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**NUCLEAR REGULATORY COMMISSION**

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on the Medical Uses of Isotopes

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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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MEETING

+ + + + +

MONDAY,

SEPTEMBER 29, 2014

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

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1        MEMBERS PRESENT:

2                    BRUCE R. THOMADSEN, Ph.D., Chairman

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

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

6                    FRANCIS M. COSTELLO, Agreement State  
7                    Representative

8                    VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

9                    SUSAN M. LANGHORST, Ph.D., Radiation Safety  
10                   Officer

11                   STEVEN R. MATTMULLER, Nuclear Pharmacist

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

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

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

16                   LAURA M. WEIL, Patients' Rights Advocate

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

18                   PAT B. ZANZONICO, Ph.D., Nuclear Medicine  
19                   Physicist

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1        NRC STAFF PRESENT:

2                RAYMOND LORSON, Acting Deputy Director, Office of  
3                Federal and State Materials and Environmental  
4                Management Programs

5                LAURA DUDES, Director, Division of Materials  
6                Safety and State Agreements

7                SUSAN ABRAHAM, Acting Deputy Director, Division  
8                of Materials Safety and State Agreements

9                MICHAEL FULLER, Designated Federal Officer

10                SOPHIE HOLIDAY, Alternate Designated Federal  
11                Officer, ACMUI Coordinator

12                MARYANN ABOGUNDE, FSME/MSSA/RMSB

13                LUIS BENEVIDES, Ph.D., RES/DSA/RPB

14                DOUGLAS BOLLOCK, FSME/MSSA/RMSB

15                SUSAN CHIDAKEL, OGC/GCLR/RMR

16                ASHLEY COCKERHAM, FSME/MSSA

17                JACKIE COOK, RIV/DNMS/NMSB-B

18                SAID DAIBES, Ph.D., FSME/MSSA/RMSB

19                GINA DAVIS, FSME/MSSA/RMSB

20                SARA FORSTER, RIII/DNMS/MLB

21                CASSANDRA FRAZIER, RIII/DNMS/MLB

22                SANDRA GABRIEL, Ph.D., FSME/MSSA/RMSB

23                LATISCHA HANSON, RIV/DNMS/NMSB-A

24                MICHELLE HAMMOND, RIV/DNMS/NMSB-B

25                VINCENT HOLAHAN, Ph.D, FSME/MSSA

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1 DONNA-BETH HOWE, Ph.D., FSME/MSSA/RMSB  
2 ANGELA McINTOSH, FMSE/MSSA/RMSB  
3 KEVIN NULL, RIII/DNMS/MLB  
4 PATTY PELKE, RIII/DNMS/MLB  
5 GRETCHEN RIVERA-CAPELLA, FSME/MSSA/RMSB  
6 KATIE TAPP, Ph.D, RES/DSA/RPB

7

8 MEMBERS OF THE PUBLIC PRESENT:

9 DEBRA BENSON, Elekta  
10 RONALD ENNIS, M.D., American Society for  
11 Radiation Oncology  
12 LYNNE FAIROBENT, American Association for  
13 Physicists in Medicine  
14 STEVEN J. GOETSCH, Ph.D., Dade Moeller Health  
15 CAITLIN KUBLER, Society of Nuclear Medicine and  
16 Molecular Imaging  
17 MICHAEL PETERS, American College of Radiology  
18 GLORIA ROMANELLI, American College of Radiology  
19 CINDY TOMLINSON, American Society for Radiation  
20 Oncology  
21 C. GIBB VINSON, Illinois Emergency Management  
22 Agency  
23 MARK WILLIAMS, Tripler Army Medical Center  
24 PAUL YURKO, Veterans Health Administration

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

2 8:32 a.m.

3 CHAIRMAN THOMADSEN: Good morning. And  
4 welcome to the Fall 2014 ACMUI meeting. And to start  
5 us will be Mr. Fuller.

6 MR. FULLER: Thank you Dr. Thomadsen. As  
7 the Designated Federal Officer for this meeting, I'm  
8 pleased to welcome you to this public meeting of the  
9 ACMUI. My name is Michael Fuller, and I am the Medical  
10 Radiation Safety Team Leader. And I have been  
11 designated as the Federal Officer for this Advisory  
12 Committee in accordance with Title 10, Code of Federal  
13 Regulations, Part 7.11.

14 Present today as the Alternate Designated  
15 Federal Officer is Sophie Holiday. This is an  
16 announced meeting of the Committee. It is being held  
17 in accordance with the rules and regulations of the  
18 Federal Advisory Committee Act and the Nuclear  
19 Regulatory Commission. The meeting was announced in  
20 the July 15, 2014 edition of the Federal Register.

21 The function of the Committee is to advise  
22 the staff on issues and questions that arise on the  
23 medical use of byproduct material. The Committee  
24 provides counsel to the staff, but does not determine  
25 nor direct the actual decisions of the staff or the

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1 Commission. The NRC solicits the views of the  
2 Committee and values their opinions.

3 I request that whenever possible, we try to  
4 reach a consensus on the issues that will be discussed  
5 today and tomorrow. But I also recognize that there may  
6 be minority or dissenting opinions. If you have such  
7 opinions, please allow them to be read into the record.

8 At this point I would like to perform a roll  
9 call of the ACMUI members participating today. Dr.  
10 Bruce Thomadsen?

11 CHAIRMAN THOMADSEN: Here.

12 MR. FULLER: Dr. Mickey Guiberteau?

13 VICE CHAIRMAN GUIBERTEAU: Present.

14 MR. FULLER: Dr. Philip Alderson?

15 MEMBER ALDERSON: Here.

16 MR. FULLER: Mr. Frank Costello?

17 MEMBER COSTELLO: Here.

18 MR. FULLER: Dr. Vasken Dilsizian?

19 MEMBER DILSIZIAN: Here.

20 MR. FULLER: Dr. Sue Langhorst?

21 MEMBER LANGHORST: Here.

22 MR. FULLER: Mr. Steve Mattmuller?

23 MEMBER MATTMULLER: Here.

24 MR. FULLER: Dr. Christopher Palestro?

25 MEMBER PALESTRO: Present.

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1 MR. FULLER: Dr. John Suh?

2 MEMBER SUH: Here.

3 MR. FULLER: Dr. Orhan Suleiman?

4 MEMBER SULEIMAN: Here.

5 MR. FULLER: Ms. Laura Weil?

6 MEMBER WEIL: Here.

7 MR. FULLER: Dr. James Welsh?

8 MEMBER WELSH: Here.

9 MR. FULLER: And Dr. Pat Zanzonico?

10 MEMBER ZANZONICO: Here.

11 MR. FULLER: Okay, I would like to note for  
12 the record that we do -- we have established a quorum  
13 for this meeting. I would also like to add that this  
14 meeting is being webcast so other individuals may be  
15 watching online.

16 We have a bridge line available, and that  
17 phone number is (888) 370-8140. And the pass code to  
18 access the conference call bridge line is 91489#.

19 Following a discussion of each agenda item,  
20 the ACMUI Chairman, Dr. Bruce Thomadsen at his option,  
21 may entertain comments or questions from members of the  
22 public who are participating with us today. We ask that  
23 one person speak at a time as this meeting is also being  
24 closed captioned.

25 At this point I would like to turn the

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1 meeting over to Dr. Laura -- I'm sorry, to --

2 MS. DUDES: Oh, thank you very much. I  
3 like that.

4 MR. FULLER: Turn the meeting over to Ms.  
5 Laura Dudes. She is the Director for the Division of  
6 Material, Safety and State Agreements, for her opening  
7 comments. Laura?

8 MS. DUDES: Good morning everyone. I'm  
9 happy to be here. I want to welcome you all back. It  
10 seems like six months has gone by very fast. And I  
11 appreciate all the efforts that have gone on in the last  
12 six months with discussions and other things for the  
13 very important work we have to do.

14 People first. So I really want to take a  
15 moment to recognize people. First of all, Dr. Suleiman  
16 will retire from the FDA and also from this Committee  
17 this year. And I can't express enough gratitude,  
18 thanks and appreciation for all that you've done both  
19 for the Committee and for the Nation in your service,  
20 so I thank you.

21 (Applause)

22 MS. DUDES: It's going to be a big pair of  
23 shoes that we'll have to fill. So I appreciate all of  
24 that.

25 Dr. Guiberteau, his term will end in

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1 January 2015 and we will be soliciting for that. But  
2 I want to thank you as well. I've only been as you know,  
3 with this Committee and with this job for about a year  
4 now. And I've come to really appreciate the  
5 individuals and their perspectives that they share.  
6 And I see them through emails and other.

7 I also go back in history to look at papers  
8 and positions from the Committee. And so thank you,  
9 you've been an incredible contributor to the ACMUI.

10 (Applause)

11 MS. DUDES: And Dr. Welsh, your term will  
12 end in February 2015. So again, the same expression of  
13 gratitude and appreciation for your opinions and your  
14 willingness to dialog on the issues. In the last  
15 meeting I thought you were a very active participant.  
16 And we appreciate that. We need that.

17 As you know, during our Commission meeting  
18 there was some discussion about how we get our medical  
19 advice. So active participants in this Committee help  
20 us shape regulations that keep people safe. But also  
21 support you know, the medical community in this country.  
22 So thank you.

23 (Applause)

24 MS. DUDES: Okay, and I'd like to extend a  
25 special welcome to Dr. Ennis who will be joining the

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1 Committee. And I am glad you could attend this meeting.  
2 Hopefully it will be a good dialog and we'll make some  
3 progress and set some future goals for our meeting in  
4 March -- March? Sometime in the spring.

5 So I just wanted to talk briefly. So Mike  
6 introduced me as the Director of Material, Safety and  
7 State Agreements. As of next week the Office of Federal  
8 and State Materials and Environmental Programs, known  
9 as FSME, which I finally learned how to say, will merge  
10 into the Office of Nuclear Materials Safety and  
11 Safeguards - which is where we came from.

12 Many of you who have been working with the  
13 medical community and the NRC and the medical branch  
14 know that this was a branch in this office. Cathy Haney  
15 will be the Office Director. Scott Moore is the Deputy  
16 Office Director.

17 We're very lucky, I'm very lucky too,  
18 because my two new bosses have extensive experience in  
19 this area. And in particular Cathy worked on the Part  
20 35 Rule. She worked on Patient Release ten years ago.  
21 So she's very familiar with what we do. And she's a big  
22 supporter of the Committee and the work that we do.

23 So -- and I know they would like to be here,  
24 and they will probably drop in at some point during the  
25 meeting. I don't feel like that this will impact the

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1 Committee at all. But if you see any impacts, please  
2 don't hesitate to call me if services or interactions  
3 change. We don't want the merge to impact the work that  
4 we're doing.

5 You also may have heard Commissioner  
6 Magwood went to Paris to head the Nuclear Energy Agency  
7 over there under the Organization for Economic  
8 Cooperation and Development. And Commissioner  
9 Apostolakis has left the Commission.

10 We have two new Commissioners. Jeff Baran  
11 will be joining us I believe mid- to end of October,  
12 planned. And also Mr. Steve Burns, who used to be the  
13 General Counsel for the NRC. And he should be here in  
14 November. So we look forward to having you know, the  
15 full compliment. Five is always better. We get more  
16 opinions and more thoughtful dialog amongst the  
17 Commission when it's full.

18 So those are a couple of the announcements  
19 I wanted to make. I also wanted to thank Ashley  
20 Cockerham who has been our technical assistant for the  
21 past five or six months. But she's not here, so I'll  
22 wait to do it so we can publically thank her later.

23 I know there's a lot of technical issues to  
24 be discussed. I know we have patient release and then  
25 Y-90 microspheres on the agenda. I did want to talk,

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1 I know we did send to all of you the draft Senate  
2 Appropriations language regarding Source Security.  
3 It's an active topic on the Hill right now.

4 Myself, Michael Weber and Mark Satorius  
5 went down to speak with the staffers in the Senate  
6 Appropriations Committee as well as the House  
7 Appropriations Committee; and then we had a meeting with  
8 some folks on the Authorizing Committee.

9 And so we're just having discussions about  
10 what's in that legislation and what it may mean for the  
11 future of Source Security. I don't really have  
12 anything more definitive than that. This -- the  
13 Congress is now in recess until after the election. So  
14 we'll keep you informed as things go on.

15 So with that, anybody have any questions?  
16 Comments? Okay. Well I look forward to the meeting.  
17 And hopefully we can all have an active and engaged  
18 dialog on these topics. Thank you.

19 CHAIRMAN THOMADSEN: Thank you. Thank  
20 you very much. And Sophie, are you ready? Yes. We're  
21 going to go over our old business and see where we stand  
22 on the issues that we dealt with. This looks like a  
23 handout that should be in front of you. Ms. Holiday.

24 MS. HOLIDAY: Good morning everyone. So I  
25 think this is our most favorite topic of every meeting,

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1 to go over our old past recommendations and see what the  
2 status of those recommendations and actions are. And  
3 see if there's anything open.

4 So as I've said probably for the past few  
5 meetings, everything here on 2007 -- bear with me, I  
6 got a new clicker, check out this brand new and fancy  
7 clicker -- maybe we're having some glitches with it.

8 Everything on 2007 is included in our  
9 current Part 35 Rulemaking. So there's no update on  
10 that. As you all know, the proposed Rule was published  
11 in the Federal Register in July and is open for public  
12 comment until November 18. So we thank the Committee  
13 for all their extensive work on that.

14 And we go over to 2008, this is the same.  
15 Everything is included in the Part 35 Rulemaking with  
16 the exceptions of Items 5, 19 and 22. Similar to the  
17 May meeting, these are delays, meaning they are not  
18 included in this current proposed Rulemaking.

19 And you go over to 2009. These two items  
20 here are again in the current Part 35 Rulemaking. 2010,  
21 of course, all those items were closed, so that chart  
22 is not included.

23 In the 2011 chart, the same thing goes.  
24 Everything is in the current Part 35 Rulemaking, with  
25 the exception of number one, which is with the release

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1 criteria. That's delayed. And then of course Item 5 is  
2 the annual reporting structure review.

3 And then you move to Item 2-- or chart 2012.  
4 That again is the annual Committee's review saying that  
5 they have to continue reviewing the Committee reporting  
6 structure.

7 We move to 2013. This was the year that we  
8 had the two teleconferences on the Rulemaking. So all  
9 these are considered in the Part 35 Rulemaking except  
10 for Item 21 which has to deal with -- I'm sorry, I'm  
11 moving a little too fast.

12 Item 21 has to do with Mr. Mattmuller's  
13 request for regulatory relief for the decommissioning  
14 funding plan for germanium/gallium-68 generators.  
15 This again is touched upon in 2014.

16 A subcommittee was formed and that  
17 subcommittee was supposed to present to the full  
18 Committee at this meeting. But it was delayed until the  
19 next spring meeting.

20 Item 27 talks about the bylaws  
21 subcommittee. I have closed, per the Committee's  
22 request at the May meeting I've removed all the  
23 subcommittees from these recommendation action charts  
24 except for the subcommittees who have not closed out  
25 their actions yet.

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1           So for Item 27 this has to do with the  
2           subcommittee that was formed to revise the ACMUI bylaws.  
3           Hopefully by this afternoon we can revise those for  
4           good.

5           Then we move over to 2014. The first Item  
6           on the report has to do with Dr. Guiberteau's  
7           subcommittee to revise the medical reporting criteria  
8           of the yttrium-90 microspheres 35.1000 licensing  
9           guidance. We look forward to hearing from that  
10          subcommittee later on this morning.

11          Item 6 has to deal with that  
12          decommissioning funding plan germanium gallium-68  
13          subcommittee which I've already mentioned. Item 7, I  
14          have this in red because I've closed this Item. I  
15          committed to providing that germanium/gallium-68  
16          subcommittee with guidelines for developing a  
17          regulatory basis. This was distributed to that  
18          subcommittee on June 6.

19          Item 8 is where the ACMUI committed to  
20          holding this meeting on September 29 and 30. And it  
21          looks like everyone is here. So we can close that Item.

22          And for the last Item, this came from the  
23          August 20 teleconference meeting where the ACMUI met to  
24          discuss revisions to the ACMUI bylaws. But it was  
25          decided that we would defer that vote and further

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1 discussion until this meeting today.

2 Are there any questions?

3 CHAIRMAN THOMADSEN: I see no questions.  
4 Thank you very much for the rundown.

5 MS. HOLIDAY: Thank you.

6 CHAIRMAN THOMADSEN: Next is the  
7 discussion of the Physical Presence -- Physical  
8 Presence Requirements for Perfexion™. And this  
9 conversation will be led by Dr. Suh and Dr. Howe. Dr.  
10 Suh, yes?

11 MEMBER SUH: Good morning. I'm going to  
12 discuss Physical Presence Requirements for the Gamma  
13 Knife Perfexion™. And the objectives are to provide a  
14 brief overview about the Gamma Knife for those of you  
15 who are not familiar with the Gamma Knife.

16 It provides some fundamental differences  
17 between the Perfexion™ Model B, C and 4C units. And  
18 discuss the current requirements for physical presence  
19 for the Gamma Knife.

20 In terms of the Gamma Knife, the Gamma Knife  
21 is a device that allows us to deliver a very high dose  
22 of radiation to a precise located target. The accuracy  
23 is within 0.5 millimeters. It's one of the major forms  
24 of stereotactic radiosurgery used to treat vascular  
25 malformations, benign brain tumors, malignant brain

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1 tumors and functional disorders.

2 In the United States since 1987, over  
3 221,000 cases have been performed with the Gamma Knife,  
4 if you look at the past 26 years. In terms of the  
5 various units, the older units, the Model B, C and 4C  
6 units, these units have 201 cobalt-60 sources which are  
7 stationary. There's an external helmet which has  
8 different sizes, 4, 8, 14 and 18 millimeter apertures  
9 which are directed towards the target.

10 And the Model B uses manual trunnions where  
11 the physician or therapist or medical physicist  
12 actually manually sets the X, Y and Z coordinates.  
13 Whereas with the automatic ignition system, which is  
14 shown here, in the Model C and 4C, this is done by the  
15 onboard system.

16 The Perfexion<sup>TM</sup> is different than the Model  
17 B, C and 4C units in that it has, rather than 201  
18 cobalt-60 sources, this has 192 cobalt-60 sources which  
19 are -- which move within eight permanently installed  
20 independent movable sectors. And these sectors are the  
21 4, 8, and 16 millimeter beams.

22 So there's one common air body with  
23 different diameters of the beams which correspond to the  
24 different positions where these beams come into place.  
25 And this is -- the machine itself uses a robotic cable

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1 which positions the patient's head position so that the  
2 beam is precisely delivered to the intended target.

3 So in the current regulations, the Model B,  
4 C and 4C are regulated by 10 CFR 35 Subpart H, whereas  
5 the Gamma Knife Perfexion<sup>™</sup> is 10 CFR 35 Subpart K as  
6 shown.

7 So here's the background of the current  
8 regulations. All Leksell Gamma Knife procedures are  
9 regulated by 10 CFR 35.615. And requirements are via  
10 the 10 CFR 35.615(f)(3).

11 It states that an Authorized User, AU, and  
12 an Authorized Medical Physicist, AMP, are physically  
13 present throughout all treatment involving the unit.  
14 The NRC defines physical presence as a distance "such  
15 that each can communicate with the other within hearing  
16 distance of normal voice."

17 In terms of Leksell Gamma Knife, there's a  
18 lot of training which is involved with this -- with these  
19 units. The training involves the device operation, the  
20 safety procedures which are involved, and the clinical  
21 uses which are involved with the Gamma Knife as well as  
22 the requirements of the Authorized User and Medical  
23 Physicist.

24 In terms of the operator, proper training  
25 is very important to ensure safety to the patient. And

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1 some of the requirements of proper training include how  
2 to release the patient from the couch. How I can move  
3 the couch out of the machine when there's a malfunction  
4 in the machine.

5 How to release the frame from the frame  
6 attachment. And also how to shield the doors manually.  
7 So these are all the forms of proper training for Gamma  
8 Knife uses.

9 In terms of rationale behind removing  
10 physical presence requirements for the Perfexion™, we  
11 know that the events requiring Authorized User or  
12 Authorized Medical Physicist are very rare. Patients  
13 -- they also, one of the thoughts is that patient safety  
14 would not be compromised by not having the Authorized  
15 User and Authorized Medical Physicist physically  
16 present throughout the entire treatment. But any  
17 person who is properly trained would be able to perform  
18 this task.

19 Now, if you take the ViewRay™ System, which  
20 also uses cobalt-60, it actually has a large source of  
21 cobalt compared to the Gamma Knife. This uses three  
22 cobalt-60 sources on a rotating gantry assembly that's  
23 integrated with an MR unit. So it's a very unique  
24 radiation delivery system.

25 This is regulated by 10 CFR 35 Subpart K.

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1 In lieu of 35.615(f)(3), this requires an Authorized  
2 User or Authorized Medical Physicist will be physically  
3 present in the department during the patient treatment  
4 and immediately available to come to the treatment room  
5 in an emergency. So this is a difference compared to  
6 the Gamma Knife Perfexion™'s regulations at this point.

7 So how often does a person actually enter  
8 the Gamma Knife unit to mainly undock a patient and close  
9 the shielding doors, which would be one of the concerns  
10 that one would have. So no one really knows the actual  
11 incidence according to the manufacturer of the Gamma  
12 Knife which is Elekta. This occurs very, very  
13 infrequently. And what they estimate is that this  
14 occurs about one in five thousand and one in ten thousand  
15 cases.

16 The time to physically undock a patient who  
17 is physically stuck to the unit and the amount of  
18 exposure that occurs, so the time to just undock the  
19 patient would take about 30 to 60 seconds. So it does  
20 not take very long. Again, this is provided that the  
21 person who is undocking the patient is properly trained.  
22 The exposure is less than 10 milligray, which has really  
23 negligible effect on the patient.

24 In terms of reasons for continuing  
25 Authorized User presence, there are a number of

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1 potential reasons why we would continue to have the AU  
2 physically present throughout the entire treatment.  
3 It would verify the integrity of the setup at the  
4 treatment machine.

5 We know that on occasions when we look at  
6 some of the reports of some of the deviation that occurs  
7 to Gamma Knife, it occurs with wrong site being treated.  
8 So actually having the Authorized User there from the  
9 very beginning would help really minimize that from  
10 occurring.

11 Also verified cart position with the use of  
12 in-room cameras that are focused on the patient and  
13 machine. So one of the things that I do when we are  
14 physically treating a case, is actually watch which  
15 direction the patient is moving so we know that if we're  
16 treating a left sided region, the patient should move  
17 over to the right and vice versa.

18 Also manage any clinical issues and/or  
19 treatment related toxicities that may occur during the  
20 Gamma Knife procedure. Also to be physically present  
21 for any critical decision making processes such as  
22 aborting the procedure in case something occurs where  
23 the patient's unstable during the treatment.  
24 Particularly for those treatments that are very long.

25 Also disconnect the patient from the

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1 machine in case of a malfunction. Which, although  
2 quite rare, is something that does require that the  
3 patient is physically released from the machine in a  
4 quick and expeditious manner.

5 And also to provide greater confidence to  
6 the patient and family during treatment by being present  
7 near the console areas. So in the rare event that an  
8 event should occur, the physician, or Authorized User  
9 is actually there to explain what has happened.

10 In terms of safety and Authorized User  
11 presence, it's important to recognize a problem when a  
12 situation does occur. So by actually physically being  
13 there to actually witness what actually occurred during  
14 the event, make a determination of the severity of the  
15 problem. And also to know the dose that was delivered  
16 to the incorrect treatment site if that were to occur  
17 as well.

18 I'll take any questions?

19 CHAIRMAN THOMADSEN: Before we take the  
20 questions and have discussion on this, one of our  
21 members who will be recusing herself, Dr. Langhorst,  
22 would you like to explain?

23 MEMBER LANGHORST: Yes, thank you. I just  
24 wanted to let the Committee know that Washington  
25 University in St. Louis has a license and sent an

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1 amendment request into our Region Three office  
2 requesting a change in Authorized User presence for  
3 Gamma Knife therapies.

4 And we're asking is what we had in place  
5 prior to the change in Part 35 in 2002, where that  
6 physical presence of the AU and AMP was first required.  
7 What we're requesting is to go back to the Authorized  
8 Medical Physicist will always be present, or an  
9 Authorized Medical Physicist. And then the Authorized  
10 User will be present at the beginning of the therapy.

11 And then either the Authorized User or the  
12 Neurosurgeon involved with this patient, who knows the  
13 patient well, who is trained in the exact same way that  
14 the Authorized User is trained by the Gamma Knife  
15 manufacturer -- Goes through that same treatment  
16 planning and all that training and emergency training  
17 and emergency medical response.

18 So I just wanted the Committee to know that  
19 I had this request into change our license. And so I  
20 was going to recuse myself from the discussion.

21 CHAIRMAN THOMADSEN: Thank you for the  
22 clarification. Now Dr. Suleiman.

23 MEMBER SULEIMAN: These may be pretty  
24 basic questions. But maybe somebody else doesn't  
25 understand them either. How many treatments per

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1 patient is it, by conventional therapy? I've got four  
2 questions, so let me run through them and maybe you'll  
3 be able to answer them all quickly.

4 How long does it take to do a single  
5 treatment? A minute? Five minutes? I have no feel  
6 for the system.

7 When you said ten milligray, is that to the  
8 target organ where you said turning the patient out  
9 would result in possibly an extra ten milligray. Is  
10 that to the target organ then is what I'd assume?

11 And when you said one in five thousand, do  
12 they know about -- are these predominantly equipment  
13 failures? Or you know, user problems?

14 And the last question was a -- a fifth  
15 actually. You said that there's been over 221,000  
16 cases through 2013. What's the annual workload on  
17 these types of devices?

18 MEMBER SUH: They're not invalid, so.  
19 Well let's go through them one by one, so.

20 Typically for a Gamma radiosurgery it's a  
21 single fraction or single session of radiation,  
22 although there is a modification with the Gamma Knife  
23 which actually allows us to do fractionated treatments.  
24 But for all intents and purposes, it's a single fraction  
25 of radiation for the various conditions, the benign

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1 tumors, malignant brain tumors, vascular malformation  
2 function disorders.

3 In terms of the treatment time, it really  
4 varies on a number of factors: the number of lesions  
5 that we're treating, the dose that we're using, and the  
6 activity of the unit itself. So a very short treatment  
7 would be 10 to 15 minutes. A very long treatment could  
8 be five hours.

9 MEMBER SULEIMAN: Okay.

10 MEMBER SUH: So it really varies from  
11 patient to patient. In terms of the dose, the organ is  
12 actually the target site itself. So one of the nice  
13 things about Perfexion™ is that the amount of radiation  
14 exposure to non-target organs is much less compared to  
15 Model B, C and 4C.

16 In terms of the actual incidence of one in  
17 five thousand, again that's what a -- that's what the  
18 manufacturer -- or one in ten thousand is what the  
19 manufacturer is estimating the risk to be. And that can  
20 typically be a malfunction.

21 One of the things that happened to us is  
22 that we had power outage, it actually kicked the patient  
23 out of the machine. But if things don't work, sometimes  
24 you have to manually retrieve the patient if that were  
25 to occur.

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1                   And then in terms of the 221,000 cases per  
2 year, that number continues to go up. Worldwide over  
3 seven hundred thousand patients have been treated with  
4 the Gamma Knife as of 2013. So each year the number goes  
5 up.

6                   And in terms of each institution, there are  
7 some institutions that don't do many cases. There may  
8 be less than a hundred per year, whereas very busy  
9 centers go over five hundred per year. So you have  
10 quite a range in terms of the number of cases being done.

11                   CHAIRMAN THOMADSEN: Mr. Costello?

12                   MEMBER COSTELLO: I have two questions,  
13 mainly to do with the NRC. You referenced the  
14 requirements for the ViewRay™, right? It got approved?

15                   MEMBER SUH: Yes.

16                   MEMBER COSTELLO: Okay. And you  
17 mentioned it's under 35.600. Why isn't the ViewRay  
18 regulated under 35.1000? I know it's going to be  
19 regulated under 35.600. So I think with that  
20 requirement, the ViewRay™ really is going to product for  
21 the ViewRay™. I think that the NRC or somebody is going  
22 to come up with requirements for the ViewRay™. Am I  
23 right there? Are they seeking that?

24                   MR. FULLER: Yes, this is Mike Fuller.  
25 Yes you are correct Mr. Costello. And in fact I think

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1 that's what Dr. Suh said. The ViewRay is being  
2 regulated under 35Subpart K, which is what we refer to  
3 as 35.1000. And yes, so they'll --

4 MEMBER COSTELLO: I thought that 35.600  
5 referenced up that for the ViewRay™. Maybe I'm  
6 figuring that --

7 MR. FULLER: Yes, so he said for the Gamma  
8 Knife, it was 35.600, Perfexion™ 35.1000. And for the  
9 ViewRay™, so that he had -- yes, 35.1000(k).

10 MEMBER COSTELLO: Okay, so the slide  
11 that's up there now says in lieu of 35.615, part (f),  
12 is that what the requirement is for the ViewRay™? Okay,  
13 thank you.

14 And the other question I have is, are the  
15 -- the position that you're taking, would that be any  
16 different than the other Gamma Knives that we've had?  
17 In other words if we were to relax the AU presence  
18 requirement for the Perfexion™, should we consider  
19 relaxing them for the other Gamma Knives?

20 MEMBER SUH: So Gamma Knife is one form of  
21 stereotactic radiosurgery that uses radioactive  
22 isotope cobalt-60. The other stereotactic  
23 radiosurgery systems actually use linear accelerators  
24 for that. But they're not regulated by ACM -- or by NRC.

25 MEMBER COSTELLO: But I meant to say, the

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1 other Gamma Knives that they've talked about, okay. If  
2 we relax the physical presence requirements for the  
3 ViewRay™, should we relax them for them as well?

4 MEMBER SUH: So apparently all the Gamma  
5 Knives, the B, C, 4C, Perfexion™, all are Authorized  
6 User presence for the entire treatment. And that's for  
7 stereotactic radiosurgery. So in my mind stereotactic  
8 radiosurgery is where you're giving a very high dose or  
9 an ablative dose of radiation in hopes of in the case  
10 of benign brain tumors to ensure the patient and to  
11 return the function where it's actually like a very  
12 small target.

13 Whereas with ViewRay™, I think in terms of  
14 clinical applications, they are -- they can use it where  
15 they're actually treating different body parts.

16 MEMBER COSTELLO: Understood, I'm not  
17 talking about the ViewRay™ anymore. Okay. I'm saying  
18 this presentation's about the Perfexion™ unit?

19 MEMBER SUH: Yes.

20 MEMBER COSTELLO: Well if we were to  
21 conclude that we want to recommend that the physical  
22 presence requirements for Perfexion™ be relaxed, should  
23 we relax them for the other Gamma Knife types?

24 CHAIRMAN THOMADSEN: Dr. Welsh?

25 MEMBER WELSH: If I could just quickly

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1 comment. My interpretation of Dr. Suh's presentation  
2 was that we were not planning on relaxing Authorized  
3 User presence for Perfexion™ or any of the other Gamma  
4 Knives.

5 MEMBER COSTELLO: Okay.

6 MEMBER WELSH: So please correct me Dr. Suh  
7 if I've misinterpreted this.

8 MEMBER SUH: No. So my position is that  
9 the Gammas have a very long and successful track record  
10 of safety. And Perfexion™ is a very -- is a great device  
11 in treating patients. And right now the current  
12 standards that we have in terms of having Authorized  
13 User, Authorized Medical Physicist present, I think has  
14 helped ensure that.

15 So I think any change from that, I think  
16 would require a lot of discussion and a lot of thinking  
17 about what implications that might have.

18 MEMBER COSTELLO: I understand. I knew  
19 there was a request, you know or an incident request,  
20 to relax the request as it were before to cause material.  
21 In fact when you talked about how infrequent these  
22 events occur, that we might want to support that be  
23 relaxed. But that's not your position.

24 MEMBER SUH: No. I'm just presenting both  
25 sides though.

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1 MEMBER COSTELLO: Thank you very much.

2 MEMBER SUH: In fact we're not going for it  
3 and we're not having the current requirement to continue  
4 at the present.

5 CHAIRMAN THOMADSEN: Dr. Alderson?

6 MEMBER ALDERSON: Yes, two questions.  
7 The first one has to do with when you're talking about  
8 wanting the Authorized User to still be present, if the  
9 Neurosurgeon's there and has been trained, do you  
10 consider an Authorized Medical Physicist plus the  
11 Neurosurgeon, is that adequate or does the Authorized  
12 User still have to be there?

13 MEMBER SUH: So right now Neurosurgeons  
14 are not Authorized Users. They have participated in  
15 the case. They're very involved with frame placement,  
16 treatment planning, helping ensure that we have  
17 accorded care of a patient. They are not an Authorized  
18 User. So that would not differentiate.

19 MEMBER ALDERSON: That would not, okay  
20 that's the answer to that question. The second  
21 question has to do with the Energy Bill that Ms. Dudes  
22 mentioned in her introduction, the Source Security  
23 Bill.

24 Now I read through that, and it states in  
25 here in concern of Source Security and cobalt-60 is a

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1 source about which the Government is quite concerned.  
2 That within five years, that they'd like to see those  
3 sources replaced with some other kind of source.

4 And as I looked at that, and I have a little  
5 experience, not like you have with the Gamma Knife. I  
6 mean I didn't know what that alternate source might be,  
7 or if that you know, proposal threatened the very  
8 existence of the Gamma Knife.

9 So I just thought -- is this Bill actually  
10 approved, or is it still just being discussed?

11 MS. DUDES: Yes, the Bill right now, it  
12 came from the subcommittee of the Senate Appropriations  
13 Committee. So what would have to happen is they'd have  
14 to conference with the House Committee on  
15 Appropriations and then agree on some language.

16 And so no. It's still in draft form. And  
17 there's still a lot of discussion on that. Although I  
18 would like to hear some discussion on that -- the issue  
19 you raised because that comes up in our discussions with  
20 the congressional staff, in terms of is there an  
21 equivalent. And what would the impact of phasing out  
22 this particular source? What type of impact would that  
23 have on the medical community?

24 And as far as I know, you know right now I'm  
25 not sure there are alternatives that are equivalent.

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1 So there's only --

2 MEMBER ALDERSON: I think that the two  
3 kinds of instruments, and I'm not trying to distract us  
4 from your issue, I'll make this brief. Blood  
5 irradiators and blood banks, that's a chromium source.  
6 And they -- there are people now that are manufacturing  
7 different types of blood irradiators that don't involve  
8 radionuclides.

9 MS. DUDES: Right.

10 MEMBER ALDERSON: So I think that would be  
11 relatively straightforward. But this one, I don't know  
12 what you would do to replace those powerful cobalt-60  
13 sources.

14 MS. DUDES: I don't know either.

15 CHAIRMAN THOMADSEN: I do want to talk  
16 about that issue later in the meeting as a --

17 MS. DUDES: Okay.

18 CHAIRMAN THOMADSEN: As a topic. But  
19 right now I think we should stick with the Physical  
20 Presence issue with this. Ms. Weil?

21 MEMBER WEIL: So the requirement for the  
22 presence of the Authorized User and the Medical  
23 Physicist clearly has a benefit to the patient in terms  
24 of safety. But is there a countervailing barrier to  
25 using this treatment? Making the availability of the

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1 treatment because of the time commitment of the  
2 Authorized User?

3 Would clinicians perhaps recommend a  
4 different, maybe the linear accelerator based LINAC, do  
5 I have that word right?

6 MEMBER SUH: Um-hum.

7 MEMBER WEIL: Go in that direction where  
8 the requirement is less onerous? I guess my question  
9 is simply, is there a -- does this create a barrier to  
10 access to treatment for patients?

11 MEMBER SUH: So in terms of access to  
12 barrier, I do not believe it impairs access to their  
13 treatments. It does from the workplace standpoint  
14 requiring an Authorized User to be physically present  
15 throughout the entire treatment, would impede his or her  
16 ability do other medical tasks.

17 So -- because the current guidelines  
18 recommend that -- or current guidelines state that the  
19 Authorized Medical User has to be within voice distance.  
20 So I can't be you know, a hundred yards away. I mean  
21 I would violate the rules in terms of what's required.

22 So from a patient standpoint, for practices  
23 where you would have a very busy Gamma Knife practice,  
24 that is something that you do need to juggle in terms  
25 of how you have an Authorized Medical User present

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1 during the entire treatment. And there are different  
2 ways of doing that in terms of ensuring that that occurs.

3 In part, it's just you know working with the  
4 schedules to make sure that it fits with this. There  
5 are some centers that actually have dedicated bays where  
6 the Authorized User actually is present for the entire  
7 treatment. So they know from start to finish that he  
8 or she will be present for that entire day.

9 Some of the centers will split up the  
10 schedules where there's an Authorized User for the first  
11 part and there's another person for the second part of  
12 the day. So there's different ways of doing it.

13 So in terms of access to care, as I  
14 mentioned, the use of Gamma Knife really varies  
15 depending on the center. There are some centers that  
16 are not very busy. They do maybe a couple of cases a  
17 week. Whereas other centers will do five to 10, 15  
18 cases in a given week with no problems. So I think it's  
19 imperative to access for patient care.

20 MEMBER WEIL: So do you think that the use  
21 of this particular therapy is impeded, because clearly  
22 it's a more precise way of delivering radiation,  
23 correct? To use the target site.

24 Do you think that there's less use of this  
25 particular modality because of the required presence of

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1 the Authorized User? Or is it simply that of those  
2 cases that need to be done are getting done this way.  
3 And loosening up the requirement would not create more  
4 availability for patients to this particular modality?

5 MEMBER SUH: So there are different forms  
6 of stereotactic radiosurgery, there's high dose, high  
7 precision radiation. Gamma is one of multiple units  
8 that are out there. So depending on your medical  
9 center, what you're familiar with, that's the device you  
10 would use.

11 So I do not believe that this requirement  
12 is going to decrease the use of Gamma. If anything the  
13 use of Gamma is actually increased. Particularly for  
14 patients with brain metastases, which is a very common  
15 condition.

16 Each year over 200,000 Americans develop  
17 brain metastases. And it's becoming the preferred  
18 treatment modality over the traditional whole brain  
19 radiation therapy that we've used for the past 60 years.

20 So again, I don't think that's a barrier in  
21 terms of treatment. But it does from a workplace  
22 standpoint, at least for some practices it can make the  
23 work a little trickier and that one needs to work around  
24 that.

25 CHAIRMAN THOMADSEN: Dr. Welsh?

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1                   MEMBER WELSH: I have a few comments and  
2                   questions if I might. First, in regards to Dr.  
3                   Suleiman's question earlier, another factor of course  
4                   is that the duration of the treatment is inversely  
5                   proportional to the age of the cobalt-60.

