

# **Official Transcript of Proceedings**

## **NUCLEAR REGULATORY COMMISSION**

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                              of Isotopes Spring 2016 Meeting: Open

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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

+ + + + +

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

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)

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

2 (8:01 a.m.)

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

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

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

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

20 MR. BOLLOCK: Thank you, Sophie.

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

25 So the audit objective was to determine

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1 if NRC's oversight of medical use of radioactive  
2 isotopes adequately protects public health and  
3 safety. So in order to do that, they spoke with NRC  
4 staff here at headquarters, NRC regional staff,  
5 agreement state staff, and a number of licensees.

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

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

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

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

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1 definition for the purpose of medical events.

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

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

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

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

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1       it on the medical list server, sent it out to everyone  
2       on the medical list server.

3               In the current rulemaking, we are  
4       planning on adding that in the statements of  
5       consideration for the current rulemaking. And what  
6       that will do is just update it from, essentially, from  
7       saying medical misadministrations to medical events.

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

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

22              So the second recommendation, with our  
23      second recommendation we have some medical event  
24      tracking trending initiatives. Essentially, we are  
25      allowing the access to the general public, as I said

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1 yesterday, access to the ACMUI medical event slides.  
2 So the slides that Donna-Beth provides once a year  
3 and then the ACMUI, in the second meeting, provides  
4 that back to us. Those are now specifically pulled  
5 out and provided on the public website.

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

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

23 And for the last recommendation, we have  
24 updated our policy and procedures that related to our  
25 work with the ACMUI. So our Policy and Procedures,

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1 2-5, basically it didn't need any updating, because  
2 that is how we make a decision on what to include,  
3 basically major medical policy to include ACMUI but  
4 Policy Procedure 6-15 is how we actually implement  
5 our workings with the ACMUI.

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

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

16 All right, any questions?

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

19 MEMBER ENNIS: I have a few actually, if  
20 that's okay.

21 CHAIRMAN ALDERSON: Yes.

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

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1 MR. BOLLOCK: We considered, we did  
2 consider that, because we have the open, we go over  
3 the open action items list. Sophie goes over that.  
4 That's an opportunity to ask those questions. So we  
5 feel we do have that, or you have that opportunity to  
6 ask us questions there.

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

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

18 And some other things that we are actually, actually  
19 Mike and I were discussing this morning, not  
20 necessarily in regards to recommendations but just  
21 some of the staff actions. We may just take, five,  
22 ten minutes out of the ACMUI meetings and go over what  
23 staff has been working on because some of them are  
24 based on recommendations or may be tangentially  
25 associated with some of the recommendations from the

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1       ACMUI. That's something we plan to do. And that'll  
2       be more of the informal, you know, presentation during  
3       the ACMUI meetings.

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

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

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

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

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1 VICE CHAIRMAN ZANZONICO: Oh, not on  
2 this, not on the current question.

3 CHAIRMAN ALDERSON: Anything else on Dr.  
4 Ennis' suggestion?

5 (No audible response.)

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

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

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

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

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1       that is prevalent today?

2                   CHAIRMAN ALDERSON:   Yes.   Well, I think  
3       that's a very good question.   I don't think that --  
4       and I think it's a complicated question.   We're not  
5       going to answer it right now.

6                   MEMBER ENNIS:   No, no.

7                   CHAIRMAN ALDERSON:   It's probably a topic  
8       for a future meeting.

9                   MEMBER ENNIS:   Yes.

10                  CHAIRMAN ALDERSON:   Does anyone want to  
11       comment on that before we move on?

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

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

22                  CHAIRMAN ALDERSON:   Good.   All right,  
23       very good.   And we'll certainly consider that.   Yes,  
24       Dr. Langhorst?

25                  MEMBER   LANGHORST:       I   know   a   few

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1 Commission briefings ago Dr. Thomadsen was talking on  
2 safety culture. And I was also bringing up the idea  
3 of how NRC can support or undermine a licensee's  
4 safety culture.

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

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

22 Now, maybe if there are repeated problems  
23 there's another path you have to take. But can it be  
24 in a way that, yes, we need this information, we'd  
25 like to share as much, and maybe we could share it

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1 with the community and not necessarily name names but  
2 give the instance of what's happening, what led to  
3 it, how you fixed it, and what the results were.

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

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

14 MEMBER COSTELLO: And all the persons who  
15 work at the NRC.

16 CHAIRMAN ALDERSON: Yes.

17 MEMBER LANGHORST: That's why I said  
18 regulators, sorry.

19 MEMBER COSTELLO: That's right. Whatever  
20 percentage they said yesterday of licensees that  
21 belong to the Agreement States and the approaches  
22 taken by the Agreement States are not uniform with  
23 each other. In fact, NRC regions aren't always  
24 uniform with each other.

25 It is a very important point, Dr.

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1       Langhorst. And maybe if we do a subcommittee or  
2       something to look into it, if it had recommendations  
3       that go beyond the language of the purpose of the  
4       medical event, and if you go into all that you talked  
5       about, you know, perhaps some of these could be  
6       anonymous as far as, because of the public.

7                   But I've heard the same thing from  
8       licensees in our State that they don't mind reporting  
9       at all. But the idea of associating their institution  
10      with a mistake they believe is a deterrent.

11                  Now, when they tell me that there's very  
12      little solace that I can give them. I can't tell them  
13      they don't have to report, and I can't tell them we  
14      can make them anonymous. Because that's not how it  
15      is. You know, we get the report, we give it to NRC,  
16      and the process moves on.

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

25                  CHAIRMAN ALDERSON: Yes. Dr. Dilsizian?

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1                   MEMBER DILSIZIAN: Yes. I just wanted to  
2 bring the clinical stress when these things happen in  
3 medical misadministration.

4                   The first thing we actually do, besides  
5 thinking about the NRC, is call our legal counsel.  
6 So just to let you know, that we, you know, while  
7 this, you know, the culture of safety is an  
8 interesting concept. But the stress on the  
9 clinicians, and the patient, and the hospital, and  
10 legal counsel is parallel if not more stressful.

11                  And so if NRC, in any way, can soften  
12 these misadministration concepts that we should be  
13 reportable but not necessarily a medical/legal action,  
14 it really may help the physicians to report them. I'm  
15 just letting you know that it's not just the NRC, it's  
16 the other aspects of the medical/legal.

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

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

6                   You know, fortunately for us in the NRC,  
7                   you know, we have our regulations. If you're not in  
8                   compliance with a regulation then, you know,  
9                   essentially you have a violation. But it's not a,  
10                  it's legally binding to an extent, but it's not the  
11                  same things that, you know -- we understand you have  
12                  other concerns that aren't -- our concerns is not,  
13                  you know, we're not directly affecting this, well,  
14                  but we are affecting it because of the regulations.

15                  So we understand that. And we are  
16                  sensitive to that. And a lot of the efforts going  
17                  through the whole, you know, our process of we  
18                  license, we inspect and we enforce, and going through  
19                  that, we try to enforce such an inspection, and by  
20                  that the enforcement through performance base.

21                  And how our structure works and how, you  
22                  know, we understand the good safety culture, and this  
23                  is a good safety culture going not just from the NRC  
24                  reactor side. We've got a good hold on that. But if  
25                  you look at safety culture across any industry, any

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1 field, professional field, there are consistencies of  
2 good safety culture. And we do understand that.

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

8 But, because like you said, there are  
9 other aspects that you have to consider. We have to  
10 be open to that. I think we are, you know, we as the  
11 medical staff. And we can communicate that to our  
12 management. And I think, with your help, we can get  
13 the implementation to get it to work at the best way.

14 So, you know, my main points are the  
15 purpose I don't think is going to change. But you  
16 can help us with the implementation to help minimize  
17 those crossovers that cause other unintended issues  
18 from our part while still working together to get,  
19 you know, to get the good information out so that we  
20 can prevent it. And other licensees can, you know,  
21 it can prevent them from having these events occur  
22 and, at the same time, you know, promote a good,  
23 healthy safety culture.

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

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1                   MR. OUHIB: Yes. I think this is a great  
2 initiative. And let me go back to the purpose again.  
3 So what mechanism is in place currently to actually  
4 inform the users? And that is whether they are NRC  
5 States, I mean, NRC-regulated States or Agreement  
6 States.

7                   And the second is how many cases will it  
8 take to actually identify that this needs to go to  
9 users? Is it two cases, is it three cases, similar?

10                  And then the other item is that unless  
11 the information is accurate, it doesn't serve any  
12 purpose. So that means there is, like we talked  
13 yesterday, there is work that needs to be done on both  
14 sides of the aisle. There's from the regulators,  
15 perhaps education and training, and then from the  
16 users, them also.

17                  That information is really crucial. And  
18 why is it crucial? Here's why. We're trying to help  
19 and assist others. This is not because we want to  
20 get to the nitty gritty. You could help us prevent  
21 something. And that's from both parties, that is the  
22 regulator and the end user.

23                  MR. BOLLOCK: So the different levels,  
24 first the reporting, the reports that come in, they  
25 are publicly available on our website. So, I mean,

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1       that's a good and bad thing. But that's one level to  
2       get, one step to get that an event happened.

3               And so that information is available for  
4       other licensees, and regulators, and whomever to see  
5       that and say, okay, well, this happened and hope, you  
6       know, someone with a good, whatever you call it,  
7       quality assurance program, what have you, would look  
8       at that and say how can we make sure that this doesn't  
9       happen to us.

10              When we see -- one of the other things  
11       that we do is we evaluate. Because we get all the  
12       event reports that come in. We evaluate for a trend.  
13       If we see a trend or a number of issues or issues that  
14       are significant, like, that we feel are very safety  
15       significant, there could be a high impact, we have  
16       generic communications. It's one of our avenues.

17              So we would take the information that we  
18       learned from an event or a series of events and share  
19       that in a generic communication. There's different  
20       levels of generic communications.

21              The first one is an information notice.  
22       And that simply is just here's the information we have  
23       from what has happened, and here is what you can learn  
24       from it. And it's just a, you know, it's just  
25       information. There's nothing that is a requirement

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1 on any licensee.

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

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

12 CHAIRMAN ALDERSON: Dr. Langhorst?

13 MEMBER LANGHORST: To answer your  
14 question, Dr. --

15 MR. OUHIB: Zoubir.

16 MEMBER LANGHORST: Zoubir. One, you can  
17 learn something from one event, because it may be very  
18 valuable for your license. So I would say, you know,  
19 if you could just give it for all of them, and you  
20 have that consistent information, and full and  
21 accurate information, that would be great.

22 Mr. Bollock, I just want to say that a  
23 safety culture is not a thing that you write down and  
24 then you say, okay, now we're all going to follow it.  
25 It doesn't happen that way. And I know you appreciate

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1       that. It is a living, breathing thing. And it's  
2       based a lot on trust.

3                   And so trust you have to build. And it  
4       can go like that. And when there's a mistake, you  
5       have to work hard on the trust that, yes, I can bring  
6       this forward. And everybody agrees, yes, boy, we're  
7       really sorry this happened. What can we do for this  
8       instance, what can we learn, and how do we apply it  
9       every place else so that we can get that valuable  
10      lesson?

11                   I know licensees do that right now with  
12      the information that NRC puts out. I'm not aware of  
13      any Agreement States being able to put out like  
14      information. But that's helpful for my users to say,  
15      hey, this happened over here. You might look at it  
16      and see what we can learn from it.

17                   I just would like the NRC to be open, and  
18      I know Agreement States too -- when I say NRC, I mean  
19      everybody, sorry, Frank -- that we continually talk  
20      about this. And because medical use is different, it  
21      may require a little different perspective on that  
22      give and take between the regulated folks and the  
23      regulators.

24                   So it's an area that I think we want to  
25      explore. I think it will be very helpful to all of

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1       our patients. And I just cheerlead and encourage  
2       everyone to be involved in it. Thank you.

3                   CHAIRMAN ALDERSON: Yes. Ms. Weil?

4                   MEMBER WEIL: I totally agree with what  
5       Dr. Langhorst is talking about. And it devolves down  
6       to, you know, the inspector, the person who interacts  
7       with the licensee.

8                   And something that NRC and States could  
9       do is to train those folks to enforce that those folks  
10      promote this kind of a culture which is not blame,  
11      which is not punitive, hopefully, which is not  
12      negative in any way but rather that there's a positive  
13      spin. We're here to help you, we're here to help  
14      others. And I'm sure that that's not how many  
15      inspectors approach their jobs.

16                  MR. BOLLOCK: And that is a very good  
17      point. And we do, like I said, you know, we do  
18      promote, as an agency, that performance base. So,  
19      you know, we are supposed to give credit for licensees  
20      that identify the issue and correct it. And, you  
21      know, that's how we're, I mean, that is the push for  
22      the NRC.

23                  But you're right, it gets down to the  
24      individual inspectors, whether they're an NRC regional  
25      inspector or they're a State inspector. And then

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1 along with that though is when we do see a non-  
2 compliance with a regulation, you know, we have an  
3 obligation to identify it. But then what do you do  
4 with it?

