then when you factor in the ACMUI's review, review from
23 the States and NRC staff, it can tack on an extra three
24 to four months. So I will pat ourselves on the back.
25 We were able to get this out in just a fraction of that

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1 time.

2 So at this time we would like to open it for
3 any questions.

4 CHAIRMAN ALDERSON: Excellent report,
5 administrative efficiency, congratulations on that.
6 Are there comments from, yes?

7 VICE CHAIRMAN ZANZONICO: I just have a
8 general question first. How common is an NRC/OAS
9 working group in drafting guidance? My perception is
10 that typically it's an NRC only working group. Is that
11 not the case?

12 MS. HOLIDAY: No. Actually, in the past
13 maybe four years, every emerging technology has been
14 evaluated by joint NRC/OAS working groups.

15 VICE CHAIRMAN ZANZONICO: And then a
16 technical question. So there's an onboard cone beam CT.
17 Is that what is used for the simulation? I mean, I'm
18 ignorant about the technology. So I don't know if they
19 do the equivalent of a simulation for this or not.

20 MR. PERRY: What they do with the cone beam
21 CT scanner is that allows them to ensure the patient is
22 positioned properly and can be put in a position relative
23 to the focal point. And the focal point lies at the
24 coordinates of 100, 100, and 100 in the Leksell
25 coordinate system, which is relative to the machine.

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1 That allows them to position the patient so that that
2 focal point is properly positioned relative to the
3 treatment volume.

4 I believe in the past, and I'm sure Dr. Suh
5 is much more familiar with this than I'll ever be, but
6 they would attach the frame to the patient's head, make
7 use of a fiducial box and an MR scanner to properly do
8 that transformation. This allows them to do that
9 transformation essentially at the machine just prior to
10 therapy.

11 VICE CHAIRMAN ZANZONICO: So how would the
12 -- but this isn't used to define the target volume,
13 right?

14 MR. PERRY: No.

15 VICE CHAIRMAN ZANZONICO: No, that's done
16 by more conventional simulation?

17 CHAIRMAN ALDERSON: Dr. Suh?

18 MEMBER SUH: So in terms of the essential
19 difference between the Icon and Perfexion is you now have
20 onboard imaging. So from a clinician standpoint,
21 you're going to have greater confidence. And what you
22 see on the computer screen is what you're actually going
23 to treat.

24 So it actually takes into account what the
25 traditional generation oncology -- what they learned

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1 excel our base system. For many years now, we've
2 actually had cone beam guidance where, before we treat,
3 we image the patient, then we go ahead and treat the
4 patient.

5 With gamma knife, we've always gone under
6 the assumption that, with the frame in place, that the
7 image that you obtained, say MR/CT scan and then you do
8 computerized planning, when you put the patient into the
9 machine, you assume that that positioning was -- you have
10 the same fidelity between what you did before versus
11 after computerized planning. This actually will allow
12 you to do it much more in real time, right before you
13 do the treatment.

14 The other big advantage of the Icon system
15 is that you will be able to better adapt the plan. So
16 if you do some type of fractionated treatment and you
17 see shrinkage of the tumor, and you wanted to treat the
18 patient a couple of weeks later or a month later, you
19 can actually sculpt a radiation dose better than you can
20 with the Perfexion system.

21 So it does have some advantages that should
22 allow for better outcomes overall. I imagine you'd have
23 more data for that, but that's what it will allow us to
24 do.

25 VICE CHAIRMAN ZANZONICO: And all that can

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1 be done based on the cone beam CT?

2 MEMBER SUH: So in terms of, again, we don't
3 have an Icon yet, but in terms of work flow we've still
4 got the MR scanner as kind of our image of choice. And
5 then we can use the cone beam to actually help adapt the
6 plan.

7 CHAIRMAN ALDERSON: Dr. Ennis?

8 MEMBER ENNIS: I think, just to answer your
9 question, you're still going to do a pre-CT scan, MR
10 fusion for the plan. And then the cone beam allows you
11 to verify that with your plans you've got the exact same
12 location, head positioning and everything.

13 VICE CHAIRMAN ZANZONICO: Right. That was
14 my question. It seemed otherwise. Because I didn't,
15 again, so all I knew is that the quality of cone beam
16 CT really was adequate for, you know, state of the art
17 treatment planning. But it's not replacing --

18 MEMBER SUH: So the work flow can be a
19 little different. The big change in the work flow is
20 going to be you can get the image values right before
21 treatment. But in terms of the, you know, if you want
22 to use a frame placement, you know, that MR/CT, at this
23 point it would be the same.

24 VICE CHAIRMAN ZANZONICO: So the cone beam
25 is really more for verification in --

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1 MEMBER SUH: Up front. And you can also
2 perhaps use it for planning. So again, that's where
3 studies need to be.

4 VICE CHAIRMAN ZANZONICO: For fraction.

5 MEMBER SUH: For more fractions. Yes.

6 CHAIRMAN ALDERSON: Mr. Ouhib?

7 MR. OUHIB: Yes. This is nothing
8 different than what we have seen using a linear
9 accelerator, basically. We went through that
10 transition basically this same way. So, you know, we
11 went from frame to frameless basically and using cone
12 beam CT for SRS and the SBRT patient, basically.

13 So really the whole purpose, as it was
14 stated previously, is just verification that you are on
15 target basically instead of relying on fiducial markers.
16 And things can happen with fiducial markers as we know.
17 But I think having the image now, the level of confidence
18 is much, much higher.

19 CHAIRMAN ALDERSON: Other questions,
20 comments? Yes, Ms. Weil?

21 MEMBER WEIL: If this is indeed an
22 improvement in technology, would it have prevented the
23 medical events that Dr. Howe reported yesterday where
24 the gamma knife had been serviced and the bed was
25 misaligned? Would this preclude that, those errors?

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1 MR. PERRY: That's very hard to answer
2 because of, I mean, the circumstances around that
3 medical event, I'm not intimately familiar with it, as
4 I'm sure Dr. Howe is.

5 MEMBER WEIL: There were eight of them,
6 yes.

7 MR. PERRY: Well, it was eight patients,
8 one event.

9 MEMBER WEIL: One event.

10 MR. PERRY: So that's kind of hard to
11 answer. And remember that these changes to the design
12 are more about the patient's position on the couch.
13 You're still relying on the couch to properly position
14 the patient relative to the focal point.

15 CHAIRMAN ALDERSON: I'll make a comment
16 too, Laura. And this is strictly from the patient's
17 point of view. And if I'm incorrect about this, please
18 correct me. But it's my understanding that one of the
19 disadvantages of the previous version of the gamma knife
20 is the need to wear this frame.

21 Patients do not like the frame. It hurts.
22 And they will literally go to other technologies, drive
23 a long way to not do it. So the Icon allows frameless.
24 And that is a huge advantage for the patients.

25 MEMBER SUH: If I could just make a comment.

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1 So although for some patients the frame-based system can
2 be uncomfortable and perhaps not be right for some
3 patients, for some situations a frame-based system is
4 going to give you more accuracy than a frameless system.

5 So if I were doing a functional case for
6 someone with a movement disorder, or Parkinson's
7 Disease, or someone who worked between the trigeminal
8 nerve, I would want to make sure that there is very little
9 chance of me moving him between what you do for
10 pre-treatment versus the actual treatment itself.

11 So that's where I think the advantages of
12 having these very small focal beams of radiation being
13 pointed to one area. So I think the frame-based system,
14 although Icon will allow for a frameless type
15 situations, I think there is always going to be a place
16 where you do want to use a frame, just to emphasize that
17 point.

18 MS. HOLIDAY: Absolutely. So to follow
19 that up, as we were informed, the Icon, you are able to
20 use both frameless and frame. So depending on the
21 patient conditions, the physician will make the
22 determination whether or not to pursue the framed with
23 the bolts in your head, which of course I don't think
24 is very comfortable for many people, or the
25 thermoplastic frameless mask.

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1 So you are able to use either/or. And
2 depending on which mode you choose, whether you go with
3 the frame or the frameless, that will reflect in the work
4 treatment planning.

5 CHAIRMAN ALDERSON: Yes, good. Other
6 questions or comments? Hearing none --

7 MS. HOLIDAY: So may I ask a question of the
8 Committee? While we provided the Committee with the
9 draft guidance and the subcommittee was not formed, can
10 the Committee give us any feedback, although not going
11 into the particulars of the guidance since it is
12 pre-decisional and non-public?

13 Would the Committee endorse the guidance
14 knowing that we will be addressing comments that I've
15 received, that we've received from Dr. Langhorst?
16 Would the committee consider doing that?

17 CHAIRMAN ALDERSON: So that question is
18 before the Committee. Dr. Langhorst?

19 MEMBER LANGHORST: I would feel
20 uncomfortable in endorsing it just because we didn't do
21 a formal subcommittee review in presentation. Not that
22 I am not personally endorsing it, I have questions on
23 it.

24 I'd still like to see what the final version
25 comes to. Because I was a little nervous in what it was,

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1 what the expectations were of Perfexion unit licensees
2 who weren't necessarily changing to the Icon system.

3 MS. HOLIDAY: Okay.

4 MEMBER LANGHORST: So I would feel
5 uncomfortable.

6 CHAIRMAN ALDERSON: All right. So that's
7 one opinion. Mr. Ouhib?

8 MR. OUHIB: Yes. I think a review of the
9 final draft will be very useful, by a subcommittee
10 perhaps, and make any comments or what not.

11 CHAIRMAN ALDERSON: I'm going to suggest
12 that we not form a subcommittee, but rather that those
13 interested parties with that expertise who are members
14 of the ACMUI be provided with copies so that they can
15 review that. And then we can determine in the future
16 whether, at that point, they might be willing to endorse.
17 Yes?

18 MEMBER LANGHORST: Yes. I would suggest
19 that we don't hold up this, because again, they're
20 licensing guidance, we can make changes and --

21 MS. HOLIDAY: Absolutely.

22 MEMBER LANGHORST: -- suggest at any point
23 in time, as nebulous as that seems. So I wouldn't want
24 to hold up in having a full, formal review of that. So
25 that would be my suggestion.

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1 CHAIRMAN ALDERSON: All right. So I think
2 that's consistent with what I just suggested. So the
3 people who would, I'm sure, like to have this would be
4 Dr. Langhorst and Mr. Ouhib. Does anyone else like to
5 get a copy of the full guidance?

6 MEMBER O'HARA: I would.

7 CHAIRMAN ALDERSON: Dr. O'Hara would like
8 to get that.

9 MS. HOLIDAY: Absolutely. We will just
10 send it to the full Committee. And any members that wish
11 to provide comments can do so.

12 CHAIRMAN ALDERSON: Very good. Okay.
13 One final comment?

14 MEMBER ENNIS: Just a question, so I
15 understand the process. Without this final document
16 provided to NRC, are licensees able to actually use it?
17 Or they can't even start using it until the NRC has
18 provided the Agreement States with that information?

19 MR. PERRY: From the Agreement State
20 standpoint, and I'll speak for my Agreement State, we
21 would be very hesitant to amend a license or to issue
22 a license for this unit without such guidance from the
23 Commission. I know that that's not true of every
24 Agreement State. And I believe that the NRC regions are
25 not going to issue amendments prior to the guidance.

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1 And that comes from their management.

2 MS. HOLIDAY: So I know we all don't
3 understand compatibility, but 35.1000 is a
4 Compatibility D which basically means the Agreement
5 States do not have to adhere to our guidance document.
6 So we are aware of a couple of Agreement States that have
7 already begun the amendment process to add the Icon to
8 their licenses.

9 CHAIRMAN ALDERSON: So given that
10 limitation on what has, up to this point, been a very
11 efficient process, I would like to ask Dr. Langhorst and
12 Mr. Ouhib that when you are provided with the guidance,
13 I would like you to promptly respond indicating your
14 support or your lack of that.

15 And because if support there, then in fact
16 the guidance can be issued and the patients can receive
17 the benefits of this technology.

18 MS. HOLIDAY: Absolutely.

19 CHAIRMAN ALDERSON: Yes?

20 MR. OUHIB: I have a follow-up question
21 based on Dr. Ennis. What about the institution that
22 actually is going to be using the frame? So there's
23 really nothing that has changed, per se. They're not
24 going to frameless. They're going to be using the
25 frame.

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1 MS. HOLIDAY: Are you referring to if
2 they're not adding on the additional components of that,
3 kind of --

4 MR. OUHIB: And the additional components
5 --

6 MS. HOLIDAY: Just remaining as the
7 Perfexion?

8 MR. OUHIB: -- Icon and simply using the
9 frame just like they will be using it in Perfexion, so
10 there's really, other than the additional imaging
11 component that's there, that's all.

12 MS. HOLIDAY: So this is actually a
13 question that the working group had addressed early on,
14 because it was a question that was brought up by the
15 representatives in the back of the room.

16 And the working group did not feel
17 comfortable with the notion of adding an Icon to
18 someone's license and saying, you know, we know you're
19 not going to use the frameless option, but you can
20 install it anyway.

21 It kind of almost defeats the purpose of why
22 the licensee would add the Icon. Because the whole, I
23 guess, the beauty of getting an Icon is to be able to
24 use either/or, frame or frameless. So it's kind of
25 tricky.

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1 There was a question, maybe if we held off
2 on giving the licensee the thermoplastic mask, would
3 that then be okay? But also from a license reviewer
4 standpoint, it was too much of a burden to have to amend
5 the license to add the Icon, to not use the thermoplastic
6 mask, and then amend it again to be able to use it in
7 its full functionality.

8 CHAIRMAN ALDERSON: Okay. So we are going
9 to get the guidance distributed to the pertinent members
10 of the Committee who will respond promptly. And are
11 there any other comments before we close this topic?
12 One final comment? I'm trying.

13 MEMBER ENNIS: I apologize for dominating
14 the conversation. But is the manufacturer aware as soon
15 as there are -- so I'm not quite understanding, but if
16 the manufacturer's aware that users will not be able to
17 use this without guidance being issued by the NRC, I
18 guess it's a rhetorical question, but how is it that they
19 weren't running to your office very early on to get that
20 done so that things weren't delayed in the whole process?

21 MS. HOLIDAY: I can't speak for the
22 manufacturer. Perhaps the manufacturer would like to
23 speak for themselves. But I can't, you know, tell
24 anyone to do that. So I'm sorry. I can't speak for
25 them.

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1 CHAIRMAN ALDERSON: So hearing no other
2 comments, and unless the manufacturer wishes to speak,
3 they don't appear to be coming forward, so we'll move
4 on to the next topic. Thank you very much.

5 MS. HOLIDAY: Thank you.

6 MR. PERRY: Thank you.

7 CHAIRMAN ALDERSON: All right. Ms.
8 Daibes, oh, Mr. Daibes. Dr. Daibes is going to talk to
9 us about the Germanium/Gallium generator.

10 DR. DAIBES: Thank you. First of all,
11 thank you for your time today. My name is Said Daibes.
12 And I will be providing you an update on what's happening
13 with respect to the Germanium/Gallium-68 medical
14 generator.