6                   Regarding the estimated manufacturer's  
7                   figures of one in five thousand or one in ten thousand,  
8                   anecdotally, I think those are very, very conservative  
9                   figures out. I think that if you've had one instance  
10                  Dr. Suh where you've taken a patient out, and I have and  
11                  others who've used the Gamma Knife might report  
12                  something from a few years back. It amounts to  
13                  something higher than one in five thousand, one in ten  
14                  thousand.

15                  And that gets to an important point about  
16                  the Neurosurgeons not being Authorized Users and not  
17                  being fully equivalent to radiation oncologists in  
18                  terms of their appropriateness as potential Authorized  
19                  Users. Without any disrespect intended, they do not  
20                  have the training in radiation physics, radiation  
21                  biology and certainly not in radiation safety.

22                  And the one week course that I took, that  
23                  we all have to take for the vendor's specific training  
24                  from Elekta or from an institution that uses the Gamma  
25                  Knife. Certainly is not satisfactory for someone to

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1       become an Authorized User without the four year  
2       background in radiation oncology in my opinion.

3               So for radiation safety purposes, a  
4       radiation oncology Authorized User presence is still  
5       certainly justified. And as he pointed out, the track  
6       record of safety with this instrument perhaps justifies  
7       maintaining the status quo.

8               Additionally the fact that this is single  
9       fraction stereotactic radiosurgery as opposed to  
10       fractionated radiation therapy differentiates this  
11       Gamma Knife from other means of external beam radiation  
12       therapy including the ViewRay. And therefore  
13       radiation therapists who may be appropriate for a  
14       ViewRay™ management and maybe Authorized User presence  
15       could be relaxed with a ViewRay™, that analogy does not  
16       hold for the Gamma Knife which is single fraction,  
17       stereotactic radiosurgery with often with a device  
18       bolted to the cranium.

19               And removing the patient from the machine  
20       might require different efforts from what would be  
21       expected from a LINAC or a ViewRay™ device. So  
22       radiation therapists might be capable of managing the  
23       situation with the ViewRay or LINAC, but I don't think  
24       a Neurosurgeon would be the appropriate person for any  
25       of the above.

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1                   For Dr. Alderson's question, I would like  
2                   to point out that what -- an alternative device, the  
3                   CyberKnife. In my personal experience, and I've got a  
4                   fair amount of experience with both the Gamma Knife and  
5                   the CyberKnife. The involvement of the Neurosurgeon  
6                   was essentially zero because we do not bolt the device  
7                   directly to the cranium in the CyberKnife.

8                   Other institutions may have different  
9                   policy and philosophy, but the Neurosurgeons may bring  
10                  up a case in tumor board and suggest radiosurgery and  
11                  that would be the extent of their involvement. The  
12                  treatment, stereotactic radiosurgery, whether it's  
13                  done with a Gamma Knife, a CyberKnife or another  
14                  appropriate technology is radiation oncology and the  
15                  physician involved is the radiation oncologist. The  
16                  Neurosurgeons role is likely as a referral physician.

17                  That is not always the case with the Gamma  
18                  Knife where the Neurosurgeons have traditionally been  
19                  more actively involved. And they do have a hands-on  
20                  role. And that's a slight distinction between Gamma  
21                  Knife and the other approaches. But it's more of a  
22                  philosophical rather than a mental or procedural  
23                  difference.

24                  And as far as Ms. Weil's comment, I think  
25                  that in my personal experience, there really hasn't been

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1 any impedance to patient flow in the clinic from a  
2 physical presence requirement of the Gamma Knife. And  
3 it hasn't really been very different with CyberKnife  
4 versus Gamma Knife.

5 When there's a CyberKnife case going on,  
6 yes I could be doing other things perhaps. But first  
7 and foremost it's my obligation to be available for the  
8 activity going on in the CyberKnife vault.

9 So in essence, there really has been no  
10 impedance to workflow or use of the Gamma Knife because  
11 of the requirements. And for those reasons, I still  
12 advocate as Dr. Suh has mentioned, keep maintenance of  
13 the status quo in keeping the Authorized User presence  
14 the way it is.

15 CHAIRMAN THOMADSEN: Point of  
16 clarification Dr. Suh. If there's an emergency with  
17 the Perfexion™ to remove the patient from the device,  
18 do you need to unbolt the patient from the frame?

19 MEMBER SUH: Yes. We have to release them  
20 from the machine itself.

21 CHAIRMAN THOMADSEN: You release the frame  
22 from the machine?

23 MEMBER SUH: From the machine.

24 CHAIRMAN THOMADSEN: You do not unbolt the  
25 frame from the patient?

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1                   MEMBER SUH: No, that's done later on.  
2                   Yes. So you'd have to release the treatment couch, pull  
3                   the patient and release them from the -- the tact -- the  
4                   machine itself.

5                   CHAIRMAN THOMADSEN: I'm sorry what?

6                   MEMBER SUH: You'd have to release them  
7                   from the machine itself. So the frame itself is not --  
8                   you don't remove the frame while the patient's inside  
9                   the machine.

10                  CHAIRMAN THOMADSEN: Okay. Can we go to  
11                  your slide talking about -- I think it's the fourth from  
12                  the end on the requirements for -- yes, that one right  
13                  there. Of those reasons, which ones would be  
14                  compromised by having the patient be -- the Authorized  
15                  User present in the department but not necessarily in  
16                  that room?

17                  MEMBER SUH: Well the setup I think is very  
18                  important for the Authorized User to be present at the  
19                  very beginning. Because if that's set up incorrectly,  
20                  the treatment's not going to go well. So I think that's  
21                  imperative in my opinion.

22                  I think correct positioning. We have seen  
23                  cases through this Committee of wrong side being  
24                  treated. And that's the last effort of saying am I  
25                  treating the correct side and is the patient with the

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1 correct right. Typical function case, I think that's  
2 very important.

3 The -- and if there's any clinical issues  
4 or -- that occur, if I'm not -- if I'm -- again, this  
5 is where I think the definition becomes very difficult.  
6 There's what constitutes being present in the  
7 department. Because as you know, there's some  
8 departments that are buildings away.

9 So you know if I'm in a different building  
10 and I consider that being present in the department and  
11 there's some issues that occur, I'm not going to be  
12 available for the patient. So I'd say point number  
13 three is also -- would be important.

14 Current decision-making is in my opinion  
15 the -- anytime you do a -- this is called radiosurgery.  
16 And although it's not surgery in the classic sense, it  
17 does require a very high dose of radiation where we are  
18 trying to emulate what a surgeon would do in the  
19 operating room, whether it be ablated doses to a tumor  
20 or to a vascular structure or to a nerve itself.

21 I think being present for the critical  
22 decision-making process whether or not to abort the  
23 case, there's some issues with the patient, I think  
24 again require Authorized User presence. Disconnecting  
25 a patient, that's something that again, I think if

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1 someone is properly trained that can be done, although  
2 I personally would want to be present if that were the  
3 case.

4 And I think the last bullet point is really  
5 more the, you know, from the patient and family  
6 standpoint you know, if something were to occur and I  
7 were not -- or if the Authorized User were not physically  
8 present during that event, and let's say it took me five  
9 to ten minutes to come over to actually see what  
10 happened. I measure how that would be perceived by the  
11 patient and family.

12 So again, I think you could -- in my  
13 opinion, I think these are all reasons for having  
14 Authorized User presence. I think one could argue if  
15 one is more critical than the other. But I think it's  
16 very important, the set-up is very important. Making  
17 sure the correct position is very important in terms of  
18 treatment delivery.

19 And I think if there's any issues that occur  
20 during treatment, I think the Authorized User needs to  
21 be present to make that decision of -- if something  
22 should happen, to abort the case, stop the case.  
23 There's sometimes where the patient will, especially if  
24 it's a long treatment, they'll say, "I need to get up  
25 because my back is really hurting me." I've got to get

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1 up because I have to urinate. For various reasons, they  
2 have to reset the patient.

3 So, you know, for those reasons, I think  
4 having an Authorized User presence is important.

5 CHAIRMAN THOMADSEN: Yes, Dr. Zanzonico?

6 MEMBER ZANZONICO: Pat Zanzonico. I have  
7 no first-hand experience with these modalities, so I  
8 have a couple of basic questions. The first is what  
9 typically, or how do you typically recognize a problem?  
10 It strikes me that that could be subtle and really would  
11 require inside of the operation of the issuance  
12 substance and so on, that not any individual might have.

13 So what typically, if there is a typical  
14 instance, how do you recognize that a problem is  
15 occurring?

16 MEMBER SUH: So again, I think you can  
17 divide it up into several. So one could be medical.  
18 And so we really watch the patients through a couple of  
19 cameras that are in treatment. There's also a  
20 microphone above the patient so he can say something.  
21 So if the patient says, "I'm not feeling well, I need  
22 to get out of the machine", we are able to press abort,  
23 for the patient to come out.

24 So I think there are medical reasons for  
25 that. I think sometimes you'll see something -- and

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1       again, it's very rare, but something in the machine just  
2       doesn't, something isn't moving right.  And that's  
3       another case where you have to make that decision.  Do  
4       we stop and have the patient come out?  Again, it's very  
5       rare, but again I think being there and to make that  
6       decision as well.

7                   And ultimately from the patient  
8       standpoint, my personal experience has been when we go  
9       through the risks and benefits of the Gamma Knife  
10      procedure, go through what could happen, what may happen  
11      as a result of the treatment, during treatment, that  
12      patients have a seizure while they're undergoing  
13      treatment.  That I have to be actually physically  
14      present, I think it's just a lot more comfort to the  
15      patient and families that are in this, that entire  
16      treatment process.

17                   So I view this very much as being part of  
18      a surgical procedure.  As making sure that I'm there for  
19      all the parts of the treatment.

20                   MEMBER ZANZONICO:  I had a second  
21      question.  If a treatment needs to be aborted, can it  
22      be effectively resumed?

23                   MEMBER SUH:  Yes it can be.

24                   MEMBER ZANZONICO:  Or is it a one  
25      opportunity only and if it's not done correct --

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1                   MEMBER SUH: No, no, it can be done again.  
2                   So there are times where -- so there are some patients  
3                   who for physical reasons, they have a lot of back pain.  
4                   They say I really need to take a break right now. So  
5                   we just try to take it between the various shots of  
6                   radiation so that can start with the next shot.

7                   Sometimes patients will say, "You know, my  
8                   bladder's getting full, I need to use the restroom." So  
9                   again, patient comfort is also very important as well.

10                  With the Perfexion<sup>TM</sup>, one of the things  
11                  that's happened is that in terms of throughput of  
12                  patients, it's clearly better than in the older units.  
13                  So the treatment itself are faster, and which is I think  
14                  great from a patient care standpoint.

15                  Also from an Authorized User standpoint,  
16                  the physical amount of time that you're spending at the  
17                  Gamma is going to be less than if you have an older unit  
18                  like a Model B or Model 4C where you're physically  
19                  swapping out the various helmets or actually making some  
20                  changes with the trunnions if you have an older unit.

21                  MEMBER ZANZONICO: Dr. Suh, you know I  
22                  believe there's some radiobiological advantage to  
23                  delivering this dose at a high dose rate in a single  
24                  fraction. So I understand if a patient had a sort of  
25                  a easing temporarily in single imaging session, stop as

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1       you say to urinate or whatever. But what if it was  
2       something where the patient had to be treated not later  
3       that day, that same day, but a day later or a week later.  
4       Could that be done and still be effective?

5                   MEMBER SUH: Since this requires the  
6       patient to have a frame on the patient's head, we don't  
7       like to keep the frame on the patient's head for a very  
8       long time. There have been instances where we have  
9       actually kept the patient on -- the frame on the patient  
10      that evening, and treated early the next morning for  
11      various reasons.

12                   So again, we want to try to do the  
13      treatments in a specified period. So we would not keep  
14      the patient's frame on for a whole week for instance.

15                   There is a product that Elekta has made  
16      which is called the Extend System, which is a bi-plate  
17      system that using a mold in the back, which actually  
18      allows for fractionated treatment, one to five  
19      fractions of treatment.

20                   CHAIRMAN THOMADSEN: We have a member of  
21      the public who would like to speak.

22                   MS. FAIROBENT: Thank you Dr. Thomadsen.  
23      Lynne Fairobent with AAPM. Dr. Suh, of the Gamma Knives  
24      in the U.S., about how many of them are there today?

25                   MEMBER SUH: So there are about 100 and --

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1 I'd probably say 120 to 130. I don't have the exact  
2 numbers. But if it's a --

3 MS. FAIROBENT: That's fine. And of  
4 those, my understanding is most of them today are  
5 Perfexion™. That most of the older units have been  
6 replaced. Is that correct?

7 MEMBER SUH: I don't know if it's most.  
8 But I know many of them are being replaced. In fact  
9 Elekta has you know, are no longer going to be servicing  
10 the older units. They are moving towards Perfexion™.  
11 I mean that's what they want to use as a treatment.

12 And it has a lot of carry back advantages  
13 over the older units, Model B, the C and the 4C units.

14 MS. FAIROBENT: Okay. And on the slide  
15 that Dr. Thomadsen asked you to address, which of those  
16 could the Authorized Medical Physicist who has to also  
17 be physically present during the entire treatment, if  
18 the AU was -- if their requirement was relaxed so that  
19 the AU could be in the department, but the AMP had to  
20 remain physically present, is there anything there that  
21 you would see after the initial setup with the AU  
22 present, him moving into the department to do other  
23 things?

24 And I agree, if the department's in another  
25 building, we might have to look at the definition

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1 distally or geographically what that might mean. But  
2 versus personally at the console.

3 MEMBER SUH: So, I would say that bullet  
4 point number five, disconnecting the patient from the  
5 machine in case of malfunction is something that a  
6 Medical Physicist could clearly do if they're properly  
7 trained. I think in terms of the set-up, the Physicist  
8 could also be involved as well.

9 Although again, in my personal opinion, I  
10 think it is very important the physician is there for  
11 the set-up because that's where you catch potential  
12 errors from ever reaching the patient. I think  
13 verifying the position, I think ultimately the Phys --  
14 the Authorized User which is the radiation oncologist  
15 has to make that decision as well.

16 And in terms of clinical treatment-related  
17 toxicities, that's not the role of the Medical  
18 Physicist. Clearly the decision making and they can  
19 have some part. But ultimately the Authorized Medical  
20 User has to be making that decision.

21 And in terms of patients and families,  
22 Medical Physicists are very important in terms of the  
23 overall treatment. For patients with gamma  
24 radiosurgery ultimately the physician that has to be the  
25 person there.

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1 MS. FAIROBENT: Might this then be a case  
2 where the physical presence of the AMP could be relaxed,  
3 but the physical presence of the AU maintained?

4 MEMBER SUH: I think it's a team effort.  
5 And as Dr. Welsh mentioned, I think if you look at the  
6 safety record for Gamma Knife radiosurgery, I think it's  
7 really -- I think it epitomizes when proper training is  
8 done and when there's proper education and how safe  
9 directors can be quite high for radiosurgery.

10 And it is a treatment that is continuing to  
11 be used more and more often. So I think it is very  
12 important that we continue to maintain that high safety  
13 standard.

14 MS. FAIROBENT: Thank you.

15 CHAIRMAN THOMADSEN: And thank you. We  
16 have another member of the public. Please identify  
17 yourself.

18 DR. GOETSCH: Yes, I'm Steve Goetsch. I'm  
19 a Medical Physicist at the San Diego Gamma Knife Center.  
20 We're about to have our 20th anniversary. We've  
21 treated about four thousand patients there.

22 I'm appearing today as a consultant with  
23 Elekta. I've been helping them with the Gamma Knife  
24 Perfexion™ since the first one was installed in 2006 at  
25 Washington Hospital in Fremont.

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1 I obtained a license before their physicist  
2 came onboard. I'm also the Chairman of the AAPM Task  
3 Group 178, which is a group I worked for five years on  
4 QA and dosimetry calibration procedures for the Gamma  
5 Knife.

6 I want to thank John for his excellent  
7 presentation and add one more thing. Two weeks ago in  
8 ASTRO, Elekta finally unveiled, although under very  
9 restricted circumstances, the newest evolution, the  
10 Gamma Knife Perfexion™ Plus. Counting for some time,  
11 I believe it is now FDA approved. And it includes a cone  
12 beam CT.

13 The extended frame that John was talking  
14 about has not been very well accepted. There's like  
15 five or six in the United States. The new one has a face  
16 mask and head frame system. And the whole idea is to  
17 do fractionated treatments.

18 I think it's going to be very well accepted.  
19 I think it may end up changing clinical practice of the  
20 Gamma Knife. More and more Gamma Knives may go to four  
21 or five fractions.

22 To be blunt, in January of last year, the  
23 Fiscal Cliff Bill, language was inserted in that Bill  
24 strikingly reducing the amount of money for the Elekta  
25 Gamma Knife for single fraction. There's a huge

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1 financial incentive to do four or five fractions.  
2 People are looking at that.

3 So that may change things. One other  
4 comment I -- perhaps someone here could verify this. At  
5 the AAPM meeting in Texas this summer, a Medical  
6 Physicist from Texas tells me the State of Texas now  
7 places Neurosurgeons on their Gamma Knife license. I  
8 haven't verified this myself, but it's been talked about  
9 before.

10 It is an interesting idea. I am not sure  
11 I can recommend it, but it is an interesting idea.

12 CHAIRMAN THOMADSEN: Thank you Dr.  
13 Goetsch. Mr. Welsh -- or Dr. Welsh?

14 MEMBER WELSH: Just a few additional  
15 comments to a follow up. When Dr. Zanzonico asked about  
16 how we recognize patient problems and what are some of  
17 the justifications for physician presence or Authorized  
18 User presences. And as Dr. Suh pointed out, in my  
19 experience as well, sometimes these patients will have  
20 seizures. And appropriately swift intervention may be  
21 appropriate.

22 And there was one instance that I recall  
23 where a patient had a mouthpiece in and was unable to  
24 communicate through the microphone. But you could see  
25 the stomach going up and down. We recognized that this

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1 patient is about to vomit.

2 And had we not been there to recognize that  
3 -- and with all due respect to our therapists and  
4 Physicists who are there, they didn't pick this up as  
5 quickly as the physicians and the Authorized User.  
6 That could have been a disaster because of aspiration  
7 with the patient locked there in place and that was an  
8 example that I could call needing appropriate quick  
9 intervention.

10 As far as the use of fractionation in  
11 stereotactic radiosurgery, it's not infrequent and  
12 depends on the diseased entity. Maybe not so much for  
13 a brain metastases, but for other conditions such as  
14 acoustic neuroma is a good example.

15 Fractionation stereotactic radiotherapy  
16 is often used in lieu of single fraction stereotactic  
17 radiosurgery. Such fractionation has traditionally  
18 been far more frequent with LINAC-based radiosurgery  
19 such as the CyberKnife, then it has been with the  
20 cobalt-60 based Gamma Knife.

21 However, I've just heard from Dr. Goetsch  
22 that maybe with the -- in the future with the Gamma Knife  
23 Perfexion™ Plus, fractionation would be more common  
24 with the Gamma Knife as well. But from my perspective,  
25 the biggest difference and perhaps the largest

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1 justification for Authorized User presence with the  
2 Gamma Knife continuing, is that one is cobalt-60  
3 radionuclide source which cannot be shutoff if there is  
4 a malfunction.

5           Whereas with the LINAC-based radiosurgical  
6 techniques, they can always be electrically overridden  
7 and shut down. So that's one of the main reasons why  
8 Gamma Knife radiosurgery differs from say the  
9 CyberKnife.

10           Now this analogy does not hold with the  
11 ViewRay<sup>™</sup> because it's more akin to conventional  
12 fractionated radiation therapy. I would say that if  
13 we're dealing with a true stereotactic procedure with  
14 the ViewRay<sup>™</sup>, the analogy may hold. And maybe we could  
15 have an argument in favor of Authorized User presence  
16 there too, based on the same logic.

17           But as it is right now, the stereotactic  
18 radiosurgery where the patient is immobilized  
19 intensively, Authorized User presence is justified with  
20 the cobalt more than it is with the electrically  
21 administered treatments.

22           CHAIRMAN THOMADSEN: Thank you very much  
23 Dr. Welsh. Yes, Dr. Palestro?

24           MEMBER PALESTRO: Yes, just a couple of  
25 quick comments. Radiation oncology is away from my

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1 field, it's nuclear medicine.

2 And in listening to your presentation at  
3 the beginning, in terms of having an alternative to the  
4 Authorized User or the Authorized Medical Physicist, I  
5 was thinking in terms of malfunction of the equipment  
6 of one sort or another that would require shutting it  
7 down and removing the patient and so forth.

8 But as I heard you and Dr. Welsh talk, it  
9 becomes apparent particularly since most or maybe all  
10 of these therapies are devoted to the brain and central  
11 nervous system, that reasons for discontinuing the  
12 procedure may be far more than a mechanical malfunction.  
13 They can be serious complications, seizures, perhaps a  
14 cerebrovascular accident.

15 That in this slide where it says any person  
16 properly trained would be able to perform the task. I  
17 would think that that person would have to have a very  
18 sophisticated knowledge of medicine to recognize what  
19 all was going on and to be able to do more than just shut  
20 off the machine for example, or end the procedure.

21 MEMBER SUH: I agree. I agree. I think  
22 having a physician present, I think the -- and one of  
23 the things -- one of the things I also want to bring out  
24 as well is you know, when I think about stereotactic  
25 radiosurgery, it's very much a team effort between you

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1 know, there's radiation oncologists involved, the way  
2 the Gamma is done, there's much stronger a surgery  
3 presence, a strong Medical Physicist presence as well.

4 So it takes a team to ensure that treatment  
5 is delivered safely, it's delivered accurately. It's  
6 delivered precisely as well. So I think it is very much  
7 a team effort and as these slides are showing, the track  
8 record for Gamma Knife radiosurgery has been superb.

9 And I think if you compare it to some of the  
10 other radiation device policy, and we have to, it is --  
11 it is something very high. And I think part of it is  
12 there is very rigorous training involved. And the  
13 processes are -- it's somewhat very prescriptive as to  
14 how things are done.

15 So in terms of trying to, in terms of  
16 getting an error to occur, I think we want to try to  
17 minimize any of those errors from occurring. So  
18 whether the QA is on the machine, et cetera, it makes  
19 it very easy to deliver the radiosurgery very accurate,  
20 very precisely for patients.

21 There are plenty of patients who benefit  
22 from this technology.

23 CHAIRMAN THOMADSEN: Thank you for the  
24 question and for the clarification. Other comments  
25 from ACMUI? I'm hearing none. We don't seem to have

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1 any motion before us. So I will thank Dr. Suh.

2 And we have a break time scheduled at this  
3 moment. We'll be resuming at 10:00. Please be on  
4 time.

5 (Whereupon, the above-entitled matter went  
6 off the record at 9:38 a.m. and resumed at  
7 10:02 a.m.)

8 CHAIRMAN THOMADSEN: Welcome back and our  
9 first presentation will be by Ms. Holiday to enlighten  
10 us on how the NRC decides on licensing, their 10 CFR  
11 35.1000.

12 MS. HOLIDAY: Thank you.

13 So, this talk may sound a little familiar  
14 to a few people in this room since I gave it last month  
15 as OAS, so I'll speak to this a little bit for this  
16 Committee.

17 So, I will speak to you this morning on how  
18 NRC licenses, emerging technologies and your 10 CFR  
19 35.1000. We all know that this is a topic of particular  
20 interest to the Committee, especially since just last  
21 year, we issued guidance under 35.1000 for the ViewRay™  
22 device and there are other technologies that are coming  
23 down the pipeline that we suspect will also go under  
24 35.1000 in the very near future.

25 So, what is this all about? Again, 35.1000

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1 or 10 CFR Part 35, Subpart K captures emerging  
2 technologies. This was in response from the medical  
3 community.

4 A final rule was published in April of 2002,  
5 which codified into regulations what NRC has been doing  
6 for quite some time. So, we created this new section  
7 called Subpart K, or better known as 35.1000.

8 And the real beauty of 35.1000 is that it  
9 helps us avoid extremely lengthy rulemaking. As I'm sure  
10 we all know how long it takes to push a rule out, by  
11 putting emerging technologies that can't meet certain  
12 sections in the regulations into 35.1000, we're able to  
13 avoid that.

14 For example, the ViewRay<sup>TM</sup> guidance was  
15 published within nine months start to finish versus  
16 maybe ten years for the rulemaking.

17 So, today, what actually initiates the  
18 review? So, what happens here are different pathways  
19 that we are either notified or what prompts staff to  
20 start looking.

21 So, for the first bullet points, staff may  
22 hear by ear or by word of voice about the universe of  
23 technology that's coming down the line.

24 We may also hear via a formal request from  
25 an agreement state through the OAS Board or from just

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1 general conversations about new emerging technology  
2 that may be licensed in an Agreement State.

3 We may also hear from the FDA about a new  
4 emerging technology. Dr. Howe, in particular, gets  
5 information from the FDA from time to time about new  
6 devices and this may prompt her to reach out to the  
7 medical team about, hey, there's this new device, maybe  
8 we should look at it and see how this may affect our  
9 current NRC regulations.

10 In addition to this, new sources and  
11 devices have to go through a Sealed Source and Device  
12 Registration Application. So from that, our Sealed  
13 Source and Device Registration team here in our Division  
14 of Material Safety and State Agreements, as it currently  
15 is named, may pass that information along to our senior  
16 health physicist, Dr. Howe, and she then shares that  
17 with staff.

18 We may also get information by a technical  
19 assistance request from our NRC regions and they will  
20 share information with us from time to time about new  
21 devices or emerging technologies that may come through  
22 their way versus headquarters.

23 And lastly, though very rarely, and to my  
24 knowledge this has never happened, but there's a  
25 possibility, a very minute possibility, but that a

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1 manufacturer could come forward to NRC and say here's  
2 our device, how do you think this should be licensed.  
3 Although we know typically when they come to NRC, they  
4 already have in mind how they want it to be licensed,  
5 but there is that one chance.

6 So, what is the process? So, we review, we  
7 evaluate and we develop. So, a project lead or a  
8 working group, which I'll touch on a little bit later,  
9 has to review all of the information that's available.  
10 This includes information from the Sealed Source and  
11 Device Registration, manufacturer's supplied  
12 information such as owner manuals, 501(k), am I saying  
13 that -- 510(k), things such as that.

14 So, we review all that information and we  
15 take it into consideration. So, then you evaluate all  
16 this information for its resemblance to other  
17 categories in 10 CFR Part 35, whether that be in Subpart  
18 D through H and need to develop a recommendation.

19 So, do you believe that this should be like  
20 licensed under an existing category, D through H, or  
21 should it be licensed under 35.1000? Again, I'll  
22 expand on 35.1000 in just a second.

23 If the emerging technology will be licensed  
24 under one of the Subparts D through H, and it's a very  
25 thin line of, I don't know, can it be 35.1000 or could

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1 it be D through H? If it's not very clear, then it's  
2 possible that you could develop a safety basis, for  
3 example, with radium-223 dichloride which the Committee  
4 worked on pretty recently.

5 But if you do determine that it should go  
6 under 35.1000 or Subpart K, then licensing guidance must  
7 be developed. For example, the Perfexion<sup>TM</sup> device has  
8 35.1000 licensing guidance.

9 So, what makes it 35.1000? There are a few  
10 basic rules or questions that we ask ourselves when we  
11 consider or when you decide if an emerging technology  
12 should be licensed under 35.1000.

13 First of all, can it meet all of the  
14 requirements in an existing category? For example, if  
15 it's a teletherapy device, can it meet everything that's  
16 in 35.600 for teletherapy devices?

17 Next, does it have any unique components or  
18 features that would need additional radiation safety  
19 precautions? That means things that are not included  
20 in the existing regulations in 10 CFR Part 35.

21 And if not, does that mean you need an  
22 exemption or multiple exemptions? If that's the case,  
23 if any of these three things can be met, then more than  
24 likely, this device will need to go under 35.1000.

25 So, next comes a working group. I know I

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1 said a project lead or a working group. In the past,  
2 many, many years ago, it was just NRC that would develop  
3 the licensing guidance. But maybe within the past  
4 decade, there have been 35.1000 licensing guidances  
5 that have come out as the result of working group  
6 efforts.

7 A working group can be created using an  
8 Agreement State representative, multiple Agreement  
9 State representatives; it could include a consultant;  
10 it could include ACMUI members; it could include NRC  
11 staff from headquarters and/or the regions.

12 So, for example, with the ViewRay™ device,  
13 we had staff from headquarters, we had staff from Region  
14 III, we had three Agreement State representatives on the  
15 working group who either had the SS&D Registration or  
16 they had active licensing actions. And we also had Dr.  
17 Suh serve as a temporary consultant to the working  
18 group.

19 So, there are many avenues in which the  
20 medical community can provide feedback. There's a  
21 possibility for ACMUI members to be involved if we see  
22 that we need that we need your technical expertise.

23 So, then the next question is, now that  
24 you've developed this 35.1000 guidance, do you think  
25 that it's the time for change? So, for example, I know

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1 I keep referring to Dr. Suh, but he just gave a  
2 presentation about 35.1000 guidance for the Gamma Knife  
3 Perfexion™.

4 There is a question about whether or not you  
5 wanted to change the existing guidance and because it's  
6 35.1000, staff has the ability to go in and change within  
7 the existing guidance as we've done in the past for the  
8 yttrium-90 microspheres as you will hear later on today  
9 from Dr. Guiberteau.

10 As it's stated on the NRC Medical Toolkit,  
11 where we house all of our 35.1000 guidance, licensing  
12 guidance will be updated when it's necessary to address  
13 comments from stakeholders.

14 So, you're developing this guidance  
15 because it's a new emerging technology. As time goes  
16 on and more people are using the device, you may find  
17 that there are things in there that can be relaxed or  
18 there are things that are not covered in the guidance  
19 that should be addressed. So, we're able to address  
20 that by going in and changing our 35.1000 guidance and  
21 not the lengthy rulemaking.

22 So, here's the link to the Medical Took Kit  
23 which, I am sure everyone is familiar with. There will  
24 be a chance to come in the near future. For example,  
25 on our Toolkit, the whole Toolkit is going to have a

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1 makeoever, but specifically for the 35.1000 guidance,  
2 this is all captured under a section called "Other  
3 Guidance".

4 Well, it's kind of ambiguous, you don't  
5 really know what is "Other Guidance". So, we plan to  
6 section it out so there's "Other Guidance," but then  
7 there's also a bullet that says 35.1000 Guidance. And  
8 in that section, it'll list all of the guidances, but  
9 it will also identify who is on the working group or what  
10 that current status is.

11 Do we think this emerging technology will  
12 go under 35.1000 or is it just pending?

13 So, are there any questions?

14 CHAIRMAN THOMADSEN: Yes, Dr. Langhorst?

15 MEMBER LANGHORST: Thank you. So, what  
16 silenced before us?

17 CHAIRMAN THOMADSEN: That's what that was.

18 MEMBER LANGHORST: That's what that was.

19 Sophie, thank you very much for that talk.  
20 You say that NRC staff can ask that ACMUI member or as  
21 a consultant to help with review of guidance documents  
22 and so on.

23 MS. HOLIDAY: Yes.

24 MEMBER LANGHORST: Does the reverse hold  
25 true? Can ACMUI request that a member help with certain

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1 guidance workgroups?

2 MS. HOLIDAY: Absolutely.

3 MEMBER LANGHORST: Okay. That's good to  
4 know.

5 And then the process of how you change  
6 35.1000 guidance, is there opportunity for the  
7 community to make comments before the change goes into  
8 place or is it just you have comments once the change  
9 is in place and then eventually, more change will  
10 happen? Or is there a process of changing the 35.1000  
11 guidance?

12 MS. HOLIDAY: I think what generally  
13 happens in what -- Ashley's here because she has a lot  
14 of familiarity with this topic being that the yttrium-90  
15 microspheres guidance has changed multiple times. So,  
16 please correct me if I'm wrong, Ashley.

17 When we receive multiple comments from the  
18 medical community, this is before we put out the  
19 guidance, we take them into consideration before we go  
20 forward in making any changes.

21 And then, as always, we always put the  
22 guidance up on the website so then it becomes that if  
23 there are further comments, then we take it back and we  
24 review it again -- kind of similar to when I published  
25 the ViewRay™ guidance and you came back and you had

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1 suggestions about the page edits and things like that.  
2 We went back and we changed that, I think, rather  
3 quickly.

4 So, it's just a matter of will the medical  
5 community inform us and time resources, is all this  
6 really is. Did I capture that correctly, Ashley?  
7 Thank you.

8 DR. HOWE: I think it might be helpful to  
9 understand what that process is and how the medical  
10 community can participate in that and I think that would  
11 be great to have as a short little guidance document of  
12 how you propose changes to guidance documents.

13 MS. HOLIDAY: Sure.

14 CHAIRMAN THOMADSEN: Dr. Howe?

15 DR. HOWE: I think one of the things that  
16 is documented on the NRC -- I think one of the things  
17 that the Committee needs to keep in mind is, many times  
18 when we have a licensing action where a licensee wants  
19 to use a new product and because of that, we need to act  
20 fairly quickly to get the guidance out there.

21 So, we don't have the ability to come back  
22 and ask the ACMUI in its spring meeting what its comments  
23 are and then again in the August -- in the fall meeting.

24 So, the other thing to keep in mind is that  
25 the guidance is guidance and that it is to some extent,

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1 always kind of considered as a proposed. So, anyone can  
2 provide comments on it once we publish it at any time.  
3 So, it's never in concrete the way rulemaking is. It's  
4 always flexible and a living document.

5 And Ashley has gone through many, many  
6 changes with the yttrium-90 microspheres because it is  
7 a living document.

8 And so I think that's the part the ACMUI needs to  
9 keep in mind is that even though we put it up on the  
10 website, and sometimes we aren't able to go back to the  
11 ACMUI before we get it up because we have licensing  
12 actions and our people do need to get these things in  
13 use.

14 But you always have the ability to comment  
15 whether you're nationwide or a member of the public or  
16 licensee. Okay?

17 CHAIRMAN THOMADSEN: Thank you for that  
18 clarification.

19 Other questions or comments? Dr. Welsh?

20 MEMBER WELSH: This is James Welsh.

21 As Dr. Howe has just pointed out, there are  
22 some advantages to having things in Part 1000 such as  
23 the Y-90 microspheres which, as we all know, has been  
24 a living evolution of guidances over the past several  
25 years.

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1                   But there are other situations where maybe  
2                   Part 1000 is viewed as sort of wasteland and there is  
3                   a rumor that once something is relegated to Part 1000,  
4                   it kind of stays there inordinately long.

5                   And what I'm thinking of in particular is  
6                   the Gamma Knife Perfexion™, which I think I argued many  
7                   years back, but probably could have gone right into 600  
8                   from the start when we saw that the wording in the CFR  
9                   didn't match it precisely enough and things would have  
10                  to be changed.

11                  Now, the Perfexion™ has been around for a  
12                  good number of years and it's clearly a stereotactic  
13                  radiosurgery cobalt-60 based device and it probably  
14                  should be in Part 600 by now.

15                  And I'm wondering when that's going to  
16                  happen? What the disadvantages of not having it in 600  
17                  might be? And is there a time line that we should be  
18                  thinking about for something that clearly is destined  
19                  for say 600 like Perfexion™ or maybe the ViewRay™, which  
20                  is glorified teletherapy unit within its guidance.

21                  When are they going to get to 600? Because  
22                  Part 1000 is perhaps not where they belong long term.

23                  CHAIRMAN THOMADSEN: Dr. Howe?

24                  DR. HOWE: If I could respond to that? Our  
25                  intentions are to move things out of 1000 when they

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1 stabilize and we -- the ACMUI, many of you members  
2 weren't here, but from 2002 when the last rule took  
3 effect to today, we've been bringing back things that  
4 were potential rulemaking.

5 And one of them was the Perfexion<sup>TM</sup> and we  
6 put it on our list for a request for the rulemaking  
7 people to look at and add it. And our intention was to  
8 put it in the current rulemaking, but the current  
9 rulemaking was so big that they believed they wouldn't  
10 get the rulemaking through if they added the 1000 to it  
11 also and there were a number of other issues that they  
12 dropped out.

13 So, we tried to get that into rulemaking as  
14 quickly as possible. Perfexion<sup>TM</sup> may not get into the  
15 2023 medical rule making, you know, but it does take a  
16 long while for rulemaking to happen.

17 And, in the meantime, I'm also hearing that  
18 the Perfexion<sup>TM</sup> is not the only product, it's Perfexion<sup>TM</sup>  
19 Plus and that allows for that in the Perfexion<sup>TM</sup> Plus.

20 So, we did try and get it in as quickly as  
21 we can, but we have no control.

22 CHAIRMAN THOMADSEN: Mr. Fuller?

23 MR. FULLER: Yes, just to add a little bit  
24 to what Donna-Beth said, 35.1000, and as those of you  
25 who have been around a long time understand, it was

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1 something that was done primarily to allow for us to be  
2 a little more nimble and we have a number of examples  
3 where, if it required rule making, it was just going to  
4 be a multi-year process and we really, in the  
5 Commission, made it very clear that we needed to be a  
6 little more nimble and this was the way to do that.

7 So, that's a good thing. The double-edged  
8 sword, though, is that when it comes to rulemaking,  
9 rulemaking takes a long time and you have to score. And  
10 what I mean by score is you have this thing called  
11 prioritization of rulemaking where the agency as a whole  
12 only can do so many things at one time and with  
13 everything that we do, there's multiple rulemakings  
14 going on at any one time.

15 And there's a centralized group that looks  
16 at very, very specific criteria based upon health and  
17 safety or radiation safety and review the immediate  
18 needs of that and so forth.

19 And various rulemakings, there is topics  
20 already and it is focused on safety first and then things  
21 that are prioritized. Those ones go right into rule  
22 making that multi-year process, things that are too --  
23 a little bit better but if the Commission directed, then  
24 they get ranked and so on.

25 So, the long and short about this is that

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1 because we have, and this is, I think why based upon some  
2 of the things that I've heard about the decision about  
3 this current rule making that we now have out as a  
4 proposed rule for public comment, is that when it came  
5 to the Perfexion<sup>TM</sup>, it didn't score very high because it  
6 doesn't -- there wasn't an immediate health and safety  
7 reason for pursuing it.

8 It's really frustrating for all of us, I  
9 think, but just to give you a little bit of background  
10 on that. At some point in time, we had to kind of --  
11 the agency had to sort of had to cut it off and so that's  
12 where it allowed.

13 But as Dr. Howe said, we never stop thinking  
14 about ways that we can continue the process looking for  
15 the things that need to be addressed in rule making and  
16 we've put together those plans. We try not to do one  
17 before we finish the one.