5 MR. BOLLOCK: Right. Right. And there  
6 are, and now it gets to levels of enforcement, and  
7 follow-up action. And this is something that, you  
8 know, can be evolving. You know, it's evolved on the  
9 other side of the, on the reactor side of the house.  
10 It's evolved.

11 We went from completely compliance-based  
12 to the performance-based. They have -- the reactor  
13 oversight process has changed from purely traditional  
14 enforcement to where you look at significance. And  
15 they've got, you know, for violations, they have non-  
16 cited violations.

17 It's basically you get a finding, they  
18 correct it, and that's it. It's in a report, it's  
19 publicly available, but there's no civil penalty, you  
20 know, at that point no potential civil penalty. It's  
21 just a very cut and dry, here's your violation, here  
22 it explains it. They have to take action to correct  
23 it, and we're done. And, you know, like I said,  
24 that's really the way the agency as whole is moving  
25 towards.

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1                   And we do, we do train our inspectors.  
2                   We do, you know, try to promote that for everyone.  
3                   So, you know, we'll continue to do that, and hopefully  
4                   that will help. But there is still, you know, at the  
5                   end of the day, if there is a non-compliance we will  
6                   take some action.

7                   You know, whether it's just a report that  
8                   has a, you know, a severe Level 4 finding, you know,  
9                   with no civil penalties, but it's still in a report.  
10                  It's still publicly available. And that, in itself,  
11                  could have consequences in the medical community, you  
12                  know.

13                  But we understand that we have to work.  
14                  And this is why, you know, evaluate changing medical  
15                  events and what it takes and, you know, the aspect  
16                  from the medical community, we appreciate that you  
17                  all bring that to us.

18                  CHAIRMAN   ALDERSON:        There's enough  
19                  interest around the table that I think that we should  
20                  form a subcommittee on this particular issue and  
21                  follow it. And I don't think that, although I see  
22                  other hands up now, I mean, we could discuss this the  
23                  rest of the morning, but I think we shouldn't do that.

24                  We should, in fact, have a subcommittee.  
25                  And then we should make it our business during the

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1 off times to get together and move this issue forward.  
2 I think that, Frank, you should definitely be on that  
3 committee because of the State's issue. Vasken, you  
4 were interested in the medical/legal side. Mr. Ouhib,  
5 would you like to join that committee? I'd like at  
6 least a couple of other people. Who else would, would  
7 you like to be on that, Sue? Okay.

8 MEMBER LANGHORST: Can we also, because  
9 this is not the ACMUI members' issue, it's also an  
10 NRC staff issue. So I would like a few NRC staff to  
11 be helping us.

12 CHAIRMAN ALDERSON: I think that's a  
13 great idea. And --

14 (Simultaneous speaking.)

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

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

20 MEMBER LANGHORST: No.

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

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1 MEMBER LANGHORST: I would be so honored.

2 (Laughter.)

3 CHAIRMAN ALDERSON: Wonderful. So we  
4 probably need one more person on this subcommittee.  
5 Who else has a passion?

6 CHAIRMAN ALDERSON: All right. So I have  
7 five right now. I have you as the chair, I have  
8 Frank, Vasken, Dr. Ouhib and Laura. Is that -- Dr.  
9 Ennis?

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

11 MEMBER LANGHORST: Yes.

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

13 CHAIRMAN ALDERSON: Doctor -- yes,  
14 absolutely. So Ron Ennis, so you have six. That's  
15 the committee.

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

18 CHAIRMAN ALDERSON: Only have five?

19 MR. BOLLOCK: Right.

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

22 CHAIRMAN ALDERSON: That's because of the

23 --

24 (Simultaneous speaking.)

25 MR. BOLLOCK: Yes, we --

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1                   CHAIRMAN ALDERSON:    That's because Mr.  
2    Ouhib isn't a member yet.

3                   MR. BOLLOCK:    Yes, because Mr. Ouhib is  
4    not a member yet.

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

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

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

21                  MR. BOLLOCK:  We'll support.  But I just  
22   want to make sure we understand so I know how best to  
23   support what specifically this subcommittee is going  
24   to be.

25                  CHAIRMAN ALDERSON:  Well, the charge that

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1       you all have been talking about is this culture of  
2       safety and how to get there. And so we'll rely on  
3       Dr. Langhorst to look at the whole issue of medical  
4       events.

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

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

17                    CHAIRMAN ALDERSON: Right. It's  
18      application, implementation that's --

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

24                    CHAIRMAN ALDERSON: So I think that's  
25      actually a very good approach. One could take a very

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1 superficial kind of theoretical approach and probably  
2 finish that report in the next 20 minutes.

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

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

14 MEMBER COSTELLO: One more question.

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

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

21 I think maybe it's something you need to  
22 talk to your legal people about. But I think that  
23 could be a colossal step forward. And I know I hear  
24 from my licensees. They don't mind reporting to us  
25 really at all. They don't want to see it on the cover

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1 of the Philadelphia Inquirer, okay.

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

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

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

17 MR. BOLLOCK: Correct.

18 CHAIRMAN ALDERSON: -- should look at.  
19 So we'll proceed with that. Let's move on to a new  
20 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,  
25 that's exactly right. Okay. Next topic, wherever we

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1 are, Mr. Bollock. Go ahead.

2 (Laughter.)

3 MR. BOLLOCK: Next up is Sophie Holiday  
4 and 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  
7 Holiday, and I work with the medical radiation safety  
8 team.

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

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

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

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

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1       newest gamma knife model, the Icon.

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

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

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

24                      So for our working group, there were four  
25      members, Eric and myself are the co-chairs. Eric is

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1 from the State of Kentucky. And I'm here from NRC  
2 headquarters. Our other members were Michelle  
3 Simmons from NRC's Region IV and Ms. Debora Vail from  
4 the State of California.

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

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

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

23 And that includes this cone beam computed  
24 tomography scanner and this intra-fraction motion  
25 management, or what Elekta is now calling their high

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1 definition motion management. And that allows the  
2 system to work without the frame being rigidly  
3 attached, without a frame at all and with no rigid  
4 attachment to the patient.

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

13 Right here you see a more close-up view  
14 of that. And this was borrowed from Elekta's  
15 presentation.

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

25 And this kind of shows that. I know

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1       that's hard to see, but what that shows is kind of  
2       what the user gets from the system, from the  
3       monitoring system.

4               So the picture on the right, you can see  
5       the red line on the little screen. When the relative  
6       motion exceeds that threshold, that's when therapy is  
7       paused, until they basically reset and movement stops.  
8       And they can resume the therapy. And it monitors  
9       continuously. And it's kind of interesting.

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

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

24              Because now if you have areas that may be  
25      close to areas that you don't want to give an excessive

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1 radiation dose to, you can break that therapy up into  
2 multiple fractions and thereby reduce the dose to  
3 surrounding tissue.

4 MS. HOLIDAY: Okay. So moving on to an  
5 overview of the licensing guidance. I would like to  
6 start by saying members on the Committee were provided  
7 with the licensing guidance when the working group  
8 completed its work in January of this year.

9 So what the working group decided to do  
10 was to create a single licensing guidance document  
11 that merged both the licensing commitments for the  
12 Perfexion unit and the Icon unit. And as such, the  
13 working group attempted to marry the guidance such  
14 that all the requirements for the Perfexion unit are  
15 applicable to the Icon unit.

16 This does not apply to licensees who have  
17 a Perfexion unit but are not upgrading to the Icon  
18 unit, meaning that they are just retaining their  
19 Perfexion unit as is. They do not have to do anything  
20 to amend their license.

21 But if they are licensees who do want to  
22 upgrade their unit to the Icon unit, meaning they get  
23 the cone beam CT, and the IFMM or the HDMM system,  
24 and the thermoplastic frameless mask, then there would  
25 be additional requirements for the Icon unit. But as

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1 Eric stated, the Icon unit can use both the  
2 stereotactic frame and the frameless mask option.

3 Our guidance also incorporates, as you  
4 heard from Katie's presentation yesterday, general  
5 formatting and language that is included in all  
6 35.1000 licensing guidance documents that were issued  
7 after 2013.

8 So what is the current status of our  
9 35.1000 guidance? As I stated, we provided the  
10 guidance to the ACMUI. And I would like to note that  
11 typically NRC gives the ACMUI 60-days to review and  
12 comment on our license guidance document.

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

23 So thank you to the ACMUI for  
24 accommodating this. So we were able to get the  
25 guidance out to the Agreement States and the regions

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1 ahead of time so that we would be able to, again, meet  
2 the needs of the patient community.

3 We did receive some comments from an ACMUI  
4 member, so we do appreciate those comments. And the  
5 working group is also resolving your comments, Dr.  
6 Langhorst.

7 So in February, just last month, on  
8 February 22nd, we provided the guidance to the NRC  
9 regions for a 30-day review comment period. We also  
10 sent the guidance to the Agreement States on February  
11 25th, just a few days later, for their review and  
12 comments.

13 Currently, we have received maybe three  
14 or four sets of comments. And we've already begun to  
15 review and respond to those comments.

16 Once the working group resolves all of  
17 the comments, in approximately three to four weeks,  
18 the guidance will have to move through the general  
19 concurrence scheme, meaning through management and  
20 legal counsel review.

21 With that, we expect the guidance to be  
22 issued in early summer of 2016. I would also like to  
23 note, as I said earlier, we pursued a very aggressive  
24 schedule with developing this license guidance  
25 document.

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1                   Typically, working groups that are  
2 assembled to address 35.1000 guidance documents take  
3 between six to nine months alone to develop the  
4 guidance. Then when you factor in the ACMUI's review,  
5 review from the States and NRC staff, it can tack on  
6 an extra three to four months. So I will pat  
7 ourselves on the back. We were able to get this out  
8 in just a fraction of that time.

9                   So at this time we would like to open it  
10 for any questions.

11                  CHAIRMAN ALDERSON: Excellent report,  
12 administrative efficiency, congratulations on that.  
13 Are there comments?

14                  VICE CHAIRMAN ZANZONICO: I just have a  
15 general question first. How common is an NRC/OAS  
16 working group in drafting guidance? My perception is  
17 that typically it's an NRC only working group. Is  
18 that not the case?

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

22                  VICE CHAIRMAN ZANZONICO: And then a  
23 technical question. So there's an onboard cone beam  
24 CT. Is that what is used for the simulation? I mean,  
25 I'm ignorant about the technology. So I don't know

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1 if they do the equivalent of a simulation for this or  
2 not.

3 MR. PERRY: What they do with the cone  
4 beam CT scanner is that allows them to ensure the  
5 patient is positioned properly and can be put in a  
6 position relative to the focal point. And the focal  
7 point lies at the coordinates of 100, 100, and 100 in  
8 the Leksell coordinate system, which is relative to  
9 the machine. That allows them to position the patient  
10 so that that focal point is properly positioned  
11 relative to the treatment volume.

12 I believe in the past, and I'm sure Dr.  
13 Suh is much more familiar with this than I'll ever  
14 be, but they would attach the frame to the patient's  
15 head, make use of a fiducial box and an MR scanner to  
16 properly do that transformation. This allows them to  
17 do that transformation essentially at the machine just  
18 prior to therapy.

19 VICE CHAIRMAN ZANZONICO: So how would  
20 the -- but this isn't used to define the target volume,  
21 right?

22 MR. PERRY: No.

23 VICE CHAIRMAN ZANZONICO: No, that's done  
24 by more conventional simulation?

25 CHAIRMAN ALDERSON: Dr. Suh?

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1                   MEMBER SUH: So in terms of the essential  
2                   difference between the Icon and Perfexion is you now  
3                   have onboard imaging. So from a clinician standpoint,  
4                   you're going to have greater confidence. And what  
5                   you see on the computer screen is what you're actually  
6                   going to treat.

7                   So it actually takes into account what  
8                   the traditional generation oncology -- what they  
9                   learned excel our base system. For many years now,  
10                  we've actually had cone beam guidance where, before  
11                  we treat, we image the patient, then we go ahead and  
12                  treat the patient.

13                  With gamma knife, we've always gone under  
14                  the assumption that, with the frame in place, that  
15                  the image that you obtained, say MR/CT scan and then  
16                  you do computerized planning, when you put the patient  
17                  into the machine, you assume that that positioning  
18                  was -- you have the same fidelity between what you  
19                  did before versus after computerized planning. This  
20                  actually will allow you to do it much more in real  
21                  time, right before you do the treatment.

22                  The other big advantage of the Icon system  
23                  is that you will be able to better adapt the plan.  
24                  So if you do some type of fractionated treatment and  
25                  you see shrinkage of the tumor, and you wanted to

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1 treat the patient a couple of weeks later or a month  
2 later, you can actually sculpt a radiation dose better  
3 than you can with the Perfexion system.

4 So it does have some advantages that  
5 should allow for better outcomes overall. I imagine  
6 you'd have more data for that, but that's what it will  
7 allow us to do.