15 And just to provide a fast overview, I'm
16 going to be providing some very brief background. I
17 believe that a lot of that information was provided
18 during the ACMUI briefing of the Commission. And I will
19 provide you a current status and the regulatory options
20 that are pursuant.

21 So I think that one of the key aspects behind
22 the generator that we're currently evaluating and
23 working on is that it has been used in Europe now for
24 a while. So there's quite a bit of data that supports
25 its use.

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1 And right now one of the biggest impacts is
2 that there's a whole lot of data that outlines its use
3 for new and recurring patients. So there's data and
4 peer-reviewed data that supports that.

5 Right now, the FDA, as we heard yesterday,
6 is currently reviewing an application. And it was
7 provided to the Commission yesterday. So one of the
8 biggest components of this generator is that it's needed
9 in order to create the actual Gallium-68 regulated
10 pharmaceutical that will be used on patients. So a
11 facility that is planning on using this regulated
12 pharmaceutical will need some form of generator close
13 by or access to it.

14 So what's the current status? What we have
15 seen today is that, as you're very aware of, that a DFP
16 will be needed. What is a DFP? A decommissioning
17 funding plan.

18 And why is a DFP needed? Well, basically
19 the parent isotope, Germanium, is a very long-lived
20 isotope, 270-days half-life. Being a long-lived
21 isotope and being an unsealed radioactive material,
22 triggers a DFP requirement due to the fact that, in Part
23 30 regs, Appendix B, there's no defined value for
24 Germanium-68. So automatically a 10 millicurie limit
25 is triggered or defaulted to, in that case triggering

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1 that DFP requirement.

2 Some people have raised concerns with
3 respect to this DFP, and I believe everybody is aware
4 in the committee, is aware of this. So I'm not going
5 to go into details.

6 So what are we doing right now is that, well,
7 we saw the issue, and we're pursuing multiple regulatory
8 options that are currently available in our regulatory
9 framework.

10 The first option that we have been
11 undergoing and tasked with is a license-specific
12 exception. And what is that? What is behind this?
13 Well, it will be an exempting, it will be a specific
14 option to accept the DFP requirement for a person that
15 would like to apply for this.

16 So staff believes that the most efficient
17 and effective way to provide this regulatory relief will
18 be pursuant to this potential exemption.

19 And how will that be pursued? We're
20 granting or we're working right now in the potential of
21 granting an authority to the regions if a legally binding
22 contract exists that will allow a licensee or a client,
23 a person that requests this generator, to send it back
24 to the distributor or the vendor that provided that
25 generator to that person or licensee.

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1 A document has been drafted and is currently
2 being reviewed by management. So from the last ACMUI
3 meeting, we provided you information that has changed.
4 We informed you that we were pursuing that, but we have
5 completed that. And it's currently under review.

6 The secondary option that supports that
7 specific exemption under 35.19 is a potential direct
8 final rule that we're currently pursuing a rulemaking
9 plan on. And it's under evaluation by OGC right now.
10 So what has changed since our last ACMUI meeting is that
11 that rulemaking plan has been drafted, and right now
12 we're under evaluation right now.

13 So the effort behind this direct final rule
14 will be that it will potentially amend Appendix B of 10
15 CFR 35.35 to include that limit that does not exist for
16 Germanium-68, disallowing -- or the new license,
17 allowing that a licensee that accesses this generator
18 would not trigger DFP requirement.

19 So we believe today that the planned action
20 will be sufficient to ensure public health and safety
21 until a more permanent regulatory solution is achieved
22 through rulemaking. And that's currently under the
23 process.

24 So any questions that -- and I'm sorry,
25 before we proceed, first of all I want to appreciate the

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1 service of ACMUI to this effort. All of your guidance
2 and information has been extremely helpful in making
3 sure we can proceed with this, especially Mr.
4 Mattmuller. Thank you for your guidance and help with
5 this.

6 CHAIRMAN ALDERSON: So Mr. Mattmuller
7 clearly has been our leader in this regard. So we'd like
8 to hear from him today.

9 MEMBER MATTMULLER: Yes, very encouraged
10 by this development and very thrilled to see this
11 happening. A couple of comments/questions for you.
12 Can you explain to us the mechanics of how this exemption
13 would work through the different regions?

14 DR. DAIBES: So that's a good question. So
15 an analysis has been implemented or initiated, seemed
16 to me, of a DFP for this specific case. So through this
17 review or analysis, everything was broken down into
18 components, details, to see if there's buried behind our
19 need for this DFP for this case.

20 And that review or potential document,
21 legal document, has been drafted that breaks everything
22 into that very in-detail analysis. And what that allows
23 the regions, if approved, it allows the regions to
24 potentially exempt or exempt when a person files an
25 application or files for access for this generator for

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1 the actual requirement of the DFP.

2 So it will allow flexibility to the region,
3 at their discretion, if the licensee satisfies their
4 requirement, to exempt that licensee from that
5 requirement. And our branch chief would like to say
6 something.

7 MR. BOLLOCK: Yes. To add to that, so
8 basically when we get, you know, with the approved
9 guidance to the regions, their license reviewers would
10 then, following that, be able to allow a licensee to come
11 to them with an exemption with the specifics that we
12 talked about yesterday. The specifics being, you know,
13 there are still limits to, even based on the ACMUI report
14 recommendations, limits to how many generators,
15 basically the amount of activity allowed and then also
16 having that assurance that the generators, once they're
17 expired or once they've been used, will go back to the
18 manufacturer.

19 And our Chairman of the NRC, you know, hit
20 it right on the head. The lynch pin is that legal
21 requirement, and how is that going to be withheld and
22 how can the license reviewers ensure that that's in a
23 license amendment?

24 So, you know, the licensees would have to
25 come requesting the exemption and prove that they have

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1 those specific things in their exemption showing that
2 they meet those requirements.

3 So, you know, that is important. A
4 licensee can't just come to us and say, well, exempt us
5 from a DFP. They have to meet the specifics on what
6 we're allowing.

7 DR. DAIBES: If I may, so basically it will
8 provide specific conditions for a license reviewer to
9 be able to amend or basically to allow access for that
10 licensee.

11 And it's real important to clarify that even
12 though this may exempt the DFP, it will not exempt a
13 licensee from financial assurance that is required. So
14 the initiative is not to exempt financial assurance but
15 the DFP component that is in the ranks.

16 CHAIRMAN ALDERSON: Dr. Langhorst and Mr.
17 Mattmuller, together.

18 MEMBER LANGHORST: Essentially what you're
19 saying is there would be a license condition for that
20 licensee's --

21 DR. DAIBES: That's correct.

22 MEMBER LANGHORST: -- license that says
23 you're exempt from this and whatever the stock language
24 would be if they meet all those requirements. So they
25 would have a specific condition in their license for this

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1 exemption.

2 DR. DAIBES: Yes, ma'am.

3 CHAIRMAN ALDERSON: Mr. Mattmuller?

4 MEMBER MATTMULLER: A comment, another
5 question. In thinking about the Commissioner's
6 comments yesterday, with further thought on it, it's
7 really from a licensee's perspective.

8 We're the one that's going to require that
9 they take it back. Because the alternative would be
10 I've got stores to take care of it, which is a much
11 bigger, complicated, expensive task than just boxing it
12 up and shipping it back to the manufacturer.

13 So from a practical perspective, it's a
14 minimal issue. Legally it has to be addressed. But
15 there are some big reasons why everyone's going to want
16 to send it back to the manufacturer.

17 My question would be what about, do we have
18 to worry about a compatibility category for the
19 agreement states when it comes to exemptions like this?
20 And then -- yes.

21 DR. DAIBES: I believe not. However,
22 that's something that will be brought to our OGC
23 representative. And that person or OGC will define that
24 when that's complete.

25 CHAIRMAN ALDERSON: Mr. Costello?

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1 DR. DAIBES: We don't believe that's the
2 case.

3 MEMBER COSTELLO: There are present
4 exceptions though. Compatibility really only applies
5 to -- I'm sorry. Compatibility really applies to
6 rulemaking. So if you talk about exemptions, there's
7 no meeting compatibility there.

8 I'm sure there'll be some letter to go out
9 to the Agreement States, all the Agreement States, a
10 letter explaining this. I think that States will not
11 hesitate, really, if the NRC is, you know, recommending
12 that we give exemptions to this. I'm confident that
13 States will follow the NRC's lead here.

14 In fact, I remember, it reminds me of your
15 presentation, you talked about John Jefferson's comment
16 on it. And that came up in the context of them coming
17 to us and asking exemptions for the -- At that time, we
18 would have loved to give it to them, but we couldn't
19 see a way clear to do it, you know. We needed to find
20 a way to be consistent with the other Agreement States
21 and with the NRC.

22 But I would not worry so much about the
23 States following this. I'd be very surprised if there
24 were States that would be not following it. But
25 eventually we're going to do the direct final rulemaking

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1 which I think could --

2 DR. DAIBES: And that's why I said that
3 we'll need to pass this by OGC. Because we have that
4 direct final rule initiative that is still under review.
5 So we're not fully aware --

6 MEMBER COSTELLO: This draft is really only
7 a temporary fix, I think, just so we get this thing going.
8 The direct final rule is really the ideal way of doing
9 it.

10 CHAIRMAN ALDERSON: Dr. Ennis?

11 MEMBER ENNIS: So what's the timeframe to
12 have it, this exemption -- What's the timeframe for
13 this exemption to be completely in place and available
14 for users?

15 DR. DAIBES: I will say months. I will not
16 say a specific timeframe, but I will say in a few months
17 we believe that it shall be out. Again, it's still under
18 review by OGC. So we're hopeful, a few months.

19 MEMBER ENNIS: And second question, for the
20 final rule, are there other isotopes that we should be
21 thinking about adding to the final rule so we don't have
22 this problem again with something else coming down the
23 pike?

24 Or should we include Dr. Langhorst's
25 formula that she discovered within the final rule so when

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1 the new isotope were to come we could just apply that
2 rule and move forward?

3 DR. DAIBES: Our branch chief will -- Right
4 now for the direct final rule it's just the Germanium.
5 And that actually, that question, I predict will be a
6 question from our management and our Commission, should
7 we bring this up for direct final rule.

8 Potentially, that could be something that
9 stops this direct final rule and puts us into, the
10 looking into what else should we do to update the table
11 which likely would put us into normal rulemaking, extend
12 the process to get it done correctly with other isotopes
13 that are safe, they are practical, you know, good uses
14 for the public, and again, so in a safe manner.

15 And that's why we understand that there
16 could be those, so many obstacles to get to rulemaking
17 change that we, at parallel, went with the exemption,
18 basically the guidance for an exemption and allowing an
19 exemption.

20 At the same time, for that quick fix for this
21 specifically, should we look into that or that be the
22 next steps. Because, you know, anything with
23 rulemaking does, as you all know, it takes a lot of
24 resources, takes a lot of time.

25 The Commission is very, and the NRC staff,

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1 they're looking at everything very closely for any new
2 proposed rules. So because of that, there will be extra
3 scrutiny, even for direct final rule, to get the most
4 -- basically get the most out of the rules.

5 And so, I mean, you asked a great question.
6 And, like I said, I foresee our Commissioners asking the
7 same thing if not, you know -- and we look at it as, you
8 know, we consider it as well.

9 So that may slow up the direct final rule,
10 but open it up a little bit more and be helpful, more
11 helpful in the long run. And, you know, we're not
12 opposed to that either. But again, that's why we had
13 the parallel paths of developing some sort of guidance
14 to our regional offices that we'll share with the States
15 for specifics that we would allow an exemption.

16 CHAIRMAN ALDERSON: Dr. Langhorst?

17 MEMBER LANGHORST: For our new members, I'd
18 like to just let you know the reason that we're at this
19 point in the Part 30, Table B, or Appendix B, is that
20 Germanium was not licensed by the NRC at the time that
21 table was developed. It was not under regulatory
22 authority of the NRC, because it was cyclotron-produced.

23 The inclusion of cyclotron-produced
24 radioactive materials like Germanium came to be in 2009.
25 And this was an unfortunate miss of that full inclusion

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1 of those types of isotopes into byproduct definition.
2 So that's why we are where we are.

3 The NRC does not issue exemptions lightly.
4 But they are exactly for these types of things where an
5 unfortunate set of circumstances has made a disconnect
6 in the rules in what is needed for public health and
7 safety.

8 Commissioner Svinicki yesterday mentioned
9 Mr. Mattmuller's images of how much improved the
10 Germanium-68, or excuse me, the Gallium-68 images were
11 and the fact that having this generator out there for
12 medical use empowers many hospitals to provide this kind
13 of imaging agent when they don't have cyclotrons.

14 It's a generator that allows much more
15 expansion of this type of technology and to the benefit
16 of many patients out there. So this is an enhancement
17 of public health without any diminishment of safety.

18 And so I commend the NRC's, Said's work, and
19 everybody else that it takes to do this, to get this
20 little glitch, this disconnect of the regulations and
21 what is truly needed out there so that we can get this
22 done quickly and that we can eventually get to those
23 other issues of, you know, bringing the rest of the
24 regulations up to speed.

25 But I just thank you so much. And it's just

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1 such an impact on so many patients. And I just encourage
2 NRC staff, please keep working on it and getting it done.
3 Thank you.

4 CHAIRMAN ALDERSON: Thank you. Any other
5 comments on this particular topic? Well, thank you very
6 much, Doctor. Very good report, thank you.

7 And I think we're running a little ahead of
8 schedule. 9:45 is when the next presentation begins.
9 Are we able to begin that presentation now or --

10 MR. BOLLOCK: No.

11 CHAIRMAN ALDERSON: No.

12 MR. BOLLOCK: No, we're not. We're
13 waiting for Scott Moore to --

14 CHAIRMAN ALDERSON: Right. So we should
15 take a 15 minute recess?

16 MR. BOLLOCK: Yes. Or five, ten minute.

17 CHAIRMAN ALDERSON: So we'll begin at, 9:45
18 is what the schedule here says.

19 MR. BOLLOCK: That's fine.

20 CHAIRMAN ALDERSON: That's good. All
21 right, 9:45. And we'll be reconvened for the
22 presentation.

23 (Whereupon, the above-entitled matter went
24 off the record at 9:27 p.m. and resumed at 9:47 p.m.)

25 CHAIRMAN ALDERSON: Thanks, everyone,

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1 welcome back. We're now getting ready to have Mr. Moore
2 from the NRC make a special presentation to Mr.
3 Mattmuller.

4 MR. MOORE: Thank you, Dr. Alderson. It's
5 good to see so many of you, those of you that I know.
6 Those of you that don't know me, I'm Scott Moore. I'm
7 the acting director for the Office of Nuclear Material
8 Safety and Safeguards.

9 And I am down here to recognize Steven
10 Mattmuller for his service on the advisory committee.
11 I will be back later in the day, and I'll try to get a
12 chance to talk to many of you before you leave.

13 So Steven Mattmuller has served on the
14 advisory committee since March of 2008, that's eight
15 full years. He was renewed for a second term in 2012,
16 so two terms on the Committee.