18 So, we've got one right now that we're  
19 working, when this one's done, I'm certain there will  
20 be a list not only from our perspective as staff, but  
21 from this body's perspective as well the things that  
22 need to be addressed in the rule making space. And so,  
23 we'll all be working together on this.

24 CHAIRMAN THOMADSEN: Dr. Suleiman?

25 MEMBER SULEIMAN: 1000 has been sort of, I

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1 use the term carefully, a "temporary parking lot" but  
2 it's not really temporary because sometimes the series  
3 are too prescriptive and so you can't put something into  
4 one of the categories because you'd have to change the  
5 rules in 300 or 600 or whatever.

6 So, you take something that's 95 percent  
7 compatible but not quite and you leave it in the 1000.

8 I think the problem is that the  
9 subcategories are all too prescriptive. You know, I  
10 use an example, so bear with me, but I always felt in  
11 FDA sometimes we should say thou shalt have a dose  
12 display and leave the prescriptive nature of a better  
13 way.

14 Then you have this, and I'm sure you deal  
15 with it, the NRC deals with it too, you have our letters  
16 and our enforcers and nobody says, well, you have to  
17 spell it out because if you don't spell it out, we can't  
18 enforce it. If we can't enforce it, it has no value.

19 And so, you start -- and then we have people  
20 who really love to go into detail like we all do in  
21 different folks that you work with. And so they start  
22 to get more and more prescriptive. After a while,  
23 you've pretty much narrowed it down, but along comes a  
24 new technology that may not have some of those and the  
25 safety feature may have been incorporated.

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1           So, the art is to make the rules safe but  
2 not too prescriptive but allow some tolerance otherwise  
3 you're going to wind up parking a lot of stuff into the  
4 1000 series.

5           And, to be honest, I've said this before,  
6 the technologies are evolving; they're  
7 interdisciplinary; you have hybrid products. I think  
8 you can't really categorize them into a simple series.

9           And so, there's a fundamental problem  
10 there. So, I think rather than, I think what you have  
11 to do is let them do the best you can with what you have  
12 and, yes, this prioritization comes out of here, but,  
13 you know, back at the NRC, you're talking about  
14 competing with other priority issues.

15           CHAIRMAN THOMADSEN: A question I would  
16 have for Mr. Fuller or Dr. Howe is what's the  
17 disadvantage of having something parked in Part 1000?

18           I guess we have a volunteer answer if you  
19 could start.

20           MEMBER COSTELLO: I'm sorry. I believe  
21 that the 1000's a sort of a compatibility Category C?

22           MS. DUDES: Yes, that's correct.

23           MEMBER COSTELLO: So, the things that are  
24 in 35.1000, the States have more flexibility on how they  
25 implement it. They may just take what's on the website

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1 as we in Pennsylvania do. But States don't necessarily  
2 have to do that.

3 You may remember a discussion about the  
4 radium-223. With some States who want to have it be in  
5 35.1000 and some states at one time were, still  
6 naturally, they argued it should be 35.1000 and they've  
7 had some variety on how they licensed it -- its  
8 authorized users and so forth.

9 I think that the disadvantage of having  
10 35.1000 is that you may not get the uniformity that you  
11 get when something's in 35.200, 300, so forth. You may  
12 have some variety and, you know, we discussed this --  
13 you discussed this, the NRC discussed this, with regard  
14 to the current Part 35 rulemaking with regard to  
15 reporting requirements or permanent brachytherapy.

16 And the States argued that they would like  
17 to see compatibility C and eventually right now, the  
18 current version of it is compatibility B. And the very  
19 reason why I think the ACMUI and the community wanted  
20 it to be B, was to have their uniformity with the rule  
21 itself.

22 If it keeps up in compatibility C for a very  
23 long time, you'll have, you know, perhaps greater  
24 variability among the States.

25 CHAIRMAN THOMADSEN: Thank you for that

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1 clarification, a very important point.

2 Dr. Welsh?

3 MEMBER WELSH: If I might expand on the  
4 answer that Mr. Costello just provided, I think that the  
5 point is critically important and although Dr. Suleiman  
6 referred to as Part 1000 euphemistically as a temporary  
7 parking lot, which I think is, perhaps, politically more  
8 correct than my terminology of a wasteland.

9 I mean that if something is in Part 1000,  
10 it opens up some doors that maybe we should be cautious  
11 of. And if something is the 1000 and stays in 1000  
12 inordinately long, it provides opportunities for these  
13 doors to be wedged open very widely.

14 And, specifically, I'm thinking about the  
15 Perfexion™ unit which I argue should have been put in  
16 600 a long time ago and now the Gamma Knife Perfexion™  
17 Plus which will be a modification within which guidance  
18 and capability of fractionation. And things like the  
19 ViewRay™ which have sophisticated image guidance, these  
20 are more appropriately placed in Part 600 because they  
21 are stereotactic gamma emitting units or gamma emitting  
22 teletherapy units.

23 And, if their maintained in Part 1000 for  
24 too long, as Frank said, it opens up the possibility of  
25 variability from state to state and it also opens doors

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1 for other physicians to apply for use of these devices.

2 For example, I think we heard of  
3 neurosurgeons in one State petitioned to be authorized  
4 usage for the Gamma Knife. You can imagine the thoracic  
5 surgeons wanted to use the ViewRay™, et cetera, et  
6 cetera.

7 These might not be the best things for  
8 patient radiation safety. And, therefore, my  
9 recommendation for the NRC would be that if something  
10 obviously should be in Part 600, and I think Gamma Knife,  
11 whether it's a Perfexion™, Perfexion™ Plus or whether  
12 the modern teletherapy unit, the ViewRay™, if it belongs  
13 in 600, we should move it there as efficiently as  
14 possible.

15 And when we do move it there or make the  
16 modifications to 600, we should probably be careful and  
17 do what Dr. Zanzonico has recommended when we're talking  
18 about the radium-223, don't pigeonhole it for  
19 radium-223, open it for all alpha emitters that might  
20 come along in the future that fit this general category.

21 And, we're talking about alpha emitters,  
22 how different are they from beta emitters clinically and  
23 from a radiation safety perspective?

24 If they're not that different, modify the  
25 appropriate categories so that it can accommodate all

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1 technologies or radionuclides that belong in that  
2 category.

3 And so, I hope that it's not 2023 that we  
4 have to wait to until before 600 is appropriately  
5 modified, but when it does get modified, I would  
6 recommend that it be generalized enough so that these  
7 issues don't occur and things don't stay in 600 -- the  
8 1000 temporary parking lot for too long.

9 CHAIRMAN THOMADSEN: Thank you very much.

10 Do we have a member of the public?

11 MS. FAIROBENT: Thank you, Dr. Thomadsen.  
12 Lynne Fairobent with AAPM.

13 You asked the question of what our  
14 potential negativisms with Part 1000. I think when we  
15 all conceptualized Part 1000 a number of years ago, it  
16 sounded great. The operating history of it has  
17 probably has mixed -- if we did lessons learned on it.

18 And the mixed bag comes from the back,  
19 nothing's even been moved out of Part 1000 which was the  
20 intent; it was not to be a permanent licensing position,  
21 but a temporary place for us to be able to quickly  
22 license new and emerging technologies.

23 I see two major downsides. One is when  
24 something is licensed under Part 1000, the licensee  
25 community does not have the opportunity to provide

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1 official and formal comments on it because it's not done  
2 through the formula. So that's a negative.

3 And secondly, because it is licensed  
4 through guidance, I totally agree with graded states.  
5 There is no compatibility. The Agreement States do not  
6 have to follow any NRC guidance document or adopt it,  
7 so we have, as a matter of fact, 37 different licensee  
8 schemes.

9 We don't think that that's what we end up  
10 with but we do end up with a variability. So, I do see  
11 those as two big negativisms.

12 CHAIRMAN THOMADSEN: Thank you very much  
13 for that comment.

14 Other comments from the ACMUI or from the  
15 general public? Please introduce yourself.

16 DR. ENNIS: Hi, Ron Ennis, ACMUI member to  
17 be. This is greatly naive and the country outside  
18 sometimes.

19 So, from all this discussion, it seems  
20 clear from my involvement in the brachytherapy rule that  
21 one of the fundamental problems, and this is really for  
22 NRC to comment on, is that rule making takes just way,  
23 way too long in the modern world where things are  
24 changing too fast.

25 And it sounds like 1000 was a great idea to

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1 give some flexibility but there are clearly problems in  
2 it.

3 So, I think that goes to more core of that  
4 rules involved in rule making, that's the part that I'm  
5 really naive about, and if that's been addressed over  
6 the past and where that stands, but I think that at a  
7 core, this is really the problem.

8 CHAIRMAN THOMADSEN: Thank you very much.

9 Mr. Costello?

10 MEMBER COSTELLO: I didn't mean to suggest  
11 for a compatibility C is a better fix. I mean it didn't  
12 sit very well here. That's better than being a witness  
13 of that idea and let the record show that I didn't say  
14 that. I think it was somebody else for the next  
15 meeting.

16 I just want to point out that that is  
17 something we have to consider when we leave something  
18 in 35.1000 for a long time, is that as time goes by, more  
19 and more flexibility could be exercised. And I think  
20 it was Texas that might be, you know, including  
21 neurosurgeon or a gamma and, well, they can do that, I  
22 think, and so could Pennsylvania and so could the other  
23 Agreement States.

24 And I don't believe that that is your  
25 intention. It is our intention that if it stayed there

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1 for a very long time.

2 I did want to really suggest compatibility  
3 C is a bad idea. I just love the letter C.

4 CHAIRMAN THOMADSEN: Mr. Fuller?

5 MR. FULLER: Well, just a follow-up a  
6 little bit on Dr. Ennis' question. Yes, I think  
7 everyone would agree that rulemaking takes a long time.

8 Now, this rule making that we're currently  
9 in the middle of, or I should I should say in our public  
10 comment period, does take a number of years and there's  
11 been a number of reasons why we won't go back and revisit  
12 all that history.

13 But there's always that risk of you start  
14 a rule making, you go through the public comment period,  
15 you think you're close and then you find out you're not.  
16 I mean this is -- probably medical rulemaking is one of  
17 the toughest because of the very deliberative process  
18 in the public interaction.

19 We do continue to do other things  
20 throughout the entire process through interactions with  
21 the ACMUI and the more general medical community.  
22 Through this, we've learned a lot of things and that --  
23 but it's just a necessary evil, it takes time.

24 And so, that is our challenge. We would  
25 all like to do it faster and more efficiently but we do

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1 have requirements and really good reasons for being very  
2 deliberative and very much engaged in the public  
3 process.

4 And so, again, the double-edged sword.

5 CHAIRMAN THOMADSEN: Thank you for that  
6 clarification.

7 Any other comments from the committee?

8 In that case, thank you very much, Ms.  
9 Holiday.

10 And now Dr. Guiberteau who will discuss the  
11 Yttrium-90 Microsphere Subcommittee report.

12 VICE CHAIRMAN GUIBERTEAU: Good morning.

13 I've two disclaimers before I begin. The  
14 first is that in moving these slides back and forth  
15 through the Internet, there are some formatting errors  
16 which I believe to not be distractions, but they appear  
17 differently than what I had submitted. But they're not  
18 perfect, but I don't think they will distract you.

19 The other disclaimer has to with a personal  
20 distraction and that is on the flight here, I neglected  
21 to notice that my distance glasses were on my tray when  
22 taken away. The distance here really is defined by the  
23 back of my retina to the front of that screen.

24 So, I decline an offer, having worked for  
25 many years in low level waste disposal for the State of

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1 Texas, I'm somewhat of an expert there, but not an expert  
2 in ordinary trash, so I declined an offer to look through  
3 the trash to find them, so, I will be giving my  
4 presentation on a printed version, but I will try to keep  
5 the slides in sync with what I am reading and what you  
6 are seeing.

7 We are, of course, talking about Y-90  
8 microsphere brachytherapy which is the poster child, I  
9 think, for Subpart K and actually, our Committee felt  
10 that this was not really a consternation, but probably  
11 an opportunity for us simply because Y-90 microsphere  
12 brachytherapy is different from anything that has ever  
13 come before this organization to regulate.

14 We call it brachytherapy, but it is very  
15 different in some ways from conventional brachytherapy  
16 and in some ways, it shares characteristics of unsourced  
17 treatments in the sense that it is not transvascular but  
18 actually intravascular and we'll talk about that as we  
19 move along.

20 These are our subcommittee members and  
21 because this is a team therapy, just like Gamma Knife,  
22 all members of the medical team are represented in  
23 addition to the RSO member and a regulatory member from  
24 the States as well as our staff, Donna-Beth, who kept  
25 us on track so as not to get in pathways that had been

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1 previously tried and discarded. So, we're very  
2 grateful for her participation.

3 The one member that we didn't have actually  
4 that it would be involved in this because our Committee  
5 is recommending some changes, is the member  
6 representing the public. But we did have discussions  
7 of this because in terms of what this procedure offers,  
8 there is a lot of doctor-patient interaction which I  
9 will address in this.

10 So, originally, our charge was to determine  
11 whether and under what conditions the deposition of  
12 inter-arterial Y-90 microspheres in GI tract  
13 constitutes a reportable medical event. And  
14 specifically, regards the notation in the written  
15 directive and what actually is what actually happens,  
16 that is what is actually administered and the dose to  
17 the GI tract, and to develop recommendations for some  
18 changes with respect to the GI tract.

19 However, I think with the wisdom of Laura  
20 Dudes, who subsequently made comments about expanding  
21 this charge from the GI tract and that turned out to be  
22 a very good thing for this Committee that at the  
23 discretion, our discretion, we could develop a way that  
24 where any other aspects of this question that needed to  
25 be answered.

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1           And, in fact, in some ways, we reoriented  
2           this toward how what that constitutes a technically  
3           successful administration rather than the GI tract, per  
4           se, but we did limit this to non-target activities and  
5           to offer recommendations for changes to the guidance.

6           So, our process was to basically reduce  
7           this current treatment processes and state of the art  
8           protocols and relevant literature because the procedure  
9           has evolved significantly since its original appearance  
10          in approximately 2000, although it was before that.

11          And with the initial guidance and with the  
12          publication of commonly accepted protocols in the  
13          medical community, namely the one from ASTRO, SIR, the  
14          Society for Interventional Radiology, and the ACR. So,  
15          there had been changes and even that were not addressed  
16          in the revision of the guidance in 2012.

17          And review the scripts routinely performed  
18          to eliminate or minimize the non-target doses that we're  
19          talking about as well as to identify an appropriate  
20          measure that is a metric to determine the technical  
21          success as opposed to the clinical success of the dose  
22          activity delivery that aligned with current practice  
23          because we felt in many ways the current guidance does  
24          not align with what is actually being done.

25          And to determine what the criteria for that

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1 metric need be in order to pronounce this a technical  
2 success and to propose, obviously, changes to the Y-90  
3 guidance.

4 In addition, and not on this slide, it was  
5 also a subtheme to align this with the medical use policy  
6 of the NRC. Namely that these procedure be performed  
7 in accordance with the physicians directive and you'll  
8 see that's a very important thing here in terms of what  
9 the current guidance requires in the written directives  
10 and to not to intrude on the medical judgment of those  
11 of the medical team in terms of effecting patients,  
12 which in this instance, it's also very important.

13 I want to put in perspective what this  
14 treatment is about. It is not a curative treatment.  
15 The patients receiving this treatment are very sick and  
16 essentially terminal for most of these patients.

17 So, if it is essentially for those with  
18 unresectable tumors of the liver, metastatic as well as  
19 primary tumors, primarily from the hepatocellular  
20 carcinomas, they are to -- this treatment is to relieve  
21 pain, that is they palliate patients, make them more  
22 comfortable, to improve their survival, it can do that.  
23 It is not curative.

24 It can improve the time of progression  
25 which is very important because some patients who have

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1 unresectable primary tumors can be cured by  
2 transplantation.

3 And finally, it can be used as a clean-up  
4 procedure in say cryotherapy in which the majority of  
5 the tumor is debulked but the remainder of the tumor  
6 needs to be addressed.

7 So, that's where this stands.

8 The rationale of the procedure is  
9 essentially in terms of being different from other  
10 therapies is that the Y-90 microspheres are injected  
11 through a catheter selectably positioned in the hepatic  
12 artery because most tumors do not -- the normal liver  
13 receives its blood supply from the portal vein from the  
14 venous system. But these tumors, by and large, are  
15 primarily supplied by the hepatic artery.

16 So, that is a real boon in order to deliver  
17 a dose to the tumor with minimal effect on the adjacent  
18 liver.

19 These microspheres are too large to pass  
20 through the capillary bed so they become permanently  
21 trapped within the tumor tissue and thereby giving a  
22 therapeutic dose which is why these individual devices,  
23 each microsphere, is a device. It is a brachytherapy  
24 device and that is a very different concept.

25 So, this is an example just because we think

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1 it's important for those of you who are not on the  
2 committee who don't do this procedure or you're not a  
3 physician, and particularly since our reports --  
4 subcommittee reports are intended for the staff, and I  
5 know some staff, like Donna-Beth, are very familiar with  
6 this, but others may not be, and all of that is addressed  
7 in our actual written report that you'd be familiar with  
8 essentially what is trying to be accomplished.

9           And here you can see the tip of the catheter  
10 marked there with an arrow and the little circles there  
11 are the microspheres and you can see them being  
12 administered through the catheter into the branch of the  
13 hepatic artery and into the tumor.

14           I want you also to keep an eye on those  
15 vessels that do not have dots in them and we'll address  
16 those in a minute because those are the vessels that go  
17 to the GI tract in non-target tissues that may cause  
18 doses that need also to be addressed.

19           In terms of safety and effectiveness that  
20 each patient has to meet a strict selection criteria.  
21 I will go into those but they are strict. Some patients  
22 are not candidates for this.

23           This procedure must be meticulously  
24 individualized for each patient and I'll go into that  
25 in a little detail.

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1           And the technical success, that is the  
2           proper administration of the proper dose to the right  
3           place rather than whether it actually helps the patient.  
4           The technical success is what we are interested in and  
5           that -- it depends on very detailed physician oriented  
6           interventions and preparation of these patients. It is  
7           very complex and very individualized.

8           And this ensures accurate delivery as much  
9           as possible to the tumors while minimizing doses to  
10          non-target tissues such as the lung and the GI tract.  
11          And that is what we're talking about; we will address  
12          that part, not delivery of the dose to the tumors but  
13          delivery to the non-target tissues in this  
14          presentation.

15          So, let's start with the lung. The  
16          mechanisms in which this material gets to the lungs,  
17          these microspheres as opposed to the GI tract are very  
18          different.

19          In terms of the mechanism to the lung, it's  
20          arteriovenous shunt. Now, confusingly, both of these  
21          mechanisms are called shunting.

22          But in this instance, because these occur,  
23          these transmit occurring in normal tissue, normal  
24          liver, but the specifically in the tumor that rather  
25          than having a convenient place where the vessel narrow

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1 in the capillary bed to be tracked and give their dose,  
2 the vessels were abnormal and they go directly into the  
3 venous system.

4 And when they do that, they get to the lungs  
5 and as a consequence, the lungs can be treated and the  
6 radiation pneumonitis itself is uncomfortable, but it's  
7 the delayed effects of that, the scarring in the lungs  
8 particularly in the patients who have underlying  
9 pulmonary disease. This can be a problem.

10 So, here's just a quick clip for you that  
11 if you inject these here at the bottom there, you can  
12 see the catheter going into the hepatic artery. You can  
13 see the tumor in yellow. Those particles that aren't  
14 trapped go into the venous system and ultimately into  
15 the lung. And those are arteriovenous shunts.

16 The pretreatment of lung activity is  
17 estimated because, you know, the question is how do know  
18 they're there? We give a non-loaded with Y-90  
19 substitute, a surrogate for that, an imperfect  
20 surrogate, to be sure, but technetium showed MAA which  
21 is currently used every day for lung scans and those  
22 particles, if they appear in the lungs, represent  
23 arteriovenous shunting and that's what will happen when  
24 you give the dose.

25 And so, shunting within these tumors can't

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1 be corrected, so must be managed. And right now, the  
2 community has gotten together and decided that there is  
3 a limit to the amount that you may administer to the  
4 lungs and that is 30 gray for a single treatment and 50  
5 gray for a multiple treatment.

6 However, even though those limits are in  
7 grays, doses to the lungs are not routinely calculated.  
8 Instead, the amount of shunting is and incorporated into  
9 the formulas that determine the dose that you're going  
10 to give.

11 The administered treatment activity is,  
12 therefore, titrated down if you have shunting and at  
13 some point, for instance, if it's greater than 20  
14 percent in general, 20 percent of the dose you give, goes  
15 to the lungs, the treatment is not ordinarily performed  
16 and that is a contraindication.

17 If the lung limits would be exceeded again  
18 by using the appropriate dose, and remember that at some  
19 point, you can reduce the dose too low then it doesn't  
20 really deliver a dose to the tumor. So, this is a  
21 balance here, at some point, if that's the case, then  
22 the treatment won't be effective and that, again, would  
23 limit your ability to give this.

24 Now, let's move on to the GI tract in a  
25 moment, and that's for the next -- because these are

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1 really the two most important of the non-target tissues.

2 The mechanism is also called shunting, but  
3 in this case, these pass from the catheter and instead  
4 of going just to the branches that go to the tumor, they  
5 go to other sites resulting in GI treatment and  
6 inflammation or ulceration of the stomach, the  
7 duodenum, the gallbladder and the pancreas. The most  
8 common of these are the stomach and especially the  
9 duodenum.

10 So, you can see that those two vessels that  
11 I showed you before that if, depending on the size of  
12 the catheter, the placement of the catheter, the  
13 resistance in the vessels, that in this case, the black  
14 arrow show the one below shows that it's going to go to  
15 the GI tract.

16 The upper arrow shows that if there is  
17 stasis and reflux of this or if it's injected too quickly,  
18 it may -- you would get back flow around the catheter  
19 and into the upper vessel. So, it's there by way of in  
20 terms of administration if these vessels that you see  
21 are as positioned on that slide.

22 So, the activity in the GI tract can be  
23 estimated by using a non-treatment surrogate again, the  
24 MAA, but doses are not calculated and there are no  
25 established limits on the GI tract. There are no dose

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1 or dose thresholds for complications so we don't really  
2 know what, you know, there's an idea, but there is no  
3 established consensus on this.

4 If the shunting to the GI tract is  
5 identified, it can be managed, however, by, one,  
6 eliminating those vessels that you saw that could be  
7 shunt or put in a catheter way down into a vessel that  
8 will -- really, there's no other vessels around or  
9 identified that where this could occur.

10 And if it can't be eliminated, however, the  
11 consensus is that for most patients that this is  
12 contraindicated.

13 Here's an example in the first, you see the  
14 arrow on a vessel, it goes through the GI tract, all the  
15 other vessels are going to the liver. A catheter in to  
16 the right in Image B is put in. A coil, which will  
17 include that vessel, is put in and, as you can see,  
18 finally before therapy, it is looked at again and you  
19 can see that vessel. There is no flow so there is no  
20 danger of placement in that instance into the GI tract.

21 So, once these two things are done, that is  
22 we know and can manage lung activity and we can manage  
23 GI activity, the catheter's placed and it's  
24 administered in terms of the treatment activity  
25 according to the equipment and instructions of those

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1 devices.

2           There is certainly ample peer review  
3 literature that shows that with these things in place,  
4 that -- and with these angiointerventional techniques,  
5 at the discretion of the interventional radiologist  
6 that these techniques have greatly reduced serious GI  
7 complications.

8           And the current complications in terms of  
9 the administered activity can be mitigated in the lungs  
10 by the percentage and by reducing the dose.

11           So, now, after all these things are done to  
12 compensate, the dose is infused, once it is reexamined  
13 to make sure it is just as the surgeon has -- that the  
14 interventional radiology has planned it, that it is  
15 really at the vagary of the blood flow.

16           Once it's injected, there is no more  
17 control over this after all of this is done. And these  
18 are distributed -- each device is distributed at random  
19 into wherever it's going to go and by all planning, this  
20 is limited to the tumor, by the best of planning.

21           The treatment activity, and I want to point  
22 this out again because this a key element in one of our  
23 recommendations, that in general, it's based upon the  
24 activity that you order to administer. That's the way  
25 it's ordered and that's the way it arrives.

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1           There is no routine pre-implantation that  
2           is before the treatment of lung or GI doses nor is there  
3           any routine calculation of doses after the  
4           administration.

5           So, the subcommittee in this instance  
6           unanimously agreed, and again, there was an evolution,  
7           that's one of the great things about the subcommittees  
8           and having the representations of this committee, is  
9           that it is a microcosm of what Lynne was talking about,  
10          the public and the stakeholders and in terms of this,  
11          that there was a very vigorous, over multiple and long  
12          emails, as the staff can tell us, as well as one  
13          conference call on June 24<sup>th</sup>, to evolve to a consensus.

14          And the consensus was that in order to align  
15          for this procedure to align with the unique  
16          characteristics of brachytherapy which was neither  
17          conventional brachytherapy or unsealed source therapy,  
18          in terms to align with what has happened in this  
19          procedure and all the very detailed safeguards now  
20          involved and the current medical practice of authorized  
21          users and treatments, that some change in the guidance  
22          was necessary.

23          And there are two parts of that that I will  
24          address that deal with these non-target doses.

25          The first is the written directive. The

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1 current guidance states that maximum doses, again which  
2 are not calculated pre-dose, and activities that would  
3 be acceptable to the GI tract and lungs be put in the  
4 written directive.

5 Well, we're not sure what acceptable is  
6 simply because, you know, there is no threshold for the  
7 GI tract and doses are not routinely calculated.

8 In terms of the lungs, the pre-therapy dose  
9 again are not calculated. To review that, we do know  
10 the shunting, the amount, and we can calculate an  
11 activity, again, activity to the administered, not a  
12 dose, specific dose and if the shunting is excessive,  
13 then the procedure is not performed.

14 And so, our conclusion is that for the GI  
15 tract as well is that specification of a maximum  
16 acceptable GI tract dose is not based on any clinically  
17 relevant or consensus derived benchmark. The doses are  
18 basically thresholds or unknown.

19 The current practice guidelines state that  
20 there is no acceptable activity. And the determination  
21 of activity dose based on the surrogate imaging are  
22 problematic for reasons I won't go into. They really  
23 show a sort of, where it's going to go, but calculating  
24 a dose with this is fraught with error in most instances  
25 in the deposition and localization volume and these

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1 measurements are inexact.

2 So, the other part of this, the guidance  
3 that we are addressing is that it's necessary in terms  
4 of the medical event criteria for reporting on any event  
5 resulting a dose to an organ or tissue other than  
6 treatment site that exceeds by more than five  
7 millisieverts to an organ or tissue and again, a dose  
8 not an activity, and by 50 percent or more of the  
9 prescribed activity or administration to the non-target  
10 tissues.

11 So, what about -- talking about the  
12 pre-estimation and how difficult that is in terms of the  
13 written directive, what about afterwards? What is the  
14 current state of practice?

15 First of all, Bremsstrahlung imaging is the  
16 way we do it. That is, Y-90 does have in terms of being  
17 a pure beta emitter does, obviously, generate  
18 Bremsstrahlung. The problem with Bremsstrahlung is  
19 that there is no peak; it's a continuum.

20 Imaging that images are very, how shall I  
21 say, not up to the par of what we're used to in imaging  
22 with our standard methodology. So these calculations  
23 of doses are difficult and they vary quite largely with  
24 whatever type of technology you happen to have. And  
25 although that's evolving for a PET-CT, that's not widely

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1 available for everyone to have.

2 And after the fact, you know, many of the  
3 clinicians feel that it's of questionable value because  
4 the procedure's been done. And we don't even know if  
5 we see an image there whether it's going to cause  
6 problems or not, particularly for the GI tract.

7 So, our conclusions were that the  
8 prescribed activity, an actual infused activity, are  
9 the most important metrics. You know, once we have a  
10 metric, the question is what, you know, what is the  
11 reportable portion of that metric? What is acceptable  
12 and what is not?

13 And like we do now, it should be based on  
14 the readily determined differential between the  
15 prescribed activity, what's in the written directive  
16 and what was actually infused into the patient.

17 So, our recommendations for the change in  
18 the guidance or the specification of an acceptable GI  
19 tract and lung dose activity in the written directive  
20 prior to the Y-90 microsphere embolization procedure  
21 should not be required because for all of the reasons  
22 that I've given you, but instead, a total treatment  
23 activity to be administered should be the required  
24 compliance measure in the written directive.

25 Also, that implantation of the

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1 brachytherapy sources is considered to be in accordance  
2 to the written directive if the total administered  
3 activity does not differ from the written directive by  
4 20 percent except in situations in which there is  
5 stasis. That is in the current guidance and that is  
6 something that we felt was important to this because  
7 stasis can lead to reflux when it's not expected.

8 And that these recommendations should be  
9 incorporated into the guidance and we've added that we  
10 feel very strongly that the NRC staff, if they're  
11 adopted in consultation with ACMUI, that you should  
12 compose and disseminate an explanation for these  
13 basically in detail to the authorized users and other  
14 stakeholders who may be using them to make sure that this  
15 information gets out.

16 We have multiple members of this Committee  
17 who are experts on each piece of the things that I've  
18 been talking about and so I'm sure that if you have  
19 questions, each of us may be able to answer them.

20 Thank you.

21 CHAIRMAN THOMADSEN: Thank you, Dr.  
22 Guiberteau.

23 Comments or questions from -- ah, Dr.  
24 Zanzonico?

25 MEMBER ZANZONICO: First, I must commend

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1       you, excellent presentation.

2                   And I would endorse those recommendations  
3 enthusiastically.    There's a lot of unknown and  
4 evolving science and technology in this modality that's  
5 clearly beyond the scope of regulatory governance.

6                   And I think the metrics that you defined  
7 give current technology, current practice, current  
8 knowledge of the unknown biology so forth and so on, are  
9 moved along with practical metrics.

10                   There's no doubt this is an effective  
11 treatment for patients in very dire situations and I  
12 think it would be inadvisable to say to these regulators  
13 to try and parse this anymore finely than the  
14 subcommittee has defined.

15                   The technology is just not up to that at the  
16 moment.   So, like I said, I would just wholeheartedly  
17 endorse these recommendations.

18                   CHAIRMAN THOMADSEN:   Thank you very much.

19                   Dr. Suleiman?

20                   MEMBER SULEIMAN:   I think it's a really,  
21 really nice presentation.

22                   For clarification, these are considered  
23 medical devices.   They are not considered drugs, though  
24 it's always been interesting historically that when  
25 people are first introduced to these, I think they are,

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1 in fact, drugs. I feel their safety profile is much  
2 more similar to a radiolabeled drug than brachytherapy  
3 sources. But, it is what it is.

4 The term, you know, a rose by any other name  
5 is still a rose, so regardless of the color, you treat  
6 it appropriately.

7 My concern is the guidances are not binding  
8 and we need to push the field forward. I really like  
9 the fact that you're trying to drive home the point about  
10 dosimetry and the activity. I see this much more than  
11 I care to where people just constantly get activity and  
12 absorbed dose, you know, mixed up.

13 And I think at some point, I think all  
14 therapeutics are going to have to have patient specific  
15 dosimetry and I think you need to make sure that even  
16 if people don't do that on a regular basis, they're going  
17 to start thinking about doing that.

18 And I see value in after the administration  
19 is done to calculate the dose, otherwise you may -- that  
20 could be important in assessing the patient's outcome  
21 later on. So, you know, we gave this patient more or  
22 less than we had expected.

23 I'm not saying you mandate that, but I don't  
24 know whether you could sort of soft sell it in the  
25 guidance and say this would be a good idea to do, you

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1 know, but it's not binding and nobody's going to come  
2 down and beat you over the head because you didn't do  
3 it.

4 But I think you want to educate the  
5 community and the people at this table are not the ones  
6 who always need the education, but the people out there  
7 who are doing this, it's always good to sort of, you  
8 know, point them in the right direction.

9 So, I wouldn't be afraid to add some  
10 additional things that could push the field forward  
11 short of mandating it at this point.

12 VICE CHAIRMAN GUIBERTEAU: I think to  
13 answer that, if you read the current literature, the  
14 field and the procedure are moving forward quite  
15 robustly in the sense that, as you say, there is virtue  
16 in being able to -- for people to continue to know how  
17 to calculate doses.

18 There isn't much value in calculating doses  
19 that are not meaningful. And in this case, sometimes  
20 they are reassuring when they shouldn't be and alarming  
21 when they should not be. And that is an issue that we  
22 discussed very carefully and are concerned about.

23 Secondly, in terms of your feeling on the  
24 devices, that has become a major confusion with those  
25 dealing with these. And I'm not -- the only -- we're

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1 not dealing with that all. But, you know, in many ways,  
2 obviously, what we're proposing is somewhat similar to  
3 what we used in unscaled source therapy.

4 But then again, in terms of the ease of  
5 doing this and in terms of the understandability of this  
6 in the community and especially with respect to, you  
7 know, in terms of compatibility C, I do not believe that,  
8 you know, what we have advised in guidance has caught  
9 on with the community simply because many feel it is  
10 undoable because, for all the reasons that I gave you.

11 And we felt, after our discussions, that  
12 this was a way to be sure that the procedure, you know,  
13 that there is a metric for them to follow for patient  
14 safety reasons, but it's not one that is unreasonable.

15 And finally, if I may, and I do agree that,  
16 you know, it would be nice if we educate by intrusion,  
17 but -- and legislation, but to me, in terms of what's  
18 happening, there is already much of this happening in  
19 the community.

20 So, in terms of evolving technologies and,  
21 again, Part 1000, I mean in five or ten years, we may  
22 come back and say, you know, all this needs to be changed  
23 again and it could be sooner than that.

24 CHAIRMAN THOMADSEN: Dr. Dilsizian?

25 MEMBER DILSIZIAN: Great presentation.

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1                   We do a lot of brachytherapies and do a lot  
2 of imaging before. Most of the time, as you said, a  
3 diagnostic MAA can compute the lung shunt and if there  
4 is some gastric reflux, we tell them ahead of time.  
5 This is assessed and can be prevented by closing the  
6 gastric arteries clearly shown.

7                   I guess the question here is the  
8 unintentional reflux that you brought up and how do you  
9 identify those? Based on symptomatic subsequently  
10 even though it would -- although the preventative acids  
11 were taken care of, but there can be some reflux of the  
12 gastric artery.

13                   And what we've done recently is we are  
14 looking at pulse therapy and CT imaging to first  
15 identify that the therapy went to the liver and those  
16 identify was it reflux.

17                   Now the advantage of PET-CT even though it  
18 has a very small portion of yttrium-90 is that it can  
19 give you the anatomical co-localization where we can  
20 actually look at the stomach and we can see if there's  
21 any activity that went to the stomach post-therapy even  
22 though that wasn't the intention.

23                   Now, you say well, what was the purpose if  
24 it's already there, what can we do about it? My  
25 question is that, as you know, the most common cause of

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1 the symptoms will be ulceration. And so, if we can  
2 identify that some of these patients have already had  
3 some reflux to the stomach, perhaps it will be just for  
4 information before the patient develops symptoms to  
5 have some palliative therapy.

6 So, my recommendation is that if -- as far  
7 as recording the event even though this is an unusual  
8 event, having some imaging that can identify reflux to  
9 the stomach and then treating it palliative before the  
10 ulceration occurs may be something that we could think  
11 about.

12 VICE CHAIRMAN GUIBERTEAU: Well, you know,  
13 let me address that. I mean reflux is a consternation  
14 in performing any of these procedures, particularly  
15 with respect to SIR-Spheres that have much more embolic  
16 effect because of a number, I mean it's almost an order  
17 of magnitude different from the 1.2 million that you get  
18 with TheraSpheres and the size, although it's an  
19 excellent methodology that reflux is something that you  
20 can prevent if you have modified.

21 But on the other hand, the vascular system,  
22 I mean you can't prevent the reflux but you can mitigate  
23 the effect of that. You cannot see reflux in an after  
24 the fact image. You only see the results of the reflux.

25 So, as many of you know, when the

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1 SIR-Spheres are injected, they inject it very slowly,  
2 very carefully in little pulses with contrast to see  
3 where it's going.

4 But, in my own experience and many people's  
5 experience, one puff looks terrific, the next puff is  
6 refluxed. It happens almost without warning.

7 So, a lot of this has to do with skill and  
8 preparation. I think most of the pre-preparations try  
9 to eliminate or they presume there's going to be reflux  
10 so let's not have anything near there.

11 But, I agree wholeheartedly with what  
12 you're saying. There is nothing wrong to imaging  
13 afterwards to see, not I'm not talking calculating doses  
14 because the doses may not be meaningful, but if you see  
15 that, you could institute palliative therapy. But the  
16 calculation of doses may not be worthwhile. In fact,  
17 our Committee felt it probably wasn't in most instances.

18 I might also add that most protocols now do  
19 have antacid in blocking therapy built into their  
20 programs. They give this to everyone because it is  
21 really -- they're harmless drugs, you give it to the  
22 patient and you give it before you do the procedure.

23 So, I agree with you and, actually, I will  
24 agree with you more as soon as this procedure evolves  
25 to the extent that we have a lot more accuracy in terms

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1 of what we can do with Bremsstrahlung imaging.

2 CHAIRMAN THOMADSEN: Yes, Dr. Alderson?

3 MEMBER ALDERSON: Well, I also want to  
4 compliment you on a great presentation.

5 And the way that I hear this is, is what  
6 we're trying to do with the recommendations is to keep  
7 us from having too many misadministration reports that  
8 we have to make and then all the things that go on when  
9 one of those gets made.

10 So, in that sense, all the things that you  
11 said are correct, but, in fact, it seems to me that  
12 that's what you're driving at here and it's something  
13 that I think is appropriate and I will support it.

14 CHAIRMAN THOMADSEN: Thank you. Yes, Dr.  
15 Langhorst?

16 MEMBER LANGHORST: Can you talk about a  
17 little bit more, you mentioned it at the beginning of  
18 your talk, the interaction between the physician and the  
19 patient in regard to the practice of this therapy and  
20 the risk associated versus how a regulatory body  
21 determines whether the administration was met -- has met  
22 the medical policy criteria?

23 VICE CHAIRMAN GUIBERTEAU: Sure. Well,  
24 you know, this is no different from -- and each State  
25 has its own requirements -- but in general, each

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1 procedure that may cause significant side effects to  
2 patients whether it's surgery or whether it's, you know,  
3 radiotherapies or some medical therapies, some new  
4 medical therapies that the patient is informed of the  
5 risks and benefits and the side effects.

6 And you know, this is -- in patients who are  
7 in these dire straits, there is no absolute even though  
8 the procedure may not be performed.