8 VICE CHAIRMAN ZANZONICO: And all that  
9 can be done based on the cone beam CT?

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

15 CHAIRMAN ALDERSON: Dr. Ennis?

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

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

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1       --

2                   MEMBER SUH:    So the work flow can be a  
3       little different.   The big change in the work flow is  
4       going to be you can get the image values right before  
5       treatment.   But in terms of the, you know, if you want  
6       to use a frame placement, you know, that MR/CT, at  
7       this point it would be the same.

8                   VICE CHAIRMAN ZANZONICO:    So the cone  
9       beam is really more for verification in --

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

13                  VICE CHAIRMAN ZANZONICO:    For fraction.

14                  MEMBER SUH:    For more fractions.   Yes.

15                  CHAIRMAN ALDERSON:   Mr. Ouhib?

16                  MR. OUHIB:       Yes.       This is nothing  
17       different than what we have seen using a linear  
18       accelerator, basically.       We went through that  
19       transition basically this same way.   So, you know, we  
20       went from frame to frameless basically and using cone  
21       beam CT for SRS and the SBRT patient, basically.

22                  So really the whole purpose, as it was  
23       stated previously, is just verification that you are  
24       on target basically instead of relying on fiducial  
25       markers.   And things can happen with fiducial markers

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1 as we know. But I think having the image now, the  
2 level of confidence is much, much higher.

3 CHAIRMAN ALDERSON: Other questions,  
4 comments? Yes, Ms. Weil?

5 MEMBER WEIL: If this is indeed an  
6 improvement in technology, would it have prevented  
7 the medical events that Dr. Howe reported yesterday  
8 where the gamma knife had been serviced and the bed  
9 was misaligned? Would this preclude that, those  
10 errors?

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

15 MEMBER WEIL: There were eight of them,  
16 yes.

17 MR. PERRY: Well, it was eight patients,  
18 one event.

19 MEMBER WEIL: One event.

20 MR. PERRY: So that's kind of hard to  
21 answer. And remember that these changes to the design  
22 are more about the patient's position on the couch.  
23 You're still relying on the couch to properly position  
24 the patient relative to the focal point.

25 CHAIRMAN ALDERSON: I'll make a comment

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1 too, Laura, and this is strictly from the patient's  
2 point of view. If I'm incorrect about this, please  
3 correct me. But it's my understanding that one of  
4 the disadvantages of the previous version of the gamma  
5 knife is the need to wear this frame.

6 Patients do not like the frame. It hurts.  
7 And they will literally go to other technologies,  
8 drive a long way to not do it. So the Icon allows  
9 frameless. And that is a huge advantage for the  
10 patients.

11 MEMBER SUH: If I could just make a  
12 comment. So although for some patients the frame-  
13 based system can be uncomfortable and perhaps not be  
14 right for some patients, for some situations a frame-  
15 based system is going to give you more accuracy than  
16 a frameless system.

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

23 So that's where I think the advantages of  
24 having these very small focal beams of radiation being  
25 pointed to one area. So I think the frame-based

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1 system, although Icon will allow for a frameless type  
2 situations, I think there is always going to be a  
3 place where you do want to use a frame, just to  
4 emphasize that point.

5 MS. HOLIDAY: Absolutely. So to follow  
6 that up, as we were informed, the Icon, you are able  
7 to use both frameless and frame. So depending on the  
8 patient conditions, the physician will make the  
9 determination whether or not to pursue the framed with  
10 the bolts in your head, which of course I don't think  
11 is very comfortable for many people, or the  
12 thermoplastic frameless mask.

13 So you are able to use either/or. And  
14 depending on which mode you choose, whether you go  
15 with the frame or the frameless, that will reflect in  
16 the work treatment planning.

17 CHAIRMAN ALDERSON: Yes, good. Other  
18 questions or comments? Hearing none --

19 MS. HOLIDAY: So may I ask a question of  
20 the Committee? While we provided the Committee with  
21 the draft guidance and the subcommittee was not  
22 formed, can the Committee give us any feedback,  
23 although not going into the particulars of the  
24 guidance since it is pre-decisional and non-public?

25 Would the Committee endorse the guidance

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1 knowing that we will be addressing comments that I've  
2 received, that we've received from Dr. Langhorst?  
3 Would the committee consider doing that?

4 CHAIRMAN ALDERSON: So that question is  
5 before the Committee. Dr. Langhorst?

6 MEMBER LANGHORST: I would feel  
7 uncomfortable in endorsing it just because we didn't  
8 do a formal subcommittee review in presentation. Not  
9 that I am not personally endorsing it, I have  
10 questions on it.

11 I'd still like to see what the final  
12 version comes to. Because I was a little nervous in  
13 what it was, what the expectations were of Perfexion  
14 unit licensees who weren't necessarily changing to  
15 the Icon system.

16 MS. HOLIDAY: Okay.

17 MEMBER LANGHORST: So I would feel  
18 uncomfortable.

19 CHAIRMAN ALDERSON: All right. So that's  
20 one opinion. Mr. Ouhib?

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

24 CHAIRMAN ALDERSON: I'm going to suggest  
25 that we not form a subcommittee, but rather that those

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1 interested parties with that expertise who are members  
2 of the ACMUI be provided with copies so that they can  
3 review that. And then we can determine in the future  
4 whether, at that point, they might be willing to  
5 endorse. Yes?

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

9 MS. HOLIDAY: Absolutely.

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

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

19 MEMBER O'HARA: I would.

20 CHAIRMAN ALDERSON: Dr. O'Hara would like  
21 to get that.

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

25 CHAIRMAN ALDERSON: Very good. Okay.

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1 One final comment?

2 MEMBER ENNIS: Just a question, so I  
3 understand the process. Without this final document  
4 provided to NRC, are licensees able to actually use  
5 it? Or they can't even start using it until the NRC  
6 has provided the Agreement States with that  
7 information?

8 MR. PERRY: From the Agreement State  
9 standpoint, and I'll speak for my Agreement State, we  
10 would be very hesitant to amend a license or to issue  
11 a license for this unit without such guidance from  
12 the Commission. I know that that's not true of every  
13 Agreement State. And I believe that the NRC regions  
14 are not going to issue amendments prior to the  
15 guidance. And that comes from their management.

16 MS. HOLIDAY: So I know we all don't  
17 understand compatibility, but 35.1000 is a  
18 Compatibility D which basically means the Agreement  
19 States do not have to adhere to our guidance document.  
20 So we are aware of a couple of Agreement States that  
21 have already begun the amendment process to add the  
22 Icon to their licenses.

23 CHAIRMAN ALDERSON: So given that  
24 limitation on what has, up to this point, been a very  
25 efficient process, I would like to ask Dr. Langhorst

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1 and Mr. Ouhib that when you are provided with the  
2 guidance, I would like you to promptly respond  
3 indicating your support or your lack of that.

4 And because if support there, then in fact  
5 the guidance can be issued and the patients can  
6 receive the benefits of this technology.

7 MS. HOLIDAY: Absolutely.

8 CHAIRMAN ALDERSON: Yes?

9 MR. OUHIB: I have a follow-up question  
10 based on Dr. Ennis. What about the institution that  
11 actually is going to be using the frame? So there's  
12 really nothing that has changed, per se. They're not  
13 going to frameless. They're going to be using the  
14 frame.

15 MS. HOLIDAY: Are you referring to if  
16 they're not adding on the additional components of  
17 that, kind of --

18 MR. OUHIB: And the additional components  
19 --

20 MS. HOLIDAY: Just remaining as the  
21 Perfexion?

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

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1 MS. HOLIDAY: So this is actually a  
2 question that the working group had addressed early  
3 on, because it was a question that was brought up by  
4 the representatives in the back of the room.

5 And the working group did not feel  
6 comfortable with the notion of adding an Icon to  
7 someone's license and saying, you know, we know you're  
8 not going to use the frameless option, but you can  
9 install it anyway.

10 It kind of almost defeats the purpose of  
11 why the licensee would add the Icon. Because the  
12 whole, I guess, the beauty of getting an Icon is to  
13 be able to use either/or, frame or frameless. So it's  
14 kind of tricky.

15 There was a question, maybe if we held  
16 off on giving the licensee the thermoplastic mask,  
17 would that then be okay? But also from a license  
18 reviewer standpoint, it was too much of a burden to  
19 have to amend the license to add the Icon, to not use  
20 the thermoplastic mask, and then amend it again to be  
21 able to use it in its full functionality.

22 CHAIRMAN ALDERSON: Okay. So we are  
23 going to get the guidance distributed to the pertinent  
24 members of the Committee who will respond promptly.  
25 And are there any other comments before we close this

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1 topic? One final comment? I'm trying.

2 MEMBER ENNIS: I apologize for dominating  
3 the conversation. But is the manufacturer aware as  
4 soon as there are -- so I'm not quite understanding,  
5 but if the manufacturer's aware that users will not  
6 be able to use this without guidance being issued by  
7 the NRC, I guess it's a rhetorical question, but how  
8 is it that they weren't running to your office very  
9 early on to get that done so that things weren't  
10 delayed in the whole process?

11 MS. HOLIDAY: I can't speak for the  
12 manufacturer. Perhaps the manufacturer would like to  
13 speak for themselves. But I can't, you know, tell  
14 anyone to do that. So I'm sorry. I can't speak for  
15 them.

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

20 MS. HOLIDAY: Thank you.

21 MR. PERRY: Thank you.

22 CHAIRMAN ALDERSON: All right. Ms.  
23 Daibes, oh, Mr. Daibes. Dr. Daibes is going to talk  
24 to us about the Germanium/Gallium generator.

25 DR. DAIBES: Thank you. First of all,

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1       thank you for your time today. My name is Said  
2       Daibes. And I will be providing you an update on  
3       what's happening with respect to the  
4       Germanium/Gallium-68 medical generator.

5               And just to provide a fast overview, I'm  
6       going to be providing some very brief background. I  
7       believe that a lot of that information was provided  
8       during the ACMUI briefing of the Commission. And I  
9       will provide you a current status and the regulatory  
10      options that are pursuant.

11             So I think that one of the key aspects  
12      behind the generator that we're currently evaluating  
13      and working on is that it has been used in Europe now  
14      for a while. So there's quite a bit of data that  
15      supports its use.

16             And right now one of the biggest impacts  
17      is that there's a whole lot of data that outlines its  
18      use for new and recurring patients. So there's data  
19      and peer-reviewed data that supports that.

20             Right now, the FDA, as we heard yesterday,  
21      is currently reviewing an application. And it was  
22      provided to the Commission yesterday. So one of the  
23      biggest components of this generator is that it's  
24      needed in order to create the actual Gallium-68  
25      regulated pharmaceutical that will be used on

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1 patients. So a facility that is planning on using  
2 this regulated pharmaceutical will need some form of  
3 generator close by or access to it.

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

8 And why is a DFP needed? Well, basically  
9 the parent isotope, Germanium, is a very long-lived  
10 isotope, 270-days half-life. Being a long-lived  
11 isotope and being an unsealed radioactive material,  
12 triggers a DFP requirement due to the fact that, in  
13 Part 30 regulations, Appendix B, there's no defined  
14 value for Germanium-68. So automatically a 10  
15 millicurie limit is triggered or defaulted to, in that  
16 case triggering that DFP requirement.

17 Some people have raised concerns with  
18 respect to this DFP, and I believe everybody is aware  
19 in the committee, is aware of this. So I'm not going  
20 to go into details.

21 So what are we doing right now is that,  
22 well, we saw the issue, and we're pursuing multiple  
23 regulatory options that are currently available in  
24 our regulatory framework.

25 The first option that we have been

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1       undergoing and tasked with is a license-specific  
2       exception. And what is that? What is behind this?  
3       Well, it will be an exemption, it will be a specific  
4       option to accept the DFP requirement for a person that  
5       would like to apply for this.

6               So staff believes that the most efficient  
7       and effective way to provide this regulatory relief  
8       will be pursuant to this potential exemption.

9               And how will that be pursued? We're  
10      granting or we're working right now in the potential  
11      of granting an authority to the regions if a legally  
12      binding contract exists that will allow a licensee or  
13      a client, a person that requests this generator, to  
14      send it back to the distributor or the vendor that  
15      provided that generator to that person or licensee.

16              A document has been drafted and is  
17      currently being reviewed by management. So from the  
18      last ACMUI meeting, we provided you information that  
19      has changed. We informed you that we were pursuing  
20      that, but we have completed that. And it's currently  
21      under review.

22              The secondary option that supports that  
23      specific exemption under 35.19 is a potential direct  
24      final rule that we're currently pursuing a rulemaking  
25      plan on. And it's under evaluation by OGC right now.

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1       So what has changed since our last ACMUI meeting is  
2       that that rulemaking plan has been drafted, and right  
3       now we're under evaluation right now.

4               So the effort behind this direct final  
5       rule will be that it will potentially amend Appendix  
6       B of 10 CFR 35.35 to include that limit that does not  
7       exist for Germanium-68, disallowing -- or the new  
8       license, allowing that a licensee that accesses this  
9       generator would not trigger DFP requirement.