17 He's briefed the Commission three times
18 during public Commission meetings, including in June
19 2009, October 2010, and then we all saw him yesterday
20 talk about Germanium/Gallium.

21 Mr. Mattmuller has demonstrated expertise
22 in the field of nuclear pharmacy and represents that
23 specialty well on the advisory committee. He's talked
24 about a number of things. We mentioned the
25 Germanium/Gallium generator issue yesterday, also the

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1 advanced notice of proposed rulemaking on the Part 20
2 regulations on radiation protection standards, and the
3 licensing of radium-223 dichloride, as well as
4 challenges with the domestic supply of molybdenum and
5 revisions to the AO criteria, and the major revisions
6 to Part 35.

7 So we appreciate Mr. Mattmuller's service
8 to the Committee. He's advised the staff very well.
9 And we appreciate your participation on the Committee.
10 We have some things to give you, Mr. Mattmuller. So if
11 you could join us. Sophie?

12 MR. MOORE: So first we have a flag that has
13 been flown over the Capital and a certificate from
14 Congressman Van Hollen attesting to the fact that the
15 flag has been flown over the Capital.

16 (Laughter.)

17 MR. MOORE: And then next we have a
18 certificate from Chairman Burns in recognition of Steven
19 Mattmuller's eight years of service and leadership on
20 the ACMUI which has resulted in significant
21 contributions to the work of the NRC, signed by Steven
22 Burns on 11 March.

23 And finally, we have a gold lapel pin with
24 an eagle on it. Sophie, do you want to get in on this?

25 (Laughter.)

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1 MR. MATTMULLER: Thank you very much.

2 (Applause.)

3 MR. MOORE: So congratulations. It's
4 great to see everybody. I'll be back in a couple of
5 hours. And I hope the rest of the morning's discussions
6 go very well. Thank you.

7 CHAIRMAN ALDERSON: Well, Steve, I think
8 we're ready for you.

9 MEMBER MATTMULLER: It's worn out.

10 MEMBER LANGHORST: He's broken it already.

11 (Laughter.)

12 MEMBER MATTMULLER: So as I fade away,
13 there we go, all right. Just a reminder, this is
14 Memorial Sloan-Kettering Cancer Center, New York City.
15 This is not my place. In fact, it's my understanding
16 the top floor on the right, that whole level is Pat's
17 office. And also this is a terrific photograph,
18 probably taken by a helicopter.

19 So this is my place, Kettering, Ohio, in the
20 southwest corner of the state. We couldn't afford a
21 helicopter, so this is actually an artist's rendition.

22 (Laughter.)

23 MEMBER MATTMULLER: And my office is on the
24 back side buried next to the cyclotron. But we do share
25 this gentleman in common, Charles Kettering, who had

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1 several profound quotes, and a prolific inventor, second
2 only to Thomas Edison in patents. And his biggest was
3 the electric starter in the automobile.

4 But I went back through the old agendas for
5 the past eight years trying to pull out a few of my
6 favorite agenda items to comment on. And this one is
7 one of my personal favorites because, as you can imagine
8 I get excited about techniques and generators too, in
9 addition to all generators.

10 But just to remind us how we get our moly
11 is a very complex process and how we're trying to convert
12 the HEU targets to LEU which really is a factor of five
13 less in production and a factor of five greater for
14 waste. But there are some real challenges in solving
15 that issue. So in the end, LEU moly is always going to
16 be more expensive than what we currently produce now.

17 So progress has been made, but our reactors
18 on the left are still aging, fading away, so to speak
19 too. So we're still in a very tenuous situation. So
20 this is a topic that is worth keeping an eye on in the
21 future.

22 Here we go. Well, I did serve on a number
23 of committees. And one issue was metrication, and we
24 came to an issue of trying to figure out an old
25 traditional unit of activity versus the traditional unit

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1 of volume.

2 And we couldn't find that traditional
3 volume, so we substituted one called a firkin which, for
4 those of who know my enthusiasm for informal meetings
5 across the street, but this seemed to be an appropriate
6 choice.

7 This is a picture that's in the lobby of our
8 hospital. And it's a big one. It's about four feet by
9 six feet. And for a number of years of working there,
10 I always thought this was either Wilbur or Orville
11 Wright.

12 But it's actually Charles Kettering. He
13 was active at the time of the Wright Brothers, had his
14 own aircraft company. And it turns out this picture was
15 taken of him on his way to a committee meeting in
16 Columbus, Ohio. He was going to a committee meeting for
17 the Ohio State University.

18 So while we may think we're pretty cool
19 coming here to Rockville for an ACMUI Committee meeting,
20 we'll never be Charles Kettering cool. So another
21 profound statement from him, believe and act as if was
22 impossible to fail, which I took to heart as we worked
23 on this project of trying to get regulatory relief for
24 a Germanium DFP issue and to get Gallium out into the
25 clinical world where it can benefit these patients.

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1 So I had a lot of help with this report and
2 couldn't have accomplished it without the subcommittee,
3 especially with Sue Langhorst and the hours she spent
4 in the law library. But even Laura was very helpful,
5 and Bruce Thomadsen, and their comments to the
6 Commissioners, and past presentations, and of course the
7 staff. The staff was great in working towards getting
8 resolution of this.

9 And we're not quite there yet, but I'm very
10 confident we will get there. So it truly was a group
11 effort.

12 So I've been very fortunate in my
13 professional life that I've always been in an
14 environment of great leadership and support. And it's
15 what I found here too. And it's very much appreciated.
16 Excuse me.

17 And I've also had a lot of support from home,
18 from my wife, Michelle, as her support has never wavered.
19 And even when I had to give a lot of attention and a lot
20 of time to women named Ashley and Sophie.

21 (Laughter.)

22 MEMBER MATTMULLER: Who, she reminded me
23 Wednesday before I left, she goes, you know, I've never
24 met these women. But she does know they do exist. So
25 thank you for the opportunity to serve. And I hope I've

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1 met your expectations. Thank you.

2 (Applause.)

3 CHAIRMAN ALDERSON: Well, we are quite a
4 bit ahead of schedule at this point. It's 10:00 a.m.
5 And the next item is open forum. So would you like to
6 just move ahead with open forum?

7 MS. HOLIDAY: Yes.

8 CHAIRMAN ALDERSON: Yes, let's do that.
9 So, Sophie, I guess that means you. And so if you will
10 -- so we're now going to go to the open forum which is
11 headlined as we will discuss medical topics of interest.
12 And so Sophie, if you'd like to lead us to some that you
13 think we should discuss, we can do that. If not, we'll
14 go on our own. Yes. Or Dr. Langhorst will lead us.
15 Yes.

16 MEMBER LANGHORST: So having been here a
17 few years sitting next to this gentleman here, I'm going
18 to miss that whispering in my ear while I'm trying to
19 pay attention to others.

20 (Laughter.)

21 MEMBER LANGHORST: I do want to encourage
22 the new members. When I first was here I was, like, what
23 in the world is going on? What does this mean, how do
24 they do this? I encourage you to ask your question, and
25 don't be afraid that if you've asked it before and you

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1 still don't quite understand it ask it again.

2 I am very encouraged by our training we're
3 going to have later today on regulations and how things
4 work. Because as a radiation safety officer, I kind of
5 know a lot of that, but I didn't know a lot from the
6 perspective of NRC.

7 So I encourage you to understand that if
8 only to support your own RSO back at your place. But
9 don't be afraid to ask questions. Because you'll know
10 half of us are going, yes, I didn't know what that meant
11 either. So I just encourage the new folks to do that.
12 Thank you.

13 CHAIRMAN ALDERSON: Good. Great advice.

14 All right. Are there any other items that
15 people would like to discuss? Dr. Ennis.

16 MEMBER ENNIS: Just a question first.
17 Donna-Beth gave a very good presentation of events
18 yesterday. But I gave a presentation on the same topic
19 in October. Why is it that we do that? It seems like
20 one report from NMED, from either NRC staff or from ACMUI
21 would be adequate. Why are we duplicating that?

22 CHAIRMAN ALDERSON: You believe that it was
23 duplicative, you gave the same medical events that were
24 given by Dr. Howe?

25 (Simultaneous speaking.)

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1 MEMBER ENNIS: I think it felt -- pretty
2 similar events.

3 CHAIRMAN ALDERSON: So we'll let Dr. Howe
4 respond to that.

5 DR. HOWE: The intent of my presentation is
6 to introduce all the medical events, and organize them
7 for you. And then if you see a trend or something you
8 would really like to follow up on. Then that's supposed
9 to be your main focus on the next one. If you don't have
10 anything you want to follow up with, it's not necessary
11 to have another meeting.

12 Because it's not supposed to be I do it, then
13 you do it again. It's what does the ACMUI, from its
14 perspective looking at these medical events, glean from
15 the medical events? And bring us a new perspective. So
16 the other thing is we used to have two presentations when
17 I did mine.

18 I did one for medical events. And our
19 medical physicist did one for other events that dealt
20 with medical facilities. Loss of sources, spills,
21 those kinds of things. We haven't had that report for
22 a long time. So you may want to consider adding that
23 in. I think Sue would be --

24 CHAIRMAN ALDERSON: Dr. Langhorst.

25 MEMBER LANGHORST: So yes, when Ralph Lieto

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1 used to do those.

2 DR. HOWE: Absolutely.

3 MEMBER LANGHORST: And I know that Dr.
4 Thomadsen asked me, Sue, we used to have those. And so
5 I did put something together for your report last time,
6 which I apologize. Again, I wasn't here to help support
7 you in those.

8 And so yes, I didn't remember that it was
9 in consort with yours. So, and let me tell you that was
10 a lot of work. And I don't know that I can do it every
11 time, so.

12 CHAIRMAN ALDERSON: Mr. Fuller would you
13 like to comment?

14 MR. FULLER: Yes, just briefly. Dr.
15 Ennis, I spoke a little bit about this yesterday. The
16 presentation that you received from Dr. Katie Tapp, on
17 Yttrium-90 microspheres, and the work that one group has
18 done to make changes to some of the 35.1000 licensing
19 efforts that are underway. That was a direct result of
20 the Committee looking at what Donna-Beth had presented.

21 And deciding that they wanted to drill into
22 that. So they drilled into it. They got to sort of,
23 identified some things that perhaps were based upon the
24 medical and clinical judgment of the members of this
25 Committee. Decided that you know that's really kind of

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1 inappropriate to be reporting, and so forth.

2 So that's really the intent. That's sort
3 of where we envisioned how this would go. And as
4 Donna-Beth said -- Dr. Howe said, I'm sorry -- if you
5 look at what she provided. And you say okay, well for
6 this year it seems kind of normal. Nothing there that's
7 really striking us as something we want to dig into, or
8 drill into. Then that's fine. You can pass. But
9 really it's not, you're right, I don't think it serves
10 anyone to just simply repeat. Or maybe package it in
11 some different way and do it over.

12 It's really, we're providing you with the
13 data. And a little bit of information about some of
14 these medical events. And then it's for you to do with
15 that what you deem appropriate.

16 CHAIRMAN ALDERSON: Mr. Ouhib.

17 MR. OUHIB: Yes, first of all, let me just
18 say that what Dr. Howe presented yesterday, I find it
19 extremely valuable. But I should add that perhaps we
20 need to define some goals behind that presentation.
21 What exactly we're trying to accomplish with that
22 information, prior to seeing that data?

23 And then perhaps act on it, or provide some
24 recommendations or whatnot. But they have to be sort
25 of you know, two or three items well defined. Okay,

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1 here's the purpose of this. And it's not only
2 information that we provided, because I looked at it as
3 information. And then from there I started to think
4 like, okay, well why is this happening? And can we do
5 something about this? Or how can we improve this and
6 so on?

7 But I think if we define some goals, I think
8 that would be extremely helpful.

9 CHAIRMAN ALDERSON: So it seems that with
10 respect to medical events, in fact we have set out with
11 some things to do. So, Dr. Suh has a Committee that's
12 looking at the clarity or the definition. And then Dr.
13 Langhorst has just taken on the new Sub-Committee this
14 morning, which several of you are on. To really work
15 on the culture, the communication, and the things around
16 medical events.

17 So in fact, I think we have responded to the
18 report with some Committee actions.

19 Dr. Langhorst.

20 MEMBER LANGHORST: Always what I have felt
21 in our report is that that Sub-Committee can delve into
22 the NMED data, the nuclear materials, event data base.
23 It's not nuclear medicine. It's nuclear materials.
24 And we can do exactly what you're saying. And give that
25 perspective.

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1 We don't always delve into, I know
2 Donna-Beth, excuse me, Dr. Howe gives us that
3 information. But we can delve into it in our own way
4 to look to see, are there other items in the NMED database
5 that are of interest to us.

6 One question I do have along this lines is
7 whether -- and I realize there is budget constraints --
8 whether it's possible to get reports on what are the
9 total number of procedures at this point in time?
10 Because it's been about five years or so since we had
11 that data. So we can again look at, it's this many
12 medical events, out of this many procedures that are done
13 per year.

14 So I wondered if that could be a possible
15 thing that NRC can provide us in the next year or two?

16 MS. HOLIDAY: Hi, Dr. Langhorst. This is
17 Sophie. Just to follow up on that. I know this is
18 something that the Committee has requested. And as you
19 have recognized, this is a very tight budgetary
20 environment for us.

21 Staff will always advocate and put the
22 request forth, but ultimately it's up to whether or not
23 we have funds to purchase those reports. Because those
24 reports are several thousands of dollars. And that's
25 several thousands of dollars for just a small piece of

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1 a report. Not even a full report.

2 So when we do have funds, if we have funds,
3 staff will absolutely provide that data to the
4 Committee. Maybe we'll be able to do that at the next
5 meeting because it has been several years since we've
6 been able to purchase a report. I just can't commit to
7 that since it's not my money to play with.

8 CHAIRMAN ALDERSON: Yes, Mr. Ouhib.

9 MR. OUHIB: Yes, if I could just add one
10 more comment. It would be helpful and I believe you have
11 done it, is to get that data well in advance, prior to
12 the meeting for instance. For us to sort of brainstorm
13 on that and come up with some sort of recommendations,
14 or plan of actions, or whatnot.

15 DR. HOWE: Dr. Alderson, also just to
16 follow up on what Sophie said. The data that we purchase
17 doesn't come out with, oh, here's the number of
18 procedures for the different modalities. Sometimes on
19 some years they don't even address our issues.

20 And in other cases they lump it so largely
21 that it's difficult to tease out. So it's not as simple
22 as saying, we want the number of total administrations
23 for this, this, and this. It doesn't come that way.

24 CHAIRMAN ALDERSON: Okay.

25 Yes, Frank. Dr. Costello.

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1 MEMBER COSTELLO: A caution about mining
2 NMED data. First of all, those reports often raise more
3 questions than they answer. I mean, how many reports
4 when you look at them, do you find yourself wanting to
5 ask questions? Like, why did that happen? Or why did
6 this happen? Or what was the effects on the patient?
7 And the data, the quality of the data is very, very,
8 variable in that regard.