9 But, let me give you an example of a patient  
10 that I am familiar with -- whose case I'm familiar with  
11 and I'm not breaching anything because I'm not telling  
12 you anything about that patient.

13 That if some of these patients who are  
14 candidates for liver transplants are waiting and if  
15 there is something that can't be mitigated, the patient  
16 needs to help make the decision and say, look, we will  
17 be performing this on you against what we usually do and  
18 we see that you have risen to number ten on the list to  
19 get a transplant. It is up to you to help us make that  
20 decision.

21 These are the sorts of things, and that's  
22 rare, but I'm saying that these are the sorts of things  
23 that you're dealing with in this situation that make it  
24 much more important for these interactions not to be  
25 disturbed.

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1           And I can tell you the people doing these  
2           are -- I've seen the forms from various places and  
3           they're pretty uniform in terms of what is required.  
4           And as you know, not every -- these procedures are really  
5           limited to big centers, either big hospitals,  
6           free-standing hospitals, I mean large centers or  
7           academic centers. So we're not talking about these  
8           patients offices.

9           In terms of where we come in, that's the  
10          very interesting thing about what this Committee does  
11          is to try to determine where, you know, what does our  
12          policy mean in terms of regulating this? I mean what  
13          is best for the patient? What is not intrusive? What  
14          will protect the patient? And we think that those will  
15          be in place.

16          One brief thing I want to mention and I  
17          don't want to open it up to too much, but the original  
18          question was, are we not getting enough reports?

19          Well, and this is just speculation, but one  
20          reason we may not be getting enough reports is that the  
21          reporting metrics don't fit with what's being done and  
22          unless we resolve that and align that, then what is the  
23          purpose of our regulating?

24          So, again, we felt very strongly that this  
25          would probably -- it might increase the number of

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1 reports we get. But on the other hand, the purpose here  
2 is to make this rational.

3 CHAIRMAN THOMADSEN: A follow-up from Dr.  
4 Langhorst.

5 MEMBER LANGHORST: And I think -- thank you  
6 very much -- I think that the fact that we don't have  
7 it in this regulatory guidance document as far as  
8 following up with what you're saying, that doesn't  
9 prevent the medical treatment to be doing exactly what  
10 it should be doing. It just isn't a metric that you can  
11 regulate on.

12 And so, don't feel that if it's not in this  
13 guidance document that everybody thinks, oh, they don't  
14 have to do it because it's two different things.

15 CHAIRMAN THOMADSEN: Mr. Fuller?

16 MR. FULLER: Yes, I just have a comment and  
17 a question.

18 The first comment back to our earlier  
19 discussion about 10 CFR Part 35 Subpart K. This is a  
20 prime example of those things that while we might like  
21 to move things from the temporary parking lot to the  
22 rule, that this one would be extremely challenging, I  
23 think. And so, I guess it's good that we have been able  
24 to stay in an area where we could exercise some  
25 flexibility and be able to react and adjust to things.

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1           My question has to do, though, with the  
2           recommendation for what would constitute a medical  
3           event that needed to be reported? I believe from  
4           reading the report and what you said, Dr. Guiberteau,  
5           that it should be limited to the amount of activity that  
6           is delivered, in other words, it should be limited --  
7           the metrics should be limited to the activity that's  
8           delivered at the point of the catheter. In other words,  
9           where the catheter is placed.

10           So, my question becomes then what if the  
11           catheter is misplaced? So, we've had a number of  
12           medical events that reported over time where they  
13           actually delivered the activity, which we talked in  
14           terms of the dose, and I know how difficult that can be,  
15           but where the activity was actually delivered to the  
16           wrong lobe of the liver.

17           So, the way I read this, it would indicate  
18           or I would assume that even under those cases where  
19           someone misplaced the catheter, if they delivered the  
20           activity to the tip of that catheter, then that would  
21           not constitute something that needed to be reported.

22           So, could you comment maybe a little bit on  
23           that?

24           VICE CHAIRMAN GUIBERTEAU: Well, I think  
25           that would be instance in which this would not have been

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1 administered in accordance with the written directive,  
2 certainly in terms of the amount it would be.

3 But in terms of, you know, any time you  
4 change the metric, you need to change the associated  
5 things such as your mentioning that, according to the  
6 written directive in this instance, would be according  
7 to the position of the catheter where the treatment was  
8 planned.

9 And, you know, those are things that I think  
10 the staff and the Committee need to consider when these  
11 are revised, just as reflux, nobody knew much about  
12 reflux when this first came out. Now we know that's  
13 something that if it is anticipated, then fine. But,  
14 specifically, in terms of the delivery, the delivery  
15 needs to be according to all the planning that has gone  
16 forward.

17 MR. FULLER: Thank you.

18 CHAIRMAN THOMADSEN: And I think an answer  
19 to your question, this doesn't change any of the medical  
20 event criteria such as positioning the tip of the  
21 catheter in the wrong treatment site or the wrong  
22 patient or using the wrong isotope.

23 I think all of that would stay in place;  
24 this just clarifies the question about would a dose to  
25 the GI tract or to the lung be considered a medical event

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1 when it fell into the criteria as discussed in these  
2 recommendations.

3 MR. FULLER: Thank you, thank you.

4 MEMBER ALDERSON: So, I don't know what the  
5 parliamentary procedure is, but I would like to suggest  
6 that the Committee support this recommendation. I  
7 would move that.

8 CHAIRMAN THOMADSEN: I think that that's a  
9 good example of parliamentary procedure. We need to  
10 have a second. Actually, we don't need a second because  
11 this is coming from a subcommittee, we actually need the  
12 recommendation, although I will take that and we don't  
13 need a second, we will open the motion to a vote in just  
14 a second.

15 It is on the table for action now, thank you  
16 for bringing to action, it's what the parliamentary  
17 procedure would have been and we'll open the motion for  
18 discussion to approve these recommendations and Mr.  
19 Costello, you were about to make a comment.

20 MEMBER COSTELLO: Well, it's slightly off  
21 topic, but on this topic, you know, the Committee  
22 recommendations we've done, that's what I favored it  
23 then and I --

24 Excellent report, by the way. I mean you  
25 have great leadership with the subcommittee, we really

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1 did and I would vote in favor when it comes to a vote.

2 CHAIRMAN THOMADSEN: Very good, thank you  
3 for the support of the motion.

4 Dr. Howe?

5 DR. HOWE: Just two comments.

6 When you read the subcommittee report,  
7 there's going to be two underlying themes.

8 One is that you have fewer problems when you  
9 have more experienced physicians. That raises  
10 possible question in our regulatory idea of do the  
11 authorized users need additional training before  
12 they're authorized users? Is three cases enough?

13 The other is, you have put a lot of  
14 description into what is good medical practice before  
15 you do these -- that you do the embolization; that you  
16 do the MAA shunting; that you make a medical decision  
17 on whether to go forward with this patient or not to go  
18 forward.

19 But that doesn't show up, as Mr. Fuller was  
20 trying to point out, in your final recommendation of  
21 what is a medical event. It's just based on activity  
22 in the body, that activity at the tip when the tip is  
23 correctly placed.

24 So, you're tying it back to your written  
25 directive, but we don't have a way of capturing in the

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1 written directive right now; the tip is where it was  
2 supposed to be and then you did the administration.

3 So, I think you need to kind of address --  
4 I would hope you would address those issues.

5 VICE CHAIRMAN GUIBERTEAU: Well, we  
6 specifically did not because we wanted to keep this an  
7 undistracted change in the metric.

8 As I said, I don't believe that reflux was  
9 necessarily first addressed early on when people were  
10 thinking about this.

11 So, again, these are issues -- we did not  
12 address the dose to the tumor dose, the target dose,  
13 because that was not our charge and we wanted to move  
14 the ball forward. We do understand that any time you  
15 do that, there are other issues. But, we didn't want  
16 it to be a distraction.

17 And two, when you say experienced  
18 physicians, I believe most of the literature says this  
19 procedure complications have diminished as physicians  
20 have gotten more experience.

21 Most of that applies to the evolution of the  
22 techniques, that is, people doing this in 1998 under  
23 research protocols probably did them less well than  
24 people who do today because we know so much more.

25 I think the training is very important and,

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1       you know, if that's felt to be necessary, you know, I  
2       don't have any issues with some reasonable, you know,  
3       alternatives of that.

4               But I think in terms of experienced  
5       physicians that that was really what the report and the  
6       literature primarily addressed.

7               Now, the procedure is maturing for the most  
8       part at least the performance of the aspects from the  
9       physician team. In terms of the imaging, that is still  
10      in dose calculations, that's going forward.

11              So, you know, I just wanted to point that  
12      out.

13              CHAIRMAN THOMADSEN: Ms. Weil?

14              MEMBER WEIL: From the logistical  
15      perspective, you said that these procedures were only  
16      performed in academic medical centers --

17              VICE CHAIRMAN GUIBERTEAU: Or large  
18      medical centers.

19              MEMBER WEIL: Large medical centers.  
20      What's the likelihood that this might move out of that  
21      arena into smaller medical centers, non-hospital  
22      practices in the next couple of years?

23              VICE CHAIRMAN GUIBERTEAU: I think there  
24      are two issues at play here.

25              One is that the, you know, if you study

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1 penetration of technology, you know that it resists  
2 moving to atmospheres in which it is less well done, but  
3 inevitably, it moves into the community.

4 One thing preventing that here is the cost  
5 of the procedure, the relative rarity of the procedure  
6 in terms of where they are performed. Generally, doing  
7 these in the community that don't have access to  
8 transplantation teams, who don't have access to teams  
9 performing cryotherapy for these things.

10 I believe there is interest in doing this,  
11 but of course, I'm no crystal ball. But, I think at the  
12 moment, I think you're right to point that out, but I  
13 think at the moment, it probably is where it is for the  
14 time being. But, no guarantees.

15 CHAIRMAN THOMADSEN: Mr. Costello?

16 MEMBER COSTELLO: I have a comment. That  
17 has already -- to some small penetration, not into  
18 clinics but in the community-based hospitals and  
19 non-academic clinics.

20 And having said that, I think that -- I  
21 don't think we've seen any terrible thing resulting from  
22 that and the issues that have occurred in those  
23 hospitals would not be affected by this guidance. You  
24 know, we have a hospital treating people without a  
25 [inaudible] on the license at all.

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1                   We had another hospital treating patients  
2                   but not measuring the dose at all. They made the  
3                   radiation measurements but they never made any  
4                   calculations to know how much went out to the patient.

5                   And none of these would be affected by the  
6                   guidance. This is just, you know, bad performance  
7                   regardless of what the guidance would be.

8                   I have not seen it any place other than a  
9                   hospital, I mean I've only ever seen it in hospitals.  
10                  And most, as you say, in the large academic research  
11                  places. But I have seen it outside of there, too.

12                  CHAIRMAN THOMADSEN: Thank you very much.

13                  Dr. Alderson?

14                  MEMBER ALDERSON: Dr. Welsh was next.

15                  CHAIRMAN THOMADSEN: You were deferring to  
16                  Dr. Welsh.

17                  MEMBER WELSH: Well, thank you.

18                  Regarding the question of is three cases  
19                  enough, I think that's a good question and my response  
20                  might be that what Dr. Guiberteau said about the  
21                  technique, the technology evolving over the past decade  
22                  and, therefore, the complications being much higher  
23                  with the teams that were brand new to this and  
24                  complications being much lower today because of the  
25                  benefits of all that gleaned information is quite true.

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1                   However, there's also no doubt that  
2                   somebody who's done this a thousand time is likely to  
3                   be better than somebody who's done this three times.

4                   That is most definitely likely from the  
5                   interventional perspective where there is technical  
6                   skill involved. And while it may not be as challenging  
7                   as resecting a craniopharyngioma, there is a certain  
8                   degree of technical skill required and not all  
9                   practitioners are going to be equal in this particular  
10                  aspect.

11                  The people who have done it three thousand  
12                  times have got more experience and are better than those  
13                  who've done it three times have done it three thousand  
14                  times because they may be gifted and have talent and be  
15                  capable of doing this better than somebody who might  
16                  have tried ten thousand times and just can't do it as  
17                  well as the super skilled practitioner.

18                  Having said that, from the radiation safety  
19                  perspective and the authorized user perspective that  
20                  NRC is concerned with, that might be a slightly  
21                  different aspect than the typical skill of the  
22                  interventionalist and maybe three cases still is  
23                  sufficient for authorized user status.

24                  So that was one comment I might have.  
25                  Other comments, though, I concur with everybody's

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1 compliments of Dr. Guiberteau's presentation. I feel  
2 like it was great and Mickey, I think you missed your  
3 calling, you should have a radiation oncologist.

4 But other things that were brought up was  
5 why do you do the imaging after the treatment? Well,  
6 although you're not going to get, there are some  
7 situations where if we had the excellent imaging we  
8 could better predict whether a patient would be  
9 candidate for a repeat treatment or if we actually give  
10 the dose that we wanted to and should there be a  
11 supplemental radiation therapy technique applied or  
12 chemotherapy supplemented here.

13 The more accurate our post-implant  
14 dosimetry is, the more likely we would be able to state  
15 such things that would benefit patients in the future.  
16 This is certainly not where I want [inaudible]  
17 brachytherapy is today, and if Bremsstrahlung imaging  
18 that we have currently is more in the same ballpark as  
19 the zirconium-90 PET potential could be.

20 But, although it was brought up, most  
21 institutions can't do the PET today. But I think that  
22 in the future, that will be where we evolve to.

23 Finally, I think Dr. Langhorst brought up  
24 a question of physician-patient involvement and  
25 speaking as a radiation oncologist, I think that this

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1 is part of the reason why radiation oncologists should  
2 remain involved with this team effort because it is good  
3 for patients with a consultation from a cancer  
4 specialist, in particular cancer specialist who has a  
5 lot of experience and knowledge of radiation related  
6 issues.

7 So, those are my comments.

8 CHAIRMAN THOMADSEN: Thank you very much.

9 Dr. Alderson?

10 MEMBER ALDERSON: Right, so, thank you.

11 In part, I'm going to make a comment about  
12 what I think this Committee is trying to look at and  
13 perhaps you can correct me since I am so relatively a  
14 new member of the Committee.

15 But, it seems like that the motion or the  
16 recommendations to focus on the safe and I'll say  
17 uniform application of medical radiation versus our  
18 ability to control which we don't have biological  
19 variability or the precision of medical practice. And  
20 I think that's what some of the recent comments focused  
21 on.

22 So, I still believe having heard those  
23 comments, which are certainly good for patients, but I  
24 think are not exactly what we're trying to accomplish  
25 here. But I still support the recommendations of the

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1 subcommittee.

2 CHAIRMAN THOMADSEN: Thank you very much  
3 for the clarification.

4 Dr. Palestro?

5 MEMBER PALESTRO: A couple of comments.

6 Number one, regarding the number of  
7 therapies, the ones you perform in terms of experience,  
8 I don't know how you determine a number. I don't know  
9 that three is enough, that five is enough, I don't think  
10 there's any good way to come up with a number and be  
11 certain that that's the appropriate number. So, I  
12 certainly wouldn't advocate changing it.

13 And I also think the distinction between  
14 academic medical centers/large medical centers and  
15 community hospitals or smaller sites really is sort of  
16 irrelevant because the concern that we have is that at  
17 the moment, a medical event is based on the dose to the  
18 GI tract.

19 And yet, regardless of where the procedure  
20 is being done, we've come to the conclusion that with  
21 current technology, at least, we don't have the ability  
22 to accurately determine the dose to the GI tract and even  
23 if we could, we're not certain that that dose is  
24 necessarily a dose that will precipitate an ulceration  
25 or reaction of some sort.

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1           So, I think that that's, to me at least,  
2           that's less of a concern as to where it's being  
3           performed.

4           CHAIRMAN THOMADSEN: Thank you.

5           Dr. Suleiman?

6           MEMBER SULEIMAN: I sort of agree with the  
7           minimum three, first off, more for the newer members and  
8           some of the older ones, what's practice of medicine?  
9           What's the inherent variability associated with medical  
10          practice? And you trust your physician, that's what I  
11          tell people, if you don't trust your physician, get  
12          somebody else.

13          And you can't start using numbers and  
14          saying three procedures or five procedures, it could be  
15          somebody who worked in a hospital is now doing in the  
16          clinic. So, it's the same person now doing it in a  
17          different environment, so we want to categorize these  
18          things in such a simple bean counting way but it doesn't  
19          always translate that way.

20          So, I think the most important thing is  
21          trust your physician and appreciate that this is an area  
22          of medicine that's extremely variable and has a high  
23          level of uncertainty.

24          Again, so people don't forget, I think  
25          until patient specific dosimetry becomes routine

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1 practice, you're not going to see any improvement in  
2 radiolabeled therapies, I think even here.

3 And I've seen -- and there's experience out  
4 there and there are trials out there where you do the  
5 post-patient imaging and you find out that the dose the  
6 patient received was much different than what you had  
7 predicted.

8 So, and with adjunct therapy where you may  
9 go in with a radiolabeled in the first place and then  
10 top it off a little bit later on, that's going to be of  
11 value.

12 So, the lesson here is, you have to start  
13 accepting the fact that you're going to have to do  
14 patient dosimetry on a patient by patient basis at some  
15 point if you want to get this close to radiation therapy  
16 type pieces on accuracy.

17 But, I think in terms of radiation safety,  
18 I think you guys have met the charge. You know, I think  
19 the confusion is let's not get into practice of medicine  
20 and this is -- I mean this was originally for  
21 humanitarian use purposes, so this was just not a  
22 routine first run therapy.

23 So, we're getting into the weeds. These  
24 are interesting discussions, but I don't think they  
25 address the radiation safety issue. I think we're

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1 addressing safety issue big time.

2 CHAIRMAN THOMADSEN: Thank you very much.

3 Mr. Costello?

4 MEMBER COSTELLO: I have a question on the  
5 training and three or more than three.

6 At least most of the authorized users that  
7 I've seen while they can be interventional radiologists  
8 or not, but they're mostly radiation oncologists.

9 And of times, the procedure, the authorized  
10 users are actually out of the room for watching through  
11 a window. And the IR doctor is the one actually, you  
12 know, injecting the patient.

13 And in terms of under doses, overwhelming  
14 most of our medical events involving actual under doses,  
15 a number of them are caused by the/or related to the  
16 actions of the interventional radiologist, okay. It is  
17 a skilled thing putting it in there, well beyond my  
18 skills.

19 But, and whether or not the authorized user  
20 is not doing this, has had three or more three or five,  
21 that will affect skill of the interventional  
22 radiologist and that actually does have an effect on how  
23 medical events you have, particularly under doses.

24 Or for that matter, if you go too fast,  
25 you're going to, you know, reflux them and other things.

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1 CHAIRMAN THOMADSEN: Thank you.

2 Any other comments? I'm hearing none,  
3 we'll take a vote. The vote is to accept the  
4 recommendations of the subcommittee as those of the  
5 ACMUI. All in favor, please say aye.

6 (CHORUS OF AYES)

7 CHAIRMAN THOMADSEN: Opposed, say no.  
8 Abstentions? And it's passed unanimously.

9 Very good job on the work of the  
10 subcommittee. Good job.

11 Yes, Ms. Holiday?

12 MS. HOLIDAY: Just one final thing, I know  
13 that the committee just voted to accept our  
14 recommendations, but, you know, do I also have a formal  
15 vote to endorse the subcommittee report to become the  
16 full committee report.

17 CHAIRMAN THOMADSEN: Thank you very much  
18 for that clarification. I'm not sure I understand it  
19 entirely, but do a motion on the floor to endorse the  
20 subcommittee report?

21 Thank you very much.

22 Do we have any comments before we take the  
23 vote? None, in that case, all in favor, please say aye.

24 (CHORUS OF AYES)

25 CHAIRMAN THOMADSEN: And those opposed,

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1 say no. Any abstentions? Thank you very much.

2 I think that is now approved and endorsed.

3 At this point -- yes, Mr. Costello?

4 MEMBER COSTELLO: This is more of a process  
5 question. Now that we've done that, will sometime in  
6 the future they actually get back to us and tell us what  
7 they're doing with the recommendations?

8 CHAIRMAN THOMADSEN: I think that's part  
9 of the -- Ms. Holiday was saying at the end of the ruling  
10 of each meeting, the follow through of what actually  
11 happens with our recommendations. But, it's good to  
12 keep us on track.

13 With that, it's time to take a break for  
14 lunch. Please be back in position at 1:00.

15 (Whereupon, the matter went off the record  
16 at 11:40 a.m., and resumed at 1:01 p.m.)

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1 A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

2 (1:01 p.m.)

3 CHAIRMAN THOMADSEN: The first discussion  
4 in this session is the FDA's role in the global  
5 molybdenum-99 shortage by Dr. Suleiman.

6 MEMBER SULEIMAN: Thank you very much. We  
7 have been -- most of you have been aware of the global  
8 moly shortage, and the agency, FDA, has really been  
9 pretty involved with this. And after I did this last  
10 time, I'd better start telling people a little bit more  
11 about what we've been doing. And so that's really the  
12 purpose of this.

13 And I'm not going to have to read this much  
14 longer, but the opinions I express today may not  
15 necessarily reflect the official position of the FDA or  
16 Health and Human Services. And I want to clarify -- I  
17 think this is an important point -- since information  
18 on an investigational new drug application and a new  
19 drug application submission to FDA is considered  
20 confidential -- we are not even allowed to acknowledge  
21 that we received such applications -- I need to clarify  
22 that any information in this presentation has been  
23 obtained from public sources.

24 Similarly, the mention of any commercial  
25 products are neither an official endorsement or

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1 criticism of the product by me, the FDA, or Health and  
2 Human Services.

3 As I said, we've been pretty much -- very  
4 much involved with this dating back to the middle of the  
5 2000s. Clearly, we are aware of the other legislation  
6 that we intend to comply with, the American Medical  
7 Isotope Act of 2012, which essentially eliminates the  
8 export of highly enriched uranium in the use for  
9 molybdenum-99 production, which, as you know, decays  
10 into the tech-99m isotope.

11 We have been working with stakeholders to  
12 rebuild the fragile manufacturing infrastructure,  
13 basically aging reactors, for the production of  
14 moly-99, and we are very sensitive that we need to  
15 address security concerns and ensure a stable supply at  
16 the same time. And we have spent an awful lot of time  
17 working with industry basically to help them navigate  
18 the regulatory pathway to develop alternative  
19 technologies for the manufacturing of moly-99.

20 If people aren't aware, technetium-99m is  
21 the major medical isotope in the world. When I was in  
22 graduate school 40 years ago, I actually did my master's  
23 work with technetium. I was told it was a relatively  
24 new drug, new isotope, and it had some really unique  
25 advantages. And I think it's a testament to that

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1 radionuclide that today it basically dominates the  
2 nuclear medicine community. It dominates 80 percent of  
3 all nuclear medicine exams; that's about 14 to 15  
4 million in the U.S.

5 And the reason is basically physics. It  
6 has an optimal imaging energy of 140 keV. It has an  
7 extremely practical half-life. But aside from the  
8 physics, I think this is really the key. It has a great  
9 chemical state, and you can bind it with all sorts of  
10 drugs. And it's not the nuclide. The nuclide  
11 either -- is either a good imaging agent or a good  
12 therapeutic agent, but the -- where the drug goes is  
13 where the nuclide rides along. And so that's really  
14 what is -- what drives this.

15 And so when people say tech is going to go  
16 away, I doubt it. I mean, it's a case of when the right  
17 drugs that maybe seek certain smart probes, it will go  
18 to certain cancer, to certain sites, that will be the  
19 next major breakthrough.

20 And it's relatively easy to manufacture, so  
21 it's accessible, it's relatively inexpensive, and it's  
22 easy to use to label drugs with.

23 There are basically two ways that  
24 technetium -- excuse me, the major way that it's  
25 produced today is in reactors. You basically irradiate

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1 U-235 with neutrons and you get fission products, and  
2 you have this mass of very hot radioactive material.  
3 And so these are in the jargon called irradiators, so  
4 there are a number of reactors around the world that  
5 irradiate this uranium to produce the moly.

6 That center slide there is really often  
7 overlooked, but you have producers. These are the  
8 processing sites that actually take this fission  
9 material and then chemically extract the molybdenum  
10 from the mess of radioisotopes that have resulted. And  
11 this is a chemical separation process, and not all  
12 irradiators, you know -- you may have irradiating  
13 capacity, but you may not have the ability to process  
14 all of it.

15 For example, right now in Australia, their  
16 OPAL reactor was limited in terms of their processing  
17 facilities, but they are now -- they have broken ground  
18 and they are increasing their capacity to extract more  
19 molybdenum if they irradiate more uranium. And so then  
20 you separate the moly, and then you -- the third part  
21 of it is the traditional generator, and it's put  
22 into -- you put the molybdenum on the top and it goes  
23 through an Illumina column, and what you get out from  
24 the bottom is the radioisotope technetium-99m.

25 And that is really what FDA is concerned

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1 about, the quality and the purity of the medical  
2 isotope.

3 There have been a number of alternative  
4 manufacturing processes. These are just two of them.  
5 One is using -- these use accelerators. One uses  
6 moly-98 as the target material, and it hits it with  
7 neutrons, you get a gamma off, and you get the moly-99.  
8 The other process uses moly-100 with high energy  
9 gamma -- X-rays from an accelerator. Again, you get  
10 neutrons off, and you get moly-99. In both cases, you  
11 take the moly-99, you pack a generator with it, and you  
12 get your technetium-99m.

13 There are some alternative methods that the  
14 Canadians are using that basically involves irradiating  
15 moly-100 with a two-proton accelerator, and they get the  
16 technetium directly, bypassing the moly -- the moly  
17 pathway.

18 So these are all being worked on,  
19 developed, and we will have to see how it all plays out.

20 Separate from that, because there are  
21 several pieces of this puzzle as this evolves, was that  
22 back in 1992, Congress passed this Energy Policy Act.  
23 And at that time, they really felt that you needed to  
24 eliminate highly enriched uranium, which is uranium  
25 that has more than 20 percent U-235 in it and is

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1 considered weapons grade, and so they basically  
2 restricted it from being exported by the United States  
3 to all of these reactors that were using it for medical  
4 isotope production.

5 A few years later, in the Energy Policy Act  
6 of 2005, a different message was sent saying we are going  
7 to allow HEU to be exported for medical isotope  
8 production as long as it goes to Canada, the  
9 Netherlands, Belgium, France, and Germany. So the HEU  
10 was sort of being pushed or pulled from two different  
11 ends, and eventually the recent AMIPA, or the American  
12 Medical Isotope Act of 2012, with a different twist.  
13 They said, "Gee, we need to have production in the United  
14 States."

15 So one of the requirements of that act is  
16 to promote the production of moly-99 in the U.S., and  
17 finally put a deadline to phase out the export of highly  
18 enriched uranium for the production of medical isotopes  
19 effective seven years after the date of enactment. So  
20 it is either December 2019 or January 2020, the U.S. will  
21 no longer be allowed to export HEU for moly-99  
22 production.

23 However, there are some emergency escape  
24 clauses in there that involve the Secretary of  
25 Department of Energy, the Secretary of Health and Human

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1 Services, where if a true crisis is going to emerge where  
2 this is the only way to produce it, they could invoke  
3 that situation, if necessary. But it looks like the  
4 conversion to low enriched uranium is proceeding.

5 Now, this report is sort of a very  
6 definitive one. It was published in 2009, but  
7 basically the question that was being asked is, is it  
8 feasible to switch from highly enriched uranium to low  
9 enriched uranium? And that was a question that they  
10 hadn't answered, because you are using 97 percent  
11 enriched uranium and you are now going down to 20  
12 percent. So my simple mind said, "Gee, you are going  
13 to reduce yield, you know, by 60 to 80 percent, you know,  
14 so a reactor is not going to be able to produce as much."  
15 Wouldn't that possibly create a shortage?

16 The answer to it was no, and there  
17 are -- they found out that you may use low enriched  
18 uranium, but you can pack more -- you can make a larger  
19 target and you can affect the density. And so what I  
20 understand is the yield drops maybe 10 or 20 percent,  
21 but it's not as dramatic. And so they irradiate more  
22 of it, and they can produce it, so that hasn't been the  
23 problem.

24 However, the report did raise some real  
25 concerns about HEU production not leading to a drug

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1 shortage. Some of these were technical, as I just  
2 described to you. Some of these were economic. Some  
3 of the alternative ways cost more. And some of them  
4 were regulatory. There was concern over licensing,  
5 over transport of materials. There was concern about  
6 FDA regulatory requirements, which was actually my  
7 entree into this issue.

8 Now, this is a slide I've taken from  
9 National Nuclear Security Agency, who has sort of been  
10 leading this. The brown is the highly enriched uranium  
11 that is being used at these different sites, and the blue  
12 is the non-HEU. And you've got four or five major  
13 producers in the world. And as you can see, they are  
14 slowly shifting; they are converting to using highly  
15 enriched -- to using low enriched uranium.

16 But the real big 800-pound gorilla in the  
17 room is the Canadian reactor that will not convert to  
18 LEU. They are just ceasing production come 2016. So  
19 that takes a major player out of the game.

20 I took the next two slides -- I'm not going  
21 to go into a lot of detail -- but this was in the Nuclear  
22 Energy Agency of the Organization of Economic  
23 Cooperation Development, I will discuss them in a little  
24 bit more detail. The full report is available online,  
25 but these are the current irradiators as of April 2014.

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1 And this is their maximum capacity. This is not what  
2 they produce on a regular basis, but these are the major  
3 players.

4 Now, you've got more players now than you  
5 did a couple of years ago. And if you look over in the  
6 right-hand column, you'll see that the United States is  
7 conspicuously, you know, absent. The two red dates  
8 under stop dates, 2016 and 2015, are associated with the  
9 National Research Universal -- that's the Canadian  
10 reactor -- and OSIRIS, which is the French reactor.  
11 They are both going offline permanently in the next two  
12 years.

13 The other slide -- and I just limit it to  
14 these two tables -- shows you potential, new irradiators  
15 that plan to be commissioned by 2020. With respect to  
16 the OECD, these are efforts that have broken ground,  
17 have put money into it. These are tangible initiatives  
18 to develop -- to produce -- you know, to irradiate and  
19 produce moly.

20 There are a lot of other players. I will  
21 discuss them again momentarily. But the only -- the  
22 main thing here, you can see there are several U.S.  
23 players in different phases. One you've heard of is  
24 NorthStar, and they have been working with the  
25 University of Missouri facility, and Morgridge-SHINE

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1 out of Wisconsin, and they have -- they have also been  
2 proceeding in their plans. So these are potential  
3 irradiators.

4 Now, getting back to the NNSA, as part of  
5 some of their initiative, they funded four cooperative  
6 commercial projects. The four are listed here. The  
7 two at the bottom -- Babcock and Wilcox and  
8 GE-Hitachi -- are basically on permanent hold. They  
9 felt, for business reasons or whatever, that they  
10 stopped their work into this project.

11 The two top ones are the two I referred to  
12 earlier, NorthStar Medical Radioisotopes, which  
13 actually has a new drug application in-house at the  
14 agency, and SHINE, the Morgridge Institute for  
15 Research. They are developing a method to produce  
16 moly-99. Since they will be producing the material, it  
17 may not be necessary for them to actually apply for an  
18 NDA, but they will have some interactions with us.

19 Now, to further make the scenario  
20 interesting, there was an isotope workshop back in June  
21 in D.C. sponsored by Argonne Lab and Department of  
22 Energy and the National Nuclear Security Agency. And  
23 this information is all online, including the  
24 presentations, but these are some of the additional  
25 players that have expressed an interest in producing

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1 moly.

2           Some of them are using existing technology,  
3 so it's not a case of developing something new. They  
4 may just use a classic reactor with uranium fuel. Some  
5 of them have come up with some novel new methodology,  
6 and so there is a lot of talk, there is a lot of  
7 discussion, and some of these are in various phases of  
8 moving forward.

9           The point is there is a lot of interest in  
10 this. Currently, there are three FDA approved products  
11 in the U.S. -- Mallinckrodt, which makes the Ultra  
12 TechneKow, Lantheus TechneLite, and GE. I think last  
13 year we approved their health care Drytec generator  
14 system, which is actually manufactured in the United  
15 Kingdom.

16           Now, there can be no discussion of this  
17 without explaining what went on in Canada with -- that  
18 puts things in perspective. You have to appreciate the  
19 fact -- and why we didn't have a domestic producer was  
20 Canada is our neighbor next door, and they were  
21 producing an awful lot of moly-99. At certain times,  
22 they could produce as much as two-thirds of the global  
23 supply.

24           And this old reactor was built in 1956 at  
25 Chalk River and was to cease operation around 2005. And

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1 they had a plan. They were going to replace the NRU with  
2 two reactors referred to as the Maple reactors. And  
3 this is another interesting aside, but the reactors were  
4 built, they started to work, they found some design  
5 flaws; they had some positive coefficients of  
6 reactivity; they were never licensed; they were  
7 considered too hazardous. How you could actually wind  
8 up building something like this and learning about it  
9 at -- you know, not getting it approved.

10 So not only did it result in some difficult  
11 decisions, there was some political fallout from it as  
12 well. At one point I think the Canadian government  
13 almost lost their vote of confidence over this very  
14 issue. So for a variety of reasons, they basically  
15 decided they were going to get out of the global moly-99  
16 business. That occurred eventually.

17 But during 2007 and 2009, when this old  
18 reactor -- and a similar thing happened recently in  
19 Petten in the Netherlands, when they shut down for  
20 maintenance, they find other problems, and so they stay  
21 shut down for a longer than expected period of time.  
22 And what happened is this precipitated the first of  
23 several shortages and crises that eventually resulted  
24 in the establishment of what is referred to as this high  
25 level group of medical radioisotopes.

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1           The Organization of Economic Cooperation  
2           Development is an outgrowth of the old Marshall Plan,  
3           but it is now an international agency. There is a  
4           Nuclear Energy Agency component of it. And as best I  
5           understand, Canada and the U.S. went to them and said,  
6           "Look, we'd like for the OECD to take this issue and come  
7           up with a plan." So the HLG-MR is referred to as the  
8           high level group on the security of supply of medical  
9           isotopes. So their mission was to make sure there is  
10          a long-term stable supply of moly-99, at the same time  
11          there is security.

12                 This is sort of where FDA gets into the  
13           game. One of our primary responsibilities is to  
14           mitigate and prevent drug shortages and ensure supply,  
15           not just for technetium, for all drugs. We have  
16           facilitated the development of new technetium labeled  
17           drugs. Any time there is an approved drug that requires  
18           changes, they have to come back to us and file a  
19           supplement. And of course, you know, we inspect these  
20           sites on a periodic basis.

21                 Specifically regarding the moly-99, we  
22           have a drug shortage group that is very much in contact  
23           with the major manufacturers. And sometimes they get  
24           information before I get a chance to learn about it. So  
25           it has been pretty transparent with the companies.

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1           We have spent an awful lot of time trying  
2           to provide specific advice on the correct FDA regulatory  
3           pathways. It is not very obvious to -- a lot of these  
4           reactors and producers are really not directly involved  
5           in health care. So they are very confused when they  
6           were told that they may have to get FDA regulatory  
7           approval.

8           And we have participated in a number of  
9           outreach activities. We have participated -- I have  
10          been a member of this HLG-MR group, which has been  
11          meeting in Paris twice a year. The Office of Science  
12          and Technology Policy out of the White House has regular  
13          stakeholders meetings in the D.C. area. Department of  
14          Energy has had a series of isotope workshops. So there  
15          has been a lot of effort to get the word out about what  
16          is going on.

17          So how does this apply for moly? I will  
18          give you a few little specifics. When someone files a  
19          new drug application, the source and production of the  
20          moly-99 needs to be specified. That is just part of the  
21          application process.

22          If the product is already approved, but now  
23          there is going to be a change in manufacturing, this is  
24          really one of the focal points of some of my earlier  
25          interactions. Let's say they're going to convert from

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1 highly enriched uranium to low enriched uranium. They  
2 have to file a supplement to an approved new drug  
3 application.

4 Now, this was very daunting and threatening  
5 to some of the companies as they have never done this.  
6 So there was some confusion in those days. There were  
7 rumors that we could slow the whole process down by as  
8 much as three years.

9 If the protocol isn't spelled out,  
10 the -- you could file what's known as a drug master file  
11 to ensure confidentiality. I'll explain that very  
12 shortly. And this drug master file, which I refer to  
13 as a safe deposit box, specifies how the moly is  
14 produced, including the composition of the target  
15 material specifications, the irradiation process, the  
16 chemical separation of the moly from the fission  
17 material, and so on.

18 So it's your entire production process has  
19 to be spelled out. So this is the cookbook. So you  
20 take this cookbook and you put it in the safe deposit  
21 box, and you file that drug master file with the FDA.  
22 Nobody has access to it, not even FDA. And the reason  
23 you create this drug master file -- and we get -- I was  
24 surprised to learn we get about 6,000 of these filed on  
25 a monthly basis, so this is pretty routine. It

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1 maintains confidentiality of proprietary information.  
2 And, specifically, it permits the efficient review of  
3 the information by FDA reviewers to support the  
4 application.

5           So in this example, let's say producer  
6 C -- let's use one of the real -- the Australian reactor,  
7 OPAL; they produce moly-99, but they don't tell you the  
8 composition of their target material. They don't tell  
9 you how long they -- that's proprietary. They don't  
10 tell you how they extract the moly. That's a chemical  
11 separation process. And they are now going to sell it  
12 or provide the moly-99 to these two companies, A and B.

13           They don't need to provide any of that  
14 information to companies A and B. What they do,  
15 however, is they give a letter of authorization that  
16 says FDA reviewers can review this protocol that is  
17 filed away in this drug master file in support of any  
18 submissions or applications by companies A and B.

19           So it is pretty efficient. Companies A and  
20 B don't need to get me information. They just say, "We  
21 are getting it from producer C, and here is the DMF. And  
22 oh, by the way, the company has given us a letter of  
23 authorization allowing the FDA to look at this on behalf  
24 of our application."

25           And so an experience today -- when I got

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1 summoned to the National Academy here, it was actually  
2 in 2007, we were accused of possibly delaying this as  
3 much as three years. Well, it was really great when we  
4 finally looked at these and cleared them in five days.

5 So from that point on, my credibility, you  
6 know, improved. But I wasn't sure how long it was going  
7 to take. But basically DMFs, we don't approve them per  
8 se; we just say, "This looks like it's acceptable,  
9 because we don't approve the subpart of the application.  
10 We approve the entire drug application."

11 So, but we looked it over, we said this  
12 looks acceptable, and that was it. So it was a pretty  
13 benign and painless experience. Ultimately, how long  
14 it takes to review or clear some of these things really  
15 depends on the quality and the scope of the submission.