10              So we believe today that the planned  
11       action will be sufficient to ensure public health and  
12       safety until a more permanent regulatory solution is  
13       achieved through rulemaking. And that's currently  
14       under the process.

15              So any questions that -- and I'm sorry,  
16       before we proceed, first of all I want to appreciate  
17       the service of ACMUI to this effort. All of your  
18       guidance and information has been extremely helpful  
19       in making sure we can proceed with this, especially  
20       Mr. Mattmuller. Thank you for your guidance and help  
21       with this.

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

25              MEMBER MATTMULLER:    Yes, very encouraged

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1 by this development and very thrilled to see this  
2 happening. A couple of comments/questions for you.  
3 Can you explain to us the mechanics of how this  
4 exemption would work through the different regions?

5 DR. DAIBES: So that's a good question.  
6 So an analysis has been implemented or initiated,  
7 seemed to me, of a DFP for this specific case. So  
8 through this review or analysis, everything was broken  
9 down into components, details, to see if there's  
10 buried behind our need for this DFP for this case.

11 And that review or potential document,  
12 legal document, has been drafted that breaks  
13 everything into that very in-detail analysis. And  
14 what that allows the regions, if approved, it allows  
15 the regions to potentially exempt or exempt when a  
16 person files an application or files for access for  
17 this generator for the actual requirement of the DFP.

18 So it will allow flexibility to the  
19 region, at their discretion, if the licensee satisfies  
20 their requirement, to exempt that licensee from that  
21 requirement. And our branch chief would like to say  
22 something.

23 MR. BOLLOCK: Yes. To add to that, so  
24 basically when we get, you know, with the approved  
25 guidance to the regions, their license reviewers would

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1       then, following that, be able to allow a licensee to  
2       come to them with an exemption with the specifics that  
3       we talked about yesterday. The specifics being, you  
4       know, there are still limits to, even based on the  
5       ACMUI report recommendations, limits to how many  
6       generators, basically the amount of activity allowed  
7       and then also having that assurance that the  
8       generators, once they're expired or once they've been  
9       used, will go back to the manufacturer.

10                   And our Chairman of the NRC, you know,  
11       hit it right on the head. The lynch pin is that legal  
12       requirement, and how is that going to be withheld and  
13       how can the license reviewers ensure that that's in a  
14       license amendment?

15                   So, you know, the licensees would have to  
16       come requesting the exemption and prove that they have  
17       those specific things in their exemption showing that  
18       they meet those requirements.

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

23                   DR. DAIBES: If I may, so basically it  
24       will provide specific conditions for a license  
25       reviewer to be able to amend or basically to allow

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1 access for that licensee.

2 And it's real important to clarify that  
3 even though this may exempt the DFP, it will not exempt  
4 a licensee from financial assurance that is required.  
5 So the initiative is not to exempt financial assurance  
6 but the DFP component that is in the ranks.

7 CHAIRMAN ALDERSON: Dr. Langhorst and Mr.  
8 Mattmuller, together.

9 MEMBER LANGHORST: Essentially what  
10 you're saying is there would be a license condition  
11 for that licensee's --

12 DR. DAIBES: That's correct.

13 MEMBER LANGHORST: -- license that says  
14 you're exempt from this and whatever the stock  
15 language would be if they meet all those requirements.  
16 So they would have a specific condition in their  
17 license for this exemption.

18 DR. DAIBES: Yes, ma'am.

19 CHAIRMAN ALDERSON: Mr. Mattmuller?

20 MEMBER MATTMULLER: A comment, another  
21 question. In thinking about the Commissioner's  
22 comments yesterday, with further thought on it, it's  
23 really from a licensee's perspective.

24 We're the one that's going to require that  
25 they take it back. Because the alternative would be

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1 I've got stores to take care of it, which is a much  
2 bigger, complicated, expensive task than just boxing  
3 it up and shipping it back to the manufacturer.

4 So from a practical perspective, it's a  
5 minimal issue. Legally it has to be addressed. But  
6 there are some big reasons why everyone's going to  
7 want to send it back to the manufacturer.

8 My question would be what about, do we  
9 have to worry about a compatibility category for the  
10 agreement states when it comes to exemptions like  
11 this? And then -- yes.

12 DR. DAIBES: I believe not. However,  
13 that's something that will be brought to our OGC  
14 representative. And that person or OGC will define  
15 that when that's complete.

16 CHAIRMAN ALDERSON: Mr. Costello?

17 DR. DAIBES: We don't believe that's the  
18 case.

19 MEMBER COSTELLO: There are present  
20 exceptions though. Compatibility really only applies  
21 to -- I'm sorry. Compatibility really applies to  
22 rulemaking. So if you talk about exemptions, there's  
23 no meeting compatibility there.

24 I'm sure there'll be some letter to go  
25 out to the Agreement States, all the Agreement States,

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1 a letter explaining this. I think that States will  
2 not hesitate, really, if the NRC is, you know,  
3 recommending that we give exemptions to this. I'm  
4 confident that States will follow the NRC's lead here.

5 In fact, I remember, it reminds me of your  
6 presentation, you talked about John Jefferson's  
7 comment on it. And that came up in the context of  
8 them coming to us and asking exemptions for the -- At  
9 that time, we would have loved to give it to them,  
10 but we couldn't see a way clear to do it, you know.  
11 We needed to find a way to be consistent with the  
12 other Agreement States and with the NRC.

13 But I would not worry so much about the  
14 States following this. I'd be very surprised if there  
15 were States that would be not following it. But  
16 eventually we're going to do the direct final rulemaking  
17 which I think could --

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

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

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1 CHAIRMAN ALDERSON: Dr. Ennis?

2 MEMBER ENNIS: So what's the timeframe to  
3 have it, this exemption -- What's the timeframe for  
4 this exemption to be completely in place and available  
5 for users?

6 DR. DAIBES: I will say months. I will  
7 not say a specific timeframe, but I will say in a few  
8 months we believe that it shall be out. Again, it's  
9 still under review by OGC. So we're hopeful, a few  
10 months.

11 MEMBER ENNIS: And second question, for  
12 the final rule, are there other isotopes that we  
13 should be thinking about adding to the final rule so  
14 we don't have this problem again with something else  
15 coming down the pike?

16 Or should we include Dr. Langhorst's  
17 formula that she discovered within the final rule so  
18 when the new isotope were to come we could just apply  
19 that rule and move forward?

20 DR. DAIBES: Our branch chief will --  
21 Right now for the direct final rule it's just the  
22 Germanium. And that actually, that question, I  
23 predict will be a question from our management and  
24 our Commission, should we bring this up for direct  
25 final rule.

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

9 And that's why we understand that there  
10 could be those, so many obstacles to get to rulemaking  
11 change that we, at parallel, went with the exemption,  
12 basically the guidance for an exemption and allowing  
13 an exemption.

14 At the same time, for that quick fix for  
15 this specifically, should we look into that or that  
16 be the next steps. Because, you know, anything with  
17 rulemaking does, as you all know, it takes a lot of  
18 resources, takes a lot of time.

19 The Commission is very, and the NRC staff,  
20 they're looking at everything very closely for any  
21 new proposed rules. So because of that, there will  
22 be extra scrutiny, even for direct final rule, to get  
23 the most -- basically get the most out of the rules.

24 And so, I mean, you asked a great  
25 question. And, like I said, I foresee our

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1 Commissioners asking the same thing if not, you know  
2 -- and we look at it as, you know, we consider it as  
3 well.

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

11 CHAIRMAN ALDERSON: Dr. Langhorst?

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

19 The inclusion of cyclotron-produced  
20 radioactive materials like Germanium came to be in  
21 2009. And this was an unfortunate miss of that full  
22 inclusion of those types of isotopes into byproduct  
23 definition. So that's why we are where we are.

24 The NRC does not issue exemptions lightly.  
25 But they are exactly for these types of things where

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1 an unfortunate set of circumstances has made a  
2 disconnect in the rules in what is needed for public  
3 health and safety.

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

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

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

22 But I just thank you so much. And it's  
23 just such an impact on so many patients. And I just  
24 encourage NRC staff, please keep working on it and  
25 getting it done. Thank you.

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1 CHAIRMAN ALDERSON: Thank you. Any other  
2 comments on this particular topic? Well, thank you  
3 very much, Doctor. Very good report, thank you.

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

8 MR. BOLLOCK: No.

9 CHAIRMAN ALDERSON: No.

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

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

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

15 CHAIRMAN ALDERSON: So we'll begin at,  
16 9:45 is what the schedule here says.

17 MR. BOLLOCK: That's fine.

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

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

24 CHAIRMAN ALDERSON: Thanks, everyone,  
25 welcome back. We're now getting ready to have Mr.

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1 Moore from the NRC make a special presentation to Mr.  
2 Mattmuller.

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

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

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

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

20 Mr. Mattmuller has demonstrated expertise  
21 in the field of nuclear pharmacy and represents that  
22 specialty well on the advisory committee. He's talked  
23 about a number of things. We mentioned the  
24 Germanium/Gallium generator issue yesterday, also the  
25 advanced notice of proposed rulemaking on the Part 20

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

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

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

15 (Laughter.)

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

22 And finally, we have a gold lapel pin with  
23 an eagle on it. Sophie, do you want to get in on  
24 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  
6 discussions 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  
11 already.

12 (Laughter.)

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

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

24 (Laughter.)

25 MEMBER MATTMULLER: And my office is on

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1 the back side buried next to the cyclotron. But we  
2 do share this gentleman in common, Charles Kettering,  
3 who had several profound quotes, and a prolific  
4 inventor, second only to Thomas Edison in patents.  
5 And his biggest was the electric starter in the  
6 automobile.

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

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

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

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1                   Here we go. Well, I did serve on a number  
2                   of committees. And one issue was metrication, and we  
3                   came to an issue of trying to figure out an old  
4                   traditional unit of activity versus the traditional  
5                   unit of volume.

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

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

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

22                  So while we may think we're pretty cool  
23                  coming here to Rockville for an ACMUI Committee  
24                  meeting, we'll never be Charles Kettering cool. So  
25                  another profound statement from him, believe and act

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1 as if was impossible to fail, which I took to heart  
2 as we worked on this project of trying to get  
3 regulatory relief for a Germanium DFP issue and to  
4 get Gallium out into the clinical world where it can  
5 benefit these patients.

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

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

17 So I've been very fortunate in my  
18 professional life that I've always been in an  
19 environment of great leadership and support. And it's  
20 what I found here too. And it's very much  
21 appreciated. Excuse me.

22 And I've also had a lot of support from  
23 home, from my wife, Michelle, as her support has never  
24 wavered. And even when I had to give a lot of  
25 attention and a lot of time to women named Ashley and

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1 Sophie.

2 (Laughter.)

3 MEMBER MATTMULLER: Who, she reminded me  
4 Wednesday before I left, she goes, you know, I've  
5 never met these women. But she does know they do  
6 exist. So thank you for the opportunity to serve.  
7 And I hope I've met your expectations. Thank you.

8 (Applause.)

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

13 MS. HOLIDAY: Yes.

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

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

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1 (Laughter.)

2 MEMBER LANGHORST: I do want to encourage  
3 the new members. When I first was here I was, like,  
4 what in the world is going on? What does this mean,  
5 how do they do this? I encourage you to ask your  
6 question, and don't be afraid that if you've asked it  
7 before and you still don't quite understand it; ask  
8 it again.

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

14 So I encourage you to understand that if  
15 only to support your own RSO back at your place. But  
16 don't be afraid to ask questions. Because you'll know  
17 half of us are going, yes, I didn't know what that  
18 meant either. So I just encourage the new folks to  
19 do that. Thank you.

20 CHAIRMAN ALDERSON: Good. Great advice.

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

23 MEMBER ENNIS: Just a question first.  
24 Donna-Beth gave a very good presentation of events  
25 yesterday. But I gave a presentation on the same

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1       topic in October. Why is it that we do that? Is  
2       seems like one report from NMED, from either NRC staff  
3       or from ACMUI would be adequate. Why are we  
4       duplicating that?

5                   CHAIRMAN ALDERSON: You believe that it  
6       was duplicative, you gave the same medical events that  
7       were given by Dr. Howe?

8                   (Simultaneous speaking.)

9                   MEMBER ENNIS: I think it felt -- pretty  
10      similar events.

11                  CHAIRMAN ALDERSON: So we'll let Dr. Howe  
12      respond to that.

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

20                  Because it's not supposed to be I do it,  
21      then you do it again. It's what does the ACMUI, from  
22      its perspective looking at these medical events, glean  
23      from the medical events? And bring us a new  
24      perspective. So the other thing is we used to have  
25      two presentations when I did mine.