9 And just from a simple counting point of
10 view, I think we should all assume there's a certain
11 amount of under reporting. For the reason that we've
12 been talking about. You know we may discourage people
13 from reporting by the way we handle the reports.

14 So I think you know mining the data is useful
15 but you have to be cautious about making major
16 conclusions based on data that is inherently suspect.
17 Thank you.

18 CHAIRMAN ALDERSON: Dr. Metter.

19 MEMBER METTER: I was just wondering as far
20 as me looking for the denominator on how many procedures
21 are done. Since my understanding of the Y-90
22 microsphere is a unit or a standard dose is when they're
23 sent. Perhaps you could go to the manufacturer and just
24 see how many they have sold as a baseline?

25 CHAIRMAN ALDERSON: Yes, Dr. O'Hara.

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1 MEMBER O'HARA: If that, many of these
2 companies consider that proprietary, that kind of thing
3 proprietary information. We're using the Y-90
4 microspheres as an example. One company has a
5 humanitarian device exemption from the FDA, which
6 they're limited to a total number of patients per year.
7 And the other has a PMA, which is the highest review that
8 we give a medical product.

9 And the company will tell us how many units
10 they have sold in a yearly report, but again it is
11 proprietary. In some cases you can get the information
12 publicly from some of their presentations.

13 In terms of the denominators, it's
14 something that the FDA is always interested in too. And
15 with respect to using again, Y-90 microspheres as an
16 example, it's very difficult because they're used
17 off-label so much.

18 You know the glass microspheres are
19 indicated for primary liver tumors. And the polymeric
20 microspheres are indicated for colorectal mass. But
21 they both have, both companies have investigation device
22 exemptions, ongoing. Where they're looking at other
23 indications for use.

24 And there's a large number of
25 physician-sponsored studies going on too. That's where

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1 physicians are actually looking at a number different
2 indications. But so we are as challenged as the NRC with
3 our databases. And I would hazard a guess that many of
4 you have tried to look at what used to be called, the
5 MOD database in FDA, and been totally frustrated by it.

6 And it is changing, that database is
7 changing. It's now called, SUS internally. The
8 general public can't get access to SUS yet, as they could
9 get, they still have access to MOD. But MOD will
10 eventually go away, and SUS will completely take over.
11 And it's supposed to be, it's being designed to be much
12 more user friendly.

13 I still can't use it. I don't even have
14 permission to use it.

15 So, but it's the denominator, and a lot of
16 what I've heard here today from NRC, talking about the
17 problems with these databases. As I said, FDA database
18 is very vague, very vague indeed. And many times our
19 analysts look at these and they have to start
20 investigating. They have to start to see where a device
21 has failed.

22 And remember our database is different.
23 Really, we look at device failures. That's what we're
24 looking at. And we regulate the manufacturers. We're
25 not regulating the users, as NRC does. So there's a lot

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1 of differences.

2 But you'll see that coming out of our
3 Division of Radiological Health, you'll see at least
4 three, maybe four different methods that regulatory
5 scientists are using to analyze this subjective data,
6 from these subjective databases.

7 So you'll see you know hopefully
8 publications coming out. There's at least one that's
9 close to coming out right now.

10 CHAIRMAN ALDERSON: Yes, Dr. Palestro.

11 MEMBER PALESTRO: Yes, in response to your
12 comment, Darlene. I can tell you that I spent a
13 considerable amount of time in preparation for the
14 presentation regarding alpha and beta emitters, trying
15 to get those data for the other beta emitters that are
16 on the market and for the alpha emitters. And it was
17 absolutely impossible.

18 I contacted the companies, and they
19 referred me to many different people within their
20 organization. And that went nowhere. And I tried
21 looking on line, on the web and so forth to see, but I
22 just could not find the data.

23 And then several of these agents have gone
24 from one company to another over the years, which further
25 complicates it, so.

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1 CHAIRMAN ALDERSON: Mr. Ouhib.

2 MR. OUHIB: Yes, just a comment to Dr. Howe,
3 regarding the medical event. It is hard to swallow, the
4 idea that we are still seeing some errors that have
5 significant impact related to the unit. You know,
6 air-kerma strength versus millicuries and all that.
7 And these are really detrimental when you look at a lot
8 of it more in depth, to these errors.

9 I'm just wondering if perhaps that might be
10 the work of the Sub-Committee? To actually look into
11 that? And it's perhaps time for us to move away from
12 the millicuries and go to a single unit such as air-kerma
13 strength. And stay away from apparent activity type of
14 thing.

15 CHAIRMAN ALDERSON: Any other comments on
16 this particular subject?

17 (No audible response.)

18 CHAIRMAN ALDERSON: Hearing none, are
19 there other subjects that people would like to raise?

20 Dr. Langhorst.

21 MEMBER LANGHORST: As I said, I've been on
22 this Committee a little while and I am still frustrated
23 in not knowing how many medical licensees there are.
24 NRC publications tell how many material licensees there
25 are. I cannot find how many medical licensees there

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1 are. Could we get that data? Could we have it?

2 You know, I know there's Agreement States
3 and there's NRC licensees, but just to know how many --
4 and I'm not asking number of authorized users -- that
5 will be the next layer. I'm looking for number of
6 medical licensees.

7 Now I know, in our instance at Washington
8 University in St. Louis, we are medical use licensees,
9 but we're also a big research licensee. If they have
10 medical use approved in their license, that's the
11 numbers I want to know.

12 So that would be great. And I really don't
13 mean to diminish the medical team's resources in time
14 added, as far as getting this data. I would think it
15 would be something that you would have already, so
16 please.

17 CHAIRMAN ALDERSON: So, a clarification.
18 So if you have an institutional broad license, and
19 Washington U certainly does, you would consider that one
20 licensee. Is that right?

21 MEMBER LANGHORST: Yes. That's all I'm
22 looking for.

23 CHAIRMAN ALDERSON: A single licensee.

24 MEMBER LANGHORST: That's all I'm looking,
25 how many medical licensees are there in the country?

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1 CHAIRMAN ALDERSON: Okay, all right.

2 MEMBER LANGHORST: And how many are
3 Agreement States? How many are NRC? You don't even
4 have to tell me what they are per Agreement State.

5 CHAIRMAN ALDERSON: Dr. Howe would like to
6 comment.

7 DR. HOWE: We have to do what's called an
8 OMB approval. And renew these things for regulatory
9 reasons. And one of them is Part 35, and in doing Part
10 35 we have to come up with the number of NRC licensees.
11 And we do that by program code. So we know how many NRC
12 licensees we have. We know what their program codes
13 are. They don't always have primary program codes.
14 They may have secondary tertiary program codes.

15 So we have that data. That is accessible
16 to us. What we do not have is the same level of detail
17 for the Agreement States. So in our OMB clearances, we
18 do have on a yearly basis, the number of Agreement State
19 licensees.

20 Now that covers all materials. And so it's
21 not just medical. And so what we do is we make an
22 assumption which may not be a safe assumption anymore,
23 that the ratio of NRC medical use licensees should be
24 the same as the ratio of Agreement State licensees.

25 So we know the total number of NRC

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1 licensees. We know the number of medical use licensees.
2 We develop a ratio and then we take the total number of
3 Agreement State licensees, and we multiply by that
4 ratio.

5 Now when we had more NRC licensees than now,
6 that was a good approximation. I'm not so sure that's
7 a good approximation anymore. But that is how we
8 determine how many medical use licensees there are. We
9 don't have the ability in the Agreement States, other
10 than using a ratio, to go from NRC modalities to
11 Agreement State.

12 But that information we can provide very
13 easily.

14 CHAIRMAN ALDERSON: So what you say, you
15 already have the information you just described.

16 (Simultaneous speaking.)

17 DR. HOWE: We already have the information.

18 CHAIRMAN ALDERSON: You just have to look
19 it up. Yes?

20 MR. BOLLOCK: Short answer is we can get you
21 the number of NRC licensees and give you an estimate of
22 Agreement State or total.

23 MEMBER LANGHORST: I would love to have
24 just even that shared with the whole Committee.

25 CHAIRMAN ALDERSON: Dr. Langhorst will be

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1 very happy if you provide this information.

2 (Laughter.)

3 CHAIRMAN ALDERSON: Mr. Costello.

4 MEMBER COSTELLO: I can't speak to any
5 States other than Pennsylvania, but we use the same
6 program codes.

7 MEMBER LANGHORST: Is your mic on?

8 MEMBER COSTELLO: Yes.

9 (Laughter.)

10 MEMBER COSTELLO: I can't speak for any
11 States other than the fine Commonwealth of Pennsylvania,
12 but we use the same program codes as the NRC does. And
13 if someone were to ask us, I'm pretty sure we could give
14 you the same breakdown that the NRC can give you.

15 Okay, not only the total number, but we can
16 probably give you the total by program code. How many
17 are cardiologists. How many there are whatever they may
18 be.

19 Far as the other States go, you have to ask.
20 Then if you would ask, you might get information.

21 CHAIRMAN ALDERSON: Dr. Langhorst.

22 MEMBER LANGHORST: Maybe will be answered
23 later this morning, or early this afternoon, but is the
24 ACMUI allowed to ask Agreement States if they could give
25 us this information?

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1 MEMBER COSTELLO: I think it would be
2 better if the NRC asked, would be much better.

3 MEMBER LANGHORST: Are we allowed to ask?

4 MEMBER COSTELLO: Allowed?

5 MEMBER LANGHORST: Without a big formal, oh
6 we need to have this --

7 (Simultaneous speaking.)

8 CHAIRMAN ALDERSON: Yes, Dr. Bollock.

9 MR. BOLLOCK: I don't know that we can ask
10 this. We may be able to, but it may -- issue, I think
11 what Dr. Langhorst eluded to is OMB clearance.
12 Typically when we ask questions that aren't specific to
13 what we're regulating, we need an OMB clearance if we
14 ask more than nine entities.

15 Agreement States are each their own entity.
16 Unfortunately, that may be the case. So in the
17 meantime, we can get you our numbers and the estimates.
18 And you know that gives you know a relative ballpark for
19 denominators for events. And so we do know generally,
20 have those numbers. But yes, we would have to look into
21 it to see if we could ask all the States something like
22 that.

23 I mean it seems, I know it seems like a
24 simple question.

25 MEMBER COSTELLO: I think that I, not being

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1 bound by OMB requirements myself, I could probably get
2 Pennsylvania numbers myself. A guy just send them to
3 somebody.

4 MEMBER LANGHORST: Okay, thank you.

5 CHAIRMAN ALDERSON: Well it would be
6 interesting if we have the data that the NRC already has
7 based on ratios. And then if you were to get some data
8 from, you could at least do a comparison in Pennsylvania
9 and see how close they were.

10 But you still would have an overall numbers,
11 you know. Just from what the NRC can provide. So I
12 think it's great that that can be provided. And we
13 should go ahead and do that.

14 MR. BOLLOCK: Yes, we'll get you what we
15 can.

16 CHAIRMAN ALDERSON: Right and when you have
17 that number, just obviously send the answer around to
18 all of us on the ACMUI.

19 Dr. Ennis.

20 MEMBER ENNIS: May as well go to the second
21 layer then, because what about authorized users? We
22 were hampered in our Committee about the alpha/beta
23 emitters with this issue. And we really could not make
24 an intelligent decision in the end.

25 MR. BOLLOCK: And that is true because not

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1 every -- authorized users don't have to necessarily be
2 listed on every license. So for that we could only give
3 an estimate. And there's some other things.

4 Broad scopes have multiple authorized
5 users. So those numbers getting to that, the number of
6 authorized users, it really does get to where we don't
7 think we can get other than a rough estimate, anything
8 close to an accurate number, unfortunately.

9 CHAIRMAN ALDERSON: Dr. Palestro.

10 MEMBER PALESTRO: Yes, I was just going to
11 echo Ron's sentiments. It would be nice to have. And
12 it would have been particularly valuable to the type of
13 discussion that went on over, is there or is there not,
14 a lack of authorized users?

15 But again, there's no reliable way to get
16 to that information. Because certainly New York which
17 is an agreement state, our own institution has a broad
18 human use license. New York State doesn't have the
19 individual authorized user data. They have the
20 licensee, but not the AUs.

21 MR. BOLLOCK: Exactly right. Just, this
22 was a question, as many of you know with the training
23 experience. We actually have going on and answering
24 questions to Congressional oversight staffers, both
25 Senate and Congress, our Commission. And those are

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1 questions that we were asked. Because those are some
2 of the points that the pharmaceutical company was
3 making.

4 And right, we can't get to the number of AUs.
5 But for 35,300 licensees, we have an estimate of about
6 2500. It's probably low, a low estimate. But about
7 2500 across the country that you know. And we were able
8 to find that and we used, because we know the number of
9 NRC licensees, and we used that rough ratio to estimate
10 the Agreement States.

11 CHAIRMAN ALDERSON: Sophie answer, yes.

12 MS. HOLIDAY: If I may follow up, both Dr.
13 Palestro and Dr. Ennis, also got, we were requested by
14 professional organizations for the numbers as well.
15 And NRC has what is called, Web Based Licensing, WBL.
16 And that's how we our license reviewers input licenses,
17 medical use licenses and such.

18 And so in that system currently they do not,
19 you're are not able to pull out the specific number of
20 AUs. However, you are able to pull up if someone is
21 authorized under 300, not 390, but 300, or 200, or 400.
22 Something along those lines. So the number that Doug
23 gave you, is how we got it from just the general number
24 of who is authorized under 300.

25 Now we're also saying, to answer Dr.

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1 Langhorst's question, there was a letter that went out
2 to the Agreement States. And I will have to give credit
3 Dr. Sandy Gabriel, who used to be a member of the medical
4 team. She's apparently listening, because she sent me
5 this lovely document that went out that has the results
6 of the annual count of radioactive material licenses
7 within the National Materials Program.

8 So I will share that with the Committee
9 because I don't know if this non-public information, but
10 I will send this to the Committee at the conclusion of
11 this meeting.

12 CHAIRMAN ALDERSON: Thank you.

13 Dr. Howe.

14 DR. HOWE: Just to clarify, that number is
15 published every year in the information guide. Yes,
16 that NRC publishes. And so that's publicly available.

17 CHAIRMAN ALDERSON: Very good. All right.

18 MEMBER LANGHORST: So if you let me
19 clarify. It's material licenses, it's not medical
20 licenses?

21 MS. HOLIDAY: That is correct. Just
22 materials.

23 MEMBER LANGHORST: Thank you.

24 CHAIRMAN ALDERSON: So that's something
25 different, yes.

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1 Mr. Mattmuller.

2 MEMBER MATTMULLER: Now that I'm leaving
3 the Committee, I've lots of ideas for work for you guys.

4 (Laughter.)

5 MEMBER MATTMULLER: But I don't know if
6 it's work worth doing. Actually, I just have two. And
7 the first one I would suggest would be an update on the
8 moly-99 supply issue. And I'm not throwing my successor
9 underneath the bus. I've already talked to him and he's
10 agreed to do this, so. I think that would for the
11 Committee to consider.