16 So where are we right now? My take as of  
17 today is we are probably 30 to 40 percent LEU globally.  
18 I think the trend -- you are seeing a number of reactors  
19 making the transition the next few years. You are  
20 seeing a lot of interest with alternative technologies  
21 or existing technologies in terms of producing moly-99,  
22 and they are all in various phases of development.

23 And the concerns -- this is sort of my  
24 negative slide. Although moly seems to be stable for  
25 2014, there are some challenges in the 2015 to 2020

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1 period. In 2015, the Belgium BR-2 reactor will be shut  
2 down for a year and a half. The intent is to refurbish  
3 it and get it back up online before the Canadian NRU  
4 shuts down. So it is a coordinated effort. But they  
5 will be out of commission for a year and a half.

6 The French reactor shuts down permanently  
7 in 2015. They are supposed to be replaced by I think  
8 the Jules Horowitz reactor sometime around 2020. Those  
9 usually don't come online when everybody predicts, so  
10 there will be some delay there. But that's not a large  
11 reactor, but it's still an ongoing site.

12 And in 2017, the reactor will still be  
13 operational -- they will be using it for other types of  
14 research -- but they will cease producing moly-99, and  
15 they have stated this, you know, publicly on several  
16 occasions.

17 But there are some positive sides as well.  
18 The production capacity has actually been increased  
19 recently, because you've seen other reactors, like  
20 Poland's MARIA and the Czech Republic's LVR-15 reactors  
21 enter the pool. So you've got more diversification.

22 The Australian reactor, which is really  
23 relatively new -- I think it went online in 2008 or  
24 2009 -- they found out that their producing capacity was  
25 limited, so they have broken ground to increase their

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1 production capacity. And I think 2017 is not the case;  
2 it may be online as soon as next year, 2016.

3 There are numerous -- and I referred to some  
4 of those earlier -- alternative both international and  
5 domestic initiatives to produce moly. And there are  
6 the countries that have never exported to the U.S., and  
7 they have mentioned they would be interested in selling  
8 to the North American market.

9 So my -- you know, people -- there is a list,  
10 so you can't say we're not concerned, but what I say is,  
11 if there are -- we can handle a single unplanned outage.  
12 But if there are multiple unplanned shutdowns, you know,  
13 you see a high risk of creating a real tight or shortage  
14 situation.

15 But the situation today is really more  
16 stable than in the past, primarily because of the  
17 addition of the European reactors and the current  
18 increase in Australian capacity. The 2015-2020 period  
19 is going to be very, very tight. There is concern in  
20 the 2016-2017 period. There is also concern quoted not  
21 only by the OECD but by an NNSA review of the program  
22 that there could be an overabundance of moly-99, if  
23 everybody who says they are going to produce in fact get  
24 online.

25 As far as FDA, we will continue to interact

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1 with the regulated industry to help them navigate what  
2 they need to do. And, you know, our primary concern is  
3 to make sure that the drug quality and the purity are  
4 maintained.

5 That's it. Any questions?

6 CHAIRMAN THOMADSEN: Thank you.  
7 Questions from the Committee? Yes, Mr. Mattmuller.

8 MEMBER MATTMULLER: Steve Mattmuller. A  
9 couple of comments, and then a question or two. You  
10 mentioned the cost -- what the original cost estimate  
11 in the 2009 NEA report was, and in the more recent one,  
12 they actually admitted that their earlier estimations  
13 of what the cost would be for the conversion of HEU  
14 targets, the LEU targets, and processing, and the  
15 additional waste, was far greater than what they  
16 actually anticipated. So that has complicated the  
17 efforts for this conversion to full LEU production of  
18 moly-99.

19 And just another comment in regards to how  
20 difficult and the length of time it takes for some of  
21 these new reactors to come online. There is a French  
22 reactor under construction right now, and it's -- the  
23 containment vessel has been capped. But they are still  
24 three or four -- no, excuse me, five or six years away  
25 before they can actually produce anything. So it's

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1 just -- from our perspective in nuclear medicine, it is  
2 incredibly frustrating to see them appear to be so close  
3 yet so far away.

4 And, likewise, even with -- there is a  
5 relatively brand-new reactor in Germany that was never  
6 originally designed for radionuclide production. It  
7 was just for testing, materials testing and such. But  
8 they have been trying to add a radionuclide production  
9 capability. And you think, gosh, if you've got  
10 neutrons, that would be easy, but it's still taking  
11 them -- their estimate is not until 2017 where they will  
12 actually be able to produce some moly-99, so it's  
13 frustrating.

14 And for those of us who used to get nervous  
15 about the three letters called the NRC, we now pay  
16 attention to something called the ORC, which is the  
17 outage reserve capacity, for when a reactor goes down.  
18 Hopefully, most of them are planned, as in the case for  
19 when the Belgium reactor goes down. But once that goes  
20 down, supply is going to be very, very, very tight. So  
21 if there is any additional unplanned outage from another  
22 reactor, it could get to be very ugly, again, like we  
23 have experienced in the past.

24 And to put -- so my first question for you.  
25 For the big Canadian reactor, 2016, is that going to be

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1 January of 2016 it shuts down or December of 2016?

2 MEMBER SULEIMAN: October.

3 MEMBER MATTMULLER: October. Okay.

4 That's 10 more months than I thought. Okay.

5 And then, from publicly available  
6 documents, I know that the NorthStar generator system  
7 has been submitted for an NDA application that you can't  
8 talk about or even acknowledge. But in my mind, that  
9 would be -- because in some sense moly-99 is easy for  
10 the FDA to look at as far as radionuclidic and  
11 radiochemical purity. We really don't care where it  
12 comes from; that's easy to incorporate into someone's  
13 manufacturing process.

14 But this is a whole new generator-type  
15 system that could take several years to review and  
16 approve. And what can I ask you that you can answer in  
17 public? So has the FDA allocated additional resources  
18 for an expedited review?

19 MEMBER SULEIMAN: Well, we don't -- when  
20 people talk about expedited review that means they have  
21 done everything right. And so recently I offered a  
22 suggestion that I think if people go through the regular  
23 process and do it right, it will get approved well in  
24 advance. So it's in the system, and that's all I can  
25 say, you know, at this point.

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1 I mean, there have been some delays, but  
2 they have broken ground. I mean, they have shared that  
3 information.

4 MEMBER MATTMULLER: Right. Right.

5 MEMBER SULEIMAN: They are actually  
6 getting their moly using the University of Missouri  
7 [Reactor]. They are using neutrons, but they are using  
8 reactor neutrons. So at one point I thought, are they  
9 using LEU? No, they are actually using the neutrons,  
10 irradiating the moly-98. Okay?

11 There are other production facilities that  
12 are going to be using their accelerator methodology to  
13 generate the neutrons to irradiate the moly-98. So  
14 they are going to get the neutrons one way, you know,  
15 or the other. And they sort of -- I think they are also  
16 talking about producing moly-99 using the moly-100 as  
17 a target material.

18 CHAIRMAN THOMADSEN: Other questions?  
19 Obviously, very clear. Thank you very much for the  
20 update.

21 And, Dr. Zanzonico, who will be talking  
22 about the ACMUI bylaws.

23 MEMBER ZANZONICO: Good afternoon,  
24 everyone. So we're going to take a little detour,  
25 hopefully brief, from some of the scientific and

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1 technical issues we have been talking about to address  
2 a rather longstanding -- surprisingly longstanding  
3 parliamentary issue, namely the revision and approval  
4 of the bylaws of the ACMUI.

5 And I don't have any slides to present on  
6 this topic, but you see being displayed some of the  
7 pertinent sections of the draft bylaws that still  
8 require attention.

9 Now, as you know, the Bylaws Subcommittee  
10 and the ACMUI overall have been working on its draft  
11 bylaws for some time now, and we -- that included holding  
12 a teleconference past this August. And it became clear  
13 at the conclusion of that August teleconference that  
14 there were two -- there are only two issues that still  
15 were not able to be finalized.

16 One of these was on possible language on  
17 extension of the two-term or eight-year limit of ACMUI  
18 members, and some language on recommendations of the  
19 ACMUI for exceptions to those limits. And there were  
20 a lot of compelling reasons that were put forth for that.  
21 For example, there may be ongoing issues being addressed  
22 by the ACMUI that could be disrupted if one of the  
23 members who is rotating off happened to rotate off in  
24 the midst of those deliberations, and so forth.

25 So that was one issue, possible language on

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1 extending or exceptions to the eight-year term limit.

2 The other was on the definition of a voting  
3 quorum. And the current language -- that is, the  
4 language in the current bylaws, indicated that  
5 decisions could be made by a majority vote of a quorum,  
6 which in turn could mean that a minority of the ACMUI  
7 membership could make a decision, and there was a  
8 general uneasiness with that fact.

9 So in the -- other than those two issues,  
10 there was general agreement on the bounds of the bylaws.

11 Now, the subcommittee, the Bylaws  
12 Subcommittee, has been working on this for a surprising  
13 amount of time and expending a surprising amount of  
14 effort via email since our August teleconference. And  
15 our current recommendations on those two points are as  
16 follows; namely, the subcommittee decided to leave the  
17 language in Section 3.1 -- can you just navigate to 3.1  
18 first? I know it's out of order. But basically, if I  
19 can read that for you, the pertinent language is that  
20 "the term of an appointment for the ACMUI is four years,  
21 and the Commission has determined that no member may  
22 serve more than two consecutive terms, eight  
23 consecutive years, unless directed otherwise by the  
24 Commission."

25 We went through a lot of alternative

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1 language, none of which was satisfactory to anyone,  
2 really. And so we decided to leave that language as is,  
3 recognizing, as we have been told both by the NRC staff  
4 and the Commission itself, that there is an open door  
5 policy.

6 So if the ACMUI as a whole, or individual  
7 members, felt there was a compelling need for an  
8 exception to the eight-year or two-term membership,  
9 that there was sufficient flexibility in just our  
10 general way of doing things to bring that to the  
11 attention of the NRC staff as well as the Commission  
12 itself.

13 So rather than trying to be overly  
14 prescriptive to the point of perhaps excluding certain  
15 contingencies, we thought it best to just leave this  
16 language as is and take the open door proclamations at  
17 their face value. So that's the first recommendation  
18 of the subcommittee, to leave this membership -- this  
19 language on membership as is.

20 The second point on a voting quorum was  
21 drafted in consultation with the Office of General  
22 Counsel, the OGC, of the ACMUI. And the new language  
23 is specifically designed to address this unease with the  
24 possibility of decisions being made by a majority of the  
25 ACMUI membership.

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1           And so the language on this point, which is  
2           highlighted in yellow on the screen is, "Decisions shall  
3           be made by a majority vote of the current ACMUI  
4           membership. Should one or more members be unavailable  
5           for compelling reasons, such as extended incapacity or  
6           recusal, the current membership shall be regarded as  
7           reduced accordingly."

8           And so that language, number one, would  
9           avoid a decision being made by a minority of the  
10          committee membership, but it would also avoid the  
11          possibility that a decision would be postponed  
12          indefinitely. Should a member be unavailable again,  
13          either because of recusal, illness, injury,  
14          imprisonment, whatever the case may be, they  
15          could -- that person would be no longer part of the  
16          current membership, the voting membership, and so a  
17          decision could subsequently be made in short order.

18          So what I would like to do is ask someone  
19          to make a motion to first -- if there is no discussion  
20          or comment, but that aside, someone make a motion to  
21          approve the recommendations on these two points  
22          specifically, assume that's approved, to then have a  
23          vote on approving the overall current version of the  
24          bylaws.

25                           CHAIRMAN THOMADSEN: And I assume that the

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1 subcommittee is making this motion.

2 MEMBER ZANZONICO: The subcommittee is  
3 making the motion. And if I didn't say it, I should say  
4 the subcommittee has unanimously approved both of these  
5 points, the language on both of these points, Section  
6 1.3.5 and Section 3.1.

7 CHAIRMAN THOMADSEN: So since that is the  
8 motion of the subcommittee, it is on the floor for  
9 discussion at the moment. Comments? Yes, Dr.  
10 Alderson?

11 MEMBER ALDERSON: I think you have done a  
12 great job, considering the controversies that were  
13 involved here. And I think that we should support these  
14 recommendations.

15 CHAIRMAN THOMADSEN: Thank you. Ms.  
16 Weil?

17 MEMBER WEIL: No, no. I was just -- I was  
18 pointing to --

19 MS. DUDES: I just -- I would just request,  
20 with all the work that has been done, that if the  
21 Committee would also consider -- and this is just an  
22 administrative change. But as I'm reading this, it has  
23 the acronym for our office, FSME, in there, and if you  
24 would also consider approving the staff member to just  
25 make a blanket change to reflect the merge that will

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1 occur next week. No wording other than any reference  
2 to FSME with that -- that would be replaced.

3 CHAIRMAN THOMADSEN: Are there any  
4 objections?

5 MEMBER ZANZONICO: That strikes me as the  
6 least controversial --

7 (Laughter)

8 CHAIRMAN THOMADSEN: Very fine. Hearing  
9 no other comments, all in favor please say aye.

10 (Chorus of ayes)

11 Those opposed say no. Any abstentions?

12 In that case, we will move on, since we have  
13 now approved -- we have accepted, and I assume endorsed,  
14 the report, we now need to, as a committee, adopt the  
15 recommendations of this committee as our bylaws. And  
16 I'll ask, are there any comments before we take a vote  
17 on that? I assume not, or there would have been  
18 comments before this.

19 All in favor say aye.

20 (Chorus of ayes)

21 Opposed say no. Thank you very much.

22 Great job.

23 (Applause)

24 Now, returning to something more  
25 substantive, also from previous meetings, we will have

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1 Dr. Howe talk about iodine patient release. Welcome,  
2 Dr. Howe.

3 DR. HOWE: Thank you. Now you can hear me  
4 with a microphone I hope.

5 CHAIRMAN THOMADSEN: Not very well.  
6 You're going to have to --

7 DR. HOWE: I'll move it closer. Is that  
8 better?

9 CHAIRMAN THOMADSEN: It's a little better.

10 DR. HOWE: Okay. Iodine patient release  
11 is a continuing issue with the NRC and with the medical  
12 community. And on April 28, 2014, the Commissioners  
13 gave us staff requirements for Commission Document  
14 COMAMM-14-001, and then the other COM from Commissioner  
15 Magwood, 14-0001, also.

16 And the title of this was Background and  
17 Proposed Direction to the NRC Staff to Verify  
18 Assumptions Made Concerning Patient Release Guidance.  
19 Now, we have brought to you several times another  
20 Commission SRM, Staff Requirements Memorandum, that  
21 dealt with: where do patients go after they are  
22 released; and do they have adequate instructions; and  
23 are they allowed to go to hotels and other public places?

24 This one is different. In this particular  
25 case -- and I'll go through what the Commission directed

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1 us to do -- is much more patient information oriented.  
2 So the Commission directed us to consider developing a  
3 website that would provide access for patients to clear  
4 and consistent patient information. So that would not  
5 necessarily be just radiation safety information, but  
6 it would be general information that patients would want  
7 to know if they are having, in this case, specifically  
8 I-131 treatments.

9 A standardized set of guidelines to provide  
10 instructions to patients, there was concern that  
11 different licensees have different levels of  
12 instructions to patients, and that causes confusion and  
13 there is no standardization. So they directed us to do  
14 that.

15 They also want us to determine whether we  
16 or a medical organization has a brochure that can be used  
17 for nationwide distribution that provides patient  
18 guidance. They also want us to determine if there is  
19 a significant -- if we need significant regulatory  
20 changes to our patient release program, and I'll go into  
21 that in a little more detail.

22 And as a part of all of this, if we do devise  
23 new guidance, if we do major changes in rulemaking, then  
24 we need to revise our Reg. Guide 8.39, which is the  
25 regulatory guide for patient release. And also, in

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1 conformance with that, our Appendix U in NUREG-1556,  
2 Volume 9, which right now is almost identical to the  
3 guidance that's in Reg Guide 8.39.

4 So what has the Commission directed us to  
5 do? First of all, they want us to get information from  
6 a wide spectrum of stakeholders -- the public, we always  
7 get public comment; patients, we are supposed to be  
8 trying to get down into the patient level; patient  
9 advocacy groups; physicians; professional societies;  
10 licensees; ACMUI members; and Agreement States.

11 For us to get that wide spectrum of  
12 stakeholder input, we are going to have to get an Office  
13 of Budget and Management clearance to be able to collect  
14 information from more than nine sources. So that is  
15 going to be a major component of what we are doing.

16 We are planning on going out to collect this  
17 information using a Federal Register Notice. And when  
18 we use a Federal Register Notice that means we also put  
19 it on our medical list server, and we try to go out to  
20 professional organizations also to maximize the  
21 exposure of what we are looking for, so we can get as  
22 much input as we can. And we are also planning on having  
23 public meetings.

24 Now, this initiative is going to take quite  
25 a while. I mentioned earlier that we have a Commission

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1 paper about where are patients going when they are  
2 released, what is the frequency, what kind of guidance  
3 are they getting. That has a contract that is  
4 associated with it, and the contract will take a number  
5 of years to collect the information.

6 And so we won't be making any final guidance  
7 changes or rulemaking decisions until we have the  
8 results of that contract, in addition to the results of  
9 the work on this -- as a result of this staff  
10 requirements memorandum.

11 So let's look at it in a little more detail.  
12 You can break these things into a general perspective.  
13 One is guidelines that licensees can use to provide  
14 instructions to patients. The Commission wanted to  
15 make it very clear that these were not supposed to be  
16 new requirements; they are voluntary. They can be  
17 adopted as best practices.

18 This is kind of an opposite direction than  
19 we normally go. We normally go to the medical community  
20 and say, "Well, what are your best practices?" and then  
21 we kind of work our regulations around those. In this  
22 case, the Commission wants us to provide more uniform  
23 guidance, and the medical community can use it. And the  
24 whole purpose is to reduce the variability and eliminate  
25 uncertainty with the information provided to patients.

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1           And as a result, as stated earlier, if we  
2           do develop new guidance, that guidance will be  
3           eventually implemented and put into Reg. Guide 8.39.

4           One of the things that it addressed is the  
5           potential for a model patient acknowledgement form that  
6           they envision as a form that is fairly simple that the  
7           patients can read and sign and also the licensees would  
8           sign. And one of the things that they are looking for  
9           in this patient acknowledgment form -- there are really  
10          three big categories.

11          One is that the patient understands the  
12          instructions as communicated. Two, that the patient  
13          acknowledges, for example, that they've gotten  
14          information on certain key topics -- an explanation of  
15          the treatment process, understanding of the need to  
16          reduce exposures to others, and how long they need to  
17          take special care.

18          And another major topic is that they work  
19          with the licensee to develop plans for their release,  
20          once they've left, how they're going to get to where  
21          they're going, the arrangements to protect others,  
22          minimize exposure, manage biological waste. Many,  
23          many trash trucks go to the dump and get turned back  
24          because there are chicken bones from an I-131 patient  
25          or some other contamination material that should have

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1       been held but wasn't.

2                   And the patient knows what to do if they  
3       need emergent care, emergency care, and who they contact  
4       if they have any questions.  So these are all basic  
5       concepts, but they are not necessarily radiation -- some  
6       are radiation safety, some are not.

7                   In asking us to develop a website, what they  
8       really want us to do is if somebody else has got a good  
9       website, has this information already, that we can use  
10      our NRC website to link to that information, so that we  
11      don't have to start from scratch.  But if there are some  
12      things that we don't find that we've got good websites  
13      for, then we'll have to develop the content.

14                  The website is going to have basic  
15      components, which radioactive iodine, that's something  
16      NRC can probably address easily.  The radioactive  
17      iodine treatment -- this is more medical, so we would  
18      not expect NRC to be developing this information but  
19      going out to other sites to find it.  And that's, how  
20      do you prepare for the treatment, what to expect before  
21      and after receiving, and what side effects.

22                  Basic radiation safety -- we have a pretty  
23      good handle on most of this.  This is the precautions  
24      to take after receiving a treatment, the risk to others,  
25      the appropriate statements regarding risks to young

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1 children and pregnant women.

2 And probably the most controversial thing  
3 that they have asked us to do is make a determination  
4 of whether we need significant regulatory changes to the  
5 patient release program, and to see if they are  
6 warranted for an activity-based patient release  
7 threshold under which patients could be required to be  
8 maintained in a currently sponsored facility. We  
9 didn't say "hospitalized"; we just said may be held for  
10 a period of time, and it could be minutes, hours, before  
11 their release. And to clarify whether the current dose  
12 limits in 35.75 apply to each individual administration  
13 or they apply on a yearly basis.

14 NRC believes it knows that it -- the answer  
15 to this question. The ACMUI does not agree with the  
16 NRC.

17 They want to see if we need regulatory  
18 changes for the current patient release standard. The  
19 current patient release standard in 35.75 says that you  
20 can release patients as long as the maximally exposed  
21 person does not exceed 500 millirem. That is higher  
22 than the public dose limit in Part 20. And Part 20  
23 currently says that Part 20 does not apply to doses  
24 received from patients. So the question is whether  
25 that limit should be reduced to the Part 20 public dose

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1 limit or not.

2 And also, whether we need to develop  
3 specific requirements for releasing patients that are  
4 going to be in contact with young children or pregnant  
5 women, and whether those limits need to be above the  
6 current Part 20 dose limit, which is the current 500,  
7 or whether they need to be dropped down to the Part 20.

8 So those are questions that we are going to  
9 be asking out in the public forum as we develop a  
10 Commission paper that recommends either that we go  
11 forward with a major rulemaking or we not go forward with  
12 a major rulemaking.

13 How long do we think that it will take to  
14 respond to this staff requirements memorandum? We have  
15 actually got timelines out that go -- certain items are  
16 going to be out in 2015. Those are the easier ones that  
17 we can address -- whether there is a brochure out there,  
18 whether we can come up with a website, whether we can  
19 standardize guidance. But some are going to be out in  
20 2019, and that's because we've got to wait for the  
21 information to come back from the other staff  
22 requirements memorandum and the contract.

23 So, what are we going to do for a path  
24 forward? We're going to have extensive outreach on  
25 U.S. and international practices. That was another

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1 question that came up in a slightly different Commission  
2 briefing, and so we are going to find out, what is really  
3 going on in the international practices, how do we match  
4 up with it.

5 We have started some preliminary work on  
6 that. We are also going to have extensive outreach to  
7 professional societies, patient groups, and the medical  
8 community as a whole. And that is -- we are intending  
9 to go out with our Federal Register Notice to ask for  
10 a lot of input on the questions on guidance, on websites,  
11 and the basic information that we can collect.

12 And then we will also have public meetings  
13 to go out on -- whether we should go forward with  
14 proposed rulemaking and the issues that we are going to  
15 be looking at to see if we need to address.

16 In the short term, we are developing -- or  
17 going to develop a Federal Register Notice to solicit  
18 patient-focused information from all stakeholders.  
19 But before we can send out a Federal Register request  
20 for information, we have to develop an OMB clearance to  
21 have the ability to get that information, collect that  
22 information. And then we are also going to be looking  
23 to the ACMUI for assistance in all levels of this effort.

24 So that's what we are thinking of. We've  
25 got a timeline out to about 2019. And if we go to

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1 rulemaking, the rulemaking probably wouldn't happen  
2 until our basic 2023 rule.

3 So do I have any comments or questions from  
4 the ACMUI?

5 CHAIRMAN THOMADSEN: Thank you, Dr. Howe.  
6 I think we do. Dr. Langhorst?

7 MEMBER LANGHORST: Thank you. Dr. Howe,  
8 the direction of the Commission referred to iodine  
9 patient release or all patient release?

10 DR. HOWE: Most of the specific  
11 information that they are looking for -- is I-131  
12 related. But they also asked us when we revised the  
13 guidance for 8.39 or NUREG-1556, that guidance has to  
14 be more general in global and --

15 MEMBER LANGHORST: Right.

16 DR. HOWE: -- encompass all patients.

17 MEMBER LANGHORST: Because 10 CFR 35.75 is  
18 not limited to just iodine patient release.

19 DR. HOWE: No. But right now they are  
20 focusing, because they've had more experience, they've  
21 been out to the thyroid patient conferences, and so they  
22 are focusing more on I-131. That is our largest group  
23 of patients with patient release issues.

24 MEMBER LANGHORST: Right. Right. And I  
25 have just one comment, and this is a comment that I

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1 have -- I have made to NRC staff in the past. There are  
2 two locations currently for patient release guidance,  
3 and that's the Regulatory Guide 8.39 and this Appendix  
4 U and 1556 Volume 9.

5 And I love the 1556 series. As an RSO who  
6 has to write license applications, they have been  
7 fabulous in my opinion. However, I think I was asked  
8 a few years back about whether Reg. Guide 8.39 should  
9 then just be rewritten to reference Appendix U. I  
10 recommended that it not, because I think the general  
11 public would not know to look for the 1556 guidance  
12 documents and would be lost in the amount of information  
13 that is there.

14 I think that it would be better to have one  
15 guidance document, and that should reside in the 8.39  
16 guidance document with the Appendix U referencing it,  
17 because I think those who use that 1556 are much more  
18 knowledgeable and know where to find the regulatory  
19 guides, whereas the general public I think could find  
20 the regulatory guide a lot easier. So I just wanted to  
21 make that recommendation again from my own personal  
22 opinion.

23 DR. HOWE: And our intent is to maintain  
24 Reg. Guide 8.39 as the patient release. There are a  
25 number of things that go into developing 8.39 that

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1 is -- and 8.39 is -- our NRC Office of Research is  
2 responsible for it, and it has the ability to do  
3 contracts and other needs of updating the information  
4 out there that our local medical team doesn't have the  
5 resources for. So NRC's intent is to keep 8.39 as our  
6 document.

7 Having said that, we are in the process of  
8 revising NUREG-1556. We have gone out with some risks  
9 that provide guidance on patient release -- hotels and  
10 infants and pregnant women. And that information may  
11 be incorporated into 1556 before we get to our final  
12 revision of 8.39. So there may be a period of time in  
13 which 1556 is a little more up to date on guidance,  
14 because it is incorporating things that we have already  
15 said, but we will be catching up with 8.39 for the really  
16 technical stuff.

17 MEMBER LANGHORST: Thank you.

18 CHAIRMAN THOMADSEN: Yes. Mr. Costello?

19 MEMBER COSTELLO: Dr. Howe --

20 DR. HOWE: Yes.

21 MEMBER COSTELLO: -- in anticipation for  
22 this meeting, I sent an email out to all of the Agreement  
23 States of what our agenda was going to be, and the  
24 topics, and the only topic I got any comments on was this  
25 one, and not surprisingly.

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1           And I think the States in general are not  
2           looking for changes in the basic rule. I think people  
3           have accepted that. However, there are two points  
4           that I think the States want to make. One is -- and you  
5           already talked about both of them already -- patient  
6           instruction. And the issue with patient instruction  
7           that they want help on is how to handle their waste, and  
8           you have that up there.

9           The States spend, including Pennsylvania,  
10          in fact maybe more in Pennsylvania than any other State,  
11          an incredible amount of time following up on alarms at  
12          transfer stations and landfills. We probably average,  
13          just in eastern Pennsylvania alone, maybe one a day  
14          during the working week, every day. Philadelphia has  
15          a lot of big medical institutions, constantly.

16          In addition to that, we have also had a  
17          phone call from the mother of a thyroid cancer patient  
18          whose waste hauling company is threatening to fine her  
19          thousands of dollars if their waste set off any alarms  
20          at the landfill, because in this county the landfill is  
21          not permitted to receive any -- any radioactive  
22          materials.

23                         DR. HOWE: That's not unusual.

24                         MEMBER COSTELLO: And that the hauling  
25          company, when this happens, they are threatened with

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1 fines by the landfill. They plan to pass these along  
2 to the patient.

3 Now, the woman who called our office says,  
4 you know, "I've got this daughter who has got thyroid  
5 cancer, and now I'm being threatened with fines." And  
6 she was complaining that she didn't receive sufficient  
7 guidance from the medical institution that sent her  
8 home.

9 Well, calling a regulatory agency like us,  
10 there is not much in the way of relief that we can give  
11 them. We have, in some cases, given all the relief that  
12 we can give, that this waste can be disposed of as normal  
13 waste and there is no safety or regulatory reason  
14 whatsoever that it can't be sent to a landfill.

15 But these landfills oftentimes -- and the  
16 hauling companies are private corporations, private  
17 companies, and they -- I mean, we contact them, but they  
18 don't have to do what we tell them to do. They don't  
19 have to accept the waste if they don't want to.

20 Now, this particular issue was resolved.  
21 They worked it out that they would notify the waste  
22 hauling company in advance, and they will then make a  
23 special run to pick up their waste from this residence  
24 and hold it for decay for a while, and then send it off.

25 So, basically, what we'd like is when we do

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1 have these instructions, that they explicitly help the  
2 patients, so this doesn't happen to them, and help maybe  
3 the States so we can do, like, real radiation safety  
4 things instead of responding to an incredible number of  
5 alarms.

6 Pennsylvania has got alarms everywhere,  
7 okay? I think, you know, Pennsylvania has alarms at the  
8 transfer stations, we've got alarms at the landfills.  
9 We're a state of alarms, right?

10 So we hear about these all the time. I'm  
11 sure other States hear about them, and I'm sure you hear  
12 this from other States. But we would like the guidance  
13 to be comfortable for the patient. We don't want to  
14 hear about patients being threatened with fines for  
15 doing nothing wrong, and these are cancer patients.  
16 Okay?

17 The second issue, and you've touched on  
18 this as well, is that doses of 100 millirem versus 500  
19 millirem -- question as to what should the dose be to  
20 family members when these patients are sent home. And  
21 I have not heard from a large number of States -- a  
22 few -- but I think the ones that I have heard from, they  
23 would urge 100 millirem, because 100 millirem is a safe  
24 dose for members of the public in other circumstances.  
25 Why wouldn't it be a safe dose in this circumstance?

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1                   Now, I went back and read the statement of  
2                   consideration when the rule was changed back whenever  
3                   that was --

4                   DR. HOWE:    2007.

5                   MEMBER COSTELLO:   -- but -- and they  
6                   explained that, that the 500 millirem will be for an  
7                   occasional situation, whereas the 100 millirem public  
8                   dose limit is something they would expect to be repeated  
9                   over and over again.   And I understand that.   I'll send  
10                  you a link.   It may have been earlier than 2007.

11                  DR. HOWE:    That doesn't sound familiar  
12                  from the patient relations side of it.

13                  MEMBER COSTELLO:   But I think of the States  
14                  that I talked to; I think they would understand the  
15                  rationale better for larger millirem rather than 500  
16                  millirem.   Okay?

17                  Now, the third issue that I hear from the  
18                  State -- my own State -- and which I don't know if you  
19                  can do very much about -- I hope this will call it to  
20                  your attention -- is that EPA has very, very low  
21                  standards I-131 drinking water, because they have very  
22                  low dose standards for dose to the public from that  
23                  pathway.

24                  Well, there is a creek -- there is a very  
25                  small creek.   We have a place that draws from the water

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1 from there, and sometimes we have -- EPA has made  
2 measurements which exceed this level of I-131. Okay.  
3 And we've talked about this.

4 I don't think that the patient release rule  
5 actually affects this, because patients are going to be,  
6 you know, releasing their I-131 going into the sanitary  
7 sewer, whether they're doing this in the hospital or  
8 whether they're doing this at home or whether they're  
9 doing this in a hotel. I'm just saying this is a  
10 pathway. I don't know actually if it has been looked  
11 at. And it is a pathway for population dose from this  
12 treatment.

13 So I was asked to call this to your  
14 attention, and so I have.

15 So none of this -- you've got, you know,  
16 pathways that go to 2019, so you have plenty of time to  
17 work on these.

18 DR. HOWE: Yes. And we really are looking  
19 forward to getting comments from the States that are  
20 specific to the things that they are interested in. And  
21 Laura Weil brought up a number of the points in the ACMUI  
22 discussion with the Commission, and we think the general  
23 philosophy is patients want to do the right thing.  
24 They -- we need to make sure they know how to do the right  
25 thing, and the medical licensees need to make sure they

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1 know how to do the right thing. So I think this is more  
2 of a reinforcement of that concept.

3 And I-131 released to the environment,  
4 everyone assumes dilution of the solution, but every  
5 once in a while you end up with re-concentration.

6 MEMBER COSTELLO: And so, also, I think  
7 EPA's limit is unreasonable. You know, they are  
8 talking about it's either three or four millirem in a  
9 year, which is, you know, not a significant dose. But  
10 they have their rules, and we have ours.

11 DR. HOWE: Yes. And I think most -- I  
12 mean, the guidance I have seen so far is we've got -- the  
13 patients are told to hold onto their trash for a period  
14 of time before they put it out on the street, whether  
15 they're doing that or not, and that's causing additional  
16 alarms.

17 But you never want them to stop looking at  
18 alarms because every once in a while that is really  
19 something important.

20 MEMBER COSTELLO: Yes.

21 DR. HOWE: Although the I-131s and the  
22 technetium dye, there is no substantial --

23 MEMBER COSTELLO: We approve all requests,  
24 all requests, when the I-131 is identified. If they  
25 find cesium-137, it might be different.

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1 DR. HOWE: Right.

2 CHAIRMAN THOMADSEN: Dr. Welsh?

3 MEMBER WELSH: Being a member of that  
4 Patient Release Subcommittee, I have a number of  
5 comments. First, regarding the Commission direction  
6 to create a model patient acknowledgement form,  
7 initially I was thinking that, well, maybe I'm not in  
8 favor of that, because it sounds like it could be an  
9 encroachment upon medical judgment.

10 However, after you explained it, I'm not  
11 convinced of my counterargument -- that I would be in  
12 favor of this, particularly because I hear over and over  
13 again that patients weren't told this or they  
14 misunderstood something and this is what happened with  
15 the trash, for example.

16 And I know that all patients have to sign  
17 a consent. Maybe if that consent was standardized and  
18 produced by the Federal Government or endorsed by the  
19 NRC, and the language is crisp and clear and everybody  
20 can see it, this controversy about, "Well, I was never  
21 told this" might go away. However, the possibility is  
22 that Agreement States might not follow this particular  
23 recommendation.

24 So that's one thing that I would make a  
25 comment on, and I'm in favor of the patient

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1 acknowledgement form.

2 But other points are extremely  
3 controversial, and one root cause of the controversy is  
4 the adherence in this country and many other countries  
5 on the little or no threshold hypothesis, which I think  
6 I've said many times at this -- in this venue I'm not  
7 a big fan of, because it's not supported by the science.  
8 However, it leads to tremendous consequences, and those  
9 consequences can be quite severe.

10 And people tend to underestimate the  
11 severity of these consequences. The radiophobia that  
12 the general public has is actually quite alarming and  
13 quite concerning and detrimental, I think, to the  
14 welfare of the general public. For instance, when  
15 we're talking about, should it be 100 or 500 millirem,  
16 both of them are below the annual exposure from natural  
17 background radiation depending on where in the world you  
18 live.

19 So if it's okay to live in the Rocky  
20 Mountains or if it's okay to live in parts of India or  
21 Iran, why shouldn't it be okay to receive exposure from  
22 a radioisotope in New York City, for instance. The  
23 health consequences are unlikely to be very different.

24 Therefore, when the NRC goes forward with  
25 all of this, I might recommend that when you -- I think

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1       you said you might explore international standards and  
2       possibly attempt to match them, I would caution -- maybe  
3       I misinterpreted the words, but I would say do not -- I  
4       would advise not trying to match international  
5       standards, because some of these other countries are  
6       even more radiophobic than the United States. And the  
7       consequence of this general international radiophobia  
8       is perhaps in the best interest of patients and the  
9       medical care that we would like to give to patients.

10                So those are my general comments.

11                DR. HOWE:       And we've gotten some  
12       preliminary information. We wanted to go directly to  
13       the countries and ask them what their standards were and  
14       what their release practices were, and most of them are  
15       much more conservative than the U.S., and most of them  
16       have -- some of them have implemented release standards  
17       after our 1997 rule, but they are still more  
18       conservative than what we have. We seem to be the least  
19       conservative of any of the groups.

20                So I don't think the staff's intent is to  
21       go and match the international, but we -- the Commission  
22       has directed us to see how we fit in with the  
23       international community.

24                MEMBER WELSH:   So I guess my point there is  
25       that, although the other countries are more

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1 conservative, perhaps they are not correct. And for us  
2 to get in line with the international community might  
3 be a move in the wrong direction. And I would say that  
4 the NRC is quite smart, and the United States generally  
5 is an intelligent country and can probably make its own  
6 decisions. And I would caution against getting in line  
7 with the conservative international opinions on this  
8 particular issue.

9 DR. HOWE: Thank you. Point well taken.

10 CHAIRMAN THOMADSEN: Mr. Fuller?

11 MR. FULLER: And I think I can respond to  
12 that, too, just to kind of give some perspective. At  
13 this point in time, we have been instructed to collect  
14 information and to look at things. This would  
15 definitely require a change in the rule. And before a  
16 rule would be changed, we would go through that long  
17 process I was referring to this morning.

18 It is a very deliberate process with a lot  
19 of public interaction, and so -- and, you know, the risk  
20 associated with the various limits for dose to members  
21 of the public, all of that would have to be deliberated  
22 on in several different venues. So it would not be  
23 something that the staff could just say, "Well, this is  
24 what we are going to do." So, but we do appreciate that  
25 perspective.

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1 CHAIRMAN THOMADSEN: Thank you. Dr.  
2 Suleiman?

3 MEMBER SULEIMAN: I'm not 100 percent  
4 comfortable with my memory, but I was involved with an  
5 IAEA document leading up to the basic safety standards,  
6 involved with surveying the different countries. And  
7 as I recall, they're all over the place. I didn't  
8 perceive that we were the most conservative, and I found  
9 it a surprising inconsistency. I mean, so I would -- I  
10 would reinvestigate that and be more careful.

11 We were surprised at the range of  
12 recommendations. The two things that sort of stuck in  
13 my mind was in Germany they hold urine. They don't dump  
14 it down the sewer. And as I recall, everybody -- they  
15 tried to figure out why. That was considered a much  
16 higher risk, because you are concentrating all of this  
17 radioactivity. And numerous studies have shown that  
18 with the decay and dumping it in the sewer system it was  
19 really the safest, you know, way.

20 And we could never find out why the Germans  
21 did it this way, except that once they had adopted it,  
22 and the local building codes had adopted it, they were  
23 doing it a standard way, and by God they were not going  
24 to change it. So, except for that German practice of  
25 collecting all the urine, so you had a hotspot in the

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1 hospital when you walked by those tanks --

2 DR. HOWE: I think we found more than one  
3 country that holds the waste in holding tanks and then  
4 releases it later after decay. So we are seeing that  
5 variability in the information we are getting back.  
6 The one good thing about the European Union and some of  
7 the other countries in Europe that are kind of going  
8 together is they are adopting more standardized  
9 guidance and regulations on what they're doing.