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1 I did one for medical events. And our  
2 medical physicist did one for other events that dealt  
3 with medical facilities, loss of sources, spills,  
4 those kinds of things. We haven't had that report  
5 for a long time. So you may want to consider adding  
6 that in. I think Sue would be --

7 CHAIRMAN ALDERSON: Dr. Langhorst.

8 MEMBER LANGHORST: So yes, when Ralph  
9 Lieto used to do those.

10 DR. HOWE: Absolutely.

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

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

20 CHAIRMAN ALDERSON: Mr. Fuller would you  
21 like to comment?

22 MR. FULLER: Yes, just briefly. Dr.  
23 Ennis, I spoke a little bit about this yesterday. The  
24 presentation that you received from Dr. Katie Tapp,  
25 on Yttrium-90 microspheres, and the work that one

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1 group has done to make changes to some of the 35.1000  
2 licensing efforts that are underway. That was a  
3 direct result of the Committee looking at what Donna-  
4 Beth had presented.

5 And deciding that they wanted to drill  
6 into that. So they drilled into it. They got to  
7 sort of, identified some things that perhaps were  
8 based upon the medical and clinical judgment of the  
9 members of this Committee. Decided that you know  
10 that's really kind of inappropriate to be reporting,  
11 and so forth.

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

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

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1 CHAIRMAN ALDERSON: Mr. Ouhib.

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

8 And then perhaps act on it, or provide  
9 some recommendations. But they have to be sort of  
10 you know, two or three items well defined. Okay,  
11 here's the purpose of this. And it's not only  
12 information that we provided, because I looked at it  
13 as information. And then from there I started to  
14 think like, okay, well why is this happening? And  
15 can we do something about this? Or how can we improve  
16 this and so on?

17 But I think if we define some goals, I  
18 think that would be extremely helpful.

19 CHAIRMAN ALDERSON: So it seems that with  
20 respect to medical events, in fact we have set out  
21 with some things to do. So, Dr. Suh has a Committee  
22 that's looking at the clarity or the definition. And  
23 then Dr. Langhorst has just taken on the new Sub-  
24 Committee this morning, which several of you are on.  
25 To really work on the culture, the communication, and

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1 the things around medical events.

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

4 Dr. Langhorst.

5 MEMBER LANGHORST: Always what I have  
6 felt in our report is that that Sub-Committee can  
7 delve into the NMED data, the nuclear materials, event  
8 data base. It's not nuclear medicine, it's nuclear  
9 materials. And we can do exactly what you're saying.  
10 And give that perspective.

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

16 One question I do have along these lines  
17 is whether -- and I realize there is budget  
18 constraints -- whether it's possible to get reports  
19 on what are the total number of procedures at this  
20 point in time? Because it's been about five years or  
21 so since we had those data. So we can again look at,  
22 it's this many medical events, out of this many  
23 procedures that are done per year.

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

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1 MS. HOLIDAY: Hi, Dr. Langhorst. This is  
2 Sophie. Just to follow up on that. I know this is  
3 something that the Committee has requested. And as  
4 you have recognized, this is a very tight budgetary  
5 environment for us.

6 Staff will always advocate and put the  
7 request forth, but ultimately it's up to whether or  
8 not we have funds to purchase those reports. Because  
9 those reports are several thousands of dollars. And  
10 that's several thousands of dollars for just a small  
11 piece of a report. Not even a full report.

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

18 CHAIRMAN ALDERSON: Yes, Mr. Ouhib.

19 MR. OUHIB: Yes, if I could just add one  
20 more comment. It would be helpful and I believe you  
21 have done it, is to get that data well in advance,  
22 prior to the meeting for instance. For us to sort of  
23 brainstorm on that and come up with some sort of  
24 recommendations, or plan of actions.

25 DR. HOWE: Dr. Alderson, also just to

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1 follow up on what Sophie said. The data that we  
2 purchase don't come out with, oh, here's the number  
3 of procedures for the different modalities.  
4 Sometimes on some years they don't even address our  
5 issues.

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

11 CHAIRMAN ALDERSON: Okay.

12 Yes, Frank. Dr. Costello.

13 MEMBER COSTELLO: A caution about mining  
14 NMED data. First of all, those reports often raise  
15 more questions than they answer. I mean, how many  
16 reports when you look at them, do you find yourself  
17 wanting to ask questions? Like, why did that happen?  
18 Or why did this happen? Or what was the effects on  
19 the patient? And the data, the quality of the data  
20 is very, very, variable in that regard.

21 And just from a simple counting point of  
22 view, I think we should all assume there's a certain  
23 amount of under reporting-- for the reason that we've  
24 been talking about. You know we may discourage people  
25 from reporting by the way we handle the reports.

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1                   So I think you know mining the data is  
2           useful but you have to be cautious about making major  
3           conclusions based on data that is inherently suspect.  
4           Thank you.

5                   CHAIRMAN ALDERSON: Dr. Metter.

6                   MEMBER METTER: I was just wondering as  
7           far as me looking for the denominator on how many  
8           procedures are done. Since my understanding of the  
9           Y-90 microsphere is that it's a unit or a standard  
10          dose when they're sent. Perhaps you could go to the  
11          manufacturer and just see how many they have sold as  
12          a baseline?

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

14                  MEMBER O'HARA: If that, many of these  
15          companies consider that proprietary, that kind of  
16          thing proprietary information. We're using the Y-90  
17          microspheres as an example. One company has a  
18          humanitarian device exemption from the FDA, which  
19          they're limited to a total number of patients per  
20          year. And the other has a PMA, which is the highest  
21          review that we give a medical product.

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

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1                   In terms of the denominators, it's  
2 something that the FDA is always interested in too.  
3 And with respect to using, again, Y-90 microspheres  
4 as an example. It's very difficult because they're  
5 used off-label so much.

6                   You know the glass microspheres are  
7 indicated for primary liver tumors. And the polymeric  
8 microspheres are indicated for colorectal masses.  
9 But they both have, both companies have investigation  
10 device exemptions, ongoing. This is where they're  
11 looking at other indications for use.

12                  And there's a large number of physician-  
13 sponsored studies going on too. That's where  
14 physicians are actually looking at a number different  
15 indications. But so we are as challenged as the NRC  
16 with our databases. And I would hazard a guess that  
17 many of you have tried to look at what used to be  
18 called, the MOD database in FDA, and been totally  
19 frustrated by it.

20                  And it is changing, that database is  
21 changing. It's now called, SUS internally. The  
22 general public can't get access to SUS yet, as they  
23 could get, they still have access to MOD. But MOD  
24 will eventually go away, and SUS will completely take  
25 over. And it's supposed to be, it's being designed

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1 to be much more user friendly.

2 I still can't use it. I don't even have  
3 permission to use it.

4 So, but it's the denominator, and a lot  
5 of what I've heard here today from NRC, talking about  
6 the problems with these databases. As I said, the  
7 FDA database is very vague, very vague indeed. And  
8 many times our analysts look at these and they have  
9 to start investigating. They have to start to see  
10 where a device has failed.

11 And remember our database is different.  
12 Really, we look at device failures. That's what we're  
13 looking at. And we regulate the manufacturers.  
14 We're not regulating the users, as NRC does. So  
15 there's a lot of differences.

16 But you'll see that coming out of our  
17 Division of Radiological Health, you'll see at least  
18 three, maybe four different methods that regulatory  
19 scientists are using to analyze this subjective data,  
20 from these subjective databases.

21 So you'll see you know hopefully  
22 publications coming out. There's at least one that's  
23 close to coming out right now.

24 CHAIRMAN ALDERSON: Yes, Dr. Palestro.

25 MEMBER PALESTRO: Yes, in response to

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1       your comment, Darlene. I can tell you that I spent a  
2       considerable amount of time in preparation for the  
3       presentation regarding alpha and beta emitters, trying  
4       to get those data for the other beta emitters that  
5       are on the market and for the alpha emitters. And it  
6       was absolutely impossible.

7                   I contacted the companies, and they  
8       referred me to many different people within their  
9       organization. And that went nowhere. And I tried  
10      looking on line, on the web and so forth to see, but  
11      I just could not find the data.

12                   And then several of these agents have gone  
13      from one company to another over the years, which  
14      further complicates it, so.

15                   CHAIRMAN ALDERSON: Mr. Ouhib.

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

23                   I'm just wondering if perhaps that might  
24      be the work of the Sub-Committee. To actually look  
25      into that? And it's perhaps time for us to move away

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1 from the millicuries and go to a single unit such as  
2 air-kerma strength. And stay away from apparent  
3 activity type of thing.

4 CHAIRMAN ALDERSON: Any other comments on  
5 this particular subject?

6 (No audible response.)

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

9 Dr. Langhorst.

10 MEMBER LANGHORST: As I said, I've been  
11 on this Committee a little while and I am still  
12 frustrated in not knowing how many medical licensees  
13 there are. NRC publications tell how many material  
14 licensees there are. I cannot find how many medical  
15 licensees there are. Could we get that data? Could  
16 we have it?

17 You know, I know there's Agreement States  
18 and there's NRC licensees, but just to know how many  
19 -- and I'm not asking number of authorized users --  
20 that will be the next layer. I'm looking for number  
21 of medical licensees.

22 Now I know, in our instance at Washington  
23 University in St. Louis, we are medical use licensees,  
24 but we're also a big research licensee. If they have  
25 medical use approved in their license, that's the

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1 numbers I want to know.

2 So that would be great. And I really  
3 don't mean to diminish the medical team's resources  
4 in time added, as far as getting this data. I would  
5 think it would be something that you would have  
6 already, so please.

7 CHAIRMAN ALDERSON: So, a clarification.  
8 So if you have an institutional broad license, and  
9 Washington U certainly does, you would consider that  
10 one licensee. Is that right?

11 MEMBER LANGHORST: Yes. That's all I'm  
12 looking for.

13 CHAIRMAN ALDERSON: A single licensee.

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

17 CHAIRMAN ALDERSON: Okay, all right.

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

21 CHAIRMAN ALDERSON: Dr. Howe would like  
22 to comment.

23 DR. HOWE: We have to do what's called an  
24 OMB approval. And renew these things for regulatory  
25 reasons. And one of them is Part 35, and in doing

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1 Part 35 we have to come up with the number of NRC  
2 licensees. And we do that by program code. So we  
3 know how many NRC licensees we have. We know what  
4 their program codes are. They don't always have  
5 primary program codes. They may have secondary  
6 tertiary program codes.

7 So we have those data. That is accessible  
8 to us. What we do not have is the same level of  
9 detail for the Agreement States. So in our OMB  
10 clearances, we do have on a yearly basis, the number  
11 of Agreement State licensees.

12 Now that covers all materials. And so  
13 it's not just medical. And so what we do is we make  
14 an assumption which may not be a safe assumption  
15 anymore, that the ratio of NRC medical use licensees  
16 should be the same as the ratio of Agreement State  
17 licensees.

18 So we know the total number of NRC  
19 licensees. We know the number of medical use  
20 licensees. We develop a ratio and then we take the  
21 total number of Agreement State licensees, and we  
22 multiply by that ratio.

23 Now when we had more NRC licensees than  
24 now, that was a good approximation. I'm not so sure  
25 that's a good approximation anymore. But that is how

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1 we determine how many medical use licensees there are.  
2 We don't have the ability in the Agreement States,  
3 other than using a ratio, to go from NRC modalities  
4 to Agreement State.

5 But that information we can provide very  
6 easily.

7 CHAIRMAN ALDERSON: So you already have  
8 the information you just described?

9 (Simultaneous speaking.)

10 DR. HOWE: We already have the  
11 information.

12 CHAIRMAN ALDERSON: You just have to look  
13 it up? Yes?

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

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

19 CHAIRMAN ALDERSON: Dr. Langhorst will be  
20 very happy if you provide this information.

21 (Laughter.)

22 CHAIRMAN ALDERSON: Mr. Costello.

23 MEMBER COSTELLO: I can't speak to any  
24 States other than Pennsylvania, but we use the same  
25 program codes.

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1 MEMBER LANGHORST: Is your mic on?

2 MEMBER COSTELLO: Yes.

3 (Laughter.)

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

10 Okay, not only the total number, but we  
11 can probably give you the total by program code. How  
12 many are cardiologists. How many there are whatever  
13 they may be.

14 Far as the other States go, you have to  
15 ask. Then if you would ask, you might get  
16 information.

17 CHAIRMAN ALDERSON: Dr. Langhorst.

18 MEMBER LANGHORST: Maybe will be answered  
19 later this morning, or early this afternoon, but is  
20 the ACMUI allowed to ask Agreement States if they  
21 could give us this information?

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

24 MEMBER LANGHORST: Are we allowed to ask?

25 MEMBER COSTELLO: Allowed?

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1                   MEMBER LANGHORST:   Without a big formal,  
2                   oh we need to have this --

3                   (Simultaneous speaking.)

4                   CHAIRMAN ALDERSON:   Yes, Dr. Bollock.

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

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

19                  I mean it seems, I know it seems like a  
20                  simple question.

21                  MEMBER COSTELLO:    I think that I, not  
22                  being bound by OMB requirements myself, I could  
23                  probably get Pennsylvania numbers myself and just send  
24                  them to somebody.

25                  MEMBER LANGHORST:   Okay, thank you.

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

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

10                  MR. BOLLOCK: Yes, we'll get you what we  
11                  can.

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

15                  Dr. Ennis.

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

21                  MR. BOLLOCK: And that is true because  
22                  not every -- authorized users don't have to  
23                  necessarily be listed on every license. So for that  
24                  we could only give an estimate. And there's some  
25                  other things.