12 And then the second topic would be for Dr.
13 Daibes to give us an update on the number of exemptions
14 that have been granted.

15 (Laughter.)

16 MEMBER MATTMULLER: An update, I mean --
17 implementation and success of the exemption program.

18 CHAIRMAN ALDERSON: Okay. Those are yes,
19 good suggestions. I think that time will be the issue
20 on the implementation. It won't be available
21 immediately. And the update on the molybdenum
22 situation, do you have someone in mind you'd like to do
23 that?

24 MEMBER MATTMULLER: Yes, Rich. He's
25 agreed.

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1 CHAIRMAN ALDERSON: Oh, Rich has agreed.
2 Okay, good, great. Thank you. We look forward to
3 getting that information. Yes, thanks very much.
4 Okay, good those are actual, yes fine.

5 Other topics that people would like to
6 discuss today? We are more than 30 minutes ahead of
7 schedule at this particular time.

8 Yes, Dr. Zanzonico.

9 VICE CHAIRMAN ZANZONICO: I'm just
10 wondering what efforts can be undertaken by the NRC staff
11 and or by the ACMUI to disseminate regulatory
12 information in particular, updated information, more
13 effectively to the user community?

14 I think we around this table, and I imagine
15 even more so among the NRC staff, have a skewed
16 perception that people live and breathe the regulations,
17 which believe it or not, they don't.

18 CHAIRMAN ALDERSON: Right.

19 VICE CHAIRMAN ZANZONICO: And I think
20 typical AUs who are otherwise very well informed about
21 many things, are often unaware of new developments. And
22 I mean I can account to this personally. You know before
23 I joined the Committee I thought I was pretty well
24 informed about the regulations.

25 And then once I was on the Committee, I was

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1 surprised how ignorant I was of many of the regulations
2 and the process and so forth and so on.

3 So it really strikes me that there's a
4 disconnect between what the NRC promulgates and what the
5 users in the field know. And I know there are many
6 mechanisms in place that in principle should be
7 effective. But they are not nearly as effective as the
8 NRC, and as we think they are.

9 And I'm just wondering what new mechanisms,
10 what efforts could be undertaken to improve that
11 situation? I don't know if -- I'm thinking even perhaps
12 an NRC representatives speaking regularly at
13 professional meetings. But not just with a booth, you
14 know tucked away in the area of the displays where no
15 one goes.

16 But maybe even speaking at plenary
17 sessions, you know requesting from the main professional
18 organizations and giving periodic updates on
19 regulations and what's changing. What will impact
20 practice?

21 Because as I said, I think there's a real
22 disconnect in terms of what authorized users day in and
23 day out, are aware of with respect to regulations, and
24 changes in regulations, and how they impact practice.
25 And what's actually occurring?

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1 CHAIRMAN ALDERSON: And this idea was
2 specifically mentioned in my presentation to the
3 Commission yesterday. And it is part of the
4 communications plan that we're hoping to support here.

5 The idea suggested there was that ACMUI
6 member or members, along with an NRC staff person, would
7 appear at some of the major meetings. Now you know as
8 well as I, and you do who are in the organizations, that
9 whether you're on a plenary or whether you're in another
10 session somewhere, that that is something you have to
11 organize with those societies and the people who present
12 those meetings.

13 But the fact is that all of us know people
14 who are running those organizations and can certainly
15 make an impact. So if we agree to go ahead with that
16 -- we've more or less agreed to go ahead with it -- but
17 if we actually move to implementation. Then certain
18 people who are going to be at those meeting will agree
19 to take the lead.

20 They'll make the contacts, and they'll try
21 to get onto one of those sessions that are probably
22 initially running in parallel. To just to see if any
23 one shows up. And if people are really interested that
24 --

25 (Laughter.)

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1 CHAIRMAN ALDERSON: Well, but if your
2 people are interested then you know the interest begins
3 to get greater and then you say well we, perhaps we could
4 be part of plenary at this or that point.

5 VICE CHAIRMAN ZANZONICO: It could follow,
6 but I mean the thing you want to avoid is you don't want
7 to be in the, on the display floor in the same aisle as
8 the IAEA, and the ICL. Those are the loneliest people
9 at the meeting. EFU, you have to really have a very
10 prominent role in the meeting. This is why I mention
11 something like plenary session or some such thing as
12 that. And that's just a perfunctory appearance.

13 CHAIRMAN ALDERSON: No, it's not an
14 appearance I mean, but maybe I didn't say the idea that
15 I had was that you know you would listed in the program
16 as many refresher courses are at many of these meetings.
17 And you'd be course number whatever, on a particular day,
18 and a particular room, and a particular time.

19 And there would be a hundred and fifty seats
20 in the room, and you know you would hope that some people
21 are going to come and want to talk to the NRC about
22 various things. You'd have an actual program. You
23 would have planned an actual presentation that would
24 cover topics that you would have announced. And then
25 you'd be a Q&A session as well that would probably take

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1 an hour or so. And that's the idea.

2 Mr. Ouhib.

3 MR. OUHIB: Yes, I think just to let you
4 know that has been used in the last two years within the
5 American Brachytherapy Society for instance. We have
6 had an NRC representative participate in sessions where
7 there was discussions and all that, an update on the rule
8 making. As a matter of fact, Michael perhaps can
9 testify to that. And Sandra was part of it also three
10 years ago and so on.

11 But I also think the AAPM also has been so
12 very active in that. So there, it's out there with some
13 organizations. I mean no doubt about it. But maybe we
14 just need to push a little bit more.

15 CHAIRMAN ALDERSON: So Lynne Fairobent
16 wants to make a comment.

17 MS. FAIROBENT: Yes, Lynne Fairobent with
18 the American Association of Physicists and Medicine. I
19 think it's great that you want to do something like that.
20 But I'm sorry, I think it's the wrong approach.

21 I think it's up to each of the professional
22 societies when they wish to invite an NRC, or an FDA,
23 or a CMS regulatory individual. We do that. Cathy
24 Haney last year spoke as the lead kick-off speaker at
25 AAPM spring clinical meeting for example.

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1 We have had a variety of sessions, when
2 appropriate, with NRC individuals. Many of the
3 professional societies have government relations
4 experts who do routine updates to their memberships on
5 what's pending in a variety of federal agencies. And
6 State agencies.

7 I think that, and Sue will probably cringe,
8 but the vehicle for NRC reaching out to the medical
9 community and ACMUI reaching out to the medical
10 community, should have been moving forward within NRC
11 regulatory issues conference to the medical licensees
12 or to materials licensees.

13 And there had been an effort for that, and
14 my understanding is it's not going forward at this time.

15 CHAIRMAN ALDERSON: Yes, that is correct.
16 That was suggested. It was actually discussed by this
17 Committee. And it was felt that it would be better and
18 more efficient, more cost effective for us to go to the
19 meetings, than to try to have a national meeting and have
20 people come in for that meeting.

21 I would say that for any of you who -- and
22 I know many of you have your own organizations, but in
23 leadership positions, you've heard many of the old
24 adages about communication. You know you communicate,
25 communicate, and communicate. Sometimes several

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1 different ways, several different places and ultimately
2 no matter what you try to do, you're ultimately
3 criticized for not communicating. Because somebody
4 fails to hear it.

5 So what I believe what you need to do is to
6 offer your services. You don't wait for somebody to
7 call because then they're angry that you haven't done
8 your job. You actually offer to go to them.

9 Now if we in fact go to various societies
10 and offer to put together you know a presentation for
11 one of their refresher courses. And they say, no you
12 know, we're not interested. We don't need you. Well
13 then when they have a problem in a few years, we'll be
14 able to point out that we offered and you said, no.

15 But I think if you don't offer then you
16 aren't doing what you need to do in terms of
17 communication.

18 Dr. Dilsizian.

19 MEMBER DILSIZIAN: I want to say that when
20 we organized the FDA panel, that at the SNMMI we thought
21 nobody would show up. But actually it was full house,
22 people lined up. People want to know how the
23 regulations occur and what's new.

24 I'm not sure if NRC should be separate, or
25 if FDA and NRC combination probably would work well.

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1 But to reassure you, the people do like it and do attend.

2 CHAIRMAN ALDERSON: Yes. Fifteen or more
3 years ago, and I don't remember what the issues were.
4 There was issue in the radiology community with some NRC
5 things. And I actually was involved in putting together
6 some sessions at that time. And they were reasonably
7 well attended.

8 I would also point out that the American
9 Board of Radiology came up with the idea several years
10 ago that it might be interesting to put on a regular
11 session at the large radiological meeting called the
12 Radiological Society of North America, RSNA.

13 And the initial response to that was similar
14 to this. Oh, no, no, you know, no one will come. And
15 no one will be interested but why don't you go out there.
16 It's now become a real you know, looked forward to part
17 of every annual meeting. And no they don't get a
18 thousand people, but they get a hundred.

19 And so they're out there telling each year
20 exactly what's going on. It's been very valuable for
21 them.

22 Dr. Metter.

23 MEMBER METTER: Yes, for like what you're
24 talking about, reaching out to societies. And for the
25 SNMMI big annual meeting, and we did do an NRC update.

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1 Mr. Bollock was there. And it was very well attended.
2 And they had a lot of questions. And I think the issues
3 coming up with training and experience and all that will
4 be a hot topic.

5 And I believe that many of us who are
6 involved in leadership and involved in future meetings,
7 I think we should bring that up. And I think it would
8 be a definite service to the community.

9 CHAIRMAN ALDERSON: Thank you. I think
10 that if you just listen to the controversy. You know
11 the discussions I'll say, that we have over issues like
12 the one that Dr. Palestro's Committee will deal with.
13 Over the question of medical events. I mean it seems
14 to me that there are people out there who want to know
15 the answers to these questions.

16 And we can't provide pat answers, but we can
17 certainly provide updates and get their input as well.
18 And they will enjoy that.

19 Yes, Dr. Metter.

20 MEMBER METTER: I think it would be a great
21 opportunity to educate our fellow colleagues in the
22 community about the current, the just culture, the
23 safety culture. And you know put that in. And I think
24 you know just starting it now. It'll take years and
25 years for the change.

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1 But having them realize that you know the
2 NRC is a regulator. But we're here to improve. We're
3 doing quality improvement, no blame. We want to improve
4 on what we do. And I think that would be actually a very
5 good starting point to see maybe you know different
6 motivation for reporting.

7 CHAIRMAN ALDERSON: It will certainly be
8 good for the general public to hear that message. We'll
9 have to be concerned about the fact that they will expect
10 it to happen by the next month or so.

11 (Laughter.)

12 CHAIRMAN ALDERSON: And you know that won't
13 be true. But I think it will be a good message.

14 Dr. Palestro wanted to speak.

15 MEMBER PALESTRO: Yes, just to say that I
16 agree with you Phil. I think it's better to be proactive
17 than reactive. And if the societies are not interested,
18 they'll tell us so.

19 And I also think that when in fact they are
20 interested, we'll try to identify topics that would be
21 germane to their societies. I think training and
22 experience is probably going to be germane to a lot of
23 societies. I think the technetium shortage, or the
24 potential shortage which it seems to come up
25 periodically, would be another hot topic for something

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1 like the SNMMI.

2 CHAIRMAN ALDERSON: Good, excellent.
3 Thank you.

4 Yes, Dr. Langhorst.

5 MEMBER LANGHORST: I just wanted to add one
6 other perspective to this discussion. I think it's
7 important especially in Agreement State licensees for
8 the ACMUI to promote our presence, in that we're an
9 advisory Committee for the NRC staff. But that doesn't
10 mean we only talk NRC.

11 And while it is frustrating to be able to
12 get information between NRC licensees and Agreement
13 States and all that, what we were discussing before.
14 The NRC is the driver of this bus. What they're
15 regulations say, are primarily what Agreement States
16 have to implement.

17 And so I would encourage that the promotion
18 of the ACMUI, and what we do, and why Agreement State
19 licensees need to know and be involved in, I think that's
20 really important.

21 CHAIRMAN ALDERSON: That is an important
22 topic, I agree. So if we in fact think that we should
23 be out there talking to at least the three societies that
24 were mentioned in our Commission presentation
25 yesterday, which are the physics, the AAPM, the Society

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1 of Nuclear Medicine, and the third was ASTRO I believe.

2 If we wish to move forward to get some ideas,
3 you know how far ahead meetings are planned. So it would
4 be probably very useful for us to have a representative
5 who was going to just you know on our behalf, approach
6 the organization and say, is there a place on your
7 program?

8 And you may find out that they'll say well,
9 yes sure, but not until you know 2018. But you know,
10 but we have to be out of there starting these
11 conversations in order for something to happen.

12 So it's pretty clear I think on the
13 Committee, that we have several people who would in fact,
14 be with the physics organization primarily. We have
15 several people who clearly are related to ASTRO. We
16 have other people clearly who are related to the Society
17 of Nuclear Medicine.

18 So it would seem that that might be a
19 starting place. But that isn't to suggest that other
20 organizations shouldn't also be approached if in fact
21 this effort moves forward.

22 So it would be, I think, helpful if Dr.
23 Palestro and Dr. Metter for example talked about how to
24 contact the Society of Nuclear Medicine.

25 If Dr. Ennis and Dr. Suh talked about how

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1 to approach ASTRO.

2 If Dr. Langhorst -- and many of you are
3 involved. Dr. Dilsizian also, the Society of Nuclear
4 Medicine, or cardiologic organizations for that matter.

5 And Dr. Zanzonico, Dr. Langhorst, think
6 about the physics organizations. And sort of pair up
7 and then decide how you'd like to approach the
8 organization? And then approach them.

9 Dr. Metter.

10 MEMBER METTER: Another important
11 organization I think is the American College of
12 Radiology because they do the majority of nuclear
13 medicine procedures as far as diagnostic radiologists
14 in the country.

15 And actually I was just appointed for the
16 next two years for the annual meeting, to be on the
17 Committee. And for the 2017/2018 meeting, they have our
18 annual leadership meeting in D.C.

19 CHAIRMAN ALDERSON: Yes.

20 MEMBER METTER: So --

21 CHAIRMAN ALDERSON: So will you approach
22 them for us, I mean?

23 MEMBER METTER: Yes, I'm on the Committee.

24 CHAIRMAN ALDERSON: Good, oh you are. So
25 I mean that's perfect. So please, ask them if they would

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1 be interested in such a session?

2 Yes, Mr. Ouhib.

3 MR. OUHIB: Yes, certainly let's not forget
4 the American Brachytherapy Society.

5 CHAIRMAN ALDERSON: Absolutely. Who do
6 you think might represent us there?

7 MR. OUHIB: Well, I'm the Chair of the
8 patient safety, so I could certainly push for that. And
9 we have done it with in the ABS. We have done this,
10 several sessions with NRC representatives in there.

11 But I think we need to have some sort of a
12 formal relationship there. And have it sort of like an
13 annual thing. That there is a session on, you know
14 regulatory and cultural safety and so on and so forth.
15 And I think that will improve. Yes.