10 So we are not having to see -- when we go  
11 to France, Germany, Belgium, The Netherlands, we are not  
12 seeing as -- we are seeing -- we agree with HERCA, or  
13 we agree with some other IAEA document. So we are  
14 seeing a consistency among some of the countries. They  
15 are much more conservative than we are.

16 CHAIRMAN THOMADSEN: Yes, Dr. Zanzonico?

17 MEMBER ZANZONICO: I just want to make a  
18 couple of points. First, I think there is a lot to  
19 criticize in the Commission directions. I mean, it's,  
20 frankly, based on a political reaction and not very much  
21 on science. So I just wanted to say that.

22 The other issue is I am really troubled by  
23 the possibility of an NRC website. That strikes me as  
24 a regulator interposing itself between the physician  
25 and the patient. I can see providing information,

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1 resources, and so forth to hospitals, to physicians.  
2 But as I say, I'm really troubled by the possibility of  
3 a regulator communicating directly to patients and, in  
4 effect, bypassing the caregiver.

5 So those are just the points I wanted to  
6 make.

7 DR. HOWE: And that's certainly an area  
8 that we are not in today, but it is an area that our  
9 Commission is asking us to look at. And I think they  
10 see it more as a reference document.

11 MEMBER ZANZONICO: But I think the NRC,  
12 being a federal regulator, and having their logo on the  
13 website, it is not as innocent as it sounds. It is going  
14 to be interpreted --

15 DR. HOWE: Totally understand.

16 MEMBER ZANZONICO: -- by individual  
17 patients as the final word, and they are going to go back  
18 to their patient -- to their physicians and say, "What  
19 you told me was wrong, because the NRC on their website  
20 says XYZ." I think it's just a bad idea and a bad  
21 precedent.

22 DR. HOWE: And one of our -- if we do go  
23 ahead with the website, one of our intents is to put  
24 links to more medically oriented websites that do  
25 provide more patient-oriented information. We don't

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1 want to develop the content ourselves, because that is  
2 not our level of expertise.

3 MEMBER ZANZONICO: I should say, having  
4 said that, I agree completely that the instructions are  
5 very non-uniform and very poor in many respects, and  
6 very poorly communicated. My problem is not with the  
7 concept of a standardized set of recommendations and  
8 safety precautions. My problem is with that  
9 originating with the NRC, with the regulator, and being  
10 communicated directly to patients.

11 CHAIRMAN THOMADSEN: Dr. Guiberteau?

12 VICE CHAIRMAN GUIBERTEAU: I have the same  
13 concerns as were just expressed. I do think  
14 understanding how government agencies, whether they be  
15 State or Federal, have a reluctance to basically appear  
16 to endorse any sorts of documents from links, that this  
17 would have to be handled very carefully.

18 But I do like that idea, and it might be part  
19 of the work of this Committee to induce a consortium of  
20 those professional societies involved in this, such as  
21 the Endocrine Society, the Society of Nuclear Medicine,  
22 the ACR, et cetera, to work on a -- you know, a set of,  
23 say, minimum safety precautions, or however you wish to  
24 word it, so that you would sort of be working from the  
25 back side in, because I think if you have a whole list

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1 of these listed there, I mean, someone could say, "Well,  
2 it was recommended" -- and they will, they will say, "It  
3 was recommended on your website, and I just happened to  
4 hit the wrong one, because if I had done this one, then,  
5 you know, I would have been better off about controlling  
6 my waste."

7 But I think that's something that we have  
8 talked about here, and we haven't really -- if you are  
9 going to outreach in the communities, and this would be  
10 the perfect community -- this would be the perfect  
11 Committee to do that.

12 Second of all, if you don't mind, I have  
13 some questions, but I don't want to conflate them. So  
14 the second -- my second question is on this model patient  
15 acknowledgement form. I presume -- it says model form  
16 read and signed. I presume that you mean a model for  
17 patient acknowledgement that this -- these would be  
18 elements that would be in your form.

19 But, for instance, at our institution we  
20 are very conservative, so we might want a form that was  
21 even more conservative than what this model would be.  
22 But I presume by "model" it is something that would be  
23 used but not mandatory. Is that correct, or is that not  
24 the intent here?

25 DR. HOWE: The Commission's intent is not

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1 to have this be a required form, but a model form that  
2 people could pick up and use. We are having a  
3 difficult -- and we will have a difficult balancing act.  
4 Our previous process has been to be more  
5 performance-based. The guidance we are getting in this  
6 particular staff requirements memorandum is more  
7 prescriptive.

8 And in the end, how do we balance that  
9 performance-based with the prescriptive? In other  
10 words, if it were performance-based, we might say, "It  
11 would be beneficial to have a form patients could sign,"  
12 and just list the bullets. Have you talked about these  
13 elements with the patient and the patient talked about  
14 these elements with the physician? And they would be  
15 in very general global terms, but we may be directed to  
16 be more specific than that, and I don't know. But we  
17 are going to be working that balance.

18 VICE CHAIRMAN GUIBERTEAU: One of the  
19 things in my career has been the decidedly beneficial  
20 movement of regulations nationwide, but particularly  
21 with the NRC, from moving from being too prescriptive  
22 to being performance-based. So I would hope there  
23 would be a balance here. And I do understand sometimes  
24 that prescription is needed, but I do think that just  
25 what I hear from all of my colleagues that this is

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1 something everyone appreciates. So I would hate to  
2 see -- I would hate to see a movement back in the other  
3 direction.

4 My final question is here on your path  
5 forward, because it says short term, and for any  
6 government agency short term is usually longer than one  
7 would like. But in terms of what do you mean by short  
8 term, particularly with respect to a Federal Register  
9 Notice soliciting patient-focused information from all  
10 stakeholders, and what does that mean, patient-focused  
11 information?

12 DR. HOWE: Well, if you went back and  
13 looked at some of the earlier slides, that I have a  
14 standardized set of guidelines. We are looking for,  
15 what do people have now? What do the medical facilities  
16 have now for guidelines? And we'll look at those and  
17 see what looks really good, and some things may not look  
18 quite as good and they standardize and make that. So  
19 that is the kind of information we are going to be  
20 looking for.

21 We are also going to be looking to see if  
22 people have other things that they think ought to be part  
23 of that dialogue between the patient and the physician  
24 for a patient acknowledgement form. And we will also  
25 be looking for, you know, the things that are discussed

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1 and our website information.

2 So we are trying to collect a lot of  
3 information that we could be using for the general  
4 guidelines, and we could be using for the website, and  
5 we could be using for developing the model standard  
6 patient form. And that's what that Federal Register  
7 Notice is. It's to collect a lot of information from  
8 patients, physicians, facilities, Agreement States,  
9 societies, so that we have a very broad perspective of  
10 what the community wants and what the community has  
11 available to it.

12 VICE CHAIRMAN GUIBERTEAU: And this begs  
13 the question, once all of this -- and this will be a lot  
14 of information --

15 DR. HOWE: It will be a lot of information.

16 VICE CHAIRMAN GUIBERTEAU: -- and it will  
17 be large bell curve, that -- who will be the arbiter of  
18 what is the proper -- you know, what is the proper level  
19 for -- and position for the NRC to take? Would that be  
20 part of this Committee's duty?

21 DR. HOWE: Certainly, this Committee would  
22 be a big part of that. Sometimes it is very easy. We  
23 go out for public information, and we get formal  
24 letters. Okay. Five thousand people said this.  
25 Okay. We don't have one document we've got to read.

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1 Other times we get little variations and we have to meld  
2 it all together. That's what we normally do.

3 But we will be coming back to you with  
4 guidance, and I'm hoping I'm going to get some  
5 assistance from the ACMUI.

6 VICE CHAIRMAN GUIBERTEAU: And so that we  
7 will be forewarned, when do you anticipate such a call  
8 for information?

9 MR. FULLER: I'm sorry to interrupt. Just  
10 to clarify, because we had an earlier discussion.  
11 There is actually two things. Very, very early on when  
12 Dr. Howe starts working on drafting this Federal  
13 Register Notice, we are going to -- we are seeking some  
14 volunteers, if you will, not the whole subcommittee, to  
15 get back and forth and go through that formal process.  
16 But just some folks on the Committee who could review  
17 and work with Donna-Beth and make sure that we are  
18 getting the right message in this Federal Register  
19 Notice and also that we are focused on the right  
20 audience.

21 So some early involvement with some key  
22 folks from the ACMUI would be very, very helpful to us  
23 as we develop this. But certainly anything that we then  
24 draft or work on or get to some point where it's ready  
25 for review, that will definitely be coming right back

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1 to this Committee.

2 And we have the timeframes worked into the  
3 time -- that's another reason why it seems like we should  
4 do things quickly, but it takes a year or more. We have  
5 built in those timeframes where we know that the ACMUI  
6 and the agreements, probably subsequent to that, would  
7 have an opportunity to look at these drafts, tell us if  
8 we are headed in the right direction or if we are way  
9 off course, or what have you, and so this body, through  
10 the Patient Release Subcommittee and other ways, will  
11 have its normal opportunity to work with us and help us  
12 get it right.

13 VICE CHAIRMAN GUIBERTEAU: So those are  
14 very welcome comments. Thank you.

15 CHAIRMAN THOMADSEN: Ms. Weil?

16 MEMBER WEIL: I'd like to comment on Dr.  
17 Zanzonico's concern about the NRC as a regulator  
18 interposing itself between patient and clinical team.  
19 And I think we need to twist that a little bit, because  
20 what is being proposed really doesn't affect treatment  
21 and treatment decisions. It -- what is being proposed  
22 will protect the public health, non-patients, family  
23 members, the general public, from radiation exposure.

24 So it is not really sticking its nose into  
25 the clinical decision-making. It is after the

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1 treatment is completed, how do we protect the public  
2 health?

3 CHAIRMAN THOMADSEN: Dr. Dilsizian?

4 MEMBER DILSIZIAN: It's just -- this  
5 discussion reminds me of inappropriate use of a lot of  
6 procedures when society has had to take charge rather  
7 than regulators of creating appropriate use criteria.

8 And I think this falls into the same  
9 category for me. I think that we have several societies  
10 here represented, a lot of members. I think that the  
11 societies already have some of these guidelines on their  
12 website. What we need to do is come together and  
13 propose our societal guidelines to the NRC, so that it  
14 will be from us to the regulators instead of from the  
15 regulators to us.

16 DR. HOWE: And part of our going out for  
17 information is asking what you have out there that is  
18 available. We don't want to reinvent the wheel.

19 CHAIRMAN THOMADSEN: Mr. Mattmuller?

20 MEMBER MATTMULLER: In regards to the  
21 website, I am almost embarrassed to say that I caught  
22 this, but in the -- what is it called? A COMWDM, which  
23 is some sort of MO from the Commission -- when they talk  
24 about the website, they say develop a joint website or  
25 a link with relevant medical organization and patient

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1 advocacy links.

2 But then, when Mr. Satorius describes the  
3 website, he leaves out the word "joint." So I think  
4 that would allay a lot of Dr. Zanzonico's concerns and  
5 other concerns that we all have that it will be a joint  
6 website. It's not going to be a pure NRC website.

7 DR. HOWE: What this website looks like at  
8 this time is premature. Clearly, it has to be something  
9 that melds with our regulations, and so we will need some  
10 degree of control to make sure that what is out there  
11 does agree with our regulations. But most of the stuff  
12 that we're being asked to bring together for this  
13 website is beyond our regulations. It's medical  
14 treatment and other things, and we won't really be  
15 looking at that part.

16 So we are hoping to work in partnership with  
17 a number of groups, individuals, et cetera. We aren't  
18 excluding that at all.

19 MEMBER MATTMULLER: Well, I guess at  
20 some -- from a regulatory walk perspective, that the  
21 Commissioners said it must be joint, but the -- Mr.  
22 Satorius says it doesn't have to be joint. So --

23 DR. HOWE: And Mr. Satorius' memo is the  
24 memo that brings together -- the Commission had a paper,  
25 and all of the Commissioners looked at it. Two of the

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1 Commissioners sponsored it. All of the Commissioners  
2 looked at it, and they provided comments. And when all  
3 of their comments were melded together, that was put in  
4 the form of a staff requirements memo.

5 So that is still coming from the  
6 Commission, but it is sent to us through SECY and  
7 Satorius. So it does represent the Commission view,  
8 but after the initial paper was written. So it's a more  
9 consolidation of all five Commissioners on what they  
10 want the staff to do.

11 MR. FULLER: I think the key -- if I may,  
12 I think the key here is that we -- the staff feel very  
13 confident that we are clear that we are not to do this  
14 by ourselves, that we are to do this with as much help,  
15 if you will, and appropriate participation.

16 You know, a number of us, I know over the  
17 years have seen the presentations in various venues  
18 about the Image Wisely campaigns and the Image Gently  
19 campaigns. And if we could model similar type efforts,  
20 if we could model this after similar type efforts and  
21 with similar type of organization, and so forth, we  
22 think that is probably -- or something akin to that would  
23 be sort of the ideal situation.

24 CHAIRMAN THOMADSEN: Dr. Alderson? Yes.  
25 You. You're the Dr. Alderson I'm calling on. Yes.

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1                   MEMBER ALDERSON: Thank you very much. So  
2 the thing that -- a well-intentioned proposal,  
3 unfortunately, my concern is that there is enormous  
4 potential for misunderstanding as you pull all of this  
5 together. And in the ability of -- and I'm not being  
6 pejorative about the general public, but the ability of  
7 the general public to correctly understand these kinds  
8 of issues is, you know, appropriately limited because  
9 they haven't been educated in any of these issues. And  
10 the fear potential that is associated with radiation is  
11 well known to everybody.

12                   So it seems to me that the real challenge  
13 here -- and this will seem axiomatic initially, but I'll  
14 expand on it -- is to do it right. And if you can really  
15 do it right, that would be great, but I think that is  
16 going to cost a lot of money. I think to really do it  
17 right you have to really get a lot of groups together,  
18 not just medical organizations but groups that are  
19 sophisticated in how they market and project to the  
20 public. And it would cost a lot of money.

21                   I don't know anything about the  
22 appropriations side of the NRC or how that happens, but  
23 I think this -- to do it right is going to cost a lot  
24 of money. I just hope that somebody is really committed  
25 to doing this right, because I think if you don't, it

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1 could go wrong.

2 DR. HOWE: Point well taken.

3 CHAIRMAN THOMADSEN: Yes. Thank you for  
4 that comment. Ms. Fairobent?

5 MS. FAIROBENT: Thank you, Dr. Thomadsen.  
6 Lynne Fairobent with AAPM. Dr. Guiberteau, just to  
7 follow up on your point and perhaps let you know what  
8 staff has been doing from the association standpoint.  
9 Society of Nuclear Medicine and Molecular Imaging has  
10 convened a group of medical association staff who have  
11 already had an initial phone call, taking a look and  
12 talking about a strategy going -- collective strategy  
13 going forward from the medical side.

14 So we will be looking at this issue  
15 collectively and coming forward with some unified  
16 recommendations.

17 DR. HOWE: And we look forward to that.

18 CHAIRMAN THOMADSEN: What was that?

19 DR. HOWE: And we look forward to that.

20 CHAIRMAN THOMADSEN: Thank you. Thank  
21 you both. Other comments from the Committee? Yes, Mr.  
22 Mattmuller?

23 MEMBER MATTMULLER: Steve Mattmuller. I  
24 was inspired by your radioactive chicken bones comment.  
25 Is there any talk of providing some guidance to poor

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1 individuals, such as Mr. Costello, and the States, that  
2 when these landfills find a minute amount of I-131 in  
3 their trash, that they just -- it's below -- be  
4 classified below regulatory concern and they can dump  
5 it and not save it and call out the teams to measure it  
6 to say yes?

7 I mean, because it's my understanding these  
8 sites that had the sophisticated detector system can  
9 also have handheld multi-channel analyzers, so they can  
10 readily identify it right there on the spot.

11 DR. HOWE: One of the big issues is we don't  
12 regulate them. They handle non-radioactive material,  
13 and many localities, when they put in a landfill, they  
14 say, "Okay. We'll accept the landfill if it has no  
15 radioactive material, no bio-hazardous waste," and they  
16 list all the things that they don't want, and they put  
17 the level at zero. And then we don't regulate them.

18 And, in many cases, they get detectors  
19 because they are trying to comply with their local  
20 standards. But it's difficult for us to reach them.  
21 It's easier for Mr. Costello to reach them in his state  
22 because he is also part of the State regulatory --

23 CHAIRMAN THOMADSEN: Mr. Costello?

24 MEMBER COSTELLO: Yes. Some of these  
25 places have incinerators, and sometimes the public, you

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1 know, prefer this stuff not be incinerated even though  
2 the dose to them is zero basically. Even with  
3 non-spatial assumptions, it's still zero.

4 We get phone -- we get requests coming in  
5 where they're measuring 20 microR per hour or 10 microR  
6 per hour background and asking us approval to send them.  
7 I mean, it would have to be more than trivial. But  
8 because of the situation we spend an inordinate  
9 amount -- not just in Pennsylvania, but many States  
10 spend a lot of time on this.

11 And they would find that if the patients  
12 were instructed such that this wasn't happening that  
13 would be a good thing, because I know in Pennsylvania  
14 when they chased down this one individual whose daughter  
15 had -- you know, was threatened a fine of thousands of  
16 dollars, well, we knew the hospital that this patient  
17 was treated at.

18 So we would contact the hospital. You  
19 know, "Why is this happening? Why are you -- is your  
20 patient, you know, being threatened with thousands of  
21 dollars of fines because she didn't receive any  
22 instructions really at all what to do with her waste?"

23 So it -- something needs to be done, because  
24 otherwise you wind up with having States imposing  
25 requirements on hospitals, so they are not hearing from

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1 patients calling, because a patient can just as well  
2 call up a legislator and then it would even be --

3 DR. HOWE: And my understanding is back  
4 when they started putting the detectors on the  
5 landfills, the hospitals, all their stuff was going back  
6 and they -- in self-defense, they had to put radiation  
7 monitors at the door where the trash was going out, and  
8 pull aside certain items, so that they could then  
9 successfully send them off to the landfill.

10 MEMBER COSTELLO: And I -- of course, all  
11 of this stuff is deregulated. All of this patient waste  
12 and the risk from this patient waste is not regulated.  
13 But we spend a lot of time working on it.

14 CHAIRMAN THOMADSEN: Dr. Welsh?

15 MEMBER WELSH: I'd just like to chime in  
16 and agree with what Mr. Costello has just said, because  
17 if taken to its logical but absurd extreme, if we have  
18 very, very sensitive devices, and we continue to have  
19 this inordinate and inappropriate fear of radiation,  
20 then what is going to happen when there is a bunch of  
21 bananas or a can of Brazil nuts or a batch of oranges  
22 that have been thrown in the dumpster and people worry  
23 that it's radioactive. Well, it is. But is there a  
24 threshold below which you really are concerned or not?

25 And I think we are all in agreement that the

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1 low doses that we're talking about presently are of no  
2 health consequences, but you could continue this  
3 argument until you wind up doing things that are just  
4 totally inappropriate. And I think there does have to  
5 be some common sense and reason imposed along the way.  
6 So I agree with Frank.

7 DR. HOWE: I think you have a public  
8 comment.

9 CHAIRMAN THOMADSEN: Oh. Thank you very  
10 much. Please identify yourself.

11 DR. GOETSCH: Steve Goetsch from San Diego  
12 Gamma Knife Center, Dade Moeller Associates. I was  
13 teaching a course at Dade Moeller Academy in Las Vegas  
14 in June, had four students who were learning radiation  
15 safety who are actually New Jersey State highway patrol  
16 officers. I learned as much from them as they learned  
17 from me, I think.

18 They were telling me they have a device that  
19 they use on the New Jersey Turnpike, sit on the side of  
20 the road with a very sensitive detector, multi-channel  
21 analyzer, and they can watch passengers in the cars  
22 going by and spot technetium-99 and iodine-131,  
23 fluorine-18, and can just watch people going by at 65  
24 miles an hour and identify the isotopes.

25 I asked, "What do you do when that happens?"

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1 "Well, we very rarely stop -- you know, if we saw a huge  
2 amount of, say, cobalt-60, we would be more interested."  
3 But the power of that technology is out there in all the  
4 states. They see it all the time now. I had no idea  
5 they could do that.

6 CHAIRMAN THOMADSEN: Yes, Dr. Suleiman?

7 MEMBER SULEIMAN: I mean, just a  
8 refresher, you know, a couple of years ago two people  
9 were coming across the border, and they got detected by  
10 portable detectors. And the protocol of Homeland  
11 Security -- they have these little gauges. If I  
12 remember right, the maximum scale on that is barely what  
13 would be defined as a radiation area, and their intent  
14 was just to say if you pick up something, you bring in  
15 somebody who knows more about the topic. But anything  
16 you detect is a pretty safe level unless it's the  
17 maximum.

18 DR. HOWE: Well, they all did -- they had  
19 a multi-channel analyzer, and what they saw wasn't the  
20 normal peaks.

21 MEMBER SULEIMAN: Oh, no. Yes, I'm  
22 talking about -- they have like these little devices.  
23 But the portable detector thing, I was surprised,  
24 because one came in from Niagara, drove in, and the other  
25 one flew into one of the international airports. And

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1 for those of you who don't remember, they picked  
2 up -- these patients had the nuclear medicine scans two  
3 and four months previously, and they had had a  
4 CardioGen -- it's a rubidium, 75-second half-life  
5 agent. So what were they detecting? They were  
6 detecting the parent nuclide, which was strontium,  
7 which stuck on the bone. And so this eventually led to  
8 a recall of the product.

9 So those are low here. I mean, and it  
10 wasn't handled irresponsibility. I mean, Customs  
11 picked it up, deferred it to Homeland, because they have  
12 an inventory of materials that they couldn't identify  
13 this nuclide, because it wasn't a commonly used nuclide.  
14 Actually, went to a Los Alamos group whose job is to look  
15 at the spectra and they nailed it. They actually said,  
16 "This is a medical isotope contaminant."

17 And by then, we got -- you know, FDA got  
18 involved and the NRC got involved, so it was one of the  
19 few times where this detector system, you know, picked  
20 up something that turned out to be -- resulted in an  
21 important outcome.

22 DR. HOWE: And I think that builds on the  
23 idea of the State troopers. They see fluorine-18 go by,  
24 or there is a -- "I know what that is. They see  
25 technetium go by. I see thallium go by. Oh, I see

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1 something here. Oh, I don't know what that is."

2 MEMBER SULEIMAN: I mean they're not  
3 looking for medical isotopes.

4 DR. HOWE: No. They are just looking for  
5 things that they know they don't have to worry about,  
6 and then they get concerned about the others.

7 CHAIRMAN THOMADSEN: Any other comments?  
8 Mr. Mattmuller?

9 MEMBER MATTMULLER: I'm not sure anyone in  
10 New Jersey drives 65.

11 (Laughter)

12 But to go back to the radioactive chicken  
13 bone idea, I know you don't regulate landfills,  
14 but -- and maybe I'm just very naïve, despite my years  
15 on this Committee -- but would it not have -- I guess  
16 it's more directed to Mr. Costello -- have any effect  
17 with the States that the NRC had a memo of some sort,  
18 a notification, that this I-131 you might be seeing in  
19 your landfills is coming from patients that we have  
20 regulated. But it's -- if you're finding it in  
21 landfills, it is below regulatory concern. So --

22 DR. HOWE: We never use the word "below  
23 regulatory concern." I mean, we used that in the '90s  
24 and were severely punished for it.

25 MEMBER MATTMULLER: Oh.

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1                   MEMBER COSTELLO: In the building I work  
2 in, are radiation people -- and then there are people  
3 who regulate waste facilities, or -- they are aware, and  
4 they are very aware, that the radioactive chicken bones  
5 are not a hazard.

6                   The problem is there are some landfills  
7 that deal with people other than us. You know, they  
8 have populations around them who are -- they are  
9 permitted, they have local organizations and things,  
10 and we can say that it's perfectly safe that these things  
11 are in a landfill or an incinerator for that matter.

12                   But we can say this until the cows come  
13 home, okay, but we aren't the main people who are worried  
14 about it. And so if they have told the population we  
15 are not going to put any radioactive material in there,  
16 then we can't make them do it. You know, we can allow  
17 them to do it, and, if they asked me, I would encourage  
18 them to do it. But that's as far as we can go.

19                   DR. HOWE: And it's also the radioactive  
20 kitty litter.

21                   CHAIRMAN THOMADSEN: Let's talk about  
22 biohazard. If they could detect biohazard as easy as  
23 radiation, they would just be collecting stuff from  
24 garage sales.

25                   Any other comments? Thank you very much,

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1 Dr. Howe. Very interesting topic.

2 Dr. Langhorst, would you like to -- you are  
3 next on the list. I'm sorry. I got ahead of myself.  
4 Ms. Holiday. I'm obviously getting ready for the  
5 break.

6 (Simultaneous speaking.)

7 MS. HOLIDAY: Actually you guys discussed a  
8 lot of what I was going to talk about, when you were  
9 talking about international practices of patient  
10 release. So, this should go very quickly.

11 So, I gave -- I'm giving this presentation  
12 at the request of Dr. Langhorst. She said she kind of  
13 wanted to discuss the May Commission meeting that we had  
14 on May 9th. So, I'll kind of set you up for her  
15 presentation right after me.

16 So, of course, the topics that were  
17 discussed were Dr. Thomadsen gave an overview of the  
18 ACMUI's activities. Dr. Zanzonico gave a presentation  
19 on the Committee's position on patient release. Ms.  
20 Weil gave a presentation on the reliability of radiation  
21 safety instructions for patients released following  
22 Iodine-131 therapy.

23 Dr. Thomadsen gave a presentation on the  
24 Committee's view, which was to not make any revisions  
25 of NRC's Medical Policy Statement. Dr. Suleiman gave

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1 a presentation on FDA's radiation role  
2 responsibilities, and then lastly, Dr. Langhorst gave  
3 a presentation on her view of the regulation of the  
4 medical use of byproduct materials. So, as a  
5 result of that Commission meeting, the Commission  
6 issued what is known as a staff requirements memorandum,  
7 an SRM. That SRM came down on June 5th, 2014, and  
8 basically the task that came out was they requested  
9 staff to provide information to them on the  
10 international practices of patient release following  
11 Iodine-131 therapy, and to provide a CA briefing to  
12 discuss our experience with the Medical Visiting  
13 Fellows Program.

14 The first half came, of course, as a result  
15 of Dr. Zanzonico and Ms. Weil's presentation. Then the  
16 last half came as a result of Dr. Langhorst's  
17 presentation.

18 So, just very quickly, staff provided a  
19 memorandum to the Commission on August 29th, and the ML  
20 number, which I will also distribute this to the  
21 Committee, is ML14217A350.

22 So, basically the gist of the memorandum  
23 was to inform the Commission that staff worked with the  
24 Office of International Programs, where we solicited  
25 responses from countries. We asked them specifically,

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1 "What are your requirements or your regulations for the  
2 release of patients who were administered Iodine-131  
3 therapy?"

4 "In addition to your requirements and  
5 regulations, what are your standard practices? Are you  
6 keeping them in a hospital? Are you keeping them in a  
7 separate hospital-owned facility? Are you releasing  
8 them to hotels?"

9 Then we also asked them, "What is the  
10 typical activity that is administered in a procedure,  
11 and what was the date of the latest revision to your  
12 regulations?"

13 So, actually what we got was similar to what  
14 everybody has said: that the response from those  
15 countries is varied. The majority of them, their  
16 responses were that what they have is regulations and  
17 requirements, and some even say that they don't have set  
18 forth requirements.

19 In fact, their release permits are either  
20 at or below NRC's pre-1997 release criteria. That  
21 pre-1997 release criteria is that patients may be  
22 released if their dose rate is less than 5 millirem per  
23 hour at one meter, or their retained activity is 1,110  
24 megabecquerels or 30 millicuries.

25 So, I know that Dr. Suleiman mentioned the

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1 BSS, IAEA's Basic Standards of Safety. I think I'm  
2 saying -- Safety Standards, excuse me.

3 IAEA published guidance in 1996 that had  
4 this guidance level of 1,100 MBecquerels, or close to  
5 the 30 millicuries. They also listed a good practice  
6 of 400 MegaBecquerels.

7 Then we also found out about this  
8 organization called HERCA, which is the Heads of  
9 European Radiological Protection Competent  
10 Authorities, which is -- which was spearheaded by  
11 France, and they set a guidance of 800 MBecquerels.

12 So, we got a total of 17 responses.  
13 Seventeen countries responded to our request, and we  
14 found that Germany, Australia, Japan and South Africa  
15 typically adhere to IAEA's '96 suggested guidance level  
16 of 1,100 MegaBecquerels.

17 China and Lithuania went with a good  
18 practice limit of 400 MegaBecquerels. Then for the  
19 countries that followed HERCA's guidelines of 800  
20 megabecquerels was France, the United Kingdom, Poland,  
21 Spain and New Zealand.

22 Then we found that there were also  
23 countries that were more stringent than these set forth  
24 requirements. Germany, while they did adhere to the  
25 1,100 MegaBecquerels, they said that they hold their

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1 patients for at least 48 hours, and they have to have  
2 a local dose rate of 0.35 millirem per hour at 2 meters.

3 Philippines don't release until there's  
4 300 millirem. Japan is 500 MegaBecquerels. South  
5 Africa holds their patients until it is 2.5 millirem per  
6 hour at 1 meter.

7 There were countries that talked about this  
8 isolated waste treatment system. There was another  
9 country that talked about how no matter how much they  
10 administered their patients, they require their  
11 patients to stay in the facility for at least three days.

12 So, there is a varied amount of responses  
13 that we got. This was just information gathering. So,  
14 we did share that with the Commission. As Dr. Howe  
15 mentioned, as a result of this Commission SRM for the  
16 patient release project, staff will be looking into and  
17 working with international community to better  
18 understand what they do. Not necessarily adopt what  
19 they do, but just to get a more well-rounded perspective  
20 of what's going on in other nations.

21 For the second task, staff was requested to  
22 provide a CA briefing, or Commissioner's Assistance  
23 briefing, to discuss the Medical Visiting Fellows  
24 Program.

25 As it turns out, there are maybe two staff

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1 in the NRC that have a recollection of this program, Dr.  
2 Howe being one of them. And so, this program actually  
3 came in 1990. It was pre-1990, as a result of a request  
4 from the medical community.

5 We currently had a few rules that were  
6 coming up: Quality Management rule, the Patient Release  
7 rule and the Pharmacy rule. A solicitation was sent out  
8 in the Federal Register, similar to how it is for the  
9 ACMUI.

10 So, we requested a nuclear medicine  
11 physician. What we got was actually a nuclear  
12 pharmacist, and Dr. Myron Pollycove as our nuclear  
13 medicine physician. What actually happened was the  
14 nuclear medicine physician was on loan to us from NIH.  
15 I'm sorry? Yes, the nuclear pharmacist. Did I say  
16 physician -- I'm sorry.

17 The nuclear pharmacist came to us from NIH,  
18 and after the radiopharmacy rule was passed, he returned  
19 back to NIH. Dr. Myron Pollycove was here during  
20 Patient Release rule and the Quality Management rule,  
21 and then after that he kind of went on to pursue other  
22 things.

23 So, from there on, staff didn't really see  
24 a dire need for another medical fellow. I think we  
25 would like to think that over the past decade or so, our

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1 interactions with the ACMUI have greatly expanded, and  
2 there's so much more open communication in terms of  
3 subcommittee reports that are submitted, or general  
4 recommendations that are put forth.

5 I know that every two years, we do an  
6 evaluation, and it seems that the ACMUI is very pleased  
7 with our current reporting structure. So, we kind of  
8 agreed with this position that there's no real need for  
9 a medical fellow at this time.

10 The Committee has 13 positions on it, of  
11 which we get a varied amount of perspectives and  
12 expertise that we need to properly promulgate our  
13 regulations. So, that just summarizes those two tasks  
14 that the Commission directed us with.

15 Then lastly, that SRM mentioned the open  
16 door policy that has been mentioned a few times at least  
17 during this meeting. The Commission, as well as Ms.  
18 Dudes has reiterated numerous times, has an open door  
19 policy here.

20 When Dr. Malmud was here as the chair, I  
21 know that he mentioned the Commission had always offered  
22 up to him that if he ever wanted to come into town and  
23 drop in and just talk with them, he had the option to  
24 do so. The same option is here for the Committee.

25 So, if there are ever any issues or items

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1 that you would like to discuss with the Commission, they  
2 have this open door policy. If you have issues that you  
3 don't necessarily go to the Commission with, you can  
4 always come and speak to Ms. Dudes, or any one of us if  
5 you don't want to talk to me.

6 [Laughter]

7 Now, I have to say, do you have any  
8 questions?

9 CHAIRMAN THOMADSEN: Yes. Is it possible  
10 then to get a list of phone numbers and emails of the  
11 commissioners?

12 MS. HOLIDAY: Absolutely. Absolutely.  
13 It is available on the website, but I can submit a list.

14 CHAIRMAN THOMADSEN: Thank you very much.

15 MS. DUDES: I just wanted to be reflective  
16 on what Dr. Welsh said earlier, in looking at that first  
17 item we talked about, which was the memo on  
18 international practices and not necessarily get  
19 distracted by that information.

20 We will make sure that it's a healthy, open  
21 informative exchange, but we have very important work  
22 to do. You saw Dr. Howe's timeline, and hopefully we  
23 can do some things in short order working with the  
24 communities and the societies to get the guidance  
25 documents on a website or some linkage to that, develop

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1 brochures in conjunction with the societies and this  
2 committee.

3 I'm always worried when I see papers that  
4 say, "This country does it this way. This country does  
5 it this way." Because then you're not comparing the  
6 entire system. You're comparing a release practice not  
7 in context of the medical system and other things, other  
8 societal factors.

9 So, I think it's valuable information. I  
10 think you should always be aware of it, but I think our  
11 focus going forward is to try and get some of the tasks  
12 that we can really accomplish safety and make an impact  
13 on the safety of the patient release, and then continue  
14 to be aware and inform internationally.

15 It is -- you know, when we wrote that up,  
16 it was a separate request. It was a result of your  
17 meeting, rather than part of the overall requirements  
18 memorandum we got on patient release.

19 So, we gathered the information. We  
20 didn't do a lot of analysis of this information. So,  
21 contextually it may not be as useful, but I just wanted  
22 to share that point with the Committee.

23 MEMBER COSTELLO: I just had a suggestion  
24 on members of ACMUI going to meet with Commissioners or  
25 the Commission. I would think the members would share

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1 this with the rest of the Committee. If -- if someone  
2 is going to talk to the Commission, let's say, it should  
3 be clear that they're representing themselves; they're  
4 representing the whole ACMUI or just what is it they're  
5 doing individually to seek appointments with the  
6 Commission or Commissioners without doing this  
7 collegially I don't think is the best way of doing it.

8 CHAIRMAN THOMADSEN: I think if you talk to  
9 the Commissioners, it would have to be as individuals  
10 and not representing the ACMUI, unless the ACMUI is  
11 officially sending somebody, in which case I think it's  
12 probably not a good idea to recommend people let  
13 everybody know that they're going to. They may want to  
14 discuss with the Commissioners something about the  
15 Committee that they feel uncomfortable talking to the  
16 Committee about.

17 MEMBER COSTELLO: It would be  
18 uncomfortable.

19 CHAIRMAN THOMADSEN: I would too. That  
20 could happen. Any other comments? Thank you, Ms.  
21 Holiday. Now, Dr. Langhorst. With great  
22 anticipation, we've been waiting for your comments.  
23 Safety culture: Interactions between licensees and  
24 regulators.

25 MEMBER LANGHORST: Well, for those new

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1 members and soon to be new members, when you're asked,  
2 "What kind of topics do you think need to be discussed  
3 at our next meeting?", be prepared to discuss those  
4 topics as the leader. I didn't expect to do both, but  
5 that's okay.

6 So, as you said, I felt it was important to  
7 bring up some issues that had been discussed at the May  
8 9th Commission briefing by the ACMUI. I'm leading the  
9 discussion but not the total discussion. So, I hope you  
10 all feel comfortable in jumping in at any point.

11 So, my goal was to do just that, and discuss  
12 how interactions between medical licensees and  
13 regulators may or may not support a positive safety  
14 culture.

15 So, I think NRC is to be commended on  
16 keeping up the evaluation of safety culture and what it  
17 means to them and what it means to licensees.

18 So, just this summer or spring - I can't  
19 remember exactly - they've updated their safety culture  
20 brochure. In looking at the brochure, there's lots of  
21 good information in this on safety culture. But  
22 there's no real specific mention of medical uses, and  
23 you all may have heard me say that those medical uses  
24 can be different than other uses of radioactive  
25 material.

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1           So, NRC's definition of nuclear safety  
2 culture: Safety culture is the core values and behaviors  
3 resulting from a collective commitment by leaders and  
4 individuals to emphasize safety over competing goals to  
5 ensure protection of people and the environment.

6           Nine positive safety culture traits have  
7 been developed, and this didn't just come from NRC.  
8 This came from a concerted effort of reaching out to  
9 various licensee communities, including medical use in  
10 developing these safety culture traits.

11           Now, I'm going to focus, because I only have  
12 a half hour but maybe not even that anymore. So,  
13 problem identification and resolution; issues  
14 potentially impacting safety are promptly identified,  
15 fully evaluated and promptly addressed and corrected  
16 commensurate with their significance.

17           So, what is meant by safety? We may have  
18 some different perspectives on that. I think we were  
19 just discussing perspectives on safety. And what is  
20 the perspective on what is commensurate with their  
21 significance? So, there are those topics to be looked  
22 at.

23           Work processes: The process of planning  
24 work activities as implemented so that safety is  
25 maintained. Again, I'll point out that word safety.

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1 Environmental raising concerns. A safety  
2 conscious work environment is maintained where  
3 personnel feels free to raise safety concerns without  
4 fear of retaliation, intimidation, harassment or  
5 discrimination.

6 Safety? I'll come to that. The  
7 retaliation, intimidation, harassment and  
8 discrimination.

9 NRC can look at this in regard to an  
10 individual's fear of how their licensee will treat them  
11 in raising issues. But I think we discussed in our  
12 Commission briefing how an individual may be influenced  
13 on how the regulator responds to an issue being raised,  
14 and what that could do to the potential impact of any  
15 use of radioactive material for that licensee.

16 I will point out that yes, NRC is a  
17 regulatory body. Agreement States are regulatory  
18 bodies. But I think we need to discuss how these  
19 influence people in raising concerns.