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

6                   CHAIRMAN ALDERSON: Dr. Palestro.

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

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

18                  MR. BOLLOCK: Exactly right. Just, this  
19                  was a question, as many of you know with the training  
20                  experience. We actually have going on and answering  
21                  questions to Congressional oversight staffers, both  
22                  Senate and Congress, our Commission. And those are  
23                  questions that we were asked. Because those are some  
24                  of the points that the pharmaceutical company was  
25                  making.

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1                   And right, we can't get to the number of  
2           AUs. But for 35.300 licensees, we have an estimate  
3           of about 2500. It's probably low, a low estimate.  
4           But about 2500 across the country that you know. And  
5           we were able to find that and we used, because we know  
6           the number of NRC licensees, and we used that rough  
7           ratio to estimate the Agreement States.

8                   CHAIRMAN ALDERSON: Sophie answer, yes.

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

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

23                   Now we're also saying, to answer Dr.  
24          Langhorst's question, there was a letter that went  
25          out to the Agreement States. And I will have to give

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1 credit Dr. Sandy Gabriel, who used to be a member of  
2 the medical team. She's apparently listening,  
3 because she sent me this lovely document that went  
4 out that has the results of the annual count of  
5 radioactive material licenses within the National  
6 Materials Program.

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

11 CHAIRMAN ALDERSON: Thank you.

12 Dr. Howe.

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

17 CHAIRMAN ALDERSON: Very good. All  
18 right.

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

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

24 MEMBER LANGHORST: Thank you.

25 CHAIRMAN ALDERSON: So that's something

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1 different, yes.

2 Mr. Mattmuller.

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

6 (Laughter.)

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

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

17 (Laughter.)

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

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

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1                   MEMBER MATTMULLER:     Yes, Rich.     He's  
2     agreed.

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

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

10                  Yes, Dr. Zanzonico.

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

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

20                  CHAIRMAN ALDERSON:   Right.

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

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1 well informed about the regulations.

2 And then once I was on the Committee, I  
3 was surprised how ignorant I was of many of the  
4 regulations and the process and so forth and so on.

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

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

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

23 Because as I said, I think there's a real  
24 disconnect in terms of what authorized users day in  
25 and day out, are aware of with respect to regulations,

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1 and changes in regulations, and how they impact  
2 practice. And what's actually occurring.

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

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

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

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

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1 -

2 (Laughter.)

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

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

16 CHAIRMAN ALDERSON: No, it's not just an  
17 appearance, but maybe I didn't clarify. The idea that  
18 I had was that you would listed in the program as  
19 leading one of the many refresher courses that are at  
20 these meetings. And you'd be course number whatever,  
21 on a particular day, and a particular room, and a  
22 particular time.

23 And there would be a hundred and fifty  
24 seats in the room, and you know you would hope that  
25 some people are going to come and want to talk to the

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1 NRC about various things. You'd have an actual  
2 program. You would have planned an actual  
3 presentation that would cover topics that you would  
4 have announced. And then you'd be a Q&A session as  
5 well that would probably take an hour or so. And  
6 that's the idea.

7 Mr. Ouhib.

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

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

20 CHAIRMAN ALDERSON: So Lynne Fairobent  
21 wants to make a comment.

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

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

7 We have had a variety of sessions, when  
8 appropriate, with NRC individuals. Many of the  
9 professional societies have government relations  
10 experts who do routine updates to their memberships  
11 on what's pending in a variety of federal agencies.  
12 And State agencies.

13 I think that, and Sue will probably  
14 cringe, but the vehicle for NRC reaching out to the  
15 medical community and ACMUI reaching out to the  
16 medical community, should have been moving forward  
17 with an NRC regulatory issues conference to the  
18 medical licensees or to materials licensees.

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

22 CHAIRMAN ALDERSON: Yes, that is correct.  
23 That was suggested. It was actually discussed by this  
24 Committee. And it was felt that it would be better  
25 and more efficient, more cost effective for us to go

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1 to the meetings, than to try to have a national meeting  
2 and have people come in for that meeting.

3 I would say that for any of you who --  
4 and I know many of you have your own organizations,  
5 but in leadership positions, you've heard many of the  
6 old adages about communication. You know you  
7 communicate, communicate, and communicate. Sometimes  
8 several different ways, several different places and  
9 ultimately no matter what you try to do, you're  
10 ultimately criticized for not communicating because  
11 somebody fails to hear it.

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

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

23 But I think if you don't offer then you  
24 aren't doing what you need to do in terms of  
25 communication.

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1 Dr. Dilsizian.

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

7 I'm not sure if NRC should be separate,  
8 or if FDA and NRC combination probably would work  
9 well. But to reassure you, the people do like it and  
10 do attend.

11 CHAIRMAN ALDERSON: Yes. Fifteen or more  
12 years ago, and I don't remember what the issues were,  
13 there was issue in the radiology community with some  
14 NRC topics. And I actually was involved in putting  
15 together some sessions at that time. And they were  
16 reasonably well attended.

17 I would also point out that the American  
18 Board of Radiology came up with the idea several years  
19 ago that it might be interesting to put on a regular  
20 session at the large radiological meeting, the  
21 Radiological Society of North America, RSNA.

22 And the initial response to that was  
23 similar to this. Oh, no, no, you know, no one will  
24 come. And no one will be interested but why don't  
25 you go out there. It's now become a really popular,

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1 looked forward to part of every annual meeting. And  
2 no they don't get a thousand people, but they get a  
3 hundred.

4 And so they're out there telling each year  
5 exactly what's going on. It's been very valuable for  
6 them.

7 Dr. Metter.

8 MEMBER METTER: Yes, I like what you're  
9 talking about, reaching out to societies. And for  
10 the SNMMI big annual meeting, and we did do an NRC  
11 update. Mr. Bollock was there. And it was very well  
12 attended. And they had a lot of questions. And I  
13 think the issues coming up with training and  
14 experience and all that will be a hot topic.

15 And I believe that many of us who are  
16 involved in leadership and involved in future  
17 meetings, I think we should bring that up. And I  
18 think it would be a definite service to the community.

19 CHAIRMAN ALDERSON: Thank you. I think  
20 that if you just listen to the controversies, you know  
21 the discussions that we'll have over issues like the  
22 one that Dr. Palestro's Committee will deal with--and  
23 over the question of medical events. It seems to me  
24 that there are people out there who want to know the  
25 answers to these questions.

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1                   And we can't provide pat answers, but we  
2                   can certainly provide updates and get their input as  
3                   well. And they will enjoy that.

4                   Yes, Dr. Metter.

5                   MEMBER METTER: I think it would be a  
6                   great opportunity to educate our fellow colleagues in  
7                   the community about the current ideas about a just  
8                   culture, the safety culture. And you know put that  
9                   in. And I think, you know, just starting it now.  
10                  It'll take years and years for the change.

11                  But having them realize that you know the  
12                  NRC is a regulator. But we're here to improve. We're  
13                  doing quality improvement, no blame. We want to  
14                  improve on what we do. And I think that would be  
15                  actually a very good starting point to see maybe you  
16                  know different motivation for reporting.

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

21                  (Laughter.)

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

24                  Dr. Palestro wanted to speak.

25                  MEMBER PALESTRO: Yes, just to say that I

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1 agree with you, Phil. I think it's better to be  
2 proactive than reactive. And if the societies are  
3 not interested, they'll tell us so.

4 And I also think that when in fact they  
5 are interested, we'll try to identify topics that  
6 would be germane to their societies. I think training  
7 and experience is probably going to be germane to a  
8 lot of societies. I think the technetium shortage,  
9 or the potential shortage which it seems to come up  
10 periodically, would be another hot topic for something  
11 like the SNMMI.

12 CHAIRMAN ALDERSON: Good, excellent.  
13 Thank you.

14 Yes, Dr. Langhorst.

15 MEMBER LANGHORST: I just wanted to add  
16 one other perspective to this discussion. I think  
17 it's important especially in Agreement State licensees  
18 for the ACMUI to promote our presence, in that we're  
19 an advisory Committee for the NRC staff. But that  
20 doesn't mean we only talk NRC.

21 And while it is frustrating to be able to  
22 get information between NRC licensees and Agreement  
23 States and all that, what we were discussing before.  
24 The NRC is the driver of this bus. What they're  
25 regulations say, are primarily what Agreement States

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1 have to implement.

2 And so I would encourage that the  
3 promotion of the ACMUI, and what we do, and why  
4 Agreement State licensees need to know and be involved  
5 in, I think that's really important.

6 CHAIRMAN ALDERSON: That is an important  
7 topic, I agree. So if we in fact think that we should  
8 be out there talking to at least the three societies  
9 that were mentioned in our Commission presentation  
10 yesterday, which are the physics, the AAPM, the  
11 Society of Nuclear Medicine, and the third was ASTRO  
12 I believe.

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

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

23 So it's pretty clear I think on the  
24 Committee, that we have several people who would in  
25 fact, be with the physics organization primarily. We

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1 have several people who clearly are related to ASTRO.  
2 We have other people clearly who are related to the  
3 Society of Nuclear Medicine.

4 So it would seem that that might be a  
5 starting place. But that isn't to suggest that other  
6 organizations shouldn't also be approached if in fact  
7 this effort moves forward.

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

11 If Dr. Ennis and Dr. Suh talked about how  
12 to approach ASTRO.

13 Dr. Dilsizian also, the Society of  
14 Nuclear Medicine, or cardiologic organizations for  
15 that matter.

16 And Dr. Zanzonico, Dr. Langhorst, think  
17 about the physics organizations. And sort of pair up  
18 and then decide how you'd like to approach the  
19 organization? And then approach them.

20 Dr. Metter.

21 MEMBER METTER: Another important  
22 organization I think is the American College of  
23 Radiology because they do the majority of nuclear  
24 medicine procedures as far as diagnostic radiologists  
25 in the country.

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1                   And actually I was just appointed for the  
2                   next two years for the annual meeting, to be on the  
3                   Committee. And for the 2017/2018 meeting, they have  
4                   our annual leadership meeting in D.C.

5                   CHAIRMAN ALDERSON: Yes.

6                   MEMBER METTER: So --

7                   CHAIRMAN ALDERSON: So will you approach  
8                   them for us, I mean?

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

11                  CHAIRMAN ALDERSON: Good. So I mean,  
12                  that's perfect. So please, ask them if they would be  
13                  interested in such a session?

14                  Yes, Mr. Ouhib.

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

17                  CHAIRMAN ALDERSON: Absolutely. Who do  
18                  you think might represent us there?

19                  MR. OUHIB: Well, I'm the Chair of the  
20                  patient safety, so I could certainly push for that.  
21                  And we have done it with in the ABS. We have done  
22                  this, several sessions with NRC representatives in  
23                  there.

24                  But I think we need to have some sort of  
25                  a formal relationship there. And have it sort of like

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1 an annual thing. That there is a session on, you know  
2 regulatory and cultural safety and so on and so forth.  
3 And I think that will improve. Yes.

4 CHAIRMAN ALDERSON: Dr. Zanzonico.

5 VICE CHAIRMAN ZANZONICO: This is just a  
6 comment for NRC and for all of us as well. I think  
7 in these presentations you really have to go to make  
8 an effort to avoid citation of CFR numbers, and of  
9 abbreviations. I've been to these presentations  
10 where you are very knowledgeable people, and they just  
11 don't speak in plain English.

12 It's all acronyms, abbreviations,  
13 citation of as I said, CFR numbers so forth and so  
14 on. And I think you immediately lose a large fraction  
15 of your audience and the people who are most needy of  
16 this sort of information.

17 I mean I think these presentations to  
18 people who are not really engrossed in the regulations  
19 need to be very much in plain English.

20 CHAIRMAN ALDERSON: You're absolutely  
21 correct. Absolutely correct.

22 Dr. Langhorst.

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

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1                   MR. FULLER:    Yes, that's correct.    To  
2                   some of the organizations, and then you know as folks  
3                   on our team move on.    Then we try to actually replace  
4                   some of those.    To be specific, and I don't know  
5                   that's it's actually formalized, but I am very much  
6                   involved on a regular basis with both the American  
7                   Brachytherapy Society and with ASTRO.

8                   We have a little bit more formalized  
9                   relationship with the AAPM.    We have two folks that  
10                  are actually members.    One of their Government  
11                  Regulatory Affairs Committee and one with the Therapy  
12                  Physics Committee.    And then the Society of Nuclear  
13                  Medicine, Mr. Bollock, Doug, has been involved most  
14                  recently with those folks and has made presentations  
15                  and so forth.

16                  So and we have team members, several team  
17                  members who are actually members of the Health Physics  
18                  Society as well as past members, who are members of  
19                  the Society of Nuclear Medicine and Molecular Imaging.