16 CHAIRMAN ALDERSON: Dr. Zanzonico.

17 VICE CHAIRMAN ZANZONICO: This is just a
18 comment for NRC and for all of us as well. I think in
19 these presentations you really have to go to make an
20 effort to avoid citation of CFR numbers, and of
21 abbreviations. I've been to these presentations where
22 you are very knowledgeable people, and they just don't
23 speak in plain English.

24 It's all acronyms, abbreviations, citation
25 of as I said, CFR numbers so forth and so on. And I think

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1 you immediately lose a large fraction of your audience
2 and the people who are most needy of this sort of
3 information.

4 I mean I think these presentations to people
5 who are not really engrossed in the regulations need to
6 be very much in plain English.

7 CHAIRMAN ALDERSON: You're absolutely
8 correct. Absolutely correct.

9 Dr. Langhorst.

10 MEMBER LANGHORST: I just wanted to ask Mr.
11 Fuller. I think, do members of the medical teams serve
12 as liaisons to some of these organizations too?

13 MR. FULLER: Yes, that's correct. To some
14 of the organizations, and then you know as folks on our
15 team move on. Then we try to actually replace some of
16 those. To be specific, and I don't know that's it's
17 actually formalized, but I am very much involved on a
18 regular basis with both the American Brachytherapy
19 Society and with ASTRO.

20 We have a little bit more formalized
21 relationship with the AAPM. We have two folks that are
22 actually members. One of their Government Regulatory
23 Affairs Committee and one with the Therapy Physics
24 Committee. And then the Society of Nuclear Medicine,
25 Mr. Bollock, Doug, has been involved most recently with

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1 those folks and has made presentations and so forth.

2 So and we have team members, several team
3 members who are actually members of the Health Physics
4 Society as well as past members, who are members of the
5 Society of Nuclear Medicine and Molecular Imaging.

6 So to answer your question, I think I
7 covered a lot of them. I know I didn't cover everybody.
8 I might have missed a few but we work hard and try hard
9 to stay engaged and we have several people on the medical
10 team who wear multiple hats in that regard.

11 I would like to take this opportunity and
12 I'm just trying to poke fun a little bit here. Dr.
13 Zanzonico, I just made three presentations a few weeks
14 ago to the American Brachytherapy Society and I was
15 trying to be very careful to use plain language. But
16 I did remark that we've got nothing on the medical
17 community when it comes to acronyms.

18 (Laughter.)

19 MR. FULLER: I've actually attended many
20 sessions and I was taking so many notes so that on break
21 I could ask folks what does that acronym mean? Or what
22 are those initials for? And so I actually remarked in
23 one of my presentations that, I said to the audience,
24 I said, you folks got nothing on us. I said, I thought
25 we were bad. But it's true.

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1 I mean again, just in fun. We as any other
2 group, if you will, we do have our own jargon. We have
3 our own acronyms. And we have to be very, very mindful
4 of that and not just blurt out the initials as if
5 everybody understands what we're talking about. You're
6 exactly right.

7 CHAIRMAN ALDERSON: We have a comment at
8 the microphone.

9 MS. KUBLER: Hi, this is Caitlin Kubler.
10 I'm with the Society of Nuclear Medicine and Molecular
11 Imaging. I was just texting our education department
12 to figure out if we actually had a spot open for an ED
13 session of our upcoming annual meeting. And I will get
14 back to you with that.

15 But as far as governance updates go, we are
16 happy to do those at any time. And we would gladly
17 welcome an update from the NRC, especially since there's
18 so much going on with the training and experience
19 requirement issue, as well as Part 35.

20 I know Doug presented at our mid-winter
21 meeting. And we were very receptive and we were glad
22 that he was there to provide an update.

23 CHAIRMAN ALDERSON: Excellent and clear.
24 Delighted to hear that. Thank you.

25 Yes.

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1 MEMBER ENNIS: Just as a professional with
2 ASTRO, you know was really engaged with Mike as he
3 mentioned the last few years. We've got a relations
4 Committee that I'm involved in, and in the annual
5 meeting. And I think it's been very well received. I
6 know we had actually, Mike O'Hara also to talk about the
7 issues, which happens to be a lot of equipment issues
8 in that session. You know I got really a lot of good
9 feedback from it.

10 So I do think the membership you know are
11 interested in these things. And the more we do, the
12 better.

13 CHAIRMAN ALDERSON: Excellent.

14 Yes. Dr. O'Hara.

15 MEMBER O'HARA: To follow up on that.
16 ASTRO also had invited a few years ago, it had invited
17 the Commissioner of Food and Drug Administration to give
18 a plenary lecture at ASTRO. And ASTRO hid their concern
19 that the request for the Commissioner showed up, ended
20 up with me.

21 They held their, they were very gracious but
22 you could really tell that they were a little
23 disappointed --

24 (Laughter.)

25 MEMBER O'HARA: -- that the Commissioner

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1 wasn't standing there instead of me.

2 CHAIRMAN ALDERSON: Dr. Langhorst.

3 MEMBER LANGHORST: And I can understand
4 that because it's not just the talks or the lectures that
5 are given. It is the opportunity to mingle and interact
6 with people on a one-on-one basis, which I know is not
7 real effective at those booths. But that is an
8 opportunity not only for the societies to learn about
9 the regulators. But the regulators to learn about the
10 issues important. And what is on the minds of those
11 people, so.

12 CHAIRMAN ALDERSON: Absolutely.

13 We have another comment at the microphone.

14 MS. TOMLINSON: Hi, this is Cindy Tomlinson
15 from ASTRO. I'm guilty of inviting Dr. O'Hara and Mike
16 Fuller to our Government Relations Council Meeting last,
17 at our last annual meeting. We are working with Mike
18 Fuller to figure out ways of engaging our membership with
19 the NRC. And our annual meetings really are focused on
20 science and it's very hard for us to get folks to policy
21 type discussions.

22 So we are working on other ways to engage
23 with NRC. We will likely -- Michael O'Hara you're
24 learning this for the first time -- also engage with FDA
25 as well. But outside of our annual meeting. Sometimes

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1 it's just too difficult to get those things in.

2 CHAIRMAN ALDERSON: Absolutely. Well
3 that's the start of a fact finding that we'll discover
4 as we move forward with this initiative.

5 Yes, Dr. Suh.

6 MEMBER SUH: So one way to try to help with
7 awareness and communication, perhaps expectations as
8 well, is that actually to make change in any culture,
9 we're talking about the just, safety culture we were
10 talking about, and how do we -- the transparency through
11 to medicine is.

12 I think that one of the things to consider
13 is also to start at the grass roots of actually the
14 trainees, the residents. Because I can tell you during
15 my residency, I didn't even know that NRC really had any
16 impact in terms of what I would do in my career.

17 I had no idea of the ACMUI just until I
18 started getting these phone calls. Hey, John would you
19 like to serve on this Committee? So I think those are
20 the type of things which I think, just to help increase
21 that awareness. And I know there are several residents
22 which are actually very interested in policy.

23 I mean some of them have their MBAs and MDs.
24 So I think if they were aware that this is a potential
25 opportunity, just to increase the awareness. I think

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1 that would also be very effective as well because I think
2 just the transparency of sharing what type of medical
3 events have actually occurred.

4 And if that was shared with residents,
5 they'd think wow, I really need to pay attention to which
6 side of the brain I treat when I do radiosurgery. I
7 really need to pay attention to making sure I do a time
8 out, ask for their name, and their birth date before I
9 treat the patient.

10 I really need to you know pay attention when
11 I put in an applicator in a GYN patient, it doesn't slip.
12 I mean all these things if you read about it -- and I'm
13 just a big believer that the more you see, the more you
14 do, the more you hear, it becomes part of your habits.

15 I think that's where, I think as a Committee
16 -- I mean one of the valuable efforts we can provide to
17 our patients which is why we're here for, is to make sure
18 that we provide best care possible.

19 And I think we start from the grass roots
20 level of the residents and they're aware of it. And
21 they're saying, you know the NRC is not the enemy.
22 They're here to help facilitate. You know with your
23 education really to keep you out of trouble. I think
24 that would go a long way.

25 CHAIRMAN ALDERSON: Well John, I think

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1 that's the first time I've heard that idea. I think it's
2 a fascinating idea actually. I'm just trying to think
3 of the various ways one could approach it.

4 I'll ask you one follow-up question. Do
5 you think in that context, which would be, or is either
6 of these the correct answer? Would you think that you
7 would try to organize something like this, or approach
8 this through the Accreditation Council for Graduate
9 Medical Education, the ACGME? Through the American
10 Board of Radiology? How would you approach the
11 trainees?

12 MEMBER SUH: No, so I think you could use
13 that approach right now. I was thinking more of a grass
14 roots you know in radiation oncologists, called ARRO,
15 the American -- there's an association for radiation
16 oncology graduates.

17 CHAIRMAN ALDERSON: There is?

18 MEMBER SUH: They meet every year. They
19 meet this Saturday before ASTRO. And maybe a
20 possibility of approaching their leadership to say, we
21 would like to do just a very short presentation about
22 what the NRC does.

23 CHAIRMAN ALDERSON: Okay.

24 MEMBER SUH: What, how this may impact you
25 as you're talking about experience, we're talking about

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1 competency. Just let them start thinking about
2 competency. It's not, just because you finished a
3 radiation oncology residency does not give you perhaps
4 in the future, the right, or the authority to say, okay,
5 I'm going to go ahead and be the expert in this.

6 I mean it's flung with kind of
7 self-regulated as well. And I think that one of the ways
8 you try and keep yourself out of danger is to know what
9 your limits are. So if you've really not been formally
10 trained in procedure X, it's probably not a good idea
11 to say, okay, let me just watch a video and I'm going
12 to try this on this patient.

13 So I think there's multiple facets of how
14 to approach this. But one I think is to just increase
15 the awareness and I think now that -- when I read these
16 medical events I always scratch my head like, wow, this
17 is, I wonder why this happened? And if this was shared
18 more openly with the trainees I think it would be very
19 impactful.

20 Because they're like, that would never
21 happen to me. Well, look this has happened 20 times now.

22 CHAIRMAN ALDERSON: Right.

23 MEMBER SUH: So I think they'll start to see
24 that.

25 CHAIRMAN ALDERSON: I think that it's just

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1 a great idea. Potentially very impactful. I hope that
2 we can pursue this idea with you.

3 Dr. Metter, next and then --

4 MEMBER METTER: I think that's an excellent
5 idea. And most of these societies do have organizations
6 for trainees or young professionals. Like the ACR has
7 young professionals and the resident and fellowship
8 section. The Society of Nuclear Medicine has their own
9 group too.

10 And the other people I think, that is
11 another layer, would be the program directors. Because
12 they are their, quote, "parents during the training
13 period." And if you can get the idea of the safety
14 culture you know starting to happen. Then they'll say
15 well you know we're doing this to help with our patient
16 care. So it doesn't happen again.

17 And so I think like the Nuclear Medicine
18 Program Directors. It's a great organization and the
19 Association for Program Directors in Radiology, a large
20 group of people. And I think if the NRC comes to these
21 meetings, they can meet with those groups too. And so
22 it could be you know something that would be you know
23 more than one audience for that visit.

24 CHAIRMAN ALDERSON: Mr. Ouhib.

25 MR. OUHIB: And I think not only the new

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1 graduates will benefit from that, but even senior
2 practitioners. Because there are emerging
3 technologies coming. And we're seeing some errors
4 happening. So I think it would be great to have some
5 sort of refresher course per se. And update, you know
6 the organization about what's going on. What this
7 modality or what this technology, and so on and so forth.

8 And then you know, it's an opportunity to
9 sort of share what kind of errors are happening. And
10 how can these be prevented? Maybe there's some feedback
11 from the attendees. And so on. So it would be like a
12 discussion, not just simply a presentation type thing.

13 CHAIRMAN ALDERSON: Interesting. So as we
14 begin to expand and explore this idea, it's quite clear
15 that it has many tentacles moving out into various
16 different directions, valuable directions.

17 So I believe, that we have discussed the
18 idea of communication more or less in the abstract thus
19 far. I mean now we're really beginning to discuss how
20 we would get it done. And it seems that we're sort of
21 a Committee of the whole.

22 So that the question that I'm wrestling
23 with, please help me with it right now in this
24 discussion, is should we move ahead with our
25 communication initiative, which was well received by the

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1 Commissioners?

2 Should we move ahead with the communication
3 issue as a Committee of the whole? That is the whole
4 ACMUI is going to focus on this issue and work on it
5 together through our various societies. Or should we
6 actually appoint a Sub-Committee on communication,
7 which would require that there would be people on it who
8 basically represent different facets of the ACMUI? I'd
9 just like to have your advice on that question.

10 Dr. Zanzonico.

11 VICE CHAIRMAN ZANZONICO: Well I think it
12 would be most effective if the entire Committee was
13 engaged in it. Simply because by definition the
14 membership is defined to represent all different
15 stakeholder groups in the regulatory environment. And
16 we don't want to miss any by not including them on a
17 Sub-Committee. So I think if everyone was engaged that
18 would be the most effective way to go.

19 CHAIRMAN ALDERSON: Okay. Other
20 opinions?

21 Ms. Weil.

22 MEMBER WEIL: I hate to take over Sophie's
23 spot but I think that the entire Committee cannot act
24 except in a public forum, whereas a Sub-Committee can.

25 CHAIRMAN ALDERSON: Where did she go? Oh,

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1 there she is. You're hiding.

2 MR. BOLLOCK: I mean yes, so it would we
3 could probably --

4 CHAIRMAN ALDERSON: Technicality for
5 Sophie.

6 MS. HOLIDAY: Technically speaking, the
7 Committee, if you're taking on a full action, each
8 individual member is reaching out to their respective
9 organizations. That's fine.

10 It's just a matter if you guys are
11 deliberating on an item. An item that needs a vote, or
12 Committee consensus if you will, that's when we get into
13 the whole public realm type issues. That's a fact of
14 governance.

15 So it's here while we're in the room
16 discussing and Dr. Alderson put up a suggestion, or Dr.
17 Zanzonico put up the suggestion that we look at this as
18 a whole. That's saying that each individual member on
19 this whole Committee will go do something with their
20 respective organizations. That's fine. If all of you
21 agree, that's your public discussion.

22 You only need a Sub-Committee if I guess
23 you're doing a report, or you're putting up formal
24 recommendations. Something along those lines to NRC
25 staff, which will eventually end up as a vote from the

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1 full Committee, or an endorsement. In this case I think
2 what you're pursuing is absolutely acceptable.

3 CHAIRMAN ALDERSON: Mr. Costello would
4 like to comment.

5 MEMBER COSTELLO: If we were to meet as a
6 Committee in the whole, which I would recommend by the
7 way. And sometime down the line we want to have a
8 conference call where we've all discussed it. If that
9 were made public that wouldn't bother me.

10 You know, we have phone conferences that are
11 made public and I think that we are all candid and effect
12 during these phone conferences. And if we had
13 teleconference of discussing communications, it would
14 be public. That might even be a benefit. There might
15 be people who would learn something about our
16 communications effort by looking into our -- why to
17 anything would you want to keep an effort at
18 communication secret?