20 Effective safety communications;  
21 communication maintain a focus on safety. Again, what  
22 do we mean by safety?

23 So, I searched for a definition for safety  
24 on NRC's website, and was not fully satisfied with my  
25 search there. Under the glossary, there are

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1 definitions for safety limits, safety-related, safety  
2 significance.

3 So, the best I could find was in regards to  
4 radiation protection, where Congress has charged the  
5 NRC with protecting people and the environment from  
6 unnecessary exposure to radiation as a result of  
7 civilian uses of nuclear materials.

8 I did find a definition for safety that  
9 comes from the Canadian Nuclear Safety Commission  
10 website. On that website where they talk about how they  
11 utilize the definition of safety, they reference a  
12 Canadian court definition for safety.

13 Safety is not measured. It is judged, and  
14 it is judged according to an assessment of an acceptable  
15 risk. An acceptable risk is essentially a value based  
16 proposition determined by policy and or those  
17 authorized by the government to judge safety and/or  
18 those exposed to the risk.

19 That's the best I found on a definition for  
20 safety other than, "something that is safe." So, let  
21 me come back to our cardinal principles of radiation  
22 protection and how they relate to medical use.

23 Any decision that alters the radiation  
24 exposure situation should do more good than harm.  
25 That's the basis of medicine. Optimization, "A

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1 likelihood of incurring exposure, the number of people  
2 exposed and the magnitude of their individual doses  
3 should be kept as low as reasonably achievable, taking  
4 into account economic and societal factors."

5 This principle seems to be the basis of some  
6 of those special exemptions or limits that we apply for  
7 patients administered with radioactive material. You  
8 were just discussing a few of those.

9 Then the application of those limits. Any  
10 individual from regulated sources in planned exposure  
11 situations other than medical exposure of patients  
12 should not exceed the appropriate limits specified by  
13 the Commission.

14 This one specifically points out medical  
15 use of radiation is different than other uses of  
16 radiation and radioactive material.

17 Now, the healthcare arena has been working  
18 on safety culture for many years, and I know NRC has  
19 looked at these references. So, the National Academy  
20 began their endeavor in this with these two reports.  
21 "To Err is Human," in 2000, and "Crossing the Quality  
22 Chasm," in 2001.

23 So, healthcare needs to be safe, avoiding  
24 injury to the patients from care that is intended to help  
25 them; effective, providing services based on scientific

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1 knowledge to all who would benefit and refraining from  
2 providing services to those not likely to benefit.

3 Timely: reducing waits and sometimes  
4 harmful delays for both those who receive and those who  
5 give care. Efficient: avoiding waste including waste  
6 of equipment, supplies, ideas, energy. You were  
7 talking about wasted energy.

8 Equitable: providing care that does not  
9 vary in quality because of personal characteristics  
10 such as gender, ethnicity. It's the end of the day.  
11 Ethnicity, geographic location and socioeconomic  
12 status.

13 So, let's go to our traits. Respectful  
14 work environment. Trust permeates the organization.  
15 Trust and respect. Trust and respect has been an issue  
16 that healthcare has had to deal with. Some of you work  
17 in a medical environment. There can be some issues of  
18 personalities sometimes, but that endeavor the medical  
19 community has been addressing, and perhaps this could  
20 be an area of a case study for NRC's education efforts  
21 to look at how this trait could be communicated to  
22 others.

23 Questioning attitude, individuals avoid  
24 complacency, and continually challenge existing  
25 conditions and activities in order to identify

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1       discrepancies that might result in error or  
2       inappropriate action.

3               So, I feel like I might have challenged that  
4       existing condition in giving my viewpoints to the  
5       Commission. I think the community and the NRC need to  
6       work at how discrepancies might result in other errors.

7               The most common barriers to reporting of an  
8       issue is, "I just don't know what to report or how to  
9       report it." "Oh my gosh. I can't believe that just  
10      happened. I don't even want to think about it anymore,  
11      and I'm just going to forget it. No one will notice."

12              "Why should I even bother? Nothing is  
13      going to change." Or, "I may not trust who I can tell."  
14      Or, "My gosh. Am I going to have to start writing some  
15      reports? This is not going to end for a long time?"  
16      Or, again, that fear of reprisal.

17              I would hope that there's not a wall erected  
18      across the table of the regulator and the regulated  
19      community, which inhibits these kinds of discussions on  
20      how people -- how the two groups interact, and how this  
21      can impact the safety culture, in particular in the  
22      regulated community.

23              The perspectives of the NRC -- did I skip  
24      one? The perspectives of the NRC? A lot of the focus  
25      on safety culture is on fuel cycle safety culture. NRC

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1 licenses 100 percent of these licensees. Also applies  
2 to medical or radioactive use, but NRC licenses only in  
3 13 States and 4 US territories.

4 In medical licensees, NRC only applies to  
5 radioactive materials used in clinical settings. It  
6 doesn't apply to radiation producing machines.

7 The NRC has again put together a really nice  
8 NUREG on safety culture common language. If you take  
9 a look at that, you'll notice it is heavily focused on  
10 non-medical use. It doesn't really address -- it is  
11 much more focused on reactor and other material uses,  
12 and not on medical use.

13 That's the majority of licensees. So,  
14 versus that influence are medical licensees, positive  
15 safety culture, caring for our patients and our  
16 employees.

17 We have a big influence by the Joint  
18 Commission on other accrediting organizations that have  
19 their own set of criteria we have to meet or utilize NRC  
20 in Agreement State criteria in their own inspections.

21 There's the Centers for Medicare and  
22 Medicaid Services and insurance companies. Those are  
23 a big driving force in a medical licensee. There are  
24 other regulators, and one thing I keep looking at here  
25 because I forgot to put in there is HIPAA. A big one.

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1           There is the competition for business, and  
2           that is not only between hospitals or clinics. It is  
3           also within hospitals. It is one service versus  
4           another service, and who is allowed to provide that  
5           medical care and the legal liability, especially  
6           involved in malpractice and so on.

7           Healthcare is increasingly complex, and  
8           this is one of the themes of the National Academy of  
9           Science. At my location, at Washington University in  
10          Saint Louis, there are lots of condemnations. There  
11          are PET-CT's that we routinely use now.

12          We now have a PET-MR unit that is going to  
13          do great things, especially for our pediatric patients,  
14          and we also have the ViewRay™, which marries up the real  
15          time imaging, MRI with teletherapy sources.

16          So, this is a complex environment. I'm  
17          missing something here. So, if we -- I think I had  
18          things moved around.

19          So, during safety culture talks, I did find  
20          AAPM comments very helpful in this regard in the medical  
21          community trying to state that one size does not fit all.  
22          It is applaudible to try to have a single definition,  
23          but it is equally important to note that implementation  
24          of the traits and behaviors as they apply to specific  
25          licensee categories may differ.

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1           In medical uses, nuclear safety does not  
2 preempt or override patient safety especially in  
3 emergency situations. For example, life saving  
4 measures should always preempt the need to  
5 decontaminate a patient in an emergency room.

6           So, I offer up those comments to the  
7 Committee, and welcome your input, your discussion.

8           CHAIRMAN THOMADSEN: Thank you, Dr.  
9 Langhorst. Comments from the Committee? We have a  
10 comment from --

11           MS. TOMLINSON: Hi. I'm Cindy Tomlinson  
12 from ASTRO. I just wanted to let the Committee know  
13 that ASTRO had a meeting a couple weeks ago in San  
14 Francisco. We had one of our keynote speakers, Dr.  
15 Sidney Dekker, who is a human factors guy.

16           You could actually access his presentation  
17 on our website. And what I'll do is I'll send the link  
18 to Sophie, and she can send it out to you. I think it  
19 is very timely in terms of this discussion. He talks  
20 a lot about safety culture and how it works both ways;  
21 not just those reporting but those being reported to.

22           So, I think you guys will find that useful.  
23 So, I'll send the link to Sophie.

24           CHAIRMAN THOMADSEN: Thank you. Yes, Ms.  
25 Dudes?

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1 MS. DUDES: Thank you. Thank you for the  
2 presentation. That was good. I appreciated that.  
3 Maybe this will come in your next presentation, because  
4 I guess I wouldn't be looking for ways -- or things that  
5 we can take away that would do more positively  
6 influence. So, I try not to look too far ahead, but if  
7 that's coming after the break, then I'll reserve my  
8 question until then.

9 MEMBER LANGHORST: I did have a question.  
10 During the Commission briefing, I was asked whether my  
11 comments were supported by the Committee. I know there  
12 was a great wave of nodding heads behind me, but I think  
13 I will ask that question of our Committee right now, as  
14 to whether am I -- am I being representative of the  
15 committee's views? Am I just my own views being voiced  
16 here?

17 MEMBER ALDERSON: I think you've expressed  
18 a complexity and subjectivity associated with this  
19 subject matter, and that's why in the previous session  
20 it isn't good enough just to have content experts. You  
21 have to really be able to see the big picture about how  
22 you communicate these ideas to people from different  
23 backgrounds, and how you can make an impact. That is,  
24 at least from my experience, very difficult.

25 CHAIRMAN THOMADSEN: Thank you, Dr.

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1 Alderson. Mr. Costello?

2 MEMBER COSTELLO: I would have to actually  
3 go through your whole presentation again to say whether  
4 for me or not. For the most part, I tend to agree with  
5 what you talked about. I think, just speaking for  
6 myself, I think there might've been some implementation  
7 that the Commission itself needed to have someone on it  
8 with medical experience.

9 I think that's a little beyond what the  
10 ACMUI would likely be commenting on is the make-up of  
11 the Commission itself. I think you made your claim.  
12 I'll make this claim. I think it is true that staff  
13 needs all the help it can get at this point because you  
14 have the numbers up there.

15 The declining number of non-Agreement  
16 States and the -- and the aging of its own staff, the  
17 NRC's core experience is a challenge. It's a  
18 management challenge. This area, I think, is getting  
19 here -- you're importing some new talent, and that's  
20 good. But the fact is it only regulates a small  
21 fraction of licensees, and so the NRC's experience  
22 really needs to be supplemented with experience from  
23 industry, experience for the States, and so forth.

24 I think you have said words along those  
25 lines, and if you did, I would agree with that. But the

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1 idea that we comment on the make-up of the Commission?  
2 I probably wouldn't.

3 CHAIRMAN THOMADSEN: Dr. Suleiman?

4 MEMBER SULEIMAN: I think I'll hold back my  
5 opinion. I don't remember the details, but I generally  
6 agreed with pretty much everything you said. I think  
7 the message was, and we had a discussion beforehand,  
8 where I thought -- this is my recommendation. If you  
9 look at the economic value of medical care, and compare  
10 it with nuclear power generation, the ratio may be much  
11 more different than the weight of the Commission  
12 membership.

13 The only good thing is they are all  
14 consumers. So, in some way, they are all participating  
15 in the healthcare and delivery system, but  
16 professionally, it would be nice to have somebody who  
17 could relate with us a little bit more. I agreed with  
18 your message.

19 CHAIRMAN THOMADSEN: A member of the  
20 public?

21 MS. FAIROBENT: Thank you, Dr. Thomadsen.  
22 Not an answer to this specific question, but just a  
23 comment on the safety culture process that NRC went  
24 through. AAPM was very much part of that process, and  
25 at the initial meetings, it was very much heavily

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1 weighted towards nuclear power and the fuel cycle.

2 I do feel that not only the staff but the  
3 other licensee categories, nuclear power, fuel cycle,  
4 research reactors, et cetera, did hear and listen to the  
5 concerns from the medical community. We were  
6 successful in getting the language changed to be more  
7 reflective of the diversity of the licensees that NRC  
8 regulates.

9 So, from that standpoint, I do want to  
10 compliment the staff and the process that we went  
11 through, and also that so far would've been successful  
12 in keeping safety culture at a policy level, and not down  
13 into the regulations.

14 CHAIRMAN THOMADSEN: Dr. Guiberteau?

15 VICE CHAIRMAN GUIBERTEAU: I think your  
16 presentation at the meeting with the Commission did us  
17 all a favor. Very much so. I think it is easy when -- I  
18 know the Commission has many lofty things to think  
19 about. I know they have other directions, but I think  
20 the less we express the fact that, as you said in this  
21 talk, one size does not fit all, that medicine is not  
22 a clockwork orange and you can't -- and you have to take  
23 into consideration what we were talking about earlier  
24 about performance versus regulation by precision more  
25 or less, that these are things that we need to bring to

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1 the forefront because we are different.

2 I think the litany of things you said in  
3 your talk were important for them to hear. I know when  
4 you do that, people on the other side may have taken  
5 those as criticisms, but I didn't take it that way at  
6 all. I took them as being just a reminder that there's  
7 some things that this division needs and that  
8 this -- that this group needs that they may not remember.  
9 So, I applaud you for doing that.

10 CHAIRMAN THOMADSEN: Dr. Welsh?

11 MEMBER WELSH: Your question, whether or  
12 not we agree with you. I would say that I personally  
13 do agree with you. I agreed with you back during the  
14 Commission briefing. A number of years back when there  
15 was a vacancy on the Commission, I personally wrote a  
16 letter to the President, suggesting that the Commission  
17 have a member with more medical expertise than has  
18 historically been the case.

19 I think a professional society, at least  
20 one, wrote a similar letter. Now, I've heard estimates  
21 of anywhere from 5 percent to 20 or 25 percent of what  
22 NRC is involved with has to do with medical uses of  
23 byproduct material. I don't know what that figure  
24 truly is, but if it is anywhere near 20 percent, then  
25 one could argue that at least one of the five

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1 Commissioners should have a good deal of medical  
2 background or expertise.

3 I don't know that the professional  
4 societies had the opportunity to comment before the  
5 vacancies have been filled, but I do think that going  
6 forward, it'd be wonderful for at least one member of  
7 the Commission to have general medical expertise or  
8 background.

9 So, it's a long way of saying, yes, I agree  
10 with you.

11 MEMBER LANGHORST: I will clarify that I  
12 did not, in my talk there, say, "They needed that." I  
13 just pointed out that very few over the history have had  
14 that.

15 CHAIRMAN THOMADSEN: Dr. Suh?

16 MEMBER SUH: Clarifying question. It's  
17 the President though who appoints, right? You guys  
18 just sort of sit back and watch.

19 MS. DUDES: Yes, the President will  
20 nominate, and the Senate will confirm.

21 CHAIRMAN THOMADSEN: Well, at the moment,  
22 I think we will take a break and come back to hear about  
23 enhancing interactions between the NRC and the medical  
24 community, which we've already been discussing.

25 (Whereupon, the above-entitled matter went

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1 off the record at 3:25 p.m. and resumed at 3:45 p.m.)

2 CHAIRMAN THOMADSEN: Dr. Langhorst.

3 (Pause.)

4 MEMBER LANGHORST: Here I am again. Thank  
5 you very much.

6 (Laughter.)

7 MEMBER LANGHORST: Okay. So, another topic  
8 that we talked about at the Commission briefing May 9th  
9 of this year was what could be done to enhance  
10 interactions between the NRC and the medical community,  
11 and I probably should say also the Agreement States.

12 So, my goal here is to explore ways to  
13 enhance the relationship and to engage interactions  
14 between all of us and to discuss the challenges we need  
15 to bravely face together in fostering this relationship  
16 and continuing interactions.

17 And I put that "bravely" in there, because  
18 it's not easy to hear people talk about, no, they don't  
19 think like Sue does.

20 Well, that's okay. I want to hear that.  
21 That's part of the safety culture and figuring out what  
22 is it that causes stresses, causes issues. And so,  
23 that's part of what we do here.

24 The ideas presented here are mine. And  
25 they're presented to you all for the purpose of

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1 stimulating the discussion of this group, NRC staff,  
2 members of the public. And what order I put them in was  
3 the order I put them in and should not reflect my  
4 preference or what I feel is their importance.

5 So, radioactive material regulations. We  
6 have NRC and we have this group called Agreement States,  
7 but it's not just two situations. There are 37  
8 different Agreement States.

9 MS. DUDES: I'm so glad that got bigger,  
10 because if that graph -- if the Agreement States saw that  
11 graph, I'd be hearing about it.

12 (Laughter.)

13 MEMBER LANGHORST: Don't worry. I had to  
14 have space on my slide. It was not intended, but those  
15 all stem from NRC-regulated authority. So, I have to  
16 say that.

17 So, there can be 38 different ways to do  
18 things depending on the level of compatibility and so  
19 on.

20 There are things called Master Licenses and  
21 I know the VA Hospital has that. I can't remember who  
22 else has that.

23 MEMBER COSTELLO: Navy.

24 MEMBER LANGHORST: The Navy.

25 MS. DUDES: And the Air Force.

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1 MEMBER COSTELLO: Air Force.

2 MEMBER LANGHORST: And the Air Force for  
3 medical use?

4 MEMBER COSTELLO: Yes.

5 MEMBER LANGHORST: All right. Thank you.

6 And there are few, from what I understand,  
7 like city-based things for the larger cities like New  
8 York, Los Angeles. So, there's a lot of different  
9 players in this situation.

10 There are 17 of us. And I say "us," because  
11 I'm from Missouri. And, yes, that is how you say it.

12 (Laughter.)

13 MEMBER LANGHORST: 17 NRC States and  
14 territories. We all face other regulatory bodies in  
15 dealing with radiation, radioactive materials.

16 We have this thing called the Joint  
17 Commission that keeps getting involved here. A very  
18 important organization. So, there are a lot of  
19 players. A lot of different perspectives.

20 The National Academies just recently  
21 released a report this summer regarding the promotion  
22 of a culture of safety.

23 And from that report, I got this quote:  
24 "It is especially important for improving the exchange  
25 of safety-related information, fostering collective

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1 mindfulness and sense-making, empowering workers to  
2 speak up and to share what they know, and creating a  
3 learning and improvement focus."

4 This report was focused on academic  
5 chemical programs. There have been some issues in the  
6 academic realm and chemical safety. And this report  
7 committee brought together expertise and outlooks in  
8 many areas.

9 One member is a university provost, has  
10 been a dean, a chemistry department chair chancellor.  
11 There are environmental health and safety officials  
12 from academia, from industry and national labs.

13 There were senior faculty chemistry  
14 members. There were young, junior faculty chemistry  
15 members.

16 There were experts on safety culture and  
17 behavioral sciences and the quote that I just quoted was  
18 from the second reference here.

19 Now, for full disclosure, the chairman of  
20 this report, that provost is my provost at my  
21 university.

22 So, we have a very strong light shone on our  
23 safety culture not only in chemical labs, but our entire  
24 safety culture at our university.

25 So, I want to talk about the regulatory

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1 environment of Agreement State medical licensees. And  
2 so, this is off of NRC's website and you can see my State  
3 is an NRC State surrounded by Agreement States.

4 And in Agreement States, they have the  
5 oversight for medical licensees of the use of  
6 radioactive materials in medicine.

7 They also regulate x-ray machines and other  
8 radiation-producing machines. There is levels of  
9 medical licensing for physicians, for nurses, for  
10 techs, for sometimes physicists.

11 And maybe there is an opportunity to take  
12 all of that information to judge the relative risk of  
13 those uses of radiation, radioactive materials within  
14 medical licensees.

15 It tends to be a smaller regulated  
16 community within a State. Maybe perhaps an allowed  
17 development of licensee/regulator relationships.

18 I think that's particularly true when it  
19 involves a university medical center for a State -- for  
20 an Agreement State.

21 It can be influenced by the State and their  
22 radiation control program safety culture within the  
23 State.

24 There can be differences of how each of the  
25 Agreement States handle things and that -- and NRC that

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1 can cause a challenge for those licensees, medical  
2 licensees who have branches in many different  
3 locations.

4 And so, what might work in one State is not  
5 allowed in another State or there are slightly different  
6 requirements. And so, that can be a challenge  
7 especially when if you have people moving between those  
8 two locations, well, why is it this way and how do I keep  
9 track of what I'm supposed to do?

10 And perhaps that Agreement State, that  
11 smaller community can provide a level of a safe  
12 environment to discuss safety and compliance issues  
13 with the regulators.

14 I will have to say I have never been an RSO  
15 in an Agreement State. So, I've always been an RSO in  
16 an NRC State. That's what I know.

17 This is NRC's Mission off their website:  
18 "The NRC licenses and regulates the Nation's civilian  
19 use of radioactive materials to protect public health  
20 and safety, promote the common defense and security and  
21 protect the environment."

22 And in their value statement: "In achieving  
23 our mission, the NRC adheres to the principles of good  
24 regulation, independence, openness, efficiency,  
25 clarity and reliability. The Agency puts these

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1 principles into practice with effective, realistic and  
2 timely regulatory actions consistent with our  
3 organizational values and our open, collaborative work  
4 environment."

5 I feel we are a poster child for that in this  
6 committee. So, our Committee is one of those focal  
7 points for medical uses of radioactive material and also  
8 in regard to radiation-producing machines.

9 That level of expertise was added to the  
10 Committee when Dr. Guiberteau was brought on first as  
11 a consultant, and then as a full Committee member.

12 And I think that has been essential for our  
13 combined modalities that are more and more in use these  
14 days.

15 We comment. I'll let you guys read that.  
16 It necessarily doesn't need to go into the record, but  
17 this is some of what we do in our advisory of the NRC  
18 and of Agreement States to look at the issues to be  
19 brought to the attention of the Commission.

20 We are, as we said before, 13 members. We  
21 have two in-person meetings per year. There are  
22 various teleconferences on special topics and we have  
23 the subcommittee structure that is used to work on these  
24 special topics and develop the recommendations.

25 So, here are some of my ideas beyond us as

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1 a focal point. So, Sophie already talked about this in  
2 regard to the Visiting Fellow.

3 I raise this as a potential way of the NRC  
4 having a more onsite medical expertise readily  
5 available to them.

6 Here's another suggestion that I did bring  
7 up at the meeting that perhaps there could be a periodic  
8 regulatory information conference devoted to medical  
9 use issues.

10 There is already a regulatory information  
11 conference that happens every year. And that is  
12 involving the reactor and fuel cycle licensees.

13 This is an annual three-day meeting here in  
14 Washington, D.C. They have a website on the NRC's  
15 website.

16 March of this year there were by my count,  
17 and it's a rough count, about 2,400 registrants. About  
18 50 percent of those people were US licensees,  
19 contractors and so on.

20 There were about 40 percent of the  
21 individuals were NRC or Agreement State individuals.  
22 And out 10 percent were international.

23 I found very important on that website is  
24 that the dates for March 2015 and 2016 are already on  
25 the calendar.

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1                   So, people who are interested in coming to  
2 this conference know when it's going to be and it's here  
3 in DC.

4                   Here are some of the topics that I pulled  
5 off of that conference: Agency efforts to address  
6 cumulative effects of regulation, interacting with NRC.  
7 Medical radioisotope production was a topic. Safety  
8 culture journey: Lessons learned from culture change  
9 efforts.

10                  These are topics that could go right into  
11 a medical use conference, but think of what we've  
12 discussed here today. I-131 patient release issues  
13 comes to mind. Again, the production of medical  
14 isotopes.

15                  Now, the NRC and Agreement States work  
16 jointly on developing guidance. And I was glad to hear  
17 that Dr. Suh had been involved in helping on guidance  
18 for ViewRay.

19                  So, technical teams, you can see this is  
20 some of the make-up that was suggested. And I think  
21 it's good to include an ACMUI member or perhaps to reach  
22 out to other medical experts in helping work with those  
23 technical working groups.

24                  And that source of those medical experts  
25 could perhaps be the organizations that support these

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1 specialty board for certification that are recognized  
2 by NRC.

3 That could be a way to be inclusive of some  
4 of those groups and to develop people for potential  
5 service on ACMUI potentially. And as I say here,  
6 perhaps that could be used with the 35.1000 guidance  
7 too.

8 As I said, NRC is working on safety culture  
9 and you guys are continually looking at what can we do  
10 to promote this, how can we do this.

11 And so, there are brochures that have come  
12 out. They're called Trait Talks. And they are being  
13 developed to focus on those nine safety culture traits  
14 that we talked about in the previous presentation and  
15 to give some real world situations and so on.

16 Perhaps because medical use can be  
17 different, perhaps NRC, Agreement States and medical  
18 community could help develop some of these that are  
19 pertinent to medical uses of isotopes.

20 Because of our focus of medical uses in  
21 discussions here, maybe we could add another ACMUI  
22 in-person meeting a year with the focus on having the  
23 medical community come in and give us presentations and  
24 focus discussions on issues they're concerned about.

25 This might not be as needed if we have a

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1 regulatory issue conference annually, but maybe we  
2 could get started in this way.

3 The ACRS has procedures to augment  
4 expertise and bringing in additional people to help with  
5 subcommittees and so on.

6 Perhaps some of our subcommittees, let's  
7 say, on our Y-90 microspheres subcommittee, it might  
8 have been very helpful to have an interventional  
9 radiologist available for that perspective.

10 On Gamma Knife, it may be very helpful to  
11 have a neurosurgery representative to have that  
12 perspective.

13 Remember I used the word "bravely."  
14 Fostering a positive safety culture takes people  
15 working with people.

16 It's really helpful when people understand  
17 why is this regulation in place and how does its risk  
18 that it's trying to mitigate relate to this risk,  
19 because we want to try to minimize our confusion of what  
20 needs to be done by having consistent and compatible  
21 expectations for regulations.

22 And when you're talking about radioactive  
23 materials, the use of radiation for medical uses, it is  
24 a different perspective.

25 Implementing these ideas takes additional

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1 resources. That means people. That means dollars.  
2 The NRC medical team as it stands now could not possibly  
3 try to do a regulatory issues conference. They  
4 wouldn't do anything else, but it takes people and  
5 dollars from the medical community too to be  
6 participants in this and from the Agreement States.

7 And that may be asking a lot of our  
8 Agreement States given economic issues involved with  
9 state funding and so on.

10 We all need to lend leadership and demand  
11 respect in raising these concerns and be able to  
12 identify problems and talk about the challenges that  
13 exist in light of all of the patient safety issues and  
14 not just those related to radioactive material use.

15 You can't talk safety culture if you're  
16 only going to take one little slice of the pie. You have  
17 to look at it in the whole picture. Thank you.

18 CHAIRMAN THOMADSEN: Thank you, Dr.  
19 Langhorst.

20 Reflections from the Committee?

21 MEMBER DILSIZIAN: Enjoyed your  
22 presentation.

23 The part that I'm a little bit confused  
24 about is when you said to involve other specialties of  
25 physicians to present to us.

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1 I'm new on the Committee, but I feel like  
2 as a nuclear cardiologist I'm representing the nuclear  
3 cardiology community.

4 So, when I'm at the AHA/ACC meetings,  
5 anybody who has any concerns or any issues, I am their  
6 representative, I feel.

7 And, therefore, I would feel it's not  
8 necessary, if you will, or if someone does have a point,  
9 I would feel that why wouldn't I have been approached  
10 as a person rather than coming here separately and  
11 having to. So, I'm a little bit confused.

12 Again, I'm new. Maybe you can teach me  
13 what I'm missing about that point.

14 MEMBER LANGHORST: From my perspective--

15 MEMBER DILSIZIAN: Yes.

16 MEMBER LANGHORST: -- and you mean  
17 involved with like having a regulatory issue conference  
18 where you bring in -- I know that NRC has been excellent  
19 in the past several years of outreach to various parts  
20 of its community, but it tends to, okay, go to the Health  
21 Physics Society meeting and present there, and go to the  
22 CRCPD meeting and present there to the State folks, and  
23 go to your organization, but maybe there's some value  
24 in bringing some of the organizations together, too, in  
25 a focus of the regulatory environment rather than

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1 everybody just talking on their own and not coming  
2 together.

3 So, I present that as a possibility.

4 CHAIRMAN THOMADSEN: Dr. Suleiman.

5 MEMBER SULEIMAN: The lines are blurry,  
6 okay, because I think -- this is my perspective. I  
7 happen to represent FDA, but I have to, depending on  
8 what part of my career I'm either a health physicist or  
9 medical physicist, but I think most of the people here  
10 at this table are professionals in their own light.

11 They may have been nominated by a society.  
12 Do they really represent that society at this table, or  
13 not?

14 I mean, so, are we professionals  
15 constituting a Committee to give our best opinion and  
16 we happen to be associated with a variety of  
17 organizations, or are we in fact representing those  
18 organizations collectively at the table? So, which is  
19 it?

20 And I think sometimes, sometimes I think we  
21 forget that responsibility ourselves. Are we  
22 representing the public health? Are we looking out for  
23 parochial interests from our societies? Which hat do  
24 we have on, I guess, when we speak?

25 Maybe we should have three hats so when we

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1 say, this is me, this is my organization, or this is the  
2 society I happen to belong to.

3 CHAIRMAN THOMADSEN: Mr. Fuller.

4 MR. FULLER: I think I can answer that  
5 question and it may have been more rhetorical. But just  
6 so that everyone is clear because we go over this each  
7 time we select a new member, it's very, very clear in  
8 that process, but sometimes maybe people forget our  
9 expectation for all the members. Just so everybody  
10 knows, all the members represent yourselves.

11 You represent what you know and what you  
12 believe and what you think is in the best interest of  
13 the ACMUI and that's the perspective we expect you to  
14 bring.

15 You cannot know what you know. We  
16 understand that. You're members of various  
17 professional organizations and so you will have that  
18 perspective.

19 But any time you're here as a group, our  
20 expectation is, is that you are representing yourselves  
21 and that you are not here to promote a position of a  
22 particular professional organization.

23 CHAIRMAN THOMADSEN: Mr. Costello.

24 MR. FULLER: And that goes for the  
25 organizational groups --

1 MEMBER COSTELLO: Yeah, I know.

2 (Laughter.)

3 MR. FULLER: -- as well, because that has  
4 been a bit of a point of confusion.

5 MEMBER COSTELLO: You and I have discussed  
6 this before. I've got a few comments on your  
7 presentation which I thought was very good.

8 But to start with the last, I do reach out  
9 to the Agreement States, not to the Organization of  
10 Agreement States. Although, I might use them as a  
11 vehicle because they have more email addresses than I  
12 do. So, I know what the States are thinking.

13 So, the agenda for today, I wanted to know  
14 if they had any positions or things they were interested  
15 in.

16 In fact at the OAS meeting for those who  
17 were there, I threatened people who did not get in touch  
18 with me, you know.

19 I want to hear from them so I can do a better  
20 job. I'm keeping track of all the States who talk to  
21 me during the year and I'll pull out bells and never hear  
22 from them, but I'll do my job better if I know the issues  
23 that are going on out there.

24 Okay. I've worn lots of hats over the  
25 years. The hat I've had on the longest is health

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1       physicist, but I'm a regulator and I'm a patient. I do  
2       a lot of things, but mostly I'm me and I try to do the  
3       best job of being me as I can.

4               As far as a rep for medical licensees, this  
5       is a logistical thing as I think about it. I don't know  
6       how many people would come, okay.

7               For the reactors, these are well-funded  
8       organizations. There's big pockets out there and NEI  
9       and so forth. You all know better than I do, individual  
10      hospitals, are they going to be sending their radiation  
11      oncologist to take a week off to come to Rockville and  
12      talk about - I don't know. I have no idea. I would like  
13      to think they would, but I think it might be a challenge.

14              I was intrigued by your idea of an extra  
15      meeting where you invite whoever you invite to basically  
16      educate us, you know.

17              We're supposed to be doing that, but I  
18      imagine some of these medical organizations might want  
19      to come and give us a presentation. I just don't know  
20      how it works.

21              As far as supporting it goes, I won't go to  
22      individual States, because no individual State is going  
23      to -- times are hard.

24              I think if you were to go to particularly  
25      CRCPD, you know, because they cover, you know, x-rays

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1 and everything else, and asked them for help for  
2 supporting some sort of meeting, you know, they might  
3 listen.

4 And they actually have some, you know, paid  
5 staff that might be able to help, but you're asking a  
6 hard thing to do for Agreement States because basically  
7 what we are paid to do is do things for safety in our  
8 own State and we don't got a whole lot of budget for  
9 national issues.

10 And Pennsylvania is very, you know, nice  
11 enough to let me do this, but you all realize we are not  
12 going to leave.

13 So, I love the concept. I just don't --  
14 maybe if you do a poll and ask people if they'd be  
15 interested, I don't know.

16 MEMBER LANGHORST: This is Sue Langhorst.

17 I think that it is going to be very  
18 dependent on how worthwhile those types of meetings are  
19 and it's not going to be something that will just  
20 necessarily catch on immediately.

21 Maybe one of the things that could be  
22 discussed is how quickly can regulations in this realm  
23 move forward, because that's one issue that we were  
24 talking about that needs to be discussed.

25 I don't know -- it will be dependent on how

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1           successful a meeting like that could be. Maybe it is  
2           starting out with an extra ACMUI meeting.

3                         CHAIRMAN THOMADSEN: Dr. Dilsizian.

4                         MEMBER DILSIZIAN: Yeah, just regarding  
5           organizations I've noticed that in the public a lot of  
6           organization representatives are here voicing their  
7           opinion officially or unofficially.

8                         So, I think that if there are issues, I  
9           would think that they would be here. They know the  
10          meetings and I've seen two or three of these  
11          organizations represented.

12                        CHAIRMAN THOMADSEN: Doctor -- Ms. Holiday.

13                        MS. HOLIDAY: Dr. Holiday.

14                        (Laughter.)

15                        CHAIRMAN THOMADSEN: Doc Holiday.

16                        (Laughter.)

17                        MS. HOLIDAY: I just wanted to remind the  
18          Committee that during the May 2014 ACMUI, Dr. Zanzonico  
19          presented the Bylaw subcommittee's report that did  
20          include that question about the ACMUI meeting for an  
21          additional meeting.

22                        And I believe that it was a consensus among  
23          the full Committee that you did not want to go with more  
24          than two face-to-face meetings.

25                        However, I will also note that in a meeting

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1 prior to that, there was discussion about possibly  
2 having another in-person meeting for specific topics,  
3 for example, with the Part 35 rulemaking.

4 And of course with such a meeting we have  
5 said before that there are budgetary constraints. But  
6 as long as we put that request in early enough, because  
7 I don't know about your institutions, but NRC has to  
8 submit their budget request at least a year or two in  
9 advance.

10 So, that would be something that we would  
11 have to go ahead and put in at least on the Commission's  
12 radar in order to do that. Thanks.

13 MEMBER COSTELLO: If I could, I think the  
14 budgetary impact of a third issue would be than another  
15 reg.

16 MS. HOLIDAY: Absolutely.

17 CHAIRMAN THOMADSEN: Dr. Alderson.

18 MEMBER ALDERSON: Thank you. I think this,  
19 you know, as an idealistic approach, this is -- it's a  
20 great idea and I think education is a wonderful thing  
21 whoever gets it, but I think this is practically very  
22 hard to achieve.

23 And I think if you had another  
24 person-to-person meeting, I'm concerned about the high  
25 likelihood of it failing.

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1                   And depending on who you bring in, how far  
2 you extend it out, does it go just to the medical  
3 community and what part of the medical community, the  
4 experts, the physicists, do we go to societies?

5                   And then we get societies with, frankly, we  
6 all recognize those who have been in societies, their  
7 agenda is to come talk about do we go to the public?  
8 Because the public wants to hear about all this and where  
9 do you cut it off? And so, I think there's just a lot  
10 of organizational problems.

11                   One way that you might think about turning  
12 it around or if I want to try to think about it, which  
13 I am not now.

14                   (Laughter.)

15                   MEMBER ALDERSON: It would be to think about  
16 maybe putting on a video conference, a national video  
17 conference because, you know, you can project your ideas  
18 out. The expense of the people who have to attend,  
19 minimal. All they have to do is get on their computer.

20                   And people do these things now and, you  
21 know, you can have, you know, call-in lines and all sorts  
22 of things, you know.

23                   You might be able to try that. And if that  
24 -- nobody likes it, well, they won't dial in the next  
25 time or you'll get some feedback as part of your meeting.

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1 So, I'll just suggest that as a possibility.

2 MEMBER LANGHORST: As I tell my researchers,  
3 if it was easy, it would have already been done.

4 CHAIRMAN THOMADSEN: Absolutely.

5 MEMBER LANGHORST: And so, that's why I put  
6 that word "bravely" in there.

7 CHAIRMAN THOMADSEN: Dr. Howe.

8 DR. HOWE: Well, we kind of discussed, you  
9 know, very informally internally about a medical RIC and  
10 one of the things we keep coming to is it's very  
11 difficult for the medical physicians to get away from  
12 its practice and come to NRC, but it's easier for us to  
13 go to a society that's maybe more therapy-oriented for  
14 the therapy-type discussions, a society that's more  
15 nuclear medicine-oriented for the nuclear  
16 medicine-type discussions.

17 And then I think we might get more bang for  
18 our bucks as far as actually having physician  
19 participation.

20 So, that's just one of the thoughts we've  
21 been batting around.

22 MEMBER COSTELLO: Next week is the Penn  
23 State Roundtable in which RSOs from the region, not just  
24 Pennsylvania, but all around --

25 -- RSOs from all around the area come

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1 together for I think it's a three-day or two and a  
2 half-day meeting this year. And for one day they invite  
3 the regulators in. They fear if they're too long  
4 they'll be taking names and --.

5 (Laughter.)

6 MEMBER COSTELLO: And wearing my  
7 Pennsylvania hat, I finagled my way on the agenda.  
8 Basically have a discussion between the regulators and  
9 I'll have a very short presentation on how the RSOs can  
10 do better and then I expect to hear from them on how I  
11 can do better.

12 And I assure you I know most of these people  
13 forever anyway and we'll reach out. You go to OAS  
14 meetings, you have HPS meetings and other ones.

15 And maybe we can't do a whole lot better  
16 than that. I don't know. Health physics is a way to get  
17 a lot of information, not just medical, but a lot of  
18 non-medical.

19 And maybe as you talked about, it's hard for  
20 them to give up their medical practices and maybe us  
21 going to them may be a better way.

22 CHAIRMAN THOMADSEN: Mr. Mattmuller.

23 MEMBER MATTMULLER: Yes, to follow up with  
24 what Mr. Costello was saying, I too was thinking that  
25 instead of the NRC putting on a RIC, given the 37

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1 Agreement States, that a group like the CRCPD would be  
2 a more appropriate organization to sponsor such a  
3 meeting.

4 Plus, it also has the advantage that their  
5 meetings move around on a national basis giving people  
6 in different areas of the country a chance to attend  
7 because travel budgets are basically nonexistent in a  
8 lot of hospitals.

9 So, then if it's within an easy drive, a lot  
10 more people have a chance to attend than coming to  
11 Rockville, not that Rockville is bad.