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

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1 I would like to take this opportunity and  
2 I'm just trying to poke fun a little bit here. Dr.  
3 Zanzonico, I just made three presentations a few weeks  
4 ago to the American Brachytherapy Society and I was  
5 trying to be very careful to use plain language. But  
6 I did remark that we've got nothing on the medical  
7 community when it comes to acronyms.

8 (Laughter.)

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

16 I mean again, just in fun. We as any  
17 other group, if you will, we do have our own jargon.  
18 We have our own acronyms. And we have to be very,  
19 very mindful of that and not just blurt out the  
20 initials as if everybody understands what we're  
21 talking about. You're exactly right.

22 CHAIRMAN ALDERSON: We have a comment at  
23 the microphone.

24 MS. KUBLER: Hi, this is Caitlin Kubler.  
25 I'm with the Society of Nuclear Medicine and Molecular

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1       Imaging. I was just texting our education department  
2       to figure out if we actually had a spot open for an  
3       ED session of our upcoming annual meeting. And I will  
4       get back to you with that.

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

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

13              CHAIRMAN ALDERSON: Excellent and clear.  
14       Delighted to hear that. Thank you.

15              Yes.

16              MEMBER ENNIS: Just as a professional  
17       with ASTRO, you know ASTRO was really engaged with  
18       Mike as he mentioned the last few years. We've got a  
19       relations Committee that I'm involved in, and in the  
20       annual meeting. And I think it's been very well  
21       received. I know we had actually, Mike O'Hara also  
22       to talk about the issues, which happens to be a lot  
23       of equipment issues in that session. You know I got  
24       really a lot of good feedback from it.

25              So I do think the membership you know are

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1 interested in these things. And the more we do, the  
2 better.

3 CHAIRMAN ALDERSON: Excellent.

4 Yes. Dr. O'Hara.

5 MEMBER O'HARA: To follow up on that.  
6 ASTRO also had invited a few years ago, it had invited  
7 the Commissioner of Food and Drug Administration to  
8 give a plenary lecture at ASTRO. And ASTRO hid their  
9 concern that the request for the Commissioner showed  
10 up, ended up with me.

11 They held their session and they were very  
12 gracious but you could really tell that they were a  
13 little disappointed --

14 (Laughter.)

15 MEMBER O'HARA: -- that the Commissioner  
16 wasn't standing there instead of me.

17 CHAIRMAN ALDERSON: Dr. Langhorst.

18 MEMBER LANGHORST: And I can understand  
19 that because it's not just the talks or the lectures  
20 that are given. It is the opportunity to mingle and  
21 interact with people on a one-on-one basis, which I  
22 know is not real effective at those booths. But that  
23 is an opportunity not only for the societies to learn  
24 about the regulators, but the regulators to learn  
25 about the issues important. And what is on the minds

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1 of those people, so.

2 CHAIRMAN ALDERSON: Absolutely.

3 We have another comment at the microphone.

4 MS. TOMLINSON: Hi, this is Cindy  
5 Tomlinson from ASTRO. I'm guilty of inviting Dr.  
6 O'Hara and Mike Fuller to our Government Relations  
7 Council Meeting last, at our last annual meeting. We  
8 are working with Mike Fuller to figure out ways of  
9 engaging our membership with the NRC. And our annual  
10 meetings really are focused on science and it's very  
11 hard for us to get folks to policy type discussions.

12 So we are working on other ways to engage  
13 with NRC. We will likely -- Michael O'Hara you're  
14 learning this for the first time -- also engage with  
15 FDA as well. But outside of our annual meeting.  
16 Sometimes it's just too difficult to get those things  
17 in.

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

21 Yes, Dr. Suh.

22 MEMBER SUH: So one way to try to help  
23 with awareness and communication, perhaps  
24 expectations as well, is that actually to make change  
25 in any culture, we're talking about the just, safety

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1 culture we were talking about, and how do we -- the  
2 transparency through to medicine is.

3 I think that one of the things to consider  
4 is also to start at the grass roots of actually the  
5 trainees, the residents. Because I can tell you  
6 during my residency, I didn't even know that NRC  
7 really had any impact in terms of what I would do in  
8 my career.

9 I had no idea of the ACMUI just until I  
10 started getting these phone calls. Hey, John would  
11 you like to serve on this Committee? So I think those  
12 are the type of things which I think, just to help  
13 increase that awareness. And I know there are several  
14 residents which are actually very interested in  
15 policy.

16 I mean some of them have their MBAs and  
17 MDs. So I think if they were aware that this is a  
18 potential opportunity, just to increase the awareness.  
19 I think that would also be very effective as well  
20 because I think just the transparency of sharing what  
21 type of medical events have actually occurred.

22 And if that was shared with residents,  
23 they'd think wow, I really need to pay attention to  
24 which side of the brain I treat when I do radiosurgery.  
25 I really need to pay attention to making sure I do a

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1 time out, ask for their name, and their birth date  
2 before I treat the patient.

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

9 I think that's where, I think as a  
10 Committee -- I mean one of the valuable efforts we  
11 can provide to our patients which is why we're here  
12 for, is to make sure that we provide best care  
13 possible.

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

20 CHAIRMAN ALDERSON: Well John, I think  
21 that's the first time I've heard that idea. I think  
22 it's a fascinating idea actually. I'm just trying to  
23 think of the various ways one could approach it.

24 I'll ask you one follow-up question. Do  
25 you think in that context, which would be, or is either

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1 of these the correct answer? Would you think that  
2 you would try to organize something like this, or  
3 approach this through the Accreditation Council for  
4 Graduate Medical Education, the ACGME? Through the  
5 American Board of Radiology? How would you approach  
6 the trainees?

7 MEMBER SUH: No, so I think you could use  
8 that approach right now. I was thinking more of a  
9 grass roots you know in radiation oncologists, called  
10 ARRO, -- there's an association for radiation oncology  
11 graduates.

12 CHAIRMAN ALDERSON: There is?

13 MEMBER SUH: They meet every year. They  
14 meet this Saturday before ASTRO. And maybe a  
15 possibility of approaching their leadership to say,  
16 we would like to do just a very short presentation  
17 about what the NRC does.

18 CHAIRMAN ALDERSON: Okay.

19 MEMBER SUH: What, how this may impact  
20 you as you're talking about experience, we're talking  
21 about competency. Just let them start thinking about  
22 competency. It's not, just because you finished a  
23 radiation oncology residency does not give you perhaps  
24 in the future, the right, or the authority to say,  
25 okay, I'm going to go ahead and be the expert in this.

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

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

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

18 CHAIRMAN ALDERSON: Right.

19 MEMBER SUH: So I think they'll start to  
20 see that.

21 CHAIRMAN ALDERSON: I think that it's  
22 just a great idea. Potentially very impactful. I  
23 hope that we can pursue this idea with you.

24 Dr. Metter, next and then --

25 MEMBER METTER: I think that's an

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1       excellent idea. And most of these societies do have  
2       organizations for trainees or young professionals.  
3       Like the ACR has young professionals and the resident  
4       and fellowship section. The Society of Nuclear  
5       Medicine has their own group too.

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

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

20             CHAIRMAN ALDERSON: Mr. Ouhib.

21             MR. OUHIB: And I think not only the new  
22      graduates will benefit from that, but even senior  
23      practitioners because there are emerging technologies  
24      coming. And we're seeing some errors happening. So  
25      I think it would be great to have some sort of

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1       refresher course per se. And update, you know the  
2       organization about what's going on. What this  
3       modality or what this technology, and so on and so  
4       forth.

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

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

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

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

25                   Should we move ahead with the

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

9 Dr. Zanzonico.

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

18 CHAIRMAN ALDERSON: Okay. Other  
19 opinions?

20 Ms. Weil.

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

24 CHAIRMAN ALDERSON: Where did she go?  
25 Oh, there she is. You're hiding.

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

3                   CHAIRMAN ALDERSON:       Technicality for  
4                   Sophie.

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

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

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

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

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1 I think what you're pursuing is absolutely acceptable.

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

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

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

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

23 CHAIRMAN ALDERSON: Good. All right.  
24 Now that's two opinions that we, that it is  
25 appropriate for us to look at this issue as a committee

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1 of the whole. And two opinions that that would be  
2 the right thing to do.

3 Ms. Weil.

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

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

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

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

23 MEMBER ENNIS: This is for Doug, and  
24 Sophie and others on staff. It sounds like we may be  
25 asking you to make a fair amount of trips and

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

5 MR. BOLLOCK: It wouldn't hurt.

6 (Laughter.)

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

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

25 But we still have a plan I discussed with

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

6 So you may not see, I may not be at the  
7 next SNMMI meeting, but Said will be there. And he'll  
8 be able to speak on all the topics, or you know Mike  
9 will go to ASTRO. Sophie will be at HPS. So you  
10 know we will still, we still plan to continue that.  
11 And be nimble with our, conservative with our travel  
12 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  
16 to 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  
20 I call it, like just happen to ask the regulator, just  
21 a chance for us to say, this is what we're working  
22 on. And I think we have seen it you know be beneficial  
23 at SNMMI. You know made them aware of training  
24 experience issues that were going on.

25 Because it wasn't necessarily in the

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

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

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

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

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

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

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

22                  And that's actually something that we have  
23 to think about going forward. But we fully support  
24 and we recognize the importance of it. And so does  
25 my management. And so any support or any direction

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1       that we can get from ACMUI and can help us with the  
2       message back and forth, you know. Help us help you,  
3       help us.

4                   CHAIRMAN ALDERSON: Very good.

5                   MR. BOLLOCK: We appreciate that.

6                   CHAIRMAN ALDERSON: Dr. Langhorst.

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

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

21                   CHAIRMAN ALDERSON: Good. Thank you.

22                   MR. BOLLOCK: And if I could also, to go  
23      back to a half an hour ago when we began this  
24      conversation. Dr. Zanzonico brought up a good point  
25      about you know, when we get new guides out. We do

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1       you know, we try our best to pass on any new guidance  
2       as best we can. We put out communications, send them  
3       out to the States. And then the States are to pass  
4       it on to their licensees. We sent out --, you know,  
5       mail out to our licensees.

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

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

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

25             So I want to go back to when we talked

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1 about like who's going to contact whom? Because  
2 that's the first step. You have to contact.

3 We've already heard some things. Because  
4 we have people in the audience from SNMMI and from  
5 ASTRO. So we've learned for example when you make a  
6 contact with ASTRO, that they want to meet, but they  
7 don't want it to be at their scientific meeting. They  
8 want it to be at a meeting of the government group.  
9 So that's something with which we'll have to adjust.

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

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

24 So we've got to go through that particular  
25 set of steps, so for ASTRO, Ron Ennis and John Suh

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1       were going to be involved. And you've got this great  
2       idea about the trainees, and please I hope we can  
3       pursue that. And we don't know exactly where that's  
4       going to go yet.

5               For SNMMI Chris is going to represent us.  
6       Darlene you can be involved there too, but you're  
7       clearly going to ACR and talk to them for us.

8               Who's going to AAPM? I don't have that  
9       clear. Who --

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

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

16              MR. OUHIB: But the clinical symposium is  
17       an opportunity.

18              (Laughter.)

19              CHAIRMAN ALDERSON: She wants to make a  
20       comment, Lynne Fairobent.

21              MS. FAIROBENT: Lynne Fairobent from  
22       AAPM. Dr. Alderson, my point was not that AAPM isn't  
23       interested. We already have a mechanism in place that  
24       we have used successfully multiple times with NRC and  
25       other federal agencies. And far as that goes, you

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1 did hear from Mike for example, we have had  
2 historically NRC staff as liaisons formally to our  
3 appropriate scientific as well as our government  
4 relations Committee.

5 We have had the Chairman of NRC speak at  
6 AAPM's meeting. We have had several office directors  
7 and several staff. So it's not that we're not  
8 interested.

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

13 And as far as AAPM, I am the point of  
14 contact for AAPM for any federal agency, for any  
15 issue. And that was the point of my comment earlier.

16 CHAIRMAN ALDERSON: Okay, thank you. I  
17 stand corrected. And Mr. Ouhib will be in touch with  
18 you shortly. Okay.

19 So basically we'll work in this way with,  
20 and there are other people here. Good people who  
21 probably are related to other organizations and you  
22 should be thinking also about what contact might be  
23 there. But we have to watch out for that tendency to  
24 sort of go from nowhere to all of a sudden we're  
25 reaching out to 15 organizations. And then it just

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1 becomes an overwhelming task. And the NRC can't quite  
2 keep up. So we have to balance our enthusiasm with  
3 pragmatism.

4 Yes.

5 MEMBER COSTELLO: Philip, since I'm a  
6 member of the Committee, it's not addressed to the  
7 medical practitioners. But I do update the  
8 Organization Agreement States and activities of the  
9 ACMUI. Now for the most part, they're pretty familiar  
10 with the regulations. But all these parties are  
11 interested in what we do here.

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

15 CHAIRMAN ALDERSON: Good, great. Well I  
16 think that we have a starting point. That is the  
17 point of contact. We have already made some contacts  
18 and learned some things. So in fact I would hope that  
19 the people that we just talked about and named would  
20 actually begin to make those contacts.