19 You know, we keep that laying in our bushel
20 basket. So maybe if we did, you know sometime
21 accomplish -- we're deliberating before we go forward.
22 I'd be happy to have the public see that, and think that
23 we're doing our jobs.

24 CHAIRMAN ALDERSON: Good. All right.
25 Now that's two opinions that we, that it is appropriate

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1 for us to look at this issue as a Committee of the whole.
2 And two opinions that that would be the right thing to
3 do.

4 Ms. Weil.

5 MEMBER WEIL: If we want to be nimble and
6 able to act in timely way, as a full Committee, then we
7 have to be aware that that kind of a public
8 teleconference requires notice in the federal register.
9 And you know there has to be, we just need to keep in
10 mind the process, which takes time.

11 CHAIRMAN ALDERSON: Yes, Dr. Ennis were you
12 going to comment on that point?

13 I would say that as we get this effort
14 started working as a Committee of the whole, that we
15 would just communicate with one another, rather than
16 have you know Committee Y, you know teleconferences.
17 And we would work on the individual sort of initiatives
18 that we discussed this morning. And then we'd come back
19 here and discuss them as part of our group meetings. So
20 that we wouldn't raise that particular technicality in
21 process.

22 Someone else had their hand up and I forgot
23 who it was. Yes, Dr. Ennis.

24 MEMBER ENNIS: This is for Doug, and Sophie
25 and others on staff. It sounds like we may be asking

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1 you to make a fair amount of trips and presentations.
2 Do you need us to say that in some formal way so that
3 you can go to your funders and say, hey, we need funds
4 to be able to carry out our requirements the ACMUI
5 expects us to do?

6 MR. BOLLOCK: It wouldn't hurt.

7 (Laughter.)

8 MR. BOLLOCK: And I envision all this
9 discussion and we are, I know I've spoken with the
10 medical team. And Mike and I have many discussions, and
11 discussions at the last meeting with Dr. Alderson. We
12 are 100 percent behind all this you know. We fully agree
13 with you. You know outreach is very important,
14 communication is important. And we have just amongst
15 ourselves planned and have been -- you know Mike's gone
16 out to ASTRO and Donna-Beth, and that's why I'll go to
17 FICA. It's another important outreach to get the
18 patient aspect.

19 I was at SNMMI two months ago. So we do you
20 know, plan on doing that and that outreach. But like
21 you said, it is, you know we do run on a budget. So our,
22 and funds are limited, and travel funds to get out there.
23 But we've with that, because you know we are right now
24 we're in a constricting budget environment in NRC. So
25 less and less travel funds.

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1 But we still have a plan I discussed with
2 the medical team, and my branch as a whole. Like we
3 still would get at least one person to each of the
4 meetings that is important to get out to. And that will
5 be our goal. And I can sell that to management. And
6 kind of as a whole, put that as a higher priority.

7 So you may not see, I may not be at the next
8 SNMMI meeting, but Said will be there. And he'll be able
9 to speak on all the topics, or you know Mike will go to
10 ASTRO. Sophie will be at HPS. So you know we will
11 still, we still plan to continue that. And be nimble
12 with our, conservative with our travel funds.

13 But any input that you can get to us. Any
14 other subjects or topics prior to these meetings that
15 are important, that you know you feel are important to
16 your community that we can speak on, we feel that's
17 greatly appreciated. Helps us deliver the message,
18 answer questions, be prepared.

19 And then kind of what like what Mike and I
20 call it, like just happen to ask the regulator, just a
21 chance for us to say, this is what we're working on. And
22 I think we have seen it you know be beneficial at SNMMI.
23 You know made them aware of training experience issues
24 that were going on.

25 Because it wasn't necessarily in the public

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1 forum other than you know the Sub-Committee was doing
2 their work and they're given the recommendations. But
3 there was a lot more going on behind the scenes. Not
4 just from the NRC, but the political pressure. And so
5 there are definite benefits. We see all the benefits
6 and we will strive and work to be able to do that as much
7 as possible.

8 So you know if, any recommendation, yes it
9 can't hurt to say well, you know help. We should be able
10 to fund this communication with whatever travel is
11 needed.

12 CHAIRMAN ALDERSON: So in front of the
13 Commission we mentioned three meetings. It for
14 example, but we mentioned three meetings. And so it
15 might be useful to go back to the funding side and for
16 the NRC, to say to us, well we think that in our current
17 fiscal year, the next fiscal whatever, we can afford each
18 year to go to three meetings, five meetings?

19 There are other ways to handle this problem.
20 Once you establish a communication pathway, then
21 probably at sometimes there can be one or two members,
22 usually two would be better of this Committee, who might
23 create you know a reasonable communication pathway with
24 another organization.

25 There's also all sorts of electronic

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1 mechanisms that can be brought to bear this day and age
2 in the right sort of facility, where if certain people
3 could be in present and others could be on a video
4 conference. But I think Dr. Langhorst comment was very
5 useful. It isn't just the session, it's also the
6 mingling and them getting to know you. And being more
7 comfortable.

8 So as much as we can in the early going, I
9 would hope that we'd be able to have a representative
10 who would be along there with a member of the ACMUI.

11 MR. BOLLOCK: And Dr. Alderson you hit it
12 right on. You know it may become where we have to kind
13 of one year go to, one year represent this meeting, the
14 next year this meeting. Hopefully we can get to the ones
15 that have the more, you know signs that we have, already
16 have very good relations with. You know those will
17 probably still go to every year. And we will work to
18 prioritize. And that's on us, and that's on me with
19 budgeting the staff and making sure.

20 And that's actually something that we have
21 to think about going forward. But we fully support and
22 we recognize the importance of it. And so does my
23 management. And so any support or any direction that
24 we can get from ACMUI and can help us with the message
25 back and forth, you know. Help us help you, help us.

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1 CHAIRMAN ALDERSON: Very good.

2 MR. BOLLOCK: We appreciate that.

3 CHAIRMAN ALDERSON: Dr. Langhorst.

4 MEMBER LANGHORST: I appreciate Dr.
5 Zanzonico's comment that he's learned a lot being on this
6 Committee. And from our profound comments by Mr.
7 Mattmuller, how it gets into your heart. So I wanted
8 to point out a resource ACMUI members have that staff
9 put together for us a couple years ago.

10 I asked that staff give a history of who has
11 served on ACMUI. I invite you to look at those lists
12 and have those people help you at your societies.
13 Because they know. They know already and I think they'd
14 be thrilled to help promote this too. So I just wanted
15 to point out that's on the website. And use that.
16 Because I think that's a very valuable tool.

17 CHAIRMAN ALDERSON: Good. Thank you.

18 MR. BOLLOCK: And if I could also, to go
19 back to a half an hour ago when we began this
20 conversation. Dr. Zanzonico brought up a good point
21 about you know, when we get new guides out. We do you
22 know, we try our best to pass on any new guidance as best
23 we can. We put out communications, send them out to the
24 States. And then the States are to pass it on to their
25 licensees. We sent out --, you know, mail out to our

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1 licensees.

2 We sent out medical List servers, something
3 that we highly encourage people. Anybody can sign up
4 I believe and that just, when we add something to the
5 medical List server, they'll get the update. And
6 they'll see that this new guidance is out, or what have
7 you.

8 So there is actually a lot of information
9 on the public website. Such as the information, Dr.
10 Langhorst is bringing up, and among many other things.
11 So that is helpful and you know I encourage you all to
12 communicate that out to your societies, to your peers.
13 And hopefully that will help. Because you know we
14 recognize there is only so much we can do.

15 CHAIRMAN ALDERSON: Right. So as we
16 promulgate this, it may be that you know we wind up in
17 the beginning, getting NRC people physically at the
18 meetings for the major societies. And not the ones not
19 as large, but hopefully eventually you'll get there.

20 So I want to go back to when we talked about
21 like who's going to contact whom? Because that's the
22 first step. You have to contact.

23 We've already heard some things. Because
24 we have people in the audience from SNMMI and from ASTRO.
25 So we've learned for example when you make a contact with

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1 ASTRO, that they want to meet, but they don't want it
2 to be at their scientific meeting. They want it to be
3 at a meeting of the government group. So that's
4 something with which we'll have to adjust.

5 In each case we ought to contact and find
6 out that we can make a schedule, yes this year, and this
7 is where it is. And maybe the Society of Nuclear
8 Medicine will say, they would rather have it at the
9 mid-winter meeting than the main meeting. Who knows?

10 Then the content, and in part they help
11 define the content. What, you know we say to them, what
12 is it? Here's some things we're thinking about, what
13 do you want to hear about? And then you begin to develop
14 a content that you know the audience is interested in.
15 And then you sort of create your educational or
16 communication objectives and then you get into the
17 details of how you're going to present it. And so on
18 and so forth.

19 So we've got to go through that particular
20 set of steps, so for ASTRO, Ron Ennis and John Suh were
21 going to be involved. And you've got this great idea
22 about the trainees, and please I hope we can pursue that.
23 And we don't know exactly where that's going to go yet.

24 For SNMMI Chris is going to represent us.
25 Darlene you can be involved there too, but you're clearly

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1 going to ACR and talk to them for us.

2 Who's going to AAPM? I don't have that
3 clear. Who --

4 MR. OUHIB: I'm a member of the AAPM of
5 course. And a member of the ABS by the way.

6 CHAIRMAN ALDERSON: Okay, so you would
7 contact them. And we've also heard from AAPM that they
8 may not be as interested in this as some of the other
9 organizations, but --

10 MR. OUHIB: But the clinical symposium is
11 a --

12 (Laughter.)

13 CHAIRMAN ALDERSON: She wants to make a
14 comment, Lynne Fairobent.

15 MS. FAIROBENT: Lynne Fairobent from AAPM.
16 Dr. Alderson, my point was not that AAPM isn't
17 interested. We already have a mechanism in place that
18 we have used successfully multiple times with NRC and
19 other federal agencies. And far as that goes, you did
20 hear from Mike for example, we have had historically NRC
21 staff as liaisons formally to our appropriate scientific
22 as well as our government relations Committee.

23 We have had the Chairman of NRC speak at
24 AAPM's meeting. We have had several office directors
25 and several staff. So it's not that we're not

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1 interested.

2 My point was that there are already
3 mechanisms in place for various societies. And that
4 those mechanisms should be what ACMUI or federal agency
5 staff work through. Not to create a new thing.

6 And as far as AAPM, I am the point of contact
7 for AAPM for any federal agency, for any issue. And that
8 was the point of my comment earlier.

9 CHAIRMAN ALDERSON: Okay, thank you. I
10 stand corrected. And Mr. Ouhib will be in touch with
11 you shortly. Okay.

12 So basically we'll work in this way with,
13 and there are other people here. Good people who
14 probably are related to other organizations and you
15 should be thinking also about what contact might be
16 there. But we have to watch out for that tendency to
17 sort of go from nowhere to all of a sudden we're reaching
18 out to 15 organizations. And then it just becomes an
19 overwhelming task. And the NRC can't quite keep up. So
20 we have to balance our enthusiasm with pragmatism.

21 Yes.

22 MEMBER COSTELLO: Phillip, since I'm a
23 member of the Committee, it's not addressed to the
24 medical practitioners. But I do update the
25 Organization Agreement States and activities of the

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1 ACMUI. Now for the most part, they're pretty familiar
2 with the regulations. But all these parties are
3 interested in what we do here.

4 I'm on the agenda every year, and I update
5 them on the many issues that you listed for the
6 Commission yesterday. And I do it every year.

7 CHAIRMAN ALDERSON: Good, great. Well I
8 think that we have a starting point. That is the point
9 of contact. We have already made some contacts and
10 learned some things. So in fact I would hope that the
11 people that we just talked about and named would actually
12 begin to make those contacts.

13 And then I would say that if you would work
14 through Sophie and myself, you know on how these things
15 are evolving. Just email us and so on and that should
16 suffice. And then we can see where we do from there.

17 And Mr. Fuller would like to comment.

18 MR. FULLER: Thank you Dr. Alderson. Mike
19 Fuller with the medical team. I just wanted to share
20 a little bit about my own personal experience with how
21 successful this can be. This is also very, very, this
22 communication, this two-way communication or this
23 effort to continually open up these lines of
24 communication is very, very beneficial to us when it
25 comes to specifically the emerging medical

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1 technologies.

2 If we follow a normal process, which means
3 a normal fulcrum or process, where we don't really know
4 about new technologies until someone applies for it. We
5 have, I mean there's no better way of saying it. We have
6 failed. Because we will be in the way. We will be the
7 deterrent or the obstacle.

8 So through these communications, and I
9 could give you many, many examples in the last few years,
10 where we have sort of under our own initiative, but at
11 the invitation of various professional societies -- and
12 I'm taking another opportunity because this is a public
13 meeting. The earlier that we know of something that's
14 in the pipeline or coming down the road, the better.

15 I can give you examples, I'm not going to
16 name names, but I could give you examples of how this
17 has been extremely successful in my opinion because I
18 found out about something at a national meeting. Simply
19 by going on the exhibit hall, and walking around, and
20 asking questions.

21 And then I could give you examples of where
22 we found out too late about something. And by the time
23 we got our, we kind of got up and running and got focused
24 on it, that perhaps the medical community could have
25 benefitted from the availability of this newer

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1 technology, or a new drug, or what have you, sooner.

2 So I just applaud this. I think we all on
3 the medical team and NRC staff would agree that there's
4 really nothing negative that can come from this
5 initiative. And I thank you for the effort and the
6 initiative.

7 CHAIRMAN ALDERSON: Thank you. Well I
8 think that we have a plan about how to move forward at
9 this particular time. Let's implement that plan.

10 We have actually run over our allotted time
11 for the open forum by just a few minutes. And Sophie
12 is prepared to provide some important logistic details
13 in what we call the Administrative Closing. But
14 remember we still have a very important session coming
15 up from Ester Houseman. So we still have some good
16 things to do here.

17 MS. HOLIDAY: Okay. So to follow-up from
18 my presentation yesterday. This is your second most
19 important presentation that you'll hear.

20 (Laughter.)

21 MS. HOLIDAY: And that is planning for your
22 next meeting which will be the fall meeting. And as we
23 stated that is typically held in September and October.
24 And then prior to this meeting I do send out a meeting
25 wizard to pulse the Committee on their availability.

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1 I am happy to say that all members said they
2 were available September 14th and 15th. I'd like to
3 confirm that that has not changed. It's very hard to
4 see. It's the very last page in your packet.

5 VICE CHAIRMAN ZANZONICO: Sophie, just
6 from the 6th through the 9th, actually through the 10th
7 is the World Molecular Imaging Congress meeting.