12 MS. DUDES: But it's an expensive place to  
13 come, yeah.

14 MEMBER MATTMULLER: Yes.

15 MS. DUDES: I understand that.

16 CHAIRMAN THOMADSEN: Yes, Mr. Fuller.

17 MR. FULLER: I'll just add on my perspective  
18 when it comes to our meetings and things to consider,  
19 and of course we'll do whatever we can to support the  
20 ACMUI in any way that we possibly can.

21 The one thing I remind folks is that any  
22 time the ACMUI gets together and deliberates, it must  
23 be publicly noticed well in advance, the agenda posted,  
24 the meeting has to be a public meeting and so forth and  
25 so on.

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1                   So, as we think about the outreach that we  
2 do especially with the issues related to release of  
3 patients with iodine-131 therapies and so forth, we're  
4 putting the plan together.

5                   Donna-Beth described some of it today, but  
6 part of the logistics of that is a lot of public  
7 interaction.

8                   We have some workshops in mind at this point  
9 in time that we're sort of starting to plan around and  
10 we will appreciate it and we will be asking for  
11 participation from the ACMUI in those sorts of public  
12 outreach meetings as well. So, I see these as other  
13 opportunities.

14                   When we go to some of the professional  
15 societies, for the last few years we've been primarily  
16 in the attendance mode because early on with the  
17 rulemaking which was the last big thing we worked on,  
18 we were doing presentations. But then we found that,  
19 you know, it was better to listen than it was to talk  
20 sometimes.

21                   And so, the model I think will be back on  
22 that note of explaining and sharing sort of what we're  
23 planning to do and again trying to encourage more and  
24 more participation by the public and the professional  
25 organization.

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1                   So, interacting with the medical community  
2                   is something that we will always rely upon this body to  
3                   help us with, but we do not plan to wait around. And  
4                   we will not be bashful in asking certain folks of this  
5                   Committee to work with us as we start on this next big  
6                   effort.

7                   CHAIRMAN THOMADSEN: Thank you. Ms.  
8                   Fairobent.

9                   MS. FAIROBENT: Thank you, Dr. Thomadsen.

10                  Lynne Fairobent with the AAPM. I know it  
11                  probably surprises you all to think I might have an  
12                  opinion on this, but I've been around far too long.

13                  And going back to 1977 and '78 when I  
14                  started with NRC, I think that it's time to try a  
15                  regulatory issues conference for medical or perhaps for  
16                  even materials.

17                  It's been bounced around a number of times  
18                  over the past 30 odd years. We don't know that it won't  
19                  work unless we try it.

20                  A key difference that I see in a RIC versus  
21                  when we have a roundtable discussion based on an advance  
22                  notice of proposed rulemaking like we have done with  
23                  Part 20, like we did with Part 35 back in 2002, is the  
24                  general nature of the dialog in the discussion topics.

25                  It is not focused on a one-way discussion.

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1 NRC is holding a public meeting on an active proposed  
2 rule that is out for comment. There is give and take  
3 in the dialog.

4 The difference in the presentations, the  
5 difference in the interactions, the availability of the  
6 commissioners to attend and listen to interact with the  
7 licensees in a non-enforcement or regulatory  
8 environment, I think, is very different.

9 I think there are ways that we could look  
10 at perhaps tracking the first RIC. And if it was not  
11 a standalone, perhaps we look at attaching it to the OAS  
12 meeting, which is a regulatory conference, versus  
13 CRCPD, or perhaps we look at doing it as part of one of  
14 the professional society's meeting as an extra day.

15 The difference that I see in doing a RIC in  
16 an open discussion and forum not only with NRC, but with  
17 the Agreement State representatives versus inviting NRC  
18 or a representative from the Agreement States either as  
19 the Organization or a particular State to come to, say,  
20 an AAPM meeting and give a talk, is that is a talk. It  
21 is a presentation. It is not a give and take. It's not  
22 open dialog.

23 Even when we give an hour-long talk if it's  
24 at our annual meeting, you have competing sessions. We  
25 have 15 parallel tracks at AAPM during our annual

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1 meeting.

2 The need for our members to get continuing  
3 education credits towards board certification or  
4 recertification is great.

5 Oftentimes the regulatory sessions are not  
6 going to be the draw for that interaction. So, I do  
7 think that perhaps it's time to take a look at let's see  
8 what we can put together, let's see what we get as a  
9 turnout and then decide that, okay, it's not worthwhile.  
10 But if we don't try it, we don't know what the likelihood  
11 of the support of the benefit will be.

12 CHAIRMAN THOMADSEN: Thank you very much.

13 Dr. Ennis.

14 DR. ENNIS: Ron Ennis again. I want to just  
15 go back to Susan's presentation, but change the focus  
16 a little bit to an area where I think maybe there is need  
17 for work, but not from personal experience, but just  
18 from things that I hear from others.

19 And that is developing a culture of safety  
20 and collaboration and being able to talk honestly and  
21 openly for the benefit of the public when it comes down  
22 to the enforcement level.

23 And the actual regulators who come into the  
24 departments and the relationships that they may or may  
25 not have with the physicians, for example, that culture,

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1 my sense is, is not a healthy culture or not as healthy  
2 as it could be and maybe there's work that needs to be  
3 done at that level involving Agreement States and NRC  
4 States to really improve so people are really working  
5 in a collaborative kind of way.

6 My own personal experience has been very  
7 positive with my regulators, but -- and I really will  
8 throw this out for discussion because I don't have any  
9 data. I don't really have even good anecdotes, but it's  
10 the sense that what you're talking about is really an  
11 issue, but at a lower level than ACMUI versus NRC.

12 CHAIRMAN THOMADSEN: Thank you.

13 Yes, Ms. Dudes.

14 MS. DUDES: Thank you. I just wanted to  
15 sort of echo, Lynne, your comment. And I think you're  
16 correct that we may want to try adding some sessions to  
17 some existing forum and see what we get.

18 I had an individual who was a vendor with  
19 a poster at the Organization of Agreement States meeting  
20 in Chicago say something very similar to me is that we  
21 were very happy that the regulators are meeting and  
22 discussing these issues. When do you bring the larger  
23 community in to discuss these issues?

24 And that resonated with us. And so, I  
25 think we'll at least, you know, try and see what small

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1 step could be taken, you know.

2 To undertake a two or three-day event, not  
3 knowing what kind of reception we would get, may be a  
4 big step, but some level of effort in that area I think  
5 you're correct that it's timely and if we could tack it  
6 onto an OAS meeting.

7 And the reason I would like to tack it onto  
8 an OAS meeting rather than a society meeting or a CRCPD  
9 meeting is because you do have the Agreement States  
10 there.

11 And so, you have the regulatory body of the  
12 National Materials program in one place that would be  
13 probably the better venue to take the next step and then  
14 include licensees.

15 Of course we'd do that in a public way. So,  
16 anyone would be available or able to attend and that  
17 dialog would be open to the public as well.

18 CHAIRMAN THOMADSEN: Any further comments  
19 from the Committee or the NRC?

20 Yes, Ms. Langhorst.

21 MEMBER LANGHORST: I just wanted to say that  
22 my intent is to throw pebbles in the pond to send out  
23 ripples and for you all to take the ripples and see what  
24 you can make of them and again come back to this  
25 questioning attitude about how do we look at avoiding

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1 complacency and challenge existing conditions and  
2 activities.

3 I think this is never going to be, oh, we  
4 got to safety culture, okay, we're done. It is a  
5 continual dialog.

6 And so, I offer up my ideas and I hope you  
7 take them as inspiration to figure out what you think  
8 might work.

9 CHAIRMAN THOMADSEN: Well, I'm hoping  
10 you're going to offer more than your ideas, because I'm  
11 going to -

12 (Laughter.)

13 CHAIRMAN THOMADSEN: -- ask you and one  
14 other person on the Committee, a volunteer if there is  
15 one, to work with somebody who is designated by the NRC  
16 to come up with a very concrete proposal not just for  
17 the first meeting, but possibly for maybe up to three  
18 or something that would include some idea of the cost  
19 that they could then put into a budgetary item for the  
20 future to at least give this a try in the beginning and  
21 how it should be organized.

22 Do I have a volunteer to work with Sue on  
23 this? We do. We have Mr. Costello who is willing to  
24 also serve on that. I think that's great.

25 Where this goes, we'll find out. As has

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1           been said, we won't know until we try it and let's see.

2                       Thank you very much, Dr. Langhorst.

3                       MEMBER LANGHORST: Thank you.

4                       CHAIRMAN THOMADSEN: Now, we have Dr. Welsh  
5           talking about the medical events for the fiscal year  
6           2013.

7                       (Pause.)

8                       MEMBER WELSH: Thank you, Dr. Thomadsen.

9                       Much of what I'm going to say here today is  
10          going to sound like a rehash of things I've said in years  
11          previously and that is in part because we have some new  
12          members and we will have future members and I will rotate  
13          off shortly as the subcommittee chair and somebody will  
14          have the honor and pleasure of inheriting this role of  
15          putting together this annual report.

16                      So, much of what I'm saying here today is  
17          for the benefit of the subcommittee members and the  
18          Committee members as a whole regarding use of the NMED  
19          database.

20                      When you look at the events in the past  
21          fiscal year, you can review them and identify them for  
22          a variety of different approaches.

23                      The approach that I prefer personally is to  
24          go to NMED under Advanced Search, event type, medical,  
25          and then plug in the dates reported.

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1           And when you do that, you come up with a  
2           total of 62 events for the year in question and they are  
3           described as tabulated here.

4           None in the eye applicator brachytherapy.  
5           None in the brachytherapy of intravascular, et cetera,  
6           et cetera.

7           I won't go through the detailed list. It's  
8           in your handout, but I'll throw in some comments right  
9           now because for those who are not familiar with NMED,  
10          you'll see that there are some categories that remain  
11          poorly defined and they're still in the menu.

12          For example, linear accelerator and x-ray,  
13          which we know the Nuclear Regulatory Commission doesn't  
14          regulate, and then the undefined NA/NR categories, but  
15          the NMED team has listened to some of our concerns and  
16          has changed a good deal of what's in the NMED database.

17          For example, Zevalin didn't previously  
18          have its own category - did have its own category, but  
19          Bexxar did not. So, that was hard to understand.

20          Well, part of this was self-rectifying  
21          because Bexxar has bit the dust and is no longer  
22          available as a product, which I think is most  
23          unfortunate for our patients, but the Zevalin category  
24          has been eliminated. And also radiolabeled antibodies  
25          as a separate category has been eliminated. Zevalin is

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1 now listed in radiopharmaceuticals T.

2 So, things do change and it's obvious that  
3 the NMED team has listened to some of our suggestions,  
4 but there are some things that are very difficult, if  
5 not impossible, to change.

6 And when you're going through the NMED  
7 database, you'll see that the events are not in  
8 chronological order. And this is because some events  
9 from months, maybe even years previously get reported  
10 and eventually logged during the period in question.

11 That means that some events from the period  
12 in question are not entered for many months and,  
13 therefore, the only way to practically do a search is  
14 to focus on the events reported during the time in  
15 question.

16 When you do that, you'll see some  
17 discrepancies. For example, in our spring meeting when  
18 Dr. Howe gave her report, there were 43 events. And  
19 now, we're saying that there are a total of 62.

20 So, there's a difference of 19 certainly  
21 not because Dr. Howe isn't counting as accurately as we  
22 are. If there's ever a discrepancy, I personally would  
23 side with Dr. Howe every time -- but there is a  
24 difference of 19 here even though the searches were done  
25 only a few months apart.

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1           And this is not a phenomenon unique to the  
2           current fiscal year. For example, last year in 2012 we  
3           saw that in the spring there were 52, and in the fall  
4           we tallied up 61. So, we saw the exact same pattern of  
5           a number getting popped or logged later on in the year.

6           Even though we're talking about the  
7           previous year, the previous fiscal year, things get  
8           logged a bit late.

9           And I bet you if we do this again for the  
10          same fiscal year, there could be a different number, but  
11          the important thing is at the bottom there that this  
12          year's total is virtually the same as previously, 61  
13          versus 62. So, the current fiscal year is not anything  
14          alarming.

15          Another comment that I'll make at this  
16          early stage is that we've brought up many times in the  
17          past that it would be nice if the NMED database were  
18          organized by 10 CFR.

19          However, I don't think that's going to  
20          happen and I don't think it's -- maybe we don't need to  
21          insist that it happen.

22          We talked earlier today about some of the  
23          challenges. For instance, one Gamma Knife device is  
24          600 and another Gamma Knife device is Part 1000.

25          And then for manual brachytherapy Y-90 is

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1 categorized in NMED as manual brachytherapy, but it's  
2 listed in Part 1000. Are these things going to stay  
3 1000?

4 So, 1000 might be the right number or could  
5 be. In practice I think it's not proved to be the case,  
6 but the point is that it can be challenging to try to  
7 organize things along 10 CFR.

8 But this begs the question do we really need  
9 to categorize things along the Code of Federal  
10 Regulations categories, because this makes our -- our  
11 effort to do so adds significant burden to this task and  
12 some of us might not find it as enjoyable because of the  
13 burden that we place upon ourselves trying to organize  
14 things in accordance with 10 CFR.

15 So, perhaps during this report in the  
16 future just according to what's in NMED rather than  
17 trying to translate it into 10 CFR might be more  
18 constructive and educational.

19 So, getting into some of the details we saw  
20 that there were two in the Part 300. One of them was  
21 a Zevalin case which the calculated dose for the patient  
22 would have been higher than a standard dose.

23 So, they intended to give the typical  
24 maximum activity of 32 millicurie, but the written  
25 directive had transposed the numbers and the number 23

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1       rather than 32 was written.

2                       But then they gave 32 millicuries, so it  
3       didn't follow the letter of the written directive and  
4       is logged as a medical event even though the intended  
5       activity was ultimately given to the patient.

6                       Another case involved mIBG,  
7       metaiodobenzylguanidine, for metastatic  
8       neuroblastoma. I presume this was a pediatric case.  
9       The age of the patient wasn't given in the report.

10                      One millicurie was administered. The  
11       Foley catheter leaked and eventually this was  
12       discovered. The patient was cleaned. The catheter  
13       was removed and replaced and the sheets and clothing  
14       were changed and the patient was discharged with no  
15       evidence of skin irritation, but a few weeks later  
16       examination for consideration of the second possible  
17       treatment revealed skin irritation consistent with  
18       radiation injury.

19                      It was estimated that the patient's skin  
20       received 1,000 centigray due to that urinary  
21       contamination that was unaddressed for a bit.

22                      So, the report says the patient and the  
23       doctor were notified. Again, I think this was a  
24       pediatric case. So, I presume that it was the patient's  
25       parents who were notified.

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1                   Corrective actions include procedure  
2 modifications and providing additional training to  
3 personnel.

4                   The next event of note was a situation which  
5 technetium cardiac stress test was administered despite  
6 the order being cancelled.

7                   The procedure was changed from a stress  
8 test to an echocardiogram, but the technologist  
9 allegedly failed to notice the change and the procedure  
10 was performed.

11                  A small dose was administered to the  
12 patient. No adverse health effects are expected, but  
13 it was a medical event because this procedure was  
14 cancelled and byproduct material was nevertheless  
15 administered.

16                  So, corrective actions include going  
17 forward using a computer to schedule and cancel orders,  
18 encouraging physicians to write more legibly, moving  
19 from handwritten to electronic orders.

20                  This next one was a most unusual event.  
21 Cardinal Health reported dispensing 34 unit doses of 12  
22 millicuries each of technetium-99 sestamibi.

23                  At the hospitals, the radiopharmaceutical  
24 was found to be taken up in the soft tissues rather than  
25 the heart.

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1                   So, this investigation led to the  
2 conclusion that the material contained only  
3 technetium-99m rather than the radiopharmaceutical  
4 technetium-99m sestamibi.

5                   So, how did this happen? It appears that  
6 the doses were incorrectly labeled, the technetium-99m  
7 was diluted and then incorrectly labeled as  
8 technetium-99m sestamibi. So, it seems like a  
9 manufacturing or perhaps a compounding problem.

10                   It was concluded that Cardinal Health  
11 failed to follow established procedures. So, Cardinal  
12 Health completed and passed erroneously the QA testing  
13 which should have demonstrated that these were  
14 mislabeled.

15                   So, corrective actions include providing  
16 additional training to the personnel, but it sure begs  
17 the question of whether or it's not just Cardinal Health  
18 who's totally at fault here.

19                   Could or should the local hospitals have  
20 caught this error? And that's hard to answer. One bit  
21 of information that we don't have the answer for is  
22 exactly what was the activity that was sent?

23                   Was it truly the 12 millicuries? And if it  
24 was not, could the clinics have possibly caught this?  
25 Although, given that these were unit doses, perhaps that

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1 wouldn't have happened regardless.

2 Another question that comes up is, is this  
3 really -- should this really be in the category of  
4 medical events?

5 One could argue that the authorized users  
6 and the facilities did nothing wrong, but we've had many  
7 conversations about what a medical event is supposed to  
8 be and what that definition should encompass ideally.

9 And even though maybe they didn't do  
10 anything wrong, maybe we need to still categorize it as  
11 a medical event.

12 However, this one is just unusual enough  
13 that it begs the question of whether it would be an  
14 abnormal occurrence rather than a medical event.

15 Another case involved sodium iodide in  
16 which the patient was prescribed a therapeutic dose, but  
17 instead received a diagnostic dose.

18 And without going into the details that are  
19 written here, I'll just say that a new electronic  
20 medical records system was implemented and there was a  
21 constellation of errors that led to a perfect storm  
22 culminating in this event which fortunately is  
23 extremely unlikely to have any medical consequences  
24 since a therapeutic dose was prescribed, but a  
25 diagnostic low dose was administered.

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1           The order that was requested was a whole  
2 body scan, but it appeared to be something different.  
3 And when the patient presented for the study, the  
4 imaging center was down and was sent to another  
5 hospital.

6           At that hospital after the procedure was  
7 administered, somebody identified that there was  
8 something unusual about that particular order and going  
9 forward they had some corrective actions that were  
10 pretty standard stuff.

11           Perhaps this is an example of a medical  
12 event that was due to implementation of a new electronic  
13 medical records system.

14           And as more and more institutions  
15 transition, we need to be on the lookout for such events  
16 and perhaps institutions will benefit from this  
17 happening to somebody else so it doesn't happen at their  
18 institution to their patients.

19           Moving on to the manual implant  
20 brachytherapy category, when you search for this using  
21 event type equals medical and then the dates and then  
22 plug in procedure, brachytherapy manual implant, you  
23 get a total of 32.

24           But because Y-90 microspheres are Part  
25 1000, this means that only 14 were Part 400 classical

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1 manual brachytherapy, manual implant brachytherapy.

2 Here's how they are broken down. And  
3 compared to last year, this was a good year. There were  
4 20 events in 2012 with 34 patients. But this year in  
5 2013 there were only 16 events involving 19 patients.

6 And I'll comment more on that one on the  
7 bottom, because it's been very difficult to categorize  
8 exactly where this one really belongs.

9 So, I'd lump it with the 400 even though  
10 it's really 1000, but it's certainly not brachytherapy.

11 Two of these events were cesium-137 GYN  
12 cases. One was involving 450 centigray that was  
13 delivered to the skin of the patient because the packing  
14 came out early. Another one was caused because one of  
15 the two sources fell out of the applicator.

16 Specifically in that first event, a patient  
17 received an unintended dose to his thigh because at six  
18 o'clock in the morning the patient felt something move  
19 and probably that was when something, the material  
20 popped out and it was subsequently discovered at 9:15.

21 The physicist was the one who discovered  
22 that the implant was out of the patient. The team  
23 removed the sources. And the reason for why this  
24 happened most likely was because of some accommodations  
25 and adjustments that were made during the procedure to

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1 accommodate that patient's particular anatomy.

2 The next case involved a Fletcher-Suit,  
3 Fletcher-Suit ovoids. The text says that 30 gray to  
4 each ovary was prescribed. Perhaps that means ovoid.

5 At the completion of the procedure, it was  
6 discovered that the sources were not present on the left  
7 side and the source was instead found on the IV monitor  
8 stand.

9 What happened, apparently, was that one of  
10 the sources was never placed properly and was on the bed.  
11 The nurse found it 12 hours later, didn't know what it  
12 was, apparently, and just put it by hand on that IV  
13 stand.

14 The nurse had an estimated dose to the hand  
15 of about 13 rem. This was an example of human error and  
16 inadequate training.

17 Moving on to the -- to that other unusual  
18 event that was listed in manual brachytherapy, probably  
19 technically it belongs as a Part 1000 medical event,  
20 involved a seed that migrated after being placed in the  
21 axilla and was not retrievable during axillary surgery.

22 If you look at the activity and the doses  
23 here, you can see that this is not a brachytherapy  
24 procedure, but it was listed under manual brachytherapy  
25 perhaps because it doesn't have a convenient

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1 categorization.

2 This was the event [that] occurred  
3 primarily because of scarring in that patient's axilla  
4 due to previous surgery and maybe there was no way that  
5 that seed could ever have been removed easily without  
6 causing damage.

7 The corrective action at the institution  
8 was the decision to cease doing radioactive seed  
9 localizations for axillary node lesions.

10 Moving on to prostate brachytherapy, this  
11 again is the biggest single category. 14 medical  
12 events involving 16 patients this year.

13 Two events involved medical patients, 10 of  
14 these were underdoses, and a couple of them were  
15 reported years after the procedure itself.

16 One was an overdose. There were two seed  
17 migrations, two anatomical barriers and one has to  
18 wonder if the seed migration and anatomical barrier  
19 cases really should be labeled as medical events.

20 Should they be categorized as patient  
21 intervention? And that's something we might discuss  
22 later on if we have time. There was one plan error and  
23 four seed misplacements.

24 The breakdown in the isotopes is as  
25 follows: One of those palladium-103 cases was

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1 retracted.

2 Of course these categories that I just  
3 listed are not mutually exclusive. One hasn't gleaned  
4 a whole lot of earth-shattering information from  
5 reviewing these medical events this particular year.

6 It's the usual causes; human error,  
7 inadequate training, inadequate supervision, et  
8 cetera.

9 There was one palladium implant that was  
10 initially called a medical event because of  
11 underdosing, but upon closer inspection was retracted  
12 in 2013 because of perhaps edema causing the  
13 miscalculated underdose.

14 At least one of these cases it seems like  
15 the seeds were correctly placed and then subsequently  
16 migrated leading to an underdose, which again begs the  
17 question of whether or not such case should be labeled  
18 as a medical event.

19 There was one situation in which the wrong  
20 plan was used. Clearly a classic medical event. A  
21 monotherapy plan was used instead of a combined modality  
22 plan and of course corrective actions include  
23 modification of default settings for the treatment  
24 planning system.

25 There were two events listed this year in

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1 the anatomical category or anatomical issues because of  
2 pubic arch interference specifically.

3 In the first one, five seeds were implanted  
4 out of the planned 106. So, corrective actions that are  
5 listed include verifying that there are no anatomical  
6 obstructions. But I'm sure that as we all know when we  
7 do these procedures, you always try your best to make  
8 sure that there are no obstructions that you're  
9 anticipating. This patient went on to receive external  
10 beam radiation.

11 The second event was similar. The procedure  
12 was aborted early on after it was clear that the pubic  
13 arch was in the way. Only 14 seeds were placed. And  
14 so, 65 percent of the intended dose was delivered.

15 The written directive was revised, but I  
16 was disturbed to see that the corrective actions were  
17 to discontinue the program.

18 I don't have any information about whether  
19 this was a top-notch program and it's a shame that this  
20 is not available for patients anymore, or if this is a  
21 program that really needed to be terminated, but thanks  
22 to our list of anecdotes, tough regulations or  
23 inappropriate regulations or medical event definitions  
24 possibly influenced the decision of practitioners to do  
25 this form of brachytherapy.

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1 I've always argued that, yeah, I think that  
2 if you have an inappropriate definition of a medical  
3 event and you're going to get cited with a medical event  
4 and your competition might say we don't have medical  
5 events at our hospital, it might discourage you from  
6 doing this procedure in favor of the more lucrative, but  
7 not necessarily better for the patient, external beam  
8 strategy.

9 So, I don't know exactly what happened, but  
10 I was disturbed to see that this program was terminated.

11 Moving along -- I'm finished with the  
12 commentary there. Moving along to the Part 600, we can  
13 see that it was a good year with nine events compared  
14 to 17 in the previous year.

15 Most of these were HDR with only one Gamma  
16 Knife and then one Perfexion<sup>TM</sup>. This is how they break  
17 down in terms of the HDR itself.

18 The causes were the standard problems,  
19 length problems, wrong patient plan used, incorrect  
20 applicator placement, a source that got stuck in the  
21 transfer tube.

22 We talked about the Gamma Knife. One was  
23 a conventional Gamma Knife unit, the 600, in which case  
24 the wrong side was treated despite the fact that the AMP  
25 thought the coordinates looked odd, but didn't bring it

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1 up or didn't say anything before the treatment  
2 proceeded.

3 The next one was a Perfexion™ unit medical  
4 event categorized as a 1000. And this was a mechanical  
5 failure of the sensor resulting in only -- in an  
6 underdose, but this was fixed and the patient treatment  
7 was completed. So, it's very questionable about  
8 whether this should be labeled as a medical event or not.

9 Moving on to 1000, you can see that 2013 was  
10 a good year. That upward trend going from 2011 to 2012  
11 was reversed with only 14 medical events. And the 1000s  
12 were essentially all microspheres with the exception of  
13 that one Perfexion™ Gamma Knife case.

14 And you can see, and I'll bring this up  
15 again, that the ratio of resin to glass medical events  
16 was reversed this year compared to years previously  
17 consistent with what we have said here at the ACMUI.

18 Here are the specifics regarding the  
19 SIR-Spheres events. The usual causes, blocked  
20 catheter, leaky vials, leaky catheters, needles not in  
21 the optimal position. Shunts to the duodenum, one was  
22 treated, one was classified as a recording error.

23 With the three TheraSphere cases, two of  
24 them were blocked catheters and one was a procedural  
25 error because no other cause was determined.

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1           So, the general observations we have are  
2           that as previously there's not a whole lot of detailed  
3           information available in the NMED report which is not  
4           a criticism, it's just a reality that we have to contend  
5           with.

6           So, it's a good source of tallying numbers,  
7           but you're not going to get the specifics here.

8           The training and procedural changes are the  
9           most common remedial actions, but, as I mentioned, there  
10          was at least one situation which the program itself was  
11          discontinued. And that's always something that is  
12          disturbing or concerning.

13          The yttrium-90 microsphere medical events  
14          demonstrated a reversal in their preponderance with  
15          more resin than glass this time around.

16          And I recall a year or so ago I was charged  
17          with analyzing medical events in Y-90 microsphere  
18          brachytherapy in particular to see if there was a trend  
19          that was real. And we predicted that the perceived  
20          trend of more medical events occurring in glass was just  
21          a fluke. And I think that this observation of the  
22          reversal in ratio confirms our conclusions.

23          So, in conclusion of this year's report, we  
24          see no obvious trends, no patterns, nothing that's truly  
25          concerning.

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1                   And it's important to underscore the fact  
2                   that there are maybe 15 million diagnostic procedures,  
3                   150,000 therapeutic procedures using byproduct  
4                   material annually. And the tiny fraction that we're  
5                   talking about here today is quite reassuring. It  
6                   confirms the generally safe fashion that these  
7                   materials are administered to patients in this country.

8                   One of the questions that did come up during  
9                   our conversations, email deliberations was what  
10                  constitutes patient intervention?

11                  And that might be the most important  
12                  question that arose during this year's discussion of the  
13                  medical events report analysis, because patient  
14                  intervention classically is perceived as something  
15                  that's intentional.

16                  But if the patient's physiology changes or  
17                  if their anatomy changes, should this be a medical  
18                  event, or could this be construed as patient  
19                  intervention?

20                  Specifically when there might be a change  
21                  in pubic arch position or interpretation of pubic arch  
22                  location and we find in the operating room that it's  
23                  impossible to place those needles, should that be  
24                  categorized as a medical event, or is that more  
25                  appropriately considered patient intervention because

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1 the anatomy is different?

2 So, these are some of the questions that we  
3 had. Are there any questions for us now?

4 CHAIRMAN THOMADSEN: Thank you very much,  
5 Dr. Welsh.

6 Mr. Costello.

7 MEMBER COSTELLO: Dr. Welsh, you know, I  
8 think I was the one who raised the question of patient  
9 intervention and I've raised it because I thought I saw  
10 a disconnect between what at least appeared to me to be  
11 the majority of medical opinion of our subcommittee and  
12 what I am called to be the view of the NRC patient  
13 intervention and I like to describe it like this,  
14 actually one or the other.

15 You know, if you look at the rule, patient  
16 intervention talks about being something active, either  
17 intentional or unintentional, because I think the rule  
18 allows for unintentional patient intervention.

19 And what means is if a patient pulls out  
20 something during HDR treatment or gets off their  
21 external beam treatment or for something like that,  
22 okay.

23 What was clear when we were discussing it,  
24 that what I would call passive patient intervention, you  
25 know, something that happens because of the anatomy of

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1 the patient or something like that, in my previous life  
2 I would not have thought of that as being patient  
3 intervention. Doesn't mean that I would have been  
4 right, it's just I wouldn't have thought of it that way.

5 So, it's sort of a battle in my head and I  
6 heard, you know, discussion and I think it was the  
7 majority of the subcommittee, actually, were agreeing  
8 that patient intervention could be what is called  
9 passive patient intervention.

10 And just to complete my thought about that  
11 is and you have in one of your slides if the authorized  
12 user and the staff does everything correct, everything  
13 according to procedures, everything according to  
14 accepted medical practice, but the outcome is that the  
15 intended organ didn't get, you know, the dose intended  
16 or the unintended organ did, does that constitute a  
17 medical event, or does it not constitute a medical event  
18 because they could not have done anything to prevent it?

19 And my thought was that -- and I don't think  
20 we could possibly totally discuss it here, because --  
21 and I'll leave this up to the Chair that this might be  
22 a good topic for a subcommittee to look at to make  
23 recommendations to the NRC just what do we mean by  
24 patient intervention and what do we mean by medical  
25 event.

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1           If the regs cannot have prevented it, and  
2           I hear this in my own State, it couldn't have been  
3           prevented or how could it be medically prevented, I  
4           think that's a subject worth pursuing.

5           MEMBER WELSH: Well I would concur and I'm  
6           very appreciative of you bringing this up, because it's  
7           not something that was on my radar, nor was it on most  
8           of the other subcommittee members' radars.

9           But I think now that you've raised this  
10          question, we realize that this is a crucial, important  
11          question that doesn't have an easy answer that will  
12          likely come up within the next five minutes.

13          I think that as I said, perhaps the most  
14          important conclusion of our exercise this year was just  
15          this question that doesn't have an answer just yet.

16          And with Dr. Guiberteau's presentation  
17          this morning on Y-90 microspheres, one has to wonder  
18          about what if the team did the MAA scan and did the  
19          angiography and everything was done according to the  
20          book and looks perfect, and then you do a lung scan and  
21          you find that there's more activity in the lungs than  
22          anticipated.

23          Has something happened in terms of the  
24          vascularity or the shunting that is over and above what  
25          could be controlled by the authorized user and team?

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1           Should that be given the unfortunate marker  
2 of medical event which comes along with some negative  
3 connotations? But what do you call it?

4           So, I would agree that maybe this question  
5 does need to be asked in subcommittee form to  
6 specifically try to answer that.

7           CHAIRMAN THOMADSEN: Thank you for the  
8 comment.

9           Yes, Dr. Zanzonico.

10          MEMBER ZANZONICO: Those two 35.400 MEs for  
11 the anatomical for the pubic arch, I'm not familiar with  
12 this at all.

13          Is that something that should have or could  
14 have possibly been detected by some pre-procedure  
15 imaging procedure?

16          MEMBER WELSH: So, in practice we often do  
17 a pre-plan a couple of days, weeks ahead of the actual  
18 case.

19          And in principle it could be identified,  
20 but that planning procedures is imperfect and is  
21 imperfect, in terms of determining the degree of pubic  
22 arch interference that you will actually face when you  
23 start placing needles.

24          An experienced team, experienced  
25 authorized user will probably get a good sense of

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1       whether or not there's likely to be anatomical  
2       interference or not and may be able to say, ah, we've  
3       just done this procedure, this planning procedure and  
4       we realize that the arch is going to interfere, we're  
5       not going to get to the anterior prostate, let's choose  
6       external beam instead.

7                       But like I said, it's not as perfect as we'd  
8       like it to be.

9                       MEMBER     ZANZONICO:     Some     follow-up  
10       questions.   The numbers in some cases seem almost too  
11       good to be true, and I doubt they are.

12                      I mean, at the end you estimated there were  
13       15 million diagnostic procedures per year, yet there  
14       were zero, if I understood correctly, zero  
15       radiopharmaceutical diagnostic medical events since  
16       2004.

17                      Am I interpreting that correctly? I think  
18       it was on your Slide Number 4.

19                      (Comments off record.)

20                      MEMBER     WELSH:     That might be the NMED  
21       categorization of diagnostic radiopharmaceuticals.  
22       Like I said, there are, there's the NA that's there,  
23       there's the radiopharmaceuticals D, there's the iodide  
24       on the next page, et cetera. So, that might be an  
25       illusion because of the NMED nomenclature.

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1                   But having said that, yes, it is almost too  
2                   good to be true, but I think it's true that there are  
3                   very, very few medical events.

4                   CHAIRMAN THOMADSEN: I think Dr. Howe has  
5                   the answer to that.

6                   DR.    HOWE:    Back    when    we    did    the  
7                   radiopharmaceutical in 1994, we adjusted the definition  
8                   for a medical event for diagnostic nuclear medicine and  
9                   put a dose threshold.

10                  And so, and the intent was that 99 percent  
11                  of    the    diagnostic,    what    were    diagnostic  
12                  misadministrations prior to that day, would no longer  
13                  be diagnostic.    So, the reason you're seeing zero is  
14                  because of that.

15                  And I'd like to also comment on the  
16                  difference between the number of medical events that Dr.  
17                  Welsh gets when he does an NMED search and the number  
18                  I present.

19                  I get the same number, 62, but I review each  
20                  one of those paragraphs carefully and some Agreement  
21                  States have not adopted the dose threshold for the  
22                  diagnostic misadministrations.

23                  And so, many of these like the sestamibi's  
24                  and the technetium ones, they aren't medical events  
25                  under NRC's criteria.

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1                   And so, I bring to the ACMUI the  
2                   NRC-accepted medical events and that's why there is such  
3                   a -- where you have a fairly large number, 16, 15, 14,  
4                   that's the difference in reporting between Agreement  
5                   States and NRC.

6                   And then sometimes something will still be  
7                   labeled as a medical event if it got retracted later,  
8                   and I'll take out the retracted ones.

9                   So, I have essentially gone through and  
10                  filtered the data so that you see only NRC medical  
11                  events.

12                 MEMBER WELSH: Thank you for that  
13                  clarification.

14                 MEMBER ZANZONICO: I just have one other  
15                  question.

16                 CHAIRMAN THOMADSEN: Yes.

17                 MEMBER ZANZONICO: You indicate that the  
18                  date associated with a medical event is the date of  
19                  reporting, not the date of the incident.

20                 So, to me, that means that any of these  
21                  trend data, you know, are almost meaningless since the  
22                  date, if I understood it correctly, since the date of  
23                  the incident could be completely dissociated from the  
24                  date of reporting, yet the dates in your tabulation  
25                  presumably reflect the date of reporting therefore.

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1 Am I interpreting that correctly?

2 MEMBER WELSH: I think so. I think that  
3 there is this hazard of over interpreting what's  
4 available to us in NMED and we have to be cognizant of  
5 the fact that as an example I think it was in Wisconsin,  
6 that the State elected to do a review of all prostate  
7 brachytherapy cases and started picking up cases going  
8 back five, ten years and then tabulating them last year  
9 or the year before.

10 So, you have to be cautious when  
11 interpreting those trends.

12 CHAIRMAN THOMADSEN: Dr. Suleiman.

13 MEMBER SULEIMAN: I mean, these numbers,  
14 we've always said this, are so low that they, they're  
15 almost, I mean, they're insignificant.

16 And so, trying to track trends with such low  
17 numbers, I mean, the only encouraging thing is that  
18 they're low. Clearly they're probably  
19 underrepresented, but that's always the case, you know.

20 What happens if something gets reported and  
21 gets picked up by the community or the media? All of  
22 a sudden there's an increased sensitivity and awareness  
23 and we may see an uptick.

24 It's not necessarily there are more events.  
25 It's just that people are made more aware, but I just

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1 don't see any of these numbers as being suggestive of  
2 any major problem.

3 MEMBER WELSH: Well, I would agree that  
4 there is no major problem, but I would disagree that  
5 they're over-reported.

6 MEMBER SULEIMAN: Underreported.

7 MEMBER WELSH: Okay. Because, you see,  
8 medical event criteria, in my opinion, might be a bit  
9 stern and it might be relatively easy for a perfectly  
10 good medical procedure to be labeled as a medical event  
11 and, therefore, we've had the pregnant implant  
12 brachytherapy medical event definition subcommittee,  
13 et cetera, et cetera.

14 But even with the increased sensitivity  
15 because of a definition that may be imperfect, there's  
16 still a very, very small number of these per year.

17 And if you're to compare these numbers to  
18 what we see in surgery, medical oncology, we see that  
19 this is a very, very safe procedure.

20 However, because what we said or I said  
21 earlier that I think in this country there is inordinate  
22 fear of radiation, even a dozen or a hundred cases per  
23 year when the denominator is tens of thousands or  
24 hundreds of thousands, it gets picked up by the media  
25 and overblown all too readily.

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1                   But the bottom line is that this is a safe  
2                   and effective use of medical use of byproduct material.

3                   CHAIRMAN THOMADSEN: Dr. Langhorst.

4                   MEMBER LANGHORST: One thing I wanted to  
5                   mention, too, is that even if you don't meet the criteria  
6                   of a medical event, which is an NRC regulatory  
7                   definition, doesn't mean that the medical community  
8                   doesn't investigate what went wrong there, because  
9                   there are a lot of other of these organizations that  
10                  require that investigation.

11                  So, just because it doesn't reach the level  
12                  of medical event doesn't mean that, oh, we don't have  
13                  to worry about it, we'll forget about it.

14                  There's a lot of investigation and review  
15                  of what was the lessons learned there.

16                  CHAIRMAN THOMADSEN: Any other comments or  
17                  questions for Dr. Welsh?

18                  (No response.)

19                  CHAIRMAN THOMADSEN: If that's the case,  
20                  thank you very much. And with that, we stand adjourned  
21                  for today. Tomorrow we start at eight o'clock.

22                  (Whereupon, at 5:18 p.m. the meeting was  
23                  adjourned.)

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