21 And then I would say that if you would  
22 work through Sophie and myself on how these things  
23 are evolving. Just email us and so on and that should  
24 suffice. And then we can see where we do from there.

25 And Mr. Fuller would like to comment.

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1                   MR. FULLER:     Thank you Dr. Alderson.  
2                   Mike Fuller with the medical team. I just wanted to  
3                   share a little bit about my own personal experience  
4                   with how successful this can be. This is also very,  
5                   very, this communication, this two-way communication  
6                   or this effort to continually open up these lines of  
7                   communication is very, very beneficial to us when it  
8                   comes to specifically the emerging medical  
9                   technologies.

10                   If we follow a normal process, which means  
11                   a normal fulcrum or process, where we don't really  
12                   know about new technologies until someone applies for  
13                   it. We have, I mean there's no better way of saying  
14                   it. We have failed. Because we will be in the way.  
15                   We will be the deterrent or the obstacle.

16                   So through these communications, and I  
17                   could give you many, many examples in the last few  
18                   years, where we have sort of under our own initiative,  
19                   but at the invitation of various professional  
20                   societies -- and I'm taking another opportunity  
21                   because this is a public meeting. The earlier that  
22                   we know of something that's in the pipeline or coming  
23                   down the road, the better.

24                   I can give you examples, I'm not going to  
25                   name names, but I could give you examples of how this

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1 has been extremely successful in my opinion because I  
2 found out about something at a national meeting.  
3 Simply by going on the exhibit hall, and walking  
4 around, and asking questions.

5 And then I could give you examples of  
6 where we found out too late about something. And by  
7 the time we got our, we kind of got up and running  
8 and got focused on it, that perhaps the medical  
9 community could have benefitted from the availability  
10 of this newer technology, or a new drug, or what have  
11 you, sooner.

12 So I just applaud this. I think we all  
13 on the medical team and NRC staff would agree that  
14 there's really nothing negative that can come from  
15 this initiative. And I thank you for the effort and  
16 the initiative.

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

20 We have actually run over our allotted  
21 time for the open forum by just a few minutes. And  
22 Sophie is prepared to provide some important logistic  
23 details in what we call the Administrative Closing.  
24 But remember we still have a very important session  
25 coming up from Esther Houseman. So we still have some

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1 good things to do here.

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

5 (Laughter.)

6 MS. HOLIDAY: And that is planning for  
7 your next meeting which will be the fall meeting. And  
8 as we stated that is typically held in September and  
9 October. And then prior to this meeting I do send  
10 out a meeting wizard to pulse the Committee on their  
11 availability.

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

16 VICE CHAIRMAN ZANZONICO: Sophie, just  
17 from the 6th through the 9th, actually through the  
18 10th is the World Molecular Imaging Congress meeting.

19 MS. HOLIDAY: Okay.

20 VICE CHAIRMAN ZANZONICO: And I'll be  
21 there. But I don't know if other people will be  
22 there.

23 MS. HOLIDAY: Sure.

24 CHAIRMAN ALDERSON: The dates again,  
25 Sophie that you were proposing?

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1 MS. HOLIDAY: September 14<sup>th</sup> and 15<sup>th</sup> that  
2 is a Wednesday and a Thursday.

3 MEMBER LANGHORST: So that is not a time  
4 I can be here.

5 MS. HOLIDAY: Not for you.

6 MEMBER LANGHORST: And I think I said  
7 that.

8 MS. HOLIDAY: Okay.

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

12 MS. HOLIDAY: Okay. Then I stand  
13 corrected, I think that's the only day that only had  
14 one conflict. Sorry, Dr. Langhorst.

15 MEMBER LANGHORST: That's okay.

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

20 The only other options I had in yellow  
21 although there some that Dr. Zanzonico said, the week  
22 of the 4<sup>th</sup> is out of the question since there is a  
23 conference going on that week.

24 I had responses for September 1<sup>st</sup> and 2<sup>nd</sup>.  
25 And then October 6<sup>th</sup> and 7<sup>th</sup>, so I'll start with the

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1 September 1st and 2nd. Does anybody have a conflict  
2 for September 1st and 2nd?

3 (No audible response.)

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

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

9 MEMBER LANGHORST: Sophie, just to  
10 clarify, the 1st and 2nd is the Thursday, Friday  
11 before Labor Day weekend. But that's okay with me.  
12 And the 6th and 7th is before, in case anybody has  
13 that day off, Columbus Day.

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

16 MEMBER LANGHORST: I have no problem at  
17 all because your name is Holiday.

18 (Laughter.)

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

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

25 The other option I had was September 15th

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1 and 16th.

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

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

8 MEMBER LANGHORST: Not on time.

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

12 Or September 14th and 15th which is a conflict  
13 for Dr. Langhorst.

14 Or did anybody have an issue with coming October  
15 6th and 7th? Understanding that that is Mrs. Ennis'  
16 birthday weekend.

17 MEMBER ENNIS: I could leave early --

18 MEMBER LANGHORST: We could have Dr.  
19 Thomadsen send her flowers.

20 (Laughter.)

21 MR. OUHIB: It's actually becoming  
22 Mattmuller's responsibility to go.

23 CHAIRMAN ALDERSON: So either of these  
24 dates that you're talking about is fine with me, but  
25 I didn't understand the discussion about the 15th and

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1 16th. Because your meeting ran from the 11th to the  
2 14th, right, so?

3 MEMBER LANGHORST: Actually it goes  
4 through the 15th.

5 CHAIRMAN ALDERSON: Oh, it goes through  
6 the 15th. I'm sorry.

7 MEMBER LANGHORST: The 15th, okay, sorry.  
8 I was --

9 CHAIRMAN ALDERSON: I missed that part.  
10 All right so that's fine.

11 MEMBER LANGHORST: I would prefer October  
12 6th and 7th.

13 MEMBER LANGHORST: Sorry, but --

14 MEMBER ENNIS: Okay if everyone would be  
15 okay with me leaving at noon? And that works in my  
16 personal area.

17 CHAIRMAN ALDERSON: And the meeting is  
18 usually over in the early afternoon.

19 (Simultaneous speaking.)

20 MS. HOLIDAY: No, the fall meeting is our  
21 longer meeting, since that's when we have all of our  
22 annual required training such as ethics, allegations,  
23 and information security. We can plan that for the  
24 first day, that you can meet your annual required  
25 training. It's too early to kind of plan when the

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1 meeting will actually end.

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

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

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

11 MS. HOLIDAY: Okay. So then to confirm,  
12 I have our first choice for the fall meeting as October  
13 6th and 7th. And our backup date as September 1st  
14 and 2nd.

15 Okay, so at this time I would like to go  
16 over the new recommendations that were mentioned  
17 during this meeting.

18 As you will see on the screen -- I will  
19 provide this electronically and hard copies to the  
20 Committee prior to your departure today.

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

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1 Sub-Committee members include Dr.  
2 Langhorst, Dr. Metter, Dr. Palestro as the Chair, Dr.  
3 Suh and Ms. Weil.

4 Are there any comments or questions about  
5 Item 16?

6 (No audible response.)

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

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

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

23 Item 21, Dr. Alderson formed a Sub-  
24 Committee today to 1) explore the impact of medical  
25 event reporting and its impact on self-reporting

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1 safety culture, if you will;

2 2) identify potential ways to improve  
3 effectiveness of self-reporting in support of a  
4 culture of safety, and 3) suggest ways to share any  
5 reports and lessons learned with the medical community  
6 to promote safety.

7 I'm sorry, I forgot to list the Sub-  
8 Committee members.

9 CHAIRMAN ALDERSON: Dr. Langhorst is the  
10 Chair. We certainly remember that.

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

13 CHAIRMAN ALDERSON: I've got it, it's Sue  
14 Langhorst as the Chair. Frank Costello is on for  
15 States. Vasken, and Susan M is on for medical, legal  
16 whatever. Laura Weil is on, Ron Ennis is on. And  
17 Mr. Ouhib is going to be a consultant at this time.  
18 That is the membership.

19 MS. HOLIDAY: Excellent. Thank you.

20 Item 22 is that NRC staff will provide  
21 the ACMUI with a draft final 35.1000 licensing  
22 guidance document for the Leksell Gamma Knife  
23 Perfexion and Leksell Gamma Knife Icon. Interested  
24 members will be encouraged to provide comments to the  
25 working group, understanding that it will be on an

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1       abbreviated time schedule so that we can issue the  
2       guidance as early as possible for the patient  
3       community.

4               The last item I believe, Item 23 is that  
5       Dr. Langhorst requested that NRC staff provide the  
6       ACMUI with the total number of medical use licensees  
7       within the United States. This includes NRC and  
8       Agreement States.

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

14              MS. HOLIDAY: Just to clarify, the  
15      document that I provided breaks down all materials  
16      licenses including industrial, medical, and academic.  
17      So that document does include the data that you're  
18      looking for.

19              So does anybody agree to my closing Item  
20      23?

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

24              MS. HOLIDAY: Sure I can tell you that  
25      Ms. Weil's pulled it up in your email. But it does

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1 include the information.

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

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

8 MEMBER LANGHORST: That would be great.

9 MS. HOLIDAY: And then Item 24, obviously  
10 not listed is that we have planned the fall meeting  
11 with a first choice as October 6th and 7th. And your  
12 second choice, or backup date as September 1st and  
13 2nd.

14 CHAIRMAN ALDERSON: I think you should  
15 have an item in here about this extensive discussion  
16 we just had on how we're going to begin to implement  
17 the communications plan.

18 MS. HOLIDAY: I didn't include it because  
19 typically items that we include are items that staff  
20 will be doing, or providing to the ACMUI and then if  
21 the ACMUI requests something from the staff, or a Sub-  
22 Committee is formed, or a recommendation is passed.  
23 If you do feel that this is an action item, and it  
24 should be captured. I'm more than happy to add that.

25 CHAIRMAN ALDERSON: Well that's an action

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1 item because as we make contacts and this effort  
2 evolves, we're going to come back to you and to Mr.  
3 Bollock and look for your availability to join us in  
4 this implementation plan. So there will in fact be  
5 items for the NRC. And there will be budget impact,  
6 although modest, there will be budget impact.

7 MS. HOLIDAY: Okay, so then the action  
8 item will be, the ACMUI will contact their respective  
9 professional organizations for possible interactions  
10 between NRC staff and ACMUI members with their  
11 societies.

12 CHAIRMAN ALDERSON: Yes, that's fine. I  
13 accept that.

14 MS. HOLIDAY: Okay.

15 MR. BOLLOCK: Can I just --

16 MS. HOLIDAY: Sure.

17 MR. BOLLOCK: As you know Lynne pointed  
18 out, we already in a lot of cases, we do already have  
19 a lot of conferences, right. So we can, we do have  
20 contact information that work with us, ASTRO, SNMMI,  
21 so we do already have a lot of those contacts. So  
22 you don't have to reinvent the wheel. Or --

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

24 MR. BOLLOCK: So we'll provide you with  
25 that, who we have just so that the ACMUI members are

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1 talking to the same people that we talk to.

2 CHAIRMAN ALDERSON: And so the people who  
3 are going to talk to those respective organizations,  
4 you need to be in touch through Sophie, with Mr.  
5 Bollock, and work in particular way.

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

9 MS. HOLIDAY: I think you have a comment  
10 from Dr. Howe.

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

13 CHAIRMAN ALDERSON: Microphone.

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

18 CHAIRMAN ALDERSON: That was mentioned.

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

20 CHAIRMAN ALDERSON: Every time you give  
21 it?

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

25 CHAIRMAN ALDERSON: That's correct.

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1 DR. HOWE: Sophie was entertaining that  
2 it was like a one-time thing that she would provide  
3 information.

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

7 It wasn't conclusive to say that they  
8 would only be getting it at the next meeting and that  
9 would stop.

10 DR. HOWE: So --

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

17 MS. HOLIDAY: Exactly.

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

21 CHAIRMAN ALDERSON: That's right.

22 MS. HOLIDAY: That's correct.

23 DR. HOWE: That's fine.

24 CHAIRMAN ALDERSON: That's good.

25 Yes.

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1                   MEMBER ENNIS:   Mike Fuller had offered  
2                   much more than that slide gave us.

3                   DR. HOWE:   He had indeed.

4                   MEMBER ENNIS:   So I just want to be clear,  
5                   what we --

6                   (Laughter.)

7                   MEMBER ENNIS:   Are you talking about  
8                   giving five years, or are getting decades' worth of  
9                   data going forward.

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

13                  MEMBER ENNIS:   Sounds good.

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

21                  CHAIRMAN ALDERSON:   Yes, I think as you  
22                  lengthen out the years, you sort of magnify the  
23                  denominator problem.   And maybe five or six years  
24                  doesn't make a difference.   But something that hardly  
25                  anyone ever talks about when they talk about all these

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

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

9 Thank you.

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

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

21 (No audible response.)

22 CHAIRMAN ALDERSON: Hearing none, a  
23 motion 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  
3 went off the record at 11:37 a.m.)

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