8 MS. HOLIDAY: Okay.

9 VICE CHAIRMAN ZANZONICO: And I'll be
10 there. But I don't know if other people will be there.

11 MS. HOLIDAY: Sure.

12 CHAIRMAN ALDERSON: The dates again,
13 Sophie that you were proposing?

14 MS. HOLIDAY: September 14th and 15th that
15 is a Wednesday and a Thursday.

16 MEMBER LANGHORST: So that is not a time I
17 can be here.

18 MS. HOLIDAY: Not for you.

19 MEMBER LANGHORST: And I think I said that.

20 MS. HOLIDAY: Okay.

21 MEMBER LANGHORST: There is a meeting in
22 St. Louis on moly-tech supply. And I really want to be
23 at that meeting.

24 MS. HOLIDAY: Okay. Then I stand
25 corrected, I think that's the only day that only had one

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1 conflict. Sorry, Dr. Langhorst.

2 MEMBER LANGHORST: That's okay.

3 MS. HOLIDAY: With that being said, that's
4 the only date that only had one person as a conflict.
5 So I think as it stands that might still be the
6 Committee's first choice. I know not preferable.

7 The only other options I had in yellow
8 although there some that Dr. Zanzonico said, the week
9 of the 4th is out of the question since there is a
10 conference going on that week.

11 I had responses for September 1st and 2nd.
12 And then October 6th and 7th, so I'll start with the
13 September 1st and 2nd. Does anybody have a conflict for
14 September 1st and 2nd?

15 (No audible response.)

16 MS. HOLIDAY: Okay. Likewise does anybody
17 have a conflict for October 6th and 7th?

18 MEMBER ENNIS: Those are my -- I think
19 Friday would be difficult for me. Friday is my wife's
20 birthday. If home for it. But I don't have --

21 MEMBER LANGHORST: Sophie, just to -- the
22 1st and 2nd that is the Thursday, Friday before Labor
23 Day weekend. But that's okay with me. And the 6th and
24 7th is before, in case anybody has that day off, Columbus
25 Day.

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1 MS. HOLIDAY: I mean you don't want to spend
2 your last few days before a holiday with me?

3 MEMBER LANGHORST: I have no problem at all
4 because your name is Holiday.

5 (Laughter.)

6 MEMBER COSTELLO: I think I just said to you
7 one day, but I can't recount now though. I forget what
8 my one day is.

9 MS. HOLIDAY: Okay. Dr. Langhorst if I may
10 ask, is your meeting on the 14th and the 15th, or just
11 the 14th?

12 The other option I had was September 15th
13 and 16th.

14 MEMBER LANGHORST: The meeting that I have
15 conflict with starts on the 11th and goes through the
16 14th.

17 MS. HOLIDAY: Okay. So that means there's
18 high likelihood that you'd not be able to make for the
19 15th and 16th meeting.

20 MEMBER LANGHORST: Not on time.

21 MS. HOLIDAY: Yes. Okay, so then it sounds
22 like we can either go with our first choice as September
23 1st and 2nd with a conflict for Dr. Ennis.

24 Or September 14th and 15th which is a conflict for
25 Dr. Langhorst.

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1 Or did anybody have an issue with coming October
2 6th and 7th? Understanding that that is Mrs. Ennis'
3 birthday weekend.

4 MEMBER ENNIS: I could leave early --

5 MEMBER LANGHORST: We could have Dr.
6 Thomadsen send her flowers.

7 (Laughter.)

8 MR. OUHIB: It's actually becoming
9 Mattmuller's responsibility to go.

10 CHAIRMAN ALDERSON: So what was, either of
11 these dates that you're talking about is fine with me,
12 but I didn't understand the discussion about the 15th
13 and 16th. Because your meeting ran from the 11th to the
14 14th, right, so?

15 MEMBER LANGHORST: Actually it goes
16 through the 15th.

17 CHAIRMAN ALDERSON: Oh, it goes through the
18 16th. I'm sorry.

19 MEMBER LANGHORST: The 15th, okay, sorry.
20 I was --

21 CHAIRMAN ALDERSON: I missed that part.
22 All right so that's fine.

23 MEMBER LANGHORST: I would prefer October
24 6th and 7th.

25 MEMBER LANGHORST: Sorry, but --

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1 MEMBER ENNIS: Okay if everyone would be
2 okay with me leaving at noon? And that works in my
3 personal area.

4 CHAIRMAN ALDERSON: And the meeting is
5 usually over in the early --

6 (Simultaneous speaking.)

7 MS. HOLIDAY: No, the fall meeting is our
8 longer meeting, since that's when we have all of our
9 annual required training such as ethics, allegations,
10 and information security. We can plan that for the
11 first day. So that you can meet your annual required
12 training. It's too early to kind of plan when the
13 meeting will actually end.

14 But given that we can plan around that, so
15 I guess with that being said. Perhaps our first choice
16 then will be October 6th and 7th for the Committee.

17 And then your second, your backup date would
18 you like that to be either Sept 1st and 2nd or September
19 14th and 15th?

20 CHAIRMAN ALDERSON: 1st and 2nd. I think
21 we should try to have Dr. Langhorst here.

22 MS. HOLIDAY: Okay. So then to confirm, I
23 have our first choice for the fall meeting as October
24 6th and 7th. And our backup date as September 1st and
25 2nd.

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1 Okay, so at this time I would like to go over
2 the new recommendations that were mentioned during this
3 meeting.

4 As you will see on the screen -- I will
5 provide this electronically and hard copies to the
6 Committee prior to your departure today.

7 Item 16 was not on there before, but since
8 Dr. Alderson mentioned it during yesterday's open forum,
9 this is when he formed the Sub-Committee to review and
10 evaluate the training and experience requirements for
11 all modalities in CFR Part 35.

12 Sub-Committee members include Dr.
13 Langhorst, Dr. Metter, Dr. Palestro as the Chair, Dr.
14 Suh and Ms. Weil.

15 Are there any comments or questions about
16 Item 16?

17 (No audible response.)

18 MS. HOLIDAY: Okay. Moving on, Item 17 and
19 18, and also Item 19 on the following page, have to deal
20 with the teleconference meeting that we had on last
21 Thursday related to the training experience
22 requirements for authorized users of alpha beta gamma
23 emitters and their 10 CFR 35.390.

24 Those items were not on your lists earlier,
25 so I've added them now that our meeting is in session.

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1 So Items 20 through 22, relate to the spring
2 meeting that we have had these past two days. Item 20
3 is the action item that Mr. Fuller suggested. That NRC
4 staff will provide data to the ACMUI for medical events
5 reported over a five year span, for training purposes.
6 And I will provide that data to you prior to the fall
7 meeting.

8 Item 21, Dr. Alderson formed a
9 Sub-Committee today to one, explore the impact of
10 medical event reporting and its impact on self-reporting
11 safety culture, if you will.

12 Two, identify potential ways to improve
13 effectiveness of self-reporting in support of a culture
14 of safety. And three, suggest ways to share any reports
15 and lessons learned with the medical community to
16 promote safety.

17 I'm sorry, I forgot to list the
18 Sub-Committee members.

19 CHAIRMAN ALDERSON: Dr. Langhorst is the
20 Chair. We certainly remember that.

21 MS. HOLIDAY: Dr. Langhorst is the Chair.
22 We have Ms. Weil. I believe we have Dr. Suh.

23 CHAIRMAN ALDERSON: I've got it, it's Sue
24 Langhorst as the Chair. Frank Costello is on for
25 States. Vasken, and Susan M is on for medical, legal

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1 whatever. Laura Weil is on, Ron Ennis is on. And Mr.
2 Ouhib is going to be a consultant at this time. That
3 is the membership.

4 MS. HOLIDAY: Excellent. Thank you.

5 Item 22 is that NRC staff will provide the
6 ACMUI with a draft final 35.1000 licensing guidance
7 document for the Leksell Gamma Knife Perfexion and
8 Leksell Gamma Knife Icon. Interested members will be
9 encouraged to provide comments to the working group,
10 understanding that it will be on an abbreviated time
11 schedule so that we can issue the guidance as early as
12 possible for the patient community.

13 The last item I believe, Item 23 is that Dr.
14 Langhorst requested that NRC staff provide the ACMUI
15 with the total number of medical use licensees within
16 the United States. This includes NRC and Agreement
17 States.

18 I did forward that to you guys during this
19 meeting. So that will be waiting on you in your email.
20 And since I did send it, I am asking if can close this
21 item as it is now sitting in your email in-boxes?

22 MS. HOLIDAY: Just to clarify, the document
23 that I provided breaks down all materials licenses
24 including industrial, medical, and academic. So that
25 document does include the data that you're looking for.

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1 So does anybody agree to my closing Item 23?

2 MEMBER LANGHORST: I'd like to just say I
3 want to see it before it closes. Sorry, I can't. I'm
4 not ready to do that instantaneously.

5 MS. HOLIDAY: Sure I can tell you that Ms.
6 Weil's pulled it up in your email. But it does include
7 the information.

8 MEMBER LANGHORST: I'd like to look at it
9 and think about it. So if you don't mind, I think that
10 we could close it next time.

11 MS. HOLIDAY: That's fine. I'll just
12 follow up at the fall meeting to say that I provided it
13 on the 18th.

14 MEMBER LANGHORST: That would be great.

15 MS. HOLIDAY: And then Item 24, obviously
16 not listed is that we have planned the fall meeting with
17 a first choice as October 6th and 7th. And your second
18 choice, or backup date as September 1st and 2nd.

19 CHAIRMAN ALDERSON: I think you should have
20 an item in here about this extensive discussion we just
21 had on how we're going to begin to implement the
22 communications plan.

23 MS. HOLIDAY: I didn't include it because
24 it, typically items that we include are items that staff
25 will be doing, or providing to the ACMUI and then if the

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1 ACMUI requests something from the staff, or a
2 Sub-Committee is formed, or a recommendation is passed.
3 If you do feel that this is an action item, and it should
4 be captured. I'm more than happy to add that.

5 CHAIRMAN ALDERSON: Well that's an action
6 item because as we make contacts and this effort evolves.
7 We're going to come back to you and to Mr. Bollock and
8 look for your availability to join us in this
9 implementation plan. So there will in fact be items for
10 the NRC. And there will be budget impact, although
11 modest, there will be budget impact.

12 MS. HOLIDAY: Okay, so then the action item
13 will be, the ACMUI will contact their respective
14 professional organizations for possible interactions
15 between NRC staff and ACMUI members with their
16 societies.

17 CHAIRMAN ALDERSON: Yes, that's fine. I
18 accept that.

19 MS. HOLIDAY: Okay.

20 MR. BOLLOCK: Can I just --

21 MS. HOLIDAY: Sure.

22 MR. BOLLOCK: As you know Lynne pointed
23 out, we already in a lot of cases, we do already have
24 a lot of conferences, right. So we can, we do have
25 contact information that work with us, ASTRO, SNMMI, so

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1 we do already have a lot of those contacts. So you don't
2 have to reinvent the wheel. Or --

3 CHAIRMAN ALDERSON: No, we won't. Right.

4 MR. BOLLOCK: So we'll provide you with
5 that, who we have just so that the ACMUI members are
6 talking to the same people that we talk to.

7 CHAIRMAN ALDERSON: And so the people who
8 are going to talk to those respective organizations, I
9 mean you need to be in touch through Sophie, with Mr.
10 Bollock, and work in particular way.

11 And the wording that Sophie just used was
12 sufficiently general and vague that it allows us to do
13 those sorts of things. That's the reasons for it.

14 MS. HOLIDAY: I think you have a comment
15 from Dr. Howe.

16 DR. HOWE: It's not about this one, but one
17 of the earlier ones --

18 CHAIRMAN ALDERSON: Microphone.

19 DR. HOWE: Not about this one, but one of
20 the earlier ones. I believe when you were, when I was
21 giving my medical event, that you wanted to see the five
22 year on --

23 CHAIRMAN ALDERSON: That was mentioned.

24 DR. HOWE: -- every time I give it.

25 CHAIRMAN ALDERSON: Every time you give it?

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1 DR. HOWE: Yes, and when I give it you want
2 to see five years. And then I go into the rest of it.

3 CHAIRMAN ALDERSON: That's correct.

4 DR. HOWE: Sophie was entertaining that it
5 was like a one-time thing that she would provide
6 information.

7 MS. HOLIDAY: I didn't define it as a one
8 time. I just said that they would have the data before
9 the next meeting.

10 It wasn't conclusive to say that they would
11 only be getting it at the next meeting and that would
12 stop.

13 DR. HOWE: So --

14 CHAIRMAN ALDERSON: It's assumption based
15 on the discussion we had when Mr. Fuller pointed out.
16 The word for something like this, well it might be a
17 little hard the first year, but once we get the data put
18 together it'll be really easy to do it year after year.

19 MS. HOLIDAY: Exactly.

20 DR. HOWE: So the expectation is every time
21 I give the medical data, I include that, not that I have
22 to do something separate for the fall meeting?

23 CHAIRMAN ALDERSON: That's right.

24 MS. HOLIDAY: That's correct.

25 DR. HOWE: That's fine.

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1 CHAIRMAN ALDERSON: That's good.

2 Yes.

3 MEMBER ENNIS: Mike Fuller had offered much
4 more than that slide gave us.

5 DR. HOWE: He had indeed.

6 MEMBER ENNIS: So I just want to be clear,
7 what we --

8 (Laughter.)

9 MEMBER ENNIS: Are you talking about giving
10 five years, or are getting you know decades worth of data
11 going forward.

12 MR. FULLER: The way I took the action, that
13 I read up there, is that we'll provide a minimum of five
14 years. How's that?

15 MEMBER ENNIS: Sounds good.

16 MR. FULLER: I want to give, what we want
17 to do is take a look at what we have frankly, and let's
18 provide you with the most meaningful and beneficial
19 information and data that we have. And present it in
20 a way that's most helpful. So at a minimum it will be
21 five years. And then we'll see what else we can do.

22 CHAIRMAN ALDERSON: Yes, I think as you
23 lengthen out the years, you sort of magnify the
24 denominator problem. And maybe five or six years
25 doesn't make a difference. But something that hardly

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1 anyone ever talks about when they talk about all these
2 issues going on in medicine, is we have about 30 or 35
3 percent more people in the United States like now, than
4 we had just 30 years ago. And it makes a big impact in
5 a lot of different ways.

6 So as you go out too long, then the
7 denominator problem becomes really complex. So I think
8 a minimum of five years is a very nice way to start. If
9 that's all right with you, Dr. Ennis?

10 Thank you.

11 MS. HOLIDAY: Thank you. Then that
12 concludes my administrative closing portion. This is
13 also our time and labor week. And generally I would have
14 sent you an email to tell you to give me your hours. But
15 since you're here, you may write your hours down on a
16 piece of paper. And we'll let you officially adjourn
17 the open session before our session this afternoon.

18 CHAIRMAN ALDERSON: All right. Are there
19 any other items, new business to come before the meeting
20 before we officially adjourn the open meeting?

21 (No audible response.)

22 CHAIRMAN ALDERSON: Hearing none, a motion
23 to adjourn. All in favor?

24 (Chorus of aye.)

25 CHAIRMAN ALDERSON: Thank you. We are

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1 adjourned.

2 (Whereupon, the above-entitled matter went
3 off the record at 11:37 a.m.)
4

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